Managing the Morbidity Related to Flap Reconstruction in Major Maxillofacial Oncology Surgery.

Thesis Submitted for the
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University of Leicester

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Abstract

There is substantial systemic and local morbidity associated with complex reconstruction of the maxillofacial (face, mouth, jaws and neck) region and the distant donor site of the free flap used to reconstruct the defect. This morbidity may be alleviated by careful patient preparation, selection of operation, improving wound care and new surgical procedures. Many aspects of morbidity are not readily amenable to investigation because of a multitude of confounding clinical factors. Improvements in the quality of care may be obtained by careful evaluation of outcomes and comparison with the literature. This body of work represents a reflection on my surgical practice, animal experimental studies and computer modelling techniques which have reduced morbidity and improved my ability to counsel patients.

Major elements include the techniques of suprafascial dissection of the soft tissue radial flap and prophylactic internal fixation of the osteocutaneous radial donor site which have become increasingly accepted within the United Kingdom and overseas. The impact of differing flap choice, particularly in the medically compromised group, has been considered. The quality of the clinical documentation has been improved.

Biomechanical issues raised by the clinical studies were investigated in laboratory work using the sheep tibia model of the human radius. A computer based model of the sheep tibia, created using a finite element analysis technique, was validated against the preceding biomechanical studies. This simulation was used to investigate the most effective design of osteotomy cuts and type of plate for reinforcement of a straight osteotomised bone, such as the radius, or segmental defects of the mandible.

Interest in my work is reflected in the high rate of presentations at the Annual Scientific Meetings of the British Association of Oral & Maxillofacial Surgery [1] combined with the joint second highest rate of successful conversion to publication in the United Kingdom [2].

Summary of key findings

Chapter 1
Soft-tissue radial free flap and donor site

- The suprafascial dissection (and septocutaneous radial flap) is a safe and reliable surgical technique. This dissection technique is increasingly recognised and practised. It is now the preferred method of radial flap harvest of the Author.
- Flap success rates with the septocutaneous flap are comparable to the conventional fasciocutaneous radial flap.
- Retention of the deep fascia over the forearm donor site is associated with a reduced incidence of 3 key donor site morbidity outcomes: loss of the skin graft, flexor tendon exposure and delayed healing.
- The majority of radial defects may be repaired with a full thickness skin graft to avoid the morbidity associated with a partial thickness skin graft donor site.
- A full thickness graft undergoes less contraction and may have marginally better sensory recovery.
- The sensory changes at the subfascial and suprafascial donor sites are comparable except for decreased sensation in the palmar cutaneous branch of the median nerve at the subfascial site.
- Excessive hair growth on intra-oral flaps may be successfully managed with alexandrite laser therapy.
- The current role of the radial soft tissue free flap and optimal management of the donor site has been reviewed.
- The Author is able to advise patients more fully of the morbidity associated with the radial forearm free flap.

Chapter 2

Osteocutaneous radial free flap and donor site

- The introduction of prophylactic internal fixation of the osteocutaneous radial donor site with a plate, by the Author, has substantially reduced the incidence of fracture of the radius after operation and is now well established in International practice.
- It has been demonstrated in clinical and biomechanical studies that between 40 – 50% of the circumference of the radius may be safely harvested if prophylactic internal fixation has been applied.
- The anterior plate position is less effective than the posterior position under bending loads but has a similar strengthening effect under torsional loading. The anterior plate position is similarly effective in clinical practice.
- Routine prophylactic fixation in the anterior plate position is now the preferred practice of the Author.
- Several plating systems are effective for prophylactic internal fixation including; straight 3.5 mm stainless steel with bicortical screw fixation, straight and T-shaped 3.5 mm titanium with unilocking screw fixation.
- The sheep tibia model of the human radius may be satisfactorily simulated using a finite element analysis technique.
- Further refinements in the finite element modelling of bone and hardware interfaces to simulate the complex biomechanics under loading would be helpful.
- The introduction of prophylactic internal fixation has consolidated and expanded the current role of the radial osteocutaneous free flap.
- The Author is able to advise patients more fully of the morbidity associated with the radial forearm osteocutaneous free flap.

Chapter 3

Osteotomy and reconstruction plate design

- Refinements in osteotomy design may yield significant reductions in peak stress levels and by implication reduce the risk of fracture.
- Overcutting at osteotomy sites substantially increases peak stress concentrations.
- A stop-hole at the intersection of osteotomy cuts substantially reduces peak stress levels.
- The surgical technique for creating a stop-hole is simple and has widespread applications within surgery.
- Common segmental defects of the mandible may be modelled and reconstruction with a bone plate simulated using the finite element analysis technique.
- Locking plates with monocortical screw fixation systems induce lower levels of stress than non-locking plates and are by implication more stable.
- The effects of varying hardware and bone factors should be investigated further.

Chapter 4

Choice of flap reconstruction, outcomes and morbidity

- A maxillofacial surgeon may safely insert a percutaneous endoscopic gastrostomy tube with a high degree of success and minimal complications.
- Early gastrostomy insertion under general anaesthetic is appropriate either before treatment or at the time of definitive surgery.
- Gastrostomy duration was not related to the type of flap reconstruction.
- Prolonged gastrostomy duration was associated with advanced oral malignancy, metastatic neck disease, the combination of surgery and radiotherapy, two or more surgical procedures and segmental bone resection.
- The indications for a gastrostomy have been reviewed.
- The Author is able to advise patients more fully of the morbidity associated with a gastrostomy.
- The pectoralis major flap retains an important role within the developing world and the United Kingdom, but the general pattern of use is unknown.

Chapter 4

Choice of flap reconstruction, outcomes and morbidity

- Advanced malignancy and substantial medical comorbidity are the main indications for the pectoralis major flap when utilised as the preferred option for reconstruction.
- The most common defects reconstructed are large resections of the mandible, oropharynx and neck.
- Salvage reconstruction after free flap failure and for recurrent or further disease are significant indications.
- Salvage reconstruction following complications is an uncommon indication.
- 5-year overall and cancer-specific survival outcomes have improved substantially.
- There have been significant reductions in recurrent disease, wound infection and duration of admission.
- These outcomes support the strategy of aggressive surgical treatment of advanced disease and a pragmatic approach to reconstruction.
- The Author is able to advise patients more fully of the morbidity associated with the pectoralis major flap.
- A new flap, the sternocleidomastoid perforator flap, has been described by the Author.
- The sternocleidomastoid flap is robust and suitable for small to medium sized defects of the tongue and lower oral cavity.
- The sternocleidomastoid perforator flap is an option when other flaps are not available or in the presence of substantial medical comorbidity.
- The planning of maxillofacial oncology surgery and provision of informed consent is complex.
- A structured planning proforma significantly improved the range and completeness of data capture, particularly for advice on complications and outcomes of surgery.
- The improvement was progressive and sustained over a decade.

List of contents

Statement of originality

The work described in this Thesis has not previously been published for any degree nor is it being submitted for any other degree. The Candidate is the first or senior author for the majority of publications. The concepts and work are entirely those of the Candidate with contributions from my co-authors under supervision. The work was undertaken within the Maxillofacial Department of Surgery at the University Hospitals of Leicester; the Orthopaedic Research Laboratories at the University Hospitals of Leicester; the Department of Engineering Laboratories at the University of Leicester and in collaboration with the Faculty of Mechanical Engineering at the Department of Machine and Product Design at the Budapest University of Technology and Economics, Hungary. The work was conducted in accordance with the University Hospitals of Leicester Ethical and Good Clinical Practice requirements.

This body of work includes Publications in Peer Reviewed Journals from 2007 to 2014. The work was undertaken whilst the Candidate was a full-time NHS Consultant Maxillofacial Surgeon at the University Hospitals of Leicester and also held the Honorary position of Lecturer or Senior Lecturer within the Department of Cancer Studies & Molecular Medicine.

Acknowledgements

I thank my co-authors for their invaluable contributions to this work and in particular Dr Peter Bujtar and Janos Simonovics who have collaborated with the computer simulation work. Other significant contributions are acknowledged within the individual publications. The Candidate is grateful for general support from Professors Nick London [Department of Surgery] and William Steward [Department of Cancer Studies & Molecular Medicine] at the University Hospitals of Leicester. I thank Professor Jingzhe Pan [Department of the Mechanics of Materials, College Director of Research] at the University of Leicester for supporting and overseeing the development of our biomechanical and computer simulation studies. Dr Jonathan Willets [Postgraduate Tutor] and David Parker [Head of Student Programmes Administration] at the University of Leicester for supporting and facilitating this application.

I am grateful to my partner Karen and my children, Sebastian and Catherine, for their patient understanding of the demanding nature of my work throughout this period.

This Thesis is dedicated to my many courageous patients.

Synopsis of publications by chapter

Chapter 1 Soft-tissue radial free flap and donor site

1. **Avery C. [Invited Review]**
Review of the radial free flap: is it still evolving or facing extinction? Part one: soft tissue radial flap.
Br J Oral Maxillofac Surg 2010;48:245-252.

In 2010 the Author published an invited Review Article on the current status of the radial free flap. Topics covered included the Author's publications and perspective on minimising morbidity at the donor site. A review of the evidence for reduced morbidity at the donor site with the suprafascial dissection technique was presented. The alternative flaps to the radial free flap were considered.

2. **Avery C.**
Prospective study of the septocutaneous radial free flap and suprafascial donor site.
Br J Oral & Maxillofac Surgery 2007;45:611-616

The soft-tissue fasciocutaneous radial free flap remains the most frequently used flap for reconstruction of the oral cavity. However, the forearm donor site is prone to the early wound healing complications of skin graft loss, tendon exposure and delayed healing.

The septocutaneous radial flap represents an evolution in flap design with a more demanding suprafascial, rather than subfascial, dissection technique. In 2007 the Author published the largest personal series with the septocutaneous flap. In a prospective study of 121 consecutive procedures the flap survival rate was 97%. The incidence of skin graft loss (4%), tendon exposure (3%) and delayed healing (4%) was relatively low compared to the subfascial flap. This study confirmed the septocutaneous flap is a safe surgical technique. The majority of donor sites may be effectively repaired with a full, rather than partial, thickness skin graft and this has additional advantages in reducing morbidity at the skin graft donor site.

3. **Avery C.** Sundaram K, Jasani V, A Peden, Neal C.
Comparison of sensory changes at the suprafascial and subfascial radial donor sites.
Br J Oral Maxillofac Surg 2012;50:495-499.

The sensory changes at the radial subfascial site have been scantily reported and there were no substantive studies of the suprafascial forearm donor site. The superficial radial nerve is less exposed to manipulation during the suprafascial dissection because of the retained fascial covering. The Author speculated this may result in a better sensory outcome. A retrospective comparison of the subfascial and suprafascial donor sites found few differences in sensory outcomes, except for significantly better sensation in the distribution of the palmar branch of the median nerve in the suprafascial group. This may be because this nerve is more exposed to manipulation or injury during a conventional subfascial dissection. This paper also allows the Author to give better advice on the expected pattern of sensory changes after surgery.

4. Shim T, Abdullah A, Lanigan S, **Avery C.**
Hairy intraoral flap – an unusual indication for laser epilation: a series of 5 cases and a review of the literature.
Br J Oral Maxillofac Surg 2011;49:e50-52.

The skin of the radial forearm flap, and other flaps, may develop excessive hair growth, which is aesthetically and functionally unsatisfactory. The Author reported the novel use of an alexandrite laser to successfully depilate 4 severe cases. Although access may be hindered by limited mouth opening, this technique has widespread applications.

Chapter 2 Osteocutaneous radial free flap and donor site

5. **Avery C. [Invited Review].**
Review of the radial free flap: still evolving or facing extinction? Part two: osteocutaneous radial free flap.
Br J Oral Maxillofac Surg 2010;48:253-260.

In 2010 the Author published an invited Review Article on the current status of the radial osteocutaneous flap. Topics covered included the Author's publications and perspective on minimising morbidity at the donor site.

The radial flap may be raised with a segment of the radius as an osteocutaneous flap but the donor site is prone to fracture (mean 25%), causing considerable morbidity. In 1999 the Author introduced the technique of prophylactic internal fixation (PIF) with a straight 3.5mm dynamic compression plate (DCP) to substantially reduce the incidence of fracture (2 to 3%). The paper reviews the weakening effect of an osteotomy and the biomechanical and clinical studies supporting the strengthening effect of PIF. Additional issues included the most appropriate design and position of the bone plate, and the cost-effectiveness of PIF. The introduction of PIF has resulted in the almost complete elimination of the main complications associated with the radial osteocutanous flap. The Author considers the current role of this flap for selected mandible and maxillary bone defects or when managing patients with considerable medical comorbidity.

6. **Avery C,** Martin T, Parmar S.
The use of a T-shaped contoured unilocking titanium radial plate for prophylactic internal fixation of the radial osteocutaneous donor site.
Br J Oral Maxillofac Surg 2011;49:152-153.

Anatomically designed T-shaped radial plates, secured with unilocking screw systems, have recently been introduced for managing fractures of the distal radius. In 2011, the Author published the first clinical series utilising these plates for PIF of the radial osteocutaneous donor site. These lower profile and lighter plates may have advantages in reducing the risk of stress shielding and achieving greater fixation in osteoporotic bone whilst the shape facilitates harvest of distal bone when space is limited.

7. **Avery C**, Skidmore M, Peden A, Pan J.
Biomechanical study of a unilocking T-plate system for prophylactic internal fixation of the radial osteocutaneous donor site using the sheep tibia model.
Oral Oncol 2011;47:268-273.

In this biomechanical laboratory study, the sheep tibia model was used to investigate whether different sizes of the new titanium T-plates with unilocking screw systems were as effective for PIF as the straight 3.5 mm DCP with bicortical fixation, as originally described by the Author. All bone-plate constructs significantly strengthened an osteotomised bone under bending [factor 1.73 to 2.43] and torsional [factor 1.54 to 2.63] loads. The anterior and posterior plate positions were also compared. The 3.5 mm unilock titanium T-plate and straight DCP steel plates were the strongest constructs and most suitable for PIF in clinical practice.

8. **Avery C,** Bujtar P, Simonovics J, Sándor G, Pan J, Váradi K A.
A finite element analysis of bone plates available for prophylactic internal fixation of the radial osteocutaneous donor site using the sheep tibia model.
J Med Eng Phy 2013;35:1421-1430.

This computer modelling study investigated and validated a finite element analysis (FEA) technique as an accurate representation of the sheep tibia model previously described by the Author in paper 4. A computer aided design (CAD) model of different types of plate and screw fixation was created. The new titanium 3.5 mm and 2.4 mm T-plates with unilocking screw systems were compared with conventional straight 3.5 mm DCP steel plates secured with bicortical fixation. Only the anterior plate position was considered, as this is the most common surgical practice. Peak stress values at the screw and osteotomy sites were measured. The strengthening effects were comparable to the previous sheep tibia laboratory experiment under bending [factor 1.89 to 3] and torsional [factor 1.24 to 1.67] loads. A straight 3.5mm locking compression plate (LCP) simulation (not tested in the previous biomechanical laboratory experiment) was the strongest form of reinforcement.

Chapter 3 Osteotomy and reconstruction plate design

9. Bujtar P, Simonovics J, Sándor G, Pan J, **Avery C**.
Refinements in osteotomy design to improve structural integrity: a finite element analysis.
Br J Oral Maxillofac Surg 2013;51: 479-485.

The FEA technique developed in publication 8 was refined to investigate the impact of general osteotomy design on stress concentration using the sheep tibia CAD model. Relative stress values were measured at the intersection of osteotomy cuts. Peak stress values for 4 point bending and torsion were 24-30% greater at the right-angled osteotomy compared to a bevelled end cut. Overcutting increased peak bending and torsional stress values by 48% and 71% respectively., The peak stress concentrations were significantly reduced (bending 38% & torsion 60%) by utilising a stop-hole at the site of osteotomy intersection, and this will reduce the risk of fracture.

10. **Avery C**, Simonovics J, Bujtar P.
The stop-hole osteotomy technique.
Br J Oral Maxillofac Surg 2014;52:475-476.

In paper 9, the Author demonstrated the importance of avoiding an overcut at osteotomy sites, as this creates a significant increase in peak stress concentration. This is the first clinical description of a stop drill hole technique designed to substantially reduce the risk of fracture in maxillofacial and other surgical practice.

11. Bujtar P, Simonovics J, Váradi K A, Sándor G, **Avery C.**
The biomechanical aspects of reconstruction for segmental defects of the mandible: A finite element study to assess the optimisation of plate and screw factors.
J Craniomaxillofac Surg 2014:6:855-862.

This FEA study investigated the biomechanical stability of plate reconstruction options following segmental resection of the mandible. Four segmental defects commonly created during oncology surgery were simulated on a CAD model of the mandible. A standardised load was applied to mimic the human bite. The peak stress and strain levels, and spatial changes at the screw-bone interfaces were recorded. The locking plate and monocortical screw fixation systems were most effective. The current model provides a good basis for developing refinements in plate or bone holding scaffold design.

Chapter 4 Choice of flap reconstruction, outcomes and morbidity

12. **Avery C,** Shenoy S, Shetty S, Siegmund C, Iqbal M, Taub N.
The prospective experience of a maxillofacial surgeon with the percutaneous endoscopic gastrostomy technique.
Int J Oral Maxillofac Surg 2008;37:140-148.

In 2008 the Author reported the largest personal series of percutaneous endoscopic gastrostomy (PEG) insertion by a head and neck oncology surgeon. The rate of successful PEG insertion was 97.3% (219/225) with a median duration of 337 (SE 31) days. Removal of the PEG is an indirect marker of adequate oral intake. Duration was significantly longer for stage T3-4 tumours, N1 or greater neck disease, following surgery with radiotherapy, particularly glossectomy and maxillectomy procedures, after two separate surgical procedures with radiotherapy and following a composite bone resection, or radiotherapy alone when compared to surgery alone. Interestingly, there was no relationship to the type of flap reconstruction. This study improved our understanding of patient survival and functional outcomes. It also facilitated informed counselling of patients with regard to potential complications and likely duration of PEG dependency.

13. **Avery C,** Clifford N, Niamat J, Vaidhyanath R.
Early detection of bone union with transcutaneous ultrasound in the management of non-union of the mandible.
Br J Oral Maxillofac Surg 2011:49;661-663.

The return of oral intake is prolonged if delayed union of the bony free flap used to reconstruct the mandible occurs. External fixation may be used to stabilise the osteotomy sites whilst healing occurs but is inconvenient for the patient. However, it is often uncertain when sufficient bone union has occurred to allow safe removal of the fixation. The Author describes the novel use of ultrasound to detect evidence of bone union several weeks before it is visible on radiographs in a small series of patients. This is reassuring for both the patient and surgeon and allows the earlier removal of the fixation.

14. **Avery C,** Crank S, Neal CP, Hayter JP, Elton C.
The use of the pectoralis major flap for advanced and recurrent head and neck malignancy in the medically compromised patient.
J Oral Oncology 2010;46:829-833.

In 2010 the Author published the largest review of a cohort of patients (71) with substantial medical comorbidity and advanced oral tumours managed with a pedicled pectoralis major (PPM) flap. The majority had advanced stage IV primary disease, or extensive recurrent or metastatic neck disease. The PPM flaps were increasingly used in the latter half of the series but there was no evidence of an increase in age, American Society of Anaesthesiology (ASA) comorbidity grade or extent of malignant disease. The flap and patient survival outcomes compared favourably with the literature. The Author believes the PPM flap retains a role in the management of selected patients with advanced disease and substantial medical comorbidity. Aggressive surgical treatment was advocated in combination with a pragmatic outlook on the morbidity of reconstruction and functional outcome.

15. **Avery C**. Ghandi N, Peel D, Neal CP.
Indications and outcomes for 100 patients managed with a pectoralis major flap within a UK maxillofacial unit.
Int J Oral Maxillofac Surg 2014;43:646-554.

The number of patients in the cohort described in paper 11 had increased to 100 (102 flaps). The indications and outcomes for these oncology patients managed with a PPM flap were reviewed. The majority (88.2%) of patients had advanced oral malignancy with stage IV (75.6%) disease and substantial comorbidity (47% ASA 3 or 4). The PPM flap was often the preferred reconstruction (80.4%) but also followed free flap failure (19.6%). The majority of patients (n=57) had previously undergone major surgery and/or chemo-radiotherapy. Flap loss of any degree was independently associated with ischaemic heart disease (P=0.028), diabetes mellitus (P=0.040) and infection with Methicillin resistant *Staphylococcus aureus* (MRSA) (P=0.013). Total (2%) and major (6.9%) PPM flap loss was independently associated with previous free flap failure (P=0.044).

Chapter 4 Choice of flap reconstruction, outcomes and morbidity

Contd **Avery C**. Ghandi N, Peel D, Neal CP.
Indications and outcomes for 100 patients managed with a pectoralis major flap within a UK maxillofacial unit.
Int J Oral Maxillofac Surg 2014:43:546-554.

Cancer-specific 5-year survival for stage IV primary SCC and salvage surgery improved in the second half (2005-2012) of the study period (22.2% vs. 79.8%, P=0.002 and 0% vs. 55.7%, P=0.064).There were also declines in recurrent disease (P=0.008), MRSA (P<0.001) and duration of admission (P=0.014). The Author believes the PPM flap retains a valuable role in the management of advanced disease combined with substantial comorbidity, and following free flap failure. This paper improved our understanding of patient and flap survival outcomes, the range and incidence of complications and has facilitated informed patient counselling.

16. **Avery C. [Invited Review].**
A perspective on the role of the pectoralis major flap in maxillofacial oncology surgery.
Oral Surgery 2014:7:130-142.

This paper sought to review global utilisation of the PPM flap and set the practice of the Author in context. The evidence for this review is mainly based on retrospective case-series or cohort studies (level III and IV). The versatile PPM flap remains a valuable reconstructive option both in centres predominantly within the developed world, which preferentially practice free tissue transfer, and also throughout the developing world when free tissue transfer is not an option. The PPM flap is utilised in varying proportions as either the preferred reconstruction or for salvage reconstruction following free flap failure, further disease or complications. Refinements in surgical technique and an experienced surgeon may yield total flap success rates comparable with or better than free tissue transfer. Adverse factors such as: serious or multiple comorbidities, advanced disease and previous treatment are common indications. The defects most commonly reconstructed included extended radical neck dissection, parotid, postero-lateral mandible, large glossectomy and oropharyngeal defects. In some major centres a second free flap is increasingly used after initial failure. However, the PPM flap remains the most common salvage option. Survival outcomes for advanced oral malignancy may be improving. The needs of the local population vary and informed patient choice may increasingly influence flap selection.

17. **Avery C.**
The sternocleidomastoid perforator flap.
Br J Oral Maxillofac Surg 2011;49:573-575.

The applications of the conventional pedicled sternocleidomastoid SCM flap are limited by a poor arc of rotation and precarious vascularity. The Author describes a novel SCM flap that is completely detached except for the perforating branches of the superior thyroid artery. The arc of rotation is greatly increased allowing the flap to safely reach the lower oral cavity. Several patients with extensive medical comorbidity and/or in whom all other flap options had been exhausted were salvaged with this new technique.

18. **Avery C**. Clifford N, Sundaram K, Jasani V, Neal C.
Impact of a structured proforma for improving documentation at the planning stage of major maxillofacial oncology surgery.
Face Mouth & Jaw Surg 2011;2:33-39

The management of major maxillofacial oncology surgery is complex and several consultations are necessary to cover all aspects of care and to obtain informed consent. Although the shortcomings of general medical and surgical operating records have been well documented, there is little information on the clinical records used for planning surgery and obtaining informed consent. This retrospective audit study covered a decade of practice that included the introduction of a structured planning proforma designed by the Author. There was a statistically significant and progressive improvement in a wide range of individual variables documented. The quality of the clinical records has been improved and sustained. The proforma is also a valuable educational tool for the trainee as it provides a logical framework for coordinating investigations, planning many aspects of care and providing informed consent.

Importance of published work.

1. The Thesis is based on 18 peer reviewed articles in which I have been the leading or senior Author. The range of journals includes those with the highest impact factors (IF) within the specialty of Oral & Maxillofacial Surgery. The IF of the British Journal of Oral & Maxillofacial Surgery has risen to 2.72 in 2013. The British Journal is the highest ranked Oral & Maxillofacial Journal in the world and is within the top 30 Surgical or top 10 Dentistry/Oral Surgery Journals. This is comparable with the most highly ranked Oral Oncology journals such as Head & Neck (2013 IF 2.8) and the Journal of Oral Oncology (2012 IF 2.69), in which I have also published. Publications were also included in the International Journal of Oral & Maxillofacial Surgery (2012 IF 1.5) and Journal of Cranio-Maxillofacial Surgery (2012 IF 1.6). Publication in the Journal of Medical Engineering and Physics (2012 IF 2.2) established the scientific credibility of the finite element analysis model.

2. The most frequently downloaded paper in the British Journal of Oral & Maxillofacial Surgery [August 2010].

   Avery C: Review of the radial free flap: is it still evolving or facing extinction? Part one: soft tissue radial flap. Br J Oral Maxillofac Surg 2010;48:245-252 [42].
   www.elsevier.com/wps/find/journaldescription.cws_home/623007/description#description

3. **ResearchGate Annual Summary 2013**
   My high ResearchGate score reflects the level of interest in my research .

   Publication Views in 2013: 2000
   Profile Views: 410
   Full-text downloads: 69
   RG Score: 34.46
   RG Impact points 174.93
   RG impact score is greater than 92.5% of ResearchGate members

   https://www.researchgate.net/profile/Christopher_Avery/stats/report/2013?ch=reg&cp=re291_cv_p2001&pli=1&loginT=XjQTf6wWE5VoDwf95wolPob-twQDZSZ5a110I0m5ptIVOfgcl1e9YQ,,
   https://www.researchgate.net/profile/Christopher_Avery/?ev=hdr_xprf

4. **Hirsch H-Citation Index April 2014**
   A high H-Index citation score of 17 reflects the level of interest in this and other related research.

   Total citations: 743
   Citations/year: 32.30
   H Index 17
   G Index 26

5. Most frequently presented author at the Annual Scientific Meeting (ASM) of the British Association of Oral & Maxillofacial Surgery (BAOMS) over the last decade.

   Avery C, Clifford N, Thakrar M, Neal CP, Brennan P. Leading Article: Trends in presentations at BAOMS Annual Scientific Meetings. Face Mouth & Jaw Surg 2011;1:38-47 [3].

6. Leicester is the joint second Maxillofacial surgical department in UK with the highest rate of converted presentations to publication from the ASM of the BAOMS, and the Author is the most frequent individual contributor.

   Collier JM, Vig N, Hammond D. Publish or perish? A survey of abstracts accepted for meetings of the British Association of Oral and Maxillofacial Surgeons, and subsequently published. Br J Oral Maxillofac Surg 2010;48:540-43 [2].
   http://dx.doi.org/10.1016/j.bjoms.2009.08.037

7. The Trent region was the Deanery with the joint highest number of contributions at the BAOMS ASM over the last decade. Leicester contributed 50% of this work and the Author nearly 90% of the Leicester activity.

   Avery C, Clifford N, Neal CP.
   Oral & Maxillofacial surgery "presentation hotspots" in the UK over the last decade from the BAOMS annual meetings. Br J Oral Maxillofac Surg 2013;51:453-456 [1].
   http://dx.doi.org/10.1016/j.bjoms.2012.09.019

8. Several of the research areas included in this MD submission have also been published as book chapters. This includes a core training operative Maxillofacial surgery textbook in which the new surgical techniques of the suprafascial radial flap and prophylactic internal fixation of the radial osteocutaneous donor site were included for the first time (Appendix B). Both of these techniques have become increasingly popular. The use of prophylactic internal fixation has been widely adopted throughout the developed world. I am currently updating the 3rd Edition of this textbook.

9. This paper on the pectoralis major flap featured on the American MDLinx website in November 2013 as the number 10 ranked article of interest to the Editorial Panel and Readers. This reflects the International interest in the publication.
   http://www.mdlinx.com/dentistry/author-comment.cfm/A1cf4b895ca8b12ff/?utm_source=author-recruit-commentary&utm_medium=email&utm_campaign=author-email1-addcomments
   Avery C. Ghandi N, Peel D, Neal CP.
   Indications and outcomes for 100 patients managed with a pectoralis major flap within a UK maxillofacial unit.
   Int J Oral Maxillofac Surg 2014;43:546-554 [309].
   http://dx.doi.org/10.1016/j.ijoms.2013.10.009

10. This work was cited on the Doctors.Net clinical problem discussion forum as a new treatment modality.
    Shim T, Abdullah A, Lanigan S, **Avery C.**
    Hairy intraoral flap – an unusual indication for laser epilation: a series of 5 cases and a review of the literature. Br J Oral Maxillofac Surg 2011;49:e50-52 [144].
    http://www.doctors.net.uk/Forum/viewPost.aspx?post_id=5227600

11. Invited Faculty on the Liverpool Microvascular course. This is the premier UK educational course for trainee surgeons and the Author lectures on the topic of the radial free flap and management of donor site morbidity.

12. This paper was awarded UHL Surgical Specialties Audit prize 2012.
    Avery C. Clifford N, Sundaram K, Jasani V, Neal C.
    Impact of a structured proforma for improving documentation at the planning stage of major maxillofacial oncology surgery. Face Mouth & Jaw Surg 2011;2:33-39 [313].

13. The research work on plate design and reducing morbidity at the radial donor site was highlighted in a recent article in the local Leicester Mercury newspaper.
    http://www.leicestermercury.co.uk/teamwork-improve-patients-lives/story-20954129-detail/story.html

Abbreviations

AJCC	American Joint Committee on Cancer
ASM	Annual Scientific Meeting
BAOMS	British Association of Oral & Maxillofacial Surgery
Bi	Bicortical
cm	Centimetre
CAD	Computer Aided Design
CI	Confidence Interval
CT	Computerised Tomography
DCIA	Deep Circumflex Iliac Artery
DCP	Dynamic Compression Plate
DICOM	Digital Imaging and Communications in Medicine
(E)	Young's Modulus
FEA	Finite Element Analysis
g	grams
IF	Impact Factor
IFS	Inter-fragmental Strain
Lock	Locking
LCP	Locking Compression Plate
LRI	Leicester Royal Infirmary (Leicestershire. UK)
mm	millimetre
Mono	Monocortical
MPa	MegaPascal
MRSA	Methicillin resistant *Staphylococcus aureus*
Nd:YAG	Neodymium-doped Yttrium Aluminium Garnet laser
NHS	National Health Service
Non-lock	Non-locking
nos	Number
NPWD	Negative Pressure Wound Dressing
PEG	Percutaneous Endoscopic Gastrostomy
PIF	Prophylactic Internal Fixation
PT	Partial Thickness
P value	Probability value
SD	Standard Deviation
SE	Standard Error
TNM	Tumour – Node – Metastases [AJCC Staging Manual 2002 [4]]
T2-4	Tumour Stage 2, 3 or 4
UHL	University Hospitals of Leicester
UK	United Kingdom
USA	United States of America
Von Mises	von Mises (Peak) Stress Value
V-Y	V to Y wound closure

Symbols

%	Percentage
(-) or -	Not tested, not available or none

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Introduction

"… it is of considerable importance first to set forth those things which have been published by others, and to take notice of the things which have been commonly said and taught, so that what has been rightly spoken may be confirmed and what is false corrected in the light of anatomical dissection, personal experience many times repeated, and diligent and precise observation"

William Harvey (1628) [5]

There is considerable morbidity associated with major surgery for malignancy of the maxillofacial region. General morbidity affects multiple body systems whilst there is specific morbidity associated with both the donor sites of flaps throughout the body and where the flap is inset in the head and neck region [6, 7]. Nevertheless, reconstruction of the oral cavity, jaws and face is important for the restoration of form to avoid deformity and to optimise function, particularly speech and swallowing [8-11]. The introduction of pedicled myocutaneous flaps, and particularly the pectoralis major flap, in the 1980's was a significant advance, as large defects could be more safely restored [12-14]. This innovation was followed by the popularisation of free tissue transfer, and especially the radial forearm free flap, in the 1990's. The radial flap provided a large area of soft, thin, pliable and relatively hairless skin with which to resurface complex oral and facial defects, resulting in improved aesthetic and functional outcomes [15-26].

It is now over 30 years since the original description of the radial free flap [27] and this versatile and reliable flap [28, 29] has replaced the bulky pedicled pectoralis major flap [12, 17, 18] as the "workhorse" flap in modern maxillofacial practice. The pre-eminence of the soft-tissue radial flap has been challenged, with only limited success, by other flaps offering potentially less donor site morbidity, such as the fasciocutaneous ulnar flap [30-32], the septocutaneous lateral arm flap [33-37] and, most recently, the antero-lateral thigh perforator flap [38, 39]. These developments reflect the increasing success and sophistication of free tissue transfer techniques which are being driven by a desire to improve the versatility of flap design whilst also minimising morbidity at the donor site [39, 40]. During this period, the incidence of complications at the donor site of the radial flap has remained appreciable, but

techniques have become available to ameliorate the shortcomings of both the soft and hard tissue radial flaps and their respective donor sites [41-43].

The radial flap is composed of either soft-tissue alone (fasciocutaneous or septocutaneous) or a composite of bone and soft-tissue (osteocutaneous). Healing at both types of donor site is complicated by three key events; loss of the skin graft, exposure of the flexor tendons and delayed healing [44]. These complications may lead to a loss of function of the wrist or hand [44, 45]. The osteocutaneous donor site may also fracture, causing substantial deformity and functional loss [46], and this led to a substantial decline in the popularity of the flap [43]. The subsequent development of an increasing range of soft tissue and composite osteocutaneous free flaps has further expanded the reconstructive options available for managing complex defects of the oral cavity and facial skeleton [17, 47-51]. At the same time, there has been increasing interest in minimising the morbidity associated with this prolonged and complex surgery.

This thesis reviews the experience of the Author in managing and minimising the morbidity associated with flap reconstruction. The first chapter reviews the anatomy of the conventional fasciocutaneous soft tissue radial flap and subfascial donor site before introducing the concept of the septocutaneous radial flap and suprafascial donor site. Developments in flap harvest technique are described. This includes the experience of the Author in the largest prospective study of the septocutaneous radial flap. A comparatively low incidence of complications was reported. The sensory changes at the suprafascial and subfascial donor sites are also compared.

The second chapter reviews the role of the osteocutaneous radial flap and the impact of the introduction of prophylactic internal fixation (PIF) by the Author in minimising the incidence of fracture at the radial donor site. Lower profile anatomically contoured plates have recently been introduced in orthopaedic practice and may have several advantages, including greater fixation in osteoporotic bone. The first report of the clinical use of T-shaped titanium plates, with a unilocking (monocortical) screw system, was described by the Author for PIF at the radial osteocutaneous donor site. The Author investigated the biomechanical issues related to clinical practice with an experimental laboratory system using the sheep tibia model of the human radius. The conventional straight plates using bicortical screw fixation were compared with the new T-shaped plates utilising

monocortical fixation. The Author then simulated this model using the techniques of Computer Aided Design (CAD) and finite element analysis (FEA). The simulation technique was validated by comparing the strengthening effect of differing types of straight and T-plate screw fixation systems with bicortical or monocortical screw systems. The FEA technique allows various clinical scenarios to be simulated without relatively costly, slow and inconvenient laboratory testing.

In the third chapter, the Author used the FEA technique to study the effect of refinements in osteotomy design that are applicable to the radial donor site and other sites within the body. The introduction of a stop-hole at the site of osteotomy intersection to reduce peak stress concentration, and the risk of fracture, is described by the Author for the first time. The FEA technique was then utilised to investigate the biomechanical stability of a locking plate, with monocortical screw fixation, at a variety of segmental mandible defects commonly created during oncology surgery. This FEA model provides a good basis for developing refinements in plate design or the creation of a bone holding scaffold. The latter is a potential alternative to free tissue transfer that would reduce the morbidity associated with a bone flap donor site.

Finally, the fourth chapter is an overview of the differing types of flap used by the Author for oral reconstruction over more than a decade. A variety of clinical outcomes are considered including: duration of gastrostomy dependency, surgical and medical complications, flap success and complications, infection with Methicillin resistant *Staphylococcus aureus* (MRSA), disease recurrence and cancer survival. The Author describes the largest reports of a cohort of patients with advanced oral tumours and substantial medical comorbidity managed with the pedicled pectoralis major (PPM) flap. Although the outlook with advanced or recurrent disease is poor [52-58], in the experience of the Author survival appears to be improving. Aggressive surgical treatment, in combination with a pragmatic outlook on the morbidity of reconstruction and compromised functional outcome associated with the PPM flap, is advocated. This chapter seeks to set the practice of the Author within the context of global utilisation of the PPM flap. The Author proposes that the versatile PPM flap remains a valuable reconstructive option both in the developed world, where free tissue transfer is established, and throughout the developing world when free tissue transfer is not an option.

Chapter 1

Soft-tissue radial free flap and donor site

Publications by Author

Avery C. [Invited Review].
Review of the radial free flap: is it still evolving or facing extinction? Part one: soft tissue radial flap.
Br J Oral Maxillofac Surg 2010;48:245-252.
http://dx.doi.org/10.1016/j.bjoms.2009.09.004

Avery C.
Prospective study of the septocutaneous radial free flap and suprafascial donor site.
Br J Oral Maxillofac Surg 2007;45:611-616.
http://dx.doi.org/10.1016/j.bjoms.2007.04.008

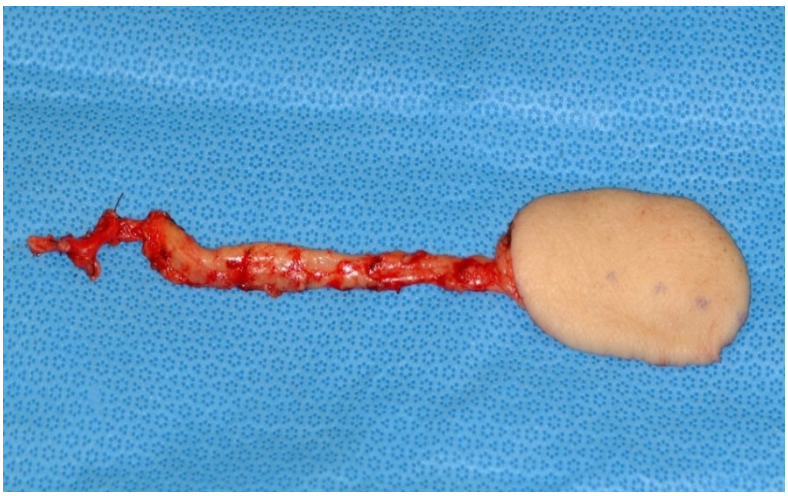
Avery C. Sundaram K, Jasani V, A Peden, Neal C.
A comparison of sensory changes at the suprafascial and subfascial radial donor sites.
Br J Oral Maxillofac Surg 2012;50:495-499.
http://dx.doi.org/10.1016/j.bjoms.2011.10.011

Shim T, Abdullah A, Lanigan S, **Avery C.**
Hairy intraoral flap – an unusual indication for laser epilation: a series of 5 cases and a review of the literature.
Br J Oral Maxillofac Surg 2011;49:e50-52.
http://dx.doi.org/10.1016/j.bjoms.2010.11.021

1.1.i The radial soft tissue free flap

The radial soft tissue flap remains the most popular flap for reconstruction of the maxillofacial region **(Figure 1.1)** [50]. The Author reviewed the role of the radial flap and management of the donor site in 2010 [42]. The flap is still probably most commonly raised as a non-sensate fasciocutaneous flap using the original subfascial dissection technique [17, 29, 44, 59, 60]. The subfascial dissection technique was first described in the Chinese literature in 1981 by Yang [61]. The blood supply of the flap came from the deep (subcutaneous) and superficial (subdermal) vascular plexus with perfusion to the skin via direct cutaneous branches of the radial artery.

Figure 1.1
The radial flap with vascular pedicle. The long pedicle is ideal for reaching from the vascular anastomosis in the neck up to the oral cavity.



1.1.ii Classification of fasciocutaneous flaps

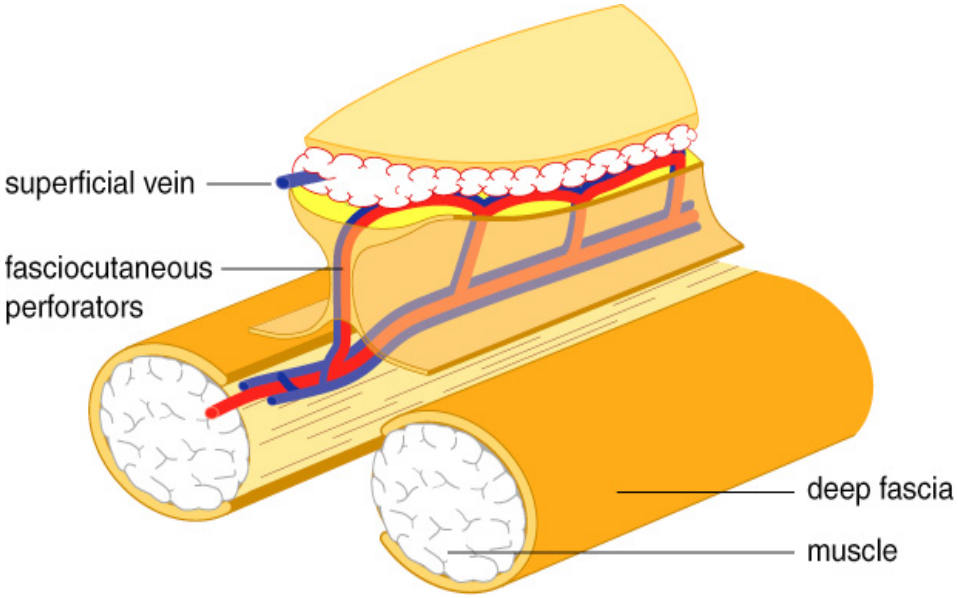
In 1984 Cormack [62] introduced a flap classification system based on the pattern of the blood supply **(Table 1.1)**. The key principle is that fasciocutaneous vessels pass along the fascial septae between muscles to form a deep fascial plexus from which blood perfuses the skin. The radial flap is a Type C fasciocutaneous flap with multiple perforating vessels passing arranged along an intermuscular septum in a ladder-like configuration **(Figure 1.2)**. Venous drainage is through the subcutaneous vein system [63], although in the experience of the author and others [64, 65] it is also commonly through the venae comitantes or the conjoined system of deep and superficial veins.

Table 1.1

The classification of fasciocutaneous flaps by Cormack & Lamberty [62]

Type of flap	Blood supply
A	Multiple independent perforating vessels entering flap with a proximal base
B	Solitary perforator at proximal end of islanded flap
C	Compartmental artery, septum containing perforators and flap, in continuity
D	Extension of C, with bone in continuity with fascial septum

Figure 1.2
A Type C fasciocutaneous flap [From Avery [66]].



1.1.iii Anatomy of the fasciocutaneous radial flap

Within the anatomical [67, 68] and surgical [28, 69-72] literature the radial artery is described as lying deep to or within a condensation of the deep fascia of the forearm **(Figure 1.3).** The fascia was initially considered essential for skin perfusion [28, 69-72]. In the first report of the surgical technique within the British literature, Soutar [28] described a subfascial plane of dissection which ensured the radial artery was safely elevated with the skin flap.

1.1.iv Morbidity at the radial subfascial donor site

The subfascial dissection technique removes the fascial covering over the flexor tendons and exposes the delicate paratenon. This site is unsatisfactory as a skin graft recipient bed because it is irregular, and the flexor tendons are mobile and poorly vascularised **(Figure 1.4)**.

Figure 1.3
Subfascial dissection of fasciocutaneous flap resulting in exposure of the flexor tendons. Radial artery within the condensation of fascia [From Avery [66]].

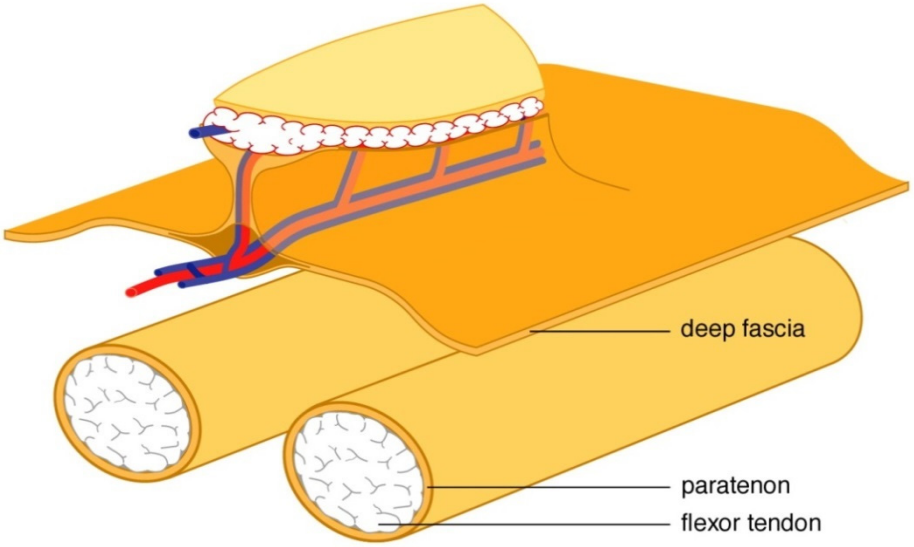
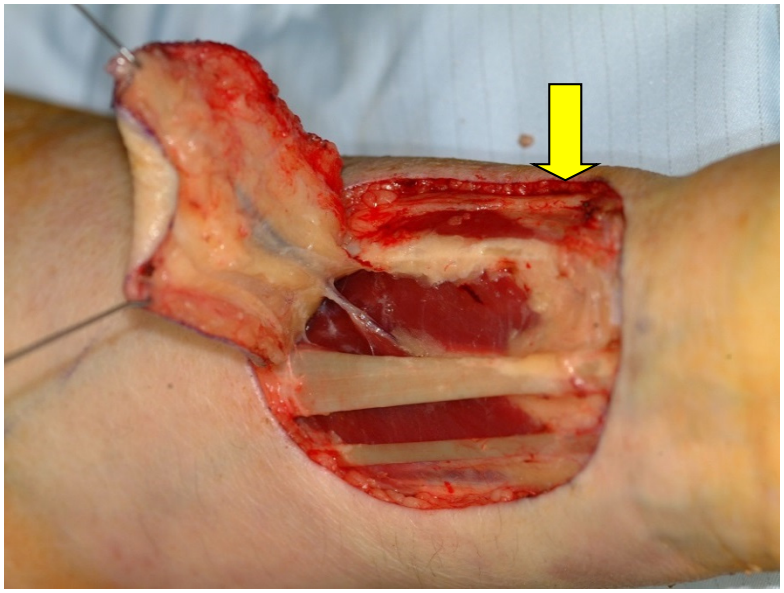


Figure 1.4
The subfascial donor site with exposed muscle and paratenon. Arrow indicates superficial branch of radial nerve.



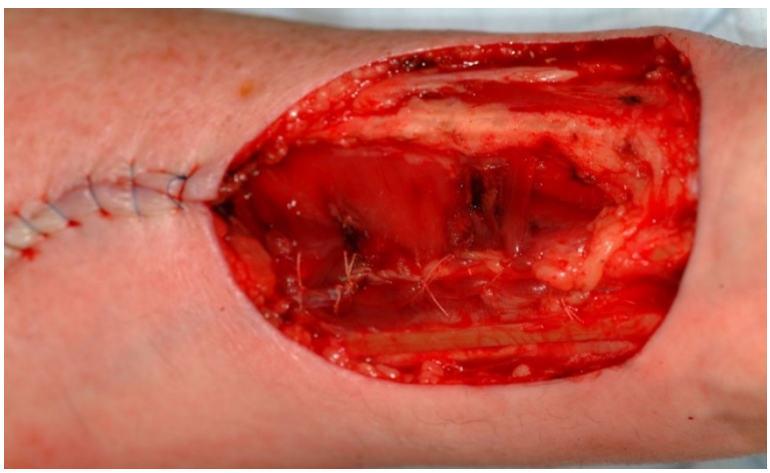
Although long term morbidity at the subfascial radial donor site is often considered relatively minor [44, 73], and of secondary importance to oncology patients, prolonged wound healing is an additional undesirable inconvenience after major surgery which may lead to significant loss of function and a poor aesthetic result [44]. The incidence of the three most

widely reported indicators of unsuccessful initial wound healing has remained significant in large clinical studies (**Table 1.2**). The rate of skin graft loss is as high as 16% [44] to 28% [45]. Recent prospective series have claimed improved rates of healing of 91% [74] and 93% [75] but excluded loss of less than 25% of the grafted area and late wound breakdown respectively, both of which are not uncommon. Loss of the skin graft often leads to exposure of the flexor tendons and delayed healing. The scarring and deformity of the forearm may be unsightly but is often apparently well tolerated [76, 77] except with elective reconstructions for benign disorders or female patients [78].

1.1.v Reducing morbidity at the radial subfascial donor site

Numerous techniques have been described to reduce morbidity at the subfascial donor site either by primary closure of the wound or improved healing of the skin graft. The early literature is composed of small retrospective reports with limited assessments of morbidity [70, 71, 79, 80]. Great importance has been placed on preserving the delicate layer of paratenon, excision of the palmaris longus tendon, immobilisation of both the wrist and skin graft within a plaster of Paris cast [81] and oversewing of the tendons [81] **(Figure 1.5)**. The defect is most commonly repaired with a partial thickness skin graft [44, 82, 83]. However, the skin graft donor site commonly suffers from complications [82] including; discomfort, slow healing, itching, unsightly scarring and also requires more dressing changes than a full thickness donor site [75]. Despite these measures, loss of all or part of the skin graft remains relatively common (**Table 1.2**).

Figure 1.5
Oversewing of the flexor tendons at the subfascial donor site with the flexor pollicis longus and flexor digitorum superficialis muscles.



To avoid the morbidity of a skin graft donor site radial defects may also be closed primarily [84], with an ulnar flap [85], Z-plasty [86], bilobed flap [87] or V-Y advancement closure [88-90] but these techniques may further distort the sensibility and appearance of the forearm [45, 85]. Repair with an acellular human dermis matrix [91, 92] or artificial dermis material in combination with a partial thickness skin graft [93, 94] has little substantive benefit.

Table 1.2
Morbidity at the subfascial and suprafascial radial donor sites in major series [From Avery [66]].

	Subfascial		Suprafascial	
	Bardsley 1990	**Richardson 1997**	**Lutz 1999**	**Avery 2007**
Type of study	Retrospective	Prospective	Prospective	Prospective
Nos of donor sites (n)	67	86	95	121
Skin graft thickness	Partial	Partial	Mainly Partial	Mainly Full
Skin graft loss (%)	28*	16	6	4
Tendon exposure (%)	28*	13	0*	3
Delayed healing (%)	28*	22	5*	4

* Implied

1.2.i Anatomy of the septocutaneous radial flap

It is still not generally appreciated that the distal radial artery, together with the skin paddle, may be safely separated from the underlying deep fascia. When Boo-Chai [95] translated the original Chinese description of the radial flap in 1982, it was stated that Yang [96] had described the flap as "reticulovascular" in nature but this was not widely recognised. The subfascial, fascial and prefascial (suprafascial) vessels have a minor role in radial flap perfusion. In dissection studies the blood supply to the skin of the forearm is primarily from the extensive subcutaneous vascular plexuses lying superficial to the deep investing fascia [97-99] and multiple longitudinal perforating septocutaneous vessels [100]. These findings were subsequently confirmed by Schaverien in 2008 [101] using an anatomical dissection and perfusion study to compare the subfascial and suprafascial harvest of the radial flap.

In the distal forearm, the layers of deep fascia between the brachioradialis and flexor carpi radialis tendons form an investing septum around the radial artery **(Figure 1.6)**. This fascia may be divided to raise the flap in a suprafascial plane and leave the fascia over the flexor tendons intact **(Figures 1.7 & 1.8)** [66, 102, 103]. This meets the criteria used to define a septocutaneous perforator flap, as the vessels pierce the superior layer of deep fascia before traversing only a septum to supply the skin as described by Wei [104] and then Blondeel [105]. This interpretation and classification may depend on whether a specific septum has been dissected and is a matter of debate [39].

Figure 1.6
In the distal forearm the radial artery is enveloped within a tunnel of investing fascia [From Avery [66]].

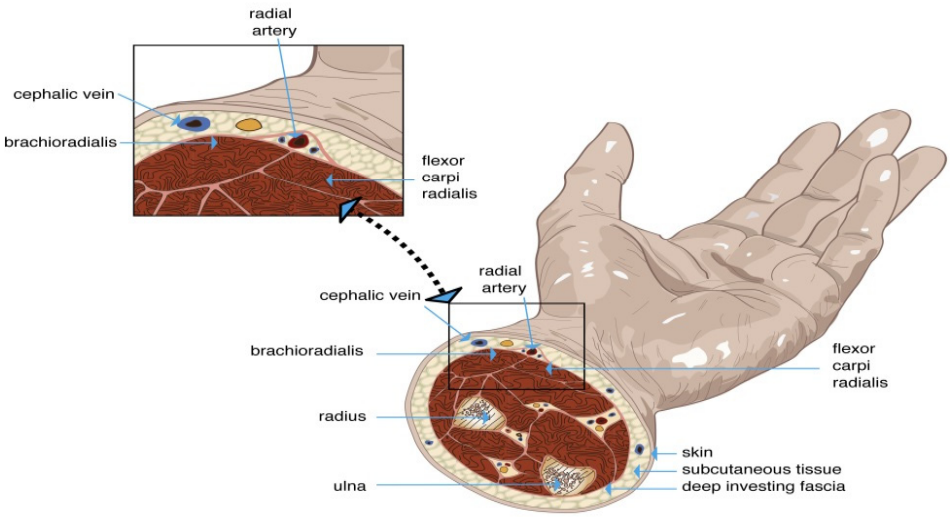


Figure 1.7
Division of the lateral aspect of the fascial envelope. The height of the perforating septocutaneous vessels is exaggerated [From Avery [66]].

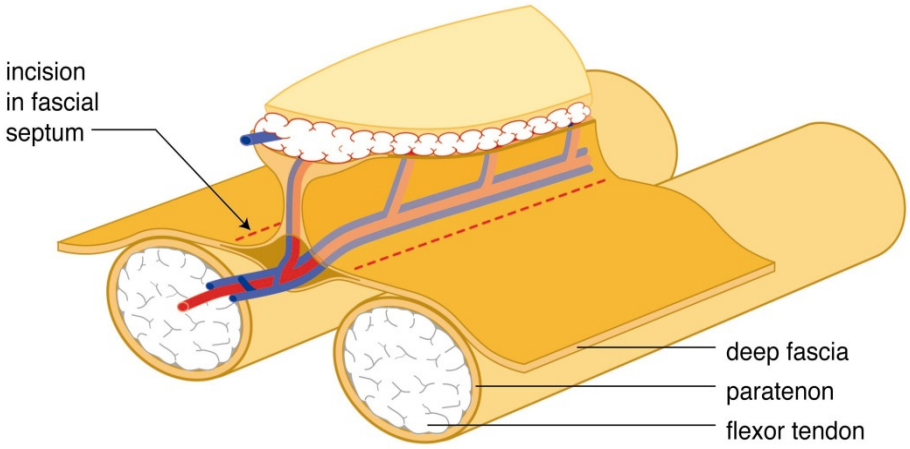
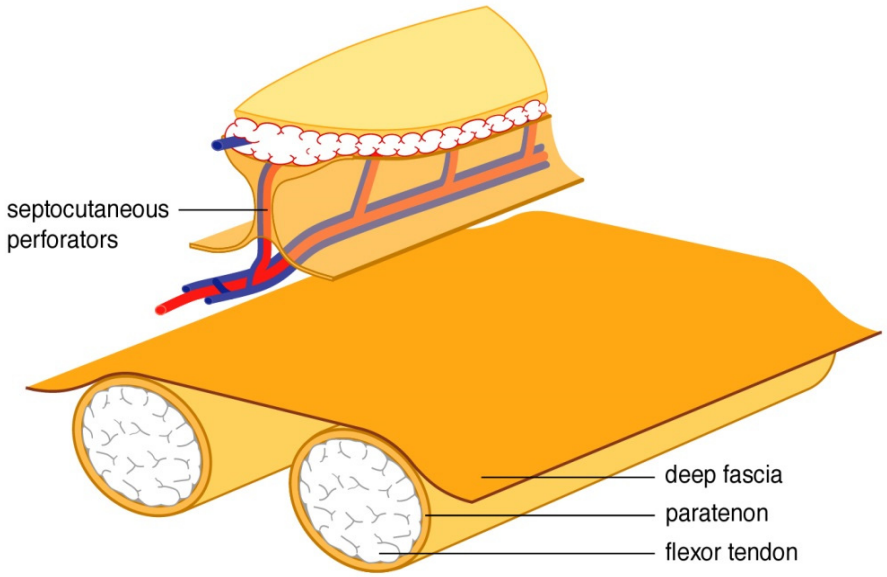


Figure 1.8
Preservation of the deep layer of fascia. The height of the septum has been exaggerated. [From Avery [66]].



1.2.ii The suprafascial dissection technique

The radial flap may be safely raised as a septocutaneous flap by utilising a suprafascial dissection technique [42, 66, 102, 103, 106, 107] with re-innervation if necessary [11], although some spontaneous sensory recovery will occur as previously described by the Author [108]. In 1996, Chang [102] first described division of the deep fascia investing the radial artery to

raise a septocutaneous flap. In 2007, the Author reported the most detailed anatomical description of the septocutaneous flap and suprafascial dissection technique [66].
The dissection continues beneath the subcutaneous plexus and along the fascial tunnel **(Figures 1.9 & 1.10)**.

Figure 1.9
Suprafascial dissection below the subcutaneous plexus [From Avery [66]].

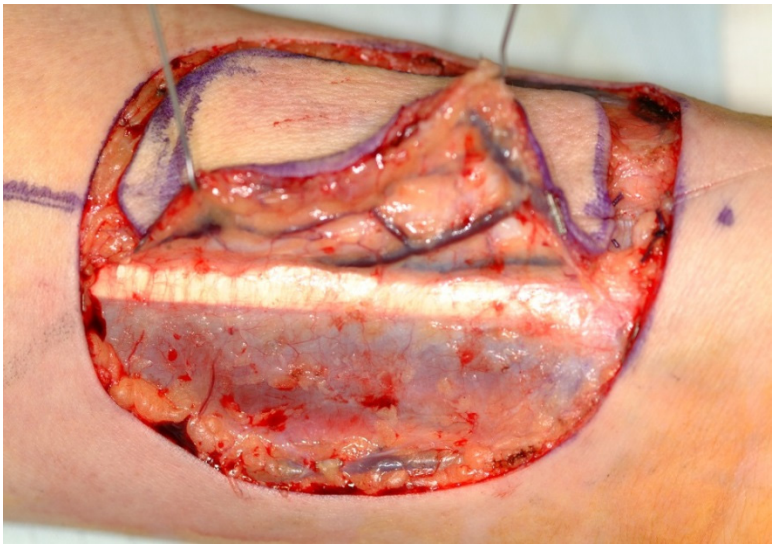
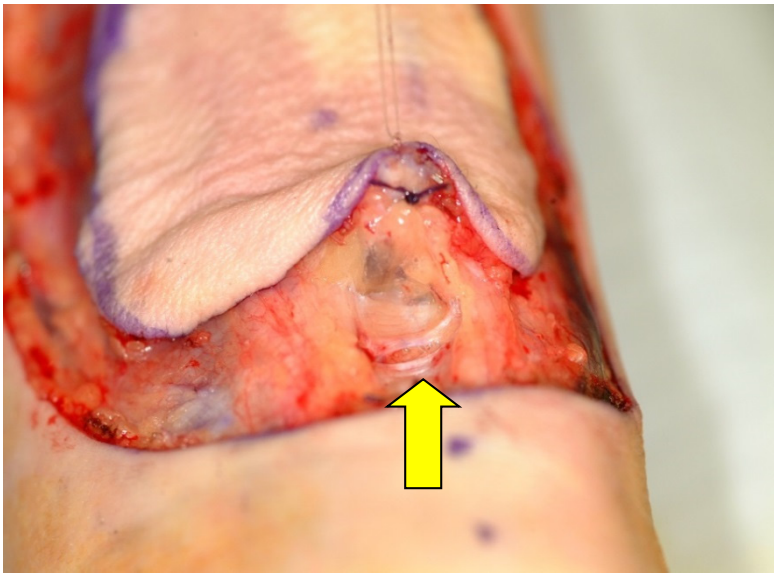


Figure 1.10
Vascular pedicle elevated from the floor of the fascial envelope [From Avery [66]].



The only vessels between the deep investing fascia and the flap were perforating muscular and periosteal vessels on the under surface of the pedicle, and a few fasciocutaneous vessels to or from the fascia **(Figure 1.11)**. This is consistent with the hypothesis that the fascia has a minor role in perfusion of the flap. The distal skin flap is elevated in close proximity to the deep subcutaneous tissues **(Figure 1.12)**. The proximal dissection is then completed in the conventional manner.

Figure 1.11
Perforating muscular and periosteal vessels from the under surface of the radial artery [From Avery [66]].

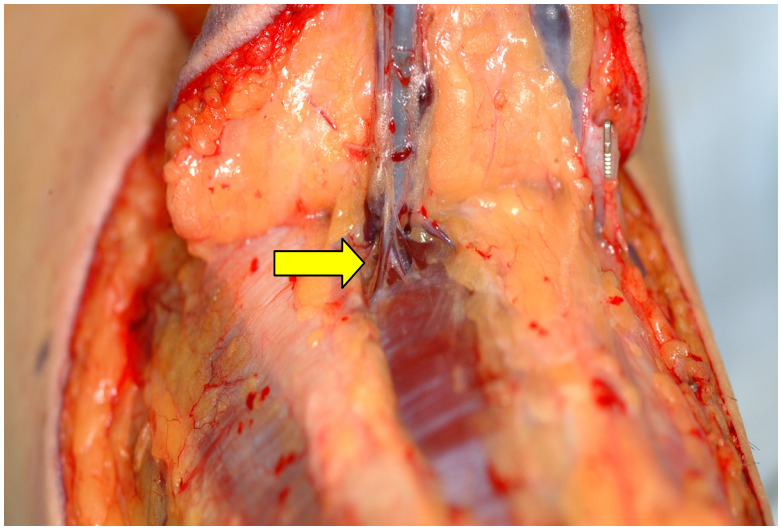
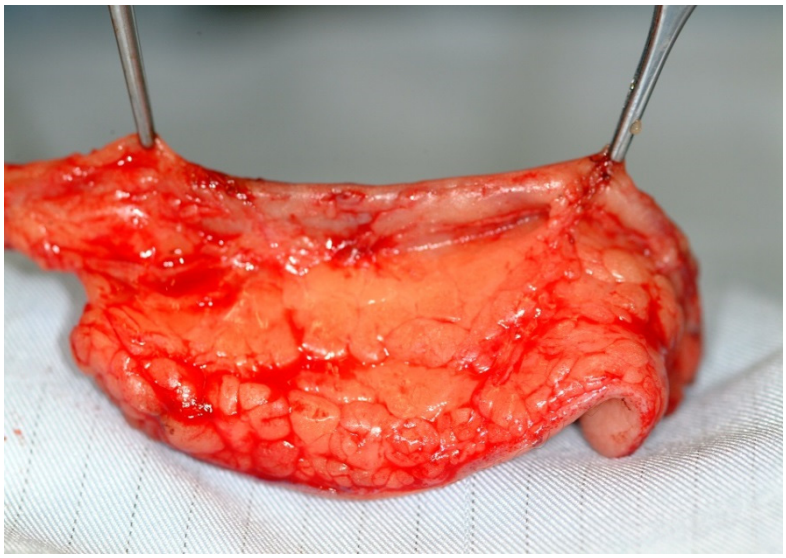


Figure 1.12
Radial flap with the vascular pedicle intimately related to the deep subcutaneous tissues [From Avery [66]].



1.2.iii Reliability of the septocutaneous radial free flap

The suprafascial technique had previously only been reported by the Plastic Surgery Department at the Chang Gung Memorial Hospital, Taipei (Taiwan), with flap success rates of 96.8% to 100% [11, 65, 106]. These outcomes were initially corroborated by the Author in 2001 [103] and then confirmed in the largest prospective series (121 septocutaneous flaps) in 2007, which described a flap success rate of 97% [66]. These outcomes were comparable with free flap success rates in general (97%) from this major unit in Taiwan [109] and with the incidence of exploration and salvage of flaps within the literature [65, 109-112].

In contrast, many of the large series of fasciocutaneous radial flaps have not stated flap success outcomes [44, 45, 74, 75] whilst others describe similar rates of 92.5 % [113], 96.6% (excluding partial failures)[59], 96.7% [111] and 98% [112]. The Author believes a success rate of 95% has become an informal benchmark figure.

1.2.iv Morbidity at the radial suprafascial donor site

Prospective reports of wound healing at the suprafascial donor site by Lutz [106] and the Author [66, 106] support the hypothesis that this donor site provides a superior skin graft recipient site. The fascia and residual soft-tissue on the radial aspect is vascularised and the skin graft is protected from the movement of the underlying tendons **(Figures 1.13 & 1.14**). In the most detailed study by the Author [66] all complications were captured. The incidence of skin graft loss (4%), tendon exposure (3%) and delayed healing (4%) were comparatively low and consistent with the later findings of Lutz [106] **(Table 1.2).** In the only prospective randomised comparison between the suprafascial and subfascial donor sites, the incidence of tendon exposure was substantially lower at the suprafascial site (3%, 1/30 vs. 21%, 6/28) [114].

Figure 1.13
The vascularised suprafascial donor site. Arrow indicates superficial branch of radial nerve [From Avery [66]].

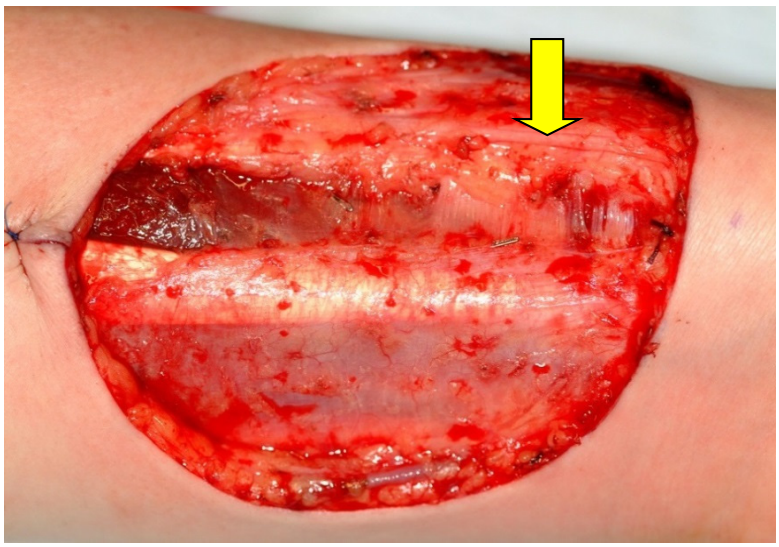
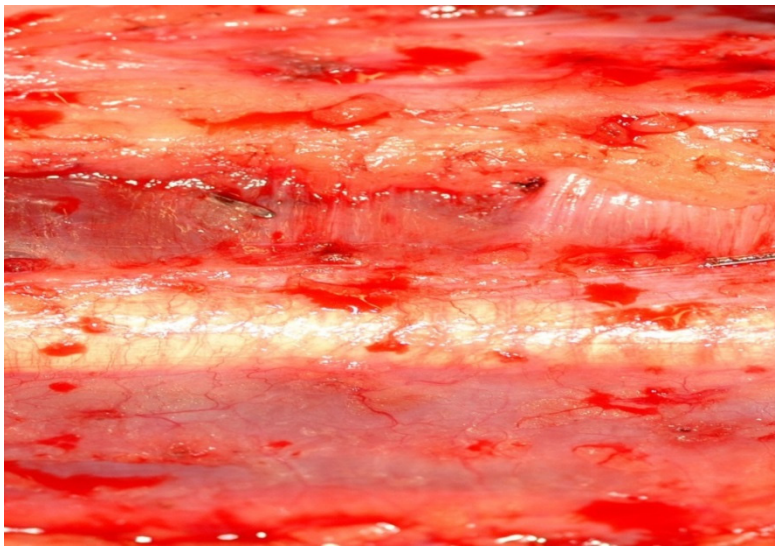


Figure 1.14
Close up view of deep fascia covering the paratenon of the flexor tendons, which creates a smooth vascularised bed for skin grafting [From Avery [66]].



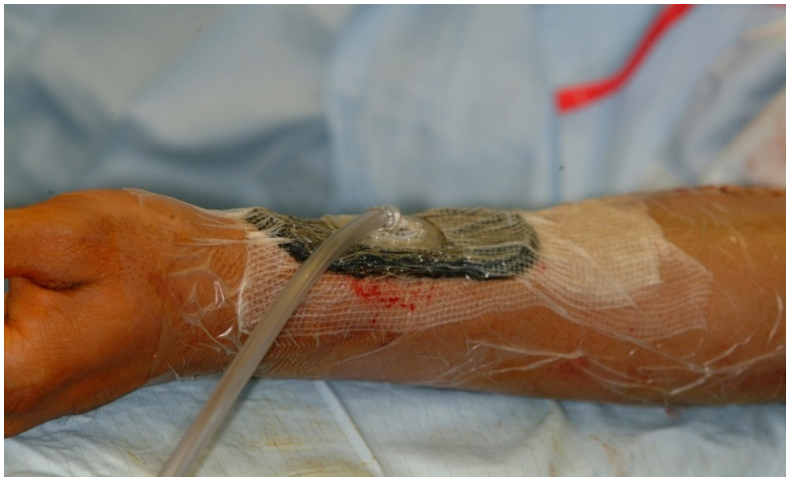
1.2.v Management of the radial suprafascial donor site

The Author prefers to repair the majority of radial defects with a full thickness skin graft and to close the graft donor site primarily to avoid the morbidity associated with a partial thickness donor site. The Author first described the inner upper arm skin graft donor site in

2005 [77] and subsequently noted full thickness grafts heal with less contraction in 2007 [66] and possibly marginally better sensory recovery in 2011. Full thickness grafts may also offer better functional and aesthetic outcomes [76, 77, 89, 115, 116] although this has been disputed [75, 117].

The type of wound dressing is an important, but unquantified, factor in healing at the radial donor site. The use of a negative pressure wound dressing (NPWD) at the radial donor site was first described by the Author in 2000 [118, 119]. The NPWD may expedite early revascularisation and healing of skin grafts [120-122] although not all studies have supported these findings [123]. The NPWD closely adapts the skin graft to the recipient site, minimising movement and eliminating dead space (**Figure 1.15**). At the radial site an additional advantage is that it is unnecessary to extend the NPWD over the hand, and the wrist may be immediately mobilised [103], unlike conventional support dressings. Excellent rates of graft healing at both the subfascial and suprafascial donor sites with either partial or full thickness skin grafts have been described [66, 83, 118, 119], together with superior results in a small retrospective comparison with the conventional bolster technique [124]. The NPWD dressing has also been used to stimulate healing by secondary intention over exposed flexor tendons [83] and by the Author to facilitate early re-grafting following infection with MRSA [125].

Figure 1.15. The negative wound pressure dressing holds the skin graft on to the radial recipient site.



1.3.i Sensory recovery at the subfascial and suprafascial radial donor sites

Sensory recovery following flap reconstruction of the oral cavity is incomplete and has been widely reported, including a comparison of the fasciocutaneous and septocutaneous variants of the radial flap by the Author [108]. In contrast, the incidence and pattern of sensory changes at the radial forearm donor site are poorly described. Sensory loss is widely variable and occurs at between 17% to 80% of subfascial donor sites [44, 73, 113, 126-130]. Previous reports have mainly noted sensory changes in the distribution of the superficial branch of the radial nerve (SBRN). The SBRN lies above the investing fascia and has to be mobilised with a subfascial dissection **(Figure 1.4)** but with a suprafascial approach this is not required **(Figure 1.13)**. Initially, Chang [131] reported "little or no significant numbness" at the suprafascial donor site and Lutz [132] later described SBRN paraesthesia at 54% of sites with "transient and mild" dysaesthesia.

It was unknown whether improved sensory recovery occurred at the suprafascial donor site so the Author undertook the first detailed objective comparison of the respective donor sites and reported the results in 2011 [133]. The pattern of sensory recovery was variable, with no significant differences in either global or individual site perception for most sensory modalities except for superior thenar palmar light touch in the suprafascial group **(Table 1.3)**. This may be due to injury to the palmar cutaneous branch of the median nerve which lies just beneath the flexor tendons mobilised in the subfascial dissection [134, 135]. Nerve injury may also occur in the proximal part of the forearm dissection regardless of the distal flap elevation technique employed, so reduced mobilisation of the SBRN may have no beneficial effect on sensory outcomes.

This study allows the Author to inform patients of the expected long-term morbidity. The majority will have reduced two-point discrimination and loss of sharp touch of the anterior forearm and approximately half have some reduced light touch sensation, but temperature sensation will be altered in only a third or fewer. Whether these changes are noticeable to the patient has not been studied. The recovery of sensation in the skin graft used to repair the radial donor site was very poor. The marginally better light touch sensation at the suprafascial donor site may be related to the predominance of full thickness skin grafts and greater potential for random regeneration of cutaneous nerves at the subdermal level [108, 136], but this is just speculation.

Table 1.3
Percentage of patients with reduced or absent perception of different sensory modalities (relative to non-donors arm) affecting at least one anatomical zone [From Avery [133]].

Modality	Subfascial group % (n)	Suprafascial group % (n)	p-value
Sensory modalities reduced but not lost			
Light touch	50% (15)	56.7% (17)	0.61
Two-point discrimination	96.7% (29)	96.7% (29)	1.00
Sensory modalities lost			
Sharp touch	89.9% (27)	83.3% (25)	0.71
Hot temperature	26.6% (8)	16.7% (5)	0.35
Cold temperature	33.3% (10)	26.7% (8)	0.57
Loss or reduction in perception of multiple modalities			
Loss/reduction at least one modality	100% (30)	100% (30)	1.00
Loss/reduction in at least three modalities	73.3% (22)	63.3% (19)	0.41

1.3.ii Management of the intra-oral hairy radial flap

The skin flap used to reconstruct the oral cavity, oropharynx or oesophagus will typically contain hair bearing tissue. Excessive unwanted hair growth may present as irritation, pooling of saliva, trapping of food and postoperative dysphagia and is difficult to manage [137-140]. Treatment may include regular trimming of hairs, sometimes under endoscopic guidance [137, 140]. Electrolysis is technically difficult to perform within the posterior oropharyngeal folds or hypopharynx [139]. Complete hair depilation may occur with postoperative radiotherapy [141], but the result is unpredictable and radiotherapy is not always necessary.

Hair depilation of a radial flap with an Nd:YAG laser may be effective [139] but not permanent [142, 143]. The alexandrite laser using fibre-optic instrumentation has offered promising initial results [138, 143]. In 2011, the Author reported a small series of 5 patients, of which 4 had a radial flap, successfully managed for the first time with the alexandrite laser [144]. Treatment was most effective when the hair pigment is darker than the surrounding skin pigment and is apparently long lasting **(Figures 1.16 & 1.17).** This treatment has become increasingly popular at the Birmingham (UK) centre with high levels of patient satisfaction [145].

Figure 1.16
Radial flap with hair on reconstructed aspect of tongue (Arrow) [From Shim [144]].

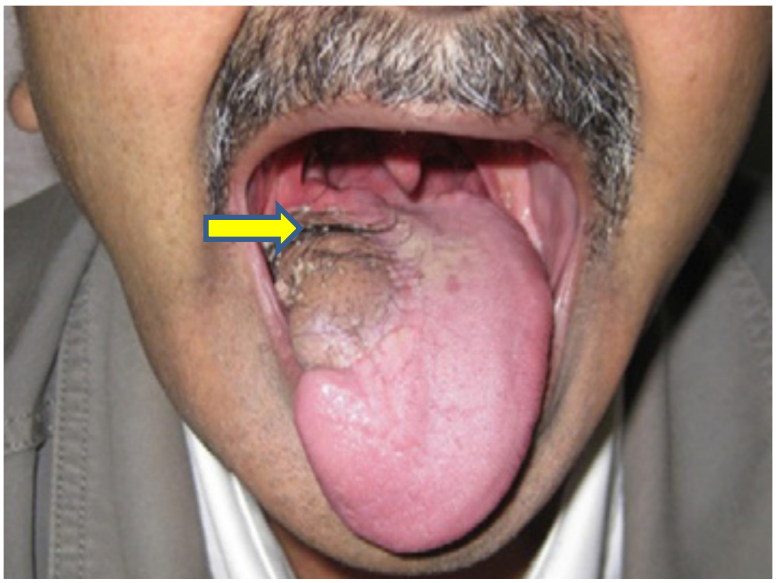
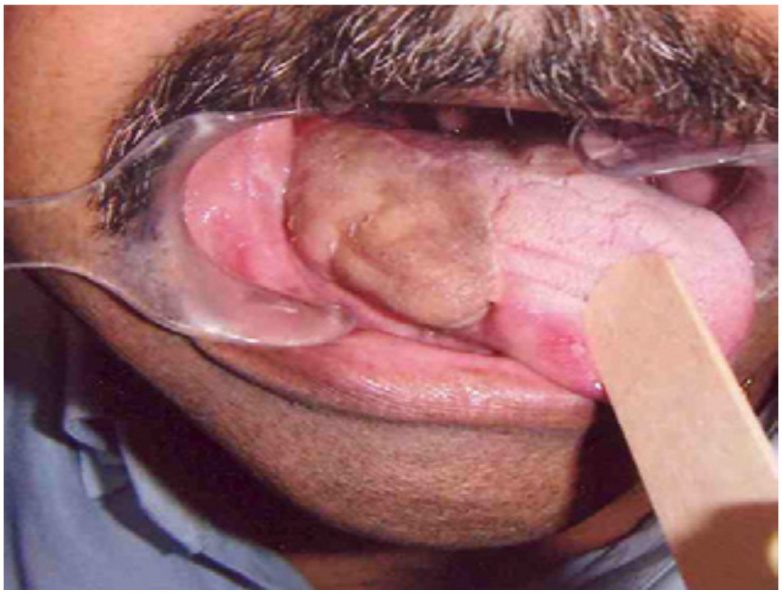


Figure 1.17
Significant reduction after alexandrite laser therapy [From Shim [144]].



1.3.iii Current role of the radial soft tissue flap

The popular and versatile fasciocutaneous radial flap is robust, reliable, simple to harvest, produces a satisfactory outcome and will remain the most popular flap for oral reconstruction in the foreseeable future. However, it suffers from appreciable initial morbidity at the donor site. Many surgeons employ a limited repertoire of flaps and these qualities will ensure that in the intermediate future the majority of surgical trainees will continue to be primarily exposed to the basic fasciocutaneous variant. However, in a large oncology practice it is important to expand the armamentarium of flap options available to optimise the management of a wide range of defects. In order to remain the flap of choice there is increasing support for the use of evolutionary techniques, such as the suprafascial dissection together with repair of the radial donor site with a full thickness graft. A negative pressure wound dressing may further minimise morbidity at the donor site. These technical refinements probably produce the best outcomes currently achievable when managing the inherent flaws of the radial donor site.

Chapter 2

Osteocutaneous radial free flap and donor site

Publications by Author

Avery C. [Invited Review].
Review of the radial free flap: still evolving or facing extinction? Part two: osteocutaneous radial free flap.
Br J Oral Maxillofac Surg 2010;48:253-260.
http://dx.doi.org/10.1016/j.bjoms.2009.09.017

Avery C,Martin T, Parmar S.
The use of a T-shaped contoured unilocking titanium radial plate for prophylactic internal fixation of the radial osteocutaneous donor site.
Br J Oral Maxillofac Surg 2011;49:152-153.
http://dx.doi.org/10.1016/j.bjoms.2010.01.013

Avery C, Skidmore M, Peden A, Pan J.
Biomechanical study of a unilocking T-plate system for prophylactic internal fixation of the radial osteocutaneous donor site using the sheep tibia model.
Oral Oncol 2011;47:268-273.
http://dx.doi.org/10.1016/j.oraloncology.2011.02.004

Avery C, Bujtar P, Simonovics J, Sándor G, Pan J, Váradi K A.
A finite element analysis of bone plates available for prophylactic internal fixation of the radial osteocutaneous donor site using the sheep tibia model.
J Med Eng Phy 2013;35:1421-1430.
http://dx.doi.org/10.1016/j.medengphy.2013.03.014

2.1.i The radial osteocutaneous flap

The radial osteocutaneous flap was the first reliable free flap reconstruction for continuity defects of the mandible [29, 45, 72, 146]. The two main factors contributing to the decline in popularity of the flap were the limited quantity of bone available and the morbidity at the donor site, particularly after fracture. In leading centres [50, 147] the radial flap has gradually been replaced by the iliac [48, 148-151], fibula [152-154] and scapula [155-157] flaps for reconstruction of large segmental defects of the mandible. However, the radial flap remains useful for limited mandible, maxillary or palatal defects with a significant soft-tissue component [50, 158, 159] and in the presence of significant comorbidity [43, 160]. The Author reviewed the role of the osteocutaneous flap and management of the donor site in 2010 [43].

2.1.ii Anatomy of the osteocutanous radial flap

The osteocutaneous flap includes a strut of the radius **(Figure 2.1)** and is harvested from the antero-lateral surface of the distal radius between the insertions of the pronator teres muscle proximally and the brachioradialis muscle distally **(Figures 2.2 & 2.3)**.

Figure 2.1
The osteocutaneous radial flap. Arrow indicates bone element.

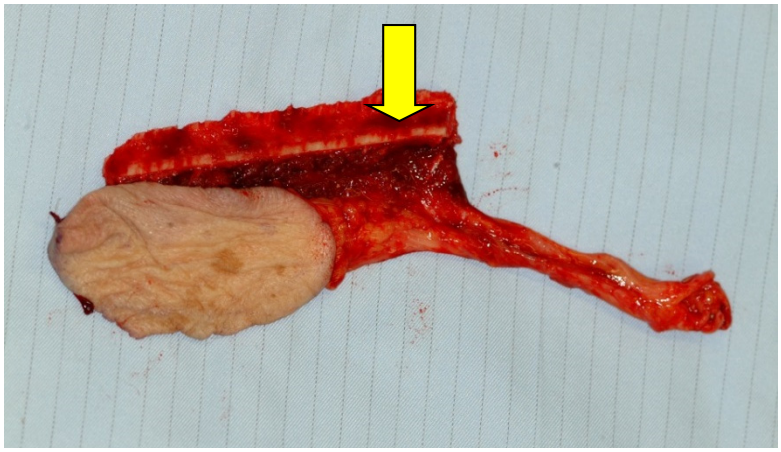


Figure 2.2
Skin markings of the radial styloid (arrow) and osteocutaneous flap.

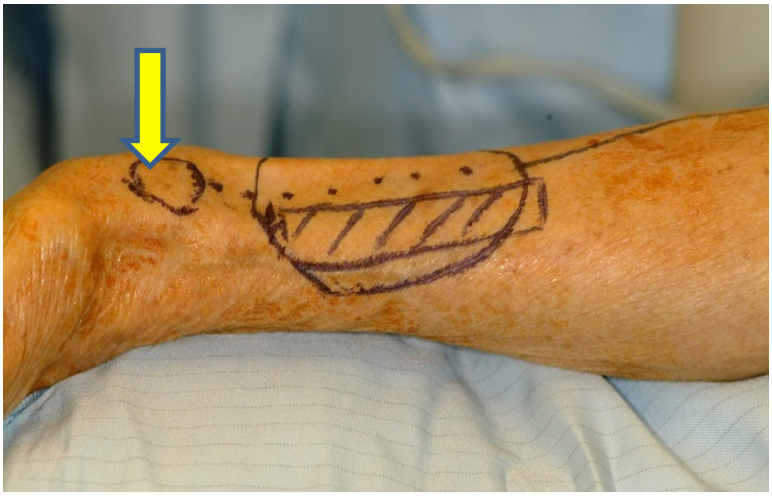
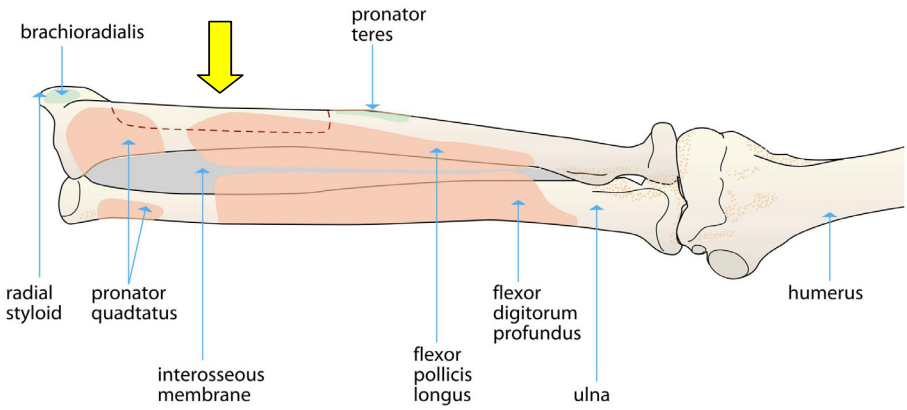


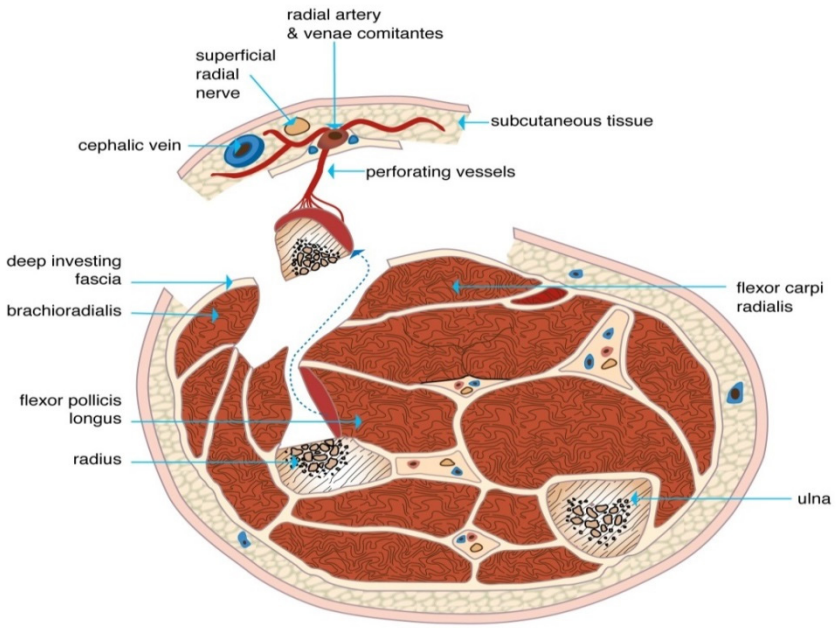
Figure 2 .3
The donor site of the osteocutaneous flap [From Avery [43]]



2.1.iii Classification of osteocutaneous radial flap

The vascular supply of the bone component is from fascio or septoperiosteal branches of the radial artery and the musculoperiosteal plexus of the flexor pollicis longus muscle. It is a Type D flap [62, 161, 162]. The flap is commonly harvested using a subfascial dissection but an incomplete suprafascial approach may also be used [43, 160] (**Figure 2.4**).

Figure 2.4
Cross-sectional view of osteocutaneous radial flap. [From Avery [41]].



2.1.iv Morbidity at the radial osteocutaneous donor site

The main cause of significant functional and aesthetic morbidity at the forearm is fracturing of the osteotomised radius [44, 45]. Management of a displaced fracture may include prolonged immobilisation or open reduction and bone grafting [163, 164]. The incidence of fracture in early reports varied from 28% to 43% [29, 72, 79, 165] and in subsequent larger series was 23% to 31% [45, 166]. In the most recent large reports the incidence was lower at 15% to 19% [44, 164, 167] (**Table 2.1**) but with a mean of 25% in one major review [46]. These are the lowest rates of fracture that may be achieved using conventional surgical techniques.

Table 2.1
Morbidity at the osteocutaneous donor site [From Avery [43]].

	Richardson 1997 [44]	**Thoma 1999 [164]**	**Clark 2004 [167]**
Type of study	Prospective	Retrospective	Retrospective
Donor sites (n)	35	60	68[a]
Type of osteotomy	Keel[b]	Keel	Bevel and right-angle
Mean bone length (cm)	8.5	9	7.7
Radial circumference (%)	30 -50[b]	30-50	30-50[b]
Type of cast (weeks)	Above elbow (6)	Below-elbow (-)	Above-elbow (8)
Incidence of fracture % (n)	17 (6)	15 (9)	19 (13)
Secondary surgery % (n)	-	10 (6)	9 (6)
Statistically at higher risk	Women	None	Women

- Unknown
[a] 71 donor sites of which 3 with PIF excluded
[b] Confirmed by author

2.1.v The weakening effect of an osteotomy

The main weakening effect of an osteotomy comes from disruption of cortical integrity [79] following the creation of an "open-section" defect [167, 168]. This causes a significant loss of strength in torsion by reducing the ability of the bone to absorb energy [169, 170]. The greatest effect is on bones, such as the radius, with thin cortical walls and with long transcortical defects [171]. Most fractures of the radius are spiral and probably caused by relatively low-

energy torsion forces as the radius is able to withstand much greater bending forces [46, 168, 172, 173].

Seventy-five percent or more of the strength of both the human radius in bending [172], and a sheep tibia model in torsion [168] is lost by removing up to 50% of the bone circumference. Bevelling the proximal and distal osteotomy cuts or varying the dimensions of the osteotomy defect has relatively little strengthening effect [168]. The recommended amount of the radius which may be "safely" removed is one third of the diameter [172], 30% of the cross-sectional area [168] or 40% of the circumference [29, 174].

2.1.vi External and internal support of the osteotomised radius

External support has an important but limited and undefined role in protection of the osteotomised radius [167, 175, 176]. Six weeks of immobilisation in an above-elbow cast has been recommended [176] but the fracture rate with this typical regimen is still as high as 19% [167] (**Table 2.1**).

An intramedullary nail may be inserted by an orthopaedic surgeon [177] but is ineffective in reducing rotational forces if incorrectly applied [178]. A more familiar fixation method, which may be applied by a maxillofacial surgeon, is prophylactic internal fixation (PIF) with a cortical bone plate. Prophylactic internal fixation may prevent the pathological fracture of a long bone [179-182]. The same principle was reported for the first time at the radial donor site by the Author in 1999 [183]. A 3.5 mm steel dynamic compression plate (DCP) was placed over the donor site defect (anterior position) (**Figures 2.5 to 2.7)** in a non-compressive mode and acts as a bridging reinforcement. Fixation with a minimum of 4 bicortical screws was recommended **(Figure 2.8)**. The introduction of PIF was a significant development and the technique has become widely established as the definitive reliable method for harvesting up to 50% of the radial circumference [160, 184] and may increase utilisation of the flap [184, 185].

Figure 2.5
The osteotomy site with a cuff of the flexor pollicus longus muscle [From Avery [43]].

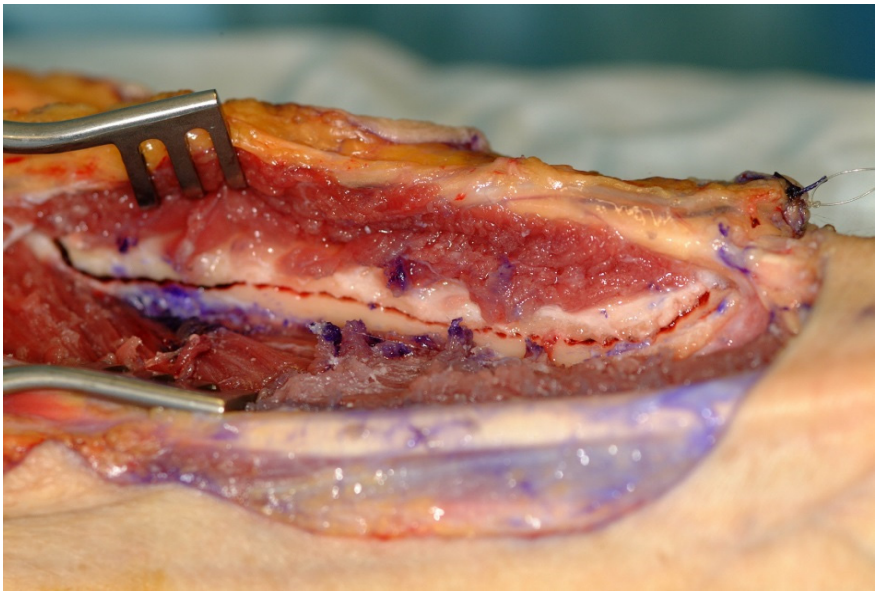


Figure 2.6
The section defect of the anterior surface of the radius with bevelled osteotomy end cuts [From Avery [43]].

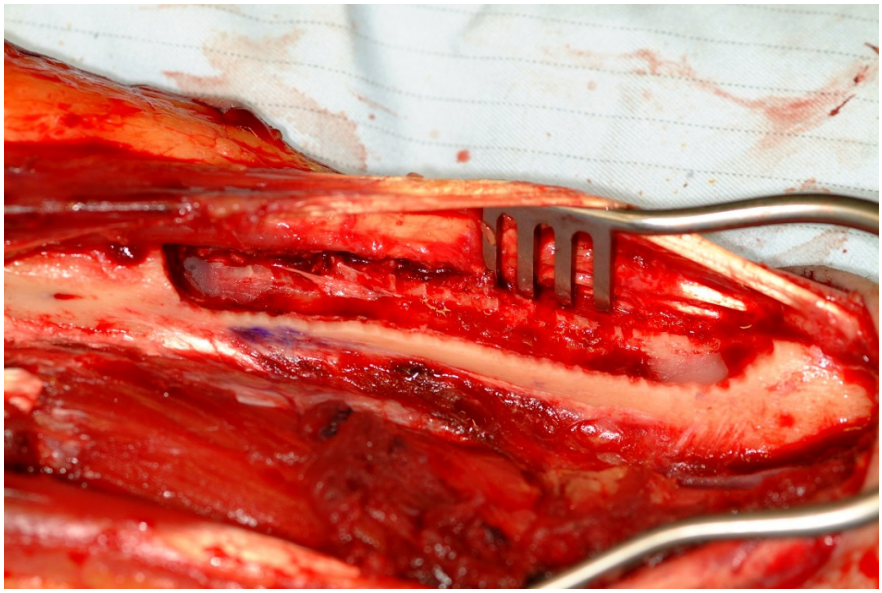


Figure 2.7
A reconstruction plate over the section defect [From Avery [43]].

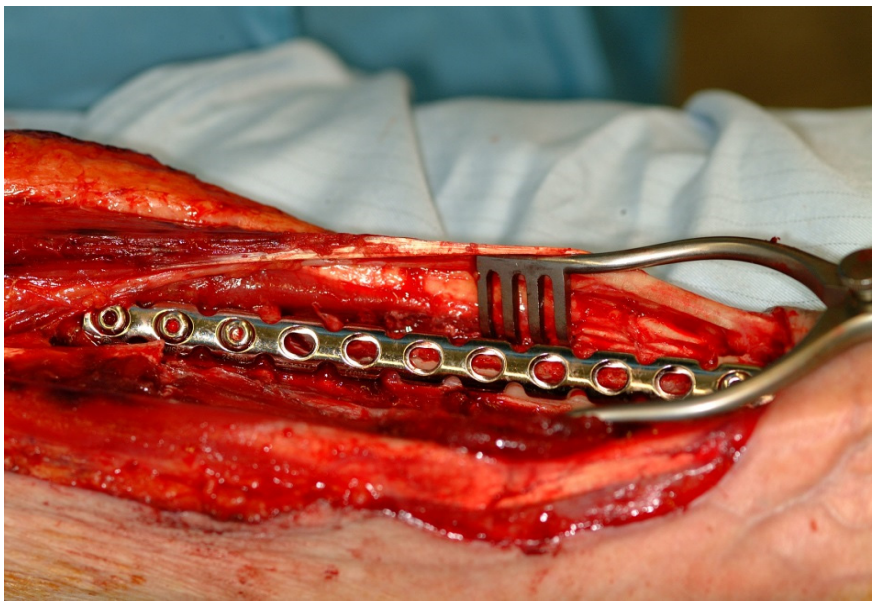
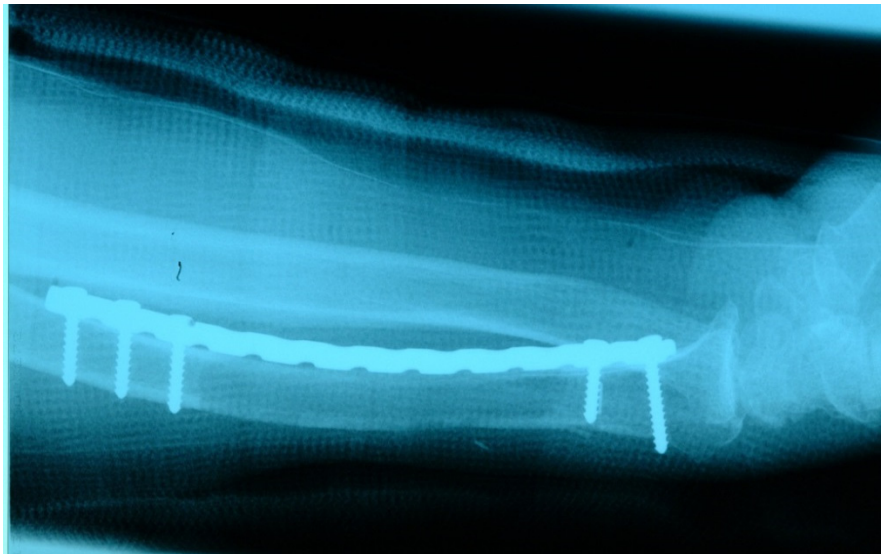


Figure 2.8
Radiograph demonstrating fixation with bicortical screws [From Avery [43]].



2.2.i Strengthening effect of prophylactic internal fixation: Initial biomechanical studies

The significant strengthening effect of PIF in either the anterior (over donor site defect) or posterior (on intact opposite radial cortex) position has been demonstrated in biomechanical studies. In 2000 Bowers [46] reported that the osteotomised human radius, supported with a 3.5 mm steel DCP in the posterior position, was 4 times stronger in torsion than an unreinforced bone or 63% of the strength of an intact bone. Under bending the reinforcement was 2.7 times greater or 73% of an intact bone. In 2007 the Author [186] described the strengthening effect of different types of plate in either the anterior or posterior positions using a validated sheep tibia model of the radius [168]. The mean torsional and bending strengths of a reinforced osteotomised bone were 1.6 and 2.8 times greater respectively than an unreinforced bone. A 3.5 mm DCP wholly restored torsional strength in either the anterior (97%) or posterior (101%) positions and partially restored bending strength in both the anterior (46%) and posterior (80%) positions. Although a posterior plate was more effective in withstanding bending forces this is probably not important in clinical practice as fracture is more likely to occur with a lower torsional force and the anterior position is equally effective at resisting torsional forces [168, 172, 186].

2.2.ii Strengthening effect of prophylactic internal fixation: Clinical studies

The posterior [187, 188] and anterior [160, 185, 189] plate positions have both been successfully employed, including by the Author [160], in retrospective clinical series with a substantially reduced overall incidence of fracture (2.6%, 7/268 donor sites) **(Table 2.2)**. The Author believes up to 50% of the radial circumference may be safely harvested [160, 187] whilst the radius is protected with a full below-elbow cast that allows early mobilisation [185, 187].

2.2.iii Reduced incidence of secondary surgery with prophylactic internal fixation

The need for secondary surgery is much lower when PIF has been applied because fewer fractures occur or become displaced. The overall incidence of secondary surgical repair with PIF is very low 0.4% (1/268 donor sites) and repair is much less frequently required should fracture occur (14%, 1/7 fractures) (**Table 2.2**). This contrasts with the much higher

rates of secondary surgery without PIF of 9% (6/68 donor sites and 46% of fractures 6/13) [167] and 10% (6/60 donor sites and 67% 6/9 of fractures) [164] **(Table 2.1).**

Table 2.2
Clinical studies of the morbidity at the radial osteocutaneous donor site associated with prophylactic internal fixation [From Avery [43]].

Author	Werle 2000 [187]	Villaret 2003 [185]	Militsakh 2005 [188]	Kim 2005 [189]	Avery 2007 [160]
Type of study	Retrospective	Retrospective	Retrospective	Retrospective	Retrospective
Type of osteotomy	Bevel	Bevel	Bevel	Keel	Mostly Bevel
Mean (range) bone length (cm)	7.6 (5.5-12)	-	6.6 (3-12)	6.3 (3-11)	7 (4-9.5)
Radial circumference (%)	50	40	50	-	33-50
Donor sites with PIF	52	34	108	52	22
Site of plate fixation	Posterior	Anterior	Posterior	Anterior	Anterior
Type of fixation plate	Steel DCP, LC-DCP, reconstruction	Steel DCP	Steel DCP	Steel DCP	Steel DCP, titanium, reconstruction
Incidence of fracture % (n)	9.6 (5)*	0 (0)	0 (0)	1.9 (1)	4.5 (1)
Secondary surgery % (n)	0 (0)	0 (0)	0 (0)	1.9 (1)	0 (0)
Number plates removed	0	1	1	0	0

\- Data not available
* No fractures after the use of monocortical screws in the section defect was discontinued

2.2.iv Potential complications and plate selection with prophylactic internal fixation

In the long term a sufficiently large plate may cause a stress protection effect leading to localised osteopenia and late fracture. The mechanisms may include mechanical unloading [190-193] and reduced cortical perfusion [194-196]. However, concerns about PIF have proved unfounded. Late incomplete remodelling of bone defect has been observed [160, 187, 197] and less than 1% (2/268) of plates inserted have been removed for complications (**Table 2.2**).

2.2.v Indications for prophylactic internal fixation

Selective PIF has been advocated for older females with a smaller radius and increased risk of osteopenia [167, 198]. A significantly higher rate of fracture for females has been reported in

two of the larger studies [44, 167] but not all series [164], and no relationship to age has been established. In the view of the Author there is no evidence to oppose the routine application of PIF but selection criteria may evolve with greater experience.

2.3.i Developments in the plate design

The main developments in plate design have been unilocking screw systems and limited contact plates to reduce the risk of osteopenia caused by a compromised periosteal vascular supply [195], although the latter has been disputed [193]. Titanium, rather than steel, plates may have less of a stress shielding effect because the elastic modulus and structural stiffness of the plate is lower and closer to bone which should allow greater sharing of the load [186, 197, 199]. Low profile contoured unilocking plates designed for fractures of the distal radius have become increasingly popular and may achieve greater fixation in osteoporotic bone [200, 201]. As many oncology patients are elderly this may be a further advantage.

2.3.ii Anatomically designed T-shaped unilocking radial plate

The 3.5 mm steel dynamic compression plate (DCP) used in the conventional PIF technique is quite bulky and requires careful adaptation. In 2010 the Author described the first reported experience of PIF of the radial donor site with lower profile 3.5 mm T-shaped anatomically contoured plates and lighter 2.4 mm T-shaped plates in a small clinical series [202]. Both designs incorporated a unilocking screw system and the angulated distal end facilitates the safe removal of the maximum amount of bone near the wrist joint (**Figures 2.9 & 2.10**). Locking technology has imparted greater angular stability and iatrogenic fracture is less likely during screw insertion as only one cortex is engaged. The plates are lighter and more readily adapted although close adaptation to the bone is less important as the unilocking screw system acts as an “internal fixation” device. The new unilocking plate systems may become the method of choice for PIF once greater clinical experience has been accumulated.

Figure 2.9
An LCP contoured titanium plate with an extended proximal shaft positioned over the anterior radial donor site [From Avery [202]].

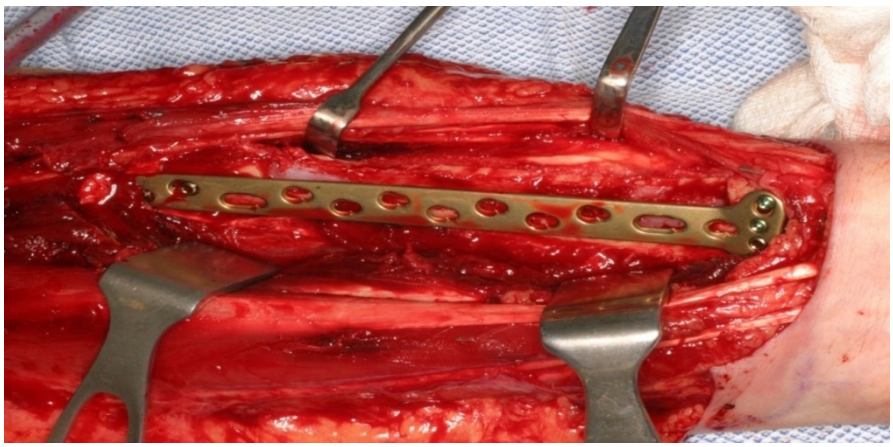
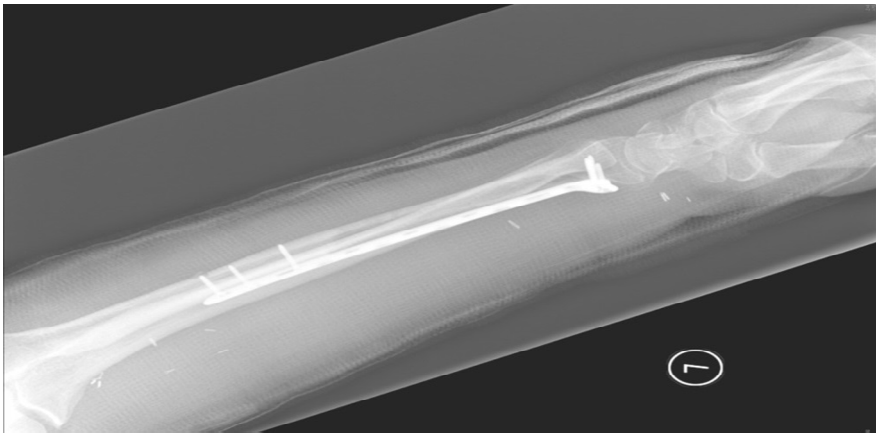


Figure 2.10
The distal screws near the wrist joint are unicortical whilst the proximal screws in the radial shaft may be uni or bicortical [From Avery [202]].



2.3.iii Strengthening effect of prophylactic internal fixation: Current biomechanical studies

Until recently, the biomechanical effectiveness of new unilocking plate systems was unknown. In 2011 the Author published the first comparison of the effectiveness of T-plate unilocking systems with a conventional 3.5 mm straight steel plate utilising bicortical screw fixation for PIF [203]. This biomechanical laboratory study used the sheep tibia model of the radius and incorporated a standardised section defect (**Figure 2.11**). A range of plates in both the anterior and posterior positions were compared **(Figures 2.12 to 2.15**).

Figure 2.11
Standardised section defect in sheep tibia [From Avery [203]].

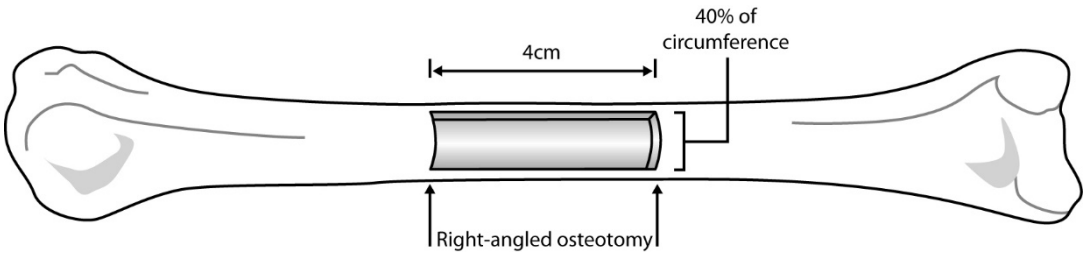


Figure 2.12
Conventional straight 3.5 mm steel plate over defect (anterior position) with 2 bicortical screws at each end in a non-compressive position. This is the minimum number of screws required for stability [From Avery [203]].

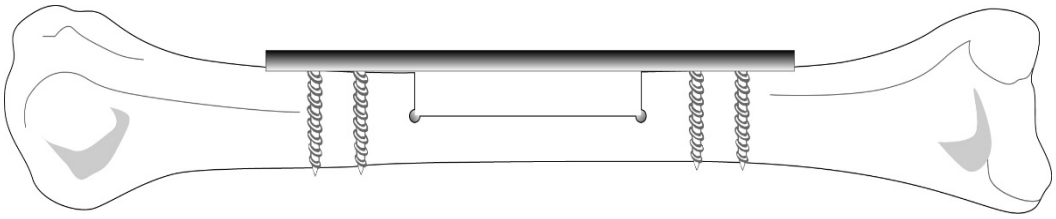


Figure 2.13
Conventional straight 3.5 mm steel plate on intact cortex (posterior position) with 4 bicortical screws [From Avery [203]].

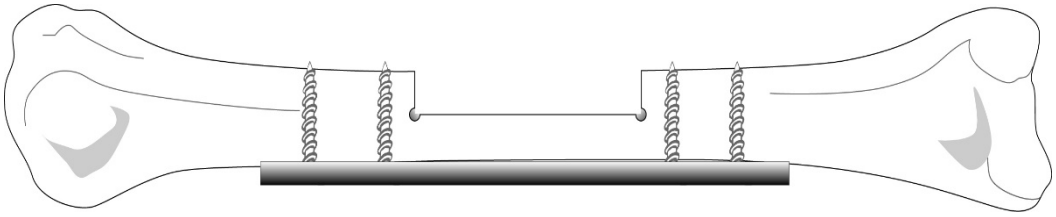


Figure 2.14

T-shaped titanium plate over defect (anterior position) with two unicortical screws either side of the section defect and within the T-shaped end [From Avery [203]].

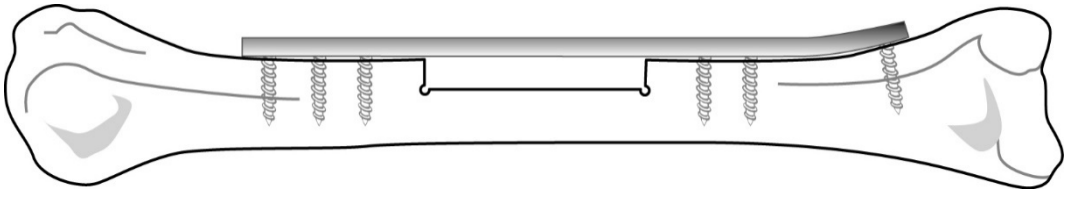
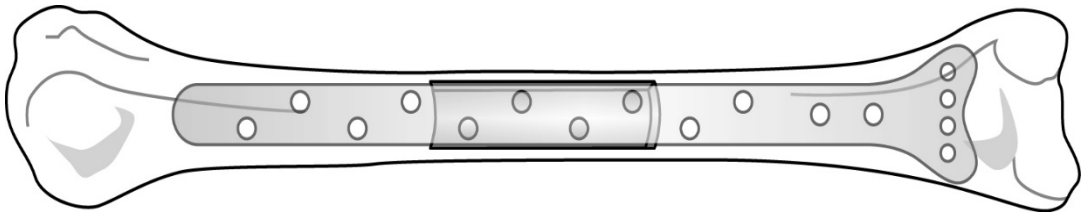


Figure 2.15
Overview of T-shaped titanium plate over the defect and in the anterior position [From Avery [203]].



All plates significantly strengthened an osteotomised bone under bending [factor of 1.73 to 2.43] and torsional [factor of 1.54 to 2.63] loading. The tibia withstood much greater bending loads, which is consistent with our previous findings [186]. When compared to an intact bone (100%) an anteriorly positioned straight steel 3.5 mm DCP almost fully restored the mean bending strength (84%) and partially restored the torsional strength (62%). A 3.5 mm titanium T-plate had a similar strengthening effect under bending loads (87%) but was not as effective under torsional loading (40%). The 2.4 mm T-shaped titanium plate was least effective (63% bending and 36% torsion) **(Table 2.3).** The 3.5 mm DCP straight plate was significantly stronger in torsion and is most effective for resisting the torsional stresses likely to cause fracture.

A posteriorly positioned plate resisted greater bending loads but in the opinion of the Author this is probably unimportant in clinical practice as the radius withstands much greater bending forces [186]. The surgical approach for a posterior plate is less popular as it is more demanding with thinner soft-tissue coverage and increased risk of tendon injury, although this risk is reduced with low profile plates [197, 200, 204]. However, there has been no direct clinical comparison between the two surgical approaches.

Table 2.3
Biomechanical studies of reinforcement of the osteotomised radius and tibia [From Avery [203]].

	Bowers 2000 [46]	Avery 2007 [186]	Avery 2011 [203]
Type of bone	Cadavaric Human Radii	Sheep Tibiae	Sheep Tibiae
Number of pairs	20	50	40
Length of osteotomy (cm)	8	6	4
Amount of bone removed	50% cross-section	40% circumference	40% circumference
Type of plate and position	DCP posterior	DCP posterior & anterior	DCP posterior & anterior T-Plate posterior & anterior
Percentage strength retained - osteotomised: intact bone (100%)			
Torsion	18	69	23
4-point bending	24	35	36
Percentage strength restored - osteotomised + DCP posterior: intact bone (100%) and ratio mean increase in strength (n)			
Torsion	63 (4)	101 (1.6)	44 (1.9)
4-point bending	73 (2.7)	80 (2.8)	62 (1.7)
Percentage strength restored - osteotomised + DCP anterior: intact bone (100%) and ratio mean increase in strength (n)			
Torsion	-	97 (1.8)	62 (2.6)
4-point bending	-	46 (2.3)	84 (2.3)

DCP = Dynamic compression plate

2.3.iv The finite element analysis technique and biomechanical testing

Biomechanical laboratory testing is time consuming and expensive, whilst access to human tissue is limited. The use of finite element analysis (FEA) techniques has become well established in engineering and biomechanical research. The FEA technique is increasingly applied within the maxillofacial surgery to study issues such as the effect of aging [205], oral surgical procedures [206], osteotomy design [207], effect of marginal resections [208, 209] and design of reconstruction plates [210, 211].

The textbook by Zienkiewicz [212] provides an excellent overview of the fundamental principles of finite element analysis. The FEA technique is mathematical and computational tool for performing engineering analyses in a virtual environment. The key

advantage is the ability to undertake relatively rapid analysis of complex problems involving multiple interdependent variables without the need to create physical prototyping models. It is possible to manipulate the shape, size and material qualities of a system to predict outcomes and meet design criteria. The effects of different types of materials and designs may be simulated under varying physical conditions leading to improvements in reliability and efficiency. The typical design requirements include minimising volume, fitting in to a constrained shape, limiting deformation and minimising stresses to avoid material failure.

In a finite element model a physical object is represented by a "mesh" of small elements. The technique utilises mathematical methods to generate the mesh that subdivides a complex problem in to smaller elements. Each element represents a different and small volume of the physical system and can be assigned different physical properties, such as a Young's modulus or density. The vertexes of the elements are known as "nodes" and the finite elements are connected to these nodes to form the finite element mesh that embodies the assigned material and structural properties. The physical properties and the boundary conditions define how the model will respond to different external conditions. In order to increase the accuracy of the modelling the density of the finite element mesh is adjusted so regions with higher levels of stress variation have greater density.

All FEA software programmes include a finite element method algorithm which is utilised for the numerical analysis which provides an approximation to the exact result. A variety of load types can be applied to the FEA model. These may include nodal forces such as biomechanical moments, displacements, velocities or accelerations and elemental forces such as loading and pressure. The type of analysis may be linear or non-linear with the latter effects caused by either parts of the model coming into contact and interacting or stresses in parts of the model exceeding the elastic limit. The typical outcomes measured are nodal displacement, together with elemental stress and strain values.

In our studies we have created the FEA model by using commercially available software. The DICOM (Digital Imaging and Communications in Medicine) data from computerised tomography (CT) imaging of the tibia was imported into a computer aided design (CAD) programme for geometrical reconstruction. The relative bone density values were obtained by linear association with the CT Hounsfield data. These values were linked to the material properties of bone such as the Young's modulus (E). The bone plates were recreated using the reverse engineering method with CAD software. Physical properties were assigned from known engineering values. These CAD models were then meshed to form a FEA model. Isotropic, linear elastic elements composed of non-homogenous 10-node quadratic tetrahedrons were used to represent physical structures and a linear analysis performed. The characteristics of the FEA model were refined with experience to optimise boundary conditions and simplify the analysis.

2.3.v Finite element analysis of bone plates available for prophylactic internal fixation

In 2013, the Author reported an FEA analysis of the plates available for PIF [208]. A FEA technique has greater relevance once an appropriate biomechanical model has been validated.

Hence the strengthening effect with both conventional DCP plates and unilocking T-plates was modelled based on our previous biomechanical laboratory studies [186, 203] to investigate whether our FEA model could provide an accurate representation of the sheep tibia biomechanical model. A standardised defect **(Figure 2.16)** was created and then strengthened with the 4 plates most commonly used for PIF. These constructs were tested under simulated torsional and 4 point bending **(Figures 2.17 to 2.19)**. Only the anterior plate position was used as this is the most common surgical practice.

Figure 2.16

Standardised simulated osteotomy defect of 40% circumference and 4 cm length with 45 degree sloping osteotomy end cuts. The bone specimen voxel values ranged from -208 to 1838 Hounsfield Units. These units have been split into 100 equal width subgroups marked by a corresponding bar on the diagram with the number of elements within each subgroup on the y-axis [From Avery [208]].

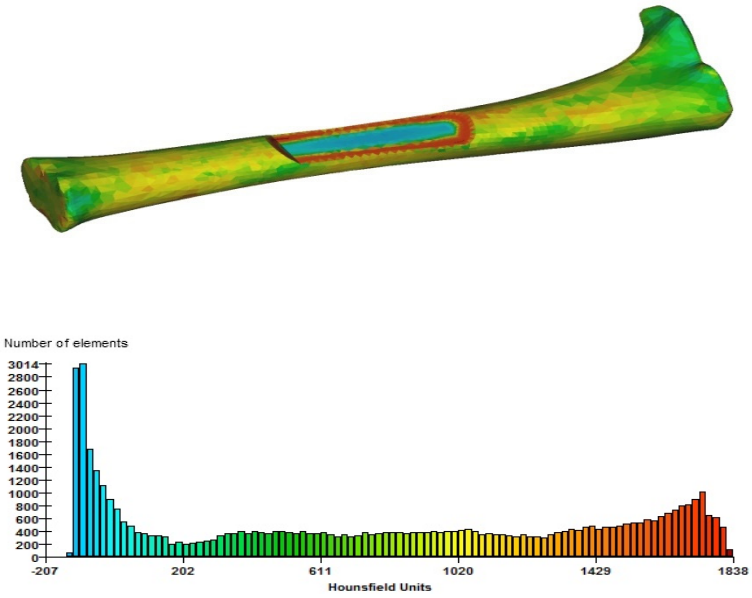


Figure 2.17

Conventional 3.5 mm steel plate over defect (anterior position) with 2 bicortical screws at each end in a non-compressive position. This is the minimum number of screws required for stability [From Avery [208]].

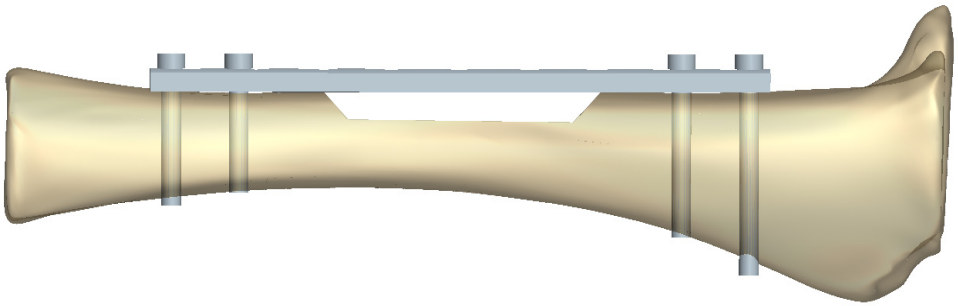


Figure 2.18

Straight 3.5 mm plate with unilocking screw fixation [From Avery [208]].

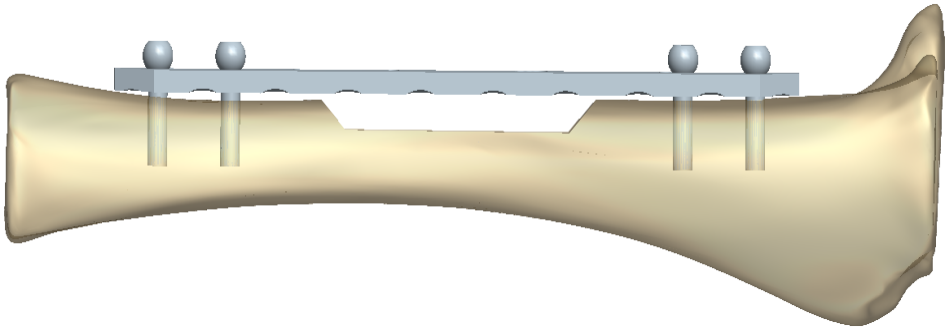
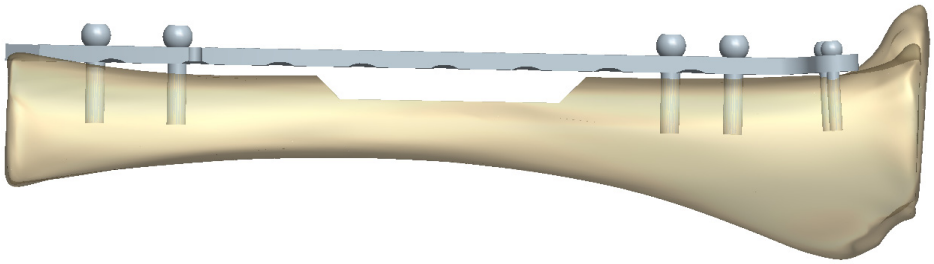


Figure 2.19

T-shaped titanium plate over defect (anterior position) with two unicortical screws either side of the section defect and within the T-shaped end [From Avery [208]].

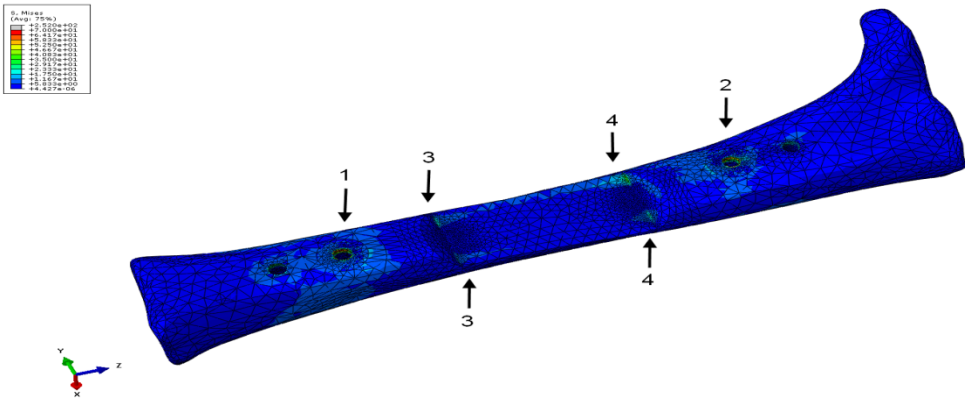


2.3.vi Strengthening effect of prophylactic internal fixation

The plates, or constructs, that generated the lowest stress values (von Mises stress or maximum principle stress) are potentially the strongest forms of reinforcement **(Figure 2.20)**.

In general the strengthening effects with the FEA model under bending [factor 1.48 to 3.71] and torsion [factor of 1.24 to 1.67] were comparable to the sheep tibia model [factor 1.73 to 2.43 under bending and 1.54 to 2.63 under torsion]. The strongest plate overall was a straight 3.5mm steel unilocking plate not previously tested in the sheep tibia experiment [203]. The 3.5 mm straight DCP plate and the 3.5 mm unilocking T-shaped plate were also both effective and all three plates are appropriate for PIF.

Figure 2.20
The regions of peak von Mises stress concentration within the reinforced construct are either around the screws or at the angle of the base of the osteotomy site [From Avery [208]].



1&2	Screws closest to osteotomy defect
3&4	Angles at base of osteotomy defect

2.3.vii Interpretation of finite element analysis

The use of FEA modelling provides a deeper understanding of the interactions between the bone and differing types of reinforcement. The FEA technique is not susceptible to the inherent variation in quality of bone specimens but is only a simulation and the quality of the modelling and characteristics of the boundary conditions are important factors that influence the outcome. Modelling of the load bearing structure of the skeleton may utilise various strategies for volumetric model generation, meshing protocols and different types of elements [213, 214]. A simplification in this study was to assign isotropic, rather than anisotropic, mechanical parameters to the FE mesh. Although bone behaves as an anisotropic composite material, the outer cortical layer of a long bone demonstrates directionally dependent isotropic behaviour with considerable variation [215, 216]. This simplification may influence the depth and direction of stress penetration, and ultimately the orientation of fracture formation but more sophisticated anisotropic features are rarely applied [205, 217-219].

The appropriate criteria for bone failure have not yet been established. It is unclear whether bone should be treated as a brittle material, in which case the maximum stress (indicating onset of cracking) should be utilised, or managed as a ductile material, as in this study,

when the von Mises stress (indicating onset of plastic deformation) was applied. Finally, this model assumed a continuous perfect bond between the screw fixation and bone to create a more linear model. However, under normal loading this connection would loosen at peak stress and create a dynamic non-linear interface resulting in separation and crack propagation or shearing. However, this simplification did not alter the rank order of the plates.

Therefore, this FEA model satisfactorily represented the sheep tibia model but is not an exact replication of the clinical situation. Many other factors may also apply, such as variations in anatomy, osteotomy design and the number or position of the screws. The tibia is also relatively short and stout compared to the human radius so the anatomically contoured radial plates may not be functioning in an optimal fashion. The patterns of stress within the region of the osteotomy defect depend mainly on the characteristics of the bone model and are relatively well understood. However the stresses around the bone-screw interface and the effect of loosening would benefit from further investigation.

2.3.viii Current role of radial osteocutaneous flap

Even without the use of PIF the radial osteocutaneous flap has remained popular with some surgeons [164, 220]. However, following the introduction of PIF there has been renewed interest in defining the current clinical indications [187-189, 197, 221] as PIF has nearly eliminated the risk of fracture [184]. The flap is considered cost-effective because of the comparatively high level of reliability combined with low systemic morbidity [188]. It is useful when bicortical fixation is not required and dental implant or prosthesis placement is not planned. The flap retains a role with small volume defects of the maxilla, nasal bones and orbital rim [158, 222-224], and the mandible [147, 185]. In the opinion of the Author it remains a first choice flap in the presence of appreciable peripheral vascular disease [225, 226], when there is other significant medical co-morbidity or as the preferred choice of the patient for functional reasons and finally as a salvage flap [43, 160].

Chapter 3

Osteotomy and reconstruction plate design

Publications by Author

Bujtar P, Simonovics J, Sándor G, Pan J, **Avery C.**
Refinements in osteotomy design to improve structural integrity: a finite element analysis.
Br J Oral Maxillofac Surg 2013;51: 479-485.
http://dx.doi.org/10.1016/j.bjoms.2012.09.015

Avery C, Simonovics J, Bujtar P.
The stop-hole osteotomy technique.
Br J Oral Maxillofac Surg 2014;52:475-476.
http://dx.doi.org/10.1016/j.bjoms.2014.02.003

Bujtar P, Simonovics J, Váradi K A, Sándor G, **Avery C.**
The biomechanical aspects of reconstruction for segmental defects of the mandible: A finite element study to assess the optimisation of plate and screw factors.
J Craniomaxillofac Surg ~ in-press.
http://dx.doi.org/10.1016/j.jcms.2013.12.005

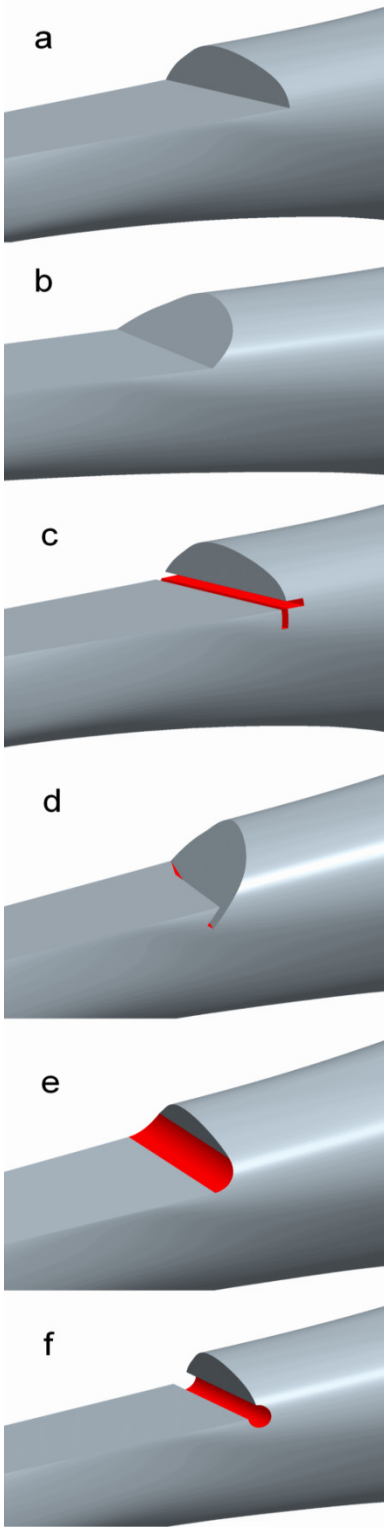
3.1.i Finite element analysis of refinements in osteotomy design

The creation of an osteotomy with a section defect in bone is a common surgical procedure. The osteotomy cuts are typically created using a saw and are primarily in a linear plane. The meeting point of two cuts, or an overcut, acts as a focus for stress concentration and is prone to failure. As discussed above, in maxillofacial oncological surgical practice this issue primarily affects resection of the mandible and the radial osteocutaneous donor site. The marginal mandibulectomy technique preserves the continuity of the lower border of the mandible with considerable functional and aesthetic advantages. However, the mandible may fracture causing significant morbidity and this is more likely when the remaining bone height is less than 10 mm [227, 228] or the resection extends below the mandibular canal [229-231].

Various techniques may reduce the risk of fracture at a section defect. Bevelling the osteotomy end cuts has a marginal strengthening effect [168, 172] and rounding out corners will reduce the creation of foci of stress concentration [232]. The 'stop drill hole method' has been utilised to block the propagation of existing crack lines during aircraft maintenance [232] and prolong the time to fatigue failure under cyclical loading [233] but has not been applied to surgical practice.

In the current FEA study, published by the Author in 2014 [207], the effect of refinements in osteotomy design were studied using the previously validated sheep tibia FEA model [208]. A standardised marginal resection defect of 4 cm length and 40% circumference was created with either a right-angled and 45 degree bevelled osteotomy end cut **(Figure 3.1 a & b)**. In order to mimic two common surgical errors overcutting defects were then created. The first a parallel overcut at a right-angled osteotomy which affected both cortices equally and the second an oblique overcut at a bevelled osteotomy affecting just one cortex (**Figure 3.1 c & d**). The strengthening effects of a stop-hole engaged either tangentially or at 90 degrees were also simulated **(Figure 3.1 e & f).**

Figure 3.1
CAD model with different designs of osteotomy defects [From Bujtar [207]].



Right-angled osteotomy

Bevelled osteotomy

Right-angled with parallel overcut

Bevelled with oblique overcut

Right-angled with tangential stop-hole

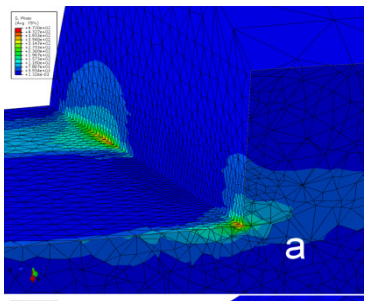
Right-angled with 90-degree stop-hole

3.1.ii Strengthening effect of osteotomy refinements

When compared to a baseline right-angled osteotomy (100%) peak stress values for 4 point bending and torsion were 24 to 30% greater at a right-angled osteotomy than with a bevelled end cut **(Figure 3.2)**. An overcut substantially increased peak stress values under bending and torsion by up to 48% and 71%, respectively, with an oblique overcut having a greater adverse effect. A stop-hole substantially decreased peak stress values with both a 90-degree (bending 38% and torsion 56%) and a tangential (bending 58% and torsion 60%) entry cut. The relative difference in stop-hole size had a minimal effect. An osteotomy with a stop-hole will benefit from both the strengthening effect of a rounded osteotomy corner and avoid the dramatic weakening effect of an overcut.

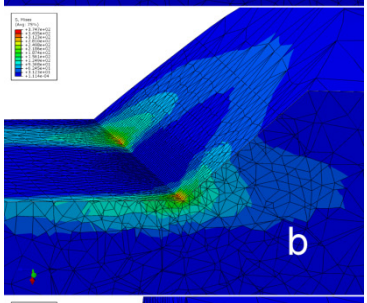
The current study used a more sophisticated FEA model than initial reports on the human and dog mandible [234, 235] and more variations in osteotomy design were studied. The findings are supported by a recent FEA comparison of right-angled and bevelled osteotomy cuts [209] but the current study included the concept of a stop-hole [207]. The removal of load bearing bone should be avoided as this weakens the remaining structure [227, 234, 235] but judicious bevelling and a stop-hole substantially reduce peak stress concentration [207, 227, 234, 235] and therefore the risk of fracture. These basic principles are applicable to all bone osteotomy sites.

Figure 3.2
Finite element analysis with the pattern of peak von Mises stress values under 4-point bending and torsional loads [From Bujtar [207]].



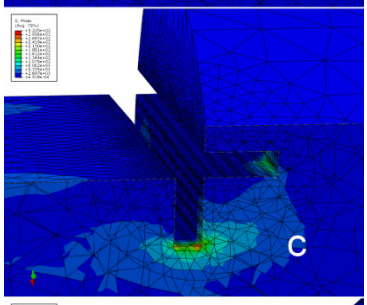
Right-angled osteotomy

4 point bending = 357 MPa
Torsion = 545 MPa



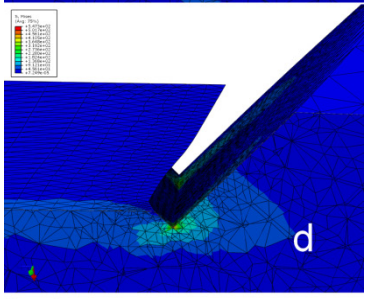
Bevelled osteotomy

4 point bending = 272 MPa
Torsion = 382 MPa



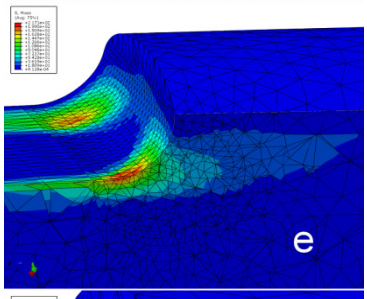
Right-angled with parallel overcut

4 point bending = 319 MPa
Torsion = 322 MPa



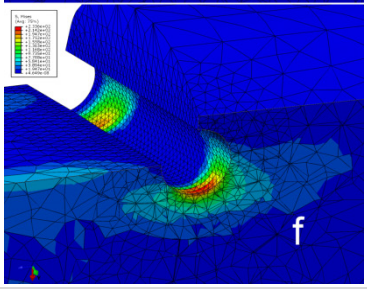
Bevelled with oblique overcut

4 point bending = 465 MPa
Stress torsion = 565 MPa



Right-angled with tangential stop-hole

4 point bending = 115 MPa
Torsion = 219 MPa



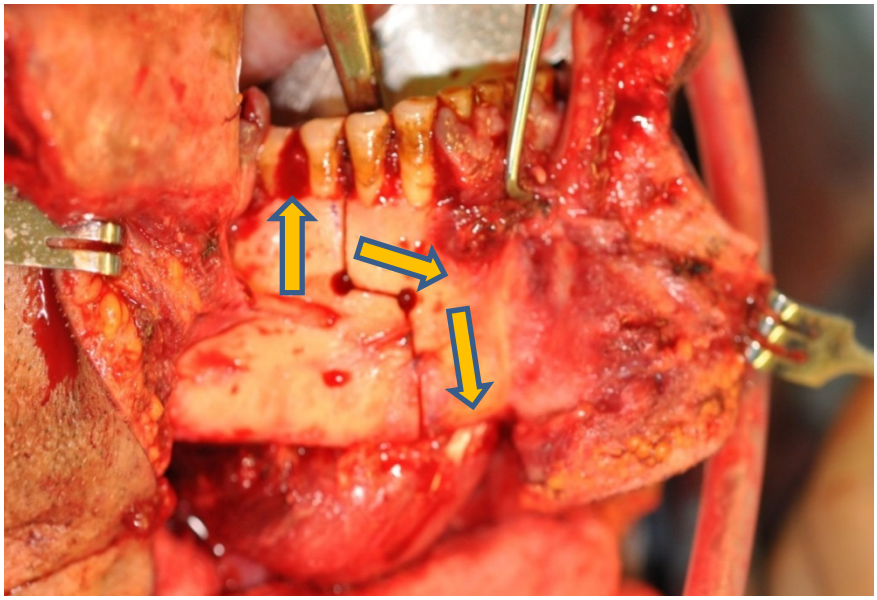
Right-angled with 90-degree stop-hole

4 point bending = 221 MPa
Torsion = 239 MPa

3.1.iii The stop-hole surgical technique

The Author described the clinical technique of stop-hole creation in 2014 [236]. In the example of a typical mandibular access step osteotomy the cuts are marked in the usual manner. A 3 mm diameter stop-hole is created at the proposed intersections. The saw enters the next stop-hole in a tangential or 90 degree approach (**Figures 3.3).** In our limited clinical experience the osteotomy is easier to perform because visualization is improved, the cuts are clearly delineated by the stop-holes, the saw is more easily engaged and there is more leeway for error when completing the cut in to the next stop-hole without creating an overcut. The surgical technique is simple and widely applicable within many surgical specialties.

Figure 3.3
A mandible step osteotomy with stop-holes. The saw is engaged in a stop-hole and the next cut made towards the other stop-hole or the upper/lower border of the mandible (arrows) [From Avery [236]].



3.1.iv Finite element analysis of reconstruction for segmental defects of the mandible

The creation of a segmental defect of the mandible is disfiguring and associated with a significant decrease in oral cavity and upper airway function. Free tissue transfer is the optimum method of reconstruction to restore bone continuity and recreate form with

function [47, 237]. The fibula and deep circumflex iliac artery (DCIA) bone and soft-tissue composite flaps are most frequently used whilst the scapula and radial flaps are less commonly utilised [47, 238, 239]. A single heavy reconstruction plate, or several light plates, secures the bone element to the mandible. A single heavy reconstruction plate, without a bone graft, may be used when a pedicled pectoralis major (PPM) flap is preferred because of advanced disease and substantial co-morbidity as described by the Author [240].

During the bone healing phase the load-bearing function of the mandible is partially restored as the hardware shares the load. The mandible regains functional integrity through bone regeneration and union, which is driven by the forces of Inter-Fragmental Strain (IFS) [241]. With healing the IFS gradually decreases until the strength and rigidity of the mandible stabilises. Ultimately the plate will act as a parallel load-bearing element that shields the mandible. The phenomenon of "stress "shielding" is one of the reasons lighter and more flexible plates of 2.0 to 2.4 mm have been favoured but these plates are more prone to fracture.

The complex biomechanics at the interfaces between the screw-plate and the plate-bone are poorly understood and the optimum management is unclear. In this study, published in 2014 [242], the Author investigated the patterns of biomechanical loading, deformation and stress which occur with segmental defects commonly encountered following resection for oral malignancy using the FEA technique developed in previous studies [205-208]. A CAD model of the mandible with 4 resections was created together with a 3mm reconstruction plate (**Figure 3.4)**. The screw and bone interfaces were modelled to represent non-locking (bicortical) and locking (monocortical or unilocking) screw fixation systems. A single simulation scenario represented unilateral biting on the 1st molar tooth [205,206]. The maximum von Mises stress values, "pull-out" strain values and spatial changes at the bone-screw interfaces were used as predictors of longer-term stability. The sites of highest peak stress levels were considered to represent potential weak points.

3.1.v Stabilisation effect of unilocking plate systems

In general, the locking plate and monocortical screw fixation systems were the most stable and effective. The non-locking systems produced substantially greater levels of stress in all scenarios and larger screw "pull-out" displacements (up to 5% strain) **(Table 3.1**). The level of von Mises stress values around all screws was acceptable apart from the number 4 screw in the hemimandible defect (**Figure 3.4).** High peak stress levels may precipitate local bone necrosis and additional screws or screws of increased diameter may be recommended. When there is a relatively elastic bone, osteopenic bone, or when screw positioning is compromised because of joint proximity, there is increasing benefit from the comparatively rigid fixation offered by a locking system to reduce screw loosening during cyclic loading [243]. Bicortical, rather than monocortical, screw fixation with a locking plate had no apparent biomechanical benefit in the context of a well-adapted plate secured to good quality bone.

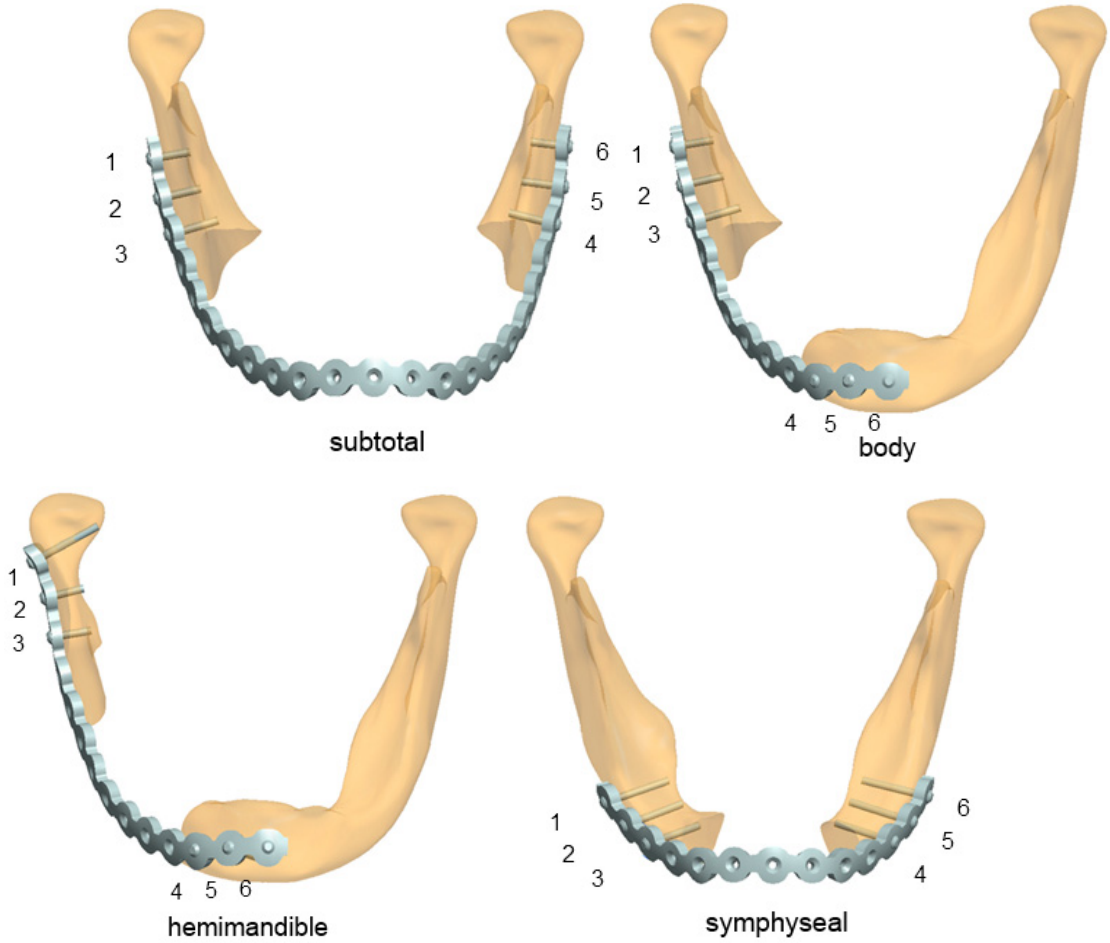
Table 3.1

Rank order of the fixation systems based on mean strain or "pull-out" and stress criteria [From Bujtar [242]].

Fixation type	Hemimandible	Body	Symphyseal	Subtotal	Hemimandible	Body	Symphyseal	Subtotal
	Rank order strain or "pull-out" values [%]				Rank order stress values [MPa]			
mono/lock	**1** (-0.013)	**1** (-0.006)	**1** (0.005)	**1** (-0.001)	**1** (94.5)	**1** (59.2)	**1** (49.5)	**1** (44.5)
bi/lock	**2** (0.027)	**2** (0.047)	**2** (0.008)	**2** (0.011)	**2** (101.0)	**2** (67.5)	**3** (64.2)	**2** (49.2)
bi/non-lock	**4** (0.847)	**3** (0.221)	**3** (0.147)	**3** (-0.080)	**3** (122.2)	**4** (77.2)	**4** (70.2)	**4** (78.7)
mono/non-lock	**3** (-0.714)	**4** (0.240)	**4** (0.156)	**4** (0.156)	**4** (130.3)	**3** (76.3)	**2** (61.7)	**3** (74)

bi = bicortical
mono = monocortical
non-lock = non-locking
lock = locking
von Mises = von Mises (peak) stress [MPa]
strain = deformed length / original length when loaded and converted into a % value
MPa = MegaPascal

Figure 3.4 CAD models of segmental mandible resections with reconstruction plates. The unilateral defects were *hemimandibulectomy* (coronoid to parasymphysis) and *body* (angle to parasymphysis) resections. The bilateral defects were *symphyseal* (parasymphysis to parasymphysis) and *subtotal* mandibulectomy (angle to angle) resecti[242]



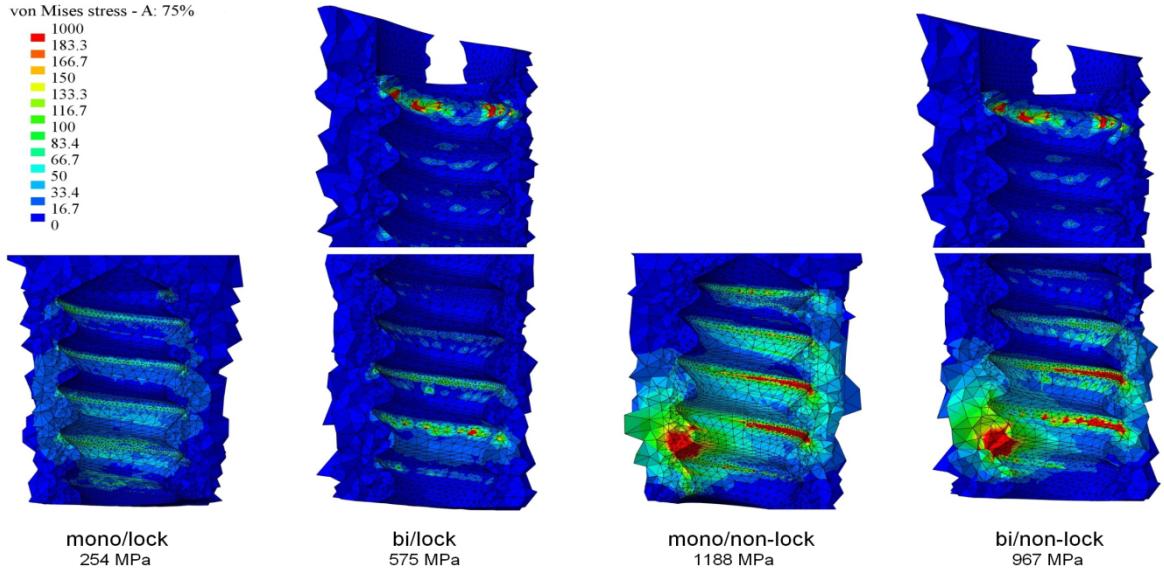
3.1.vi Interpretation of finite element analysis

The outcomes of mathematical simulations are dependent on the quality of the FEA models and variable factor analysis is often the method of choice in design engineering and FEA to show a trend supporting the significance of an individual variable [244]. In the current model we applied a greater level of fidelity than previously reported in the medical literature. Nevertheless, the simplification of screw geometry probably underestimates stress levels (**Figure 3.5**) and factors such as poor adaptation of the plate or reduced bone quality may still be indications for bicortical locking screw fixation. The reconstruction plate in the current simulation was tightly fitted to the cortical surface but this close

adaptation may not be achievable in clinical practice. Hence this model does not yet accurately represent all clinical scenarios. The number of individual variables is high and our understanding of the complex biomechanics at all sites remains incomplete. The effects of factors such as increased screw tightening, bone quality, bone-plate interface distances and lighter plates will be considered in future studies. The current model provides a good basis for developing future refinements in plate or scaffold design.

Figure 3.5

Bone stress around the refined screw thread (top halves, longitudinal cross-cut) at screw number 4 in the hemimandible defect. The colour scale represents the von Mises stress values in a linear fashion (up to 183.3 MPa) with red representing the greatest values (approximately 1000 MPa). The von Mises maximum stress levels are indicated [From Bujtar [242]].



bi = bicortical
mono = monocortical
non-lock = non-locking
lock = locking

Chapter 4

Choice of flap reconstruction, outcomes and morbidity

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Avery C, Shenoy S, Shetty S, Siegmund C, Iqbal M, Taub N.
The prospective experience of a maxillofacial surgeon with the percutaneous endoscopic gastrostomy technique.
Int J Oral Maxillofac Surg 2008;37:140-148.
http://dx.doi.org/10.1016/j.ijoms.2007.08.465

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Br J Oral Maxillofac Surg 2011;49:661-663.
http://dx.doi.org/10.1016/j.bjoms.2010.09.023

Avery C, Crank S, Neal CP, Hayter JP, Elton C.
The use of the pectoralis major flap for advanced and recurrent head and neck malignancy in the medically compromised patient.
J Oral Oncology 2010;46:829-833.
http://dx.doi.org/10.1016/j.oraloncology.2010.08.004

Avery C. Ghandi N, Peel D, Neal CP.
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Int J Oral Maxillofac Surg;2014:43:546-554.
http://dx.doi.org/10.1016/j.ijoms.2013.10.009

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http://dx.doi.org/10.1016/j.bjoms.2010.09.023

Avery C. Clifford N, Sundaram K, Jasani V, Neal C.
Impact of a structured proforma for improving documentation at the planning stage of major maxillofacial oncology surgery.
Face Mouth & Jaw Surg 2011;2:33-39.

4.1.i The percutaneous endoscopic gastrostomy technique and outcomes

A percutaneous endoscopic gastrostomy (PEG) is the preferred choice for enteral feeding of patients with head and neck malignancy, whenever nutritional support is required for more than 2 to 4 weeks. Indications include painful or ineffective mastication or swallowing, obstruction, or supplemental nutrition after surgery, during chemotherapy or radiotherapy. Retrospective studies have demonstrated early placement results in a reduction in weight loss, frequency of hospitalisation, treatment interruptions [245-248] and improvements in the quality of life [249, 250]. A PEG should only be inserted for patients likely to derive physiological benefit and respond to cancer treatment. It should not be offered when life expectancy is less than two months or no improvement in the quality of life may be expected [251, 252].

4.1.ii Gastrostomy insertion

Most of the literature is composed of retrospective cohort studies and a few prospective studies dealing with neurological dysphagia. The PEG is commonly inserted under sedation by a gastroenterologist [253], gastrointestinal or general surgeon [254-257] and occasionally by a specialist nurse [258]. It is less frequently inserted by an otolaryngologist [259-261] or maxillofacial surgeon [262]. This paper, published by the Author in 2008 [263], is the only prospective observational study of PEG insertion by a Maxillofacial surgeon.

The rate of successful PEG insertion, primarily for oral malignancy, was 97.3% (219/225) which is comparable with a large meta-analysis (95.7%) [253] and head and neck practice (90 to 98.5%) [255, 256, 259-262, 264]. The majority (75%) were inserted at the time of definitive surgery. A further 19% were inserted earlier during examination under general anaesthesia, mainly for oropharyngeal tumours managed with radiotherapy, inoperable disease, significant medical comorbidity or marked pre-treatment weight loss. Significant incidental gastroscopy findings included a 4.9% incidence of pre-malignant and malignant pathology.

4.1.iii Gastrostomy related complications

The various methods of insertion and complications have been comprehensively reviewed [258, 265, 266]. In general the incidence of major and minor complications range from 2.7% to

9.4% and 6% to 7.1%, respectively [253, 265, 267]. Complications are more frequent with malignant disease and in head and neck practice [major complications 0% to 35% and minor complications 8% to 17.5%] [255, 256, 259-262, 264]. Major complications are more frequent when the operator is a trainee [257, 264, 267] but comparatively low (3.1%) with an experienced surgeon such as the Author.

Aspiration and pneumonia are the most common major complications [265]. In head and neck practice the route of gastroscopy and airway are both compromised by oral and pharyngeal malignancy. A supine position and oropharyngeal tumour may increase the risk of aspiration, especially when the gag reflex is obtunded [267]. The incidence of respiratory distress under intravenous sedation may be as high as 7% with airway obstruction occurring in 1% [268]. Otolaryngology head and neck surgeons often have the PEG inserted as a separate episode prior to definitive surgery [261, 269] or at examination under anaesthesia both during and after surgery [259, 260]. The Author prefers to place the PEG under a general anaesthetic, immediately prior to definitive surgery, with the airway protected by an endotracheal tube or tracheotomy [255, 256, 262]. This is because oral oncology patients typically have elevated intubation complexity scores [American Society of Anaesthesiologists, ASA grade 3 or 4] [255, 256] and are at increased risk of respiratory compromise. This approach also avoids a separate treatment episode.

4.1.iv Duration of gastrostomy

The median PEG duration was 337 (SE 31) days. The duration was significantly longer for stage T3-4 tumours, N1 or greater neck disease, following surgery with radiotherapy when compared to surgery alone, and for radiotherapy alone when compared to surgery alone **(Figure 4.1)**. The radiotherapy alone group was primarily composed of stage T3 or 4 oropharyngeal tumours. Two separate surgical procedures and radiotherapy were associated with significantly longer mean durations than a single surgical procedure. Duration following a primarily soft tissue resection, with or without a rim resection of the mandible, was significantly shorter than after a segmental bone resection. There was no relationship between duration and the type of free or pedicled flap reconstruction.

Figure 4.1
Duration of PEG by modality of treatment [From Avery [263]].

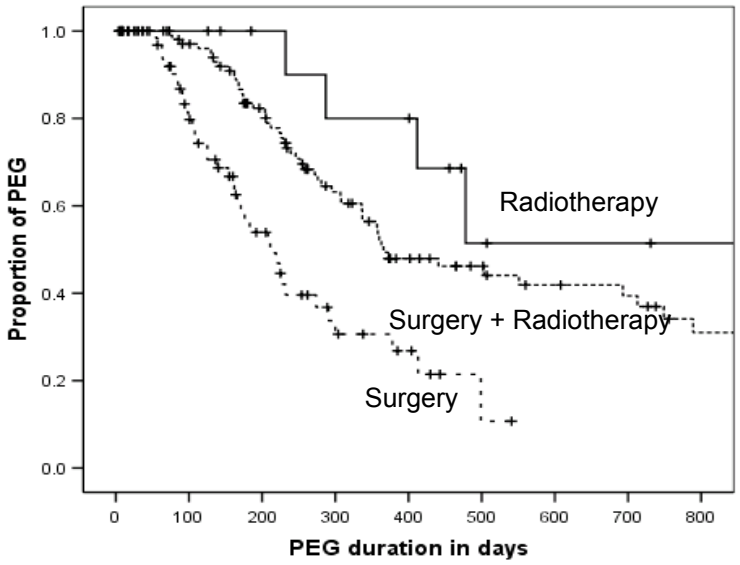
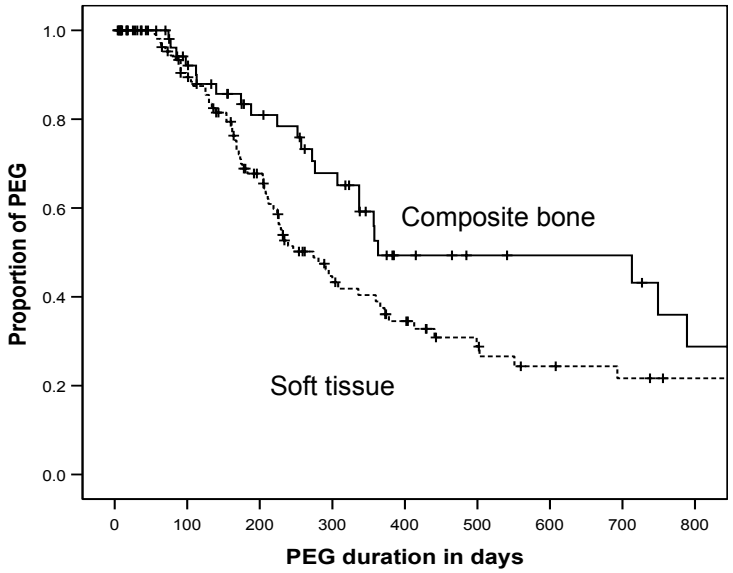


Figure 4.2
Duration of PEG by principle type of resection [From Avery [263]].



4.1.v Indications for gastrostomy

The indications and timing of PEG insertion remain contentious. The pattern of use during the phases of treatment is unknown and difficult to compare because insertion criteria vary and so do the methods of collating and presenting data. The median, or mean, PEG duration ranges from 13.8 to 67.1 weeks [256, 257, 262, 270, 271] and in the current series was 48 weeks. Four patients (less than 2%) had a long-term PEG, which compares favourably with the literature [256, 270, 272].

Predicting the need for a gastrostomy and the likely duration is difficult because of an uncertain relationship to various factors including age, medical and nutritional status, speech and swallowing function, tumour site and stage, surgical resection and type of reconstruction. The indications for PEG insertion have not been systematically studied and variable criteria have evolved with experience. The Author uses the following indications for insertion **(Table 4.1)**. All T3 and T4 oropharyngeal tumours managed with radiotherapy or oral tumours reconstructed with a free or pedicled flap. In addition smaller T2 tumours without neck disease but with significant flap reconstruction or an extra-oral resection in conjunction with a neck dissection are included. Other factors considered which adversely affect oropharyngeal function include previous surgery or radiotherapy.

A more restrictive insertion policy has been advocated, but a high incidence of major complications was an underlying consideration [264]. In this series, only two patients (less than 1%) did not utilise the PEG and the Author is unable to identify a subgroup that would not benefit from early PEG insertion.

This study has confirmed that a PEG may be inserted with a high degree of success and minimal complications by an experienced maxillofacial surgeon. The Author is now able to more accurately advise patients about the incidence of complications and likely PEG duration.

Table 4.1
Current indications for insertion of a PEG in oncology patients [From Avery [263]].

Current Indications for PEG insertion
• Fundamental criteria for insertion met and PEG not contra-indicated [252] • Recovery of oral function within 2 to 4 weeks is not expected • Malnutrition or at risk of malnutrition during treatment • T3 and T4 oropharyngeal tumours undergoing surgery or radiotherapy • Intra-oral reconstruction with free or pedicled flap • Smaller oral procedure or extra-oral surgery, particularly in conjunction with a neck dissection, likely to adversely affect oral function • Other adverse factors such as previous surgery or radiotherapy

4.1.vi Ultrasound assessment of early bone healing

The management of complicated non-union of free flap osteotomy sites is both challenging and time consuming. The return to oral function and hence removal of a PEG may be substantially delayed. When external bone fixation has been applied it is cumbersome and inconvenient for the patient (**Figure 4.3**). Unfortunately, it is difficult to know when sufficient bone union has occurred to safely remove the fixation. The progression of bony healing is conventionally monitored with radiographs and sometimes cross-sectional imaging. However, plain radiographs are insensitive to early callus formation [273] and artefacts from the fixation hardware degrade CT and magnetic resonance imaging (MRI) images.

Transcutaneous ultrasound can demonstrate early evidence of healing in long bone fractures by detecting initial callus formation [274]. This paper, published by the Author in 2011, was the first description of the successful use of ultrasound to monitor for evidence of bone healing of the mandible in a small number of patients with delayed and complex wound healing [275]. The detection of echogenic foci within the fracture gap was the criterion for evidence of healing progression **(Figure 4.4)** as this correlates with histological evidence of callus maturation [276]. Ultrasound detected early callus formation that typically preceded radiographic changes by several weeks.

Figure 4.3
Delayed union (Yellow Arrow) at left DCIA free flap to mandible osteotomy site managed with external fixation bar and pins (Green Arrow). Plain orthopantomogram film with no evidence of callus formation 12 weeks post-fixation [From Avery [275]].

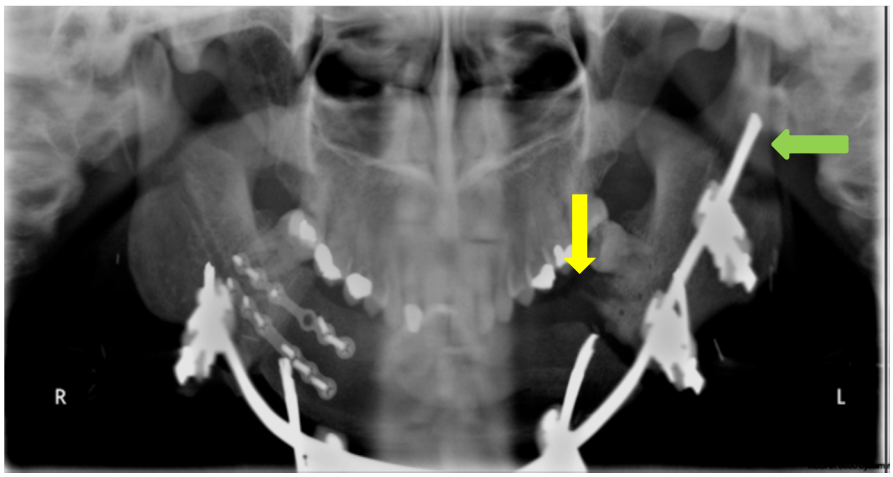
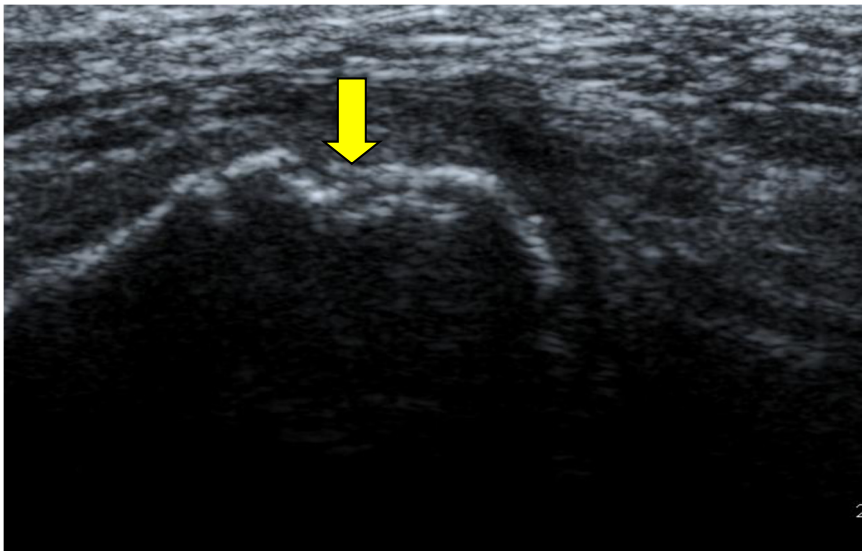


Figure 4.4
Ultrasound scan on same day demonstrates echogenic callus within the osteotomy gap (Arrow) [From Avery [275]].



Transcutaneous ultrasound provides simple, safe and early objective evidence of progressive bony healing. This is reassuring for both the patient and surgeon and in conjunction with the clinical findings facilitates prompt removal of the external fixation with an earlier return to oral function.

4.2.i Use of the pectoralis major flap for advanced and recurrent malignancy in the medically compromised patient

The pedicled pectoralis major (PPM) flap was initially described by Ariyan in 1979 [277, 278] and soon became the "workhorse" flap for head and neck reconstruction [279-282]. In the 1990s, it was still considered a reliable and effective first choice flap in major units [21, 282-284]. Gradually, free tissue transfer techniques achieved increasing reliability with apparent benefits in oral function, potentially comparable costs, fewer complications and better quality of life outcomes [15-24, 26]. Hence the PPM flap was gradually relegated to a secondary role in many units within the developed world but has continued to be used on the basis of surgeon preference, advanced disease, low costs and lack of microvascular expertise [285-289]. There are no formal UK guidelines as to when to use the PPM flap rather than free tissue transfer. The aim of this paper, published by the Author in 2010 [240], was to review the pattern of use of the PPM flap within a unit that has routinely performed free tissue transfer surgery as the reconstruction of choice.

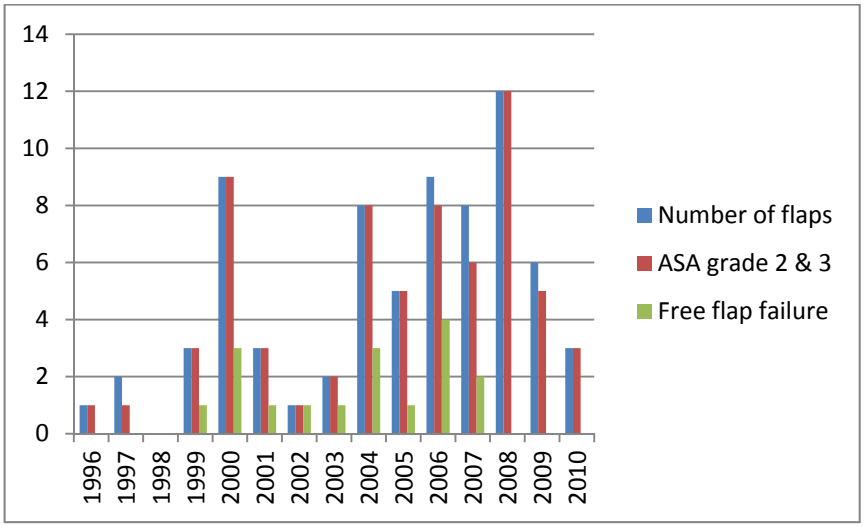
4.2.ii Indications for pectoralis major flap

The indications for 71 PPM flaps between 1996 and 2010 were retrospectively reviewed. The main pathology was oral and oropharyngeal squamous cell carcinoma (SCC). The majority was advanced stage IV primary SCC disease (57.7%), and extensive recurrent (14%) or isolated metastatic neck (12.6%) disease. The PPM flap was the preferred reconstruction on 54 occasions (76%) and the main indication, in addition to advanced disease, was significant medical co-morbidity. The majority of patients were ASA grade 3 (63%) and had undergone previous surgery and/or radiotherapy.

The most common resections involved the mandible (32.4%) or the tongue/oropharynx (26.7%). Mandible defects were reconstructed with a PPM flap either as the method of choice (19.7%) or following failure of a free flap (12.7%). The Author agrees with the contemporary principles of mandibular reconstruction which state a bone flap should be used to restore form and function [50, 290]. However, the situation is complex in the presence of advanced disease, significant medial comorbidity and after previous major surgery and/or radiotherapy. In our experience reconstruction with a PPM flap (without bone) allowed reasonable function in the context of limited life expectancy.

The majority of PPM flaps (75%) were used in the latter half of the series but there was no evidence of an increase in the extent of disease, ASA grade or age during this period **(Figure 4.5).** All except two patients had advanced Stage IV disease, or extensive recurrent disease and 70% had stage N1 or greater nodal neck disease. The limitations of the TNM classification system meant it was not possible to demonstrate an increase in the extent of disease but the threshold for a PPM flap had not been lowered. An elevated ASA grade is associated with increased morbidity and mortality [291-295] and 94% were ASA grade 2 or higher but with no increase over time. Along with others, we did not find an association between increased age and perioperative mortality [293, 296-299], although selected older patients may be a relatively healthy subgroup [297, 300]. A more detailed general or disease specific morbidity grading system [110, 291, 293, 295, 298, 301] may refine the selection process as increasing co-morbidity is an important prognostic indicator [291, 295, 302]. However, it is unclear whether this would have altered the decision to offer surgical treatment or the choice of reconstruction as no other potentially curative treatments were available and good palliation of symptoms was usually achieved.

Figure 4.5
Pectoralis major flap use by year [From Avery [240]].



Approximately one quarter (n=17) of the PPM flaps were used after failure of a free flap and there was no significant variation throughout this period **(Figure 4.5)**. The use of the PPM flap reflected an increasing number of patients presenting with significant co-morbidity together with advanced disease.

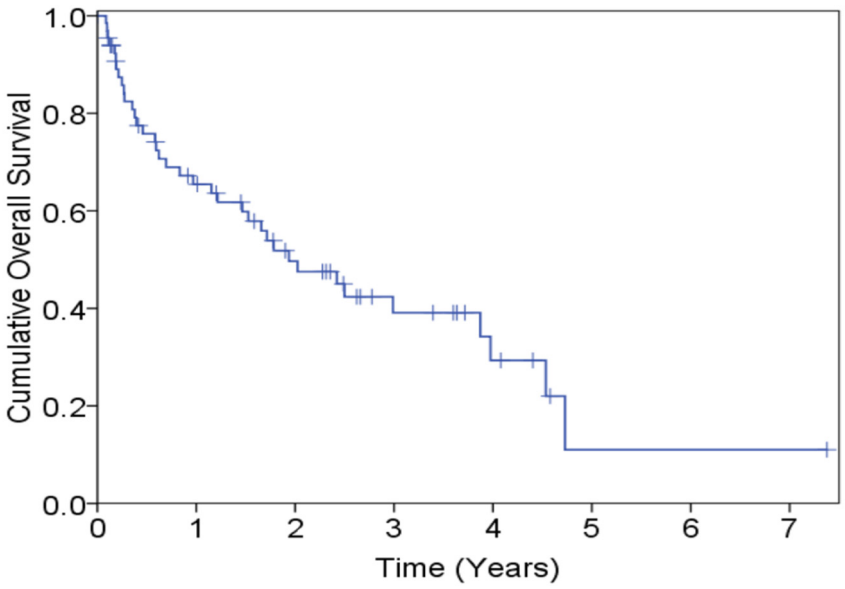
4.2.iii Outcomes with pectoralis major flap

The incidence of complete flap necrosis (2.8%) compared favourably with the literature [280, 282, 283, 286, 288, 289, 303] as did the incidence of major (8.4%) and minor (12.6%) flap loss. Although complications may delay discharge from hospital, they rarely delayed or prevented subsequent radiotherapy.

The 5-year overall survival and cancer-specific survival rates were 11.0% and 65.5%, respectively **(Figure 4.6).** These outcomes compare favourably with the literature for advanced and recurrent disease [4, 52, 53, 304-308] whilst the majority of patients succumbed to other disease related to underlying co-morbidity.

Figure 4.6

Kaplan-Meier Curve for Cumulative Overall Survival [From Avery [240]].



The Author recommended aggressive surgical treatment for advanced and recurrent disease together with a pragmatic approach to reconstruction. The PPM major flap is a reliable reconstruction for large defects of the mandible, tongue and oropharynx. The PPM flap retains a major role in the management of advanced primary or recurrent disease, extensive isolated metastatic neck disease, following previous major surgery and/or radiotherapy or after failure of a free flap when in conjunction with significant medical co-morbidity. This was the largest study of the use of the PPM flap for a group of medically compromised patients with advanced disease.

4.3.i One hundred patients managed with a pectoralis major flap within a UK maxillofacial unit

Whilst surgical units within the United Kingdom (UK) continue to use the PPM flap, its role within modern maxillofacial practice has not been defined. The aims of this study, published by the Author in 2014 [309], were to review the indications and outcomes of a cohort of patients undergoing reconstruction with a PPM flap. This paper developed themes identified in the previous publication (4.2.i) [240]. The size of the cohort had increased to 100 patients and now only included oncology patients. A more detailed retrospective analysis was made of the complications, factors associated with an adverse perioperative outcome and survival.

4.3.ii Indications for pectoralis major flap

One hundred and two consecutive PPM flaps were performed on 100 patients between 1996 and 2012. The majority (88.2%) were for oral squamous cell carcinoma (SCC) which was primarily advanced stage IV (75.6%) disease, often with neck nodal metastases (59.7%). The majority (57%) had previously undergone major surgery and/or chemo-radiotherapy and the incidence of substantial medical comorbidity was high (47% ASA 3 or 4). Both the stage of disease and ASA grade were greater than in other comparable studies [24, 286].

The PPM flap was primarily used as the initial reconstruction of choice (80.4%) or following free flap failure (19.6%). The most common primary indications were substantial medical comorbidity (39.2%), high volume metastatic neck disease (15.7%) or when a free flap was contra-indicated (13.7%) (**Table 4.2).** The defect most frequently reconstructed was a hemimandibulectomy resection (n=37) and the majority of patients had also undergone previous oncological therapy or suffered failure of a free flap **(Table 4.3)**. Major composite skin defects comprised nearly a third of resections. A few flaps were utilised for salvage reconstructions (6%) after complications (**Table 4.2).**

Table 4.2
The single primary indication for the pectoralis major flap [From Avery [309]]

Indication for PPM flap	n=102
Preferred reconstruction	**82**
Medical comorbidity	40
High volume neck disease	16
Free flap not possible	14
Vessel coverage	5
Parotid/cheek defect	4
With free flap	2(3)[1]
Close fistula	1
Failed free flap	**20**
Radial	8
Composite radial	1
Deep Circumflex Iliac Artery (DCIA)	8
Fibula	3

[1] One procedure also counted as high volume neck disease
Two flaps were contralateral.

Table 4.3
Principle types of surgical resection [From Avery [309]].

Primary Resection Type	Resection Subtype	N = 102	Composite
Mandibulectomy	Hemimandibulectomy	37	6
	Anterior mandibulectomy	8	3
	Rim resection	6	-
Glossectomy	Total glossectomy[1]	8	-
	Hemiglossectomy	8	-
	Partial glossectomy	3	-
Extended Radical Neck	-	15	15
Parotid/cheek	-	8	5
Oropharynx	-	5	-
Buccal	-	1	-
Fistula	-	1	-
Maxillectomy[2]	-	1(2)	-
Bleeding major vessels[3]	-	1(2)	1

[1]Two total glossectomies with laryngectomy.
[2]One maxillectomy combined with hemimandibulectomy as primary procedure.
3One bleeding episode with loss of free flap listed as rim resection of mandible as the primary procedure and the second was a late carotid blow out complication after chemoradiotherapy.

The failure of a previous free flap was a significant indication (19.6%) and most commonly involved a radial (8) or Deep Circumflex Iliac Artery (DCIA) flap (8), of which 25% had previously undergone oncological treatment**.** The median ASA grade was lower

in the free flap failure subgroup than the PPM preferred reconstruction subgroup, confirming that the latter had greater medical comorbidity. A second free flap following an initial flap failure has an increased failure rate of 6% [109] to 11% [310] and healing is complicated by the poor quality of tissues [109, 240]. The Author considers that, unless there has been a technical error, a PPM flap is the safer option and more likely to facilitate prompt chemo-radiotherapy following surgery [240]. Although minor complications are common with the PPM flap only two patients required a further significant operation for major complications.

4.3.iii Morbidity and mortality

The level of general medical morbidity following major head and neck surgery is known to be high [6, 7] (**Table 4.4).** The majority of patients were managed on a high dependency unit and unplanned admission to the intensive treatment unit (4.9%) was only associated with ischaemic heart disease. The mortality rate within 30 days of 5% is acceptable in the context of otherwise incurable disease and was independently associated with diabetes mellitus. Lower rates of mortality have been reported with less advanced disease and lower levels of comorbidity (2.2% [286] and 2.7% [283]).

4.3.iv Pectoralis major flap complications

The majority of patients with oral cancer are in poor health with a history of smoking and alcohol abuse. The incidence of PPM flap complications in the literature is high and ranges between 18 to 36% [21, 24, 282, 283, 286, 288]. Complications are more frequent following salvage surgery and within the oral cavity or oropharynx [21, 306, 307, 311]. The 2% incidence of complete flap loss in this series is the same as reported by Milenovic [288] in the largest series of PPM flaps (10/506) and the typical range is zero to 7% [282, 283, 286, 303, 312]. The incidence of major (6.9%) and minor (12.7%) flap loss, including orocutaneous fistula (10.8%) were also comparable to the literature [major loss 6% to 10% and minor loss 8.3% to 15 % or higher] [282, 283, 286, 288, 303, 312]. Flap complications were unrelated to the type of surgical resection or previous salvage surgery. The systemic factors independently associated with all degrees of flap loss were ischaemic heart disease, diabetes mellitus and acquisition of MRSA. These factors implicate a poor quality microcirculation and

compromised wound healing. Similarly, previous free flap failure was independently associated with subsequent total (2%) and major (6.9%) partial loss of the PPM flap.

Table 4.4
Complications following the PPM flap [From Avery [309]].

Morbidity	n (%)
Flap-related morbidity	
Total flap loss	2 (2.0)
Major flap loss	7 (6.9)
Minor skin loss	13 (12.7)
Mild skin dehiscence	17 (16.7)
Orocutaneous fistula	11 (10.8)
Donor site infection	2 (2.0)
Other morbidity	
Lower respiratory tract infection	11 (10.8)
Myocardial infarction	6 (5.9)
Cardiac arrhythmia	2 (2.0)
Fractured mandible	2 (2.0)
Gastrointestinal bleeding	1 (1.0)
Lingual bleed/necrosis	1 (1.0)
Carotid blowout	1 (1.0)
Pneumothorax	1 (1.0)
Tracheal stenosis	1 (1.0)
Tracheostomy bleed	1 (1.0)
Cerebrovascular accident	1 (1.0)

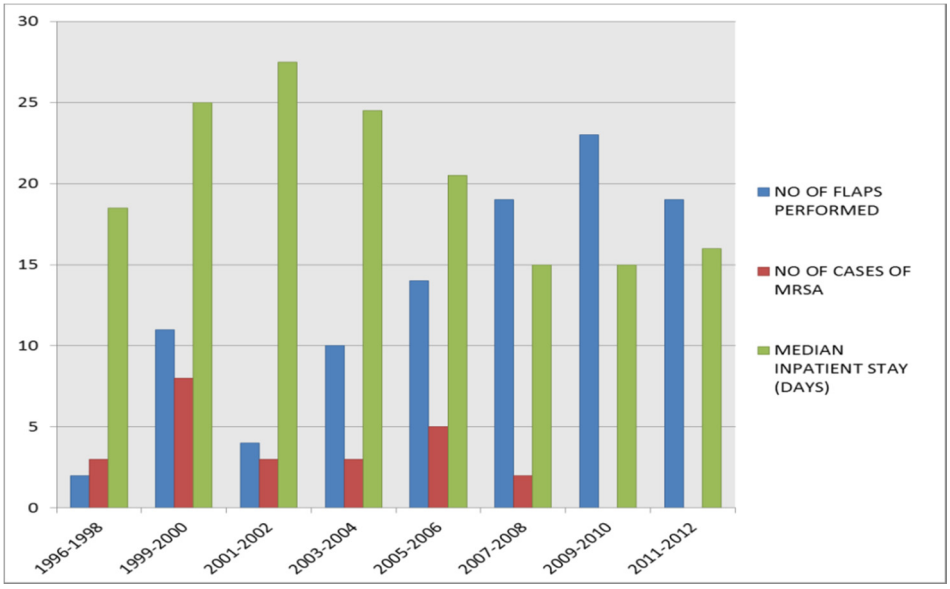
4.4.i Comparison of the first (1996 to 2004) and second (2005 to 2012) halves of the study period

The majority of PPM flaps (73.5%) were performed in the latter half of this series, but this was unrelated to the pattern of free flap failure or ASA grade. The ASA co-morbidity classification system probably lacks sufficient sensitivity to detect an underlying trend of increasing levels of comorbidity. There were a significantly greater number of primary stage IV SCC treated in the second halve of the series (22.2% vs. 48.0%), which may indicate increasing numbers and/or a more aggressive approach to surgical treatment. The introduction of a multidisciplinary team may have encouraged a more cautious approach to the choice of reconstruction and there may also be an element of increasing patient choice following the introduction of a surgical consent and planning proforma by the Author [313].

Patients with substantial co-morbidity, advanced disease and a poor prognosis may prefer a PPM flap because of the reduced donor site morbidity and greater flap success rates when compared to a composite free flap, commonly the DCIA or fibula flap [51]. Many patients had previously undergone surgery and/or chemo-radiotherapy, or suffered failure of a free flap, so the surgeon and patient probably felt a free flap procedure would not be tolerated.

There was no significant variation in the type of surgical resections performed during this study period. The mean duration of hospital admission decreased significantly from 30.2 to 20.8 days, which is comparable with recent reports [14-30 days] [21, 24, 307, 312]. Prolonged hospital admission is known to be associated with significant complications [21, 307] including infection with MRSA [314]. Acquisition of MRSA occurred in 23.5% of patients but declined dramatically after 2006. This was the only factor independently associated with prolonged hospital admission **(Figure 4.7)** and is in agreement with the Author's previous findings following free flap surgery [314]. Flap complications in general declined and this is also possibly related to increasing experience and refinements in surgical technique.

Figure 4.7
Decline in acquisition of MRSA and length of hospital admission with time [From Avery [309]].

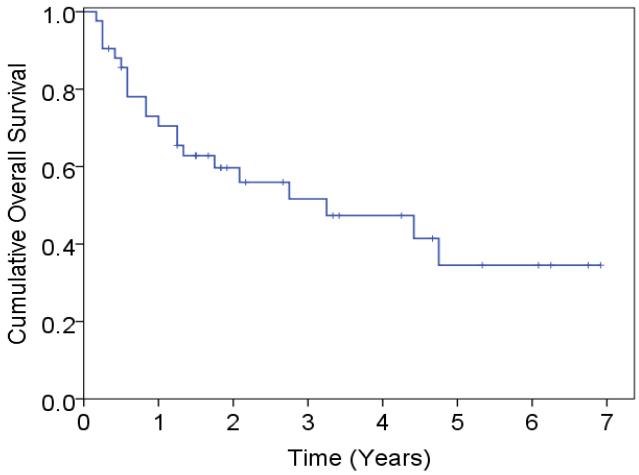


The 5-year overall (34.5%) and cancer-specific (71.8%) survival outcomes for stage IV primary SCC compare favourably with historical data and a recent review of UK outcomes up to 2003 [315] **(Figure 4.8)**. The incidence of recurrent and metastatic disease also declined

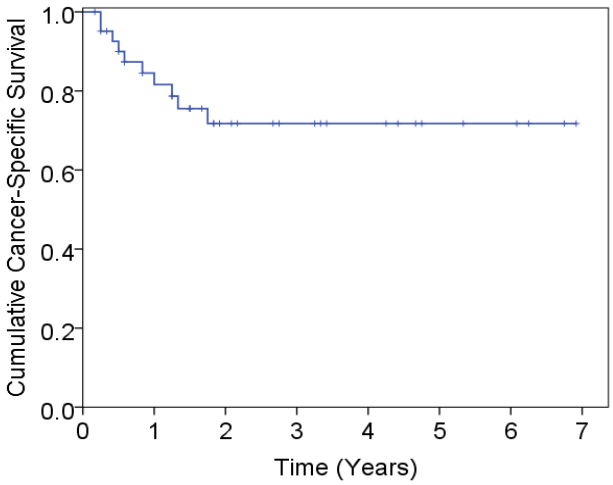
significantly after the first quarter (1996 to 2000). Moreover the 5-year outcomes for both overall (0% vs. 44.9%) and cancer-specific (0% vs. 79.8%) survival with stage IV SCC improved significantly in the latter half of the study period.

Figure 4.8
Overall and cancer specific survival for primary stage IV SCC (n=42) [From Avery [309]].

a) Overall survival with primary stage IV SCC



b) Cancer-specific survival with primary stage IV SCC



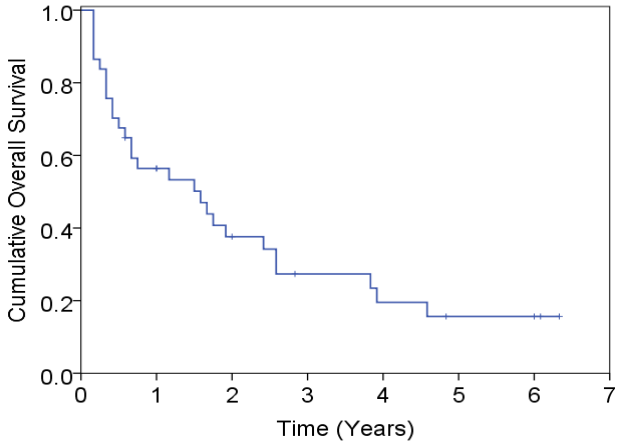
The 1-year, 3-year and 5-year overall survival rates for surgery for primary stage IV SCC (n=42) were 70.5%, 51.7% and 34.5%, respectively (median 39.0 months, 95% CI 5.3-72.7 months). Cancer-specific survival was 81.6%, 71.8% and 71.8%, respectively.

Survival outcomes following salvage surgery are variably described and direct comparisons with other reports are difficult because of relatively small numbers, differing

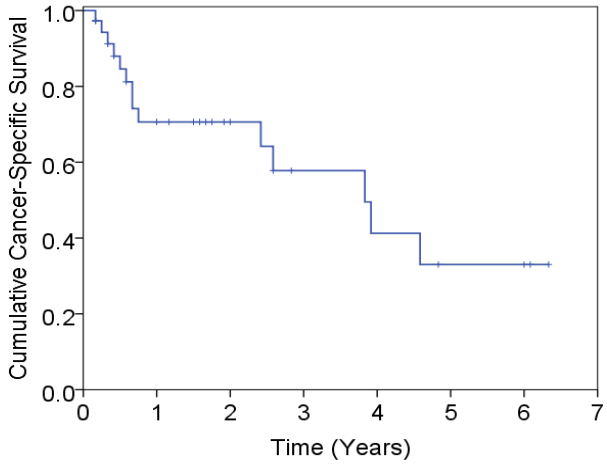
anatomical sites, early or late recurrent disease and differing treatment modalities. In the salvage surgery subgroup the 5 year overall (0% vs. 35.9%) and cancer-specific (0% vs. 55.7%) survival figures also improved significantly in the latter half of the study and compare favourably with recent reports [21, 240, 306, 307, 311].

Figure 4.9
Overall and cancer-specific survival for all stages of SCC salvage surgery (n=37*) [From Avery [309]].

a) Overall survival for salvage surgery



b) Cancer-specific survival for salvage surgery



*One patient was treated with palliative intent and one patient is alive with recurrent disease.
One patient was excluded from long-term survival analyses as died within 30 days of operation.

The 1-year, 3-year and 5-year overall survival rates for all stages of SCC salvage procedures were 56.4%, 27.3% and 15.6%, respectively (median 19.0 months, 95% CI 4.5-33.5 months) and cancer-specific survival 70.6%, 57.8% and 33.0%, respectively (median 46.0 months, 95% CI 23.4-68.6 months).

In 2004 post-operative Cisplatin based chemotherapy was introduced in Leicester. Although various combinations of treatment modalities have been used in this cohort, the dramatically improved survival outcomes are likely to be related to radical surgery combined with aggressive weekly concurrent Cisplatin therapy. In 2004 Bernier [316] described a similar Cisplatin regimen with 5 year overall and "progression-free" survival figures of 53% and 47%, respectively, for a broadly comparable cohort of stage III & IV SCC disease of the oral cavity, oropharynx and larynx.

One of the limitations of the current study is that the findings are restricted to a cohort selected on the basis of reconstruction with a PPM flap. Nevertheless, this group with advanced disease and substantial co-morbidity would be expected to have a comparatively poor outcome. These initial findings warrant further analysis of a larger and broader patient group.

This paper is the largest and most detailed overview of experience from the UK. The main indications for the PPM flap were reconstruction for advanced malignancy, often following previous surgery and/or chemo-radiotherapy treatment or failure of a free flap, and frequently in the context of substantial pre-existing comorbidity. When comparing the first and second halves of this study period there have been significant declines in: recurrent disease, MRSA acquisition, duration of admission and a trend towards less PPM flap loss (all degrees) whilst cancer survival rates have dramatically improved. These outcomes support the strategy of aggressive surgical and chemotherapy combination therapy in this most challenging of patient groups.

4.5.i Perspective on the role of the pectoralis major flap in maxillofacial oncology surgery

Free tissue transfer has become the preferred reconstruction [17, 50, 106, 109, 110, 317, 318], with fewer complications and better functional outcomes, based mainly on comparisons with the radial free flap [15, 17, 20, 24, 292, 319-322]. Most recent developments have included perforator flaps [38-40, 66, 323] , with an emphasis on improving cosmetic, functional and quality of life outcomes in combination with less morbidity at the donor site [24, 26, 39, 42, 43].

In general, the PPM flap is a secondary choice in the "developed" world whilst remaining popular in the "developing" world. The recent major series are from: Eastern Europe [Croatia] [288], South America [Brazil] [286, 324]and Asia [India] [312, 325], [Taiwan] [26], [Korea] [326]. Whilst reports from the developed world are typically smaller and collected over a longer period: North America [Canada] [21], [United States of America, USA] [289, 303, 327] and Europe [Ireland] [321], [United Kingdom, UK] [240, 309]. Although maxillofacial surgical units within Western Europe continue to use the PPM flap, few units report their experience. The aims of this paper, published in 2014 by the Author [328], were to establish a unique overview of the literature on the PPM flap and set the Leicester experience within the context of International practice.

4.5.ii Advantages of pectoralis major flap

The advantages of the PPM flap include: a relatively quick and easy harvest, good coverage, versatility and reliability [286, 288, 327] **(Table 4.5).** The initial costs of free tissue transfer are greater because of infrastructure, personnel and equipment [21] but the overall financial burden is often similar once duration of admission, complications and subsequent care have been considered [19, 21, 23, 319, 329-332]. However, financial comparisons between differing health care systems are complex and strongly influenced by medical complications [22], the end result being that within the developing world the costs of free tissue transfer, to both patient and institute, are usually [312] but not always prohibitive [333].

The PPM flap is generally considered a lesser procedure than a free flap, but it is unclear whether overall morbidity is lower because of selection bias and confounding clinical factors. Retrospective comparisons have failed to demonstrate major differences [26, 287, 321, 332] but the shorter operation duration [24, 26, 287, 319, 332] with a PPM flap should result in fewer medical and surgical complications [110, 293, 297]. The lack of a microvascular anastomosis, at risk of revision or failure, may be beneficial with a compromised patient [240].

In general, the duration of hospital admission with the PPM flap and free tissue transfer is similar. The Leicester experience [free tissue 20 days and PPM flap 21 days] [314] is comparable to other recent reports [radial 18 to 24 days and PPM flap 23 to 25 days] [23, 24, 26]. Shorter admissions with the PPM flap have been described (9 and 10 days) [289, 324, 334] but the duration increases with the complexity of surgery (7.5 days primary reconstruction and

20 days salvage reconstruction) [327]. All series are skewed by infective, cardio-respiratory and alcohol related complications [21, 22, 307, 335] and may be influenced by increasing financial demands to discharge promptly [336-340].

Table 4.5

Advantages of the pectoralis major flap [From Avery [328]].

Advantages
• Quick and easy to harvest • Reliable anatomy • Microsurgical skills not required • No microvascular anastomosis • Versatile design • Muscle and skin coverage • Short operation • Minor donor site morbidity • Most complications managed conservatively or minor treatment • Total failure rare • Occasional major secondary operation
Best used for large defects in the tongue, lateral mandible and pharynx, parotid and neck. Coverage of major vessels and brachytherapy tubes, closure fistulae.

4.5.iii Disadvantages of pectoralis major flap

The shortcomings of the PPM flap include: restricted arc of rotation and pedicle length with a watershed at the zygomatic arch and superior pole of the tonsil [321]. The functional [20, 319-321 322] and cosmetic [26, 312, 327, 341] outcomes are a compromise whilst the bulk and the limited pliability make it unsuitable for small or superficial defects. Reduced shoulder and neck function may adversely affect the quality of life [327, 342] (**Table 4.6**).

Greater complications and gastrostomy dependence with the PPM flap following pharyngeal reconstruction and radiotherapy are based on historical data [343] and more recent studies, primarily with oral malignancy, revealed comparable gastrostomy dependency [24, 332]. In the Leicester experience, prolonged gastrostomy duration was unrelated to the type of flap but associated with advanced stage disease, surgery with radiotherapy, radiotherapy alone and bone resections [263].

The quality of life domains of most importance are speech, chewing and swallowing [344, 345]. The worst functional outcomes occur with advanced stage III & IV disease and combination therapy [345]. In the largest comparison of the PPM flap with free tissue transfer for oral defects there were significant disadvantages in mood, speech and shoulder function but not the majority of outcomes, including global quality of life [26]. Outcomes may be influenced by many factors, including cultural and ethnic considerations [344, 346].

Table 4.6

Disadvantages of the pectoralis major flap [From Avery [328]].

Disadvantages
• Restricted arc of rotation • Limited pedicle length • Excessive bulk • Limited pliability • Frequent minor wound complications • Supraclavicular bulge • Poor skin match • Hair growth • Deformity of chest wall donor site • Variable & limited functional outcomes • Restricted neck movement, discomfort and deformity • Not ideal for small or superficial oral soft tissue defects, anterior segmental mandible, soft palate or maxilla.

4.5.iv Pectoralis major flap complications

The incidence of complications is high (18 to 63%) [21, 24, 282, 283, 286, 288, 312, 324, 326, 334, 347] and minor wound complications are more frequent than with free tissue transfer [15, 292], including wound dehiscence [24, 321] and blood loss [26], but there are often no other substantive differences [26, 287, 321, 332]. Complications are greatest following salvage surgery, at oral cavity and pharyngeal sites [21, 306, 307, 311, 324, 343], and are variably described as either associated with [289, 324, 334, 348] or unrelated to [280, 286, 307, 311, 321, 326, 349] radiotherapy.

The incidence of total flap failure ranges from zero to 7% [282, 283, 286, 288, 303, 312, 324, 326, 347, 350] and is generally lower (0 to 2%) in more recent reports [288, 289, 303, 312, 324, 326, 327, 347, 350, 351], including the Leicester experience (2%) [309]. Major (4% to 10%) or minor (8% to 15 % or higher) partial skin flap loss and orocutaneous fistulae (3% to 29%) are frequent complications [282, 283, 286, 288, 289, 303, 312, 326, 350] but also less common in recent reports and only occasionally delay adjuvant treatment. Conservative wound care procedures are common (10% to 50%) [21, 24, 289, 309, 341] but major secondary surgery is infrequent (2% to 5%) [283, 288, 289, 303, 309, 312]. In the Leicester study, a reduction in complications coincided with a lower incidence of MRSA [309, 314] and is consistent with increasing surgical experience [287, 341].

4.5.v Refinements in surgical technique

The refinements in surgical technique to optimise success are primarily related to accurate positioning of the skin paddle [351 287, 303]. Full mobilisation with skeletonisation of the pectoral vascular pedicle is also safe [287, 288] **(Figures 4.10 & 4.11)**. Attempts to create a thinner or longer flap have not been popular and may have increased complications [352 311, 326, 352 286 353]. The true island musculocutaneous paddle variant has advocates in the developing world: Brazil [286], India [354] and Korea [287]. Attempts to minimise donor site morbidity with a segmental muscle design [348] or perforator flap design [355, 356] have not become popular. The simplicity of the conventional technique is a major advantage of the PPM flap.

Figure 4.10
Retraction of pectoralis minor and mobilisation of pectoral branch vascular pedicle (arrow) which may be skeletonised [From Avery [328]].

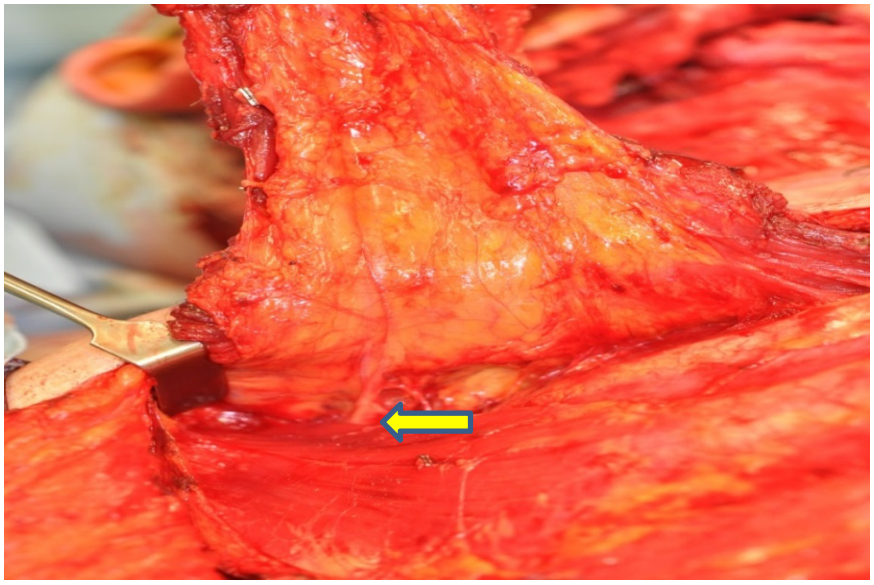
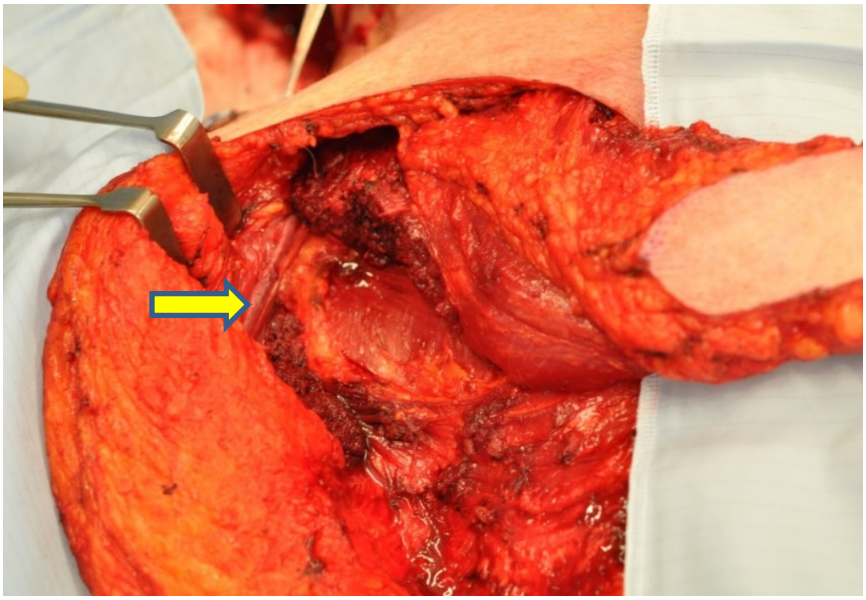


Figure 4.11
Complete mobilisation of pectoralis major muscle insertion (Arrow cephalic vein) [From Avery [328]].



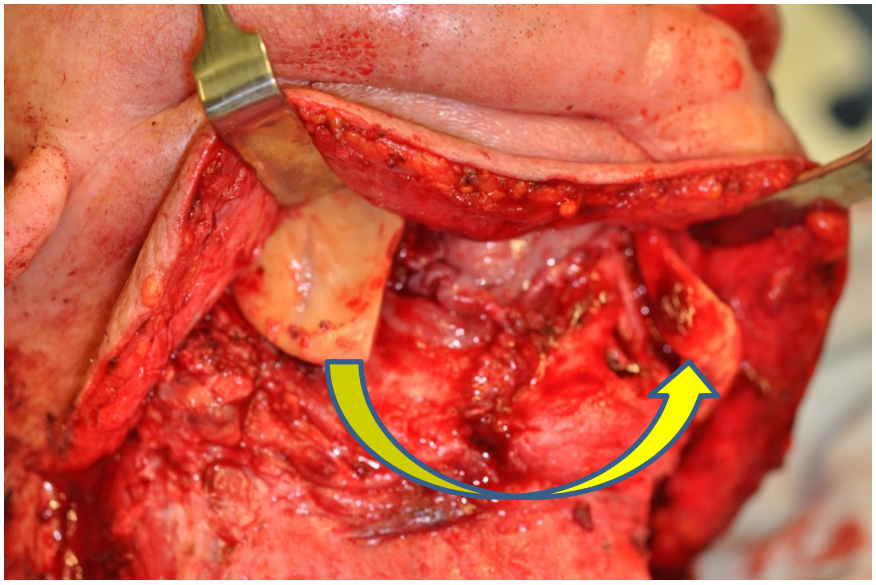
4.5.vi Preferred choice of flap reconstruction

The use of the PPM flap as the first choice flap rather than a free flap varies widely and ranges from 5 to 62% within the few series indicating the relative proportion of free and pedicled flaps [26, 312, 327, 357]. In a 2001 review of academic otolaryngology practice, in the USA, the PPM flap remained twice as popular as free tissue transfer [358].

The PPM flap is generally utilised for primary disease or salvage reconstruction with the latter group including free flap failure, further disease or wound complications. Selection depends on the preference and training of the surgeon often in combination with several other factors. The frequency of use as the preferred reconstruction within series just utilising the PPM flap ranges from 33% to 97% [21, 289, 312, 326, 327, 350]. The main indications being: financial (36%) [312], medical comorbidity (21 to 40%) [309, 312], extended radical neck dissections (13% to 20%) and vessel depletion (9 to 14%) [309, 312, 326, 350]. The Leicester experience [309] was comparable, with the PPM flap being preferred on 80% of occasions and primarily selected for substantial comorbidity (40%), large mandible (36%) or glossectomy (19%) defects, extended radical neck dissection (15%) or parotidectomy (8%) procedures and vessel depletion (14%) **(Figures 4.12 to 4.14)**. The stage of disease [24, 286], ASA grade [24], comorbidity [312, 326] and incidence of previous malignancy [312, 324, 326, 350, 359] were greater than in comparable studies.

Figure 4.12 (a & b)
Typical hemimandibulectomy defect: clinical and radiographic appearance (Arrow indicates osteotomised ends of mandible) [From Avery [328]].

a)



b)

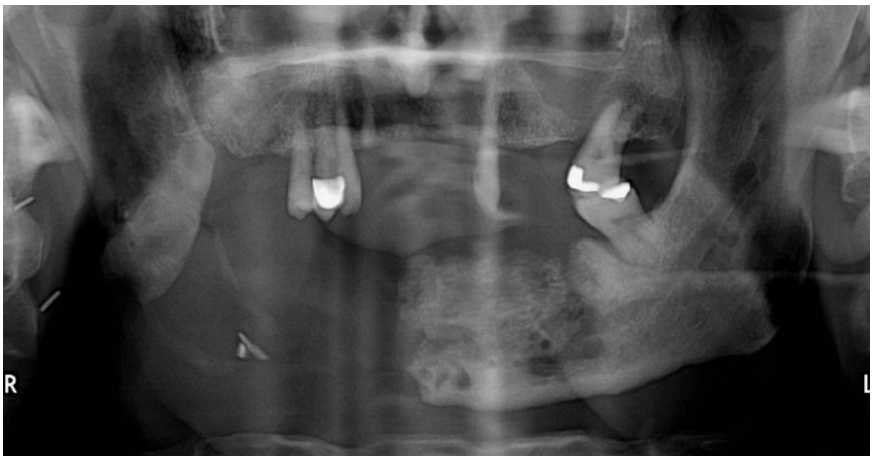
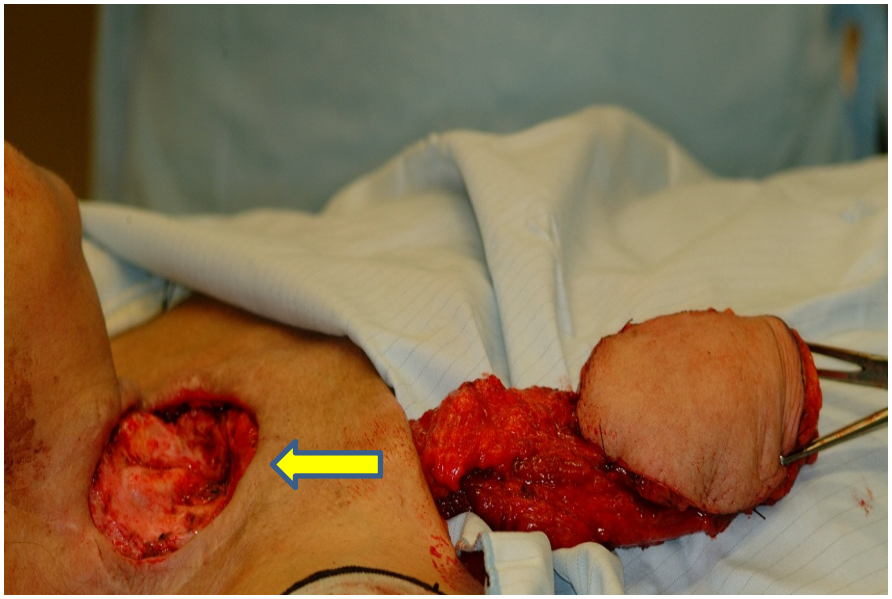


Figure 4.13 (a & b)
Radiation damage with exposure of carotid artery (Arrow) protected with PPM flap [From Avery [328]].

a)



b)

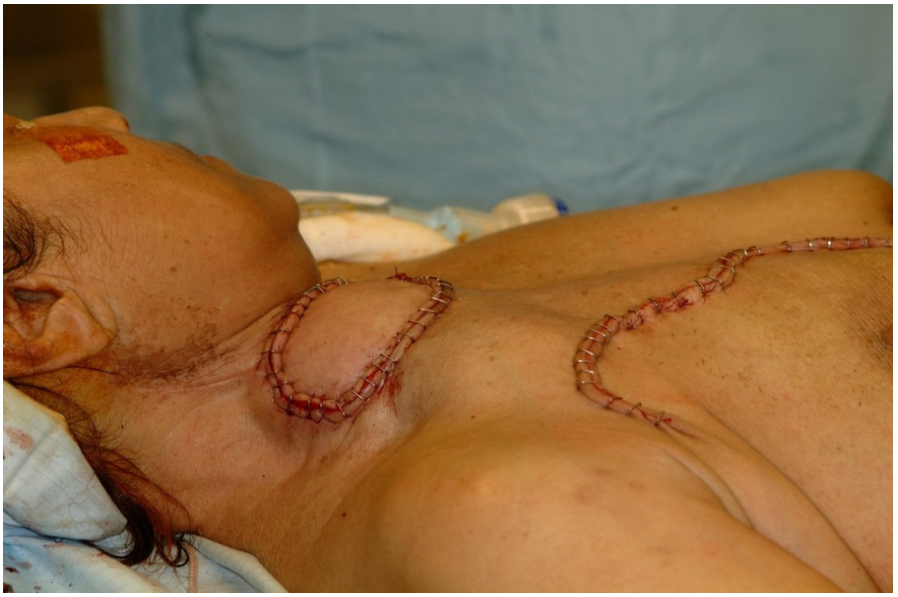
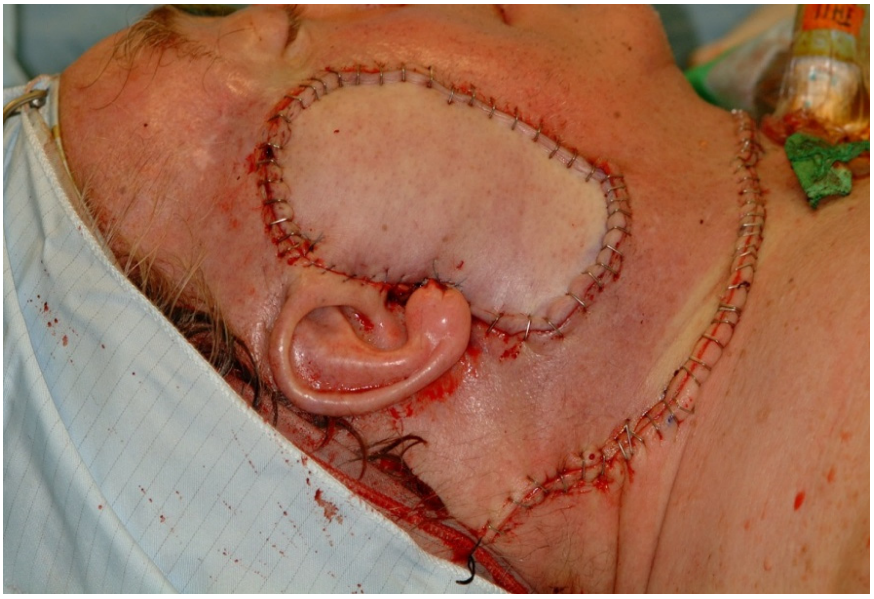
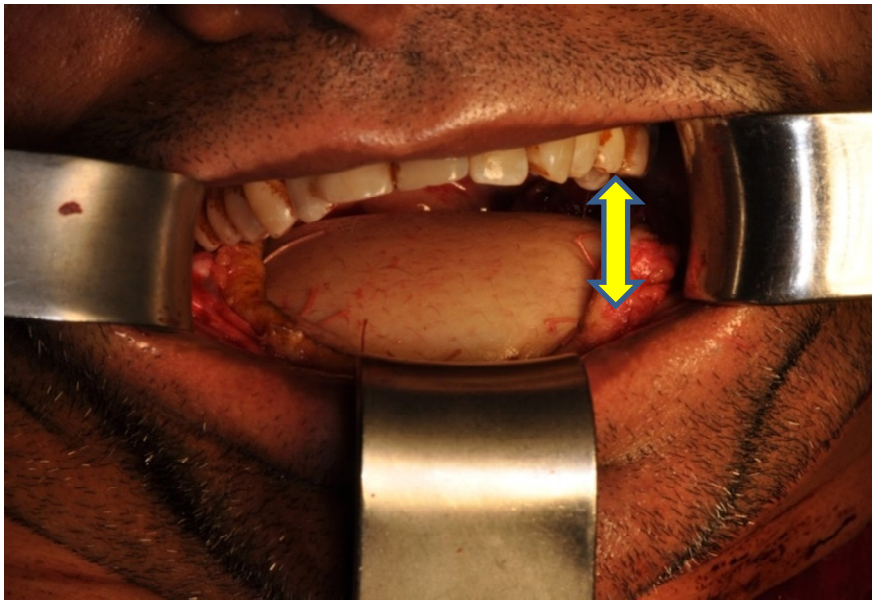


Figure 4.14
Radical parotidectomy with skin resection defect. The zygomatic arch is the superior watershed area [From Avery [328]].



The aging population within the developed world has increasing levels of multiple medical comorbidities [360-363]. In head and neck oncology this is often caused by tobacco and alcohol abuse with an adverse impact on prognosis, mortality, morbidity, quality of life and costs [298, 361, 363-365]. In the Leicester study [309] one quarter of patients were of Asian origin. This subgroup has an increased prevalence of oral cancer [366, 367], diabetes mellitus and cardiovascular disease, with the latter comorbidities associated with increased complications and mortality [368-376], including flap related complications [309]. Both patient and surgeon may perceive the PPM flap as the safer compromise in the context of previous treatment, substantial comorbidity, advanced disease and poor prognosis [240]. Patient opinions are most important for bone flaps because of the greater donor site morbidity [377] and lower flap success rates (93%) [51]. A PPM flap provides reasonable mandibular function in the context of limited longevity and a reconstruction plate was not usually placed as it is often compromised by complications [282, 288, 325, 378-380]. Oral submucous fibrosis is not uncommon in the Leicester Asian population and the benefits of free flap reconstruction are reduced by persistent trismus after surgery [26] making the PPM flap a realistic alternative option [325] (**Figure 4.15)**.

Figure 4.15
Total glossectomy in an Asian patient with trismus (Arrow) caused by oral submucous fibrosis [From Avery [328]].



4.5.vii In conjunction with a free flap

Two free flaps may optimise functional reconstruction for large composite defects but substantially increase complexity, operation duration and may reduce flap success rates [51, 325, 381, 382]. Free tissue transfer may be successfully combined with a PPM flap, particularly for lateral mandible defects or extended radical neck dissection following irradiation [383, 384]. However, this option has been utilised infrequently (3% or less) in Leicester [309] and elsewhere [288, 327].

4.5.viii Salvage reconstruction following complications

The PPM flap retains an established role in the management of surgical complications but this is a minority indication in most series, including the Leicester experience. Typical indications include: orocutaneous fistula (1 to 5%), osteoradionecrosis (0 to 5%), major vessel protection (1 to 3%) or rupture (1 to 2%), obliteration of dead space, coverage of exposed hardware or wound breakdown (1 to 4%) [21, 309, 312, 327, 350]. Exceptions include the high incidence of pharyngeal fistulae (17%) [350] and major vessel exposure (51%) [326] associated with radiotherapy, primarily in otolaryngology practice.

4.5.ix Salvage reconstruction following free flap failure

Reconstruction following partial or complete free flap failure is often necessary for large or composite defects, exposure of vital structures or hardware, and to facilitate prompt adjuvant chemoradiotherapy. The difficulties include: enhanced comorbidities, malnutrition, wound breakdown and infection, poor tissue vascularity, previous surgery and/or chemoradiotherapy, lack of recipient vessels and psychological issues [385-388].

A second free flap for failure has been performed with varying frequency in small numbers of patients in major centres such as Taipei (Taiwan) [35% to 53%] [38 109], Liverpool (UK) [51] [70%] and Texas (USA) [385] [70%]. Refinements in surgical technique [109, 385-387] mean that the failure rate for an immediate second free flap is generally slightly raised but improving: 4% to 11% [385 51, 109, 310, 388]. However, failure may sometimes be comparatively frequent: 25% to 47% [327, 389, 390]. In general, the majority of second free flaps selected were not bone flaps and a PPM flap has been the preferred alternative. In Leicester the PPM flap remains the preferred salvage reconstruction in the absence of technical error with a success rate which is comparable to the best free flap outcomes (95%), although wound complications were common [309].

Overall, the PPM flap probably remains the most frequently used reconstruction salvage option in the UK and elsewhere. The case is most compelling with substantial comorbidity, advanced or further disease with a limited prognosis and for large tongue, oropharyngeal and lateral mandible defects [220, 325, 347].

4.5.x Salvage reconstruction of recurrent or further primary disease

Free tissue reconstruction is effective for both recurrent and further primary disease [57, 380, 391-394] with comparable or slightly lower flap success rates after irradiation. However, complications are more frequent [380, 385, 387, 393, 394], and especially with large mandible defects, larger flaps and active infection [380]. It is unclear how often a free flap or PPM flap is selected for recurrent disease but the proportion typically ranges from 1% to 36% [17, 59, 317, 393] and 13% to 52% [311, 312, 324, 326, 350, 359], respectively.

The prognosis for recurrent disease is generally poor [52-58] so free tissue transfer may not be appropriate. However, the PPM flap remains a versatile option although complications are frequent at all sites (53% to 63%) [307, 311, 334] and following surgery with radiotherapy [334]. The outcomes are difficult to compare because these studies have small sample sizes, multiple clinical variables, differing reconstruction and radiotherapy regimens, and variable outcome definitions. In the Leicester study [309], a comparatively higher proportion of further malignant disease was managed without significant increases in either general or PPM flap related complications and with improving survival outcomes.

4.5.xi Current role of the pectoralis major flap

The evidence for this review is mainly based on retrospective case-series or cohort studies (level III and IV) [395]. The PPM flap remains a valuable versatile reconstructive option both in centres practicing free tissue transfer and throughout the developing world. The flap is utilised in varying proportions as either the preferred choice of reconstruction or for salvage reconstruction following free flap failure, further disease or surgical complications. A refined surgical technique and an experienced surgeon may yield total flap failure rates comparable or better than those of free tissue transfer. A combination of adverse factors such as: serious or multiple comorbidities, advanced disease and previous treatment are common indications. The defects most commonly reconstructed include: extended radical neck dissection, large lateral mandible, tongue and oropharyngeal defects. In some major centres a second free flap is increasingly used after initial failure as success rates improve. However, the PPM flap probably remains the most commonly utilised salvage option. The PPM flap is occasionally used together with a free flap. The needs of the local population vary and patient choice may increasingly influence flap selection decisions. The Leicester experience is broadly compatible with International practice although there is a comparatively higher incidence of advanced disease together with substantial medical comorbidity whilst the cancer survival outcomes are generally superior.

4.6.i The sternocleidomastoid perforator flap

The sternocleidomastoid (SCM) flap is conventionally raised as a superiorly or inferiorly based pedicled flap and may be either a muscular, myocutaneous or myo-osseous flap [396]. The flap was unpopular for reconstruction of the oral cavity because of the poor arc of rotation, precarious skin vascularity, proximity to nodal disease and the introduction of free tissue transfer [396, 397]. In 2011 the Author described a new technique for raising the SCM flap based on the perforating vessels of the superior thyroid vascular pedicle that overcomes these limitations [398].

4.6.ii Anatomy of sternocleidomastoid flap

The SCM flap is a type II flap with a segmental vascular supply based superiorly on the occipital and posterior auricular arteries, the superior thyroid artery and/or branches of the external carotid artery supply the middle third and there is a variable supply to the lower third from the thyrocervical trunk [396, 399]. The rotational SCM is commonly raised as a superiorly based myocutaneous flap [396, 400], often with preservation of the occipital and superior thyroid arteries to reduce the risk of ischaemic complications [396, 401, 402], but this significantly restricts the arc of rotation and applications for the flap.

4.6.iii Surgical technique

A conventional transverse cervical incision is utilised with the myocutaneous skin paddle positioned directly over the mid to lower half of the SCM muscle to preserve the perforating vessels [403, 404] and cutaneous branch of the superior thyroid artery [405]. The sternal and clavicular muscle origins are divided 2 cm above the clavicle. The muscle is elevated based on the superior thyroid vascular pedicle **(Figures 4.16 & 4.17)**. The superior muscle insertion is divided 2 cm below the mastoid and the accessory nerve preserved **(Figure 4.17).** The bulk of the flap is composed of the middle third of the muscle. The greatly increased arc of rotation allows placement in the floor of the mouth or tongue without tension **(Figure 4.18)**. The donor site is closed primarily. The muscle only variant of the flap is illustrated in the publication by the Author [398].

Figure 4.16
Markings of myocutaneous flap paddle.

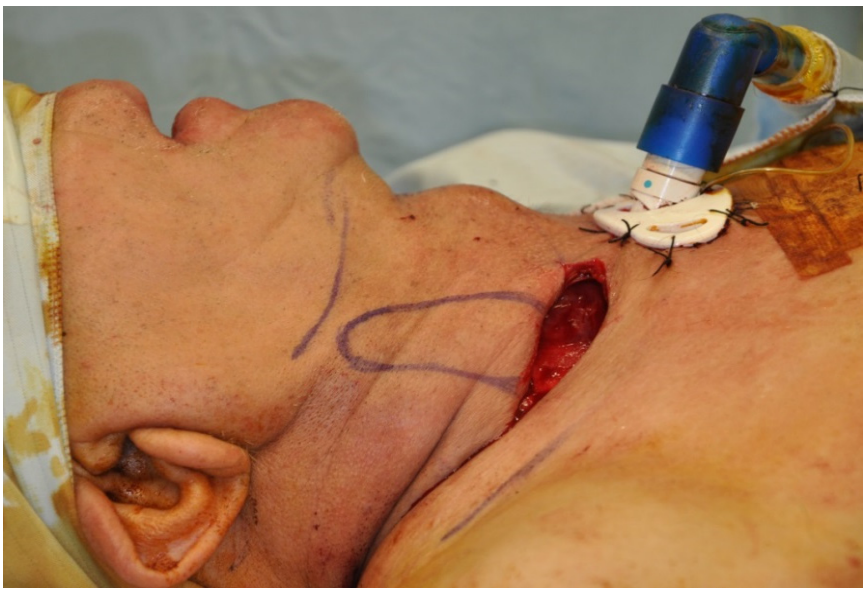


Figure 4.17
The inferior and superior attachments of the muscle are divided and the flap mobilised on the vascular pedicle fully.

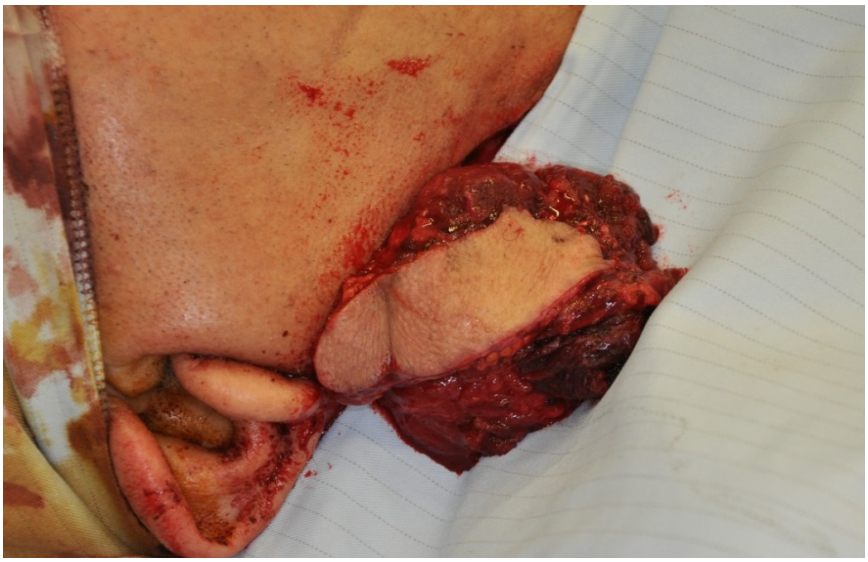
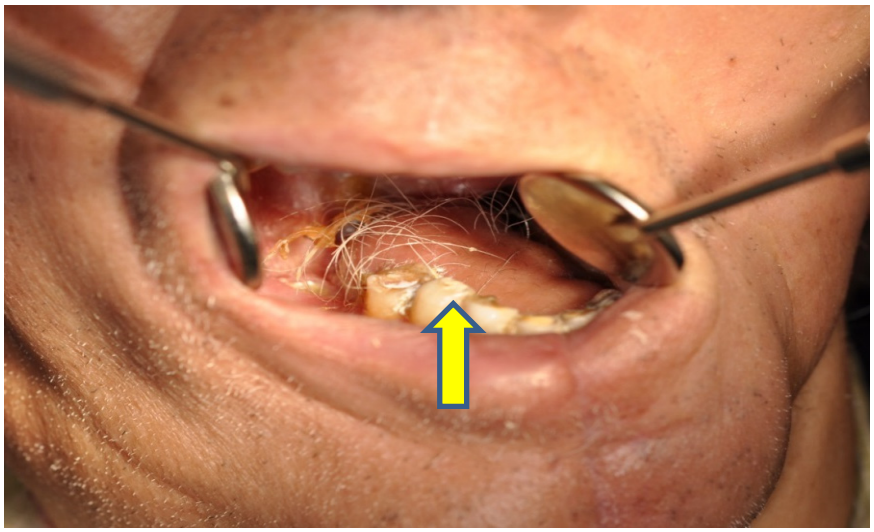


Figure 4.18
Flap inset in floor of anterior mouth with some hair growth evident (Arrow).



4.6.iv Outcomes and indications

The incidence of complications, mainly partial loss of the skin paddle, with a conventional rotational SCM flap is substantial (20 to 52%) [396, 400, 404, 406] and may be higher after radiotherapy [396, 402]. Total flap loss in the largest series was 7.3% [400] and in a meta-analysis was 4.2% (12/282) [396]. In the current small series all perforator flaps survived without complication and functioned satisfactorily**.**

This new technique is a logical development of the increasing utilisation of perforator flaps to minimise donor site morbidity [39]. The perforator SCM flap was selected when a free flap or pectoralis major flap were not ideal because of local wound factors, substantial medical co-morbidity or other flap options had been exhausted. The perforator SCM flap is contraindicated with significant radiation damage if the vascular pedicle cannot be mobilised and when complete coverage of the major neck vessels is essential. The established use of selective and modified radical neck dissections means safe oncological principles are not contravened with an N0 neck or with discrete nodal involvement that does not involve the SCM, however no survival data are available [396, 402]. In this limited experience the perforator SCM flap was effective for repair of small to medium sized defects of the lower oral cavity and the use of the flap has now been expanded.

4.7.i A structured planning proforma for maxillofacial oncology surgery

The planning of major maxillofacial oncology surgery is complex and challenging. Management involves many specialist investigations and a multidisciplinary approach [407].

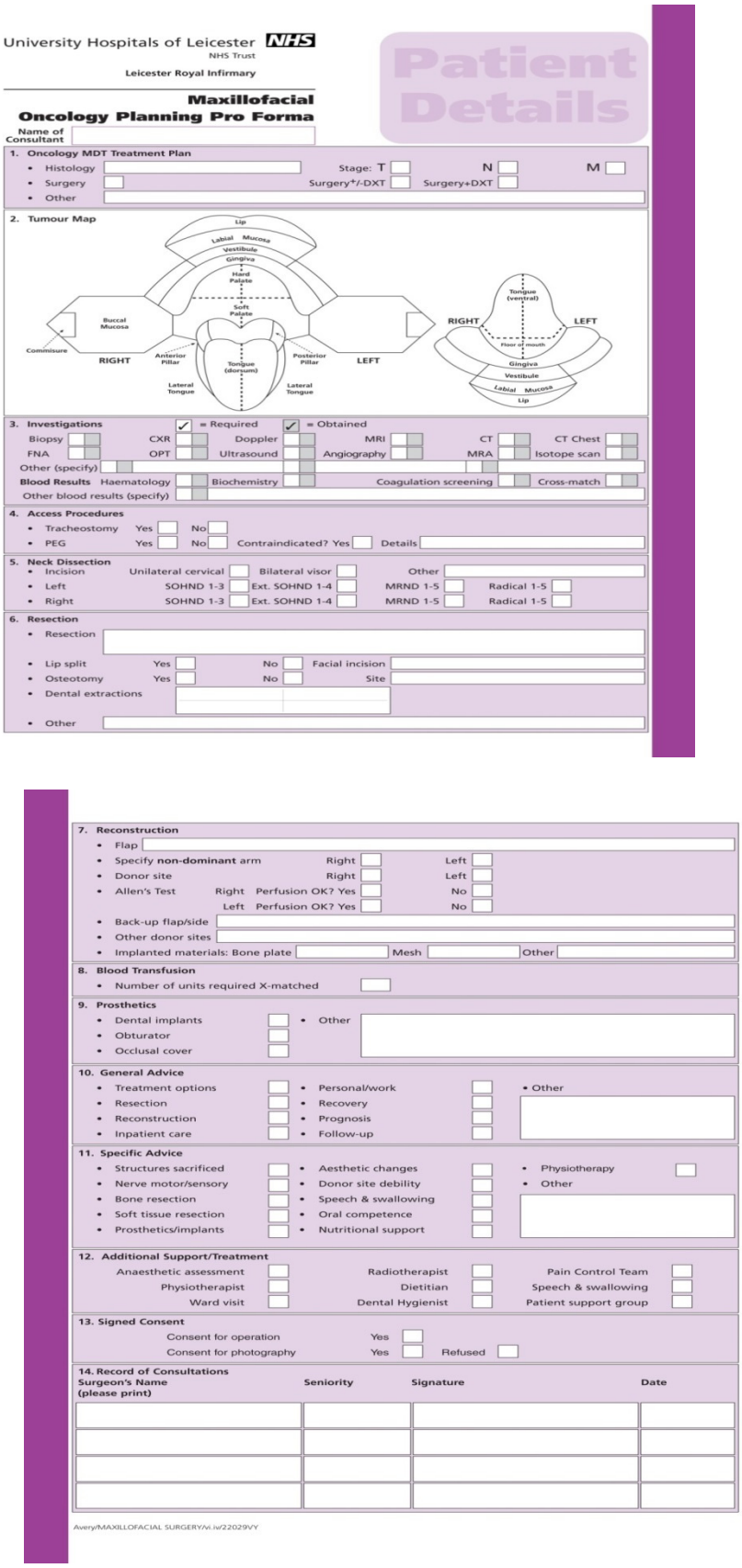
Treatment affects many important functions, the surgical techniques are complex and complications are frequent. Good communication and obtaining informed consent are essential components of modern surgical practice [408]. The quality of the surgical consultation record has received little attention but may not meet the basic criteria of the General Medical Council [409]. The majority of operation records in the UK are hand written [410] and frequently lack basic or critical elements [411, 412 410]. This may be because of lack of training, time constraints, complexity, limited awareness and tiredness. Similar factors probably apply at the consultation and planning stages.

Medical records should be of the highest standard to protect the patient and facilitate good quality care and clinical governance, audit, research, education, and the management of medico-legal litigation. The aim of this paper, published by the Author in 2011 [313], was to assess the quality of documentation before and after the introduction of a novel planning proforma designed to facilitate the process of obtaining and recording informed consent. The Author is not aware of any similar systems for organising the complex information required by maxillofacial oncology patients.

4.7.ii Oncology planning proforma

The proforma is placed in the case record to act as a focus for reviewing clinical management. It is composed of 14 sections with a comprehensive analysis of tumour site and stage, investigations, resection and reconstruction, general and specific advice, complications, morbidity, and multidisciplinary support. It also acts as a record of the length and frequency of planning consultations (**Figure 4.19**).

Figure 4.19
Maxillofacial oncology planning proforma [From Avery [313]].



University Hospitals of Leicester NHS
NHS Trust
Leicester Royal Infirmary

Maxillofacial Oncology Planning Pro Forma

Patient Details

Name of Consultant

1. Oncology MDT Treatment Plan
- Histology — Stage: T N M
- Surgery — Surgery+/-DXT — Surgery+DXT
- Other

2. Tumour Map

3. Investigations ✓ = Required ✓ = Obtained

Biopsy CXR Doppler MRI CT CT Chest
FNA OPT Ultrasound Angiography MRA Isotope scan
Other (specify)
Blood Results Haematology Biochemistry Coagulation screening Cross-match
Other blood results (specify)

4. Access Procedures
- Tracheostomy Yes No
- PEG Yes No Contraindicated? Yes Details

5. Neck Dissection

• Incision	Unilateral cervical	Bilateral visor	Other	
• Left	SOHND 1-3	Ext. SOHND 1-4	MRND 1-5	Radical 1-5
• Right	SOHND 1-3	Ext. SOHND 1-4	MRND 1-5	Radical 1-5

6. Resection
- Resection
- Lip split Yes No Facial incision
- Osteotomy Yes No Site
- Dental extractions
- Other

7. Reconstruction
- Flap
- Specify **non-dominant** arm Right Left
- Donor site Right Left
- Allen's Test Right Perfusion OK? Yes No / Left Perfusion OK? Yes No
- Back-up flap/side
- Other donor sites
- Implanted materials: Bone plate Mesh Other

8. Blood Transfusion
- Number of units required X-matched

9. Prosthetics
- Dental implants
- Obturator
- Occlusal cover
- Other

10. General Advice
- Treatment options
- Resection
- Reconstruction
- Inpatient care
- Personal/work
- Recovery
- Prognosis
- Follow-up
- Other

11. Specific Advice
- Structures sacrificed
- Nerve motor/sensory
- Bone resection
- Soft tissue resection
- Prosthetics/implants
- Aesthetic changes
- Donor site debility
- Speech & swallowing
- Oral competence
- Nutritional support
- Physiotherapy
- Other

12. Additional Support/Treatment

Anaesthetic assessment Radiotherapist Pain Control Team
Physiotherapist Dietitian Speech & swallowing
Ward visit Dental Hygienist Patient support group

13. Signed Consent

Consent for operation Yes
Consent for photography Yes Refused

14. Record of Consultations

Surgeon's Name (please print)	Seniority	Signature	Date

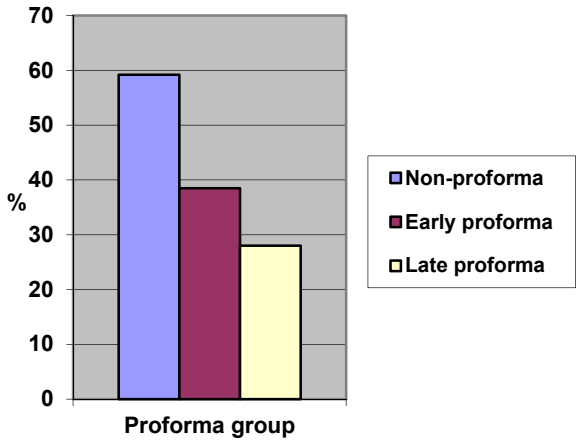
Avery/MAXILLOFACIAL SURGERY/vi.iv/22029VY

4.7.iii Methods & outcomes

Ninety case records from 1998 to 2009 were subdivided in to 3 groups of 30 records and retrospectively analysed. The first subgroup predated the proforma (**non**-proforma 1999 to 2002), the second subgroup from soon after introduction (**early** proforma 2003 to 2006) and the third subgroup during established practice (**late** proforma 2007 to 2009). Sixty key variables were subdivided in to 5 domains, namely: initial management, operation plan, complications, postoperative care and specialist support.

The rate of missing proforma's decreased from 27% in the early subgroup to 13% in the late subgroup. The late subgroup demonstrated a significantly lower overall variable omission rate than both the non and early proforma subgroups (**Figure 4.20**). When comparing the non-subgroup with early and late subgroups there were 40% and 63.3% improvements respectively in the documentation of variables with significant improvements within all five domains.

Figure 4.20
Percentage of applicable variables omitted in case records [From Avery [313]].



The introduction of a structured planning proforma resulted in a substantial improvement in the documentation of both a wide range of individual variables and the overall percentage of variables recorded. Improvement was most marked soon after introduction and was progressive over the decade.

The proforma was particularly effective at documenting advice on potential complications and the outcomes of surgery. Whilst this advice may have been given in the non-proforma group it was not documented and this has important implications for the quality of informed consent in the event of medico-legal litigation.

The proforma is also a valuable educational tool as it provides a logical framework to guide the trainee through all the important aspects of care. The format continues to evolve and an electronic version may be developed as computer based operation templates or electronic synoptic records demonstrate superior rates of data capture [413-415]. This work was awarded the UHL Surgical Specialties Audit Prize 2012.

Current and Future Research

Chapter 1

Soft-tissue radial free flap and donor site

The Author continues to maintain a contemporaneous database of outcomes with the radial and other free flap procedures hence future updates on morbidity outcomes will be possible. Ideally a randomised controlled study would be performed to compare donor site morbidity at the suprafascial and subfascial donor sites, both with and without a negative pressure wound dressing. A substantial number of patients would be required to generate sufficient statistical power. The Dermatology department in Birmingham has continued to expand the laser de-epilation service.

Chapter 2

Osteocutaneous radial free flap and donor site

The Author continues to maintain a contemporaneous database of outcomes with the radial and other free flap procedures. In particular the longer-term clinical outcomes with anatomically contoured unilocking plate systems will be reviewed. The Author has collected CT data on the human radius and this may be used to create a CAD model for further finite element simulation of current and future plate designs.

Further FEA studies will include refinements in simulation of the bone – screw – plate hardware interfaces in order to gain a better understanding of the complex biomechanics under loading. The Author has considered the potential for bioresorbable materials to replace steel or titanium plates.

Chapter 3

Osteotomy and reconstruction plate design

The scope for studying areas within maxillofacial surgery with a refined FEA technique is broad. The Author will continue to integrate refinements in osteotomy design in to further FEA studies pertaining to oncology surgery but also related specialties such as facial orthognathic surgery and orthopaedic surgery. The influence of variable bone quality and the most appropriate method of simulating bone failure are still incompletely understood. The Author will monitor outcomes with the stop-hole osteotomy technique in practice.

The reconstruction of segmental defects of the mandible is challenging and associated with significant morbidity at the donor site of bone flaps. An area of ongoing research is the simulation and development of bone bearing scaffolds, possibly hybrid or entirely bioresorbable in structure, which may avoid the morbidity associated with harvesting a large bone flap. A greater understanding of the biomechanical forces acting on an implanted construct over a period of healing would be valuable.

Chapter 4

Choice of flap reconstruction, outcomes and morbidity

The Author continues to maintain a contemporaneous database of outcomes following percutaneous gastrostomy insertion for oncology patients. The indications and timing of nutritional support continue to be an area of controversy and a future review of the Leicester experience will be possible. Our experience with free flaps, the pectoralis major flap and the sternocleidomastoid flap will increase. There were significant improvements in overall and cancer-specific survival outcomes in the cohort with advanced disease managed with a pectoralis major flap. This has led to an ongoing review of outcomes for all patients with advanced disease.

Finally, the format of the oncology planning continues to evolve and an electronic version may be developed as computer based templates or electronic synoptic records have superior rates of data capture. Although the software development would be comparatively simple this process would require an improvement in the support available from the hospital information technology service. Standardisation of the consent process and audit of compliance is being considered.

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415. **Laflamme, M.R., Dexter, P.R., Graham, M.F., Hui, S.L. & McDonald, C.J. Efficiency, comprehensiveness and cost-effectiveness when comparing dictation and electronic templates for operative reports. *AMIA Annu Symp Proc* 425-429 (2005).**
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Appendix A: National & International presentations

National Meetings

1) **Avery C.** (2005).
5-Year experience with the radial flap suprafascial dissection technique.
British Association Oral & Maxillofacial Surgeons ASM, Gateshead.

2) Fleming K, **Avery C.** (2006).
The use of a surgical planning proforma in head and neck oncology.
British Association Oral & Maxillofacial Surgeons ASM, Eastbourne.

3) **Avery C**, Shenoy S, Shetty S, Siegmund C, Mazhar I, Taub N. (2008).
The prospective experience of a maxillofacial surgeon with the percutaneous endoscopic gastrostomy technique.
British Association Oral & Maxillofacial Surgeons ASM, Cardiff.

4) Crank S, Hayter J, **Avery C**. (2009).
The current role of the pedicled pectoralis major flap in reconstructive surgery.
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5) Naimat J, Gahir D, Vaidhyanath R, Avery C. (2009).
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British Association Oral & Maxillofacial Surgeons ASM, Bournemouth.

6) **Avery C,** Clifford N. (2009).
A practical aid to planning oncology surgery.
British Association of Head and Neck Oncology, London.

7) **Avery C**, Martin T, Parmar S. (2010).
Prophylactic internal fixation of the radial osteocutaneous donor site with an anatomically countoured unilocking plate.
British Association Oral & Maxillofacial Surgeons ASM, Manchester.

8) Gahir D, **Avery C**. (2010).
The sternocleidomastoid flap as a salvage procedure.
British Association Oral & Maxillofacial Surgeons ASM, Manchester.

9) Shim T, Talsania N, Chittari K, **Avery C**. Lanigan S, Adullah A. (2010).
Hairy intraoral flap – an unusual indication for laser depilation.
British Association Dermatologists ASM, Manchester.

10) **Avery C**, Skidmore M, Peden A. (2011).
Biomechanical study of the effectiveness of unilocking T-plate systems for prophylactic internal fixation of the radial osteocutaneous donor site.
British Association Oral & Maxillofacial Surgeons ASM, Nice. France.

11) **Avery C,** Jasani V. (2011).
Sensory recovery of donor arm following radial flaps after subfascial and suprafascial dissection.
British Association Oral & Maxillofacial Surgeons ASM, Nice. France.

National Meetings

12) Jasani V, **Avery C.** (2011).
An audit of the impact of a structured proforma for planning of maxillofacial oncology surgery.
British Association Oral & Maxillofacial Surgeons ASM, Nice. France.

13) **Avery C**, Bujtar P, Simonovics J, Dézsi T, Peden A, Pan J, Váradi K, Bojtos A, Robinson C. (2011).
Finite element analysis of bone plates used for prophylactic internal fixation of the radial osteocutaneous donor site using a sheep tibia model.
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A finite element analysis of the plates used for prophylactic internal fixation of the radial osteocutaneous donor site.
Joint Scientific Meeting of British Association of Head and Neck Oncology and British Society for Oral and Maxillofacial Pathology. Royal College Physicians. London.

15) Bujtár P, **Avery C**, Simonovics J, Sándor G, Pan J, Váradi K.(2012).
The relative strengths of differing types of osteotomy design.
Joint Scientific Meeting of British Association of Head and Neck Oncology and British Society for Oral and Maxillofacial Pathology. Royal College Physicians. London.

16) Bujtár P, **Avery C**, Simonovics J, Sándor G, Pan J, Váradi K.(2012).
An assessment of the stability of differing types of fixation following segmental resection of the mandible.
British Association Oral & Maxillofacial Surgeons ASM. London.

17) Simonovics J, Sandor G, Varadi K, **Avery C,** Attila S, Attila B, Batista WO, Zombori G, Pan J. (2014).
Emerging computer bioengineering technologies 1: Scanning (CBCT versus MSCT), modelling (bio-CAD) and functional simulation (FEA): Steps towards validation.
British Association Oral & Maxillofacial Surgeons ASM, Edinburgh.

International Meetings

1) **Avery C**, Best A, Patterson P, RoltonJ, Ponter ARS. (2007).
Biomechanical study of prophylactic internal fixation of the radial osteocutaneous donor site using the sheep tibia model.
First World Congress of the Academy of Oral Oncology. Amsterdam. Holland.

2) **Avery C,** Danford M, Johnson PA. (2007).
Prophylactic internal fixation of the radial osteocutaneous donor site.
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The anterior approach for prophylactic internal fixation of the radial osteocutaneous donor site.
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5) **Avery C.** Ormiston I. (2008).
Reducing the donor site morbidity of the radial free flap.
8th Asia Congress on Oral & Maxillofacial Surgery. Bangkok. Thailand.

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The indications for PEG insertion in maxillofacial oncology surgery.
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7) **Avery C.** (2009).
Factors affecting the duration of gastrostomy use after maxillofacial oncology surgery.
2nd World Congress of the International Academy of Oral Oncology. Toronto. Canada.

8) Crank S, Hayter J, **Avery C**. (2009).
The current role of the pedicled pectoralis major flap in reconstructive surgery.
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9) Ormiston I, Crank S, Gahir D, **Avery C.** (2009).
A 10-year review of the indications for the pedicled pectoralis major flap in modern maxillofacial reconstructive surgery.
19th International Conference on Oral and Maxillofacial Surgery, Shanghai, China.

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Defining the role of percutaneous endoscopic gastrostomy in head and neck oncology practice.
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Ultrasound assessment of bony healing in the management of mandibular non-union.
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International Meetings

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Danubius (Debrecen). Hungary.

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14) **Avery C**. (2013).
Applications for the sternocleidomastoid flap
4th World Congress of the International Academy of Oral Oncology.
Rhodes. Greece.

15) **Avery C**, Ghandi N, Peel D, Neal CP. (2013).
A review of the indications and outcomes of 100 patients managed with a pectoralis major flap in a UK maxillofacial unit.
4th World Congress of the International Academy of Oral Oncology.
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16) Butjar P, **Avery C**, Simonovics J, Pan J. (2013).
A failure proof surgical technique for marginal resections and angulated osteotomies?
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Rhodes. Greece.

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Biomechanical evaluation of mandible segmental reconstructions using different methods of fixation.
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Appendix B: List of related book chapters

1) **Avery CME.** (2007).
The biomechanical basis for internal fixation of the radial osteocutaneous donor site.
In: Oral cancer research advances (Nikolalakos A, ed). New York: Nova. 2007;7:183-194.
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In: Advances in medicine and biology (Berhardt LV ed). New York: Nova. 2011;26:49-69.
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Appendix C: Published works in order of Thesis chapters

1) **Avery C. [**Invited Review] (2010).
Review of the radial free flap: is it still evolving or facing extinction? Part one: radial soft tissue flap.
Br J Oral Maxillofac Surg 2010;48:245-252.
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Br J Oral Maxillofac Surg 2007;45:611-616.
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3) **Avery C.** Sundaram K, Jasani V, A Peden, Neal C. (2012).
Comparison of sensory changes at the suprafascial and subfascial radial donor sites.
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Br J Oral Maxillofac Surg 2011;49:e50-52.
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5) **Avery C. [**Invited Review] (2010).
Review of the radial free flap: still evolving or facing extinction? Part two: osteocutaneous radial free flap.
Br J Oral Maxillofac Surg 2010;48:253-260.
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7) **Avery C**, Skidmore M, Peden A, Pan J. (2011).
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8) **Avery C,** Bujtar P, Simonovics J, Sándor G, Pan J, Váradi K A. (2013).
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10) **Avery C**, Simonovics J, Bujtar P. (2014).
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Br J Oral Maxillofac Surg 2014;52:475-476.
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The biomechanical aspects of reconstruction for segmental defects of the mandible: A finite element study to assess the optimisation of plate and screw factors.
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The use of the pectoralis major flap for advanced and recurrent head and neck malignancy in the medically compromised patient.
J Oral Oncology 2010;46:829-833.
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15) **Avery C**. Ghandi N, Peel D, Neal CP. (2014).
Indications and outcomes for 100 patients managed with a pectoralis major flap within a UK maxillofacial unit.
Int J Oral Maxillofac Surg 2014;43:546-554.
http://dx.doi.org/10.1016/j.ijoms.2013.10.009

16) **Avery C. [**Invited Review] (2014).
A perspective on the role of the pectoralis major flap in maxillofacial oncology surgery.
Oral Surgery 2014;7:130-142.
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17) **Avery C**. (2011).
The sternocleidomastoid perforator flap.
Br J Oral Maxillofac Surg 2011;49:573-575.
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Review

Review of the radial free flap: is it still evolving, or is it facing extinction? Part one: soft-tissue radial flap

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Abstract

The versatile fasciocutaneous radial flap is robust and reliable, straightforward to harvest, and often produces a satisfactory reconstruction with relatively little long-term morbidity at the donor site. Many surgeons prefer to use a limited number of trusted flaps, and these qualities will ensure that in the intermediate future most surgical trainees will continue to be shown the fasciocutaneous radial flap as both the basic training flap and the established option for reconstruction. Evidence from observational clinical studies and one randomised clinical trial indicates that there is increasing support for the use of the evolutionary technique of suprafascial dissection to minimise morbidity at the donor site. The suprafascial donor site may be repaired with either a meshed or unmeshed partial-thickness skin graft, or a fenestrated full-thickness skin graft, with good rates of successful healing. The application of a negative pressure dressing to the wound seems to facilitate the healing of all types of skin graft. The subfascial donor site, however, remains more prone to complications. It may be helpful to position the donor site of the flap more proximally, but this has not been proven. These refinements probably produce the best outcomes that can currently be achieved, given the inherent flaws of the radial donor site.

Keywords: Radial flap; Morbidity; Donor site; Fasciocutaneous; Septocutaneous; Skin graft; Negative pressure wound dressing

Introduction

It is now nearly 30 years since the original description of the radial free flap.[1] This versatile and reliable flap[2,3] soon replaced the bulky, pedicled, pectoralis major flap[4–6] as the reconstruction flap of choice for thin defects of the oral cavity and head and neck region. Although osteocutaneous flaps have largely been superseded, the pre-eminence of the soft-tissue radial flap has been challenged with only limited success by other flaps that offer potentially less donor site morbidity such as the fasciocutaneous ulnar flap,[7,8] the cutaneous lateral arm flap,[9–13] and (most recently) the anterolateral thigh perforator flap.[14,15] These developments reflect the increasing success and sophistication of techniques of free tissue transfer that are being driven by a desire to improve the versatility of flap design while minimising morbidity at the donor site.[15,16]

During this period the incidence of complications at the donor site of the radial flap has remained high, but techniques have been developed to ameliorate the shortcomings of both the soft and hard tissue donor sites.[17] In this paper I consider whether the radial soft-tissue flap is now in inexorable decline, or whether is it evolving to meet these new challenges.

The radial soft-tissue flap: a fasciocutaneous and septocutaneous flap

The radial soft-tissue flap is still probably most commonly raised as a non-sensate fasciocutaneous flap using the conventional subfascial dissection technique.[3,6,18,19] However, it may also be raised as a septocutaneous flap by using a suprafascial dissection technique[20–23] with reinnervation if

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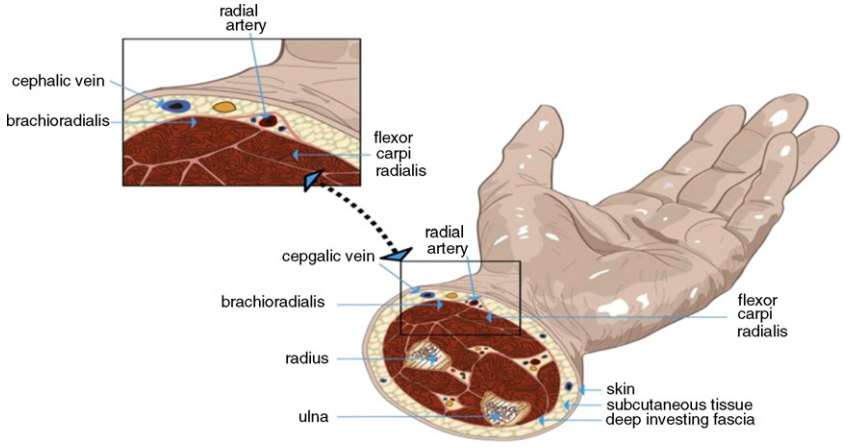

Fig. 1. The radial artery in the distal forearm is enveloped within a tunnel of investing fascia.[23]

necessary,[24] although there will be a variable degree of spontaneous sensory recovery.[25] It is not generally appreciated that the distal radial artery together with the skin paddle may safely be separated from the underlying deep fascia, which has a minor, although undefined, role in perfusion of the flap.[26] Perforating vessels pass through the deep fascia to form subfascial, intrafascial, and suprafascial plexuses. The fascia provides a degree of additional protection to the distal pedicle and integrity to the flap.[26–29] The blood supply to the skin of the forearm is primarily from the extensive subcutaneous vascular plexuses that lie superficial to the deep investing fascia[26–28,30] and perforating septocutaneous vessels.[31]

In the distal forearm the layers of deep fascia between the brachioradialis and flexor carpi radialis tendons form an investing septum around the radial artery (Fig. 1), which may be divided to raise the flap in a suprafascial plane and leave the fascia over the flexor tendons intact (Figs. 2–5).[20,22,23] This meets the criteria used to define a septocutaneous perforator flap, as the vessels pierce the superior layer of deep fascia before traversing only a septum to supply the skin.[32,33] This interpretation may depend on whether it is considered a specific septum that has been dissected, and there is an ongoing debate as to the most appropriate classification system for perforator flaps.[15] The reliability of the septocutaneous radial flap is comparable to the fasciocutaneous version of the flap,[18,19,21,34–39] with reported flap success rates of 96–100%.[21–24,40]

The radial free flap remains a reliable and versatile method of reconstruction that is suitable for a wide range of defects by incorporating bone, tendon, and neural and adipofascial components.[41] Several refinements of its design have been described to manipulate the shape and volume of the soft-tissue components of the flap, and improve functional outcomes. These modifications are of varying merit and complexity, and include the bilobed,[42] longitudinal,[43] omega,[44] and rectangular template[45] techniques. Additional subcutaneous tissue may safely be included beyond the skin paddle, such as in the beavertail technique,[46] but the volume of the flap is not always ideal, as the thickness of the skin paddle remains relatively fixed (Fig. 6).

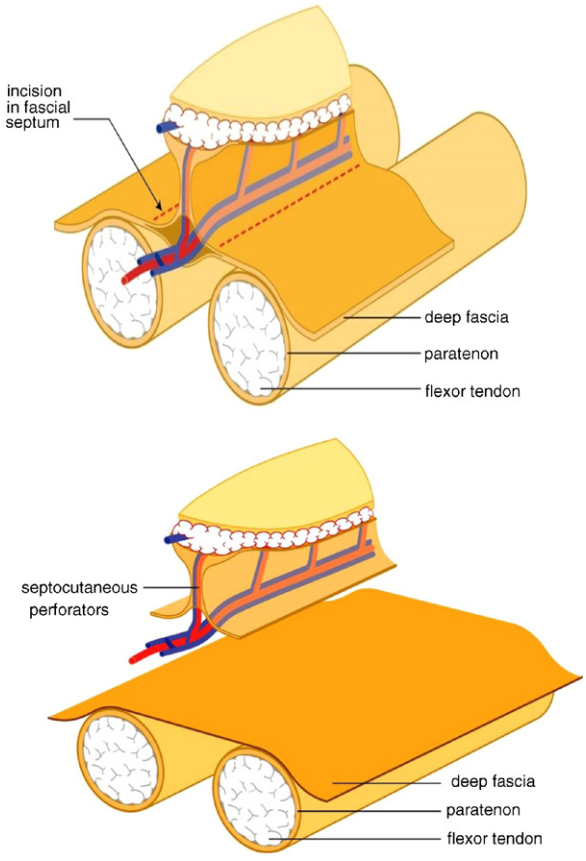

Fig. 2. Division of the medial and lateral aspects of the fascial envelope to lift the pedicle and flap off the underlying deep fascia. The height of the perforating septocutaneous vessels is exaggerated.[22,23]

Morbidity at the radial soft-tissue donor site

Although the long-term morbidity at the subfascial radial donor site is often relatively minor,[18,47] and of secondary

Table 1
Morbidity at the radial soft-tissue donor site.

	Subfascial donor site		Suprafascial donor site	
	Bardsley 1990[34]	Richardson 1997[18]	Lutz 1999[21]	Avery 2007[23]
Type of study	Retrospective	Prospective	Prospective	Prospective
No. of donor sites (*n*)	67	86	95	121
Skin graft thickness	Partial	Partial	Mainly Partial	Mainly Full
Skin graft loss (%)	28[a]	16	6	4
Tendon exposure (%)	28[a]	13	0[a]	3
Delayed healing (%)	28[a]	22	5[a]	4

[a] Assumed or estimated.

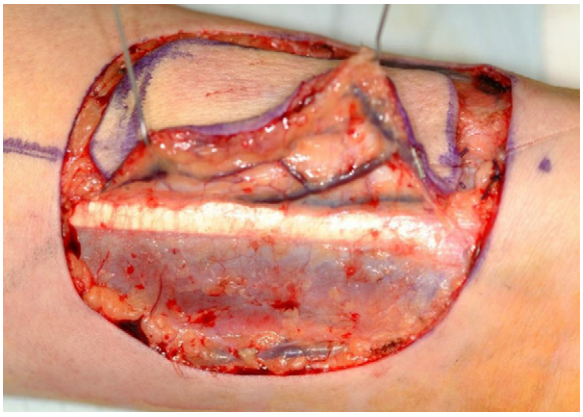

Fig. 3. The suprafascial dissection is at a deep subcutaneous level to minimise disruption of the overlying subcutaneous plexus and just above the inferiorly placed superficial fascial plexus, particularly on the ulna aspect. Dissection continues over the brachioradialis and flexor carpi radialis tendons towards, but not quite as far as, the radial artery.

importance to most oncological patients, prolonged wound healing is an undesirable inconvenience and may lead to appreciable loss of function and a poor aesthetic result.[18] The incidence of the three most widely reported indicators of unsuccessful initial wound healing has remained considerable in the large clinical studies (Table 1). The rate of loss

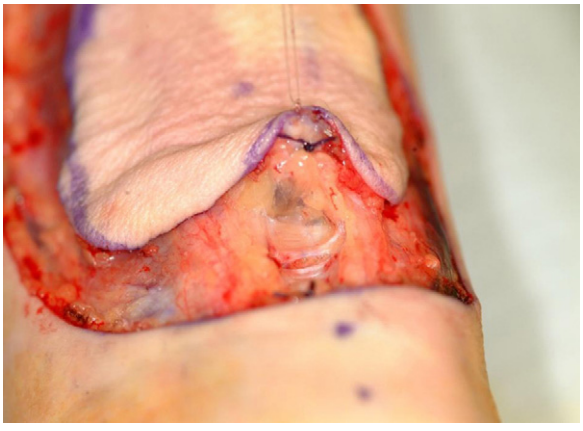

Fig. 4. The distal pedicle is raised to expose the floor of the fascial envelope between the flexor tendons. As the dissection proceeds proximally, the fascial floor becomes progressively thinner. There are few vessels passing between the deep fascia and the subcutaneous tissue.

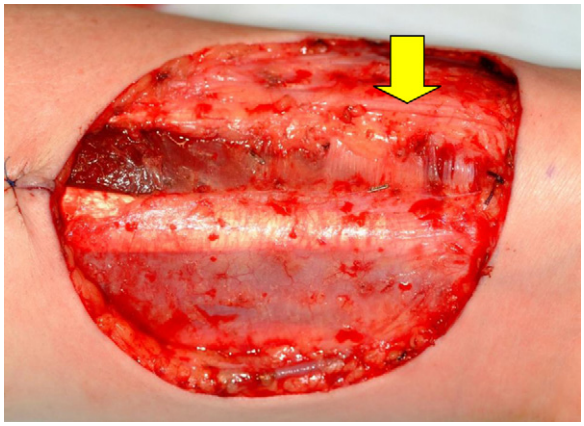

Fig. 5. The suprafascial donor site remains covered with investing fascia and some deep subcutaneous tissue on the radial aspect. The arrow indicates the superficial radial nerve.

of skin grafts in major operative series is as high as 16%[18] to 28%.[34] Two more recent prospective series have claimed improved rates of healing of 91%[37] and 93%,[36] but these findings must be interpreted in the knowledge that the former study excluded loss of less than 25% of the grafted area, and the latter excluded late breakdown of the wound, which is common. Loss of the skin graft often leads to

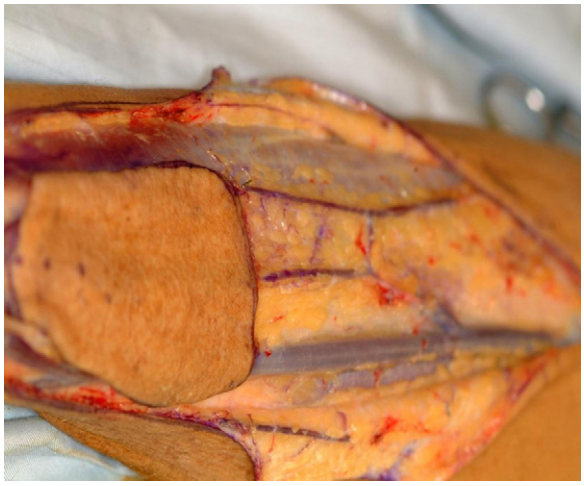

Fig. 6. Additional subcutaneous tissue may be harvested to include more septocutaneous perforating vessels and increase the bulk of the reconstruction.

exposure of the flexor tendons and delayed healing. Sensory loss is common but relatively minor.[48] The scarring and deformity of the forearm may be unsightly but is often well-tolerated,[49,50] although it may be more of a concern with elective reconstructions for benign disorders or among female patients.[51]

Reducing morbidity at the radial soft-tissue donor site

Repair of the donor site defect

The subfascial donor site is commonly managed by oversewing of the flexor tendons with the musculature,[52] and then repair with a partial-thickness skin graft.[18,53,54] This approach is convenient and often thought to heal more readily than a full-thickness graft.[55] Unfortunately the partial-thickness donor site commonly results in discomfort, slow healing, itching, and unsightly scarring. It also requires more changes of dressing than a full-thickness donor site.[36]

To avoid the complications of a donor site for a skin graft, small radial defects may be closed primarily,[56] and medium-sized defects may be managed with an ulnar flap,[57] Z-plasty,[58] bilobed flap,[59] or V-Y advancement flap,[60–62] but these techniques may further distort the sensitivity and appearance of the forearm.[34,57] Alternatively, the defect may be repaired with an acellular human dermal matrix, but healing is prolonged.[63,64] Artificial dermis in combination with a partial-thickness skin graft has been advocated at both the subfascial[65] and suprafascial[39] donor sites, but with little apparent benefit.

Most radial defects may be repaired with a full-thickness skin graft, and the donor wound closed primarily with minimal morbidity.[50] Large defects may be reduced in size with a purse-string,[19,37] or cross-suturing technique,[66] meaning that only the largest defects should require closure with a partial-thickness graft. Excellent results have been achieved with full-thickness grafts in small retrospective studies,[49,67,68] and in larger prospective studies of lower abdominal[36] and inner upper arm[50] donor sites. Full-thickness grafts heal with less contraction[23] and seem to provide a better functional and aesthetic outcome[50,61,67,68] than partial-thickness grafts, but this has been disputed.[36,69] A recent prospective randomised study reported a superior initial functional and aesthetic outcome after repair of the suprafascial donor site with an unmeshed, partial-thickness skin graft compared with repair of the subfascial donor site with a meshed, partial-thickness graft, but a subgroup of full-thickness grafts was not included.[70]

The suprafascial donor site

Detailed prospective operative series that have studied wound healing at the suprafascial donor site[21,23] have supported the hypothesis that this donor site provides a more suitable skin graft recipient site than the subfascial site. The fascia and residual soft tissue on the radial aspect are vascularised, and the skin graft is protected from the movement of the underlying tendons. The incidence of graft loss is relatively low with either partial-thickness (6%),[21] or full-thickness (4%),[23] grafts. The donor site also seems to be more resistant to exposure of the flexor tendons and delayed healing (Table 1).[21,23,71] In the only prospective randomised study, to my knowledge, in which morbidity at the suprafascial and subfascial donor sites was compared, the overall incidence of exposed tendons at the suprafascial site (3%, 1/30) was significantly lower than at the subfascial site (21%, 6/28).[70] The incidence of exposed tendons in the subfascial subgroup that was managed with a meshed partial-thickness graft was highest (33%, 5/15), but analysis of subgroups with relatively small numbers should be interpreted with caution.

Type of wound dressing

The type of wound dressing is an important but unquantified factor in healing. The negative pressure wound dressing has yielded excellent rates of graft healing at both the subfascial and suprafascial donor sites with either partial or full-thickness skin grafts,[23,53,72,73] and superior results in a small retrospective comparison with the conventional bolster technique.[74] The negative pressure dressing closely adapts the skin graft to the recipient site, minimises movement, and eliminates dead space. It is not necessary to extend the negative pressure dressing over the hand, and the wrist may be mobilised immediately.[22] The dressing may expedite early revascularisation and healing of skin grafts,[75–77] although not all studies have supported these findings.[78] At the radial donor site the dressing has also been used to stimulate healing by secondary intention over exposed flexor tendons[53] and facilitate early re-grafting after loss of a graft as a result of infection.[71]

Additional methods of harvesting radial flaps

To avoid exposure of the distal flexor tendons, the radial flap has been harvested with a shortened pedicle from the midforearm and successfully used for oral reconstruction; however, the incidence of complications at the donor site was not reported.[19] To achieve primary closure of the skin at the donor site an adipofascial flap may be harvested through linear,[79] T-shaped,[80] or multiple[81] small incisions, but the flap may heal with fibrosis and dimensional changes.[80] Alternatively the forearm skin may be expanded,[82,83] or the distal fascia prelaminated with a partial-thickness skin,[84] or mucosal[85–87] graft, although this may also reduce the pliability of the flap.[86] These latter techniques introduce a delay, but occasionally have a role in elective reconstructions,[88,89] or when radiotherapy and chemotherapy are the initial oncological treatments.[85,86,88]

Alternatives to the radial flap

Many factors influence the choice of most appropriate reconstruction for an individual patient and defect. Occasionally a local flap,[90,91] or a pedicled flap, usually the pectoralis major flap,[4,92–94] provides a credible alternative to free tissue transfer. This may be because free tissue transfer techniques are either unavailable, not possible, or there is a higher risk of failure after an unsuccessful previous free flap, and the local vasculature and wound conditions have been compromised[95]; even then a further free flap may still be considered appropriate.[96]

Reconstruction with a free flap is usually the preferred option, and an ideal alternative should have a high rate of predictably successful harvest and revascularisation, permit synchronous two-team operating, improve the qualities of the skin or other components, have a long vascular pedicle with a large calibre, be capable of reinnervation if required,[24,97] and cause minimal functional and aesthetic morbidity at the donor site. The ulnar[7,8,98,99] and lateral[9–13] arm flaps may substitute for the radial flap in the oral cavity with a comparable functional outcome, and also offer advantages such as variable skin thickness, relative lack of hair, and potentially less donor site morbidity. However, these flaps have not replaced the radial flap in most surgical units, probably because the potential benefits are considered inconsequential or relatively minor and there may be a perception that the anatomy is unfamiliar, harvesting is technically more difficult, availability of tissue is limited, there is potential for nerve injury, and the pedicle may be shorter or of smaller calibre.

The anterolateral thigh perforator flap is the latest credible alternative that is achieving popularity. Although initially described at a similar time as the radial flap it has only recently been advocated as the reconstruction of choice in reports of patients of far-eastern or asian origin.[14,100–104] The success rate is similar to that of the radial flap, and concerns about the variability of the perforating vessels have lessened, with unsuitable vessels present in less than 5% of flaps.[103,105,106] However, the anatomy of the perforating vessels is not constant and the profunda femoris and lateral circumflex femoral artery may also be affected by peripheral vascular disease, which is uncommon with the radial flap.[107,108] The surgeon therefore needs to be prepared to modify the dissection, occasionally to convert to an anteromedial thigh flap, change to the other limb, or select another donor site.[109] The advantages of the anterolateral thigh flap include the large and flexible size of the often relatively hairless tissue paddle or paddles in the eastern or asian population, together with a vascular pedicle that is comparable in length and calibre to the radial pedicle,[15] although less robust.[110] Like the radial flap it may also be reinnervated, although the functional benefits are controversial. Appreciable advantages are that the donor site may usually be closed primarily with a hidden scar,[111] and no major vessel is lost. The sensory and functional morbidity can become appreciable if a considerable amount of the vastus lateralis is removed or repair with a skin graft is necessary.[112] In a western population the flap is often thicker, particularly in women; less pliable and more hairy in men; but it has successfully been used for oral reconstruction.[113] Primary thinning of the flap is challenging[114,115] and a secondary procedure is probably more appropriate unless the surgeon is experienced.[116,117] This may be a serious disadvantage when superficial oral defects are being repaired, although initial comparative studies with the radial flap have shown no significant differences in functional outcomes.[118,119] The anterolateral thigh flap, therefore, does not currently possess all of the qualities necessary to render the radial flap obsolete, and the role for this flap will become more defined with experience and refinements in harvesting techniques. It should play a complementary part as the "big brother" of the radial flap.[120] It may be more suitable for defects after hemiglossectomy and subtotal glossectomy, tubed oropharyngeal reconstructions, and larger, more complex oral and facial defects when the versatility of the design of the flap and inclusion of a muscular component with variable volume of tissue are important.[101,121,122]

The anterolateral thigh flap is less appropriate for partial glossectomy or superficial defects of the floor of mouth and buccal mucosa for which the radial flap is usually the reconstruction of choice. It should be considered, together with other options, when the radial skin is particularly thin or the wrist especially narrow and harvest of a large flap would cause significant aesthetic or functional morbidity or when the vascularity of the flap or hand is compromised. Finally, it may be a matter of preference to the patient when, the quality of the donor site defect is also of paramount importance for functional or aesthetic reasons.

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Prospective study of the septocutaneous radial free flap and suprafascial donor site

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Abstract

This is a prospective study of 121 consecutive radial septocutaneous flaps harvested by one surgeon. There were 117 successful flaps (97%). The incidence of early return to theatre for potential problems with the flap or the neck wound was 12/121 (10%) and the flap salvage rate was 3/7 (43%). The incidence of three early wound healing complications at the suprafascial donor site were: loss of the skin graft (4%), tendon exposure (3%) and delayed healing (4%). A full-thickness skin graft, usually from the inner upper arm, was used to repair three-quarters of donor site defects. The median time to healing was significantly longer for partial thickness grafts (14 days compared with 10 days, $p < 0.001$). The degree of contraction of the skin graft used to repair the radial defect was significantly less for full thickness than partial thickness grafts (median −21% compared with −33%, $p = 0.01$). There was more relative contraction with larger grafts ($p < 0.001$) and in older patients ($p = 0.01$).

The septocutaneous radial flap is reliable. The early morbidity at the suprafascial donor site is relatively low in comparison to that reported at the subfascial donor site.

Keywords: Free flap; Radial forearm; Suprafascial; Septocutaneous; Donor site; Skin graft; Morbidity

Introduction

The radial flap is commonly raised in the subfascial plane as a fasciocutaneous flap. It was classified by Cormack and Lamberty[1] as a Type C flap with several fasciocutaneous vessels that pass along the intermuscular fascial septae to form a deep fascial plexus that perfuses the skin. However, in the original description by Yang and co-workers[2] in 1981 it was described as a "reticulovascular" flap. Timmons[3] subsequently noted that the major vessels and anastomoses between the cutaneous perforating vessels all lay superficial to the deep investing fascia. The fascial plexuses seemed to have a limited role in perfusion of the flap, but the fascia may protect the vascular pedicle during harvest.[3,4] This was supported by observations that the blood supply to the skin of the forearm is primarily from the subcutaneous plexuses.[4,5]

In 1996 Chang et al.[6] described a conjoining of the two layers of deep fascia between the distal brachioradialis and flexor carpi radialis tendons to form an investing septum around the radial artery (Fig. 1), which may be divided either side of the pedicle to allow the flap to be raised in a suprafascial plane and leave the fascia of the forearm over the flexor tendons intact (Figs. 2 and 3).[7,8] Here I describe the largest published prospective series, to my knowledge, by a single surgeon using this dissection technique. My aim was to study the septocutaneous flap and three early outcome measures at the suprafascial donor site: loss of the skin graft, exposure of the flexor tendons and delayed healing.

Methods

Technique of suprafascial dissection

The technique is slightly more demanding than the conventional subfascial approach. All flaps were raised under a

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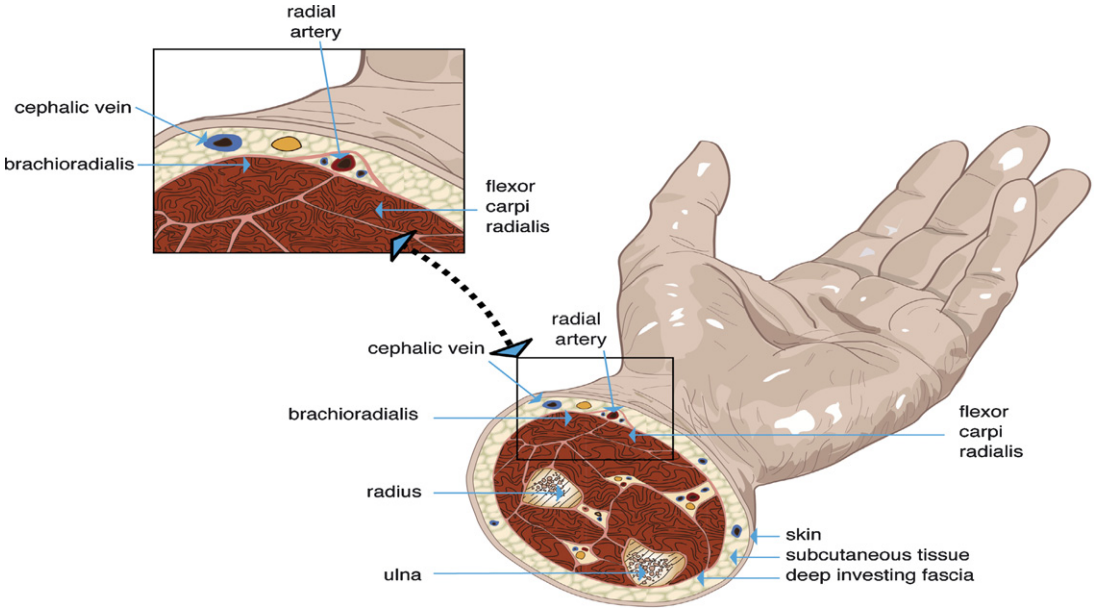

Fig. 1. In the distal forearm the radial artery is enveloped within a tunnel of investing fascia.

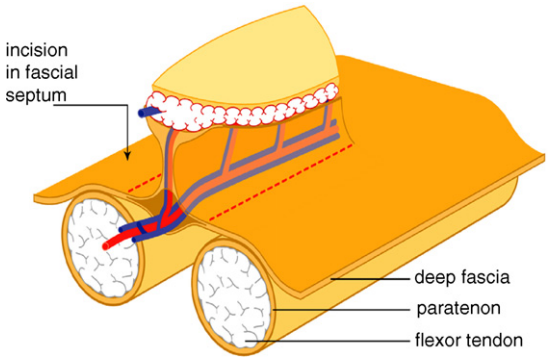

Fig. 2. Division of the lateral aspect of the fascial envelope. The height of the perforating septocutaneous vessels is exaggerated (based on Avery et al.[8]).

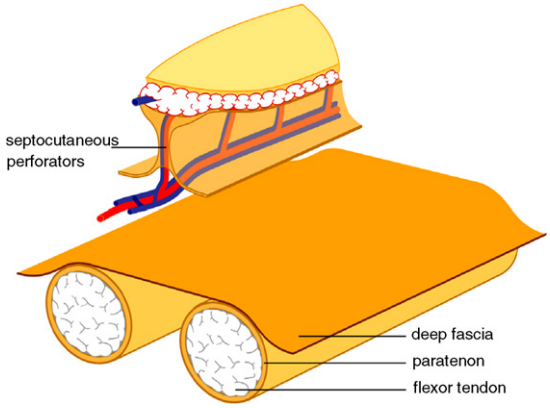

Fig. 3. Preservation of the deep layer of the fascia (based on Avery et al.[8]).

brachial tourniquet using binocular loupes. The dissection is at a deep subcutaneous level to minimise disruption of the overlying subcutaneous plexus and inferiorly placed superficial fascial plexus, particularly on the ulna aspect. Dissection continues over the brachioradialis and flexor carpi radialis tendons towards, but not as far as, the radial artery (Fig. 4). The radial artery and venae comitantes are then divided distally and the pedicle sutured to the skin. The distal pedicle is raised to expose the floor of the fascial envelope between the flexor tendons (Fig. 5). The medial and lateral aspects of the fascial envelope are incised. As the dissection proceeds proximally the fascial floor becomes progressively thinner, and it may be difficult to remain entirely above the fascia but this is not important over the musculature. Perforating vessels to the periosteum and muscles are ligated (Fig. 6). The superficial radial nerve and thenar cutaneous branch of the lateral antecubital nerve are identified within the subcutaneous tissues, and dissection along these structures is the correct plane on

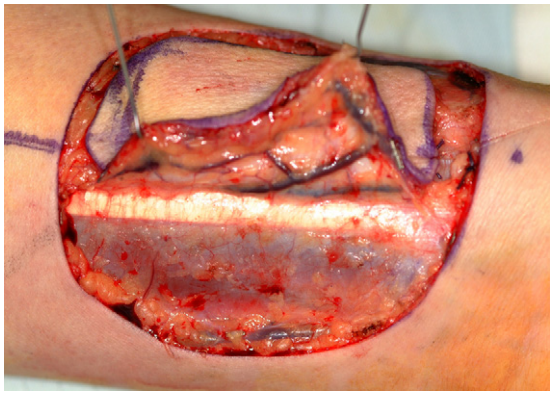

Fig. 4. Suprafascial dissection below the subcutaneous plexus.

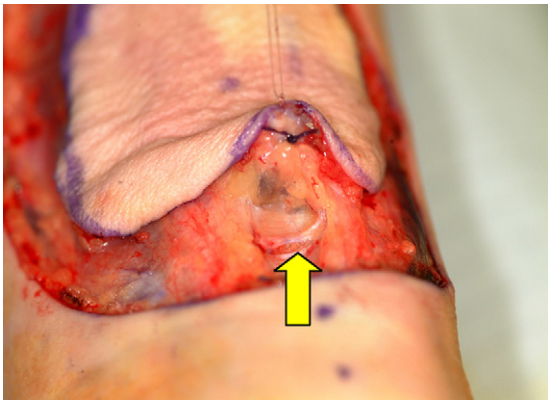

Fig. 5. Pedicle raised from the floor of the fascial envelope.

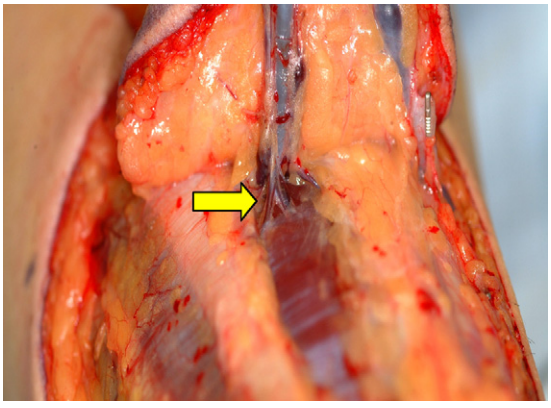

Fig. 6. Deep perforating vessels.

the radial aspect. The investing fascia of the forearm is incised as the pedicle passes within the lateral intermuscular septum and the proximal dissection is completed in the conventional manner. The donor site remains covered with investing fascia and some deep subcutaneous tissue on the radial aspect (Figs. 7 and 8). The radial pedicle is intimately related to the subcutaneous tissues (Fig. 9). A dressing that applied a constant subatmospheric pressure was placed at between −75 to −125 mmHg (VAC system, KCI Medical Ltd., England).

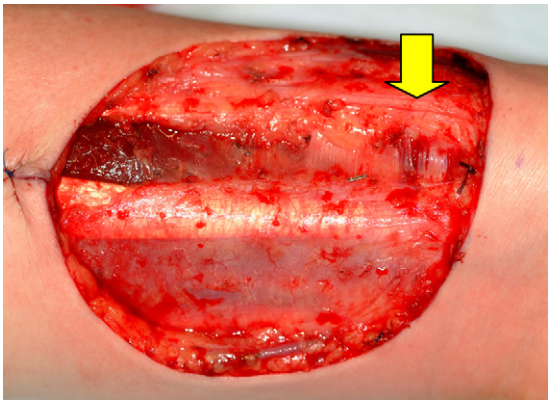

Fig. 7. The suprafascial donor site. Arrow indicates the superficial radial nerve.

Fig. 8. Vascularised deep fascia covering the paratenon of the flexor tendons.

Data

The following data were recorded prospectively for each patient: age, sex, donor arm, ischaemic time, healing of the donor site, and wound complications. Osteocutaneous sites were excluded. A full thickness skin graft was applied whenever possible. The size of the donor site defect with the skin graft in place was recorded using a template technique at the time of operation. The template was transferred to 1 mm graph paper and the area (cm^2) calculated.

The dressing was initially removed on the fifth postoperative day but this was soon changed to the 10th day, although the negative pressure was still discontinued by the fifth day. The area of healing graft was recorded after removal of the dressing, and at day 30 and later if healing was delayed. Healing of the graft was defined as the time to when a dry dressing was sufficient, and healing that took more than 30 days was considered delayed. The area of the graft was measured again at a minimum of 4 months to assess late contraction of the graft.

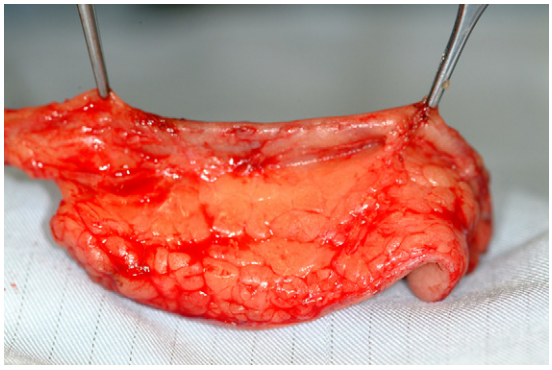

Fig. 9. The vascular pedicle intimately related to the subcutaneous tissues.

Table 1
Septocutaneous flaps and donor sites

No of patients	120
No of operations	121
Mean (SD) age (years)	57 (14)
Male:female ratio	77:43
Median (range) follow-up (months) ($n = 84$)	16 (1–49)
Left:right arm	110:11
Dominant arm	4
Median (range) ischaemic time (min)	65 (35–95)

Data are number of observations unless otherwise stated.

Statistical analysis

The groups who had full and partial thickness skin grafts were compared using the Mann–Whitney *U* test for time to healing, duration of follow-up, size of skin graft, and percentage of late contraction. Spearman's correlation coefficient (r) was used to measure the association between the extent of the late contraction and the length of follow-up, age, and size of graft. The Wilcoxon signed rank test was used to compare the percentage of skin graft that healed between days 10 and 30.

Results

Patients

One hundred and twenty consecutive patients were studied between March 1999 and January 2006 (Table 1). The initial 21 patients could not be reviewed after 1 month. Five patients (4%) died within 30 days of operation.

Septocutaneous flaps

A total of 121 flaps were used to reconstruct oral or facial defects ($n = 113$) and limbs (Table 2). Four flaps failed completely, there were no partial failures. Some flaps suffered transient desquamation. The flap success rate was 97%. Two flaps failed to perfuse and one of these patients had previously received radiotherapy. Two flaps failed because of venous thromboses on days 2 and 12.

Table 2
Healing of full and partial thickness skin grafts

Healing of grafts	Day	
	10 ($n = 119$)	30 ($n = 116$)
No (%) that had healed completely	109 (92)	111 (96)
Mean (SD) percentage area of full and partial thickness grafts that had healed	98 (13)	98 (11)
Mean (SD) percentage area of full thickness grafts that had healed	98 (11)	98 (13)
Mean (SD) percentage area of partial thickness grafts that had healed	95 (20)	100 (2)

Figures have been rounded to nearest percentage point.

The incidence of early return to theatre for potential problems with the flap or the neck wound was 12/121 (10%) and the flap salvage rate was 3/7 (43%). Two thrombosed venous pedicles were salvaged on days 1 and 2, and one bleeding artery was repaired on day 3. Two flaps remained viable despite unsalvageable early thromboses of the pedicle. Three cervical haematomas were drained. Two oral fistulas healed spontaneously, and a fistula of the soft palate required secondary closure.

Suprafascial donor sites

Most donor sites were repaired with a fenestrated full thickness graft (93/120, 78%), mainly from the inner upper arm, or a meshed partial thickness graft (27/120, 22%). At one site both types of graft were used because of an error in assessment, and this site is excluded.

A total of 109/119 skin grafts had healed completely by day 10 (92%) and by day 30 it was 111/116 (96%) (Table 2). There was no significant difference between the full and partial thickness grafts at either time. The median time to healing was significantly longer for partial thickness grafts (14 compared with 10 days, $p < 0.001$).

Some skin was lost at 11% (13/116) of donor sites at some stage during the healing period. Loss was usually incomplete (11/13) and minor, ranging from 5 to 65% of the grafted area. Methicillin-resistant *Staphylococcus aureus* was isolated from six sites. A single tendon was exposed at 3/116 sites (3%) and one tendon was excised. Significant graft loss was managed with a subatmospheric pressure dressing to encourage the early formation of granulation tissue and re-epithelialisation. Six sites were regrafted, of which four healed within 30 days. Healing was delayed beyond 30 days at 5/116 sites (4%).

Size and contraction of the skin graft

The overall median size of the skin grafts was 38 cm^2 (range 11–126). As expected the partial thickness grafts were significantly larger than the full thickness ones ($p = 0.001$). Eighty-two patients were available for assessment of late contraction of the graft. The overall median percentage skin graft contraction, after a minimum of 4 months was −26% (range −75 to +13). There was more relative contraction the larger the area of the graft ($r = 0.42$, $p < 0.001$), and the older the patient ($r = 0.29$, $p = 0.01$), but less association with the duration of follow-up ($r = 0.16$, $p = 0.17$). Men's grafts contracted slightly less than women's (median −22% compared with −30%, $p = 0.02$). Full thickness grafts contracted less significantly than partial thickness ones ($p = 0.01$) (Table 3).

Discussion

The success rate of the septocutaneous radial flap in this series is comparable with reports of the technique from the Chang

Table 3
Size of skin graft and late contraction of grafts

	Thickness of graft	
	Full	Partial
Early graft (*n*)	94	27
Median days to healing (range)	10 (5–49)	14 (10–35)
Median size of graft (cm^2)	35 (11–96)	72 (36–126)
Late contraction (minimum 4 months) (*n*)	64	18
Median duration of follow-up (range)	15 (4–49)	19 (4–36)
Median percentage contraction (range)	−21 (−75 to +13)	−33 (−66 to −15)

Gung Memorial Hospital, Taipei, Taiwan (96.8–100%).[7,9,10] A review of 3361 different free flaps done for various indications from the same hospital reported a success rate of 97%.[11] Many of the larger series of fasciocutaneous radial flaps have not stated success rates,[12–15] but retrospective reports have described rates of 92.5%,[16] 96.6% (excluding partial failures),[17] 96.7%,[18] and 98%.[19] A success rate of 95% has become a benchmark figure. The incidence of exploration and salvage of flaps in this series is comparable with those reported.[9,11,18–20]

The only vessels between the deep investing fascia and the flap were perforating muscular and periosteal vessels beneath the pedicle, and a few fasciocutaneous vessels from the fascia. This is consistent with the hypothesis that the fascia has a minor role in perfusion of the flap. The increasing popularity of perforator flaps has led to a review of flap terminology. A septocutaneous perforator flap is currently defined as having vessels that pierce the outer layer of deep fascia before traversing only a septum to supply the skin.[21] A radial flap raised in the suprafascial plane may fit within this definition but if a septum is present it must be short. The septum has been exaggerated in Figs. 2 and 3.

The conventional technique of subfascial dissection is associated with an appreciable incidence of early complications at the donor site (Table 4).[12,13] The incidence of skin graft loss may be as high as 28%[12] and 16%.[13] Two recent prospective series have claimed improved rates of healing 93.4%[14] and 91% using a purse-string closure,[15] but these reports excluded late breakdown of the wound or loss of less than 25% of the grafted area, respectively. At the suprafascial donor site Lutz et al.[7] reported complete healing of 94% of grafts, which were mainly partial thickness. Although partial thickness grafts are thought to heal more readily than full thickness grafts there was no difference in the extent of healing in this study, and the median time to healing was actually shorter for full thickness grafts. Partial thickness grafts also require more changes of dressings.[14] I therefore prefer to use a full thickness graft from the inner upper arm whenever possible, where there is excellent healing of the donor site.[22] Lutz et al.[7] lost several full thickness grafts because of haematoma formation, but the subatmospheric pressure wound dressing may avoid this problem, and have an undefined beneficial effect on wound healing.[8]

Exposure of a tendon has not previously been reported at the suprafascial donor site.[6,7] The incidence of 3% in the present series is lower than at the subfascial site, which is typically 28%[12] or 13%.[13] The suprafascial donor site seems to be resistant to tendon exposure,[23] which is a major cause of delayed healing.[12,13] Delayed healing is not unusual at the subfascial donor site, where it has been reported as 28%[12] and 22%.[13] The incidence of delayed healing in the present study of 4% is similar to that reported by Lutz et al.[7] (Table 4). Recent studies have not specified the incidence of these complications.[14,15,24] Smith et al.[17] sited the flap more proximally to avoid exposure of the flexor tendons, but this shortens the pedicle and the flap may be bulkier with fewer perforating vessels.

The contraction of the full thickness grafts (median −21%, range −75% to +13%) was significantly less than partial thickness grafts (median −33%, range −66% to −15%) at the suprafascial donor site. In the only other study of graft contraction, at subfascial donor sites managed with partial thickness grafts, Moazzam and Gordon[25] reported a mean contraction rate after purse-string closure of −65%, which was significantly more than that of −38% after conventional closure. There was a relatively low incidence of skin graft loss and tendon exposure in this small series.

This prospective study has shown that the septocutaneous radial flap is reliable. The incidence of three early complica-

Table 4
Morbidity at the radial donor site

	Subfascial donor site		Suprafascial donor site	
	Bardsley (1990)	Richardson (1997)	Lutz (1999)	Avery (2007)
Type of study	Retrospective	Prospective	Prospective	Prospective
No. of donor sites	67	86	95	121
Type of skin graft	Partial thickness	Partial thickness	Partial and full thickness	Full and partial thickness
Loss of skin graft (%)	28[a]	16	6	4[b]
Exposure of tendon (%)	28[a]	13	0[a]	3
Delayed healing (%)	28[a]	22	5[a]	4

Figures have been rounded to nearest percentage point.
[a] Assumed or estimated.
[b] At day 30.

tions at the suprafascial donor site was less than that reported at the subfascial site. However, direct comparison with other papers is constrained by uncontrolled factors and the different methods of collection and presentation of data. A comparative study would be useful.

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Comparison of sensory recovery at the subfascial and suprafascial donor sites of the free radial flap

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Abstract

The radial flap may be raised using a subfascial or suprafascial approach. The latter donor site is associated with fewer healing complications. We retrospectively evaluated the quality of sensory recovery within two comparable groups of 30 patients with subfascial and suprafascial donor sites. When considering the two groups, two-point discrimination was the modality most commonly reduced, with 97% of patients in both groups having reduced sensation in at least one anatomical zone. Sensation of sharp touch was most often lost; 90% in the subfascial and 83% in the suprafascial groups lost sensation in at least one anatomical zone. Roughly half the patients had reduced perception of light touch (43% and 50%), whilst perception of heat (27% and 17%) and cold (33% and 27%) were lost least often. At least one modality in at least one anatomical zone was lost or reduced in all patients, and roughly two-thirds (73% and 63%) had a reduction in 3 or more. The only significant difference between the donor and non-donor arms was reduced perception of sharp touch in the anterior forearm in both groups ($p < 0.001$). Perception at the two sites (including the anatomical snuff box) was similar except for superior thenar palmar light touch ($p = 0.015$) in the suprafascial group, which may indicate injury to the thenar cutaneous sensory branches during subfascial dissection.

Keywords: Radial flap; Morbidity; Donor site; Sensation

Introduction

Defects of the oral cavity are most commonly reconstructed using the fasciocutaneous radial flap.[1] Wound healing complications at the subfascial donor site have been widely reported and often include loss of the skin graft, exposure of tendons, and delayed healing,[1–3] but the incidence and pattern of sensory changes have been studied less well. Sensory loss is variable and typically occurs at between a half to three-quarters of fasciocutaneous donor sites.[4]

The radial flap may also be raised as a septocutaneous flap by using the suprafascial dissection technique which retains the fascial covering over the flexor tendons. The incidence of wound complications at the suprafascial donor site was lower than at the subfascial site in several large operative series[1,5–7] and in one relatively small comparative study.[8]

The superficial branch of the radial nerve lies just above the fascia (Fig. 1) and suprafascial dissection proceeds along the superior aspect of the nerve. The branch is readily identified and requires minimal mobilisation, but it is not known whether this results in improved sensory recovery. To our knowledge, sensory recovery at the suprafascial donor site has not previously been studied objectively, and this report is the first to compare the extent of sensory recovery at subfascial and suprafascial donor sites.

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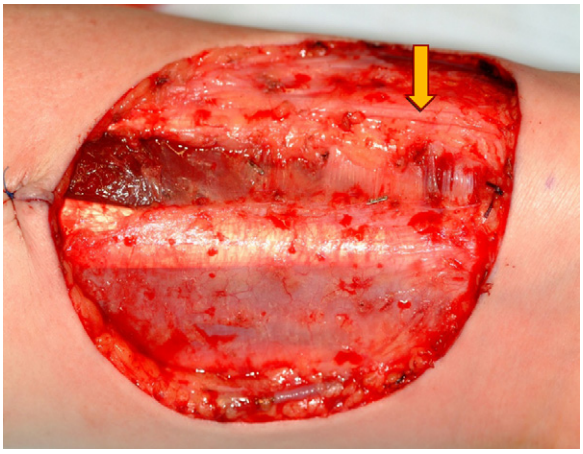

Fig. 1. Suprafascial radial donor site covered by investing fascia. In the suprafascial dissection the sensory branches of the superficial branch of the radial nerve (arrow) usually remain within the subcutaneous tissue and do not require formal mobilisation.

Method

Patients who had undergone harvest of a non-sensate radial free flap and who had been followed up for over one year were recruited at the time of clinical review. Ethical approval and appropriate informed consent were obtained. Data collected included demographic details, type of radial flap, size and type of skin graft; and wound complications such as loss of graft, exposure of tendons, and healing delayed beyond 30 days. Full thickness grafts were primarily harvested from the inner upper arm,[9] and partial thickness grafts were harvested from the proximal ipsilateral forearm or outer upper arm.

Assessment of sensory recovery

The forearm and hand were subdivided into anatomical zones based on the Touch-Test (North Coast Medical, Inc. CA, USA) sensory evaluator mapping system. Sensation of the skin graft at the donor site was also assessed. Patients closed their eyes during testing. The stimulus was applied up to three times and a single response was positive; the most sensitive value was recorded. To minimise false responses a test stimulus was not always done.

Light touch

Light touch was tested using Semmes-Weinstein monofilaments. A single response was positive for monofilament sizes 1.65–4.08 (0.008–1.0 gf). A single stimulus was applied for sizes 4.17–6.65 (1.4–300 gf). The force levels were correlated to clinical sensory thresholds (Table 1).

Table 1
Sensory evaluation score and clinical threshold.

Score	Target force (g)	Clinical sensory threshold
1	0.008–0.07	Normal
2	0.16–0.4	Diminished light touch
3	0.6–2	Diminished protective sensation
4	4–180	Loss of protective sensation
5	300	Deep pressure sensation only
6	–	Tested with no response

Sharp touch

Sharp sensation was assessed using a blunted 27-gauge dental needle without breaching the skin if possible.

Temperature

Dental mirrors were equilibrated in water at 0–5 °C (cold) or 50–55 °C (warm) and applied for 10 s.

Static two-point discrimination

A Touch-Test discriminator (North Coast Medical, Inc. CA, USA) was used.

Statistical analysis

Baseline variables in population were compared between groups using the chi-square test, Fisher's exact, or Mann Whitney *U* tests as appropriate. For sensory variables, clinical inferiority was deemed present when the donor arm was at least one grade lower than the non-donor arm – for example, the difference between normal touch and diminished light touch. Comparisons between groups for retained and reduced sensation were done using the chi-square or Fisher's exact test, as appropriate.

Results

There were 30 patients in the subfascial and suprafascial donor site groups. Overall median age of patients at the time of operation was 60 years (range 35–79), and the median postoperative follow-up period was 60 months (range 17–91 Table 2). The two groups were comparable in relation to age, sex, and length of follow-up (Table 2), and the number of flaps taken from the non-dominant arm was similar in both groups (subfascial $n = 27$ and suprafascial $n = 29$).

Rates of reduced perception in different sensory tests in the subfascial and suprafascial groups are summarised in Table 3. The incidence of reduced perception of light touch at individual sites in the donor arm relative to the non-donor arm varied from 10% to 43% in the subfascial group and from 20% to 37% in the suprafascial group. Sensitivity was reduced mainly to the level of diminished light touch. There were no significant differences in the incidence of reduced sensation in individual sensory areas of the donor arm between groups,

Table 2
Subfascial and suprafascial radial donor site groups ($n = 30$ in each group).

	Subfascial	Suprafascial	p-value
Male:female ratio	19:11	18:12	0.79
Median (range) age (years)	62.5 (37–79)	59.5 (35–70)	0.56
Median (range) follow-up (months)	50 (17–73)	60 (20–91)	0.16
Soft tissue only flaps	26	28	0.67
Mean (range) area of skin graft (cm^2)	28.1 (12–50)	39.8 (18–96)	0.0004
Delayed healing > 30 days	9	1	0.006

except for thenar palmar light touch, which was superior in the suprafascial group ($p = 0.015$). There was no significant difference in the proportion of patients with maintained perception of light touch at all sites; sensation was maintained in 15 (50%) subfascial and 13 (43%) suprafascial patients.

Perception of sharp touch was significantly diminished in the anterior forearm of the donor arm relative to the non-donor arm in both groups ($p < 0.001$), but not at other sites. The incidence of loss at other individual sites varied from 0% to 27%. There was no significant difference in the proportion of patients who had maintained perception of sharp touch at individual sites or at all sites when the groups were compared. Sensation was maintained at all sites in 3 (10%) patients in the subfascial group and in 5 (17%) in the suprafascial group.

Perception of temperature was the best-preserved sensation, with perception of heat maintained similarly in all anatomical zones of the donor arm in 22 (73%) of the subfascial and 25 (83%) of the suprafascial group when compared with the non-donor arm. Similarly, perception of cold was maintained in all anatomical zones of the donor arm in 20 patients (67%) in the subfascial and 22 (73%) in the suprafascial group when compared with the non-donor arm. In relation to two-point discrimination, perception at individual anatomical sites in the donor arm was retained relative to the non-donor arm in 33%–77% of donor sites but only one patient (3%) in each group had maintained it at all sites.

There were no significant differences in the perception of temperature or two-point discrimination at global or individual sites when the results of the donor arm (relative to the non-donor arm) were compared between groups. There were no significant differences in sensory perception between soft-tissue ($n = 54$) and composite flap ($n = 6$) donor sites. Dysaesthesia was reported at 2 subfascial donor sites and there were no cases of neuroma in either group.

Sensation at the skin graft was very poor. It responded only to deep pressure in the subfascial group but was slightly more sensitive in the suprafascial group at the level of loss of protective sensation ($p = 0.05$). The mean size of the skin graft was largest in the suprafascial group (39.8 cm^2 (range 18–96) compared with 28.1 cm^2 (range 12–50); $p = 0.0004$). Two subfascial donor sites were closed primarily. The incidence of delayed healing was significantly greater in the subfascial than in the suprafascial group (9/30 (30%) compared with 1/30 (3%); $p = 0.006$). Most skin grafts in both groups were full thickness (15/28 (54%) in the subfascial, and 30/30 (100%) in the suprafascial group; $p < 0.0001$).

Discussion

The incidence and pattern of sensory changes after harvest of the radial free flap have not been studied extensively. The incidence of altered sensation varies widely and usually is not classified. Previous reports have noted changes mainly in the sensory field of the superficial branch of the radial nerve, but several sensory nerves may be damaged at various levels within the forearm. In initial studies the incidence of paraesthesia of the nerve typically varied from 17%[3] to 80%.[10–13] In a large study of 100 donor sites, Bardsley et al.[3] reported paraesthesia in 17%, hyperaesthesia in 3%, and neuroma in 2%. The relatively low incidence of complications was attributed to the radial border in the donor site being avoided. In a contemporary personal series of 104 donor sites by Vaughan,[13] the incidence of paraesthesia of the superficial branch of the radial nerve was much higher (80%, with severe dysaesthesia in 3.8%).

The first large prospective study in 1997 by Richardson et al.[2] included 74 patients who were assessed one year after operation. Paraesthesia of the superficial branch of the radial nerve was present in 32%; 5.4% developed a neuroma and 2.7% developed dysaesthesia. In 2001 Toschka et al.[14] retrospectively compared 35 patients with 15 non-surgical controls and included a questionnaire on hand function. There

Table 3
Percentage of patients with reduced or no perception of different sensory modalities (relative to non-donor arm) affecting at least one anatomical zone.

	Subfascial group No (%)	Suprafascial group No (%)	*p*-value
Sensory modalities reduced but not lost			
Light touch	15 (50)	17 (57)	0.61
Two-point discrimination	29 (97)	29 (97)	1.00
Sensory modalities lost			
Sharp touch	27 (90)	25 (83)	0.71
Hot temperature	8 (27)	5 (17)	0.35
Cold temperature	10 (33)	8 (27)	0.57
Loss or reduction in perception of multiple modalities			
Loss or reduction at least one modality	30 (100)	30 (100)	1.00
Loss or reduction in at least three modalities	22 (73)	19 (63)	0.41

was no difference in stereognosis, proprioception, and two-point discrimination of the palm and finger pads. However, 77.1% complained of hypoaesthesia of the forearm, and 8.6% of anaesthesia. A degree of sensory recovery within the skin graft was reported at 12.4% of donor sites. The recent study of 50 subfascial donor sites by Kerawala and Martin[4] provides a more detailed analysis of the pattern of sensory recovery. Although 76% of patients complained of subjective sensory loss, it was identified objectively in only 64%. A variable degree of sensory deficit was common with loss of at least one modality in 64% of patients, and two or more in 50%, whilst roughly 50% had normal sensitivity to sharp touch, light touch, and temperature.

The incidence of sensory changes at the suprafascial donor site has not been well documented. In 1996 Chang et al.[5] noted that it was possible to identify and protect the superficial branch of the radial nerve and the thenar cutaneous branch of the lateral antecubital nerve when using the suprafascial approach. In a series of 49 procedures there was "little or no significant numbness". In 1999 Lutz et al.[6] reported from the same unit on 95 donor sites and noted paraesthesia of the superficial branch of the radial nerve at 54% of sites with dysaesthesia which was "transient and mild".

Most sensory recovery occurs within the first 6 months of operation although further improvement may occur by 24 months or occasionally later.[15,16] Sensory recovery therefore was essentially fully established within both groups in our study as the median length of follow-up was 60 months. The pattern of sensory recovery was variable and there was no significant difference between the two donor sites in perception at global or individual sites for most sensory tests. This might be because nerves may be injured in the proximal part of the forearm regardless of the distal dissection technique employed, or reduced dissection of the superficial branch of the radial nerve may, have no beneficial effect on long-term sensory outcomes.

No patient in our study had complete loss of any sensory modality in any anatomical zone but all patients lost at least one modality in at least one site. Roughly two-thirds of patients had loss or reduction of sensation in three or more modalities. Sharp touch was lost most often (in over 80% of cases), particularly at the anterior forearm site where it was significantly absent in both groups when compared with the non-donor arm. No patient lost sensation of light touch or two-point discrimination completely, but they were reduced in roughly half the patients in the subfascial group and in all patients in the suprafascial group. Perception of temperature was the least affected modality with up to a third of patients affected (Table 3). Therefore, in general, patients may be advised that in the long-term, the majority will have some reduction in two-point discrimination and perception of sharp touch of the anterior forearm in particular, roughly half will have some sensation of light touch reduced, but sensation of temperature will be altered in only a third or fewer. We did not study whether these changes are noticeable to the patient.

Sensitivity to light touch was most commonly reduced to the level of diminished light touch. The only significant difference was in superior thenar palmar light touch in the suprafascial group ($p = 0.015$). We speculated that this might have been because of a greater incidence of injury to the palmar cutaneous branch of the median nerve in the subfascial group. This nerve lies just under the tendons of the flexor pollicis longus and flexor carpi radialis, having originated roughly 4–8 cm proximal to the distal wrist crease,[17,18] and is likely to be at greater risk of damage during subfascial dissection. There is, however, a variable degree of crossover in the sensory distributions of the palmar cutaneous branch of the median nerve, the superficial branch of the radial nerve, and the thenar cutaneous branch of the lateral antecubital nerve in this area. No patients in our study had motor or sensory deficit in a major nerve so it is not clear exactly which thenar branches may have been affected.

Sensation within a skin graft returns through a combination of random regeneration of cutaneous nerves at the subdermal level, and sprouting of adjacent nerves.[16,19] The recovery of sensation in the skin graft used to repair the donor site was generally very poor. Improved sensation of light touch at the suprafascial donor site may be related to the greater use of full thickness skin grafts and the retention of dermal sensory organs, but this is just speculation.

The incidence and pattern of sensory changes are broadly comparable with those reported by Kerawala and Martin[4] but it is noted that they did not detect injury to the median nerve. Light touch was maintained to a similar extent, preservation of sensitivity to sharp touch was somewhat lower, whilst sensitivity to temperature, and two-point discrimination were better preserved. No patient in our study had neuroma or dysaesthesia at the suprafascial donor site, which is consistent with the findings of Lutz et al.[6] However, there is not yet enough evidence to suggest that the incidence of these complications is consistently lower than at the subfascial donor site. We appreciate the limitations of a retrospective study, and comparisons with other papers are difficult because the methodologies and presentation of data are inconsistent.

The septocutaneous radial flap raised with a suprafascial dissection is the preferred version of the radial flap in our department primarily because of the low incidence of complications of initial wound healing, and this is supported by the findings in the current study. Superior palmar light touch at the suprafascial donor site may indicate increased injury to one or more of the thenar cutaneous branches during subfascial dissection. However, our study has failed to show other differences between the two donor sites at other anatomical zones including the anatomical snuff box.

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Short communication

Hairy intraoral flap – an unusual indication for laser epilation: a series of 5 cases and review of the literature

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Abstract

A variety of the flaps used to reconstruct defects of the head and neck region following surgery for malignant disease contain hair follicles that may result in unwanted hair growth. This can cause significant distress to the patients in a variety of ways. We report 5 cases of significant intraoral hair growth of which 4 cases were successfully managed with long-pulsed alexandrite laser. One patient was not treated due to technical difficulties. We review the literature on the management of hair growth on intraoral flaps.

Keywords: Complication; Hair; Laser; Reconstruction; Free flap; Head and neck cancer; Oral cancer

Introduction

A variety of flaps have been used to reconstruct defects of the oral cavity following surgery for malignancy. The radial forearm flap[1] is the most commonly used flap but other free flaps and the pedicled pectoralis major flap typically contain hair bearing tissue. Unwanted hair growth is a therapeutic challenge. The use of laser treatment has rarely been reported in the maxillofacial literature for the management of excessive hair growth on an intra-oral flap. We describe our experience using a long-pulsed alexandrite laser.

Methods and results

A retrospective review of case notes and photographic records of 5 patients with intraoral hairy flap referred to the Birmingham Regional Skin Laser Centre between September 2005 and January 2010. The long-pulsed alexandrite laser (Apogee Elite 755-nm; Cynosure, Chelmsford, MA, USA) was preferred. Xylocaine® 10% spray (lidocaine) was used for topical anaesthesia. The demographics, diagnosis, types of flap, symptomotology and outcome are listed in Table 1. Four cases were successfully managed but access for one case was too restricted (Figs. 1 and 2).

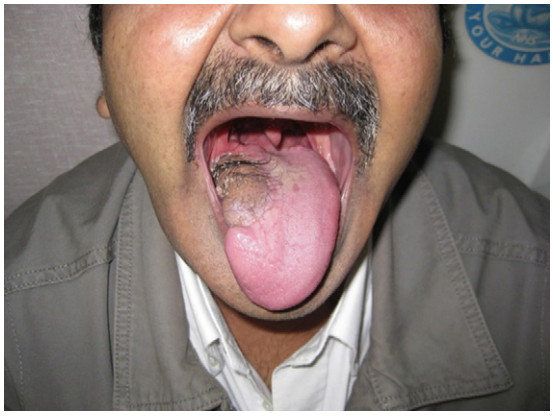

Fig. 1. Patient 1: Hairy intraoral flap before laser treatment.

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Table 1
Summary of case series.

Patient	Age (years), sex, ethnicity	Diagnosis	Types of flap used in reconstruction	Symptoms	Treatment outcome
1.	53, M, Asian	Squamous cell carcinoma (SCC) right tongue	Radial forearm free flap	Difficulty trimming hairs for one year (Fig. 1). Trapped food debris	Significant improvement (Fig. 2)
2.	53, M, Caucasian	SCC left mandibular alveolus	Radial forearm free flap	Distressed by persistent sensation of hairs. Impossible to shave hair with scissors	Significant improvement
3.	25, F, Asian	Myxoma right mandible	Fibula free flap	Bothered by hair growth	Poor visibility of the roots of hairs as the access to floor mouth restricted
4.	64, M, Caucasian	SCC right mandibular alveolus	Radial forearm free flap	Difficulty eating and poor oral hygiene	Partial response
5.	69, M, Asian	SCC left mandible and maxilla	Fibula and radial forearm free flap	Difficulty eating and poor oral hygiene	Not treated microstomia secondary to submucous fibrosis, extensive surgery and radiotherapy

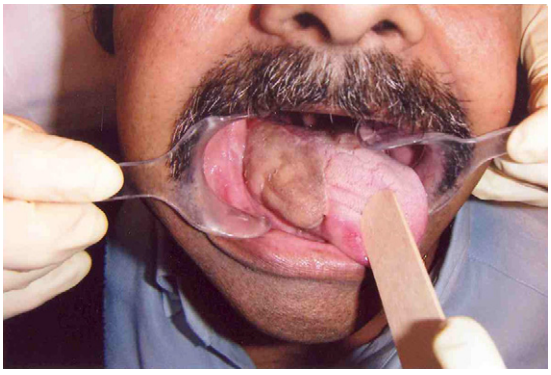

Fig. 2. Patient 1: Significant reduction of hair after laser treatment.

Discussion

A variety of the flaps used to reconstruct defects after surgery for malignancy contain hair follicles that may result in unwanted hair growth. Patients with excessive hair growth may present with irritation, pooling of saliva, trapping of food, and postoperative dysphagia.[2–4] Epilation may be important to avoid a misdiagnosis of recurrent disease.

Ectopic hair growth may be treated in several ways. This includes long-term regular trimming of hairs under endoscopic guidance.[2,3] Electrolysis before flap transfer can be time-consuming, technically difficult to perform within the posterior oropharyngeal folds and hypopharynx[5] and is rarely appropriate. Electrolysis has been used with partial success to manage an intraoral hairy rectus abdominis myocutaneous free-flap, however, ongoing treatment with an Nd:YAG laser was necessary.[5]

Complete hair depilation has been reported with postoperative radiotherapy[6] but the result is unpredictable and prolonged staged reconstructions may preclude the use of postoperative radiotherapy.[7] Radiotherapy as a method of epilation alone is not justifiable for traumatic, benign congenital defects or malignant conditions when additional postoperative radiotherapy is unnecessary.

Laser hair depilation with Nd:YAG (40 J/cm^2, 55-ms pulse duration) was recently reported for the management of an intraoral radial free flap.[5] Nd:YAG laser has the advantage of being transmitted using a fiberoptic cable but appears to be ineffective for long term hair removal.[8,9] The Alexandrite laser has offered promising initial results[4,9] and is our preferred choice. The procedure is performed using fibreoptic instrumentation as an outpatient procedure. In our experience the laser is most effective when the hair pigment is darker than the surrounding skin pigment. This explains the partial response in one patient.

We did experience technical difficulties similar to those described by other authors. The hand piece of the laser is bulky and instrumentation of the oral cavity and oropharnyx can be difficult. However, the only case we were unable to treat successfully had extremely limited access because of a number of factors; oral submucous fibrosis, extensive surgery requiring reconstruction with two free flaps and radical radiotherapy.

Laser depilation of intraoral flaps with a long-pulsed alexandrite laser is effective and beneficial. Treatment alleviates oral discomfort, improves the aesthetic appearance and oral hygiene. It may possibly also improve the function of the flap. Laser treatment is likely to be applicable for the majority of situations when there is troublesome or excessive hair growth and access to the oral cavity is reasonable.

Conflict of interest

None declared.

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Review

Review of the radial free flap: still evolving or facing extinction? Part two: osteocutaneous radial free flap

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Abstract

The osteocutaneous radial flap is robust, reliable, and relatively simple to harvest, which will ensure that it remains one of the established reconstructive options in most maxillofacial units. Evidence based on clinical observational studies and biomechanical studies supports the routine or selective use of prophylactic internal fixation to strengthen the radial osteocutaneous donor site. This allows safe harvesting of the maximum volume of available bone, up to half of the circumference, with minimal risk of fracture or long term complications. The incidence of fracture with the plate placed either anteriorly or posteriorly is equally low, but the anterior position is technically easier and probably less likely to cause additional morbidity. This approach probably produces the least morbidity that may currently be achieved when managing the inherent flaws of the radial hard tissue donor site. The introduction of prophylactic internal fixation consolidates the role of the osteocutaneous radial flap for repair of defects that require a relatively small volume of bone and an appreciable area of thin soft tissue, particularly when a long vascular pedicle is desirable. This includes low level defects of the maxilla, some defects of the mandible, and niche reconstructions, such as the orbital rim. It remains useful as a first choice of flap when there is appreciable peripheral vascular disease, when there are other serious coexisting medical conditions; if it is the preferred choice of the patient for functional reasons such as mobility of the lower limb or hip, and as a salvage flap when other reconstructive options have been exhausted.

Keywords: Radius; Free flap; Osteocutaneous; Plate; Prophylactic bone plating; Morbidity; Donor site

Introduction

It is now nearly 30 years since the radial free flap was first described.[1] This versatile flap[2,3] soon replaced the bulky pedicled pectoralis major flap as the reconstruction of choice for thin, soft tissue defects of the head and neck region,[4] including relining of the oral cavity and repair of composite defects of the mandible and maxilla.[5–7] However, the relatively high incidence of fracture of the remaining radius, and the limited quantity of bone available, has meant that the radial osteocutaneous flap has gradually been superseded by other flaps. During this period the incidence of reported complications at the soft and hard tissue donor sites of the radial flap has remained appreciable, but techniques are now available to ameliorate the shortcomings of both these donor sites.[8] This is an opportunity to consider whether the osteocutaneous radial flap still has a role in modern reconstructive surgery.

Radial osteocutaneous flap

The radial osteocutaneous flap initially became established as the first reliable free flap for reconstruction of continuity defects of the mandible.[3,9–11] Although the volume of available bone was limited it provided sufficient length to reconstruct most defects and was often a reasonable size

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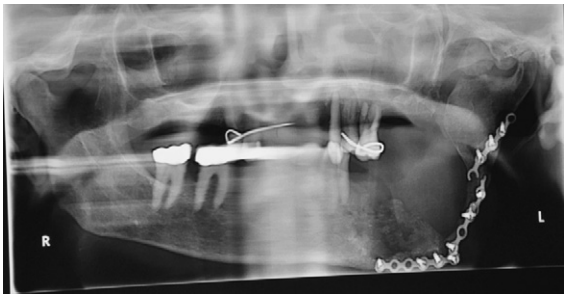

Fig. 1. A fracture of the 2 mm bone plate but the bone has united in the strut of radial bone.

match for the atrophic mandible commonly encountered in older patients with cancer. However, fracture of the radius or the bone plate was not uncommon (Fig. 1). In the maxilla the flap has been used to reconstruct limited low level defects with a considerable soft tissue component, particularly those involving the soft palate.[7,12,13]

In many units the flap was being gradually replaced by the iliac,[14–18] fibular,[19–21] and scapular[22–24] flaps for reconstruction of segmental defects of the mandible and more extensive defects of the maxilla. This trend has been confirmed in a recent 10-year review of flap selection at a major centre in the United Kingdom.[7] Two main factors have contributed to its decline, firstly the limited quantity and quality of bone available, and secondly the morbidity at the donor site. The flap is inadequate for repairing large volume or contour defects, and the lack of bicortical fixation often made it unsuitable for the placement of dental implants,[25,26] even with folding over of the radial bone. This is an important shortcoming even though relatively few patients undergo complex dental rehabilitation. In addition the soft tissue component often lacks the bulk necessity for more extensive defects even with a "sandwich" procedure[12,27] or the harvest of additional subcutaneous tissue.[28] Finally, the incidence of fracture at the radial donor site has remained relatively high, often with considerable morbidity, and has further diminished the appeal of the osteocutaneous flap.

Morbidity at the radial osteocutaneous donor site

The radial osteocutaneous flap is commonly harvested by the conventional subfascial dissection technique.[3,29,30] It may also be raised using an incomplete suprafascial dissection on the ulna aspect to minimise the risk of exposure of tendons, but the deep fascia must be incised to expose the radius once the lateral border of the flexor carpi radialis tendon has been reached.[8] Although the long term morbidity at the subfascial radial donor site is often relatively minor,[29,31] and of secondary importance to most patients with cancer, prolonged wound healing is an undesirable inconvenience and may lead to serious loss of function and a poor aesthetic result.[29] The main cause of morbidity at the osteocutaneous radial donor site is fracture of the radius after osteotomy, particularly when it is associated with displacement and poor healing.[11,29] The management of a displaced fracture may include open reduction and bone grafting.[32,33] The incidence of fracture of the radius in early reports varied from 28% to 43%,[3,9,34,35] and in subsequent larger series was 23%[11] and 31%.[36] Although the incidence of fracture has since declined, probably as a result of refinements in the osteotomy technique, this potential complication remains a major disincentive to using the flap. In a large review article the overall rate of fracture was 25% (28 out of 144 donor sites)[37] and in the latest reports the incidence of fracture was just below 20% at 17%,[29] 15%,[33] and 19%,[38] respectively (Table 1). These are probably the lowest rates of fracture that may be achieved when using conventional surgical techniques.

Reducing morbidity at the osteocutaneous donor site

Reducing the weakening effect of an osteotomy

Even a small osteotomy results in the loss of cortical integrity[34] and greatly reduces the energy absorbing capacity of the remaining bone.[39–41] Seventy-five percent or more of the strength of both a human radius in bending,[42] and a sheep tibia in torsion,[39] was lost by removing up to half

Table 1
Morbidity at the radial osteocutaneous donor site without prophylactic internal fixation (PIF). Data are number (%) unless otherwise stated.

	Richardson[29]	Thoma[33]	Clark[38]
Type of study	Prospective	Retrospective	Retrospective
Donor sites (*n*)	35	60	68[a]
Type of osteotomy	Keel[b]	Keel	Keel and squared
Mean bone length (cm)	8.5	9	7.7
Radial circumference (%)	30–50[b]	30–50	30–50[b]
Type of cast (weeks)	Above elbow (6)	Below elbow (–)	Above elbow (8)
Incidence of fracture	17 (6)	15 (9)	19 (13)
Secondary operations	–	10 (6)	9 (6)
Surgery/conservative	–	67 (6/9)	46 (6/13)
Statistically at higher risk	Women	None	Women

–, unknown.
[a] 71 donor sites of which 3 with PIF excluded.
[b] Confirmed by the author.

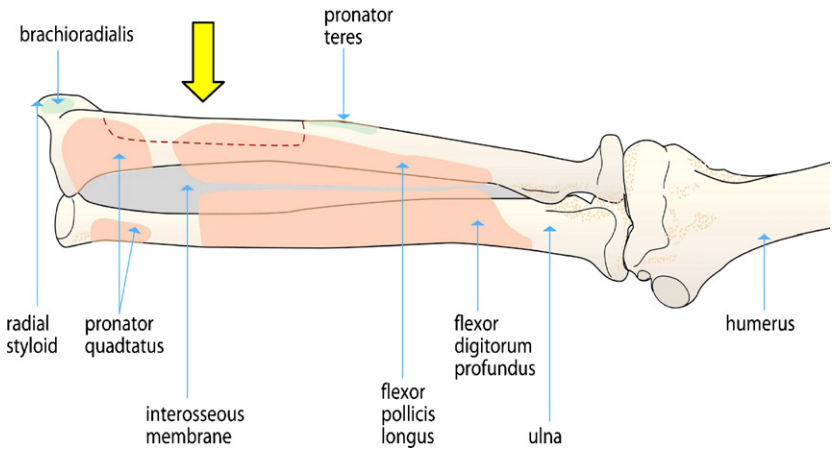

Fig. 2. Site of the radial osteotomy defect (arrow). Note proximity of the curved posterior border of the radius.

of the circumference of the bone. Bevelling the proximal and distal osteotomy cuts has a minimal strengthening effect (5%), but variations in the width, depth, or length of the osteotomy have relatively little impact on the overall strength of the remaining radius.[39] Nevertheless, it is an accepted practice to bevel or curve the osteotomy cuts to improve access and reduce the risk of overcutting. Initially it was recommended that half the radial circumference was removed,[2] but this was then restricted to one-third of the diameter,[42] or 30% of the cross-sectional area,[39] and as much as 40% of the circumference.[3,43] However, it is often difficult to assess accurately the relative sizes of the radius and the osteotomy defect. To reduce the risk of removing too much bone, the osteotomy may be planned on the basis that 40% of the radial circumference approximates to the minimum width of the radius on an anteroposterior radiograph.[43] The curved posterior border of the radius may also be identified at the time of operation using a screw hole depth gauge or a Mitchell's trimmer.[44] The radius is often narrowest at the mid-point of the osteotomy and failure to appreciate this may be a common cause of fracture (Fig. 2).[38]

Protecting the radius after osteotomy

External support with a cast or preformed splint has an important but limited and undefined role in protection of the radius after osteotomy.[38,45,46] A survey of orthopaedic surgeons within the United Kingdom recommended 6 weeks of immobilisation in an above elbow cast.[46] However, the fracture rate with either 6 or 8 weeks of immobilisation in an above elbow cast is still as high as 19% (Table 1).[38]

Strengthening the radius after osteotomy

After osteotomy, the radius may be strengthened with an intramedullary nail,[47] but this is ineffective in reducing rotational forces if incorrectly applied.[48] This approach is probably not widely used as most reconstructive surgeons are not trained in the technique. A more familiar method that may be readily applied by a maxillofacial surgeon is prophylactic internal fixation (PIF) with a bone plate. The introduction of PIF is the most important recent development in surgical techniques. In our original report a 3.5 mm steel dynamic compression plate (DCP) was placed on the anterior surface of the radius, using a conventional anterior approach, and over the donor site defect (Fig. 3).[49] The plate is non-compressive and acts as a bridging reinforcement. It requires a minimum of two bicortical screws at each end (Figs. 4 and 5). The use of a PIF bone plate has since been described in further studies in both an anterior position[44] and a posterior position, by retracting the extensor tendons and placing the plate on the intact cortex opposite the donor site defect.[50]

The strengthening effect of the anterior or posterior position with prophylactic internal fixation (PIF): biomechanical studies

The significant strengthening effect of PIF, in both torsion and bending, on a bone after osteotomy has been shown in biomechanical studies. An osteotomised human radius supported with a 3.5 mm steel DCP in the posterior position is 4

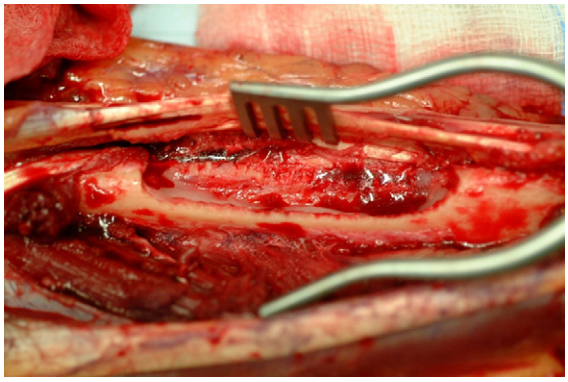

Fig. 3. Donor site on the anteromedial surface of the radius. Avoid excessive bone removal within the osteotomy defect by measuring the distance to the posterior border with a screw depth gauge or Mitchell's trimmer (arrow).

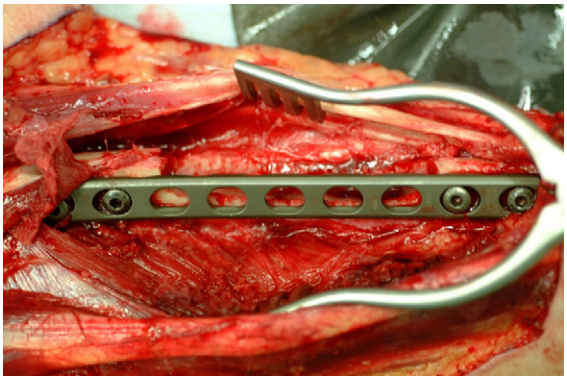

Fig. 4. Titanium plate in the anterior position fixed with a minimum of 2 bicortical screws at each end.

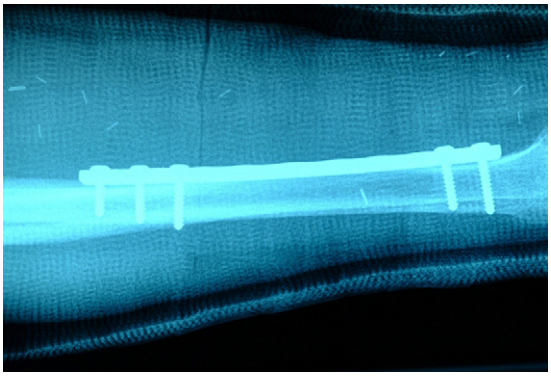

Fig. 5. A steel dynamic compression plate with bicortical screw fixation supported by a full below elbow splint.

times stronger in torsion than an unreinforced bone, and plating restored a mean of 63% of the strength of an intact bone. In bending the mean strength with reinforcement was 2.7 times greater, and 73% of the strength of an intact bone was restored.[37] The strengthening effect of different types of plate in either the anterior or posterior positions has been studied in sheep tibias. The mean torsional strength of a reinforced osteotomised bone was 1.6 times greater than that of an unreinforced bone. A 3.5 mm DCP wholly restored the torsional strength of the osteotomised bone to that of an intact bone in either the anterior (97%) or posterior (101%) positions. The mean bending strengths were 2.8 times greater than that of an unreinforced bone. A 3.5 mm DCP partially restored the bending strength of the osteotomised bone in both the anterior (46%) and posterior (80%) positions (Table 2).[51]

The strengthening effect of an anteriorly or posteriorly positioned bone plate with prophylactic internal fixation (PIF): clinical studies

The posterior[50,52] and anterior[44,53,54] positions of the plate have both been successfully used in a number of large retrospective clinical series with an overall fracture rate of 2.6% (7 out of 268 donor sites) (Table 3). The erroneous insertion of monocortical screws in the initial part of one series caused most of these fractures, and no further fractures occurred once only bicortical fixation was applied.[50] When PIF is in place the amount of bone that may safely be harvested may be increased to as much as half of the radial circumference (Militsakh ON, personal communication, 2005).[44,50] The forearm may initially be placed in an above elbow cast and then transferred to a below elbow cast, or it may be immediately placed in a full below elbow cast for a period as short as only 1 week.[50,53] However, as the bone remodels over many weeks,[55–57] and the ideal duration of external support is unknown, it may be more appropriate to continue to use a conventional 6-week period of protected mobilisation until there is evidence to support a curtailed regimen.

The posterior position has been advocated for the plate as a strong reinforcement that cannot interfere with healing of the skin graft used to repair the radial defect. Although

Table 2
Reinforcement of the radius and tibia after osteotomy.

	Bowers[37]	Avery[44]
Type of bone	Fresh frozen human radii	Preserved sheep tibias
No of pairs	20	50
Length of osteotomy (cm)	8	6
Amount of bone removed	50% cross-section	40% circumference
Type of plate and position	DCP posterior	DCP posterior and anterior
Percentage of retained strength of cut bone: intact bone (100%)		
Torsion	18	69
4-Point bending	24	35
Percentage of retained strength cut + DCP posteriorly: intact bone (100%)		
Torsion	63	101
4-Point bending	73	80
Percentage of retained strength cut + DCP anteriorly: intact bone (100%)		
Torsion	–	97
4-Point bending	–	46

DCP, dynamic compression plate.

Table 3
Prophylactic internal fixation (PIF) of the radial osteocutaneous donor site.

	Author				
	Werle[50]	Villaret[53]	Militsakh[52]	Kim[54]	Avery[44]
Type of osteotomy	Bevel	Bevel	Bevel	Keel	Mostly bevel
Mean (range) bone length (cm)	7.6 (5.5–12)	–	6.6 (3–12)	6.3 (3–11)	7 (4–9.5)
Radial circumference (%)	50	40	50	–	33–50
Donor sites with PIF	52	34	108	52	22
Site of plate fixation	Posterior	Anterior	Posterior	Anterior	Anterior
Type of fixation plate	Steel DCP, LC-DCP, reconstruction	Steel DCP	Steel DCP	Steel DCP	Steel DCP, titanium, reconstruction
No (%) of fractures	9.6 (5)[a]	0	0	1.9 (1)	4.5 (1)
No (%) of secondary operations	0	0	0	1.9 (1)	0
No of plates removed	0	1	1	0	0

–, data not available; DCP, dynamic compression plate; LC, Limited contact.
[a] No of fractures after the use of monocortical screws discontinued.

it is more effective than an anterior plate in withstanding bending forces, this is probably not important in clinical practice as the osteotomised radius can already resist substantial bending forces and fracture is likely to occur with a lower torsional force.[39,42,51] The posterior position seems to afford no advantage in terms of wound healing, as the incidence of loss of skin graft reported with this approach was relatively high, at 43%[50] and 30%.[54] Loss of the skin graft has not been a problem with an anterior plate if the musculature is sewn over the plate, and a negative pressure wound dressing applied.[8] The surgical approach for a posterior plate is more demanding, as additional retraction or stripping of the extensor tendons is required. Care must be taken to avoid the posterior interosseous nerve; the soft tissue coverage is relatively thin and the plate is more likely to irritate or rupture the tendons because it is on a convex surface, although this complication has become less common since the introduction of contoured and locking low profile plates.[58–60] The anterior position is simple and effective; however, I know of no direct comparison between the two surgical approaches.

The reduced incidence of secondary surgery with prophylactic internal fixation (PIF)

The need for a secondary operation because of fracture is much lower when PIF has been applied, because few fractures occur or become displaced. The current overall incidence of secondary repair with PIF in place is 0.4% (1 of 268 donor sites) and this is only 1 of 7 donor sites that fractured (Table 3). This contrasts with much higher rates of secondary surgery when PIF is not in place. In recent reports the overall rates of secondary surgical repair were 9% (6 out of 68 donor sites)[38] and 10% (6 out of 60 donor sites)[33] with these being 6 of 13[38] and 6 of 9,[33] respectively, of the donor sites that fractured (Table 1). Although a good outcome after fracture repair has been claimed, no objective evidence has been offered.[33] The functional loss that occurs with PIF in place should be lessened, as fractures are usually undisplaced and the additional morbidity of a secondary procedure is rarely incurred.

Potential complications and selection of the plate with prophylactic internal fixation (PIF)

In the long term, a sufficiently large plate may cause a stress protection effect that leads to localised osteopenia and late fracture. The mechanisms may include mechanical unloading[55,57,61,62] and reduced perfusion of the cortex.[63–65] However, these concerns about PIF have proved to be unfounded. The late remodelling of bone with some reconstitution of the radial defect has been seen,[44,50,59] and over the last decade less than 1% (2 of 268) of the plates inserted for PIF have been removed for complications (Table 3). Developments in the design of plates have included limited contact plates to reduce the risk of osteopenia caused by a compromised periosteal vascular supply,[64] although this has been disputed.[62]

Titanium plates may have less of a stress shielding effect because the elastic modulus and structural stiffness of the plate is lower.[51,59] There is a trend towards the use of lower profile 2 and 2.4 mm locking reconstruction plates because they are less rigid and less likely to cause stress protection. The plates seem to be equally effective in clinical practice, are more readily adapted, less palpable, and the incidence of hardware-related problems may be lower.[52] Low profile contoured locking plates designed to fit the distal radius have become increasingly popular for managing displaced fractures caused by trauma, and these plating systems achieve greater fixation in osteoporotic bone.[60,66] To minimise the risk of damage to the flexor tendons or penetration of the joint space of the wrist, plates should not be prominently positioned or placed distal to the "watershed line" of the transverse ridge of the distal radius.[60,66] In a recent series, of only two patients, a limited contact fixed angle steel unilocking plate was used for PIF of the radial donor site.[67] The ability to engage only one cortical surface may be advantageous and the contoured steel or titanium plate is easier to adapt. This technique may become the method of choice but at present there is insufficient experience with plates of this design (Fig. 6).

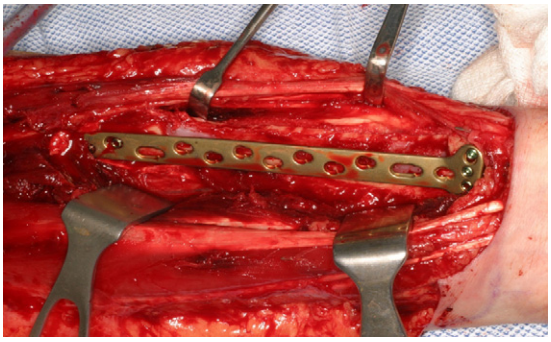

Fig. 6. A contoured radial plate with unicortical fixation.

The indications for prophylactic internal fixation (PIF)

It has been suggested that PIF may be most appropriate for the older woman whose radius is smaller and more likely to be osteopenic.[38,68] A significantly higher rate of fracture among women has been reported in two of the larger studies, [29,38] but not all,[33] and no relation has been shown with age. Fractures may also occur in men, and occasionally in younger people as well. At present there is no evidence that adults do not benefit from the routine use of PIF, but it is possible that the selection criteria may evolve with greater experience. However, it is unlikely that a randomised comparative study will be possible because of the limited numbers of patients who may be treated in one department, and the inherent problems with a larger multicentre study.

The cost-effectiveness of prophylactic internal fixation (PIF)

The cost-effectiveness of PIF has been challenged on the basis that the incidence of fracture has declined and the expense of treatment after fracture is relatively low compared with the cost of PIF.[68] However, these findings have been refuted on a number of points. The discrepancy in the estimated direct costs in this Canadian study seems disproportionately large when it is considered that placing an anterior plate requires only a little additional time together with the cost of the hardware. The incidence of complications that directly result from PIF also seems to have been overestimated, and the method has been criticised as the analytical decision model used was based on a young group of injured patients. Finally, the additional indirect costs and associated morbidity are likely to be considerably higher with older patients after resections for cancer who require complex secondary procedures to repair displaced fractures.[59] There are minimal additional associated costs caused by the need to remove plates placed for PIF, as this is rarely necessary. The elective removal of an asymptomatic plate is discouraged as it may be associated with a small risk of nerve damage and, based on studies of repair of fractures of the radius, a small potential risk of late fracture.[69–71]

The current role of the radial osteocutaneous flap

Even without the use of PIF the radial osteocutaneous flap has remained the flap of choice for reconstruction of the mandible for some surgeons.[33,72] However, the mainstream opinion is that alternative flaps such as those from the fibula, ileum, and to a lesser extent the scapula, have relegated it to a secondary role.[7,73] Nevertheless, the pattern of practice within the United Kingdom has not been audited. Following the introduction of the PIF technique there has been renewed interest in defining the current indications for the osteocutaneous radial flap.[50,52,54,59,74] The flap has been advocated when bicortical fixation is not required and no implant or dental prosthesis is planned. It has a role when only a relatively small volume of bone is required for specific areas such as the anterior maxilla, the ascending ramus, angle, and posterior non-tooth-bearing regions of the mandible, and particularly when a soft tissue lining component is required.[53,73] There are, of course, other reconstructive options available for all of these sites but, depending on body habitus, these are sometimes too bulky. It has been claimed that the radial flap is more cost-effective than other composite flaps, and in selected circumstances it may be more appropriate because of the high success rate of the flap combined with a relatively low incidence of serious systemic morbidity related to the donor site.[52]

In a large oncology practice it is important to have a wide range of reconstructive options available to manage various defects in patients with differing degrees of comorbidity and differing functional needs, all of which will be affected by morbidity at the donor site. The introduction of PIF will consolidate the role of the osteocutaneous radial flap for repair of defects that require a relatively small volume of bone and an appreciable area of thin soft tissue, particularly when a long vascular pedicle is desirable to avoid a vein graft. This includes low level, class 1 and 2 defects,[12] of the maxilla when the strut of bone provides additional support to the drape of the skin component (Fig. 7) and reconstruction of the mandible as described earlier. The flap also has a number of niche roles such as reconstruction of the orbital rim[75] and nasal defects.[76,77] It remains useful as a first choice of flap:

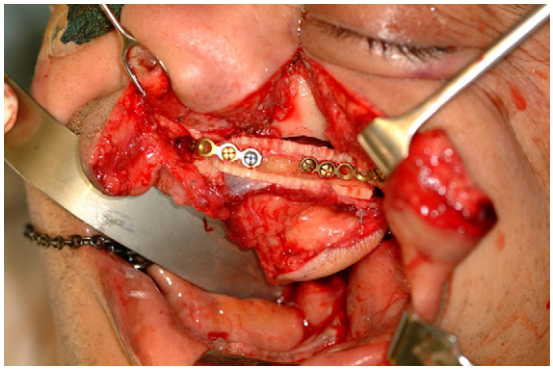

Fig. 7. Reconstruction of a low level anterior defect of the maxilla.

when there is appreciable peripheral vascular disease as the radial artery is usually relatively unaffected,[78,79] and when there is other serious comorbidity; if it is the preferred choice of the patient for functional reasons such as lower limb or hip mobility, and as a salvage flap when other reconstructive options have been exhausted.[44]

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Short communication

The use of a T-shaped contoured unilocking titanium radial plate for prophylactic internal fixation of the radial osteocutaneous donor site

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Abstract

The radial osteocutaneous flap retains a limited role in reconstructive maxillofacial surgery The application of prophylactic internal fixation, using straight 3.5 mm plates, has become established to substantially reduce the incidence of fracture at the radial donor site. New lower profile T-shaped 2.4 mm plates and anatomically contoured 3.5 mm plates are now available, both with unilocking screw fixation systems. These plates are easy to apply and allow the removal of up to 50% of the circumference of the radial bone, including the maximum amount of good quality bone from the distal radius. Although there have been no reports of complications as a result of a stress shielding effect with larger plates these refinements in plate design should lessen any remaining concerns.

Keywords: Radius; Donor site; Fracture; Morbidity; Plate; Prophylactic fixation; Unilocking; Anatomically; Contoured plate; Distal radial plate

Radial osteocutaneous free flaps still have a limited role in reconstructive surgery of the maxillofacial region.[1] The main morbidity results from fracture and displacement of the osteotomised radius.[2] In a review article the overall rate of fracture was 25% (28 of 114 donor sites),[3] and in the most recent large operative series reported the incidence of fracture has remained relatively high, at 19% (13 of 68 donor sites).[4] However, the osteotomised radius, or its equivalent, has been substantially strengthened in biomechanical studies by prophylactic internal fixation (PIF) with a bone plate placed either over the defect (anteriorly) or on the intact opposite cortical surface (posteriorly).[3,5] Both positions have been used in several clinical studies with an overall fracture rate of 2.6% (7 of 268 donor sites). The incidence of secondary intervention is also much lower because few fractures become displaced. Despite initial concerns about the potential for stress shielding and late fracture, less than 1% (2 of 268) of the plates reportedly inserted for PIF over the last decade have been removed for complications.[1]

In the original description of the technique, a 3.5 mm steel dynamic compression plate (DCP) was placed anteriorly.[6] However, the plate is quite bulky and requires careful adaptation. Developments in the design of plates have included the introduction of low profile and limited contact plates (LCP), and unilocking systems that provide strong, stable fixation with minimal disruption of the periosteal blood supply. Recently right-sided and left-sided anatomically contoured unilocking plates have become increasingly popular for managing displaced fractures of the distal radius. These plating systems provide strong reinforcement and achieve greater fixation within osteoporotic bone.[7,8]

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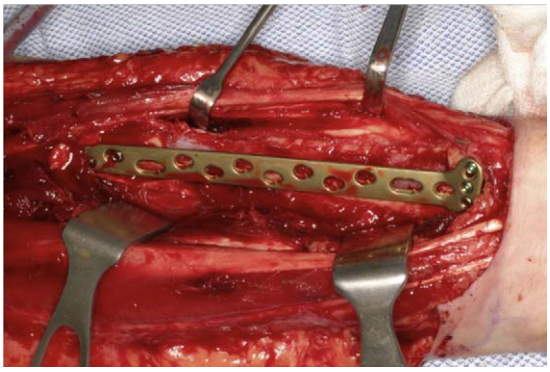

Fig. 1. A T-shaped titanium plate positioned over the anterior radial donor site.

In a recent case report a straight 3.5 mm steel LCP with a unilocking system was used on two occasions for PIF at radial donor sites.[9] We have experience, with 6 procedures, of using T-shaped limited contact low profile titanium plates for PIF of the donor site following reconstruction of the orbital rim and partial maxillectomy defects. The SYNTHES LCP Distal Radius 2.4 mm plate has an extended proximal length of 8–12 holes and although not anatomically contoured is readily adapted. The distal end of the plate is angulated and T-shaped, which facilitates the safe removal of the maximum amount of good quality bone because the space required for the two distal screws inserted with a straight plate may be partially included in the osteotomy site. The SYNTHES LCP Dia-Meta Volar Distal Radial system is a stronger, longer plate and the 3.5 mm proximal shaft is also anatomically contoured for the right or left radius, so it requires minimal adaptation. This is combined with the fixed angle 2.4 mm T-shaped distal end and is suitable for relatively long defects (Figs. 1–3). Locking technology has imparted greater angular stability to the fixation, and iatrogenic fracture is less likely during insertion of a screw as only one cortex is engaged. To avoid damaging the flexor tendons the plates have rounded edges and the screws are a flush fit. The plate should not be too prominent, or placed beyond the transverse ridge of the

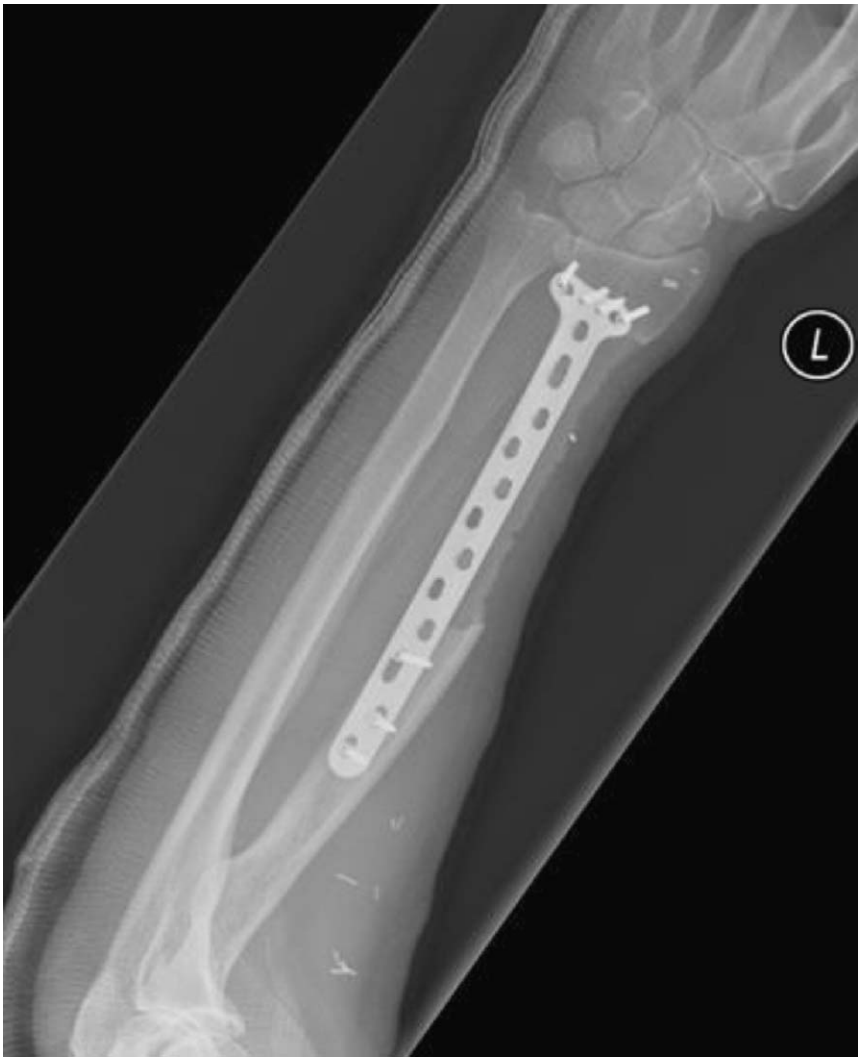

Fig. 2. Unicortical fixation screws are inserted proximally and distally but not within the donor site defect.

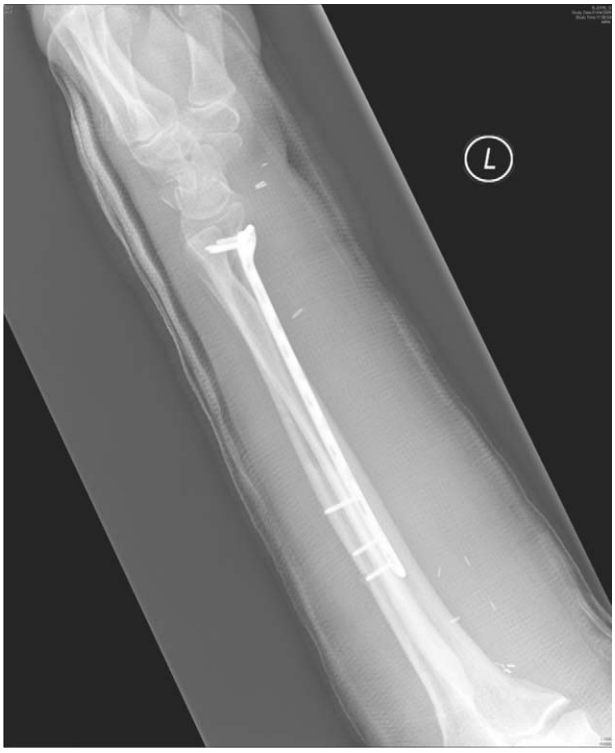

Fig. 3. The maximum amount of good quality bone may be harvested from the distal aspect of the radius as the T-shaped distal end of the plate does not encroach upon the osteotomy site.

distal radius; the latter also increases the risk of penetrating the wrist joint.[7,8]

The use of PIF has become more widely accepted as a safe and reliable method of harvesting up to 50% of the radial circumference.[1] This technique should ensure that the radial osteocutaneous flap retains a niche role, and it may even become popular again.[10] The use of low profile, T-shaped and contoured steel or titanium LCP unilocking plate systems may become the method of choice for PIF, but a larger clinical experience is desirable.

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Biomechanical study of a unilocking T-plate system for prophylactic internal fixation of the radial osteocutaneous donor site using the sheep tibia model

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SUMMARY

Prophylactic internal fixation (PIF), with a bone plate in either the anterior (over the section defect) or posterior (on intact cortex) position, has substantially reduced the incidence of fracture at the donor site of the radial osteocutaneous free flap. This study uses the sheep tibia model to compare the effectiveness of new T-shaped titanium plates utilising a unilocking screw system with a 3.5 mm steel plate and bicortical screw fixation system commonly applied for PIF.

Forty matched pairs of adult sheep tibias were tested in torsion and 4-point bending. An osteotomised bone was significantly weaker ($p < 0.001$) than an intact bone in both bending and torsion with a mean loss of 77% and 64% of strength respectively. The tibia withstood much greater bending loads. All of the constructs significantly strengthened an osteotomised bone by a factor of 1.73–2.43 times in bending and 1.54–2.63 in torsion. The 2.4 mm T-plate in an anterior position (section) was the baseline against which other plates in differing positions were compared. The 3.5 mm T-plate section, DCP section and DCP cortex constructs had 41%, 30% and 2% greater mean bending strengths respectively but only the 3.5 mm T-plate section result approached statistical significance ($p = 0.06$). In torsion the DCP section, 3.5 mm T-plate section and DCP cortex constructs had 56% ($p = 0.01$), 27% ($p = 0.06$) and 25% greater mean strengths respectively.

When compared to an intact bone the mean bending strength restored by the DCP section (84%) and 3.5 mm T-plate section (87%) constructs was greatest and effectively restored the strength to that of an intact bone (100%). In torsion the mean strength restored by the DCP section (62%), DCP cortex (44%), 3.5 mm T-plate section (40%) and 2.4 mm T-plate (36%) remained significantly less than an intact bone.

All of the plate constructs significantly strengthened an osteotomised bone but overall the 3.5 mm T-plate section and DCP section were the strongest constructs and most suitable for PIF. The lighter 2.4 mm T-shaped titanium plate was least effective. The strongest reinforcement in bending and torsion was the 3.5 mm T-plate section and DCP section respectively. The 3.5 mm DCP section plate was significantly stronger ($p = 0.01$) than the 3.5 mm T-plate in torsion and remains the most effective construct for resisting torsional stresses, which are probably the commonest cause of fracture in clinical practice.

Introduction

Although, the radial osteocutaneous free flap retains a selective role in reconstructive surgery of the maxillofacial region[1,2] the morbidity associated with fracture of the osteotomised radius,[3] combined with the restricted volume of bone available has reduced the popularity of the flap. In a review article the overall rate of fracture was 25% (28/114 donor sites)[4] and in two relatively recent large series the incidence was 15%[5] and 18%,[6] with secondary surgery required for 67% and 46% of fractures, respectively. The majority of the strength of both the human radius[7] and a sheep tibia model[8,9] is lost by removing up to 50% of the circumference. Bevelling the osteotomy end cut or varying the dimensions of the osteotomy have a minimal strengthening effect[8] as the dramatic weakening results from the greatly reduced energy-absorbing capacity[10,11] associated with the loss of cortical integrity.[8,12]

The technique of prophylactic internal fixation (PIF) of the radial osteocutaneous donor site was first described by the author in 1999.[13] The significant strengthening effect of a plate in the anterior (over section defect) or posterior (on opposite intact cortex) position has subsequently been reported in larger clinical series,[1,14–17] and verified in biomechanical studies[4,9] (Table 1). A

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Table 1
Clinical studies of the morbidity at the radial ostecutaneous donor site associated with prophylactic internal fixation.

Author	Werle 2000	Villaret 2003	Militsakh 2005	Kim 2005	Avery 2007
Type of study	Retrospective	Retrospective	Retrospective	Retrospective	Retrospective
Type of osteotomy	Bevel	Bevel	Bevel	Keel	Mostly Bevel
Mean bone length (cms)	7.6 (5.5–12)	–	6.6 (3–12)	6.3 (3–11)	7 (4–9.5)
Radial circumference (%)	50	40	50	–	33–50
Donor sites with PIF	52	34	108	52	22
Site of plate fixation	Posterior	Anterior	Posterior	Anterior	Anterior
Type of fixation plate	Steel DCP, LC-DCP, reconstruction	Steel DCP	Steel DCP	Steel DCP	Steel DCP, titanium, reconstruction
Incidence of fracture% (n)	9.6 (5)*	0 (0)	0 (0)	1.9 (1)	4.5 (1)
Secondary surgery% (n)	0 (0)	0 (0)	0 (0)	1.9 (1)	0 (0)
Number plates removed	0	1	1	0	0

–Data not available.
* No fractures after the use of monocortical screws discontinued.

Table 2
Tests used to compare the strength of matched pairs of bones with different plates and position.

Group	Pairs	Type of bone/plate/position	Type of bone/plate/position	Test
1	5	Intact	Osteotomy	Torsion
	5	Intact	Osteotomy	Bending
2	5	Osteotomy/2.4 mm T/Section	Osteotomy/DCP/Cortex	Torsion
	5	Osteotomy/2.4 mm T/Section	Osteotomy/DCP/Cortex	Bending
3	5	Osteotomy/2.4 mm T/Section	Osteotomy/DCP/Section	Torsion
	5	Osteotomy/2.4 mm T/Section	Osteotomy/DCP/Section	Bending
4	5	Osteotomy/2.4 mm T/Section	Osteotomy/3.5 mm T/Section	Torsion
	5	Osteotomy/2.4 mm T/Section	Osteotomy/3.5 mm T/Section	Bending

In each matched pair one bone was compared with the other. For example in Group 2 one osteotomised bone was reinforced with a 2.4 mm T-plate over the section defect (anterior position), and the corresponding osteotomised bone was reinforced with a 3.5 mm DCP plate on the intact opposite cortex (posterior position).

straight 3.5 mm steel dynamic compression plate (DCP) has most commonly been used but is bulky and requires careful adaptation. Low profile light-weight titanium plates with unilocking screw systems have since been introduced for fractures of the radius.[18,19] This study uses the sheep tibia model to compare the strengthening effect of T-shaped titanium unilocking plates with a conventional 3.5 mm DCP plate secured with bicortical screw fixation.

Methods

Bone pairs and plates

Forty matched pairs of intact freshly frozen adult sheep tibias of a similar size and age were tested. Four groups of matched pairs representing the common permutations of plate and position were tested. The forces at failure during torsion or bending were recorded, and a photographic record taken.

Group 1 compared 10 pairs of intact and osteotomised bones to establish the variation in strength of the bones, measure the weakening effect of an osteotomy and establish a baseline for assessing the percentage of strength restored by reinforcement. Groups 2, 3 and 4 compared pairs of osteotomised bones reinforced with different plates (Table 2). The anterior and posterior positions were simulated by putting the plate over the section defect or on the intact cortex opposite the section defect. The following plates were tested: an 8-hole steel 3.5 mm DCP plate (SYNTHES, UK) (Fig. 1) and two T-shaped titanium plates (SYNTHES, UK); the 2.4 mm LCP distal radius plate and the 3.5 mm LCP Dia-Meta volar distal radius plate (Fig. 2).

Preparation of bone and section defect

The bones were stripped of soft tissue and stored in moist sealed packages at −28 °C. A defect 40 mm long and 40% of the circumference was created in the flat midsection of the shaft. The

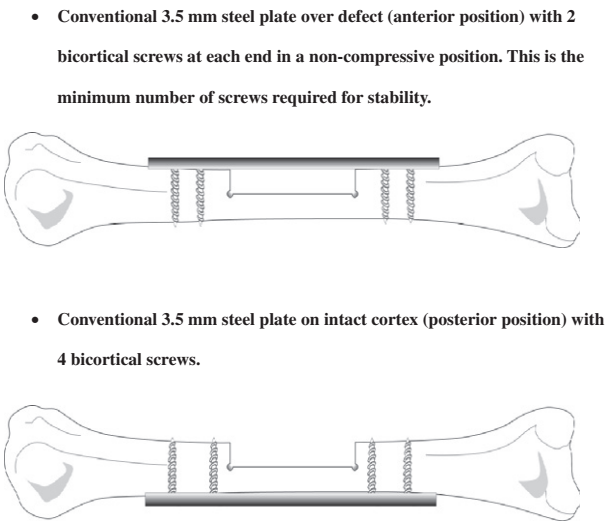


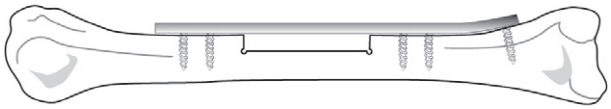
Figure 1 Conventional 3.5 mm steel plate over defect (anterior position) with two bicortical screws at each end in a non-compressive position. This is the minimum number of screws required for stability. Conventional 3.5 mm steel plate on intact cortex (posterior position) with four bicortical screws.

right-angled osteotomy at each end was drilled out to eliminated a potential point of stress concentration (Fig. 3). The constructs were mounted in an aluminium mould to create the cement endings (Dental Repair Cement, M R Dental Supplies, UK) required for insertion in the testing apparatus. If the diaphysis was too bulky it was cut down to size.

Torsion testing

A torsion apparatus (Crofts Engineering Ltd, UK) with a force transducer gave a direct reading of one millivolt (mv), equivalent

- **T-shaped titanium plate over defect (anterior position) with two unicortical screws either side of the section defect and within the T-shaped end.**



- **Overview of T-shaped titanium plate over the defect and in the anterior position.**

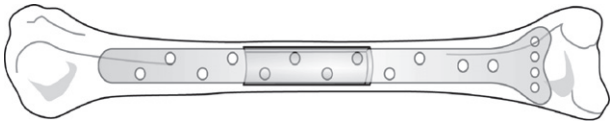


Figure 2 T-shaped titanium plate over defect (anterior position) with two unicortical screws either side of the section defect and within the T-shaped end. Overview of T-shaped titanium plate over the defect and in the anterior position.

Standardised section defect.

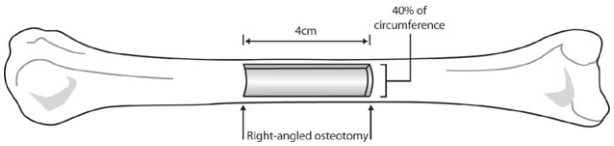


Figure 3 Standardised section defect.

to one Newton (N), and the force in Newton metres (Nm) was calculated every 1–2 s. Rotation of the apparatus at one degree/s induced a uniform torque over the length of the bone.

Four-point bending test

An MTS Star Load Frame apparatus (MTS, Minnoesota, USA) was modified with two attachments to align and secure the non-uniform bone specimens with the section defect on the superior aspect. Saddle-shaped nylon blocks were placed over the two superior steel points to avoid crushing the bone. A four point compressive bending force was applied inferiorly with a rate of displacement of 10 mm/minute and the load measured in Newtons by the MTS star software programme.

Statistical analysis

Raw data and summary results were tabulated, using means, standard errors (SE), and percentages. Approximate 95% confidence intervals (CI) were calculated for mean strength of an osteotomised bone as a ratio ($\times 100$) of the strength of an intact bone. Confidence intervals (CI) were calculated for mean strength of the various constructs as a ratio ($\times 100$) of the strength of an osteotomised bone reinforced with a 2.4 mm T-plate over the section defect and evidence that a particular construct was stronger was tested using the one-sample t test. Parametric methods were used to test for increased strength relative to an osteotomised non-reinforced bone (Student's 2 sample t test). Evidence of differences between the strengths of constructs was sought using the ANOVA and Kruskal–Wallis tests.

Results

The statistical analysis is presented in Tables 3 and 4. The results in Table 3 are expressed as a ratio 100× (intact bone/osteotomised bone 2.4 mm T-plate section) to obtain a percentage value for the pair, with the baseline value for an osteotomised bone with a 2.4 mm T-plate being 100. The wide confidence intervals with some results reflect the small number of pairs, and the variability in the increased strength ratios of individual pairs. The one sample t test examines whether the mean ratio is significantly different from 100, where 100 implies the strength is the same as an osteotomised bone reinforced with a 2.4 mm T-plate over the section defect. In Table 4 the two sample t test compares the mean strength restored of the construct with the mean for an intact bone (100%) and also illustrates the percentage increase in strength when compared with an osteotomised bone (100%).

Torsion testing

Spiral or oblique fractures occurred at the angle of the osteotomy, the section defect, between screw holes, or within the shaft of an intact bone. The mean strengths of the DCP section, 3.5 mm T-plate, and DCP cortex constructs were 56% ($p = 0.01$), 27% ($p = 0.06$) and 25% ($p = 0.20$) greater than the mean strength of the 2.4 mm T-plate (Table 3). The DCP section was 40% stronger than the DCP cortex construct (two sample t-test $p = 0.03$, Mann–Whitney U-test $p = 0.08$) and 53% stronger than the 3.5 mm T-plate section (two sample t-test $p = 0.01$, Mann–Whitney U-test $p = 0.01$).

The mean strength of the intact bone was 327% ($p < 0.001$) greater than an osteotomised bone, a loss of 77% of the intact

Table 3
Strength of an osteotomised bone with a 2.4 mm T-plate over the section defect (100%) compared with reinforcement using other plates and positions.

		How much stronger than an osteotomised bone with a 2.4 mm T-plate over section defect (100%)			Evidence stronger (One-sample t test p value)
	Nos of pairs	Mean ratio ×100*	SE	95% CI for mean	
Torsion groups					
1) DCP section	5	156	12	122–190	0.01
2) DCP cortex	5	125	16	80–170	0.20
3) 3.5 mm T-plate section	5	127	11	98–156	0.06
Bending groups					
1) DCP section	5	130	21	71–188	0.23
2) DCP cortex	5	102	5	89–116	0.65
3) 3.5 mm T-plate section	5	128	17	80–176	0.18
3) 3.5 mm T-plate section	4**	141	14	96–187	0.06

DCP = Dynamic compression plate.
* For example, a DCP plate over the section of an osteotomised bone has a mean strength of 130% of a 2.4 mm T-plate over the section defect i.e. it is 30% stronger.
** Excluding anomalous low strength result.

Table 4
Percentage of strength restored to an osteotomised bone reinforced with a variety of plates in different positions compared to an intact bone (100%) and how much greater this strength is than an osteotomised bone (100%).

	Nos of Bones	Mean moment (Nm)	SE	95% CI for Mean	% Strength restored by plate compared to intact bone (100%)*	Evidence stronger 2-sample *t* test (p value)	% Strength increased by plate compared to osteotomised bone (100%)	Evidence stronger 2-sample *t* test (p value)
Torsion groups								
1) Intact	10	33.4	3.6	25–42	100	–	427	<0.001
2) Osteotomised	5	7.83	0.6	6.2–9.5	23	<0.001	100	–
3) DCP section	5	20.6	1.7	16–25	62	0.007	263	0.001
4) DCP cortex	5	14.7	1.3	11–18	44	<0.001	188	0.004
5) 2.4 mm T-plate section	15	12.0	0.5	11–13	36	<0.001	154	<0.001
6) 3.5 mm T-plate section	5	13.4	1.2	10–17	40	<0.001	171	0.007
Bending groups								
1) Intact	10	116	4.6	106–127	100	–	279	<0.001
2) Osteotomised	5	41.7	5.6	26–57	36	<0.001	100	–
3) DCP section	5*	97.4	16	52–142	84	0.32	234	0.02
4) DCP cortex	5	72.0	3.1	63–81	62	<0.001	173	0.003
5) 2.4 mm T-plate section	15	73.1	2.3	68–78	63	<0.001	175	0.003
6) 3.5 mm T-plate section	5	92.2	11	63–122	79	0.09	221	0.006
6) 3.5 mm T-plate section	4**	101	6.9	80–123	87	0.12	243	<0.001

DCP = Dynamic compression plate.
* For example, a DCP plate over the section of an osteotomised bone restored a mean of 84% of the strength of an intact bone and there was no significant difference ($p = 0.32$) in strength between this construct and an intact bone. The mean strength of the re-inforced bone was significantly increased by 234% or 2.34 times ($p = 0.02$) that of an unsupported osteotomised bone.
** Excluding anomalous low strength result.

strength. The range of values was large (95% CI: 223–431) indicating considerable variability in bone strength. The osteotomised bone was strengthened by a factor of 1.54–2.63 but all constructs remained significantly weaker than an intact bone (100%); DCP section (62%), DCP cortex (44%), 3.5 mm T-plate section (40%) and 2.4 mm T-plate section (36%) (Table 4).

Four-point bending testing

Intact bones failed with a transverse fracture across the shaft. Osteotomised bones failed with a transverse fracture at the angle of the osteotomy or within the section defect. Bones with reinforcement failed at the screw holes or angle of the osteotomy. One 3.5 mm T-plate construct failed in an anomalous manner and this test failure has been excluded from the analysis but is included in the tabulated results.

The 3.5 mm T-plate section, DCP section and DCP cortex constructs had a mean strength 41% ($p = 0.06$), 30% ($p = 0.23$) and 2% ($p = 0.65$) greater respectively than the 2.4 mm T-plate. The difference in mean strengths between the four constructs was significant (ANOVA $p = 0.007$, Kruskal–Wallis $p = 0.04$).

The mean strength of the intact bone was 179% ($P < 0.001$) greater than an osteotomised bone, a loss of 64% of the strength of an intact bone (95% CI: 140–218). The constructs strengthened an osteotomised bone by a factor of 1.73–2.43. The mean strength restored by the DCP section (84%) and 3.5 mm T-plate section (87%) constructs was greatest and did not differ significantly from an intact bone (100%).

Discussion

The introduction of the technique of PIF has been the most significant development to reduce the incidence of fracture at the radial osteocutaneous donor site. A 3.5 mm steel dynamic compression plate (DCP) has most commonly been used in either the anterior (over the donor site defect) or the posterior (on intact opposite cortex) positions with an overall fracture rate of 2.6% (7/268 donor sites) and secondary surgery has rarely been necessary[1,14–17] (Table 1). Despite initial concerns about the potential for stress shielding, less than 1% (2/268) of the plates reported as inserted for PIF over the last decade, have been removed for complications.[1]

However, the 3.5 mm DCP plate is bulky and requires a minimum of two bicortical screws at each end, which may be impractical in the anterior position if space adjacent to the wrist joint is limited. Developments in the design of plates have included lighter, thinner titanium and steel plates with limited contact areas to reduce the risk of osteopenia and stress shielding.[20] Bone is more flexible than either stainless steel (E 200 GPa) or titanium (E 110 GPa)[21] but titanium plates may have less of a stress shielding effect because the elastic modulus and structural stiffness is closer to that of bone, which should allow greater sharing of the load.[21,22] The new plates have various potential advantages; lighter plates are more readily adapted, the T-shaped plate is anatomically contoured to the distal radius, the shaft of the 3.5 mm T-plate is anatomically contoured to the left or right radius and close adaptation of the plate may be less important with a unilocking system. Low profile unilocking plates have become increasingly popular for managing displaced fractures of the distal radius and achieve greater angular stability in osteoporotic bone.[18,19] As many oncology patients are elderly this may be an advantage. The author (CA) has limited but successful clinical experience with T-shaped titanium plates.[23] The 2.4 mm LCP distal radius plate has an extended proximal shaft of 8–12 holes which is of sufficient length for most radial defects and is readily adapted. The 2.4 mm fixed angle T-shaped distal end allows the safe removal of bone when space is limited. The LCP Dia-Meta volar distal radius plate has a stronger 3.5 mm anatomically contoured proximal shaft. To avoid damaging the flexor tendons the plates have rounded edges and flush fit screws. The plate should not be placed beyond the transverse ridge or "watershed" of the distal radius to avoid penetrating the wrist joint.[18,19]

The biomechanical effectiveness of these new plates has not previously been compared with the 3.5 mm DCP steel plates commonly used for PIF. In this study an intact tibia was significantly ($p < 0.001$) stronger than an osteotomised bone in both bending and torsion, and withstood much greater bending forces. This is consistent with previous studies (Table 5)[4,9] and supports the hypothesis that most radial fractures are probably caused by relatively low-energy torsional forces.[7,8] All of the constructs signifi-

Table 5
Biomechanical studies of reinforcement of the osteotomised radius and tibia.

	Bowers 2000	Avery 2007	Avery 2010
Type of bone	Cadavaric Human radii	Sheep Tibiae	Sheep Tibiae
Number of pairs	20	50	40
Length of osteotomy (cms)	8	6	4
Amount of bone removed	50% cross-section	40% circumference	40% circumference
Type of plate and position	DCP posterior	DCP posterior & anterior	DCP posterior & anterior T-Plate posterior & anterior
Percentage strength retained – osteotomised: intact bone (100%)			
Torsion	18	69	23
4-point bending	24	35	36
Percentage strength restored – osteotomised + DCP cortex: intact bone (100%) and ratio mean increase in strength (n)			
Torsion	63 (4)	101 (1.6)	44 (1.9)
4-point bending	73 (2.7)	80 (2.8)	62 (1.7)
Percentage strength restored – osteotomised + DCP section: intact bone (100%) and ratio mean increase in strength (n)			
Torsion	–	97 (1.8)	62 (2.6)
4-point bending	–	46 (2.3)	84 (2.3)

DCP = 3.5 mm Dynamic compression plate.

cantly strengthened an osteotomised bone by a factor of 1.73–2.43 times in bending and 1.54–2.63 in torsion. The relatively light and malleable 2.4 mm T-plate placed in an anterior position (section) was chosen as the baseline against which other constructs were compared. The 3.5 mm T-plate section, DCP section and DCP cortex constructs had greater mean bending strengths respectively than the 2.4 mm T-plate section but only the 3.5 mm T-plate section result approached statistical significance (41%, $p = 0.06$). In torsion the DCP section construct had a significantly greater mean strength (56%, $p = 0.01$) and the 3.5 mm T-plate section strengthening effect approached significance (27%, $p = 0.06$). The mean bending strength restored by the DCP section (84%) and 3.5 mm T-plate section (87%) constructs was greatest and effectively restored the strength to that of an intact bone (100%). In torsion the mean strength restored remained statistically weaker than that of an intact bone (Tables 3 and 4). Hence, the strongest reinforcements in bending and in torsion respectively were the 3.5 mm T-plate section and the DCP section constructs.

The interpretation of comparisons between the groups of paired bones and other studies are constrained by the relatively small numbers, lack of direct linkage, differing animal cohorts and techniques of testing or osteotomy design. The osteotomy defect in the current study was 4 cm as opposed to 6 cm in the previous sheep study,[9] both values are within the range used in clinical practice.[24] The number and position of the screws inserted also varies in clinical practice but was standardised for the study. The findings are consistent with the previous biomechanical studies as the forces required for fracture are of a similar order of magnitude with comparable ratios of strengthening (Table 5). However, in contrast to the previous sheep tibia study[9] the intact bones in the current study were stronger in torsion and weaker in bending. The retained strength in torsion of 69% for an osteotomised bone in the previous sheep study appears relatively high and the relative stoutness of the tibial bones when compared to the human radius is probably not the only factor. Previously the strengthening effect in torsion of the DCP section and DCP cortex constructs was similar but in the current study the DCP section construct was significantly stronger ($p = 0.08$) and under bending loads the DCP section was not weaker than the DCP cortex. The biomechanical advantage under bending loads of the posterior plate position is debateable but probably remains relatively unimportant in clinical practice as the radius will resist much greater bending than torsional forces.[9] The surgical approach for a posterior plate is also more demanding as the posterior interosseous nerve is at risk, soft-tissue coverage is thin and tendon injury is more likely, although less common with contoured low profile plates.[18,25,26] However, there has been no direct clinical comparison between the two surgical approaches and the surgeon may chose the technique that best suits their practice and experience.

The use of PIF has become more widely accepted as a safe and reliable surgical technique for harvesting up to 50% of the radial circumference. The introduction of new contoured unilocking plate systems may further consolidate, or perhaps expand, the limited role of this flap.[2] The anteriorly positioned 3.5 mm T-plate and 3.5 mm DCP constructs were the strongest overall, and in bending and torsion respectively. Either plate is suitable for PIF although the anteriorly positioned 3.5 mm DCP remains the most effective construct for resisting torsional stress, which is probably the commonest cause of fracture. The 2.4 mm unilocking T-plate was the least effective of the plates tested but still significantly increased the strength of an osteotomised bone. Whether the relative reduction in strength of the 2.4 mm plates is of clinical significance is unknown and further experience with these plating systems is desirable.

Conflict of interest statement

This study was supported by a research grant from Synthes (UK).

Ethical statement

Ethical approval was not required for this study.

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A finite element analysis of bone plates available for prophylactic internal fixation of the radial osteocutaneous donor site using the sheep tibia model

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ABSTRACT

Introduction: The strengthening effect of prophylactic internal fixation (PIF) with a bone plate at the radial osteocutaneous flap donor site has previously been demonstrated using the sheep tibia model of the human radius. This study investigated whether a finite element (FE) model could accurately represent this biomechanical model and whether stress or strain based failure criteria are most appropriate.
Methods: An FE model of an osteotomised sheep tibia bone was strengthened using 4 types of plates with unilocking or bicortical screw fixation. Torsion and 4-point bending simulations were performed. The maximum von Mises stresses and strain failure criteria were studied.
Results: The strengthening effects when applying stress failure criteria [factor 1.76–4.57 bending and 1.33–1.80 torsion] were comparable to the sheep biomechanical model [factor 1.73–2.43 bending and 1.54–2.63 torsion]. The strongest construct was the straight 3.5 mm stainless steel unilocking plate. Applying strain criteria the strongest construct was the straight 3.5 mm stainless DCP plate with bicortical screw fixation.
Conclusions: The FE model was validated by comparison with the sheep tibia model. The complex biomechanics at the bone-screw interface require further investigation. This FE modelling technique may be applied to a model of the human radius and other sites.

1. Introduction

The radial osteocutaneous flap is a useful free flap for reconstruction of small bone defects of the maxillofacial skeleton but the incidence of fracture at the donor site has remained relatively high and is typically between 15 and 25% [1–4]. The use of prophylactic internal fixation (PIF) to strengthen the donor site was first described by the author in 1997 [5] and has become increasingly popular over the last decade [6–10]. A straight 3.5 mm steel dynamic compression plate (DCP) has most commonly been used but is bulky, and requires careful adaptation to the bone surface with bicortical screw fixation. The introduction of low profile and anatomically contoured plates, secured by unilocking screw systems which do not require such close adaptation, has expanded the options available for managing fractures of the radius [11,12] and these plates are potentially suitable for PIF.

In biomechanical studies the creation of an osteotomy defect substantially weakens the human radius [13] and sheep tibia model of the radius [14] but the significant strengthening effect of PIF has been demonstrated at both of these sites [6,15,16]. The majority of the weakening effect in previous biomechanical studies has been caused by the creation of a section defect. However, our recent finite element analysis of differing types of osteotomy cut suggests that stress levels may also be substantially decreased (by up to 56%) by refinements in the osteotomy design [17]. Classical laboratory mechanical experiments are time consuming and expensive, whilst access to human tissue is limited. The use of finite element (FE) analysis has become established in bioengineering research in

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Table 1
Plate and screw material data.

	T-plates		Straight plates	
Type of plate	3.5 mm T-plate[a]	2.4 mm T-plate	3.5 mm DCP plate	3.5 mm LCP plate
Thickness	3.5 mm	2.4 mm	3.5 mm	3.5 mm
Plate materials	TiCP	TiCP	18Cr–14Ni–2.5 Mo Stainless steel	18Cr–14Ni–2.5 Mo Stainless steel
Young (GPa)	103	103	186	186
Ultimate tensile strength (MPa)	680	680	480	480
Screw – bone engagement	Unicortical	Unicortical	Bicortical	Unicortical
Screw – plate fixation	Locking[b]	Locking[b]	non-locking[c]	locking[b]
Screw materials	Ti-6Al-7Nb	Ti-6Al-7Nb	18Cr-14Ni-2.5 Mo Stainless Steel	18Cr-14Ni-2.5Mo Stainless Steel
Young (GPa)	105	105	186	186
Ultimate tensile strength (MPa)	900	900	480	480
Screw diameter	2.4 and 3.5 mm	2.4 mm	3.5 mm	3.5 mm

[a] LCP Dia – meta Volar distal radius plate: 3.5 mm contoured shaft with 3.5 mm screws and 2.4 mm distal head with 2.4 mm screws.
[b] FEA simulation with bonded connection.
[c] FEA simulation with friction grip.

general and these techniques are now beginning to be applied to the maxillofacial region [18,19]. The aims of the current study were to validate a FE analysis model of the sheep tibia model of the radius and investigate the suitability of various types of bone plate for PIF of the radial osteocutaneous donor site. The use of the FE technique may then be expanded to include modelling of the human radius.

2. Methods

A computer aided design (CAD) model of a single sheep tibia bone and 4 separate models of bone plates were created. The tibia was a randomly selected from 5 pairs of cadaver bones with similar imaging characteristics. Three plates had unilocking screw fixation systems [titanium T-shaped radial locking compression plates (LCP) in 2.4 mm and 3.5 mm thickness, 3.5 mm stainless steel straight LCP plate] and one plate utilised bicortical screw fixation [3.5 mm stainless steel straight dynamic compression plate (DCP)]. The screws were all simplified to cylinder geometry. A 3.5 mm diameter was applied throughout for the straight 3.5 mm LCP and DCP plates. A 3.5 mm screw diameter was also used along the diaphysial part for the 3.5 mm T-shaped plate and a 2.4 mm screw diameter at the epiphysial component. A 2.4 mm screw diameter was applied throughout for the 2.4 mm T-shaped plate (Synthes, UK) (Table 1).

2.1. Acquisition of bone shape and density data

The tibiae were imaged with a medical grade computerised tomography scanner (Toshiba, Aquilion) during a single sequence using the FC03 algorithm, bidirectional 512 pixel field of view (FOV) with 0.551 mm axial resolution and 0.801 mm slice increment (120 kV, 225 mAs) to yield the highest available spatial resolution.

2.2. Modelling

The DICOM data was imported in to the ScanIP (Simpleware, Exeter, UK) software program for geometrical reconstruction. Surface rendering was undertaken to replicate an outer cortical layer. The reverse engineering method was used to recreate the dimensions of the bone plates using the ProEngineer Wildfire 5 (Parametric Technology Corporation, Needham, MA, US) CAD software.

2.3. Meshing and simulation

A standardised defect of 4 cm length, 40% circumference with 45° sloping end cuts was created in the mid-shaft of the CAD model to simulate a typical osteotomised bone (Fig. 1). The CAD models of the plates, screws and tibia were meshed to form a finite element model composed of 10-node quadratic tetrahedrons. The mesh was imported back in to the ScanIP program for assignment of the material properties to each element, including the cortical and medullary bone. The simulations were run with Marc 2007 (MSC.Software, USA) software.

2.4. Test of convergence of numerical analysis

The sharp edges of the osteotomy cuts within each model created the potential for an infinite level of stress in a linear elastic model. On the other hand rounding at these domains has shortcomings as there are significant variations in clinical practice and measuring or determining an average standardised rounding pattern is impractical. It was necessary to demonstrate that the finite element results converge as the mesh is refined in the vicinity of the edges. For each of the models the initial element range of between 3 mm and 0.3 mm was first refined to 0.2 mm and then 0.1 mm, with the smallest units around the outer and inner corners, and at the osteotomy cuts. Whilst noting that this resolution is potentially below the voxel size of the input scan used for material assignment [0.551 mm × 0.551 mm × 0.801 mm]. The absolute differences in stresses between the refinement steps was less than 15% and the stress distribution patterns were very similar for each model indicating that this was a satisfactory method. At the point where the osteotomy cuts met and were rounded (0.5 mm radius) the element range was further refined in 3 steps down to a 0.05 mm mesh size (Fig. 2). The presented results are collected from the zone of rounded geometry. However, there was less than 5% absolute difference between results when the sharp and rounded geometry values were compared.

2.5. Material properties used in the finite element analysis

The radiographic density values were used for determining the mechanical elastic properties of the model elements. These covered a wide range of density from the relatively porous inner medullary bone to the dense outer cortical shell. The association between bone density (HU) and specific gravity [g/cm^3] was described with a validation procedure. Seven sets of validating cylinders, each containing 3 materials of known density, were included within the imaging FOV and the data processed using ImageJ 1.42q software (Wayne Rashband, National Institute Health, Bethesda, Maryland, USA). The correlation between the relative density of the bone and the HU value of the cylinders was described using a linear regression analysis. The correlation between the HU and the material density [g/cm^3] was defined using Eq. (1). By definition zero HU

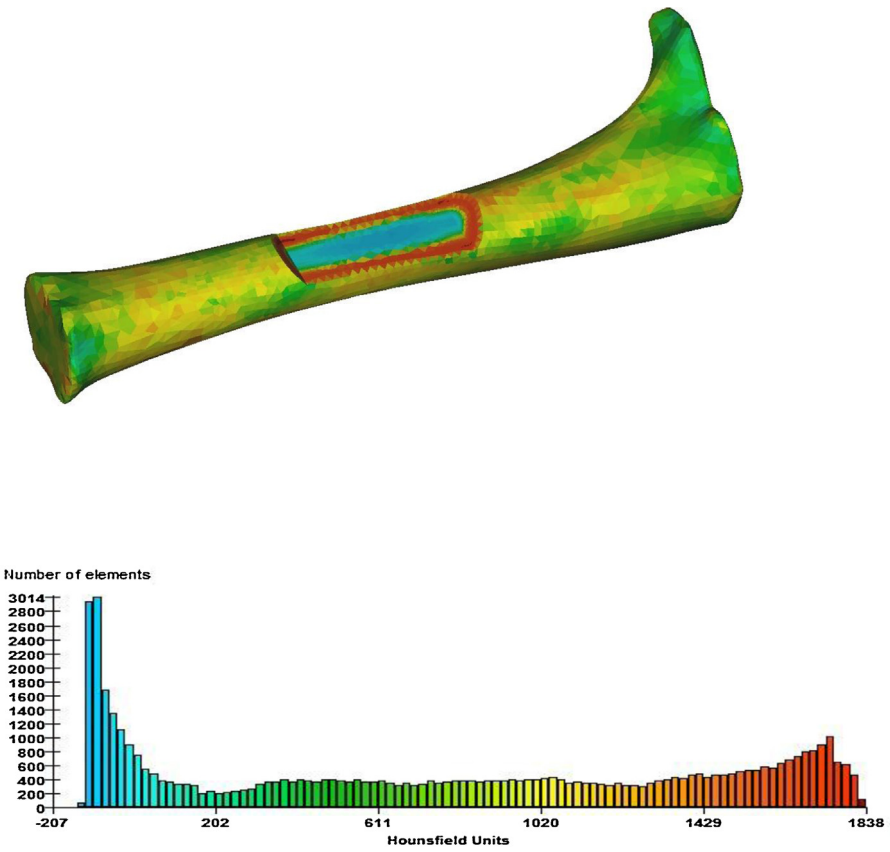

Fig. 1. Simulated osteotomy defect. A standardised simulated osteotomy defect of 40% circumference and 4 cm length with 45° sloping osteotomy end cuts.The bone specimen voxels represented a range from −208 to 1838 HU of the Hounsfield Unit scale. This range was split in to 100 equal width groups and each group marked with a bar on the diagram. The number of elements within each group and the corresponding Hounsfield values are indicated.

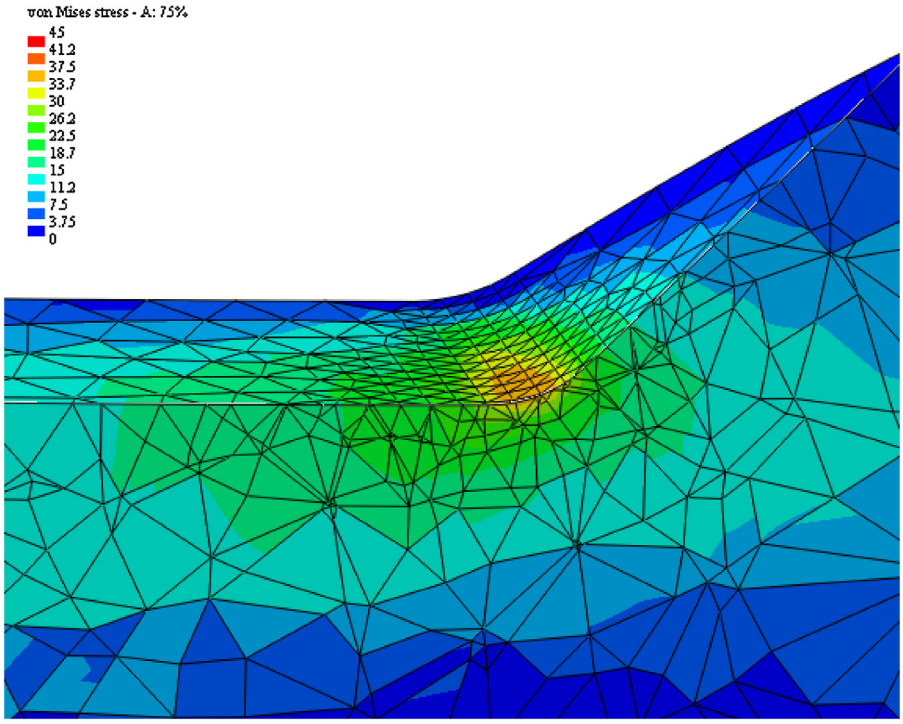

Fig. 2. Refined rounded osteotomy corner of 0.5 mm radius indicating von Mises stress values.

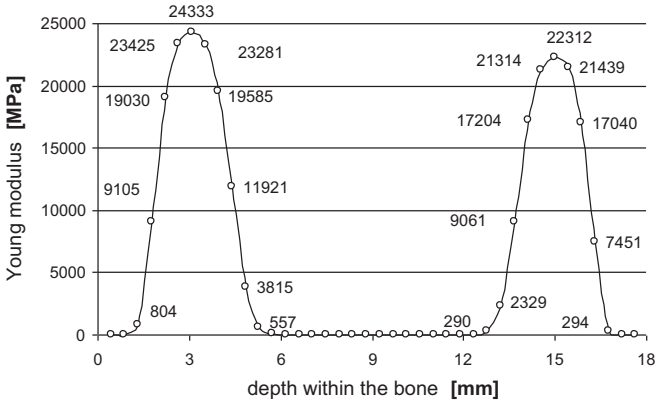

Fig. 3. Bone quality along a line (perpendicular to the surface) at the mid diaphysis of the tibia model based. The inner medullary bone had the same density as water (HU = 0) and has no attributed mechanical strength.

is the radiodensity of distilled water at standard temperature and pressure, and the density of air is −1024 HU.

$$\text{density}\rho = 0.000732 \times \text{HU} + 0.112715\,[\text{g/cm}^3] \quad (1)$$

The linear elastic modulus (E) is related to the bone density (ρ) as described in Eq. (2) [20].

$$E = 10,500 \times \rho^{2.29}[\text{MPa}] \quad [\text{MPa} = \text{Megapascal}\,1 \times 10^6] \quad (2)$$

The full range of the HU scale was equally partitioned in to100 units and the density of each element referred to the matching unit. After this classification the two previously described functions were applied. Isotropic, linear elements composed of non-homogenous tetrahedral units were used. The Poisson ratio was set as 0.3 (Fig. 3). Validation of a real model so that numerical modelling can reproduce a physical simulation is one of the major challenges for all FEA work. In this study the failure trends found in previous laboratory tests were reproduced as a part of this validation. This FE model relied on there being no displacement and a strain based validation which is consistent with classical engineering methodology.

2.6. Assembly interfaces

A bonded connection was used at the bone–screw and plate–screw interfaces with the locking screw system. A friction grip connection was applied at the bone–plate and the screw–plate interfaces using a coefficient of 0.3 [21–23] for the non-locking screw system and was also applied if bone–plate contact occurred during testing of the locking screw fixation system.

2.7. Yield criteria

A linear elastic analysis was performed. The maximum and minimum principal (σ), and von Mises stresses (σ_v) were examined to study which is responsible for the failure of the bones [24]. In addition the maximal principal strain criteria were also applied and these are considered comparable or possibly superior outcomes for predicting failure within bone specimens in some FEA [25,26] One purpose of this study was to test which criteria would be the most representative. Previous biomechanical studies have confirmed that it is the bone, not the plates or screws, which fails under loading [6,15,16].

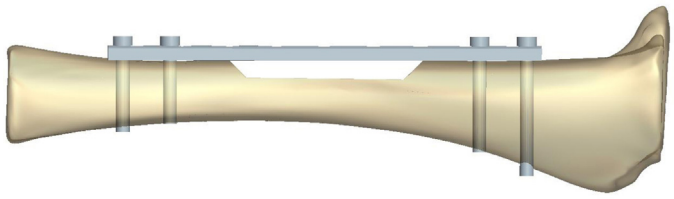

Fig. 4. Conventional 3.5 mm steel plate over defect (anterior position) with 2 bicortical screws at each end in a non-compressive position. This is the minimum number of screws required for stability.

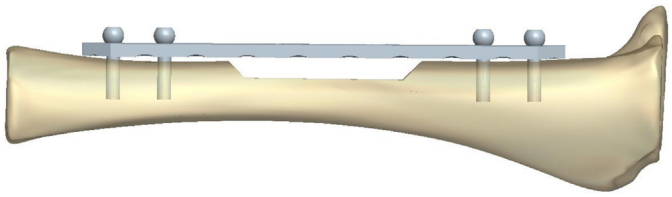

Fig. 5. Straight 3.5 mm plate with unilocking screw fixation.

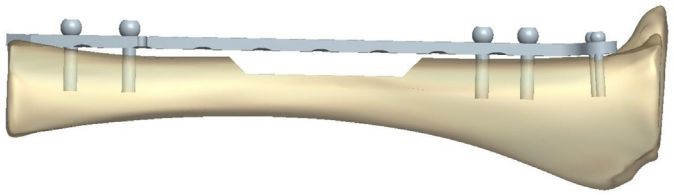

Fig. 6. T-shaped titanium plate over defect (anterior position) with two unicortical screws either side of the section defect and within the T-shaped end.

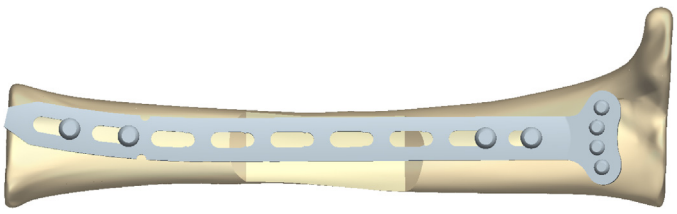

Fig. 7. Overview of T-shaped titanium plate over the defect and in the anterior position.

2.8. Test simulations

The following models were tested; intact bone, osteotomised bone and osteotomised bone reinforced with each of the different plate options placed over the section defect (Figs. 4–7). Two standard loading modes, 4-point bending and torque were used to compare the plate designs. Loading patterns in clinical practice will vary with each individual patient but the combination of bending and torsion in different proportions can reproduce many actual scenarios. Although, it can be argued that compression with bending referred to as eccentric compression and torsion at the screws are more representative.

The torque test was performed with a 5 Nm load applied whilst one end of the model was immobilised and a 30 Nm (1000 N) load was applied for the 4-point bending compression test (Fig. 8). The magnitude of the loads were set to obtain von Mises stress values known to coincide with the limits of the structural integrity of bone [27]. Data for the maximum principal stress values were also collected. The plates which generated the lowest von Mises stress values are potentially the strongest forms of reinforcement.

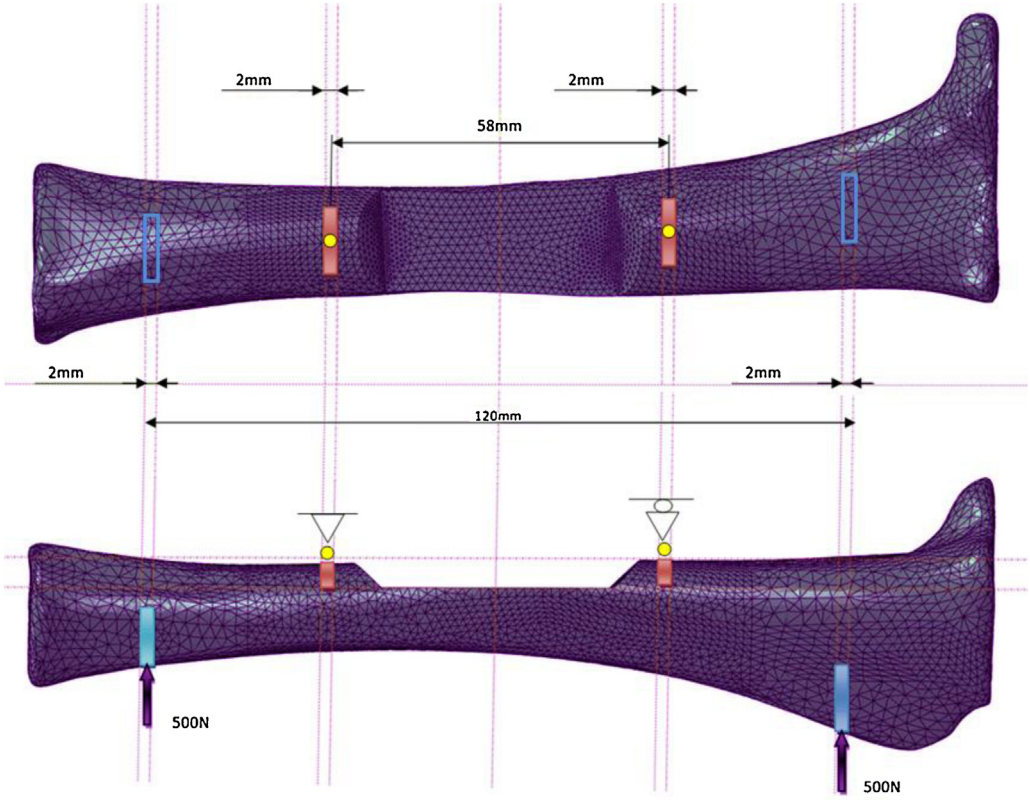

Fig. 8. Boundary conditions and loads on the osteotomised tibia model under 4-point bending.

2.9. Data analysis

To allow comparison between the differing types of construct the results were analysed by Rank Order as only a single bone model was used. The relative strengthening effect of a bone plate construct was calculated by dividing the maximum von Mises stress value of the osteotomised control sample by the maximum von Mises stress value for the construct within the osteotomy region. Similar calculations were performed for the strain results.

3. Results

Under both torsion and 4 point bending the peak von Mises stresses accumulated at both of the end angles of the osteotomy defect and around the screws closest to the defect (Fig. 9, Table 2). This is consistent with previous biomechanical studies of the sheep tibia model [15,16]. The original laboratory testing suggested that the constructs would not fail around the screws next to the resection. This meant that the detailed screw geometry of this domain could be ignored as stress and strain levels distant from this site would not be compromised. Although, an increase in the mechanical strength at the osteotomy site may change this relationship [17] and raise the possibility of shifting the site of failure towards the screw–bone interface (Fig. 10).

The stress results are tabulated in Tables 2 and 3 and represented in Fig. 11. The maximum von Mises stress values of the intact control bone at the osteotomy sites were relatively low when compared to the osteotomised bone model under 4-point bending loads (35 MPa compared with 169 and 205 MPa) and torsional loading (13 MPa compared with 249 and 292 MPa) indicating the substantial weakening effect of an osteotomy (Table 2).

3.1. 4-Point bending tests

The intact bone model had maximum von Mises stress values of 35 MPa, while the osteotomised bone had values of 205 MPa respectively. For the reinforced bones the highest stress values in descending order were; straight 3.5 mm DCP (96 MPa), 3.5 mm T-plate (53 MPa), 2.4 mm T-plate (50 MPa), and 3.5 mm straight LCP (37 MPa) (Table 2). The higher von Mises stress values around the screws (Labels 1 and 2, Fig. 9) must be interpreted with caution due to the limitations of the bonded connection modelling used at the bone-screw interface. The 3.5 mm T-plate had a marginally greater stress value at the osteotomy site than the 2.4 mm plate (53 MPa compared with 50 MPa) but the stress values at the screw sites were much lower (134 MPa and 206 MPa) hence the 3.5 mm T-plate was ranked above the 2.4 mm T-plate (Table 3).

3.2. Torsion tests

The intact bone model had maximum von Mises stress values of 13 MPa, while the osteotomised bone had a value of 292 MPa. For the reinforced bones the highest stress values in descending order were; 2.4 mm T-plate (220 MPa), 3.5 mm T-plate (184 MPa), straight, straight 3.5 mm DCP (173 MPa) and 3.5 mm straight LCP (163 MPa) (Table 2). In contrast to the 4-point bending simulation the highest stress values were around the base of the osteotomy cut (Labels 3 and 4, Figs. 9 and 10).

3.3. Decreased preload testing of the DCP plate

The preload values applied for the DCP plate were 400 N on each individual screw in the initial 4-point bending and torsion tests. The preload may alter the effectiveness of the DCP so these simulations were repeated with a lower value of 50 N. The greater of the peak stresses around the screw closest to the osteotomy defect, on each

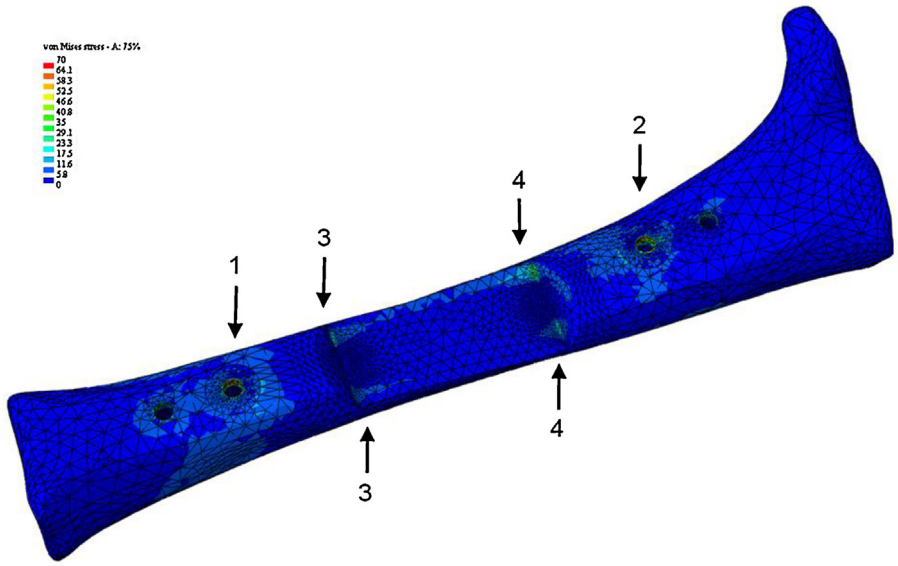

Fig. 9. The regions of peak von Mises stress concentration within the reinforced construct around the screws or at the angle of the base of the osteotomy site.

side, with a preload of 50 N [103 and 76 MPa] were lower than at 400 N [160 and 54 MPa] under torsion. The peak stress values under 4-point bending with a preload of 50 N [111 and 206 MPa] were also lower than with a 400 N preload [199 and 358 MPa] (Table 2).

At the osteotomy sites, at either end of the defect, the peak stress under torsion with a preload of 50 N [173 and 156 MPa] was similar to that with a 400 N preload [138 and 159 MPa]. The peak stress values under 4-point bending with a 50 N preload [83 and 96 MPa] were lower than with a 400 N preload [54 and 67 MPa) (Table 2).

3.4. Strain criteria

The strain results for rank order are similarly presented in Tables 2 and 4 and Fig. 12 for comparison.

3.5. Strongest construct

When assessed using stress criteria the strongest form of reinforcement under both 4-point bending and torsional loading was the 3.5 mm straight stainless steel LCP unilocking plate. If strain criteria were applied the 400 N preloaded 3.5 mm straight stainless steel DCP plate was the strongest (Tables 3 and 4).

4. Discussion

The introduction of PIF has revolutionised the management of the radial osteocutaneous donor site. A variety of plates, most commonly the straight 3.5 mm steel DCP with bicortical fixation, have been used in either the anterior (over defect) or posterior (on opposite cortex) positions. A relatively low overall fracture rate of 2.6% (7/268 donor sites) has been reported with PIF [7–10,28]. Despite initial concerns about stress shielding and the risk of late fracture less than 1% (2/268) of the plates reportedly inserted have been removed [4]. We routinely use the anterior surgical approach and this is the position which was investigated in this study.

The 3.5 mm DCP plate is effective but not ideal as it is bulky and requires a minimum of two bicortical screws at each end, which may be impractical when space is limited. Developments in plate design have included lighter and thinner titanium or steel plates with limited contact areas to reduce the risk of osteopenia and stress shielding [29]. Bone is more flexible than either stainless steel

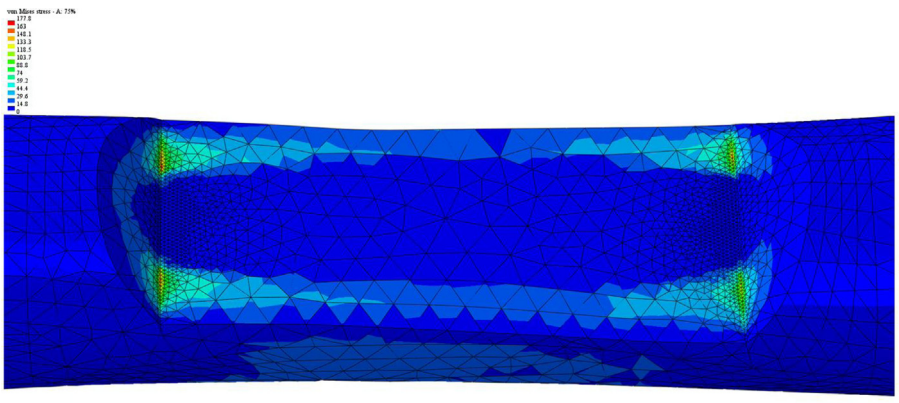

Fig. 10. The distribution of peak von Mises stress values around base of osteotomy cut under torsion testing of a 3.5 mm straight LCP plate.

Table 2
Finite element model constructs tested under 4-point bending and torsional loads.

Stress (MPa)	4-Point bending – 30 Nm				Torque – 5 Nm			
	vM	S1 (max)	S3 (min)	strain	vM	S1 (max)	S3 (min)	Strain
3.5 mm T-plate								
Region 2 – screw	112	−11	−133		56	−4	−66	
Region 4 – osteotomy	53	59	3	0.0054	158	168	−1	0.025
Region 1 – screw	134	−18	−163		88	110	12	
Region 3 – osteotomy	42	0	−45	0.0059	184	201	5	0.018
2.4 mm T-plate								
Region 2 – screw	109	−19	−138		43	−2	−49	
Region 4 – osteotomy	50	0	−54	0.0052	195	−10	−217	0.022
Region 1 – screw	206	−72	−292		107	159	49	
Region 3 – osteotomy	34	0	−37	0.0051	220	240	6	0.03
3.5 mm straight LCP plate								
Region 2 – screw	119	−29	−160		82	−10	−98	
Region 4 – osteotomy	37	41	1	0.0024	134	−7	−149	0.015
Region 1 – screw	96	6	−101		95	92	−16	
Region 3 – osteotomy	20	21	0	0.0015	163	176	2	0.02
3.5 mm straight DCP plate (400 N preload)								
Region 2 – screw	359	484	103		54	69	10	
Region 4 – osteotomy	67	0	72	0.0019	159	−9	−177	0.01
Region 1 – screw	199	264	49		160	215	46	
region 3 – osteotomy	54	−1	−59	0.0017	138	151	4	0.018
3.5 mm straight DCP plate (50 N preload)								
Region 2 – screw	206	298	81		76	−7	−90	
Region 4 – osteotomy	96	1	−103	0.0026	156	−9	−174	0.015
Region 1 – screw	111	147	28		103	136	23	
Region 3 – osteotomy	83	−1	−90	0.0027	173	187	2	0.021
Intact bone–control	35	37	1		13	8	−7	35
Osteotomised bone–control								
Region 4 – osteotomy	169	1	−181	0.0051	249	−13	−276	0.03
Region 3 – osteotomy	205	−3	−223	0.007	293	319	8	0.04

vM – von Mises stress; S1 – 1st principle stress; S3 – 3rd principle stress.
Regions 1 and 2 – screws nearest to osteotomy (Fig. 8).
Regions 3 and 4 – angle at base of osteotomy defect (Fig. 8).

Table 3
Rank order of relative strengthening effect of model constructs under 4-point bending and torsional loads – stress values.

4-Point bending			Torsional loads		
Rank order	Type of plate	Strengthening factor v osteotomisedbone[a]	Rank order	Type of plate	Strengthening factor v osteotomisedbone[a]
1	3.5 mm straight LCP	4.57	1	3.5 mm straight LCP	1.80
2	3.5 mm T-plate [b]	3.19	2	3.5 mm straight DCP (50 N preload)	1.69
3	2.4 mm T-plate [b]	3.38	3	3.5 mm straight DCP (400 N preload)	1.57
4	3.5 mm straight DCP (50 N) c	1.76	4	3.5 mm T-plate	1.59
5	3.5 mm straight DCP (400 N) [c]	2.52	5	2.4 mm T-plate	1.33

[a] The maximum von Mises stress value of the osteotomised control sample divided by the maximum von Mises stress value for the construct within the osteotomy region.
[b] The 3.5 mm T-plate strengthening factor was slightly lower than the 2.4 mm T-plate but the von Mises stress values at the screw-bone interface were significantly higher with the 2.4 mm T-plate so it has been ranked down.
[c] Similar considerations were applied with the 3.5 mm straight DCP 50 N and 400 N preload values

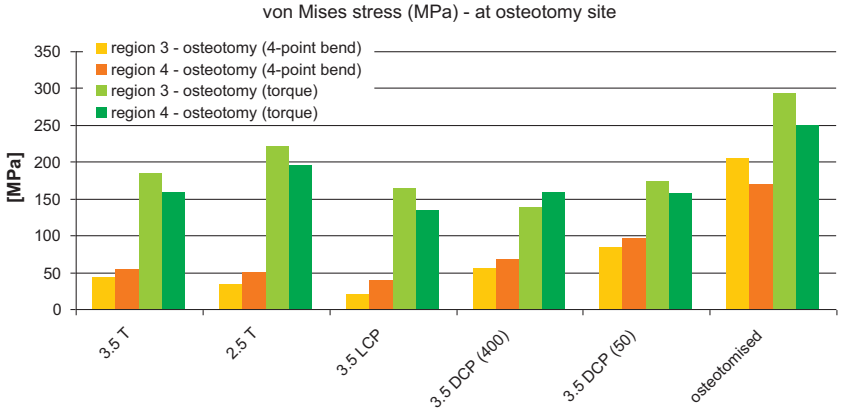

Fig. 11. Finite element model constructs tested under 4-point bending and torsional loads – stress values.

Table 4
Rank order of relative strengthening effect of model constructs under 4-point bending and torsional loads–Strain criteria.

4-Point bending			Torsional loads		
Rank order	Type of plate	Strengthening factor v osteotomised bone[a]	Rank order strain based	Type of plate	Strengthening factor v osteotomised bone[a]
1	3.5 mm straight DCP (400 N)	3.68	1	3.5 mm straight DCP (400 N preload)	2.22
2	3.5 mm straight LCP	2.92	2	3.5 mm straight LCP	2.00
3	3.5 mm straight DCP (50 N)	2.59	3	3.5 mm straight DCP (50 N preload)	1.90
4	2.4 mm T-plate	1.35	4	3.5 mm T-plate	1.60
5	3.5 mm T-plate	1.19	5	2.4 mm T-plate	1.33

(E 186 GPa) or titanium (E 110 GPa) [30] but titanium plates may have less of a stress shielding effect because the elastic modulus and structural stiffness is closer to that of bone, which should allow greater sharing of the load [30,31]. Other improvements include anatomical contouring and unilocking screw systems which do not require such close adaptation and offer greater angular stability in osteoporotic bone [11,12]. We recently studied the biomechanical effectiveness of the straight 3.5 mm DCP plate and new T-shaped plates using the sheep tibia model [16] and reported their use in a small clinical report [32]. All of the plates in this biomechanical study significantly strengthened an osteotomised bone by a factor of 1.73–2.43 times in bending and 1.54–2.63 times in torsion. The lighter 2.4 mm T-plate was the weakest construct. The strongest reinforcements in bending and in torsion respectively were the 3.5 mm T-plate and 3.5 mm DCP plate. The 3.5 mm LCP plate with a unilocking system and the DCP with a high (400 N) preload were not tested in that study [16].

The use of FE modelling provides a deeper understanding of the interactions between the bone and differing types of reinforcement. The technique is not susceptible to the inherent variation in quality of bone specimens but it remains just a simulation. The quality of the modelling and characteristics of the boundary conditions are important factors which influence outcomes and must be controlled. The modelling of the load bearing structure of the skeleton may utilise various strategies for volumetric model generation, meshing protocols and utilising different types of elements [33,34]. A reasonable simplification in this study was to assign mechanical parameters to the FE mesh for an isotropic, rather than anisotropic, model whereby a single Young modulus (E) with a single Poisson ratio was used without directional privilege.

Although, bone behaves as an anisotropic composite material the cortical layer of a long bone demonstrates directionally dependent elasticity with transverse isotropic or orthotropic behaviour. Whilst along the longitudinal axis the ultimate tensile strength and Young modulus are greater, the transverse and radial directions have minimal variations. The impact of directionally dependent elastic modulus factors on macroscopic loading values varies by up to 40% [35,36]. This simplification of the isotropic model may change the depth and direction of stress penetration, and ultimately the orientation of fracture formation. More sophisticated CT derived apparent density dependent techniques are available but the visco-elastic and anisotropic features are rarely used [18,20,37,38]. Although the maximum principal strength (maximum tensile stress among all possible directions) is also related to bone failure, by representing the initiation of crack formation, this study has primarily utilised maximum von Mises stress values which indicate the onset of plastic yielding. The impact on strain levels was also studied for comparison and in some scenarios the strain criteria appear more representative than the principle or von Mises stress values.

To create an anatomically realistic model it is important to have mechanically distinct cancellous and outer cortical bone elements as bone is not homogenous. There are also variations in the boundary conditions applied in other studies and these may benefit from optimisation. The quasi-static conditions used in this experiment are more commonly applied when testing bone–implant interactions but the response of bone differs under dynamic loading. These differences may be addressed by altering the visco-elasticity of the loading rate. Essentially, higher compressive and yield strengths with lower fracture toughness are seen when dynamic tests are performed [39]. An optimal range of mechanical stability during the healing phase is important to avoid abnormal bone union. Some mechanical stimulation is necessary for cellular proliferation and remodelling [40–45]. The optimised range varies with age but in general rigid fixation is more effective in younger patients whilst semi-rigid fixation is more appropriate for older patients [46].

In this FE model the intact bone was much stronger than the osteotomised bone. The 3.5 mm unilocking LCP plate provided the strongest form of reinforcement under both bending and torsional loading, regardless of whether the von Mises or the maximal principal stress concepts are applied, as this construct can bear loads in a relatively rigid manner. The straight 3.5 mm DCP, with bicortical screw fixation, was almost as strong under torsional loads but was weaker under bending loads. However, the DCP construct was

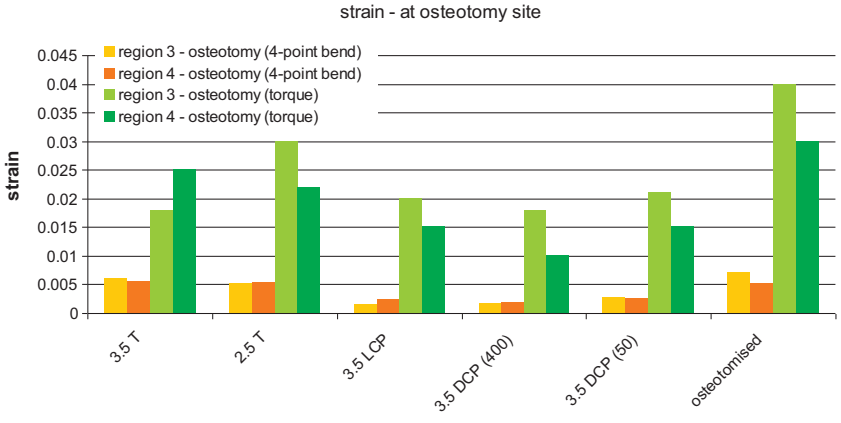

Fig. 12. Finite element model constructs tested under 4-point bending and torsional loads – strain values.

strongest if just strain criteria are considered. The higher preload value had an adverse effect on the von Mises stress values around the bone–screw interface and the biomechanics of this interface are not fully understood. The ideal torque value for screw fixation is unknown and a 400 N preload may represent the effect of over-tightening.

The FE simulation results for the torsion testing were more continuous than those for 4-point bending and this makes them more reliable. This is supported by the relatively higher von Mises stress values seen around the osteotomy cuts rather than at the bone–screw interface, and failure less likely at the latter site. In contrast with 4-point bending the highest stress values occurred around the screws. This model assumed a perfect bond without limiting the connection to a maximum stress value to create a more linear model but under normal loading conditions the connection between the bone and screw loosens at peak stress and results in a more dynamic non-linear interface as sharing of the load occurs over a larger surface area. The cohesive forces between the bone–screw surfaces are likely to be overwhelmed resulting in separation, loosening and crack propagation or simply shearing and rapid decreasing of stress levels. Ultimately this simplification does not fundamentally alter the rank order of the plates but does highlight the need for a better understanding of the bone–screw interface.

The previous biomechanical study [16] had comparable outcomes to the FE analysis with some variations. The potential confounding factors include; (1) the utilisation of isotropic rather than orthotropic Young moduli distribution for each element; (2) the bonded connection rather than a cohesive connection at the bone–screw interface and (3) the difficulties in modelling the non-locking DCP system. The magnitude of the strengthening was affected by factors (1) and (2). The FE result showed relatively greater strengthening effect in the 4 point bending tests and less under torsional loading. The sheep tibia withstands greater bending than torsional loads and all plates had a demonstrable strengthening effect which ranged from a factor of 1.73–2.43 under bending loads [FE analysis factor 1.76–4.57 stress based and 1.19–3.68 strain based] and 1.54–2.63 under torsional loading [FE analysis factor 1.33–1.80 stress based and 1.33–2.22 strain based] [16]. Unlike the previous sheep biomechanical experiment we did not include simulation of a posteriorly positioned plate (on the intact cortex). The cause of most fractures in clinical practice is thought to be torsional loading and this most commonly results in failure within the osteotomy site, either at the end cut or within the section defect. This is consistent with the findings in our sheep biomechanical study [16] and the current FE analysis. The 3.5 mm straight mm LCP plate (not tested in sheep experiment) was slightly stronger in this FE model than the 3.5 mm straight DCP plate when applying the stress level criteria. The lesser strengthening effect of the DCP system may be the result of all three factors (1, 2 and 3). Although with a high preload (400 N) this performed better to reduce strain levels at both osteotomy sites.

5. Conclusions

The most appropriate plate currently available for PIF may be the straight 3.5 mm LCP plate if the stress analysis is preferred but when applying strain criteria the straight 3.5 mm DCP is stronger and showed similar results to our previous biomechanical testing. This study confirms that the current FE model satisfactorily represents the main features of the sheep tibia model but it is not an exact replication of the clinical situation as many other factors also apply. For example; variation in anatomy, type of osteotomy, the number and position of screws inserted. The tibia is also relatively short and stout when compared to the human radius and is not an ideal shape for the anatomically contoured plates, which may function better on the human radius. The stress within the region of the osteotomy defect depends mainly on the characteristics of the bone model and these factors are relatively well understood. However the stresses around the bone-screw interface and the effect of loosening would benefit from further investigation and mechanical testing.

One central issue which still needs to be resolved for all similar studies is the choice of failure criteria applied for bone when using a finite element analysis. It is inconclusive from the literature whether bone should be treated as primarily a brittle material with the maximum stress indicating the onset of cracking or considered a more ductile material, in which case the von Mises stress value controls the onset of plastic deformation. In this FE analysis there was little difference between the von Mises stress values and the largest principle stress values (S1 and S3), and the other principle stress values were much smaller. These findings indicate that controlled loading created stress conditions with a single dominant principle stress in which a substantial difference between the von Mises and principle stress values would not occur or allow discrimination between these failure criteria. Although it was our expectation that the stress failure criteria would be more reliable when comparing strengthening effects it may be that rank ordering using strain criteria may be more appropriate.

In future the FEA method may be refined and applied to a model of the osteocutaneous radial donor site based on human CT data. This will allow the finite element model to be used to simulate realistic loading under clinical conditions for both the intact, fractured and osteotomised radius. It also has implications for developing models of other anatomical sites such as the human mandible.

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Ethical statement

Ethical approval was not required for this study.

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Conflict of interest statement

None declared.

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Refinements in osteotomy design to improve structural integrity: a finite element analysis study

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Abstract

Osteotomy cuts are typically made using a saw, and the meeting point acts as a focus for the concentration of stress and failure. We have studied the impact of different designs of osteotomy cut. Cadaver sheep tibias were scanned by computed tomography (CT) and transformed into a computer-aided design (CAD) model. A standard marginal resection defect was created and then modified, and a finite element analysis made. The relative stress concentrations at the intersection of osteotomy cuts were recorded using principal stresses S1, S3, and von Mises stress, von Mises under both 4-point bending and torsion testing. The osteotomy designs studied were: right-angled and bevelled osteotomy end cuts, overcutting, and a stop drill hole. Peak stress values for 4-point bending and torsion were 24–30% greater at the right-angled osteotomy than the bevelled end cut. Overcutting dramatically increased peak stress values caused by bending and torsion by 48% and 71%, respectively. Substantially lower concentrations of stress were noted with a stop hole using both a 90° (bending 38% and torsion 56%), and a tangential (bending 58% and torsion 60%) cut. A bevelled osteotomy has substantially lower concentrations of stress than a right-angled osteotomy. It is important to avoid creating an overcut as this causes an appreciable increase in the concentration of stress, while a stop drill hole substantially reduces the stress. The creation of a stop hole and the use of judicious bevelling techniques are modifications in the design of an osteotomy that are readily applicable to surgical practice.

Keywords: Osteotomy; Overcut; Stop hole; CAD model; Finite element analysis; Sheep tibia; Radius; Morbidity

Introduction

The creation of a defect in a section of bone is a common surgical procedure. The osteotomy cuts are typically created using a saw, and are primarily in a linear plane. The meeting point of two cuts acts as a focus for the concentration of stress, and under loading this area is prone to cracks and failure, particularly if there is an overcut.

In maxillofacial oncological surgical practice these issues affect mainly resection of the mandible and the

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radial osteocutaneous free flap donor site. The marginal mandibulectomy is used for resection of a tumour or, occasionally, osteomyelitis. Retention of an intact mandible is particularly important to retain function and cosmesis when complex reconstruction of a segmental defect is not appropriate. The mandible is most susceptible to fracture, usually in the posterior body, when the height of the remaining bone is less than 10 mm,[1–5] and a marginal mandibulectomy is usually unsuitable when the resection extends below the mandibular canal.[6–9] The incidence of fracture has remained relatively high at the radial osteocutaneous donor site, and typically ranges from 15% to 25% unless the remaining radius is supported by prophylactic internal fixation with a bone plate at the time of the initial operation.[10]

Various techniques may be used to improve the design of the section defect. Bevelling the osteotomy cuts has been reported to have a marginal strengthening effect, and rounding out the corners will reduce the creation of foci of concentration of stress.[4,5,10,11] The "stop drill hole method" has been used to block the propagation of existing crack lines during the maintenance of aircraft and in wider mechanical engineering practice,[12,13] but is not commonly applied in surgical practice. In previous biomechanical studies in which we used the sheep tibia model of the radius, we described the important strengthening effect of the various plates available for prophylactic internal fixation.[14,15] Since then we have applied the finite element analysis technique[1,3] to a computer-aided design (CAD) model of sheep tibia to reproduce these experiments and validate the technique.[16] In the present study we have used it to quantify the relative weakening effects of different types of osteotomy, and we propose refinements in surgical practice.

Materials and methods

Models and simulation

The bone CAD model was prepared similarly to previous models.[1,3] Representative samples of cadaver sheep tibias were scanned with a multidetector computed tomography (CT) scanner (Toshiba, Aquilion) using the highest available spatial criteria of 0.551 mm axial resolution and 0.801 mm slice increment (120 kV, 225 mA s). For same-time online validation of the image and field of view we used ImageJ 1.42q software (Wayne Rashband, National Institute Health, Bethesda, MD, US). The output data were converted into a high definition CAD model using Scan IP (Simpleware, Exeter, UK) visualisation software, ProEngineer (Parametric Technology Corporation, Needham, MA, US), and Catia (Simulia, Providence, RI, US) CAD systems. The numerical analysis was made using ABAQUS (Simulia, Providence, RI, US) finite element measurement software. The spatial resolution of the regions of the osteotomy cuts were refined in multiple sequential steps by decreasing the size of the internodal distance (varying from 0.2 to 0.1 mm) until there was less than a 5% of difference in stress values compared with the previous step.

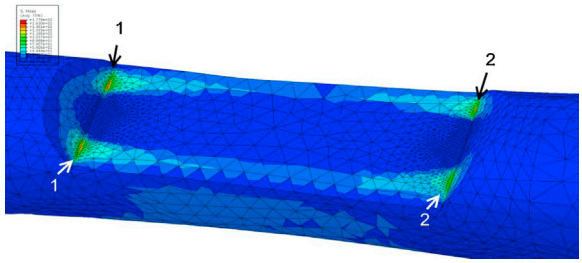


Fig. 1. Bevelled osteotomy with regions 1 and 2 identified at the confluence of the end cuts of the osteotomy.

The stress concentrations in terms of the principal stresses (S1, S3) and von Mises stress at the point of contact of the osteotomy cuts were recorded using pure nodal results for 4-point bending and torsion, respectively. The cut osteotomy ends were labelled as regions 1 and 2 (Fig. 1). Relatively increased von Mises and principal stresses (1st and 3rd) indicate greater concentrations of stress and are more likely to indicate potential sites of failure.

Osteotomy design

A standard resection defect 4 cm long and 40% in circumference was created in the midshaft of the tibia CAD model. Two basic variations of osteotomy design were studied: a right-angled and a 45° bevelled osteotomy end cut (Fig. 2a and b). We then created overcutting defects to mimic two common surgical errors. The first was a parallel overcut at a right-angled osteotomy, which affected both cortices equally, and the second was an oblique overcut at a bevelled osteotomy that affected just one cortex. The depth and width of the overcuts were 2 mm and 1 mm, respectively (Fig. 2e and d). We also tested the strengthening effects of two sizes of stop hole. A stop hole 5 mm in diameter was engaged tangentially to the perimeter and a 2.5 mm diameter stop hole was engaged at 90° (Fig. 2e and f).

Results and analysis

The highest peak nodal stress values were seen at the confluence of the osteotomy end cuts in regions 1 and 2 (Fig. 1). These sites have been compared as they indicate the most likely sites of failure.[14,15] The absolute nodal stress values (MPa) are shown in Table 1. The relative stress values (%) for each of the osteotomy designs are also compared against baseline values of 100% for the bevelled and right angled osteotomy cuts (Tables 2 and 3). In general the highest levels of stress were induced at region 2 in nearly all the simulations under both 4-point bending and torsion testing.

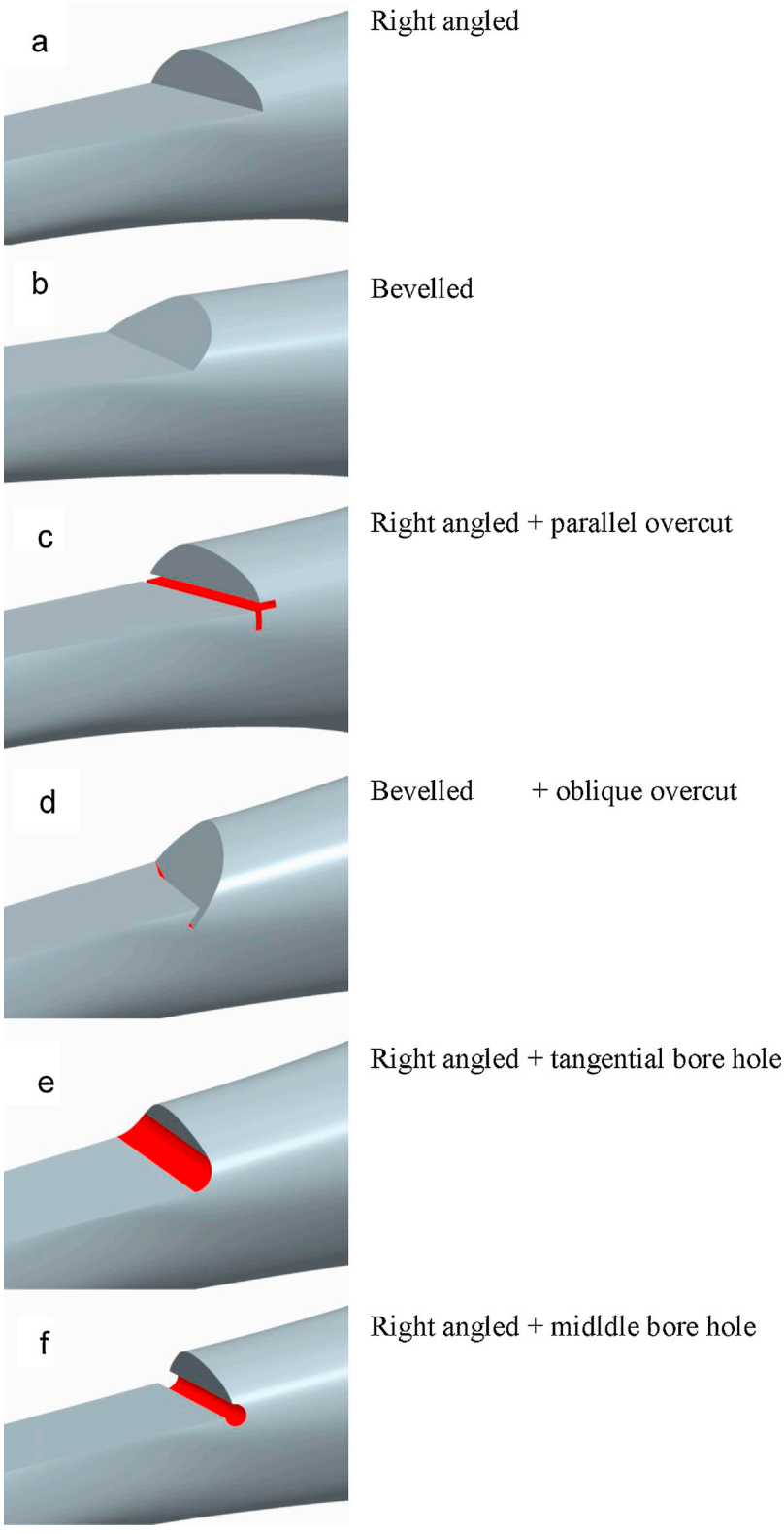


Fig. 2. Computer-aided design (CAD) model of different osteotomy defects.

Table 1
Regional peak nodal stress values (MPa) at different types of osteotomy site under bending and torsional loads.

Type of osteotomy	Bending (MPa)						Torsion (MPa)					
	Region 1			Region 2			Region 1			Region 2		
	vM	S1	S3	vM	S1	S3	vM	S1	S3	vM	S1	S3
A Right-angled	268	−17	−309	357	−33	−421	442	−43	−514	545	646	64
B Bevelled	216	−24	−257	272	−44	−333	309	−51	−376	382	479	75
C Right-angled + parallel overcut	275	−29	−327	319	−60	−397	277	295	7	322	383	54
D Bevelled + oblique overcut	423	−119	−566	465	−85	−585	520	−74	−634	565	707	100
E Right-angled + tangential bore hole	126	1	−130	151	−2	−157	196	−2	−203	219	227	3
F Right-angled + middle bore hole	184	−8	−198	221	−2	−235	204	209	−1	239	253	8

Vm = von Mises; S1 = 1st principal stress; and S3 = 3rd principal stress.

Table 2
Comparison of relative peak nodal stress values at different types of osteotomy site with bevelled baseline (100%).

Sub model examination	Bending		Torque	
	Region 1	Region 2	Region 1	Region 2
Relative strength (% compared with B: bevelled)				
Type of osteotomy				
A Right-angled	124	131	143	143
B Bevelled	100	100	100	100
C Right-angled + parallel overcut	127	117	90	84
D Bevelled + oblique overcut	196	171	168	148
E Right-angled + tangential bore hole	58	56	63	57
F Right-angled + midldle bore hole	85	81	66	63

For example, under bending loads at region 2 the bevelled type of osteotomy (B) the peak nodal von Mises stress value has been assigned as the baseline value of 100% to compare the different kind of osteotomy at the same region. The comparable relative peak stress value at region 2 for the right-angled osteotomy is 31% higher (131%).

Four-point testing

The highest level of von Mises stress values at the right-angled osteotomy was 31% greater than at the bevelled osteotomy (357 MPa compared with 272 MPa) (Fig. 3a and b). This stress at the right-angled osteotomy and with a parallel overcut was 11% less than without an overcut (319 MPa compared with 357 MPa) (Fig. 3a and c). This stress was 71% greater at the bevelled osteotomy with an oblique overcut than without an overcut (465 MPa compared with 272 MPa) (Fig. 3b and d). These stress values at the bevelled osteotomy with an oblique overcut were 46% higher than at the right-angled osteotomy site with a parallel overcut (465 MPa compared with 319 MPa) (Fig. 3c and d).

The highest level of von Mises stress values at the right angled osteotomy with a stop hole was lower than without a stop hole; 58% lower with a tangential cut (151 MPa compared 357 MPa) (Fig. 3a and e), and 38% lower with a 90° cut (221 MPa compared with 357 MPa) (Fig. 3a and f). The values with a tangential cut were 31% less than with a 90° cut (151 MPa compared with 221 MPa) (Fig. 3e and f).

Overall, the lowest von Mises stress value was seen with the right-angled osteotomy with a tangential cut into a stop hole (151 MPa) (Fig. 3e).

Torsion testing

The highest level of von Mises stress values at the right-angled osteotomy was 43% greater than at the bevelled osteotomy (545 MPa compared with 382 MPa) (Fig. 3a and b). This stress at the right-angled osteotomy with a parallel overcut was 41% lower than without an overcut (322 MPa

Table 3
Comparison of relative peak nodal stress values at different types of osteotomy site with right angled baseline (100%).

Sub model examination	Bending		Torque	
	Region 1	Region 2	Region 1	Region 2
Relative strength (% compared with A: right angled)				
Type of osteotomy				
A Right-angled	100	100	100	100
B Bevelled	81	76	70	70
C Right-angled + parallel overcut	103	89	63	59
D Bevelled + oblique overcut	158	130	118	104
E Right-angled + tangential bore hole	47	42	44	40
F Right-angled + midldle bore hole	69	62	46	44

compared with 545 MPa) (Fig. 3 a and c), but it was 48% greater at the bevelled osteotomy with an oblique overcut rather than without an overcut (565 MPa compared with 382 MPa) (Fig. 3b and d). The stress values at the bevelled osteotomy with an oblique overcut were 75% higher than at the right-angled osteotomy site with a parallel overcut (565 MPa compared with 322 MPa) (Fig. 3c and d).

The von Mises stress values at the right-angled osteotomy with a stop hole were lower than without a stop hole, 60% lower with a tangential cut (219 MPa compared 545 MPa), and 56% lower with a 90° cut (239 MPa compared with 545 MPa) (Fig. 3a and e). The comparable stress values with a tangential cut were 8% less than with a 90° cut (219 MPa compared with 239 MPa) (Fig. 3e and f). Overall, the lowest von Mises stress value was seen with the right-angled osteotomy with a tangential cut into a stop hole (219 MPa) (Fig. 3e).

Discussion

The results of this study are applicable to many aspects of maxillofacial surgical practice. The radial osteocutaneous free flap retains a role for the reconstruction of bony defects of the maxillofacial skeleton, but the incidence of fracture at the conventional donor site remains relatively high and is typically between 15% and 25%.[8,17,18] A displaced fracture causes appreciable morbidity,[19] and this is one factor that has contributed to a decline in the popularity of the osteocutaneous flap.[8]

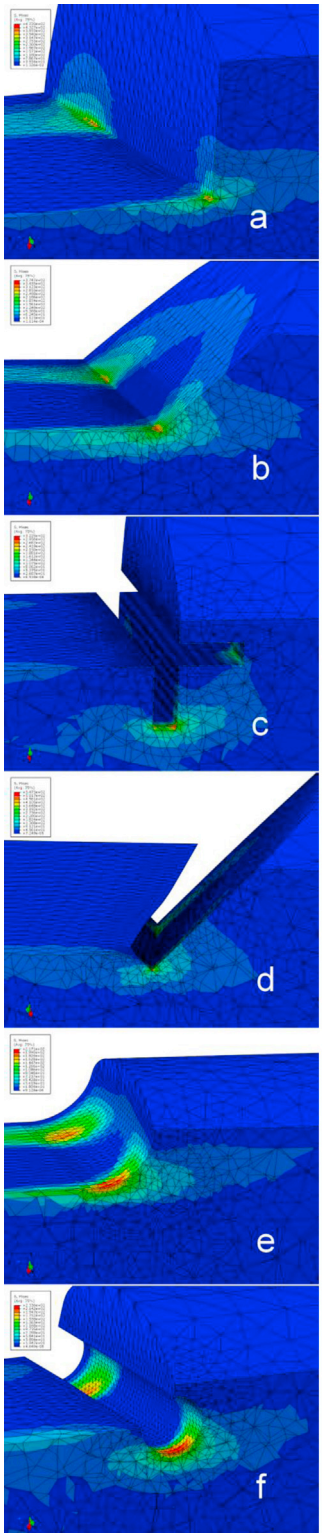
A bevelled rather than a right-angled osteotomy has been recommended for two reasons. Firstly, it may reduce the weakening effect of the section defect, and secondly it allows better visualisation of the osteotomy cut, so that overcutting is less likely.[10,11] In a previous biomechanical study, in which the sheep tibia model of the human radius was also used, the level of reduced "stress concentration" at a bevelled osteotomy was only 5% less than with a right-angled osteotomy under torsional loading.[10,11] In a biomechanical study of the human radius there was a trend towards greater strength with a bevelled osteotomy under 4-point bending, but the result was not significant.[11] These effects are relatively small components of the overall weakening effect of an osteotomy, which is typically a reduction in over 60% of the original strength of the bone.[10,11,14,15] This is primarily the result of disruption of cortical integrity, and is affected to a lesser degree by the design or extent of the section defect.[10,11] This was the rationale that we used when we developed the technique of prophylactic internal fixation of the remaining radius. This type of fixation has become increasingly popular over the past decade[8,20–24] and has resulted in a reduction in the reported incidence of fracture to roughly 2–3%.[8]

Improvements in the design of osteotomy defects may nevertheless have the potential to yield further benefits in residual strength at the radius and other osteotomy sites. In the current study the stress concentrations at the bevelled osteotomy site were 19% (4-point bending) to 30% (torsion) lower than at the right-angled osteotomy site. The incidence and pattern of overcutting during an osteotomy is unknown, but it is probably relatively common. An overcut substantially increases the concentration of stress and is likely to lead to failure, particularly if it affects the main load-bearing cross-section. In the present study an oblique overcut of one cortex at the sloped osteotomy site (Fig. 3d) had a greater adverse effect on stress concentration values under both bending (46%) and torsional (75%) loads than a right-angled osteotomy with two parallel overcuts (Fig. 3c). Analysis of the pattern of stress concentration indicated that the single deeper cortical cut produced a critical stress-collecting region, while the two parallel overcuts seemed to share the increased peak stresses. An extensive review of the modelling technique supported this as a genuine result, but we have not replicated these tests using a biomechanical bone study.

The use of a 90° or tangential cut into a stop drill hole substantially reduced the concentration of stress at the right-angled osteotomy site under both bending and torsional loading. The two stop holes were of different sizes (2.5 mm and 5 mm) but appropriate for clinical practice.

The effect was most pronounced when the larger stop hole was engaged in a tangential, rather than a 90° manner, and under bending (32%) rather than torsional loads (8%). This may be because more of the load-bearing cross-section is preserved when the stress is spread across a greater circumference. Further analysis indicated that the relative difference in the size of the stop hole had a minimal effect on peak stress values, as the geometry of stress concentration sites was similar. It would therefore be a reasonable extrapolation that a stop hole at the bevelled osteotomy site would have a similar strengthening effect, although this has not been tested. In clinical practice the stop hole should be created before the linear osteotomy to minimise the risk of overcutting, and using a larger diameter increases the tolerance for incorrect angulation of the saw. If an overcut is accidentally created, then rounding out in the manner of a tangential stop hole should be considered.

In this study we did not use a CAD model of the mandible because we used the validated sheep tibia model, but in future all anatomical sites may be modelled and the general principles will still apply. In the only previous similar study that we know of, in 1995 by Wittkampf et al.,[4,5] specimens of cadaver human mandible were incorporated in a finite element analysis model, but the methods were less well developed and fewer variations in osteotomy design were considered. The results showed less benefit overall, with a reduction in stress concentration of 33% with a 3 mm radius bore hole compared with the 58–60% with a 2.5 mm radius stop-hole engaged in a tangential manner, used in the current study. There was a smaller (13% compared with 24–30% in the current study) reduction in stress concentration with a bevelled rather than a right-angled osteotomy cut. These findings are broadly comparable and may be related to the use of a 0.5 mm diameter rounding at the corners of the osteotomy cuts, stop holes



Right angled

Peak von Mises stress 4 point bending = 357 MPa
Peak von Mises stress torsion = 545 MPa

Bevelled

Peak von Mises stress 4 point bending = 272 MPa
Peak von Mises stress torsion = 382 MPa

Right angled + parallel overcut

Peak von Mises stress 4 point bending = 319 MPa
Peak von Mises stress torsion = 322 MPa

Bevelled + oblique overcut

Peak von Mises stress 4 point bending = 465 MPa
Peak von Mises stress torsion = 565 MPa

Right angled + tangential bore hole

Peak von Mises stress 4 point bending = 115 MPa
Peak von Mises stress torsion = 219 MPa

Right angled + middle bore hole

Peak von Mises stress 4 point bending = 221 MPa
Peak von Mises stress torsion = 239 MPa

Fig. 3. Finite element analysis of computer-aided design (CAD) model with peak stress values under 4-point bending and torsional loads.

positioned differently, and a less detailed finite element analysis model.

Numerous other osteotomy designs could have been included in the current study, but would have substantially extended the length of computer processing time required. We therefore selected the design options most likely to be relevant to clinical practice. A comparable biomechanical study could be made, but there are shortcomings with this approach as well. The study would require a number of specimens of bone to be tested as the structural integrity and anatomy of the bones would be variable, and accurately reproducing the defect with identical osteotomy designs would be impossible. Additional considerations such as costs, limited time, and limited access to human material, mean that finite element analysis techniques are becoming an increasingly common tool in biomedical research.

In principle, therefore, when an osteotomy defect is being created, the removal of load bearing bone should be avoided and the remaining cross-sectional area should be carefully considered, as inappropriate removal of bone weakens the remaining structure.[1,3] However, the judicious use of bevelling and the creation of stop holes have a substantial overall benefit in reducing peak stress concentration.[4,5] These techniques should be considered at both the mandible and radius, and other appropriate sites.

Acknowledgements

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Technical note

Stop-hole osteotomy technique

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The cuts that are required to create a step osteotomy of the mandible or a section defect are primarily in a linear plane. The point at which 2 cuts meet is a focus for the concentration of stress and the area is prone to failure. The "stop drill hole method" has been used to block the propagation of existing crack lines during aircraft maintenance[1] and in wider mechanical engineering practice, but has not been commonly applied to avoid iatrogenic fractures in surgical practice. A stop-hole of sufficient diameter will prolong the time to fatigue failure under cyclical loading.[2]

We have developed a finite element analysis technique to simulate stress levels within bone. We tested the mandible under normal biting forces,[3] long bones with plate fixation,[4] and differing designs of osteotomy end cuts[5] for bending and torsional loading. When compared with a baseline right-angled osteotomy (maximum stress level 100%), the peak stress concentration at a bevelled osteotomy was substantially lower (70–81%). It was further reduced when the corner of a right-angled osteotomy was rounded out with a stop-hole, which could be entered tangentially (40–47%) (Fig. 1) or at 90° (44–69%) (Fig. 2). In contrast, an overcut oblique osteotomy (104–158%) substantially increased the stress concentration and implied a weakening effect.[5] A stop-hole at the corner of an osteotomy will therefore have a strengthening effect and will avoid the potential for creating an overcut.

The procedure requires no specialist equipment or expertise and the cuts are marked in the conventional manner. Figs. 3 and 4 show a mandibular access osteotomy using a dental bur to create a stop-hole 3 mm in diameter. The saw is engaged in the stop-hole and then enters the next stop-hole in a tangential or 90° approach.

When creating an osteotomy defect, the unnecessary removal of load-bearing bone should be avoided as it weakens the remaining structure. A right-angled osteotomy that is judiciously bevelled or rounded with an appropriately sized stop-hole will safely reduce peak stress concentrations. In our limited clinical experience an osteotomy with a 3 mm diameter stop-hole is easier to do than a conventional procedure. This is because the cuts are clearly delineated by the stop-holes, the saw is more easily located to begin the cut, visualisation is improved, and there is more leeway for error in completing the cut into another stop-hole. If an overcut is accidentally created during a conventional osteotomy, rounding out in the manner of a tangential stop-hole should also be considered.[5] The technique is simple and without complication, and is widely applicable to general, and oral and maxillofacial surgical practice.

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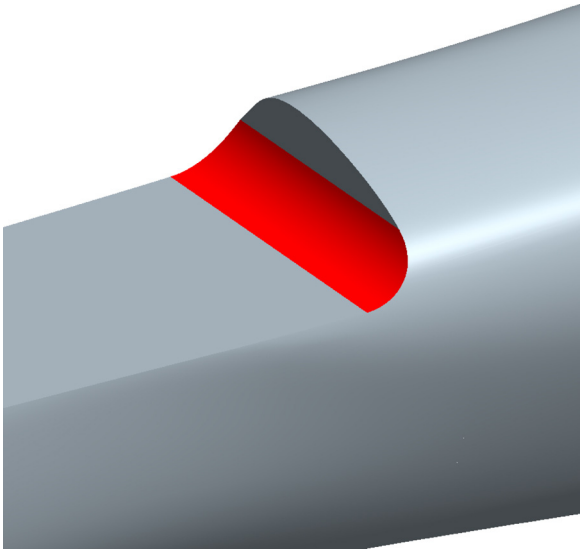

Fig. 1. Rounded osteotomy with tangential entry to stop-hole (40–47% reduction in peak stress concentrations).

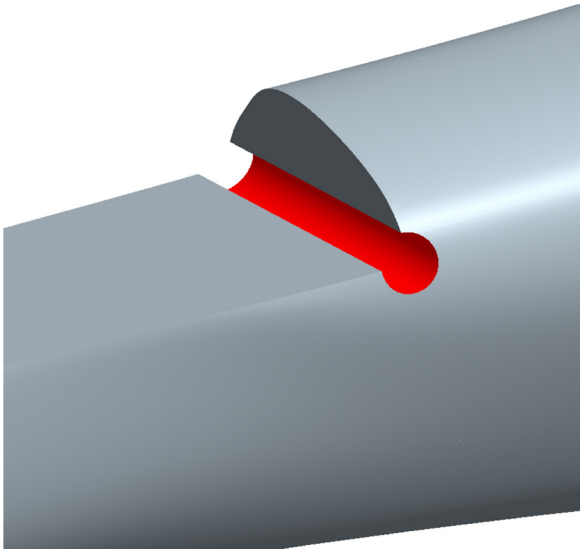

Fig. 2. Stop-hole osteotomy with 90° entry (44–69% reduction in peak stress concentrations).

Conflict of interest statement

There are no conflicts of interest.

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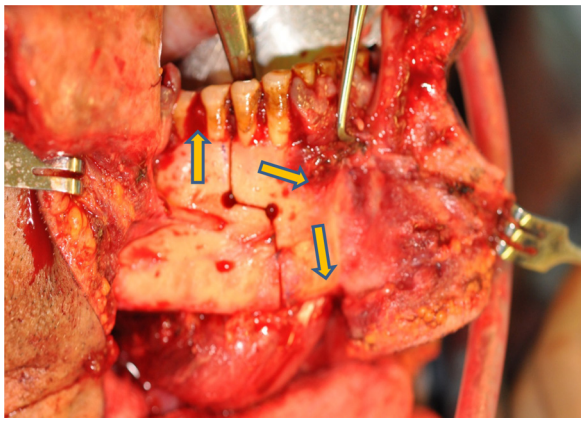

Fig. 3. Conventional step osteotomy entered at 90°. The saw is engaged in the stop-hole and the cut is made towards the next stop-hole or mandibular border and alveolus (arrows).

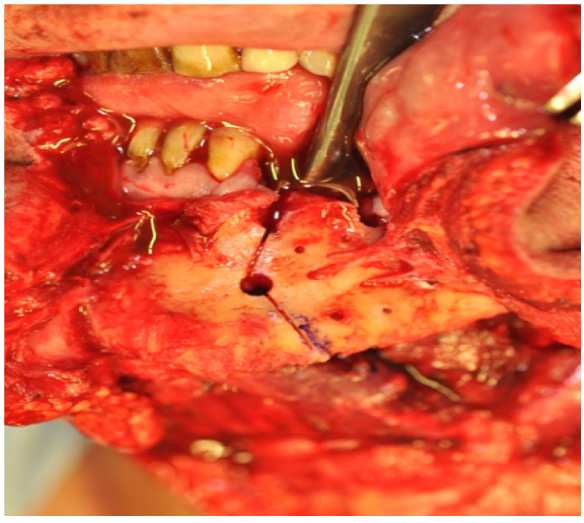

Fig. 4. Mandibular access osteotomy. V-shaped access osteotomy with stop-hole entered tangentially and at 90°. The screw holes in the proximal plate have been prepared. There were several branches of the mental nerve so a conventional step osteotomy was not done.

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The biomechanical aspects of reconstruction for segmental defects of the mandible: A finite element study to assess the optimisation of plate and screw factors

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ABSTRACT

A bone plate is required to restore the load-bearing capacity of the mandible following a segmental resection. A good understanding of the underlying principles is crucial for developing a reliable reconstruction. A finite element analysis (FEA) technique has been developed to study the biomechanics of the clinical scenarios managed after surgical resection of a tumour or severe trauma to assist in choosing the optimal hardware elements.

A computer aided design (CAD) model of an edentulous human mandible was created. Then 4 common segmental defects were simulated. A single reconstruction plate was designed to span the defects. The hardware variations studied were: monocortical or bicortical screw fixation and non-locking or locking plate design. A standardized load was applied to mimic the human bite. The von Mises stress and strain, spatial changes at the screw-bone interfaces were analysed.

In general, the locking plate and monocortical screw fixation systems were most effective. Non-locking plating systems produced larger screw "pull-out" displacements, especially at the hemi-mandible (up to 5% strain). Three screws on either side of the defect were adequate for all scenarios except extensive unilateral defects when additional screws and an increased screw diameter are recommended. The simplification of screw geometry may underestimate stress levels and factors such as poor adaptation of the plate or reduced bone quality are likely to be indications for bicortical locking screw fixation.

The current model provides a good basis for understanding the complex biomechanics and developing future refinements in plate or scaffold design.

Introduction

The creation of a segmental defect of the mandible is disfiguring and associated with a significant decrease in oral cavity and upper airway function. Free tissue transfer has become established as the optimum method for reconstructing segmental defects in order to restore bone continuity and recreate form together with function (Goh et al., 2008; Bak et al., 2010). The fibula and DCIA composite flaps are most frequently used whilst the scapula or radial flaps are less commonly appropriate (Urken et al., 1998; Cordeiro et al., 1999; Avery, 2010; Bak et al., 2010). A heavy reconstruction plate, or several lighter plates, is applied to secure the bone element. A single heavy reconstruction plate without a bone graft may occasionally be used for a delayed reconstruction or when a pectoralis major myocutaneous (PMMC) flap is preferred because of advanced disease and substantial co-morbidity (Salvatori et al., 2007; Avery et al., 2010; Onoda et al., 2012).

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During the bone healing phase the load-bearing function of the mandible is partially restored as the hardware shares the load. The mandible regains functional integrity through bone regeneration and union, which is driven by the forces of Inter-Fragmental Strain (IFS) (Perren, 1979). With time the IFS gradually decreases until no more bone maturation occurs and the strength and rigidity of the mandible stabilises. Ultimately the plate will act as a parallel load-bearing element which shields the mandible. The phenomenon of "stress shielding" is one of the reasons flexible plates of 2.0–2.4 mm are favoured for reconstruction.

The aims of this study were to study the patterns of biomechanical loading, deformation and stress which occur around the segmental defects commonly encountered following resection for oral malignancy or occasionally after major trauma. This biomechanical study used a finite element analysis (FEA) technique developed in our previous studies (Bujtár et al., 2010, 2012; Szűcs et al., 2010; Avery et al., 2013) which continuously undergoes refinements and validation. The performance of a uniform single reconstruction plate with either a locking or non-locking plate anchorage system and monocortical or bicortical screw insertion was studied. We wished to gain a better understanding of the biomechanics at the interfaces between the screw-plate and the plate-bone. This information will also facilitate simulation of a bone scaffold when used for reconstruction. Perhaps this will improve of the quality of life of the affected population (Becker et al., 2012) including the currently available (Ciocca et al., 2012) and future technologies.

Material and methods

Segmental mandible defects

Standardized osteotomy sites were created to represent 4 common resections (Fig. 1). The unilateral defects were a hemimandibulectomy and body resections. The bilateral defects were anterior symphyseal and subtotal mandibulectomy resections.

Inter-positional bone flaps

A bone flap has not yet been included within the simulated segmental defects as there is considerable variability in the dimensions and qualities of the different types of bone flaps which would make it difficult to control various simulation parameters and may lead to inaccurate and inconclusive results. In addition the principle loading conditions of the anchoring screws are similar in the presence or absence of a composite bone flap.

CAD modelling of the mandible

A Cone-Beam Computer Tomography scan (iCAT, ISI, 120 kV, 36 mAs, voxel 0.3 × 0.3 × 0.3 mm) of a single human mandible from an edentulous 67-year-old female patient was selected (Bujtár et al., 2010). After pre-processing the input DICOM data (Bujtár et al., 2012) the 4 segmental defects were reproduced using modelling in ProEngineer Wildfire 5 (Parametric Technology Corporation, Needham, MA, US) CAD engineering software.

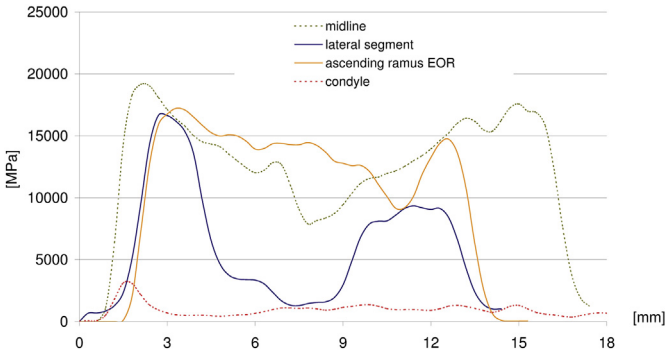

Fig. 2. Young's modulus at different region across the mandible in an orthoradial direction. **Abbreviation: EOR**, External Oblique Ridge.

CAD modelling of hardware

A 3 mm generic reconstruction plate was modelled to fit the outer cortical surface of the simulated mandible. We acknowledge that plating systems have variable profiles. Three screws either side of the defect were inserted with the closest 10 mm from the osteotomy defect. The screw geometry was simplified in to a cylindrical shape of 2 mm external diameter. This fixation either engaged the full width of the outer bone cortex (monocortical) or both the inner and outer cortices (bicortical).

Mechanical modelling by finite element analysis

The mechanical properties of the bone models were determined in two steps. Firstly, the apparent specific gravity [kg/m^3] of each element was calculated by linear association with the Hounsfield Units (HU) of the CBCT image (Eq. 1). Then the Young's (elastic) modulus was defined using the logarithmic correlation with bone density [g/cm^3] (Eq. 2.) as described in our previous studies (Bujtár et al., 2010, 2012; Szűcs et al., 2010; Avery et al., 2013).

$$\text{Density}: \ \rho = 1.14264 \times \text{HU} + 309.4935 \left[\text{kg/m}^3\right] \tag{1}$$

$$\text{Young Modulus}: \ E = 0.024 \times \rho^{1.777}[\text{MPa}] \times \text{MPa (Megapascal)} = 1 \times 10^6 \tag{2}$$

Isotropic, linear elastic elements composed of non-homogeneous tetrahedral units were used to represent the bone structure.

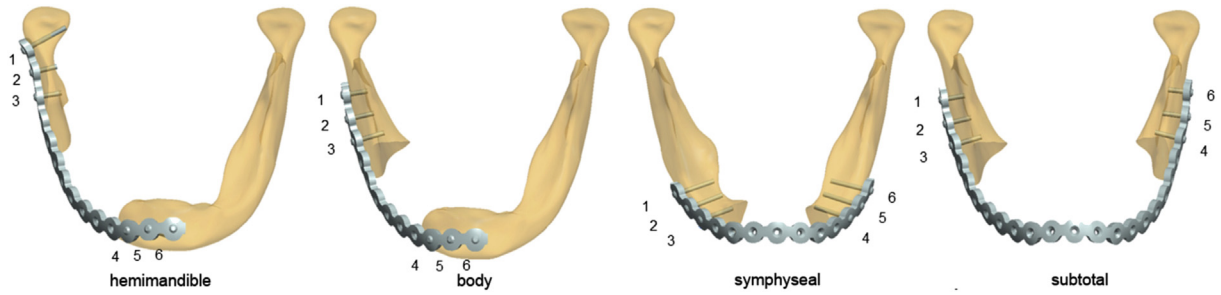

Fig. 1. CAD models of segmental mandible resections with reconstruction plates. The unilateral defects were *hemimandibulectomy* (coronoid to parasymphysis) and *body* (angle to parasymphysis) resections. The bilateral defects were *symphyseal* (parasymphysis to parasymphysis) and *subtotal* mandibulectomy (angle to angle) resections.

Table 1
Maximum von Mises stress [MPa] and strain [%] levels within the bone around the fixation screws.

Defects	Simulation variables		Non-loaded (right) side						Loaded (left) side					
			Screw 1		Screw 2		Screw 3		Screw 4		Screw 5		Screw 6	
	Screw	Plate	von Mises	Strain	von Mises	Strain	von Mises	Strain	von Mises	Strain	von Mises	Strain	von Mises	Strain
Hemimandible	Bi	Non-lock	**61**	0.390	**31**	0.550	**67**	0.503	**301/967**	**−4.969/−4.026**	**180**	−1.620	**93**	0.062
	Mono	Non-lock	**97**	0.383	**43**	0.630	**70**	0.600	**323/1188**	**−4.555/−3.786**	**155**	−1.432	**94**	0.089
	Bi	Lock	**53**	0.008	**47**	0.016	**83**	0.065	**187/575**	**−0.015/−0.038**	**155**	0.065	**81**	0.010
	Mono	Lock	**52**	−0.030	**28**	0.001	**72**	0.002	**204/245**	**−0.061/−0.066**	**130**	0.012	**81**	−0.004
Body	Bi	Non-lock	**115**	0.490	**35**	0.597	**110**	0.181	**71**	−0.591	**33**	0.237	**99**	0.409
	Mono	Non-lock	**108**	0.691	**35**	0.648	**114**	0.103	**86**	−0.557	**20**	0.180	**95**	0.377
	Bi	Lock	**24**	0.004	**30**	0.015	**121**	0.218	**60**	−0.003	**103**	0.033	**67**	0.011
	Mono	Lock	**20**	−0.003	**28**	0.008	**107**	−0.022	**58**	−0.030	**82**	0.011	**60**	−0.003
Symphyseal	Bi	Non-lock	**53**	0.254	**28**	0.243	**79**	−0.178	**76**	−0.071	**38**	0.265	**147**	0.371
	Mono	Non-lock	**45**	0.272	**27**	0.246	**75**	−0.162	**65**	−0.012	**42**	0.257	**116**	0.333
	Bi	Lock	**47**	−0.013	**34**	−0.002	**61**	−0.013	**62**	0.009	**94**	0.040	**87**	0.026
	Mono	Lock	**36**	0.007	**26**	0.016	**55**	−0.012	**56**	−0.006	**75**	0.017	**49**	0.009
Subtotal	Bi	Non-lock	**82**	−0.328	**18**	−0.210	**97**	−0.291	**136**	−0.010	**36**	0.255	**103**	0.103
	Mono	Non-lock	**83**	0.257	**20**	0.264	**83**	0.061	**119**	−0.117	**47**	0.261	**92**	0.210
	Bi	Lock	**31**	−0.005	**25**	0.007	**84**	0.032	**102**	0.049	**27**	−0.003	**26**	−0.012
	Mono	Lock	**29**	−0.001	**22**	0.004	**69**	−0.002	**99**	−0.012	**26**	0.003	**22**	−0.001

The ***simulation settings* column** contains three columns: the type of *segmental defect* (vertically), *depth of screw engagement*; either bicortical or monocortical and the *type of connection between the plate and screw*: either non-locking or locking.
The "**Pull-out**" **strain was defined** as the percentage of screw head displacement along the longitudinal axis under loading (composed of screw elongation and displacement at the bone-screw interface) compared to the non-loaded distance between the screw head and inner lingual cortical surface.
A positive strain value means the screw is pushed along the longitudinal axis toward the inner cortex whilst a negative value indicates a screw being "pulled out".
Screw number 4 in the hemimandible defect has two values. The first value represents the cylindrical screw result and the 2nd value is the refined screw thread geometry (validation).
Abbreviations: **bi**, bicortical; **mono**, monocortical; **non-lock**, non-locking; **lock**, locking; **von Mises**, von Mises (peak) stress [MPa]; **strain**, deformed length/original length when loaded and converted in to a % value.

The assigned Young's modulus across four distant mandible regions in an orthoradial direction are being presented (Fig. 2) as samples, while the uppermost (stiffest) elements within the bone model were approximately 20 GPa. The Young's modulus of the titanium hardware was set to a standard value of 105 GPa with a Poisson ratio of 0.3 (Bujtár et al., 2012; Avery et al., 2013).

Assembly interfaces

The mandible models were assembled in Marc 2007 (MSC Software, USA). The plate-screw interface was set as ***locking*** if movement between the structures was prohibited, due to interlocking structures. A ***non-locking*** plate-screw interface was simulated by allowing each screw to transmit a ***preload force***, creating a resting tension between the plate and bone, which was built-up during insertion and quantified by a torque value. In practice, the preload force retains a ***friction (grip)*** between the plate-screw-bone interfaces.

A "bond" type connection was applied at the ***locking*** screw-plate interface and at all bone-screw interfaces with cylinder screw geometry. A "**friction**" grip connection with a coefficient of 0.3 was applied at all ***non-locking*** screw-plate interfaces and when bone to plate contact occurred during the simulation (Ramos et al., 2011).

Test simulations

A single simulation scenario was designed to represent unilateral biting on the 1st molar tooth with a force of over 400 N (Bujtár et al., 2010; Szűcs et al., 2010).

There were 16 standardised and 4 additional refined sets of simulation (Table 1). The maximum von Mises (σ_v) stress values and "pull-out" strain values at the bone-screw interfaces were recorded and used as a predictor of longer-term stability. The sites of highest peak stress levels were considered to represent potential weak points.

Statistical analysis

Conventional statistics are not applicable as the mathematical model will yield the same result with each test scenario unless the parameters of the model simulation are altered. It is not possible to have a control group so the simulation validation process acts as the method for controlling the quality of the outcomes. Variable factor analysis was applied as this is the method of choice in design engineering and FEA to show a trend supporting the significance of an individual variable (Dar et al., 2002). Results are arranged by rank order as in our previous studies (Bujtár et al., 2012; Avery et al., 2013).

Results

Bone-screw interface

The peak stress and strain ("pull-out") values at each screw-bone interface are tabulated in Table 1 and Figs. 3 and 4. The results are listed in rank order using the mean stress and strain levels in Table 2.

In general, monocortical (20–204 MPa and 0.001–0.061%) and then bicortical (24–187 MPa and −0.002 to 0.218%) screw fixation in combination with a locking plate yielded the lowest peak stress and strain values. Whilst the non-locking plating systems with either monocortical (20–323 MPa and −0.012 to −4.555%) or bicortical (18–301 MPa and −0.01 to −4.969%) screw fixation developed both higher peak stress and strain values at all types of defect. The exception was the hemimandible defect (screw position number 4 which developed higher peak stress and strain levels under all test scenarios (Figs. 3–7 & Table 2)).

Validation and refined simulations

The screw in position number 4 of the hemimandible resection was considered a critical area as it demonstrated the highest (peak)

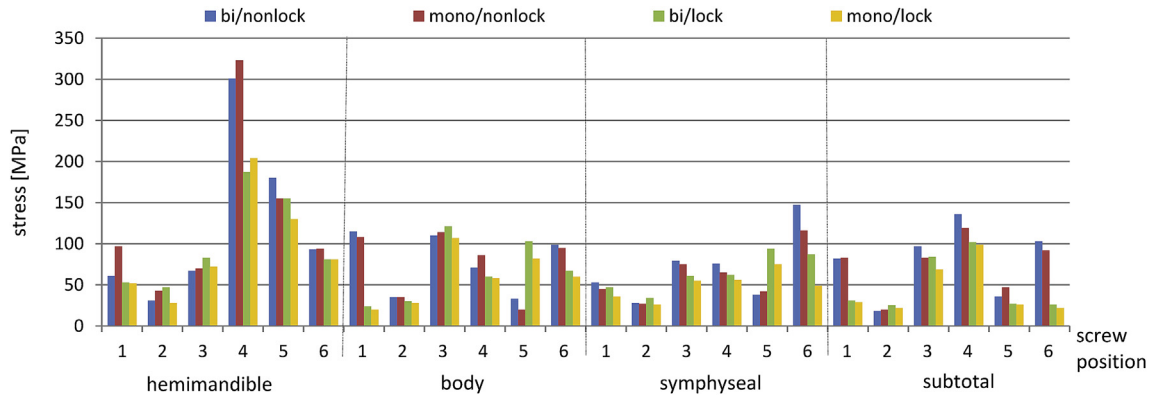

Fig. 3. Bone stress (Maximum von Mises) values distribution around the (cylindrical) screw. Abbreviations: **bi**, bicortical; **mono**, monocortical; **non-lock**, non-locking; **lock**, locking; **von Mises**, von Mises (peak) stress [MPa]; **strain**, deformed length/original length when loaded and converted in to a % value.

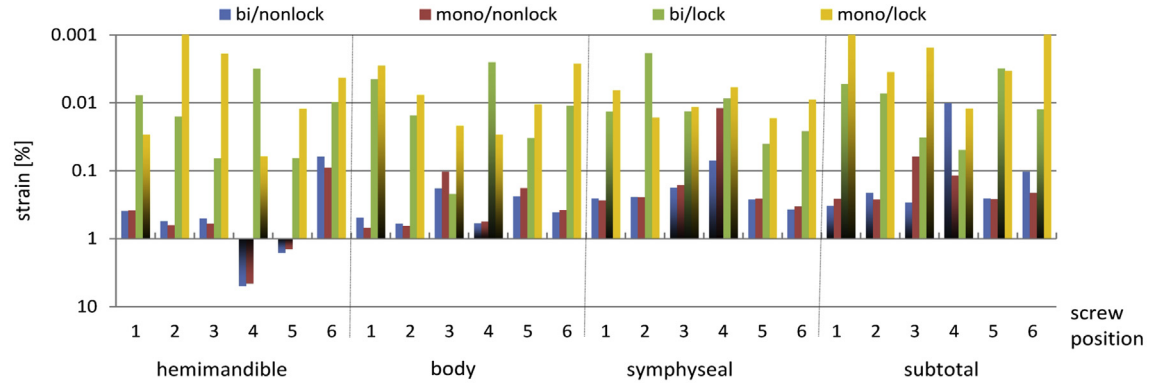

Fig. 4. Pull-out displacement of the fixation screw relative to bone (strain). The *Y*-axis is a logarithmic scale. Bars with uniform colour represent a positive value as the screw is pushed in toward the inner cortex whilst those with a colour gradient indicate a screw being "pulled out". Abbreviations: **bi**, bicortical; **mono**, monocortical; **non-lock**, non-locking; **lock**, locking; **von Mises**, von Mises (peak) stress [MPa]; **strain**, deformed length/original length when loaded and converted in to a % value.

levels of strain (up to −4.969%) and von Mises stress (up to 323 MPa) (Fig. 6). A more detailed submodel was created to further investigate the biomechanics around this screw. A generic screw thread pattern was replicated with a 2.4 outer and 1.7 mm core diameter. The differences in the simulated loading condition between the simplified and refined screws-bone models are presented in Fig. 7. The "pull-out" (strain) values of the screw were used as validation criteria. These values were expected to be in a similar range when using the detailed geometry and a more realistic "friction" type interface connection. The elevated stress levels highlighted critical sites where the bone might be expected to fail. All results are listed in Table 1 and Fig. 5.

Discussion

The use of CAD and FEA techniques has become established as the industry standard in engineering. These simulation techniques have been increasingly applied within the mid and lower facial regions in reconstructive plastic and maxillofacial surgery to study the effect of ageing (Bujtár et al., 2010), oral surgical procedures (Szűcs et al., 2010), osteotomy designs (Bujtár et al., 2012), fixation methods following marginal resections (Avery et al., 2013) and reconstruction plates (Kimura et al., 2006; Nagasao et al., 2010). The outcomes of mathematical simulations are dependent on the quality of the models and unrealistic simulations will always give unrepresentative results. In the current model we applied a greater level of fidelity, which is more realistic and descriptive, than previously reported in the medical literature to ensure the integrity of the simulations.

The aim of this paper is to improve our understanding of the optimal biomechanical characteristics required for plate and screw fixation and so reduce the incidence of complications encountered in clinical practice. The literature on general, rather than just biomechanical, complications associated with

Table 2
Rank order of the fixation systems based on mean strain or "pull-out" and stress criteria.

Fixation type	Hemimandible	Body	Symphyseal	Subtotal	Hemimandible	Body	Symphyseal	Subtotal
	Rank order strain or "pull-out" values [%]				Rank order stress values [MPa]			
Mono/lock	**1** (−0.013)	**1** (−0.006)	**1** (0.005)	**1** (−0.001)	**1** (94.5)	**1** (59.2)	**1** (49.5)	**1** (44.5)
Bi/lock	**2** (0.027)	**2** (0.047)	**2** (0.008)	**2** (0.011)	**2** (101.0)	**2** (67.5)	**3** (64.2)	**2** (49.2)
Bi/non-lock	**4** (0.847)	**3** (0.221)	**3** (0.147)	**3** (−0.080)	**3** (122.2)	**4** (77.2)	**4** (70.2)	**4** (78.7)
Mono/non-lock	**3** (−0.714)	**4** (0.240)	**4** (0.156)	**4** (0.156)	**4** (130.3)	**3** (76.3)	**2** (61.7)	**3** (74)

Abbreviations: **bi**, bicortical; **mono**, monocortical; **non-lock**, non-locking; **lock**, locking; **von Mises**, von Mises (peak) stress [MPa]; **strain**, deformed length/original length when loaded and converted in to a % value.

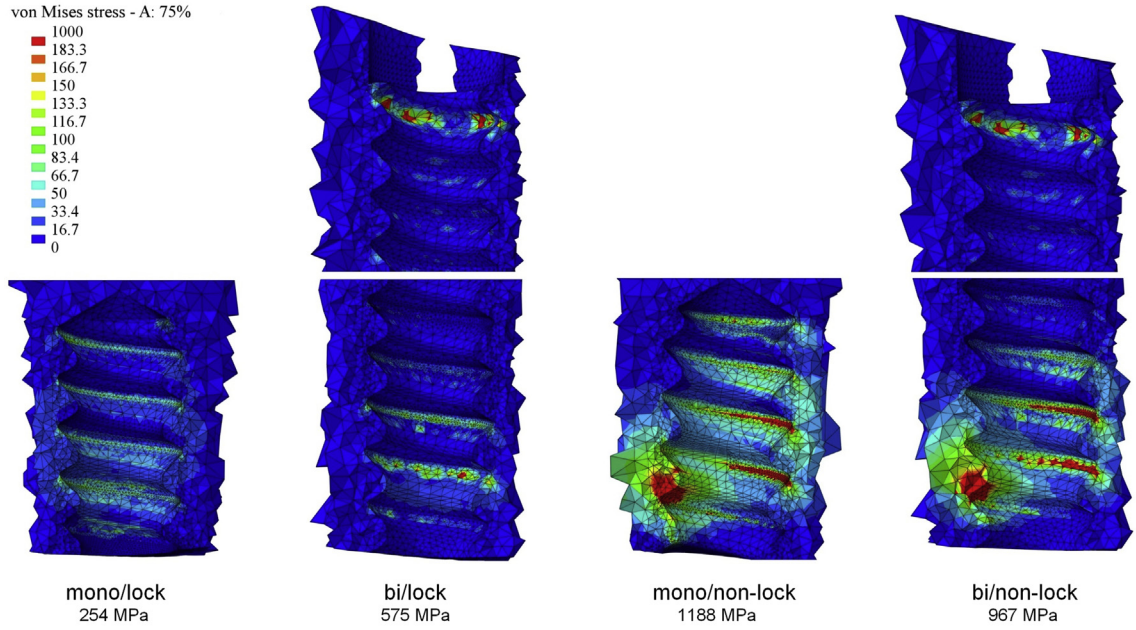

Fig. 5. Bone stress around the refined screw thread (top halves, longitudinal cross-cut) at screw number 4 in the hemimandible defect. The colour scale represents the von Mises stress values in a linear fashion (up to 183.3 MPa) with red representing the greatest values (approximately 1000 MPa). The von Mises maximum stress levels are indicated. Abbreviations: **bi**, bicortical; **mono**, monocortical; **non-lock**, non-locking; **lock**, locking; **von Mises**, von Mises (peak) stress [MPa].

mandible reconstruction indicates that both mini-plates and reconstruction plates have a similar incidence of complications when managing fractures of the mandible (Ellis, 1999; Rudderman et al., 2008) or segmental defects (Shaw et al., 2004). In a meta-analysis and review of the tension-band concept the use of bicortical rather than monocortical screws, heavier hardware or the application of more than a single mini-plate all significantly increased the rate of complications for a variety of reasons (Regev et al., 2010). Radiotherapy given both before (Schwarz et al., 2009) or after (Tchanque-Fossuo et al., 2011) the bone regeneration phase also increases the incidence of complications in a dose-dependant fashion (Fregene et al., 2009). Using in-vivo experimental models this has been shown to be partially related to detrimental changes to the biomechanical properties of the bone at the screw-bone interface and may be reversible with the application of deferoxamine (Donneys et al., 2013).

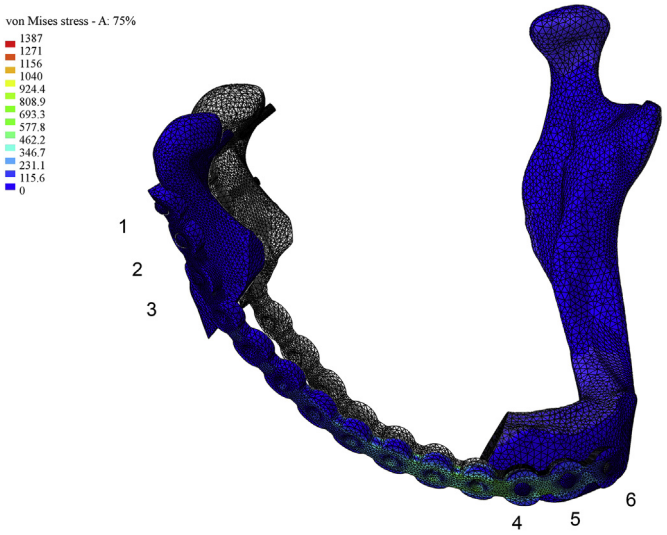

Fig. 6. Non-loaded (grey colour) and loaded (coloured) position of the reconstructed mandible. Colouring representing von Mises stress distribution.

When considering different plating systems it is important to distinguish between load-bearing *(LB)* and tension-band *(TB)* concepts. In a tension-band simulation (concept) the screws are mainly loaded along the longest dimension of the plate. In contrast in a load-bearing model this directional load is less critical as the screws are primarily loaded along the longitudinal axis of the screw ("pull-out") and the remaining axis of the screw. The most frequently investigated variables have been the number, length and core diameter of the screw. It is generally accepted that 3 screws on either side of a defect are the minimum number required for effective load-bearing (*LB*) anchorage (Ellis and Miles, 2007). The use of additional screws has not been shown to have a substantive benefit with either a 2.0 mm dynamic compression screw system (*TB*) (Haug, 1993a) or a non-locking heavy reconstruction plate (*TB*) (Haug, 1993b; Leung and Chow, 2003). However, the spatial distribution of screws with a load-bearing concept may be important (Gautier and Sommer, 2003). The screw length is a minor factor when the plate is applied using tension-band principles (Haug, 1993a). An adequate screw length is defined as sufficient engagement to achieve good bone purchase and the width of the outer cortex of the mandible will usually be adequate (Schwartz-Dabney and Dechow, 2003).

It has become increasingly common to use monocortical screws together with locking plating systems (*LB*) at many anatomical sites, including the mandible, and this work supports this practice. Bicortical screw fixation systems may have advantages at peri-articular sites, with osteopenic bone (Koonce et al., 2012) and especially with a poorly adapted plate. In general when there is relatively elastic bone, osteopenic bone, or when screw positioning is compromised because of joint proximity there is increasing benefit from the comparatively rigid fixation offered by a locking system to reduce screw loosening during cyclic loading (Koonce et al., 2012). When there is good quality bone available or bone elasticity is lower (older population), but not osteopenic, then a

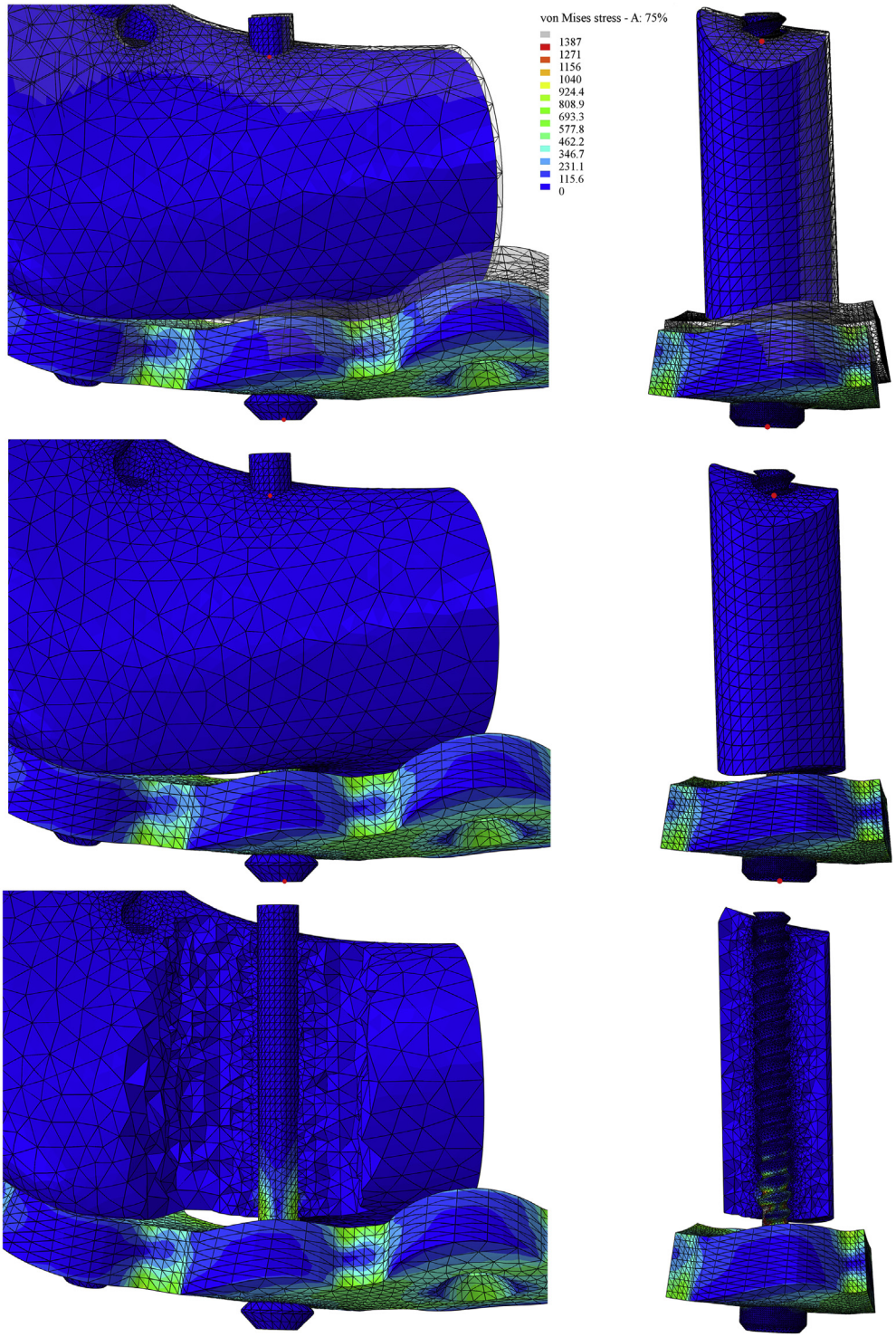

Fig. 7. The differences (geometry and design) and similarities (stress distribution, displacement and strain) of the simplified (left) and refined (right) screw models (the same views from below). The colour scales represent the von Mises stress distribution under standardized loading. The top images indicate the non-loaded fully adapted plate position [grey] and displacement under loading [coloured]. The middle images show the loaded position only. The bottom images highlight the differences between the simplified cylindrical screw and the threaded screw geometry under loading.

semi-rigid non-locking fixation system is acceptable (Koonce et al., 2012).

A 2.0 mm screw (*TB*) is most commonly used in maxillofacial practice. Increasing the screw diameter can minimise stress (*LB* with a potential 3.7 fold decrease stress around the screw) (Knoll et al., 2006). However, when two locking systems (*LB*) [THORP® 4.0 mm and UniLOCK® 2.4 mm] were compared in a human follow-up cohort there was no apparent benefit with greater screw diameter (Gellrich et al., 2004). Screw related complications may occur more often in lighter plating systems bridging small defects (Lindqvist et al., 2001) and plate related complications more frequently with heavier plates spanning longer defects (Gellrich

et al., 2004). This is consistent with the current study as the level of stress with a locking system, even with small diameter screws, is unlikely to reach a non-physiological level. However, as a wider range of screw sizes are now often available for the same reconstruction plate this is now an option to be considered. A poorly adapted plate will have a greater weakening effect with a non-locking system (Ahmad et al., 2007; Schupp et al., 2007). Bone-plate interface distances over 2 mm also significantly compromise the stability of locking connections, even when engaged bicortically (Ahmad et al., 2007; Schupp et al., 2007). In the current study the absolute strain values with the monocortical locking screws were lowest, although in practice these screws would be "pulling out" at 10 of the 24 screw positions. In contrast the bicortical locking system had fewer negative strain values (5 out of 24) meaning screw "pull-out" was less frequent (Table 1, Fig. 4). In clinical practice "pulling out" of a screw is far more destabilizing than a screw being "pushed in". The reconstruction plate in the current simulation was tightly fitted to the cortical surface but this close adaptation may often be difficult to achieve in clinical practice, even with a preformed plate, and hence this model does not yet accurately represent all clinical scenarios.

The strain theory of bone regeneration states that primary bone union occurs with an IFS value of less than 2% and secondary healing with callus formation between 2 and 10 (Perren, 1979). In this simulation the IFS strain levels were generally below 2%, and closer to 0.25% for locking systems. This indicates that both non-locking and locking systems are suitable to prevent initial screw loosening. The number 4 screw closest to the osteotomy defect in the hemimandible resection (Figs. 4–7) had the highest level of strain (4.6% or 0.8 mm "pull-out") with a non-locking system and an increased screw diameter or insertion of additional screws may be beneficial in this situation. The remaining segmental defects can be safely restored using either locking or non-locking systems. The reduced strain values with the locking system indicate that longer-term integrity is likely to be superior with a locking plate when a load-bearing function is managed with a single reconstruction plate alone. In free tissue transfer procedures some surgeons prefer to use multiple lighter (2.0 mm) plates to share the load, eliminate the difficulty of adapting a larger heavier plate and provide greater flexibility for access to the microvascular site. This study has not investigated the biomechanical features of this latter form of reconstruction but is a basis for future work.

The level of von Mises stress values around all screws was within an acceptable range (less than 200 Mpa) apart from the number 4 screw in the hemimandible defect. In some areas the peak stress was as high as 1188 MPa and this would be expected to precipitate local bone necrosis with loosening. There was an increase in stress levels of nearly 300% when using a screw thread simulation rather than the original simplified cylinder geometry (1188 versus 323 MPa) and this finding underlines the importance of a detailed simulation or refinement based validation process.

Conclusion

In conclusion, monocortical locking plate and screw systems are generally recommended for the reconstruction of segmental defects of the mandible, and especially when bone quality is poor, such as following irradiation. Bicortical screw fixation together with a locking plate had no apparent biomechanical benefit in the scenario of a well-adapted plate secured to good quality bone. However, if this situation may not be achieved in clinical practice then bicortical fixation should be considered. Non-locking systems generated substantially greater levels of stress in all scenarios and are a less preferable option which may be more likely to fail at a later stage. The number of individual variables in these simulations is high and our understanding of the complex biomechanics at all sites remains incomplete. Future studies will investigate the effects of factors such as; increased screw preload (tightening), variable bone quality, bone-plate interface distances, lighter plates or the presence of a supporting scaffold. The validity of assumptions within the bone model will be mechanically tested and verified using cadaver studies as we seek to develop this technique.

Ethical statement

Ethical approval was not required.

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Contributions

The authors J Simonovics and P Bujtár contributed equally to this work and would like to both be considered as first author. The modelling and simulations were primarily designed by P Bujtár and J Simonovics. The bone model was developed by P Bujtár, simulations and implant models were performed by J Simonovics. CME Avery and GKB Sándor gave assistance in the study design and regarding surgical practices. The results and interpretations were equally performed by J Simonovics and P Bujtár. The manuscript was written by P Bujtár and CME Avery with contributions by J Simonovics and GKB Sándor. T Dézsi was the main advisor regarding mathematical and simulation details. The principle PhD supervisors were; K Váradi for J Simonovics and GKB Sándor for P Bujtár.

Competing interests

None declared.

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Clinical Paper

The prospective experience of a maxillofacial surgeon with the percutaneous endoscopic gastrostomy technique

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C. Avery, S. Shenoy, S. Shetty, C. Siegmund, I. Mazhar, N. Taub: The prospective experience of a maxillofacial surgeon with the percutaneous endoscopic gastrostomy technique. Int. J. Oral Maxillofac. Surg. 2008; 37: 140–148.

Abstract. Insertion of a percutaneous endoscopic gastrostomy (PEG) was attempted on 225 occasions, mainly for oral malignancy. Seventy-five percent (169/225) were inserted at the time of definitive surgery. There were significant incidental findings during 5% (11/225). The rate of successful insertion was 97% (219/225). The incidence of minor complications was 12% (26/225) and major complications 3% (7/225). There was no procedure-related mortality. The 30-day mortality rate, including those with terminal malignant disease, was 6% (14/225). An increased risk of death was associated with age of 65 years and over ($P = 0.004$). The median PEG duration was 337 (SE 31) days. Duration was significantly longer for stage T3–4 tumours ($P = 0.028$), N1 or greater neck disease ($P = 0.034$), following surgery with radiotherapy when compared to surgery alone ($P < 0.001$), particularly glossectomy ($P = 0.038$) and maxillectomy procedures ($P = 0.003$), after two separate surgical procedures and radiotherapy ($P = 0.046$) and following a composite bone resection ($P = 0.031$), or radiotherapy alone when compared to surgery alone ($P = 0.003$). There was no relationship to the type of flap used for reconstruction. Four patients have a long-term PEG. Only two patients did not use the PEG. The early insertion of a PEG in all patients undergoing free or pedicled flap reconstruction appears to be appropriate. The PEG procedure may be safely performed by an appropriately trained maxillofacial surgeon.

Key words: gastrostomy; percutaneous; oral malignancy; head and neck cancer; complications; morbidity; maxillofacial.

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A percutaneous endoscopic gastrostomy (PEG) is often the method of choice for the enteral feeding of patients with head and neck malignancy. It was initially used mainly with end-stage disease[13], but is now more commonly inserted whenever nutritional support is required for more than 2–4 weeks. The indications include painful or ineffective mastication or swallowing, oropharyngeal and oesophageal obstruction, and supplemental nutrition after surgery and during chemotherapy and radiotherapy. The ethical issues surrounding insertion of a gastrostomy, particularly when an illness may be in the

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terminal phase, are complex. The therapeutic goals that may be achieved should be carefully considered together with the views of the patient[23]. An algorithm for assisting in the decision-making process has been published[27] (Fig. 1). A PEG should only be inserted for patients likely to derive physiological benefit from nutritional supplementation and respond to cancer treatment. It should not be offered when life expectancy is less than 2 months or if no improvement in the quality of life may be expected. If there is doubt a trial period with a nasogastric tube may be appropriate.

The PEG is commonly inserted by a gastroenterologist[40] or a gastrointestinal or general surgeon[3,5,6,13]. It is occasionally inserted by a specialist nurse[22], otolaryngologist[12,17,37] or maxillofacial surgeon[18]. A radiologically inserted gastrostomy (RIG) or percutaneous radiologic gastrostomy (PRG) has less commonly been inserted[39] using a variety of guidance techniques.

The gastrostomy may be performed under local anaesthetic, with or without sedation, or under a general anaesthetic. The various methods of gastrostomy insertion, and their relative merits and complications have been comprehensively reviewed[22,31,32]. Most of the literature is composed of retrospective cohort studies. There are few prospective studies of the PEG technique and most deal with the issue of nutritional support for dysphagia after a cerebrovascular accident. To the authors' knowledge, there have been only two series by a single surgeon that have dealt with the management of head and neck oncology patients and these were both retrospective studies[3,13]. This paper describes the experience of a maxillofacial surgeon in the only prospective observational study in the head and neck literature.

Materials and methods

The 'pull' technique of PEG insertion

The surgeon used the conventional 'pull' technique[30] and the Freka® (Fresenius Kabi Ltd, UK) feeding system with a size 9 Fr tube. The upper gastrointestinal tract was examined as far as the proximal duodenum with an Olympus (Keymed Ltd, UK) double-lumen or paediatric size gastroscope. Antibiotic prophylaxis with 1.5 g of cefuroxime was given at the induction of general anaesthesia. The abdomen was palpated to detect organomegaly prior to insufflation. The oropharynx was thoroughly suctioned. Contact between the equipment and the tumour was avoided by shielding the tumour with a hand. The gastrostomy site was selected with a combination of transillumination and palpation. The most favourable angle for insertion of the trocar created a well-defined indentation of the stomach wall. Indentation is more important than transillumination, which is often unsatisfactory. If indentation is equivocal then the 'safe tract' technique has been advocated[26]. A syringe of water is advanced while aspirating. If air enters the syringe before reaching the stomach then it has punctured another hollow viscous and an alternative site should be selected. In the guidelines of the British Society of Gastroenterology[24] it is recommended that all three techniques be successfully applied. This surgeon tends to use the aspiration technique only if the procedure is complicated, for example by obesity or previous abdominal surgery. If there is doubt about the safety of the procedure then a radiologically guided gastrostomy should be obtained. A second-look gastroscopy was always performed and the stomach decompressed. All patients were commenced on an antacid drug and given 30 ml of sterile water per hour overnight, via the PEG, before feeding was commenced, usually within 24 h of surgery.

Study method

Data were prospectively collected and included: patient details, the stage and site of the tumour, the timing of insertion and removal, duration of procedure, incidental findings, the surgical procedure, administration of radiotherapy with or without chemotherapy, and complications. If indicated, radiotherapy was usually given after surgery.

Statistical analysis

Kaplan–Meier survival methods were used to estimate the percentage of cases with a PEG still in place after 1 year and the median duration. PEG duration was calculated as the number of days from insertion to either (a) removal, (b) patient death with the PEG in place or (c) 10 February 2007. For patients having more than one PEG, but a continuous period of use, the duration was computed from the date of initial insertion. The log-rank test was used to compare PEG duration curves.

Results

Insertion of a PEG was attempted on 225 consecutive occasions in a total of 206 patients between May 2000 and January 2007. There was a minimum period of 30 days' follow up. During this study three patients preferred to have a nasogastric tube, of which one subsequently required a PEG during radiotherapy treatment. One patient was referred for a RIG because of a previous oesophagectomy. The patient data are tabulated in Table 1. The main indication was malignant disease of the oral cavity. Sixteen oncology patients, who had their initial PEG and surgical treatment performed at Leicester, had the gastrostomy replaced either because of a second tumour, recurrent disease, leakage or disintegration of the tube, of which 10 had continuous use that ranged from 205 to 2284 days. Two patients did not use the PEG, of which the first recovered quickly after surgery and the second received only palliative care.

Seventy-five percent (169/225) of insertion procedures followed the tracheostomy at the time of definitive surgical treatment (Table 2). The median procedure time was 10 min. The rate of successful insertion was 97% (219/225). One patient had a successful insertion at a second separate attempt, with a paediatric gastroscope, because of an oesophageal stricture. A RIG was obtained for two patients because of a post-cricoid web and morbid obesity. There were incidental endoscopic findings during 11% (24/225)

Table 1. Patient data and indications for attempted PEG insertion ($n = 225$)

Number of patients	206
Male:female	130:76
Mean age in years (SD)*	62 (14)
Malignant tumour†	206
Replacement only	10
Facial fractures	3
Benign tumour	2
Severe dysplasia	1
Osteoradionecrosis	1
Secondary reconstruction	1
Neurological deficit	1

* Age at time of first PEG for those with more than one PEG.
† Including second tumour or recurrent disease.

Table 2. Success rate and timing of attempted insertion of PEG ($n = 225$)

Successful PEG insertion	97% (219)
Failed PEG insertion	3% (6)
At examination under anaesthesia	19% (42)
At definitive surgical procedure*	75% (169)
After definitive surgical procedure†	5% (12)
During radiotherapy treatment‡	<1% (1)
Neurological indication	<1% (1)
Median duration of procedure in minutes (IQR, range)	10 (8–12, 4–21)

IQR: interquartile range.
* Includes facial trauma (3).
† Definitive surgery elsewhere (1) and replacement only (10).
‡ Initially refused PEG insertion.

Table 3. Incidental findings during endoscopy ($n = 225$)

Post-cricoid web	1*
Barratt's oesophagus	1*
Oesophageal adenocarcinoma	1*
Oesophageal stricture	3*
Benign oesophageal lesion biopsy	3*
Gastro-oesophageal reflux	1
Hiatus hernia	1
Gastritis	10
Benign gastric ulcer biopsy	2*
Retained suture at gastric resection site	1

* Significant clinical finding.

of gastrostomies, of which 11 (5%) were significant (Table 3).

The incidence of minor complications was 12% (26/225) (Table 4). A clinically detectable infection occurred at 7% (15/219) of gastrostomy sites, of which seven were infected with methicillin-resistant *Staphylococcus aureus* (MRSA). The incidence of major complications was 3% (7/225) (Table 4). There was no mortality directly related to the PEG procedure. One elderly patient with a large pneumoperitoneum and phrenic nerve injury succumbed to a chest infection exacerbated by these complications. The overall 30-day mortality rate after an insertion procedure was 6% (14/225). This included patients with terminal malignant disease. Within the malignancy subgroup that had undergone major surgery, mostly for advanced disease, the 30-day mortality rate was 5% (10/191). Those at increased risk of death were 65 years and over (12% vs. 2%, $P = 0.004$).

The PEG durations were analysed with regard to age, stage of disease, type of resection and reconstruction, and modality of treatment. The median duration was 337 days (SE 31). Duration was not significantly different for those less than 65 years of age ($P = 0.324$). Duration was significantly longer for stage T3–4 disease ($P = 0.028$), N1 or greater neck disease ($P = 0.034$) and following surgery with radiotherapy when compared to surgery alone ($P < 0.001$) but not when compared to radiotherapy alone ($P = 0.179$) (Table 5 and Fig. 1). Duration was also significantly longer for radiotherapy alone when compared to surgery alone ($P = 0.003$). The radiotherapy alone group were pri-

Table 4. Complications of PEG insertion

Major complications	
Aspiration	0
Peritonitis	0
Dislodged tube passed per rectum	2
Tube migration into gastric wall*	2
Perforation	0
Gastrocolic fistula	0
Haemorrhage	2
Major infection	0
Tumour implantation	0
Large pneumoperitoneum	1
Minor complications	
Peristomal wound infection	15
Peristomal bleed	1
Peristomal leakage	4
Tube obstruction or fragmentation	6**
Tube migration in to small bowel	0

Based on Schapiro & Edmundowicz[32].
* Buried bumper syndrome.
** One additional patient excluded as initial PEG inserted elsewhere.

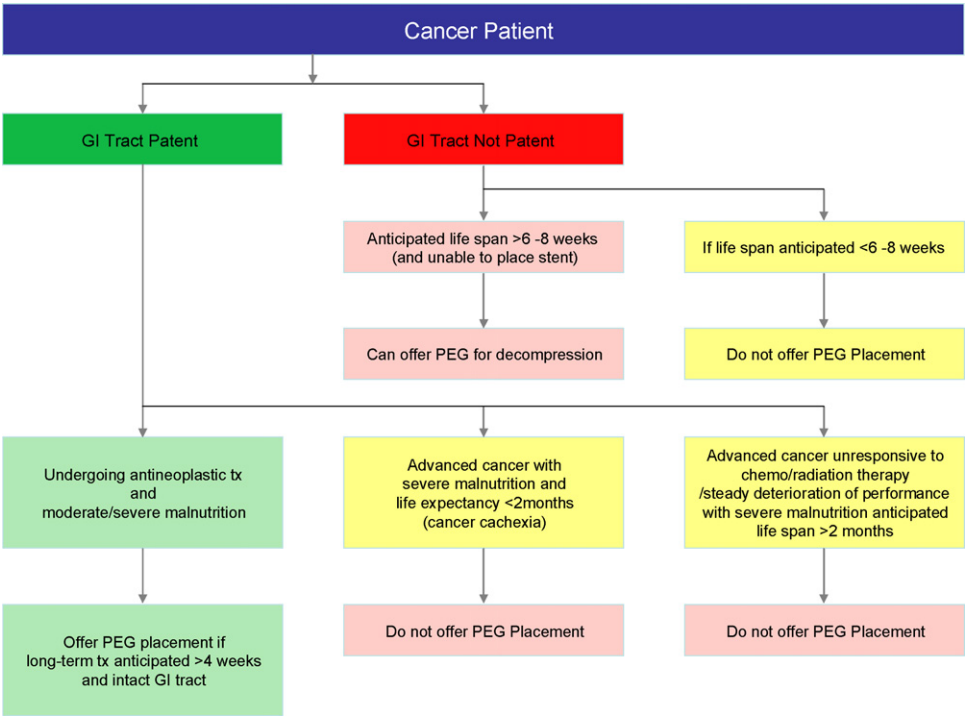

Fig. 1. Algorithm for gastrostomy insertion (based on Rabeneck et al.[27]).

Table 5. Differences in median PEG duration between treatment and operation subgroups

Variable	Median (SE) duration of PEG in days	Variable	Median (SE) duration of PEG in days	Statistical significance log-rank test
T1–2	281 (38)	T3–4	441 (85)	$P = 0.028$
N0	291 (59)	N1 and greater	441 (143)	$P = 0.034$
Surgery and radiotherapy	366 (74)	Surgery alone	211 (29)	$P < 0.001$
Radiotherapy alone	50% survival not reached	Surgery alone	211 (29)	$P = 0.003$
2 separate surgical procedures and radiotherapy	713 (437)	Surgery alone	211 (29)	$P = 0.046$
Primarily soft-tissue resection	274 (33)	Primarily composite bone resection	363 (23)	$P = 0.031$

Patients receiving additional chemotherapy are included within the radiotherapy group.

marily T3 or T4 oropharyngeal tumours, or the patient was not fit for surgery.

There was no statistically significant difference between operation subgroups with at least six patients within the surgery with radiotherapy group and within the surgery alone group (Table 6). For glossectomy ($P = 0.038$) and maxillectomy procedures ($P = 0.003$), the median duration was significantly longer with surgery and radiotherapy when compared to surgery alone. The limited numbers prevent statistical testing within other subgroups. Four patients had undergone either extensive resection[1], multiple sites of resection[2]

Table 6. Relationship between duration of PEG placement and other factors for oncology procedures ($n = 206$)

	Procedures (n)	% (SE) with PEG after 12 months	Median (SE) duration of PEG in days	Individual PEG duration (<10 cases)
Age less than 65 years	108	43 (5)	300 (49)	
Age 65 years and over	98	45 (7)	363 (48)	
T1–2	85	39 (6)	281 (38)	
T3–4	105	51 (6)	441 (85)	
N stage 1 or greater disease	83	52 (6)	441 (143)	
N0 stage disease	106	39 (6)	291 (59)	
By treatment modality and operation				
Surgery and radiotherapy	107	49 (6)	366 (75)	
Glossectomy[†]	18	45 (14)	366 (110)	
Hemimandibulectomy	15	44 (14)	363 (32)	
Anterior floor of mouth ± rim resection	11	41 (16)	212 (30)	
Anterior mandibulectomy	6	50 (25)	257 (225)	46*, 70*, 74, 257, 262*, 749
Oropharynx	13	51 (14)	308 (119)	
Partial and hemimaxillectomy	12	60 (16)	713 (347)	
Buccal resection	7	67 (19)	503 (143)	281, 360, 502*, 503, 897*, 2284*
Multiple sites of resection	6	60 (22)	–	232*, 246, 358*, 383*, 1016*, 2131*
Two separate surgical procedures and radiotherapy	7	57 (19)	713 (437)	134, 246, 295, 502*, 713, 749, 2284*
Surgery alone	77	27 (7)	211 (29)	
Glossectomy[†]	34	32 (10)	208 (33)	
Hemimandibulectomy	9	–	–	5*, 7*, 9*, 17*, 28*, 75*,
Anterior floor of mouth ± rim resection	12	30 (17)	166 (82)	113*, 385*, 541*
Partial and hemimaxillectomy	10	0 (–)	112 (15)	
Radiotherapy (no surgery)	13	51 (19)	50% survival not reached	
By principle type of resection				
Primarily soft-tissue resection	114	38 (5)	274 (33)	
Anterior floor of mouth ± rim	23	37 (11)	206 (33)	
Glossectomy[†]	52	37 (8)	226 (10)	
Oropharynx	16	48 (13)	308 (138)	
Buccal	11	51 (18)	503 (124)	
Retromolar ± rim	6	0 (–)	211 (131)	25*, 57, 91, 211, 229, 274
Primarily composite bone resection	64	49 (8)	363 (233)	
Hemimandibulectomy	30	51 (13)	337 (31)	
Partial and hemimaxillectomy	22	45 (14)	357 (109)	
Anterior mandibulectomy	8	50 (20)	257 (203)	46*, 70*, 74, 85, 257, 262*, 338*, 749

Includes oncology patients with osteoradionecrosis (1), secondary reconstruction (1) and severe dysplasia (1). Excludes oncology patients with a nasogastric tube (3), lost to follow up (1), initially unsuccessful insertion (1) and subgroups with less than six procedures or procedures not amenable to subclassification.

[†] Glossectomy includes hemi, partial and subtotal glossectomy. [*] PEG in place at death or on 10 February 2007.

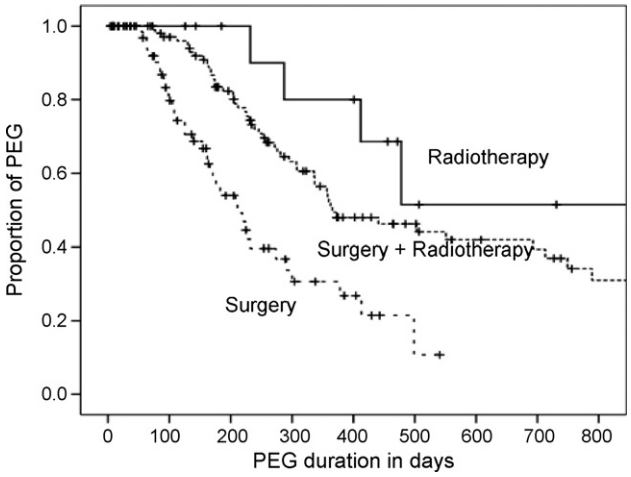

Fig. 2. Duration of PEG by modality of treatment.

or two separate surgical procedures with radiotherapy[1], and had a PEG in place for over 1000 days that is unlikely to be removed.

Patients who underwent two separate surgical procedures and radiotherapy had longer durations on average than those having a single surgical procedure (Table 5, $P = 0.046$) but the duration was similar to those undergoing a single surgical procedure and radiotherapy ($P = 0.975$). The duration following a primarily soft-tissue resection was significantly shorter than after a composite bone resection ($P = 0.031$) (Table 5 and Fig. 2). Reconstruction of the oral cavity or pharynx was performed with a variety of techniques. The free flaps included radial (102), deep circumflex iliac artery[23], fibula[11], rectus abdominus[11] and composite radial[7] flaps. Pedicled flaps used included pectoralis major[14] and temporalis[2] flaps. Primary wound closure or skin grafting[11] was also used. There was no obvious relationship between the type of free or pedicled flap and duration of the PEG. Flaps used for only extraoral defects were excluded from this analysis.

Discussion

The rate of successful PEG placement in the current study of 97% is comparable with a large meta-analysis of the gastroenterological literature by Wollman et al.[40] (95.7%) and current head and neck practice (90–98.5%)[3,5,12,17,18,37,38]. The majority of patients with common gastrointestinal pathology, including partial gastrectomy, were successfully treated. Patients with severe trismus and one patient with an oesophageal stricture were managed with a paediatric gastroscope. A RIG was the first choice for a patient with a previous oesophagectomy and was necessary after two failed insertions because of a post-cricoid web and morbid obesity.

The classification and incidence of procedure-related complications is variable and largely based on retrospective reports of differing groups of patients, often including a mix of neurological and oropharyngeal malignancy[32]. Schapiro & Edmundowicz[32] reported two reviews with mean incidences of major complications of 2.7–2.8% and minor complications of 6–7.1%. Wollman et al.[40] reported a major complication rate of 9.4% and minor complication rate of 5.9%, with a procedure-related mortality of 0.53%. In the Guidelines of the British Society of Gastroenterology[24] the incidence of major complications is stated to be about 3%. The exact incidence depends upon the patient population and is generally higher with malignant disease. The complication rates are similar irrespective of the technique used, whether this is the common pull (Ponsky) method, the push (Sachs-Vine) method or the direct introducer (Russell) method. In head and neck surgical practice the incidence of major complications ranges from 0% to 35% and minor complications from 8% to 17.5%[3,5,12,17,18,37,38]. The incidence of major complications appears to be higher when the operator is a trainee, whether a surgeon or gastroenterologist[6,24,38]. In the experience of this surgeon and Lloyd & Penfold[18] the major complication rate of an experienced maxillofacial surgeon is relatively low, 3% and 0%, respectively.

Aspiration and pneumonia are common major complications[32]. Aspiration may occur during the procedure or later as a result of oropharyngeal aspiration or gastro-oesophageal reflux. The supine position and an oropharyngeal tumour may increase the risk of aspiration, especially when the gag reflex is obtunded[24]. The incidence of respiratory distress under intravenous sedation may be as high as 7% with airway obstruction occurring in 1%[10]. It has been recommended that sedation or general anaesthesia should be avoided unless the tumour has been removed or the airway secured, sometimes with a tracheostomy, and the PEG performed in theatre[5,13,18]. Oncology surgeons often prefer to take the opportunity to place the PEG either during an examination under general anaesthetic or at the time of the definitive operation. In both instances the airway is protected by an endotracheal tube or tracheotomy. This may reduce the risk of aspiration or cardio-respiratory complications[5]. It also avoids an additional separate treatment episode[12,17]. Enteral feeding may commence 4 h after insertion but is not without risk of aspiration and death[20]. The author prefers to defer feeding after major surgery for 12 h because gastric emptying may be delayed and the airway reflexes obtunded. This also allows initial evaluation of the abdomen after harvest of free flaps such as the rectus abdominus or iliac bone.

In the current series infection of the stoma site was the commonest minor complication. Infection with MRSA may be increasingly common[4] but was of no serious consequence in the authors' experience. Two patients developed a buried bumper syndrome. This complication occurs after 1.9% of procedures[8]. It typically presents as a late complication with difficulty flushing and leakage. Excessive tension may lead to migration of the flange beneath the gastric mucosa. The PEG may be removed endoscopically or with a mini-laparotomy approach. This surgeon now has a lower threshold for gastroscopy and replacement of a PEG that has been in place for over 1 year.

The 30-day mortality rate after PEG insertion varies with many factors. Janes et al.[14] noted an increasing mortality rate, from 8% to 22%, with greater use of the technique but the procedure-related mortality decreased from 2% to 0%. In the meta-analysis by Wollman et al.[40] the mortality rate was 14.7% and in a later series by Wollman & D'Agostino[39] it was 10%. Lower mortality rates of 4.5% with a PEG and 3.1% with a RIG have recently been reported[36]. In the current study the 30-day mortality rate after an insertion procedure was 6%. This included patients that proved to have terminal disease. The risk of death was significantly higher in

those aged 65 years and over. There was no evidence that insertion of the PEG at the time of major surgery affected the mortality rate.

The value of early placement of a gastrostomy tube prior to radiotherapy and chemotherapy, for mostly advanced oropharyngeal and laryngeal malignancy, has been established in several retrospective studies on the basis of several factors, including a reduction in weight loss, duration and frequency of hospitalisation, fewer treatment interruptions[1,2,16,25] and improved quality of life issues[19,34]. The exact timing of gastrostomy insertion prior to surgery remains contentious. Head and neck surgeons with an otolaryngology background often have the tube inserted as a separate episode prior to the definitive surgical procedure[9,12], or at examination under anaesthesia and both during and after surgery[17,37].

Recent publications from maxillofacial surgeons, managing mainly carcinoma of the oral cavity, have favoured early PEG insertion, sometimes at the time of examination under anaesthesia but principally at the time of definitive surgery when a safe airway has been obtained[3,5,18]. These patients are at increased risk of respiratory compromise because of a high incidence of grade 2–4 intubation scores on the American Society of Anaesthesiologists scale[3,5]. Insertion after surgery or during radiotherapy is less frequently performed. In the current study 19% of patients had the PEG placed at the time of examination under anaesthesia. These were mainly patients with oropharyngeal tumours managed by radiotherapy, inoperable disease, poor medical condition, or marked weight loss including a few that underwent a trial period of feeding before the treatment modality was decided. It is important to try to identify patients that will not benefit from a PEG including those likely to die soon after the procedure. The risk factors for early death in other studies have included age over 75 years, urinary tract infection, diabetes mellitus, cardiac failure, severe functional impairment and dementia[14,28]. There is little information on quality of life considerations[14]. The majority (75%) of patients in the current study had a PEG inserted at the time of definitive surgery. This was immediately after the tracheostomy and before the tumour was resected. The tumour is identified and carefully shielded from the endoscopic equipment to minimise the risk of implantation. A PEG was not inserted after tumour removal because resection does not usually significantly improve access and would require re-draping of the surgical field. Placement immediately after reconstruction is undesirable because of the risk of damaging the flap. Only one patient had a PEG inserted after definitive surgery and another during radiotherapy.

There is debate as to which insertion technique is most appropriate for head and neck oncology patients. The PEG is currently the gold standard technique of gastrostomy insertion[15], but many gastrostomy tubes are placed using fluoroscopic, ultrasound and computed tomography guidance[15,36]. The relative merit of each technique is beyond the scope of this article, but the outcome is variable and probably operator dependent. In the large meta-analysis of the gastroenterology literature by Wollman et al.[40] the rate of successful insertion was significantly higher for a RIG (99.2%) than a PEG (95.7%) and major, but not minor, complications were significantly less frequent, 5.9% and 9.4%, respectively. A subsequent publication supported these findings, with no difference in the 30-day mortality rate between the techniques[39]. More recently, higher rates of successful PEG insertion of 96–100%, together with a lower incidence of complications, have been reported in the head and neck literature[3,5,36], including those inserted by a maxillofacial team[18] and in the findings of the current series. Although the rates of success reported for the RIG technique may remain marginally higher, the procedure is often less readily available. It is also not infallible, as two of the patients in the current series also failed a RIG procedure because of a previous partial gastrectomy and a severe oesophageal stricture.

A RIG has been advised on the basis of several additional factors including the limited diagnostic yield of routine gastroscopy[15]. The prevalence of incidental findings during endoscopy ranges from 10% to 71%[39]. Wollman & D'Agostino[39] noted a 30% rate of incidental endoscopic findings in their series, of which 10% had an intervention, mostly for peptic disease. In their opinion the clinical importance of many incidental findings is unproven, but in the head and neck oncology group there is a relatively high incidence of synchronous and metachronous tumours[11]. In the current series significant pathology was detected in 5% of gastroscopies including one synchronous oesophageal adenocarcinoma and a Barrett's oesophagus. Chandu et al.[3] reported one synchronous gastric carcinoma and a Barrett's oesophagus amongst 49 patients, and Rustom et al.[29] detected seven synchronous tumours in 78 patients. A further argument is that a RIG may avoid tumour implantation at the gastrostomy stoma site[15]. This rare complication is now recognized and the head and neck surgeon is ideally trained to identify and shield the tumour during the procedure[17,37].

The availability of the RIG technique and the degree of local expertise is variable. By performing a PEG the surgeon avoids the logistical issues and inconvenience of a separate procedure, and provides a seamless service. There is a short delay between diagnosis and surgical resection; hence the issue of pre-surgical feeding is usually not important. A thorough examination of the oropharynx and an endoscopy are also performed when removing the gastrostomy. The procedure may be performed within a theatre environment, with an anaesthetist, as many patients will have a compromised airway after flap reconstruction and radiotherapy. It is for these reasons that the author prefers a PEG. A RIG is the procedure of choice only when endoscopy is unlikely to succeed, for example significant oesophageal obstruction, morbid obesity or extensive abdominal surgery. Occasional additional indications may include the need to avoid disturbing a recent surgical flap or suture line.

The exact pattern and duration of gastrostomy use during the phases of treatment for head and neck malignancy are unknown. Durations of gastrostomy placement are difficult to compare because the criteria for insertion vary and so do the methods of collating and presenting data. The mean or median values range from 13.8 to 67.1 weeks[3,6,18,21,35]. In the current series the median duration was 48 weeks. The delay between the provisional decision to remove a gastrostomy and removal was less than 6 weeks in most cases. Only four (2%) patients have had a PEG in place for over 1000 days and are unlikely to have it removed. In contrast to Mekhail et al.[21], there was no evidence of dependency on the PEG as a result of atrophy of the pharyngeal musculature. Prolonged dependency was more likely to be related to massive or repeated surgery together with radiotherapy. In the only other detailed analysis of PEG duration in patients treated for oral cancer, Chandu et al.[3] usually inserted the PEG at the time of definitive surgery. The mean duration of a gastrostomy removed electively was 114 days and in those that died with the PEG *in situ* it was 470 days. A long-term PEG was required for 14% of patients because of dysfunctional swallowing. In comparison, Schweinfurth et al.[33]

inserted the gastrostomy at varying times in 142 patients with primarily laryngeal or pharyngeal pathology. The incidence of a long-term gastrostomy was 27%.

Predicting the need for a gastrostomy and the likely duration placement is difficult because of an uncertain relationship to various factors, including age, medical and nutritional status, speech and swallowing function, tumour site and stage, the surgical resection and type of reconstruction. The indications for insertion have not been systematically studied and variable criteria have evolved with experience. When considering a report it is important to identify the tumour group and treatment modality being considered as publications from otolaryngology institutes often have a minority of oral carcinoma sites and a preponderance of non-surgical treatment. Gastrostomy has been advised for Stage III and IV disease of the oropharynx treated primarily with radiotherapy[25] or surgery[9], and also for combined modality treatment, previous radiotherapy or significant pre-treatment weight loss[7]. A significant reduction in hospitalisation was seen for pharyngeal and laryngeal sites but not for oral tumours[9]. The study by Gardine et al.[7] reviewed a mixture of PEG, nasogastric and oesophagostomy routes and was unusual as it contained a majority of oral tumours. These patients had a slightly higher incidence of prolonged dependency on tube feeding, but the factors associated with a significantly increased risk of long-term nutritional support included stage IV disease, pharyngeal tumours, combined modality treatment and previous radiotherapy or significant pre-treatment weight loss. For primarily oropharyngeal and laryngeal malignancy, Schweinfurth et al.[33] also identified several predictive factors, including heavy alcohol use, base of tongue tumours treated with radiotherapy, reconstruction with a myocutaneous rather free flap, postoperative radiotherapy, mandibulectomy, moderately or poorly differentiated tumours, and large tumour size, but not TMN stage or surgical resection of the floor of mouth and oral tongue. For the surgical treatment of mainly oral carcinoma, Chandu et al.[3] listed the indications for gastrostomy insertion as Stage III and IV disease treated with surgery and radiotherapy, and Stage I and II disease in association with major neck dissections with or without distant flap. For benign disease the indications were large composite resections with free flap reconstruction. Factors that may have influenced PEG duration were not analysed.

In the current study, the duration of gastrostomy was significantly longer for stage T3–4 tumours, N1 or greater neck disease, following surgery with radiotherapy when compared to surgery alone, and for radiotherapy alone when compared to surgery alone (Table 5 and Fig. 2). The radiotherapy alone group were primarily stage T3 or 4 oropharyngeal tumours. Unlike previous studies there was a significantly increased median duration for glossectomy and maxillectomy procedures with radiotherapy when compared to surgery alone. Patients that underwent two separate surgical procedures and radiotherapy had significantly longer durations on average than those having a single surgical procedure. The duration following a primarily soft-tissue resection, with or without a rim resection, was significantly shorter than after a segmental composite bone resection (Table 5 and Fig. 3). There was no obvious relationship with the type of flap reconstruction, but this will be amenable to further analysis with greater patient numbers. A limitation of this study was the lack of a control group. Changes in weight or other physical and biochemical nutritional parameters have not been analysed.

The current indications for PEG insertion are listed in Table 7. All patients with T3 and T4 oropharyngeal tumours undergoing radiotherapy and patients with oral tumours that require reconstruction with a free or pedicled flap are offered a PEG on the basis that recovery of oral function is not expected within 2–4 weeks. This includes T2 tumours without neck disease (stage II disease) if the site of the tumour is likely to have a significant effect on function and hence a flap reconstruction is indicated. Those undergoing a smaller oral procedure or extraoral resection, particularly in conjunction with a neck dissection, that may compromise oral function are also offered a PEG. Other factors may also impact upon this decision-making process, particularly a history of previous surgery or radiotherapy. Walton[38] has advocated a more selective insertion policy on the basis of an unusually high incidence of major complications, probably as the result of not having an experienced endoscopist. In this series only two patients did not utilise the PEG and a more restrictive insertion policy would probably have led to more gastrostomies being performed at a later stage, when the patient may be in a more debilitated state. The current threshold for PEG insertion is lower than in other studies because it is difficult, at present, to identify a subgroup of patients that would not benefit from a PEG. The exact pattern of gastrostomy use during the different phases of treatment

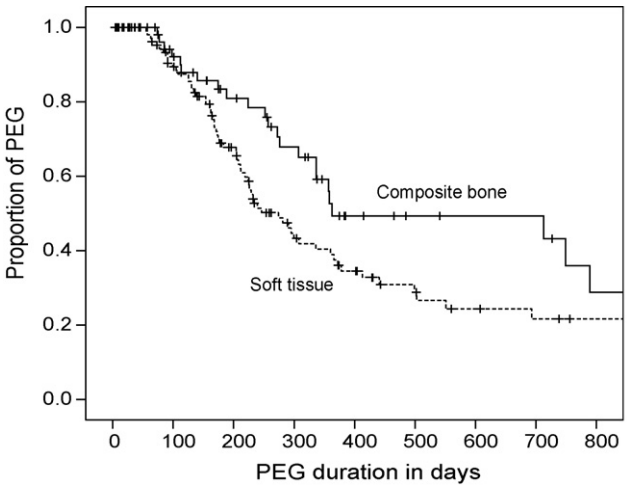

Fig. 3. Duration of PEG by principle type of resection.

Table 7. Current indications for insertion of a PEG in oncology patients

- Fundamental criteria for insertion have been met and PEG not contraindicated
- Recovery of oral function within 2–4 weeks is not expected
- Malnutrition or at risk of malnutrition during treatment
- T3 and T4 oropharyngeal tumours undergoing surgery or radiotherapy
- Intraoral reconstruction with free or pedicled flap, including T2 tumours
- Smaller oral procedure or extraoral surgery, particularly in conjunction with a neck dissection, flap or graft repair and likely to adversely affect oral function
- Other factors may be relevant, i.e. previous surgery or radiotherapy

has not been studied. It is particularly important to try to identify patients that are likely to die soon after the procedure.

This study has confirmed that a PEG may be inserted with a high degree of success and minimal complications by an experienced maxillofacial surgeon. Most gastrostomies may be inserted at the time of definitive surgery after the tracheostomy or intubation. Those patients requiring insertion at an initial examination under anaesthesia may usually be identified as having advanced oral or oropharyngeal disease, are likely to receive radiotherapy with or without chemotherapy as the primary modality of treatment, are in poor general health, are unsuitable for major surgery, and have had significant weight loss or demonstrable weight gain is desirable prior to the decision about the final treatment modality. The incidence of late gastrostomy insertion should be low. This surgeon is now able to more accurately advise patients about the likely duration of the PEG. Prolonged dependency is associated with T3–4 tumours, N1 or greater neck disease, the combination of surgery and radiotherapy and particularly two surgical procedures, and a segmental bone resection. The incidence of permanent dependency on the gastrostomy is low.

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Short communication

Early detection of bone union with transcutaneous ultrasound in the management of non-union of the mandible

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Abstract

The management of complicated non-union of free flap osteotomy sites is both challenging and time consuming. If external fixation has been applied it may be difficult to know when sufficient bone union has occurred for safe removal of the fixation device. The progression of bony healing is conventionally monitored with radiographs or occasionally computed tomography (CT). Transcutaneous ultrasound is a simple, safe, and readily available investigation that gives early objective evidence of bone healing, reassuring both the patient and the surgeon.

Keywords: Mandibular non-union; Transcutaneous ultrasound; Osteotomy; External fixation

Introduction

The management of complicated non-union of free flap osteotomy sites and complex fractures of the mandible is both challenging and time consuming. If external fixation has been applied it may be difficult to know when sufficient bone union has occurred for it to be safe to remove the fixation device. The progression of bony healing is conventionally monitored with radiographs or occasionally computed tomography (CT). However, plain radiographs are insensitive to early callus formation[1] and artefacts from the hardware used for fixation frequently degrade CT images. Magnetic Resonance Imaging (MRI) images are also degraded by hardware artefact especially from metal. MRI is also not very sensitive for detection of early callus formation. Transcutaneous ultrasound has been shown to demonstrate early evidence of healing in long bone fractures by detecting initial callus formation.[2]

Methods

The aim of this study was to assess the effectiveness of transcutaneous ultrasound evaluation in two patients with complicated non-union of free flap osteotomy sites. Ultrasound is performed using a standard linear probe suitable for scanning superficial structures. The Dental Panoramic Tomogram (DPT) is reviewed before scanning the patient. Patient is seated comfortably on a couch and scans are obtained in both axial and coronal planes. Detection of echogenic foci within the fracture gap was the criterion for evidence of healing progression as this correlates with histological evidence of callus maturation.[3]

The progression of bony healing was monitored with serial DPTs and ultrasound scans of the osteotomy or fracture sites.

Cases

Oncology Case 1

A 40-year-old female underwent a hemimandibulectomy and unilateral neck dissection for a T4N1M0 adenoid cystic car-

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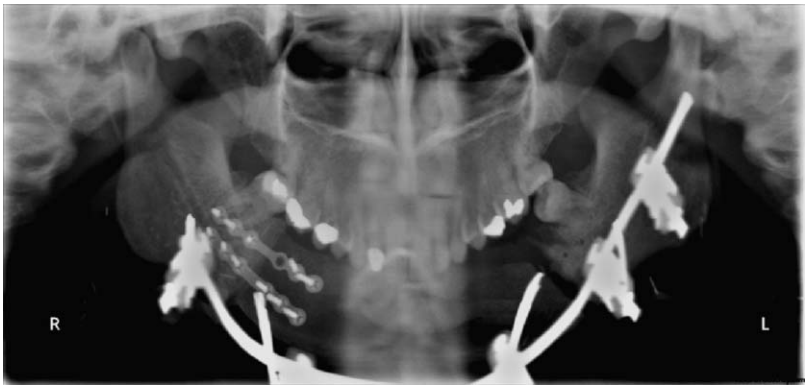

Fig. 1. Plain film orthopantomogram on left showing free flap osteotomy site with external fixator applied and no evidence of callus formation 12 weeks after applying the fixation.

cinoma of the submandibular gland. The resection defect was reconstructed with a myo-osseous deep circumflex iliac artery (DCIA) free flap. Following surgery radical radiotherapy was given. Intra and extra-oral wound breakdown developed and was further complicated by non-union at the parasymphyseal osteotomy site. Management included antibiotics, hyperbaric oxygen therapy, debridement, removal of the bone plates and a pectoralis major flap. Bony union was finally achieved with an external fixator applied for 4 months. Ultrasound performed 6 weeks following application of external fixator device showed multiple echogenic foci (white arrow) in keeping with early callus formation (Figs. 1 and 2)

Oncology Case 2

A 44-year-old female underwent an anterior segmental mandibulectomy and bilateral neck dissections for a T4N0M0 high grade fibroblastic osteosarcoma of the anterior mandible. The defect was reconstructed with a myo-osseous DCIA free flap. Following surgery neoadjuvant chemotherapy with Cisplatin and Doxorubicin was given. Healing was delayed by local infections and acute neutopenic episodes resulting in non-union of one of the osteotomy sites. Management included antibiotics, hyperbaric oxygen, debridement and removal of the bone reconstruction plates. Union was finally achieved with an external fixator applied for 3 months.

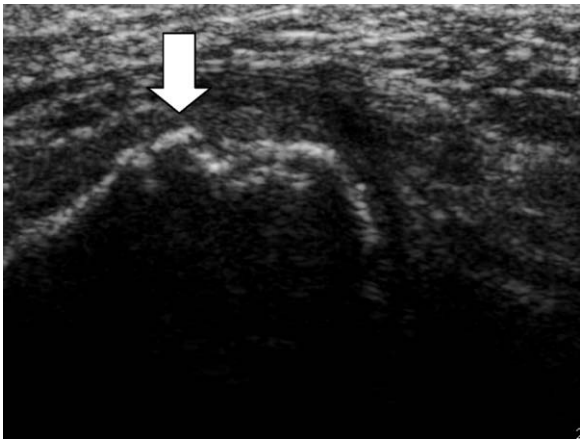

Fig. 2. Ultrasound scan on the same day clearly demonstrates echogenic callus in the osteotomy gap (arrowed). Fixation was removed 4 weeks later and the patient recovered uneventfully.

Results

During the duration of external fixation in both cases the osteotomy sites were monitored with serial radiographs, CT scans and ultrasound assessments. There was uncertainty as to when the external fixation could be safely removed as the radiographs and CT scans were often significantly distorted by artefacts from the external fixation. Initial callus formation was first seen during ultrasound scanning.

Transcutaneous ultrasound scanning detected early callus formation that preceded the radiographic changes by 4–6 weeks.

Conclusion

Transcutaneous ultrasound is a simple, safe, and readily available investigation that gives early objective evidence of bone healing. In the management of complicated wounds and non-healing osteotomy sites this provides reassurance for both the patient and surgeon. In conjunction with the clinical and radiographic findings it assists in determining when it is possible to safely remove external fixation. The use of transcutaneous ultrasound can also be applied in the management of the maxillofacial trauma patient requiring external fixation.

Conflict of interest

None to declare.

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Leicester, for his help and sharing his experience with Ultrasound imaging of osteotomy sites.

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The use of the pectoralis major flap for advanced and recurrent head and neck malignancy in the medically compromised patient

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SUMMARY

A retrospective review of seventy-one PPM flaps used between 1996 and 2010 primarily for oral and oropharyngeal squamous cell carcinoma presenting as either advanced stage IV primary disease (41/43), extensive recurrent (10) or metastatic (9) neck disease. The PPM flap was most commonly used following resection of the mandible (23) or the tongue/oropharynx (19). When the PPM flap was the preferred reconstruction option (54) the main indication, in addition to advanced disease, was significant medical co-morbidity (23). The majority of PPM flaps (75%) were used in the latter half of the series for an increasing number of patients in poor health with advanced disease. There was no evidence of an increase in age, ASA grade or extent of disease during this period. Approximately one quarter (17) of the flaps were used after failure of a free flap, most commonly a DCIA (7) or radial (6) flap. The 30 day mortality in this group of compromised patients undergoing major surgery for advanced disease was 7% (5/71). The overwhelming majority had significant co-morbidity (94% grade 2 or higher with 63% ASA grade 3) and 90% had already undergone previous major surgery and/or radiotherapy.

The 1-year, 3-year and 5-year overall survival rates were 65.5%, 39.1% and 11.0% respectively with cancer-specific survival rates of 82.0%, 65.5% and 65.5%. The majority died of disease related to the underlying co-morbidity. We recommend an aggressive approach to the surgical resection of advanced and recurrent disease but a pragmatic approach to reconstruction. The PPM major flap is reliable for reconstruction of defects of the mandible, tongue and oropharynx with a complete flap failure rate of 2.8%. Lateral defects of the mandible were managed without a plate and with an acceptable outcome in the context of limited life expectancy. This is the largest study of the use of the PPM flap for this type of patient group. The flap retains a major role in the management of advanced primary or recurrent disease, extensive metastatic neck disease and after failure of a free flap when in conjunction with significant co-morbidity.

Introduction

The pedicled pectoralis major (PPM) flap was initially described by Ariyan in 1979.[1,2] It soon became the "workhorse" flap for most reconstructive head and neck surgeons.[3–6] Subsequently free tissue transfer techniques have achieved increasing reliability with apparent benefits in oral function combined with fewer complications, although PPM flaps may still have been preferred for advanced disease.[7–13] The cost of treatment is controversial but broadly comparable for pedicled and free flaps when all aspects of care, including complications, have been considered.[14–17] Hence the PPM was gradually relegated to a secondary role in most units practising free flap surgery. The aim of this study was to review our use of the PPM flap in a unit that has routinely performed free tissue transfer surgery as the reconstruction of choice.

Patients and methods

A retrospective review was undertaken of the use of the PPM flap in the Department of Maxillofacial Surgery, The University Hospitals of Leicester. Consecutive patients were identified from theatre records and a contemporaneous database. Data recorded included demographic details, indications, pathological staging using the TNM classification system of the International Union against Cancer 1997, surgical resection, American Society of Anaesthetists ASA grade, co-morbidity, previous treatment with radiotherapy and/or major surgery. Flap related complications were classified using the categories described by Kroll.[4] Total flap loss reflected complete loss of the skin and muscle paddle. Major tissue

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loss was less extensive but delayed hospital discharge or required surgical revision and minor tissue loss did not delay discharge or require revision.

The decision to use a PPM flap was taken in conjunction with the same dedicated head and neck anaesthetist and with a multidisciplinary team over the latter half of this period. There may be several indications so only the most pertinent factor, in addition to advanced disease, was selected. A pedicled myocutaneous flap was raised utilising a defensive deltopectoral incision. Occasionally extension over the rectus sheath was necessary but tissues that appeared poorly perfused were excised. The pedicle was skeletonised preserving the lateral thoracic artery when possible and the flap tunnelled over the clavicle. A neck dissection was performed with removal of the sternocleidomastoid muscle to accommodate the pedicle if necessary. Lateral segmental defects of the mandible were not reconstructed with a plate. The overwhelming majority of patients were managed in a high dependency environment rather than an intensive care facility.

Statistical analysis

Categorical variables were analysed using the Chi-squared or Fisher's exact test and continuous variables using the Mann–Whitney U test or Spearman's correlation coefficient. The primary long-term outcome measure was overall survival (as of April 2010). Cancer-specific survival was considered as the secondary end-point. Patients who died within thirty-days of surgery were excluded from the long-term survival analysis. Kaplan–Meier survival curves were constructed to analyse long-term survival trends and associations of variables with long-term survival determined by application of the log-rank test. Statistical significance was defined as $P < 0.05$. Statistical analyses were performed using Statistical Package for the Social Sciences 14.0® (SPSS, Chicago, Illinois, USA).

Results

Between April 1996 and March 2010 seventy-three PPM flaps were performed. The complete data was available for 71 procedures and the other two were excluded. Seventy flaps were ipsilateral and one was contralateral, the latter because of an implanted cardiac defibrillator device. There were 47 males and 24 females. The ages ranged from 41 to 88 years (mean 64.2 years). There was no significant variation in age or rate of free flap failures throughout the study. The frequency of flap use fluctuated with a significant increase in the number of flaps performed per year over time ($P = 0.01$) (Fig. 1). The majority of flaps, 53 out of 71 (75%), were performed in the latter half of the series, with the most used in 2008 (12).

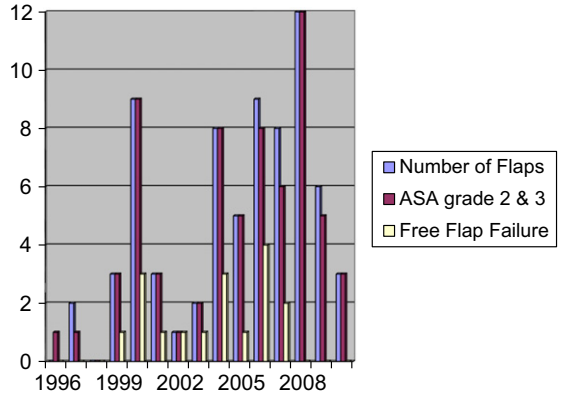

Figure 1 Pectoralis major flap use by year.

Table 1
Diagnosis and anatomical site.

	Total ($N = 71$)	Primary reconstruction (n)	Failed free flap (n)
Primary squamous cell carcinoma:	**43**	**30**	**13**
Oral tongue	14	11	3
Oropharynx	5	4	1
Mandible	23	14	9
Maxilla	1	1	–
Recurrent squamous cell carcinoma:	**19**	**16**	**3**
Oral cavity and oropharynx	10	7	3
Neck	9	9	–
Osteoradionecrosis	**2**	**2**	–
Other primary or recurrent tumour[a]	**2**	**1**	**1**
Other metastatic tumour[b]	**3**	**4**	–
Bleeding major neck vessels	**2**	–	–

[a] Melanoma and nerve sheath tumour.
[b] Meibomian gland carcinoma (1), peripheral nerve sheath tumour (1), small cell carcinoma nose (1).

The diagnosis and principle anatomical sites are listed in Table 1. Forty-three patients were treated for a primary head and neck squamous cell carcinoma. Most had pathological stage IV disease except for two patients who were stage II and III respectively. The most common stage of neck disease was N2 (15), the remainder were N0 (13), N1 (13) and N3 (2). The PPM flap was most frequently used after resection of the mandible, including lateral segmental (17), rim (4) and anterior (2) resections. Resections of the tongue and/or oropharynx comprised the other main group (19). Patients in the first third of the study were significantly more likely to have presented with recurrent disease ($P = 0.038$). Nineteen patients had recurrent squamous cell carcinoma, either at the primary site (10) or in the neck (9). Eight resections involved skin and created a full thickness oral defect. The incidence of total flap failure was 2.8% (2) and both occurred with cheek/maxillary reconstructions, major loss was 8.4% (6) and minor loss 12.6% (9).

The PPM flap was the reconstruction of choice on 54 occasions (Table 2). In addition to advanced disease the main indications were significant medical co-morbidity (23), high volume neck disease [often with skin involvement] (10), recurrent disease (6) and breakdown of the neck (5). It was occasionally used with a free flap (3) or when recipient vessels were not available for a free flap (2). Approximately one quarter (17) of PPM flaps were used following free flap failure but this has not been an indication since 2007.

Ninety-four percent of patients were ASA grade 2 (21), 3 (45) or 4 (1) (Table 3). There was no significant variation in ASA grade with

Table 2
The main indications for pectoralis major flap.

Indication	($N = 71$)
Preferred reconstruction[a]	**54**
Medical morbidity	23
Large volume neck disease	10
Salvage procedure	6
Neck wound breakdown	5
Parotidectomy defect	3
With free flap	3
Osteoradionecrosis	2
Free flap not possible	2
Failed free flap	**17**
Radial	6
Composite radial	1
Deep Circumflex Iliac Artery (DCIA)	7
Fibula	3

[a] Principle reason, usually in addition to advanced disease, as could be in more than one reason.

Table 3
ASA grade.

ASA grade	All pectoralis major flaps ($N = 71$)	Initial free flap failure group ($n = 17$)
I	4	1
II	21	15
III	45	1
IV	1	0

time. Significantly more patients in the free flap failure group were originally ASA grade I or II [before salvage with a PPM flap] than patients initially managed with a PPM flap (94% [16/17] compared with 28% [15/54], $P = 0.001$) indicating that the free flap failure patients were originally in better general health. Ninety percent of patients had previously undergone treatment with radical radiotherapy (20, 28%), major surgery (29, 41%) or both (15, 21%).

The mortality rate within 30 days was high, 7% (5/71). The overall median long-term follow-up was 1.33 years (range 0.09–7.38 years). During this period 38 patients (57.6%) died; 14 from recurrent disease and 24 from intercurrent illness. Twenty-seven patients are alive without recurrent disease and one with recurrent disease. Overall and cancer-specific survival outcomes are presented in Figs. 2 and 3, respectively. The 1-year, 3-year and 5-year overall survival rates were 65.5%, 39.1% and 11.0% respectively (mean 2.70 years, 95% CI 1.94–3.45 years). Similarly, cancer-specific survival rates were 82.0%, 65.5% and 65.5%, respectively (mean 5.27 years, 95% CI 4.33–6.20 years). There was no difference in survival between the group with a PPM flap as the reconstruction of choice and the free flap failure group but the latter numbers are small.

Discussion

In the 1990's the PPM flap was still considered a reliable and effective flap for the primary or secondary reconstruction of oral and pharyngeal defects.[6,15,18,19] It has continued to be successfully used as the main reconstructive option for a variety of reasons including preference, costs and lack of expertise.[20–24] However, during this transitional period free tissue transfer has become firmly established as the preferred method of reconstruction in many maxillofacial units, although we are not aware of any data on worldwide practices. The aim of this study was to review our practice as there are no formal guidelines as to when to use the PPM flap in preference to free tissue transfer.

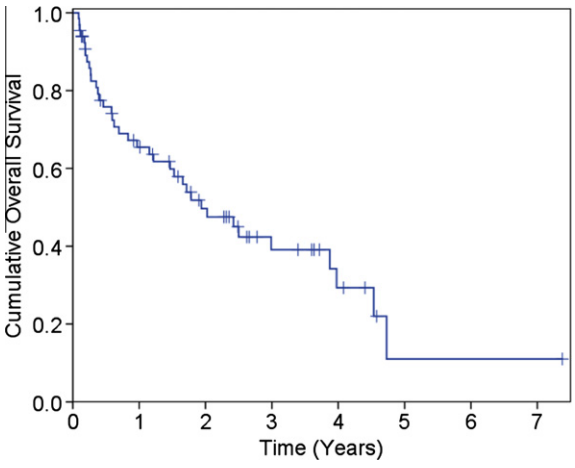

Figure 2 Kaplan–Meier curve for cumulative overall survival.

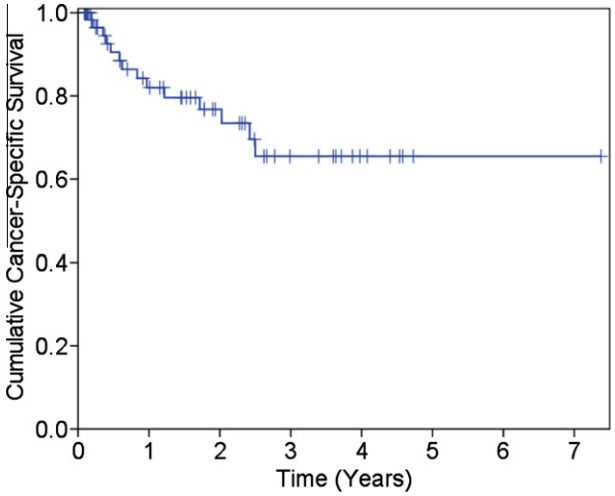

Figure 3 Kaplan–Meier curve for cumulative cancer-specific survival.

The PPM flap was mainly used as the preferred option following a salvage surgical procedure for advanced or recurrent disease, and extensive metastatic neck disease. Substantial defects involving the skin of the neck and parotid region are ideal because of the proximity of the donor site.[25] The PPM was occasionally used with a free flap (3) which creates less surgical complexity than two free flaps.[26,27] Further free flap reconstruction in the presence of recurrent disease may produce comparable rates of flap success[28] but is often complicated by the lack of good quality recipient vessels, the poor condition of the tissues, and the need to use contralateral vessels and interpositional vein grafts[29] or the ipsilateral transverse cervical vessels.[30]

Lateral segmental defects of the mandible comprised a large subgroup whether as a result of further disease or failure of a free flap. Although we agree with the contemporary principles of reconstruction of the mandible[31,32] the situation after previous major surgery and/or radiotherapy is complex. These defects were not reconstructed with a plate because of the high incidence of exposure and infection, which reduces the quality of life with further morbidity and days lost to medical treatment.[6,19,20,23,33,34] A unilocking plate has recently been advocated in the presence of advanced disease, significant co-morbidity, limited functional requirements or poor prognosis but plate exposure was common (22%).[35] In our experience the bulk of the PPM flap is sufficient to allow reasonable function in the context of limited life expectancy. Long-term survivors may be offered a delayed free flap bone reconstruction.[34]

Approximately one quarter of the PPM flaps were performed following failure of a free flap. The loss of oral integrity often requires reconstruction with either a free or pedicled flap, to expedite the return of oral function.[36] Wei[29] advocated a second free flap on the basis of a low free flap failure rate [1 of 17 (6%)] and a high incidence of complications with pedicled flaps, including flap failure [2 of 15 (13%)]. Okazaki[37] also reported a low free flap failure rate [1of 9 (11%)] but the difference in flap success rates is based on only a few procedures. In a review from the Liverpool Maxillofacial unit a second free flap was used on 19 occasions whilst a PPM flap was preferred for 5 reconstructions. However, for many surgeons a PPM flap is probably still perceived as the safest option in the immediate post-operative period in the presence of significant co-morbidity. A PPM flap can be quickly harvested to protect the neck vessels[23] and minimise the delay in healing, especially when the prognosis is dependent on subsequent radiotherapy.[36] With free flap success rates of 95% and greater for radial[38] and other flaps,[29,36] failure is often caused by the inherent risk of

thrombosis rather than an avoidable technical fault. In our experience the patient usually prefers a PPM flap because it is perceived as a smaller, safer and shorter operation, particularly if it avoids the cumulative morbidity of another osteocutaneous donor site, even though the functional outcome is often compromised. The frequent complications associated with PPM flaps have been extensively reported.[39] The 2.8% incidence of complete flap necrosis compares favourably with 2% (10/506) recently reported by Milenovic[23] in the largest series and other reports of zero to 6%.[4,6,18,21,24,40] The incidence of major (8.4%) and minor (12.6%) flap loss is also comparable to the literature, with major complication rates of 6% to 10%[4,6,18,21,23,24,40] and minor complications from 8.3% to 15% or higher.[4,18,21,23,24,40] Although complications may delay discharge they rarely delayed or prevented post-surgical radiotherapy.

Factors that may be responsible for the increased use of the PPM flap were considered. All except two patients had Stage IV disease, or extensive recurrent disease and 70% had stage N1 or greater neck disease. With the TNM classification system it was not possible to demonstrate an increase in the extent of disease but the threshold for a PPM flap had not been lowered. There was no significant variation in the rate of free flap failure. An elevated ASA grade is associated with increased morbidity and mortality.[41–45] Ninety-four percent of patients were ASA grade 2 or higher with no increase with time. Along with others we did not find an association between increased age and mortality.[43,46–49] Although selected older patients are likely to be a relatively healthy subgroup.[47,50] A more detailed general or disease specific morbidity grading system[41,43,45,48,51,52] may refine the selection process as increasing co-morbidity is an important prognostic indicator.[41,45,53] However, it is unclear whether this would have altered the decision to offer surgical treatment or affect the choice of reconstruction as no other potentially curative treatments were available and good palliation of symptoms was usually achieved. The use of the PPM flap reflects an increasing number of patients presenting with significant co-morbidity and advanced disease. The input of the multidisciplinary team over the latter half of the study may also have been a factor.

The survival rates compare favourably with outcomes for advanced and recurrent disease[54–61] but the majority succumbed to other disease. The 30 day mortality rate of 7% is acceptable in this context. Mortality rates after "major" head and neck surgery range from zero to 6%,[43,44,46,48,49,62] with the highest rates for oral cavity disease[62] and patients over 70 years.[46] However, the patients and surgical treatments in large series are diverse and typically include a minority of oral cavity disease together with other sites managed without flap reconstruction and with less co-morbidity. The mortality after free flap surgery ranges from 1% and 6.3%, but includes a spectrum of soft-tissue flaps with or without composite resections[9,42,52,63–68] and the co-morbidity status, if given, is typically lower, which this is consistent with the current study. The mortality rate with the PPM flap may be lower for a spectrum of disease and comorbidity, 2.2%[21] and 2.7%,[18] but is often not stated. Salvatori[35] reported a mortality rate of zero without a co-morbidity index when using the PPM flap for advanced disease. In the current series patients had a number of adverse factors in common; significant co-morbidity, previous extensive surgery and/or radiotherapy, advanced oral disease whether primary, recurrent or metastatic, and further major surgery with flap reconstruction. Therefore, for a number of reasons it is difficult to make comparisons with other studies.

Recently smaller reports have advocated the PPM flap for; salvage excision with extensive recurrent disease,[59] advanced disease with substantial co-morbidity[61] and both primary and recurrent disease.[69] The complication and flap failure rates were high with salvage procedures.[59,69] The current report is the largest experience of managing patients compromised by a number of adverse factors. The PPM flap is reliable for obliterating large defects of the mandible, tongue and oropharynx. It is the flap of choice for patients compromised by a number of factors including; advanced primary or recurrent oral disease and extensive neck disease, following previous major surgery and/or radiotherapy and in conjunction with significant medical co-morbidity. In this situation it remains the preferred salvage procedure after failure of a free flap. We advocate a pragmatic approach to reconstruction for this group of compromised patients with a limited life expectancy. We do not know whether this reflects common practice.

Conflict of Interest

None declared.

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Indications and outcomes for 100 patients managed with a pectoralis major flap within a UK maxillofacial unit

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Abstract. There are few studies reporting the role of the pedicled pectoralis major (PPM) flap in modern maxillofacial practice. The outcomes of 100 patients (102 flaps) managed between 1996 and 2012 in a UK maxillofacial unit that preferentially practices free tissue reconstruction are reported. The majority (88.2%) of PPM flaps were for oral squamous cell carcinoma (SCC), stage IV (75.6%) disease, and there was substantial co-morbidity (47.0% American Society of Anesthesiologists 3 or 4). The PPM flap was the preferred reconstruction on 80.4% of occasions; 19.6% followed free flap failure. Over half of the patients (57%) had previously undergone major surgery and/or chemoradiotherapy. Ischaemic heart disease ($P = 0.028$), diabetes mellitus ($P = 0.040$), and methicillin-resistant *Staphylococcus aureus* (MRSA) infection ($P = 0.013$) were independently associated with flap loss (any degree). Free flap failure was independently associated with total (2.0%) and major (6.9%) partial flap loss ($P = 0.044$). Cancer-specific 5-year survival for stage IV primary SCC and salvage surgery improved in the second half (2005–2012) of the study period (22.2% vs. 79.8%, $P = 0.002$, and 0% vs. 55.7%, $P = 0.064$, respectively). There were also declines in recurrent disease ($P = 0.008$), MRSA ($P < 0.001$), and duration of admission ($P = 0.014$). The PPM flap retains a valuable role in the management of advanced disease combined with substantial co-morbidity, and following free flap failure.

Key words: pectoralis major; flap; co-morbidity; complications; survival; mortality; oral cancer.

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The pedicled pectoralis major (PPM) flap has been used successfully for reconstruction of the head and neck region over the last three decades.[1,2] During this time, free tissue transfer has become increasingly accepted as the gold standard for reconstruction, particularly within the developed world, because of a number of factors including: improved flap success rates,[3,4] fewer complications and improved oral function,[5] and better quality of life outcomes.[6] Nevertheless, recent publications from around the world have highlighted the continued importance of the PPM flap as a reliable single-stage reconstructive option following salvage surgery,[7–11] and the flap remains popular for general applications within the developing world.[1,2] Whilst surgical units within the United Kingdom (UK) continue to use the PPM flap, its role within UK maxillofacial practice has not

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been defined. The aims of this study were to review the indications and outcomes of a cohort of 100 patients undergoing reconstruction with a PPM flap within a UK maxillofacial unit that preferentially performs free tissue transfer, and to identify factors associated with an adverse perioperative outcome.

Patients and methods

A retrospective review of case records was performed based on a contemporaneous database kept by the study institution. Data recorded included demographic details, indications, pathological staging (TNM American Joint Committee on Cancer 2002), type of surgical resection, American Society of Anesthesiologists (ASA) grade, co-morbidity, previous treatment, flap complications, methicillin-resistant *Staphylococcus aureus* (MRSA) status, length of hospital admission, recurrence of disease, and death.

A traditional myocutaneous PPM flap was raised using a defensive deltopectoral incision. Flap loss was classified based on conventional descriptions.[1,12] Total loss encompassed complete necrosis of the skin, subcutaneous tissues, and distal muscle paddle, whilst partial necrosis of the skin and subcutaneous paddle was defined as major loss if greater than 40% and minor loss if less extensive.

The decision to use a PPM flap was taken in conjunction with the same head and neck anaesthetist, and in the latter half of the study period, with a multidisciplinary head and neck oncology team. The cohort was subdivided on the basis that the PPM flap was either the preferred initial reconstruction, with the principle reason for this choice being identified, or the PPM flap was used because of initial free flap failure. Patients who had previously undergone major surgery and/or chemoradiotherapy were defined as undergoing salvage surgery.

Statistical analysis

Categorical variables were analysed using the χ^2 test or Fisher's exact test, and continuous variables using the Mann–Whitney *U*-test or Spearman's correlation coefficient. Univariable and multivariable binary logistic regression analyses were performed to identify factors associated with adverse perioperative outcomes: flap loss (any degree), major/total flap loss, prolonged hospital admission (above median stay), unplanned intensive therapy unit (ITU) admission, and 30-day mortality. Multivariable analyses were performed using a stepwise backward procedure, incorporating all variables with $P < 0.10$ on univariable analysis.

The primary long-term outcome measure was overall survival (as of September 2012). Cancer-specific survival was the secondary end-point. Patients who died within 30 days of surgery or who did not undergo resection for malignancy were excluded from the long-term survival analyses. Kaplan–Meier survival curves were constructed to analyse long-term survival trends, and the associations of variables determined by application of the log-rank test. Statistical significance was defined as $P < 0.05$. Statistical analyses were performed using IBM SPSS Statistics for Windows, version 20.0 (IBM Corp., Armonk, NY, USA).

Results

Demographic data

Between December 1996 and June 2012, 102 consecutive PPM flaps were performed on 100 patients. A full dataset was available for all patients. Demographic and disease variables are listed in Table 1. The number of flaps performed significantly increased over the study period ($P < 0.001$, Spearman correlation coefficient), with the majority of flaps (73.5%, $n = 75/102$) being performed in the latter half (2005–2012) of the series, and the greatest number in 2010 ($n = 17$). All patients had been treated for oral malignancy at some stage. Seventy-seven had primary squamous cell carcinoma (SCC), of whom 88.3% ($n = 68$) had stage IV disease and 59.7% ($n = 46$) had nodal neck disease. Patients in the first quarter (1996–2000) were significantly more likely to have either locally recurrent or metastatic disease (46.2% vs. 12.4%, $P = 0.008$, Fisher's exact test). Salvage surgery for SCC following previous major surgery and/or chemoradiotherapy was undertaken for 38 patients. One of these patients died within 30 days of surgery and was excluded from the long-term survival analyses. There was no difference in tumour parameters or the incidence of metastatic disease across the study period, except for a significantly greater incidence of primary stage IV SCC in the second half of the series (22.2% vs. 48.0%, $P = 0.008$, χ^2 test).

Indications for PPM flap

The cohort was subdivided into two main subgroups based on whether the PPM flap was used as the initial reconstruction of choice ($n = 82$, 80.4%), or because of previous free flap failure ($n = 20$, 19.6%) (Table 2). Free flap failure was most commonly a radial ($n = 8$) or deep circumflex iliac artery (DCIA) flap ($n = 8$), and 25% ($n = 5$) of these free flap failures occurred in patients who had previously had oncological treatment. The types of surgical resection undertaken are listed

Table 1. Data on 100 patients undergoing 102 pedicled pectoralis major (PPM) flap procedures.

Variable	Median (range)	*n*
Patient demographics		
Age, years	62 (28–88)	
Gender, female/male		33/67
ASA grade	2 (1–4)	
1		2
2		53
3		45
4		2
Indications for surgery	102	
Squamous cell carcinoma		
Primary		77
Stage 1		1
Stage 2		5
Stage 3		3
Stage 4		68
Recurrent (<6 months)		6
Metastatic (isolated neck)		7
Osteoradionecrosis		5
Other primary or recurrent tumour[a]		3
Other metastatic tumour[b]		2
Bleeding major vessels[c]		1 (2)

ASA, American Society of Anesthesiologists.

[a] Adenoid cystic carcinoma ($n = 1$), meibomian gland carcinoma ($n = 1$), nerve sheath tumour ($n = 1$).

[b] Melanoma ($n = 1$), small cell cancer ($n = 1$).

[c] One PPM flap for late complication of chemoradiotherapy following primary SCC resection.

in Table 3. Composite skin defects comprised 29.4% ($n = 30$) of resections. There was no significant variation in the type of surgical resection performed between the first and second halves of the study period, or when the PPM flap was used as the preferred reconstruction rather than following free flap failure.

Co-morbidity

Forty-seven percent of patients had a substantial co-morbidity (ASA grade 3 ($n = 45$) or 4 ($n = 2$)) at the time of operation (Table 1). There was no significant variation in ASA grade over the period of the study. The median ASA grade was significantly lower in the free flap failure subgroup ($P = 0.032$, Mann–Whitney U-test).

Postoperative morbidity

Postoperative morbidity is summarized in Table 4. Total flap failure occurred in 2.0% ($n = 2$). Major partial skin loss occurred in 6.9% ($n = 7$) and minor skin loss in 12.7% ($n = 13$). Minor wound dehiscence, without flap loss, occurred in 17 (16.7%), and two wounds required repair. An orocutaneous fistula occurred in 11 (10.8%), and all but one resolved spontaneously. Eleven (10.8%) secondary operations were performed for flap-related complications. There was a trend towards higher flap loss (all degrees) in the first half of the study (1996–2004) compared to the second half (2005–2012) (33.0% vs. 17.3%, $P = 0.083$, χ^2 test).

Results of the univariable and multivariable analyses for factors associated with flap loss are shown in Tables 5 and 6. There were no statistically significant associations between either the type of surgical resection or the salvage surgery group and the incidence of flap loss, wound dehiscence, or fistula formation. However, ischaemic heart disease ($P = 0.028$), diabetes mellitus ($P = 0.040$), and MRSA acquisition ($P = 0.013$, binary logistic regression) were independently associated with flap loss (any degree). Previous free flap failure was independently associated with total or major flap loss ($P = 0.044$, binary logistic regression).

Postoperative outcomes

The mean duration of hospital admission was 23.3 days (median 19 days, range 4–86 days). There was a significant reduction in the mean duration of admission in the second half of the study (30.2 vs. 20.8 days, $P = 0.014$, Mann–Whitney U-test).

Table 2. Primary indications for the pedicled pectoralis major (PPM) flap.

Indication for PPM flap	$N = 102$, n
Preferred reconstruction	82
Medical co-morbidity	40
High volume neck disease	16
Free flap not possible	14
Vessel coverage	5
Parotid/cheek defect	4
With free flap	2 (3)[a]
Close fistula	1
Failed free flap	20
Radial	8
Composite radial	1
Deep circumflex iliac artery (DCIA)	8
Fibula	3

Two flaps were contralateral; the first to avoid a cardiac defibrillator and the second to utilize a second PPM flap.
[a] One procedure also counted as high volume neck disease.

Table 3. Principle types of surgical resection.

Primary resection type	Resection subtype	$N = 102$	Composite
Mandibulectomy	Hemimandibulectomy	37	6
	Anterior mandibulectomy	8	3
	Rim resection	6	–
Glossectomy	Total glossectomy[a]	8	–
	Hemiglossectomy	8	–
	Partial glossectomy	3	–
Extended radical neck	–	15	15
Parotid/cheek	–	8	5
Oropharynx	–	5	–
Buccal	–	1	–
Fistula	–	1	–
Maxillectomy[b]	–	1 (2)	–
Bleeding major vessels[c]	–	1 (2)	1

[a] Two total glossectomies with laryngectomy.
[b] One maxillectomy combined with hemimandibulectomy as primary procedure.
[c] One bleeding episode with loss of free flap listed as rim resection of mandible as the primary procedure and the second was a late carotid blow-out complication after chemoradiotherapy.

Table 4. Complications following the pedicled pectoralis major (PPM) flap.

Morbidity	n (%)
Flap-related morbidity	
Total flap loss	2 (2.0)
Major flap loss	7 (6.9)
Minor skin loss	13 (12.7)
Mild skin dehiscence	17 (16.7)
Orocutaneous fistula	11 (10.8)
Donor site infection	2 (2.0)
Other morbidity	
Lower respiratory tract infection	11 (10.8)
Myocardial infarction	6 (5.9)
Cardiac arrhythmia	2 (2.0)
Fractured mandible	2 (2.0)
Gastrointestinal bleeding	1 (1.0)
Lingual bleed/necrosis	1 (1.0)
Carotid blow-out	1 (1.0)
Pneumothorax	1 (1.0)
Tracheal stenosis	1 (1.0)
Tracheostomy bleed	1 (1.0)
Cerebrovascular accident	1 (1.0)

Table 5. Patient, tumour, and operative variables associated with flap loss and 30-day mortality following pedicled pectoralis major (PPM) flap: univariable logistic regression analysis.

Variable	Patients ($N = 102$)	Any flap loss (minor/major/total) ($n = 22$)		Major/total flap loss ($n = 9$)		30-day death ($n = 5$)	
		OR (95% CI)	*P*-value	OR (95% CI)	*P*-value	OR (95% CI)	*P*-value
Patient variables							
Gender: female/male	33/67	1.52 (0.58–4.03)	0.40	4.65 (1.08–20.00)	0.039	2.03 (0.22–18.94)	0.53
Age: ≥65/<65 years	43/59	2.41 (0.92–6.31)	0.074	3.03 (0.71–12.86)	0.13	0.92 (0.15–5.74)	0.93
Study period: first half/second half	27/75	2.39 (0.88–6.49)	0.088	2.43 (0.60–9.80)	0.21	1.61 (0.34–7.62)	0.55
ASA grade: 3,4/1,2	47/55	0.98 (0.61–1.58)	0.95	0.96 (0.49–1.92)	0.92	1.38 (0.55–3.44)	0.50
Hypertension: yes/no	46/56	1.62 (0.63–4.19)	0.32	2.65 (0.62–11.25)	0.19	5.27 (0.57–48.93)	0.14
Ischaemic heart disease: yes/no	17/85	4.51 (1.48–13.70)	0.008	0.60 (0.07–5.15)	0.643	3.56 (0.55–23.12)	0.18
Peripheral vascular disease: yes/no	7/95	3.00 (0.62–14.55)	0.17	1.81 (0.19–16.98)	0.60	3.71 (0.36–38.58)	0.27
Cerebrovascular disease: yes/no	11/91	2.32 (0.61–8.78)	0.22	1.04 (0.12–9.18)	0.97	2.39 (0.24–23.74)	0.46
Diabetes mellitus: yes/no	16/86	3.68 (1.19–11.44)	0.024	3.08 (0.68–13.86)	0.143	9.46 (1.44–62.16)	0.019
Pulmonary disease: yes/no	35/67	0.49 (0.16–1.47)	0.20	1.60 (0.40–6.38)	0.51	8.67 (0.93–80.89)	0.058
Tumour/operative variables							
Previous oncology resection: yes/no	41/61	1.04 (0.40–2.71)	0.94	0.40 (0.08–2.01)	0.26	0.38 (0.04–3.49)	0.39
Previous failed flap: yes/no	20/82	1.55 (0.91–2.66)	0.11	2.55 (1.25–5.20)	0.010	1.00 (0.36–2.77)	0.99
Previous chemo/radiotherapy: yes/no	36/66	1.03 (0.63–1.68)	0.91	1.24 (0.62–2.47)	0.55	0.67 (0.22–2.04)	0.48
Pathology: SCC/other	90/12	2.00 (0.54–7.39)	0.30	2.37 (0.43–13.02)	0.32	2.13 (0.22–20.93)	0.52
Recurrent disease: yes/no	17/85	0.19 (0.02–1.52)	0.12	0.82 (0.27–2.49)	0.72	1.35 (0.49–3.69)	0.57
Resection: mandible/other	51/51	0.89 (0.56–1.43)	0.63	1.13 (0.57–2.25)	0.73	1.21 (0.48–3.03)	0.68
Resection: glossectomy/other	19/83	1.93 (0.64–5.87)	0.25	0.52 (0.06–4.43)	0.55	3.06 (0.47–19.74)	0.24
Composite: yes/no	30/72	0.88 (0.31–2.51)	0.80	0.66 (0.13–3.39)	0.62	0.60 (0.06–5.59)	0.65
MRSA infection: yes/no	24/78	3.00 (1.08–8.31)	0.035	4.87 (1.19–19.90)	0.028	1.00 (0.56–1.80)	0.99

OR, odds ratio; CI, confidence interval; ASA, American Society of Anesthesiologists; SCC, squamous cell carcinoma; MRSA, methicillin-resistant *Staphylococcus aureus*. Results where $P > 0.1$ rounded to 2 d.p.

Acquisition of MRSA occurred in 24 cases (23.5%), but declined dramatically after 2006, with a highly significant reduction in the second half of the study (63.0% vs. 9.3%, $P < 0.001$, χ^2 test). MRSA acquisition was the only factor independently associated with prolonged hospital admission ($P = 0.043$, odds ratio (OR) 3.43, 95% confidence interval (CI) 1.04–11.35, binary logistic regression) (Fig. 1).

Admission to the ITU occurred following eight procedures (7.8%). It was unplanned on five occasions and the presence of pre-existing ischaemic heart disease was independently associated with unplanned ITU admission ($P = 0.015$, OR 13.16, 95% CI 1.66–104.21, binary logistic regression). The mortality rate within 30 days of surgery was 5% ($n = 5$). The presence of diabetes mellitus was the only factor independently associated with 30-day mortality ($P = 0.021$, binary logistic regression) (Table 6).

Overall survival outcomes

The survival outcomes for primary stage IV oral SCC treated with curative intent and all SCC salvage procedures are given in Figs. 2 and 3. The overall median long-term follow-up was 18 months (range 2–120 months). During the period of the study, 27 patients died from recurrent disease and 28 from an intercurrent illness. As of September 2012 there are 39 patients alive and disease-free, whilst one patient is alive with recurrent disease.

Long-term survival outcomes for stage IV primary SCC

The 1-year, 3-year, and 5-year overall survival rates for surgery for stage IV primary SCC ($n = 42$) were 70.5%, 51.7%, and 34.5%, respectively (median 39.0 months, 95% CI 5.3–72.7 months). Cancer-specific survival rates were 81.6%, 71.8%, and 71.8%, respectively. When comparing outcomes for the first ($n = 6$) and second ($n = 36$) halves of the study period, both overall and cancer-specific survival were significantly longer in the second half for stage IV primary SCC ($P = 0.007$ and $P = 0.002$, respectively). The 1-, 3-, and 5-year survival figures for overall survival in the first half were 33.3%, 16.7%, and 0% (median 7.0

Table 6. Variables associated with flap loss and 30-day mortality following pedicled pectoralis major (PPM) flap: multivariable logistic regression analysis.

Variable	Patients ($N = 102$)	Any flap loss (minor/major/total) ($n = 22$)		Major/total flap loss ($n = 9$)		30-day death ($n = 5$)	
		OR (95% CI)	*P*-value	OR (95% CI)	*P*-value	OR (95% CI)	*P*-value
Gender: female/male	33/67			6.94 (1.29–37.04)	0.024		
Ischaemic heart disease: yes/no	17/85	3.84 (1.16–12.74)	0.028				
Diabetes mellitus: yes/no	16/86	3.76 (1.06–13.28)	0.040			10.46 (1.43–76.72)	0.021
Pulmonary disease: yes/no	35/67					9.54 (0.94–97.12)	0.057
Previous failed flap: yes/no	20/82			2.22 (1.02–4.83)	0.044		
MRSA infection	24/78	4.12 (1.34–12.65)	0.013	4.98 (0.98–25.21)	0.052		

OR, odds ratio; CI, confidence interval; MRSA, methicillin-resistant *Staphylococcus aureus*. Table shows results for all variables entered into the final round of regression analysis.

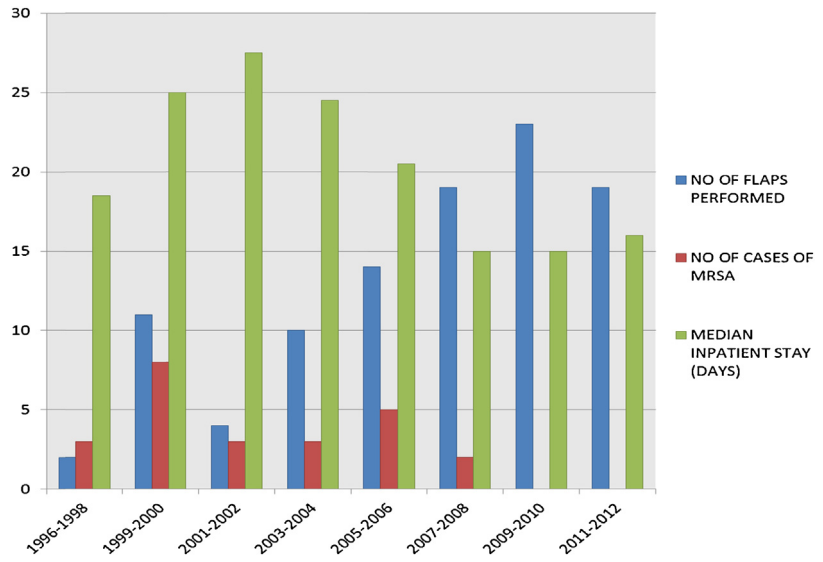

Fig. 1. Decline in acquisition of methicillin-resistant *Staphylococcus aureus* (MRSA) and length of hospital admission with time.

months, 95% CI 3.0–11.0 months), and in the second half were 80.1%, 57.6%, and 44.9% (median 53.0 months, 95% CI 19.1–86.9 months). The 1-, 3-, and 5-year survival figures for cancer-specific survival in the first half were 44.4%, 22.2%, and 0%, and in the second half were 91.2%, 79.8%, and 79.8%.

Survival outcomes for all stages of SCC salvage surgery

The 1-, 3-, and 5-year overall survival rates for all SCC oncological salvage procedures, of all stages ($n = 37$), were 56.4%, 27.3%, and 15.6%, respectively (median 19.0 months, 95% CI 4.5–33.5 months), and cancer-specific survival rates were 70.6%, 57.8%, and 33.0%, respectively (median 46.0 months, 95% CI 23.4–68.6 months). When comparing outcomes for the first ($n = 17$) and second ($n = 20$) halves of the study period, overall survival was significantly longer in the second half for oncological salvage SCC ($P = 0.011$) and there was a borderline significant trend towards longer cancer-specific survival ($P = 0.064$). The 1-, 3-, and 5-year survival figures for overall survival in the first half were 52.9%, 11.8%, and 0% (median 14.0 months, 95% CI 0.0–31.5 months), and in the second half were 58.9%, 44.9%, and 35.9% (median 31.0 months, 95% CI 0.0–68.5 months). The 1-, 3-, and 5-year survival figures for cancer-specific survival in the first half were 71.5%, 35.8%, and 0%, and in the second half were 69.6%, 55.7%, and 55.7%.

Discussion

The PPM flap remains the preferred form of reconstruction flap in most of the developing world, as it is relatively quick and easy to harvest, versatile, and reliable, whilst free flap surgery may not be possible because of financial constraints or a lack of microvascular expertise.[13,14] Over the last decade, major operative series in which the PPM flap has been the reconstruction of choice have been published from Eastern Europe (Croatia),[14] South America (Brazil),[13] North America (Canada),[7] and Asia.[2] Although free tissue transfer is now usually the preferred reconstruction within the developed world, we have also continued to use the PPM flap when indicated.

However, it is unknown how frequently the PPM is used within the UK and what are considered the current indications. In this series, the PPM flap was principally (80.4%) used as the initial preferred reconstructive choice for mainly advanced disease of the oral cavity. The most common primary indications were substantial medical co-morbidity (39.2%), high volume metastatic neck disease (15.7%), or when a free flap was considered either not possible for technical reasons or the risk of failure was judged too high (13.7%) (Table 2). The most frequent resection performed was a hemimandibulectomy ($n = 37$), and the majority of these patients had previously undergone surgery ($n = 16$), chemoradiotherapy ($n = 14$), or suffered failure of a free flap ($n = 11$) (Table 3). A reconstruction plate was only occasionally used, as the bulk of a PPM flap alone provides reasonable function in the context of limited life expectancy and the incidence of plate-related complications is high.[1,14,15] Only one longer-term survivor with substantial mandibular drift and malocclusion underwent late free tissue bone reconstruction. Nearly 30% of the defects involved a composite resection of skin, and the PPM flap was combined with a free flap on three occasions. A small number of flaps ($n = 7$) were utilized for osteoradionecrosis of the mandible, carotid blow-out, or fistula repair (Table 1).

In this series, both the stage of disease and ASA grade were greater than previously reported in comparable studies. The majority (88.3%) of patients with a primary SCC ($n = 77$) had stage 4 disease ($n = 68$), with 79.2% either T3 ($n = 5$) or T4 ($n = 56$) size tumours, and this was often combined with substantial co-morbidity (47% ASA grade 3 or 4) (Table 1). This contrasts with the second largest series of PPM flaps by Vartanian et al.[13] from Brazil in 2004, in which the incidence of advanced T3 or T4 tumours was lower (61% compared with 79.2%). In addition, in a series of 70 free and PPM flaps by Mallet et al.[5] from France in 2009, fewer patients had T3 or T4 (59%) tumours, and the level of substantial co-morbidity was lower (ASA grade 3, 26% compared with 45%).

An increasing number of PPM flaps were used in the latter half of this series and several factors may have influenced this outcome. The use of a PPM flap was not related to the incidence of free flap failure or ASA grade. The ASA co-morbidity classification system probably lacks sufficient sensitivity to detect whether there is an underlying trend of increasing levels of co-morbidity, so we have now introduced a more detailed co-morbidity score. Although there was no detectable increase in the stage of disease across the study period, there was a significantly ($P = 0.008$) greater number of primary stage IV SCC treated in the second half of the series and this may indicate a more aggressive surgical approach to treatment. The introduction of the multidisciplinary team may have encouraged a more cautious approach to the choice of reconstruction and there may also be an element of increasing patient choice in the decision. Patients now receive increasingly detailed information about functional outcomes and flap success rates following the introduction of a surgical planning proforma.[16] Those patients with substantial co-morbidity and advanced disease are likely to have a relatively poor prognosis and may

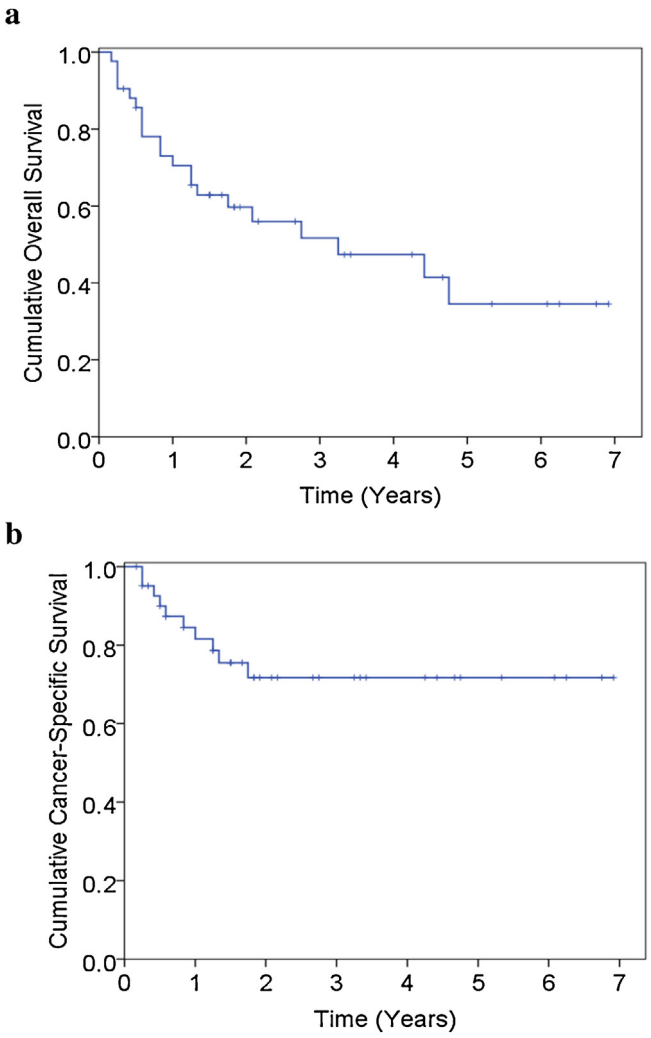

Fig. 2. Overall and cancer-specific survival for primary stage IV squamous cell carcinoma (SCC) ($n = 42$). (a) Overall survival. (b) Cancer-specific survival. The 1-year, 3-year, and 5-year overall survival rates for surgery for primary stage IV SCC were 70.5%, 51.7%, and 34.5%, respectively (median 39.0 months, 95% CI 5.3–72.7 months), and for cancer-specific survival were 81.6%, 71.8%, and 71.8%, respectively.

prefer a PPM flap because of the reduced donor site morbidity and greater flap success rate when compared to a composite free flap in particular.[4] Over half (57%) of the patients had previously undergone surgery and/or chemoradiotherapy, or had suffered failure of a free flap, so the surgeon and patient may have felt they would be unable to tolerate a free flap procedure.

A further free flap after salvage surgery is often successful, but is complicated by the poor quality of tissues.[10,17] The median ASA grade was lower in the free flap failure subgroup than the PPM preferred reconstruction subgroup, confirming that the latter patients had comparatively greater pre-existing co-morbidity. A second free flap following free flap failure has a failure rate of 6%[17] to 11%,[18] but unless there has been a technical error, a PPM flap may be perceived as the safer option, which is more likely to facilitate prompt postoperative chemoradiotherapy.[10] Although, minor complications are common with the PPM flap, only two patients in this series required a further significant operation for major complications.

The use of the PPM flap remains acceptable as long as the patient has been informed of the compromised functional and cosmetic outcomes. This study did not include a quality of life outcome assessment, but the shortcomings of the PPM are widely recognized and include: limitations of pedicle length and arc of rotation, excessive bulk, frequent minor complications, sometimes poor cosmesis, and often late problems such as reduced oral, shoulder, and neck function, which may adversely affect the remaining quality of life.[19] However, when Hsing et al.[6] reported on a comparison of radial and PPM flaps for oral reconstruction in 2011, the only statistically significant advantages with free flap reconstruction were in mood, speech, and swallowing function. The duration of the free flap operation was significantly longer and there was no significant difference in the duration of hospital stay (radial free flap 23.8 days vs. PPM flap 25.2 days). Although a significantly shorter length of admission with the radial flap has been reported (24 vs. 28 days),[20] this was longer than our recent experience with the PPM flap (mean 20.8 days). The issue of long-term gastrostomy dependence should be discussed and the incidence may be higher with a PPM flap,[21] but is quite variable and relatively low in our practice (2%).[22] An increased duration of gastrostomy use was related to advanced disease stage, surgery or multiple operations combined with radiotherapy, radiotherapy alone, and composite bone resections, but interestingly not to the type of flap reconstruction. Of course many of the selected patients in the current series already had pre-existing deficits because of previous therapy; therefore treatment must be carefully tailored to the many aspects of the patient's overall needs. A formal quality of life assessment may be appropriate in guiding treatment planning,[23] but is not yet part of our practice.

The majority of patients with oral cancer are in poor health and compromised by smoking and alcohol abuse. The incidence of PPM flap complications in the literature is high and ranges from 18% to 36%.[1,5,7,13,14,24] Complications are more frequent following salvage surgery and within the oral cavity or oropharynx.[7–9,11] The 2% incidence of complete flap loss in this series is the same as reported by Milenovic et al.[14] in 2006, in the largest series (10/506), and the typical range is 0–7%.[1,2,13,24,25] Failure of the PPM flap muscle paddle occurred following overextension to obliterate two maxillectomy defects. The incidence of major (6.9%) and minor (12.7%) flap loss, including orocutaneous fistula (10.8%), were also comparable to the literature (major loss 6–10% and minor loss 8.3–15% or higher).[1,2,13,14,24,25] Flap complications were unrelated to the type of surgical resection or previous salvage surgery, and the incidence declined in the second half of the study, possibly because of refinements in surgical technique. However, major or total flap loss was associated with previous free flap failure and had a borderline association with MRSA.

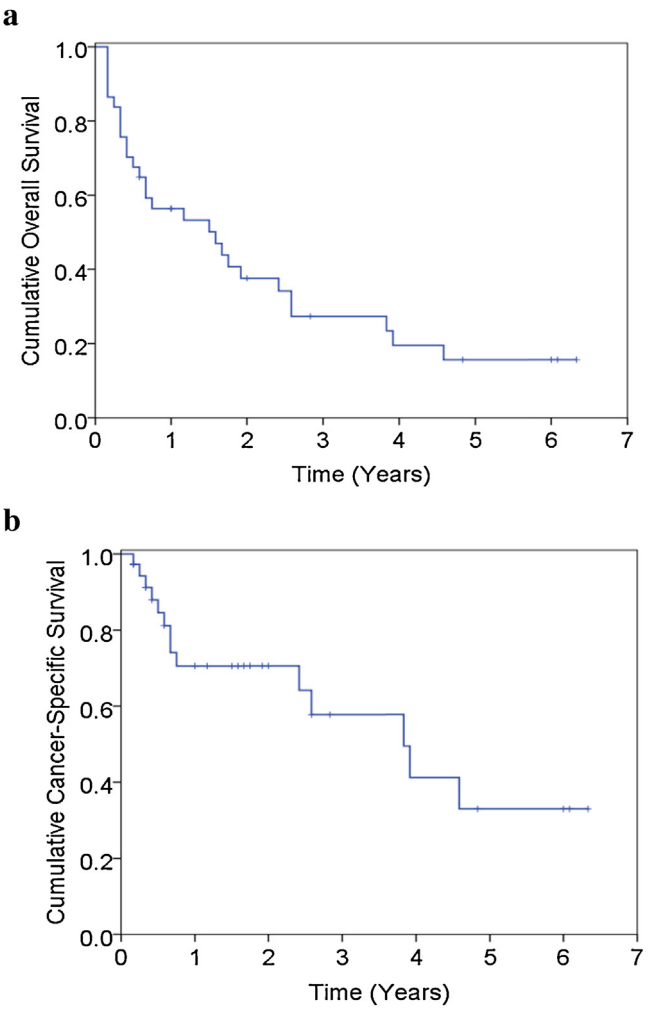

Fig. 3. Overall and cancer-specific survival for all stages of SCC salvage surgery ($n = 37$; one patient was treated with palliative intent and one patient is alive with recurrent disease; one patient was excluded from the long-term survival analyses as died within 30 days of operation). (a) Overall survival. (b) Cancer-specific survival. The 1-year, 3-year, and 5-year overall survival rates for all stages of SCC salvage procedures were 56.4%, 27.3%, and 15.6%, respectively (median 19.0 months, 95% CI 4.5–33.5 months), and for cancer-specific survival were 70.6%, 57.8%, and 33.0%, respectively (median 46.0 months, 95% CI 23.4–68.6 months).

The systemic factors associated with all degrees of flap loss were ischaemic heart disease, diabetes mellitus, and acquisition of MRSA. These factors implicate a poor quality microcirculation and compromised wound healing (Tables 5 and 6). The majority of patients were managed in a high dependency unit, and unplanned ITU admission (4.9%) was associated with ischaemic heart disease. Mortality within 30 days (5%) was associated with diabetes mellitus. Lower mortality has been reported with less advanced disease and lower levels of co-morbidity, 2.2%[13] and 2.7%,[24] but is considered acceptable in the context of otherwise incurable disease as long as the patient has been fully counselled.

There were several other interesting findings noted when comparing the first and second halves of the study period. The mean duration of hospital admission decreased significantly from 30.2 to 20.8 days, which is comparable with recent reports (14–30 days).[2,5,7,9] Admission is known to be substantially longer with significant complications[7,9] and infection with MRSA.[26] The significant reductions in both MRSA prevalence and duration of admission in the latter half of the current study are highly likely to be directly related (Fig. 1) and this is consistent with our previous findings following free flap surgery.[26]

The 5-year overall (34.5%) and cancer-specific (71.8%) outcomes in the current report for stage IV primary SCC compare favourably with historical data[27] (Fig. 2). Over the course of this study there were gradual and significant improvements in treatment outcomes. The 5-year survival figures for both overall (44.9%, $P = 0.007$) and cancer-specific (79.8%, $P = 0.002$) outcomes with stage IV SCC were significantly better in the latter half (2005–2012) of the study period. Relatively recently, postoperative cisplatin-based chemoradiotherapy regimens have demonstrated a statistically significant improvement in loco-regional control, disease-free survival, and overall survival.[28] In 2004 Bernier et al.[28] quoted 5-year overall and 'progression-free' survival figures of 53% and 47%, respectively, for a broadly comparable cohort of stage III and IV SCC of the oral cavity, oropharynx, and larynx. Improved overall 5-year survival outcomes for SCC of the head and neck region during the 7-year period up to 2003, within a region of the UK, have recently been reported by Drugan et al.[27] These crude outcome measures are consistent with international trends and the current study, but require further investigation.

The survival figures following salvage surgery for malignancy are variably described and direct comparisons with other reports are difficult because of relatively small numbers of patients, differing anatomical sites, early or late recurrent disease, and variable previous treatment modalities. However, in the salvage surgery subgroup, the 5-year overall (35.9%) and cancer-specific (55.7%) survival figures for the latter half of the current study compare favourably with recent reports.[7–11]

The introduction of postoperative cisplatin-based chemotherapy in Leicester occurred in 2004, and although various combinations of treatment modalities have been used in this cohort, the dramatically improved survival outcomes are likely to be the result of a relatively aggressive regimen of weekly concurrent cisplatin at 40 mg/m^2. In our experience this achieves a similar dose density to that of Bernier et al.[28] (3× 100 mg/m^2 every 3 weeks) but is more tolerable in a non-trial population. One patient died of chemoradiotherapy-related complications.

One of the limitations of the current study is that the findings are restricted to a cohort selected on the basis that reconstruction was with a PPM because of a number of adverse factors such as advanced disease and substantial co-morbidity, or failure of a free flap. Nevertheless, this is a group that would be expected to have a comparatively poor outcome. The median duration of follow-up was comparatively short because slightly more patients died from other disease rather than recurrent disease

and this is a reflection of the high level of pre-existing co-morbidity rather than failure of oncology treatment. Further details are beyond the remit of the current paper, but these initial findings warrant a further analysis of a larger, broader patient group.

The role of the PPM flap has continued to evolve as free flap surgery has become established throughout the world. In 2010 Liu et al.[29] reported on 202 PPM flaps performed during the period of 1998–2008 in Hong Kong. The PPM flap was increasingly used for salvage surgery of the oral cavity, although it was still being used more frequently for immediate reconstruction rather than salvage surgery (70% compared with 29%). In a recent series by You et al.[30] from Korea, over a similar time period to the current study, 120 PPM flaps were used for comparable indications within a practice that also utilizes free flap transfer. A recent smaller series of 55 PPM flaps from the USA by Schneider et al.[19] described similar findings, but the differences were that a second free flap was used more frequently after initial free flap failure and the PPM flap was more often combined with a free flap.

To the best of the authors' knowledge, this is the largest and most detailed overview of experience from the UK. The main indications were reconstruction for advanced malignancy, often following previous surgery and/or chemoradiotherapy treatment, and failure of a free flap, frequently in the context of substantial pre-existing co-morbidity. When comparing the first and second halves of the study period, there were significant declines in recurrent disease, MRSA acquisition, and duration of admission, and a trend towards less PPM flap loss (all degrees). Throughout the study period cancer survival rates improved dramatically. These outcomes support the strategy of aggressive surgical treatment in this most challenging of patient groups.

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None.

Competing interests

None declared.

Ethical approval

Not required.

Patient consent

Not required.

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REVIEW

A perspective on the role of the pectoralis major flap in oral and maxillofacial oncology surgery

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Key words:
comorbidity, complications, oral oncology, pectoralis major, pedicled flap, reconstruction

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Abstract

In general, the pedicled pectoralis major (PPM) flap has become a secondary choice for reconstruction in the developed world while remaining popular within the developing world. The pectoralis major flap is utilised in varying proportions as either the preferred reconstruction or for salvage reconstruction following free flap failure, further disease or complications. Refinements in surgical technique and an experienced surgeon may yield high total flap success rates with modest levels of wound complications. The pectoralis major flap is particularly useful with serious or multiple comorbidities, advanced disease, and previous surgery and/or chemoradiotherapy. It has primarily been used for reconstruction of extended radical neck dissection, posterolateral mandible, large glossectomy and oropharyngeal defects, and occasionally together with a free flap. A second free flap has increasingly been used after initial failure, particularly in the larger centres, but the PPM flap probably remains the most commonly used salvage option. The needs of the local population vary, survival outcomes are improving and patient choice may become an increasing factor in flap selection.

Clinical relevance

The pedicled pectoralis major flap has largely been superseded by free tissue transfer as the reconstruction of choice, but it remains a valuable reconstructive option within centres practicing free tissue transfer and throughout most of the developing world. There is surprisingly little information on the use of the pectoralis major flap within the context of surgical units practicing free tissue transfer. This article seeks to clarify the frequency and range of current indications.

Introduction

The pedicled pectoralis major (PPM) flap has been successfully used for reconstruction of the maxillofacial region as a 'workhorse' flap for over three decades[1–4]. During this period, free tissue transfer has become the preferred reconstruction with success rates of 90–95% or higher[5–11], fewer complications and better functional outcomes[5,12–19]. Recent developments include perforator flaps[20–24] with an emphasis on improving cosmetic, functional and quality-of-life outcomes together with less morbidity[15,23,25–27].

In general, the PPM flap has become a secondary choice in the 'developed' world while remaining popular in the 'developing' world. The recent major series are from: Eastern Europe (Croatia)[28]; South America (Brazil)[29,30]; and Asia (India)[4,31], (Taiwan)[25] and (Korea)[32]. While reports from the developed world are typically smaller and collected over a longer time period: North America (Canada)[33], (USA)[34–36] and Europe (Ireland)[16], (UK)[37,38].

Although maxillofacial surgical units within Western Europe continue to use the PPM flap, few other units have reported their experience[11,39]. Within the literature, the PPM flap has mainly been compared with the radial free flap. It is timely to review the qualities of the PPM flap and the current indications.

Advantages

The advantages include: relatively quick and easy to harvest, good coverage, versatile, and reliable[28,29,36] (Table 1).

The initial costs of free tissue transfer are greater because of infrastructure, personnel and equipment[33]. However, the overall financial burden is often similar once duration of admission, complications and subsequent care has been considered[12,33,40–45]. The greater cost of composite free flap reconstruction has been justified by improved functional outcomes[42]. Financial comparisons between differing health-care systems are complex and strongly influenced by medical complications,[46] but within the developing world, the costs, to both patient and institute, are often[4] but not always prohibitive[47].

The PPM flap is often considered a lesser procedure than a free flap, but it is unclear whether overall morbidity is lower because of selection bias and confounding clinical factors. Retrospective comparisons have failed to demonstrate major differences[16,25,44,48], but the shorter operation duration[12,15,25,44,48] with a PPM flap should result in fewer medical and surgical complications[8,49,50]. A two team approach reduces the operating time with free tissue transfer but is also usually possible with the PPM flap except for creation of the cervical tunnel. The lack of a microvascular anastomosis, at risk of revision or failure, may be beneficial with the compromised patient[37].

The duration of hospital admission with the PPM flap and free tissue transfer are similar. The long mean duration of admission and high incidence of reoperation reported by O'Neill *et al*. (Ireland)[16] with the radial (34.3 days) and PPM flap (29.6 days) are unusually prolonged compared with other recent reports (radial 18–24 days and PPM flap 23–25 days)[15,25,45] and the Leicester experience (free tissue 20 days and PPM flap 21 days)[51]. Shorter admissions with the PPM flap have been described (9 and 10 days)[30,34,52] and duration varies with procedure (7.5 days primary reconstruction and 20 days salvage reconstruction)[36]. All series are skewed by outliers with infective, cardiorespiratory and alcohol-related complications[33,46,53,54]. There are increasing demands, often financial, to discharge promptly and in many specialties to introduce enhanced recovery pathways[55–59].

Disadvantages

Shortcomings include: restricted arc of rotation and pedicle length with a watershed at the zygomatic arch and superior tonsillar pole[16]. The cosmetic result is compromised by the supraclavicular bulge, skin colour match, unwanted hair and gravity[4,25,36,60]. Radiotherapy may cause epilation but reduction of excessive bulk is difficult because of delayed healing following radiotherapy. The bulk and limited pliability vary with body habitus but make it unsuitable for smaller or superficial defects. Retrospective comparisons with the radial free flap demonstrate inferior speech function[12–14,16] as the thin, pliable radial flap facilitates speech and swallowing function[17]. Late contracture with reduced shoulder and neck function adversely affects quality of life[36,61], although effects may be ameliorated with botulinum therapy[62,63] or pedicle resection with Z-plasty[36] (Table 2).

Greater complications and gastrostomy dependence with the PPM flap following pharyngeal reconstruction and radiotherapy are based on historical data[64]. Recent studies, primarily with oral malignancy, revealed comparable gastrostomy dependency over the short and longer term[15,44]. In the Leicester experience, prolonged gastrostomy duration was unrelated to the type of flap but associated with advanced stage,

Table 1 Advantages of the pectoralis major flap

Quick and easy to harvest
Reliable anatomy
Microsurgical skills not required
No microvascular anastomosis
Versatile design
Muscle and skin coverage
Short operation
Minor donor site morbidity
Most complications managed conservatively or minor treatment
Total failure rare
Occasional major secondary operation
Best used for large defects tongue, lateral mandible, and pharynx, parotid and neck. Coverage of major vessels and brachytherapy tubes, closure fistulae

Table 2 Disadvantages of the pectoralis major flap

Restricted arc of rotation
Limited pedical length
Excessive bulk
Limited pliability
Frequent minor wound complications
Supraclavicular bulge
Poor skin match
Hair growth
Deformity of chest wall donor site
Variable and limited functional outcomes
Restricted neck movement, discomfort and deformity
Not ideal for small or superficial oral soft tissue defects, anterior segmental mandible, soft palate or maxilla.

surgery with radiotherapy, radiotherapy alone and bone resections[65].

The quality-of-life domains of most importance are speech, chewing and swallowing[66,67]. The worst functional outcomes occur with stages 3 and 4 disease and combination therapy[67]. Hsing *et al.*[25] reported the largest comparison of the PPM flap with free tissue transfer for mainly tongue and buccal defects in 100 East Asian patients. There were significant disadvantages in mood, speech and shoulder function but not for the majority of outcomes including global quality of life. Outcomes may be influenced by many factors including cultural and ethnic considerations, and higher global quality-of-life scores have been reported in South American[68] and Western studies[66].

Complications

The incidence of complications is high (18–63%)[3,4,15,28–30,32,33,52,69,70], and minor wound complications are more frequent than with free tissue transfer[18,19]. Complications are greatest following salvage surgery, at oral cavity and pharyngeal sites[30,33,54,64,71,72], and are variably described as either associated with[30,34,52,73] or unrelated to[16,29,32,54,72,74] radiotherapy. Many other factors have been inconsistently linked including: smoking, age, diabetes mellitus, low albumin, obesity, male or female gender, prolonged operation, and an inexperienced surgeon[32,52,60,69,75]. In recent retrospective comparisons with free tissue transfer wound dehiscence[15,16] and blood loss[25] were greater with the PPM flap, but there were often no other substantive differences[16,25,44,48].

The incidence of total flap failure (muscle and skin paddle) ranges from 0% to 7%[3,4,28–30,32,35,69,70,76] and is generally lowest (0–2%) in recent reports[4,28,30,32,34–36,70,76,77] including the Leicester experience[38]. Major (4–10%) or minor (8–15% or higher) partial skin flap loss and orocutaneous fistulae (3–29%) are frequent[3,4,28,29,32,34,35,69,76] but lower in recent reports and only occasionally delay adjuvant treatment. Conservative wound care procedures are common (10–50%)[16,33,34,38,60] but major secondary surgery infrequent (2–5%)[4,28,34,35,38,69]. In the Leicester study, a reduction in complications coincided with a reduced incidence of methicillin-resistant *Staphylococcus aureus*[38,51] and possibly increasing surgical experience[48,60]. Donor site complications are usually minor and occur in 4–6%[28,35,76]. Pulmonary function may be reduced with advanced lung disease[78]. Complications related to rib harvest and bipaddle flaps are largely of historical interest[69,79].

Refinements in surgical technique

The inferior pectoral muscle border should be identified early to locate the skin paddle entirely over muscle and medial to the nipple to capture major perforating vessels. Ultrasound localisation is an option[77]. Extension over the rectus sheath should be avoided[35,48], and therefore, the inframammary position is not advised for larger inferiorly displaced breasts[35]. Full division of muscle and nerve attachments with skeletonisation of the pectoral vascular pedicle is safe[28,48] (Figs 1, 2). Preservation of the lateral thoracic artery[3] with release of pectoralis minor[76] is optional but should not compromise passive pedicle length. Bipaddle flaps[80] are

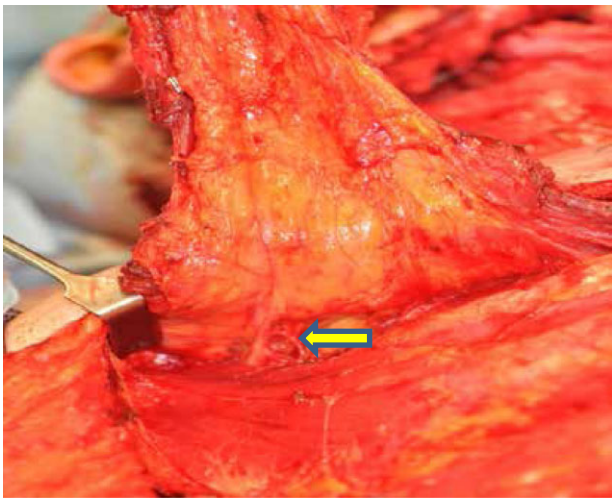

Figure 1 Retraction of pectoralis minor and mobilisation of pectoral branch vascular pedicle (arrow) which may be skeletonised.

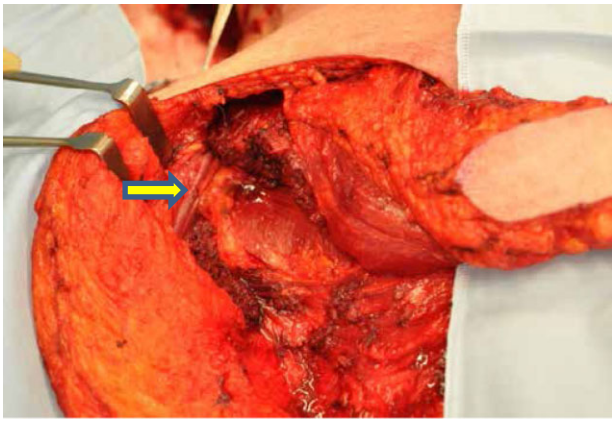

Figure 2 Complete mobilisation of pectoralis major muscle insertion (arrow cephalic vein).

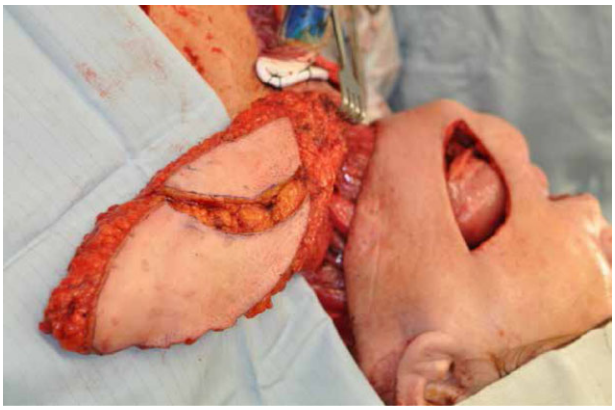

Figure 3 De-epithelialisation to create an intraoral musculocutaneous paddle. The distal skin blood supply is precarious.

usually too bulky. Division of the skin paddle creates a separate extension, but the distal skin perfusion is unreliable (Fig. 3).

The thinner muscle only[81] or myofascial[32,72,81] flap variants, either with or without a skin graft, are reliable and the donor site is easily closed, but they are probably not widely utilised because of concerns about contraction. The true island musculocutaneous paddle variant minimises muscle pedical bulk and has been successfully used, most often in the developing world: Brazil[29], India[82] and Korea[48]. The subclavicular route provides 2–3 cm of extra pedical length but may be technically difficult with obese patients or bulky flaps[29], and the incidence of total flap necrosis may be high (7%)[83]. Attempts to minimise donor site morbidity with a segmental muscle design[73] or thinner flaps based on isolating skin perforating vessels with[84] or without the muscle component[85] have been described in relatively small series with limited success.

Current indications

Preferred flap reconstruction

The frequency of utilisation as a first choice flap ranges from 5% to 62% within the few series indicating the relative proportions of free and PPM flaps (5% of 1120 flaps, USA)[36], (17% of 4730 flaps, China)[86], (42% of 137 flaps, India)[4] and (62% of 491 flaps, Taiwan)[25]. The latter study contained few composite free flaps (1.4%) so the upper range limit is probably usually lower. A 2001 review of academic otolaryngology practice, in the USA, revealed the PPM flap remained twice as popular as free tissue transfer[87].

Within series of just PPM flaps, the indications are often inconsistently subdivided in to the preferred

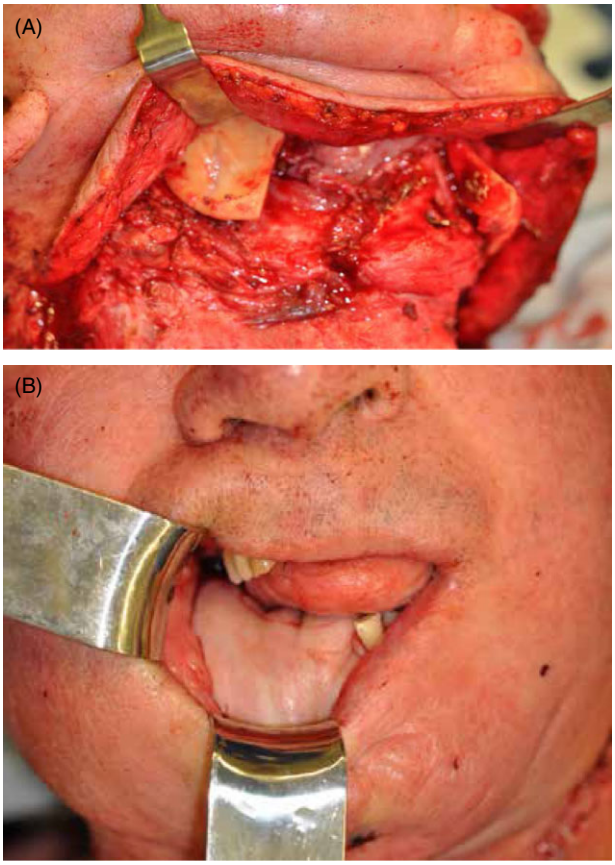

Figure 4 (a,b) Hemimandibulectomy defect with soft tissue oral reconstruction but no bone component is at risk of dental malocclusion.

reconstruction for primary disease or salvage reconstruction for complications, free flap failure or further disease. In 2010, Liu (Hong Kong)[76] still preferred the PPM flap for immediate reconstruction (70%) but in the latter part of the series, less frequently for tongue resections (48% reduced to 24%) and more often for salvage surgery (8% increased to 29%). The frequency of use as the preferred reconstruction ranges from 33% to 97%[4,32–34,36]. There are often several main indications including: financial (36%)[4], comorbidity (21–40%)[4,38], extended radical neck dissections (13–20%) and vessel depletion (9–14%)[4,32,38,76]. In the Leicester experience[38], the PPM flap was preferred on 80% of occasions, primarily for substantial comorbidity (40%), and often for lateral mandible (36%), glossectomy (19%), extended radical neck (15%) or parotidectomy (8%) procedures, and vessel depletion (14%) (Figs 4–6). The stage of disease[15,29], American Society Anesthesiologists grade[15], comorbidity[4,32] and incidence of previous malignancy[4,30,32,76,88] were greater than in comparable studies.

The aging population within the developed world has increasing levels of multiple comorbidities[89–92]. In

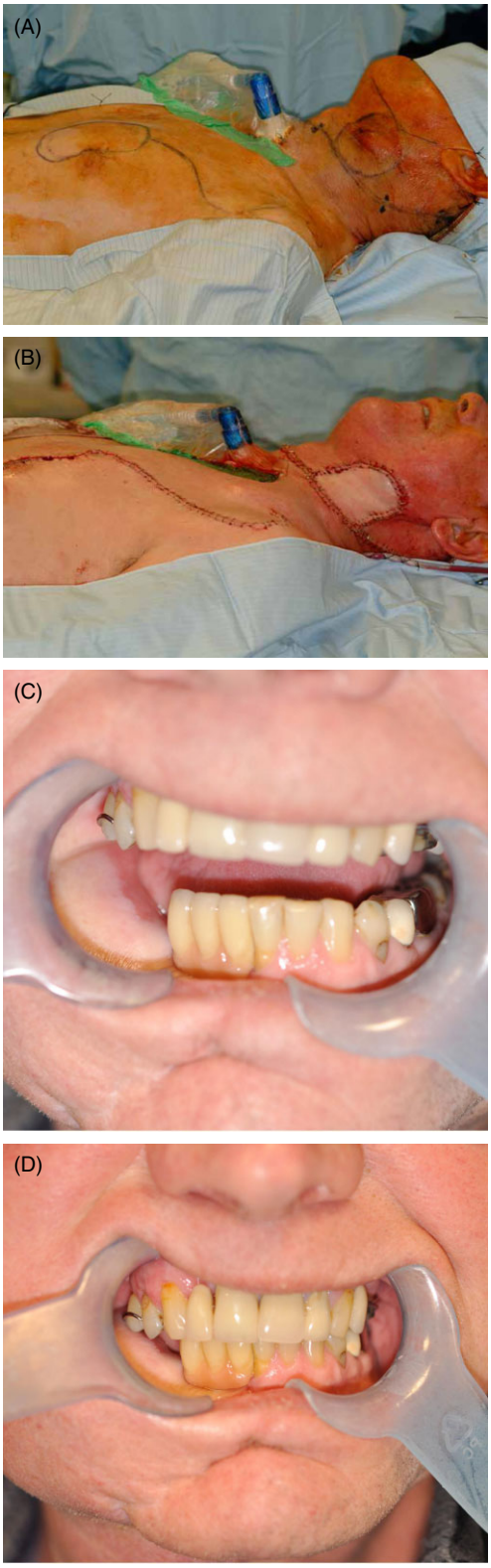

Figure 5 (a,b) Metastatic carcinoma fungating in neck and repaired with PPM flap. (c,d) Rim resection of mandible with soft tissue reconstruction and good dental occlusion.

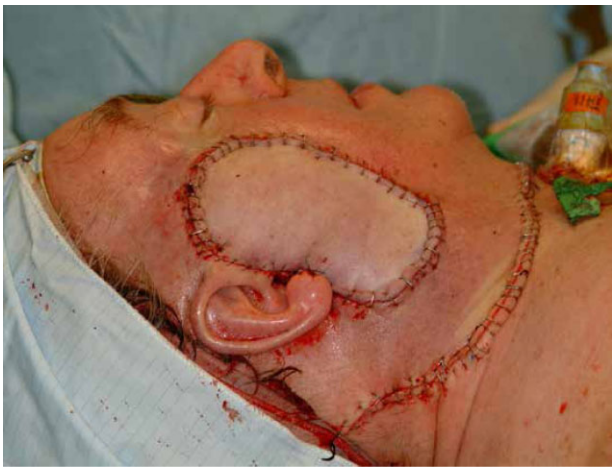

Figure 6 Radical parotidectomy with skin resection defect. The zygomatic arch is the superior watershed area.

head and neck oncology, this is often caused by tobacco and alcohol abuse with an adverse impact on prognosis, mortality, morbidity, quality of life and costs[90,92–95]. In the Leicester study[38], one quarter were of Asian origin, and this subgroup has an increased prevalence of oral cancer[96,97], diabetes mellitus and cardiovascular disease, with the latter comorbidities associated with increased complications and mortality[98–106], including flap-related complications[38]. The multidisciplinary team process[25] together with increasing patient education and preference[25,107] may increasingly influence the choice of reconstruction. Both patient and surgeon may perceive the PPM flap as a safe compromise in the context of previous treatment, substantial comorbidity, advanced disease and poor prognosis[37]. Patient opinions are most important for bone flaps because of the greater donor site morbidity[108] and lower success rates (93%)[39]. A PPM flap provides reasonable mandibular function in the context of limited longevity and without a reconstruction plate that is often compromised by complications[3,28,31,109–111]. Hsing *et al.*[25] noted that functional benefits of free flap reconstruction at the buccal site were lower than the tongue in an East Asian population. Also, in Leicester, oral submucous fibrosis is common, and significant trismus persists after surgery (Fig. 7). Kekatpure *et al.*[31] suggested excision of the entire fibrotic masticatory apparatus.

Interestingly, survival and disease control outcomes for advanced malignancy seem to be improving within the UK[112], including Leicester[38], probably following the introduction of Cisplatin therapy[113]. These findings emphasise the need to constantly refine the complex treatment decision-making process.

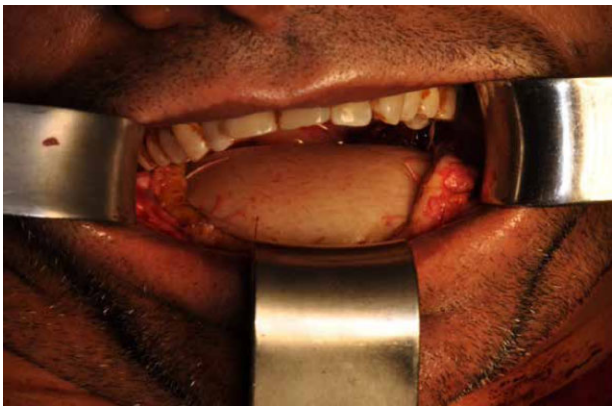

Figure 7 Total glossectomy in an Asian patient with trismus caused by oral submucous fibrosis.

In conjunction with a free flap

Two free flaps may optimise functional reconstruction for large composite defects but substantially increase both complexity and operation duration[31,114,115]. Flap survival of 95% has been reported[115], but a recent review from Liverpool (UK)[39] concluded that overall success rates were lowered. Free tissue transfer may be successfully combined with a PPM flap, particularly for lateral mandible defects or extended radical neck dissection following irradiation[116,117]. However, this option has been utilised infrequently in Leicester (3%)[38] and elsewhere (1%)[28]. Schneider *et al.*[36] occasionally utilised a PPM flap (5%) but often combined it with a free flap (33%).

Salvage reconstruction following complications

The PPM flap retains an established role in the management of surgical complications. Liu *et al.*[33] utilised a minority (17%) of PPM flaps for salvage reconstruction (including free flap failure). Complications were significantly more frequent in the salvage group (55%) than primary surgery group (31%) with a trend towards association with smoking, increased comorbidity and the oral cavity site. Salvage following complications is a minority indication in most series with typical indications including: orocutaneous fistula (1–5%), osteoradionecrosis (0–5%), major vessel protection (1–3%), or rupture (1–2%), obliteration of dead space, coverage of exposed hardware or wound breakdown (1–4%) (Fig. 8)[4,33,36,38,76]. Exceptions include the high incidence of pharyngeal fistulae and major vessel exposure, 17%[76] and 51%[32], associated with radiotherapy in some otolaryngology practices.

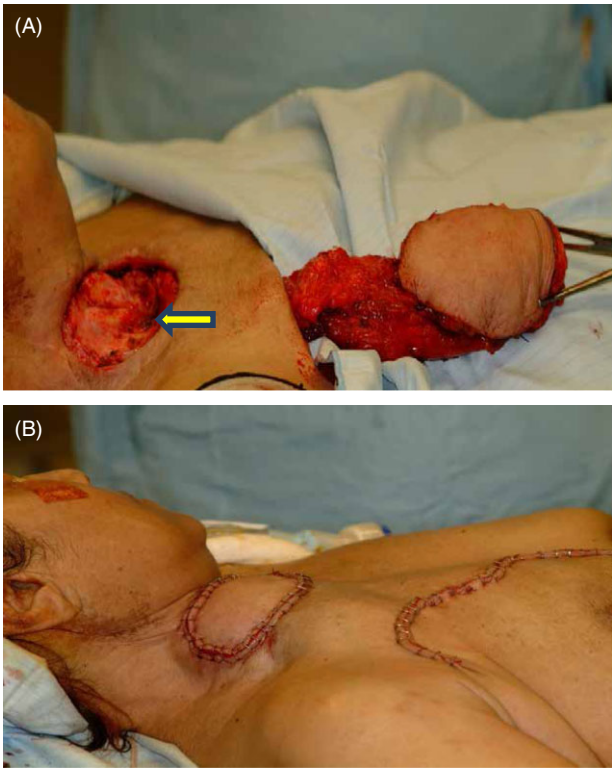

Figure 8 (a,b). Radiation damage with exposure of carotid artery (arrow) protected with PPM flap.

Salvage reconstruction following free flap failure

Reconstruction following partial or complete free flap failure is often necessary for large or composite defects, exposure of vital structures or hardware, and to facilitate prompt adjuvant chemoradiotherapy. The difficulties include: enhanced comorbidities, malnutrition, wound breakdown and infection, poor tissue vascularity, previous surgery and/or chemoradiotherapy, lack of recipient vessels, and psychological issues[118].

Wei *et al.* performed 35% (6/17)[21] to 53% (17/32)[9] of salvage reconstructions with a second free flap and described failure with a PPM flap as relatively common (13%, 2/15)[9]. A second free flap was preferred for 70% of salvage reconstructions in both Liverpool (UK) (22/31)[39] and Texas (USA) (28/40)[119]. The failure rate for immediate second reconstructions is based on small numbers and is generally slightly higher – 4% (1/28)[119], 5% (1/22)[39], 6% (1/17)[9], 8% (1/12)[120] and 11% (1/9)[121] – but occasionally substantially greater – 25% (5/20)[36], 27% (22/30)[122] and 47% (7/15)[123]. Contralateral and transverse cervical vessels have been increasingly utilised, and vein grafting has been avoided[9,119,124,125]. The majority of second free flaps

were not bone flaps, and other failures were mainly reconstructed with a PPM flap. In Leicester, the PPM flap remains the preferred salvage reconstruction in the absence of technical error and particularly with lateral mandible or large tongue defects as flap compression is minimised. The PPM flap success rate was 95% (19/20), although major partial skin flap loss was more common[38].

Overall, the PPM flap probably remains the most frequently used reconstruction salvage option. The case is most compelling with substantial comorbidity, advanced or further disease with a limited prognosis, and large tongue, oropharyngeal or lateral mandible defects[31,70,126]. Free tissue reconstruction of the mandible is the ideal[127] and achieves good quality-of-life outcomes[128], but no comparable studies exist following salvage reconstruction. Functional outcomes with small numbers of PPM flap salvage reconstructions may be worse but are adversely influenced by case selection bias[119].

Salvage reconstruction of recurrent or further primary disease

Free tissue reconstruction is effective for both recurrent and further primary disease[111,129–133] with comparable or slightly lower flap success rates after irradiation. However, complications are more frequent[111,119,125,131,133], especially with segmental mandible defects, larger flaps and active infection[111]. It is unclear how often a free flap is selected in preference to a PPM flap for recurrent disease, but within respective series, the proportion of free flaps used typically ranges from 1% to 36%[5,6,131,134] and PPM flaps from 13% to 52%[4,30,32,72,76,88].

Unfortunately, the prognosis for recurrent disease is poor[132,135–140] so free tissue transfer may not be appropriate. However, the PPM flap remains a versatile option[4,33,37,38,52,54,71,76,141], although complications are frequent at all sites (53–63%)[52,54,72] or following surgery with radiotherapy[52]. The rate of 'successful reconstruction' is variable (50–93%)[30,54,72], but these studies have small sample sizes, multiple clinical variables, differing reconstruction and radiotherapy regimens, and variable outcome definitions. In the Leicester study[38], a comparatively higher proportion of further malignant disease (37%) was managed (2% with palliative intent) without significant increases in either general or flap related complications. Management of oropharyneal or laryngeal disease with chemoradiotherapy[142–145] may increase the need for future salvage reconstructions[4,52].

Summary

The evidence for this review is mainly based on retrospective case-series or cohort studies (levels III and IV)[146]. The PPM flap remains a valuable versatile reconstructive option both in centres practicing free tissue transfer and throughout the developing world. The flap is utilised in varying proportions as either the preferred choice of reconstruction or for salvage reconstruction following free flap failure, further disease or surgical complications. A refined surgical technique and an experienced surgeon may yield total flap failure rates comparable or better than free tissue transfer. A combination of adverse factors, such as serious or multiple comorbidities, advanced disease and previous treatment, is a common indication. The defects most commonly reconstructed include extended radical neck dissection, lateral mandible, large glossectomy and oropharyngeal defects. In some major centres, a second free flap is increasingly used after initial failure as success rates improve. However, the PPM flap probably remains the most commonly utilised salvage option. The PPM flap is occasionally used together with a free flap. The needs of the local population vary, and patient choice may increasingly influence flap selection decisions.

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Short communication

The sternocleidomastoid perforator flap

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Abstract

The conventional pedicled sternocleidomastoid (SCM) flap has a poor arc of rotation, limited volume and precarious vascularity. This report describes a new technique for raising a SCM flap based on the perforating vessels of the superior thyroid vascular pedicle. The upper and lower attachments of the sternocleidomastoid muscle are divided. Four medically and/or surgically compromised patients have successfully undergone reconstruction of hemiglossectomy (1), partial glossectomy (1) and rim of mandible (2) defects for malignancy. The arc of rotation of the SCM flap is greatly increased and the potential applications for the flap expanded.

Keywords: Sternocleidomastoid muscle; Flap; Salvage surgery; Reconstruction; Head and neck cancer; Oncology

Introduction

The sternocleidomastoid (SCM) flap is conventionally raised as a superiorly or inferiorly based pedicled flap and may be either a muscular, myocutaneous or myo-osseous flap.[1] The flap did not become popular for reconstruction of the oral cavity because of the poor arc of rotation, precarious skin vascularity, proximity to nodal disease and the introduction of free tissue transfer.[1,2] This article describes a new technique for raising the SCM flap based on the perforating vessels of the superior thyroid vascular pedicle.

Methods and results

A conventional transverse cervical incision was preferred with no special planning except for a myocutaneous flap. The skin paddle was positioned directly over the mid to lower half of the SCM muscle and the defect closed directly by advancing the cervical skin. The sternal and clavicular muscle origins were divided 2 cm above the clavicle. The muscle was elevated within the investing fascia and the superior thyroid vascular pedicle identified and mobilised (Fig. 1). The superior insertion of the muscle was divided 2 cm below the mastoid and the accessory nerve preserved (Fig. 2). The bulk of the flap is composed of the middle third of the muscle. Minimal excision of proximal and distal tissue was undertaken. The neck dissection was then completed. The greatly increased arc of rotation allowed placement in the floor of the mouth or tongue without tension (Fig. 3). The technique was attempted on 5 occasions and 4 procedures were possible (Table 1). On one occasion there were no superior thyroid perforating vessels so a conventional superiorly based rotational flap was utilised but mobilisation was incomplete. All perforator flaps survived without complication and functioned satisfactorily.

Discussion

The SCM flap is a type II flap with a segmental vascular supply. The dominant superior supply is the occipital and posterior auricular arteries, the superior thyroid artery and/or branches of the external carotid artery supply the middle third and there is a variable supply to the lower third from the thyrocervical trunk.[1,3] The rotational SCM is commonly raised

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Table 1
Sternocleidomastoid perforator flap procedures.

Nos.	Age	Gender	Disease	Stage	Previous surgery	Previous radiotherapy	Resection	Type flap
1	75	M	SCC	T2N2M0	Yes	Yes	Partial glossectomy/floor mouth	Myocutaneous
2	49	M	SCC	T3N1M0	Yes	No	Hemiglossectomy	Muscle and skin graft
3	65	F	SCC	T1N1M0	No	Yes	Rim resection/anterior floor mouth	Muscle
4	74	M	SCC	T4N0M0	Yes	No	Rim resection/lateral floor mouth	Myocutaneous

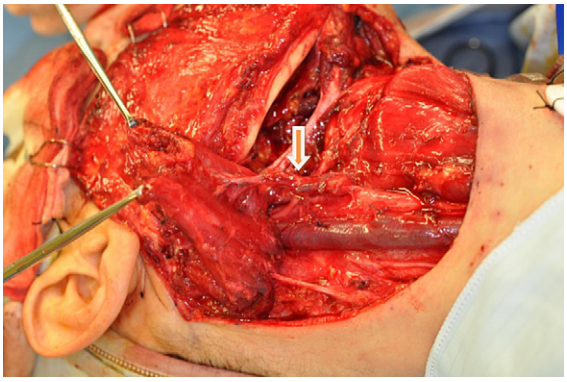

Fig. 1. Elevation of the inferior aspect of sternocleidomastoid muscle with identification of the superior thyroid vascular pedicle (arrow) and preservation of the accessory nerve.

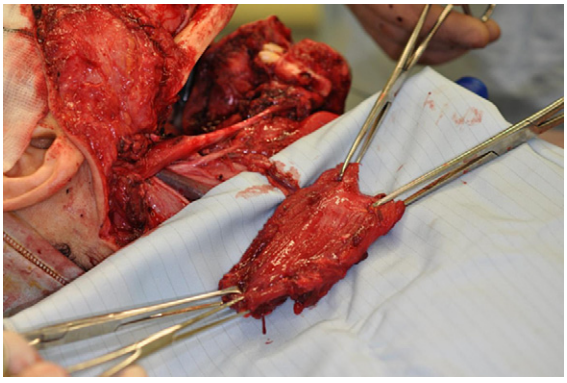

Fig. 2. The superior insertion of the muscle is divided, the vascular pedicle fully mobilised and the accessory nerve dissected free. A substantial amount of tissue may be available.

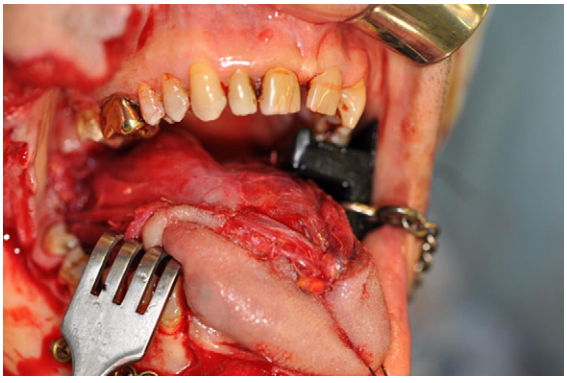

Fig. 3. Muscle only flap utilised for reconstruction of hemiglossectomy defect required partial skin grafting.

as a superiorly based myocutaneous flap[1,4] often with preservation of the occipital and superior thyroid arteries to reduce the risk of ischaemic complications.[1,5,6] However, this significantly restricts the arc of rotation and applications for the flap. A skin island should be positioned directly over the muscle to preserve the delicate perforating vessels[7,8] and cutaneous branch of the superior thyroid artery.[9]

This new technique is a logical development of the increasing utilisation of perforator flaps. Positioning the vascular pedicle and muscle passively, without kinking, minimises the risk of ischaemic compromise. The incidence of complications with a conventional SCM island flap is 20–52% and the majority relate to partial loss of the skin paddle.[1,4,8,10] Total flap loss in the largest series of 111 superiorly based SCM flaps was 7.3%.[4] Complications following radiotherapy were higher but the extent of the adverse effect is contentious.[1,6] Total flap loss in a meta-analysis was 4.2% (12/282).[1]

In this series the SCM flap was selected when a free flap or pectoralis major flap were not ideal because of local factors and/or medical co-morbidity. The perforator SCM flap is contraindicated with significant radiation damage, if the vascular pedicle cannot be mobilised and when complete coverage of the major neck vessels is essential. The established use of selective and modified radical neck dissections means safe oncological principles are not contravened with an N0 neck or with discrete nodal involvement not involving the SCM, however no survival data is available.[1,6]

In this limited experience the SCM flap was effective for repair of small to medium sized defects of the lower oral cavity in patients compromised by previous treatment and/or co-morbidity. The use of the flap may now be expanded.

Financial disclosure

There were no sources of financial support. The author has no financial interests to declare.

Conflict of interest

None declared.

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ORIGINAL ARTICLE

Impact of a structured proforma for improving documentation at the planning stage of major maxillofacial oncology surgery

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Keywords: Proforma; medical records; planning; head and neck surgery; maxillofacial; synoptic record

Abstract

INTRODUCTION: The planning of major maxillofacial oncology surgery is both complex and challenging. Treatment affects many functions, the surgical techniques utilised are complex and the incidence of complications is relatively high. Good communication is essential in the process of obtaining and documenting informed consent. This audit assessed the impact of introducing a structured proforma designed to improve the quality of record keeping at the planning stage prior to surgery.

METHODS: A retrospective audit was performed of three groups of 30 case records randomly selected from 3 periods over the last decade. The first period was prior to the use of the proforma (non-proforma group 1999 - 2002), the second period was soon after introduction (early proforma group 2003 - 2006) and the third period was when use should have become established (late proforma group 2007 - 2009).

RESULTS: There was a statistically significant and progressive improvement in the number of individual variables documented. Improvements were most noted in the detailed documentation of the operation plan, potential complications and aftercare advice.

CONCLUSIONS: The use of a structured planning proforma has led to a significant and sustained improvement in the quality of documentation. The proforma is also a potentially valuable educational tool as it provides a logical framework within which the surgical trainee may be guided through considering all the important aspects of care. The format of the proforma continues to evolve and the concept will be developed as an electronic version.

Face Mouth Jaw Surg 2011;2(2):33-39

Introduction

The planning and undertaking of major maxillofacial oncology surgery is both complex and challenging. The management involves a number of specialist investigations and opinions and success is dependent upon a multidisciplinary approach[1]. Treatment affects many important functions, the surgical techniques utilised are complex and the incidence of complications are known to be relatively high. Good communication is an essential component of surgical practice[2] and

the importance of obtaining informed consent has become a key component of the surgical journey[3]. The quality of the surgical consultation record has received relatively little attention but one study demonstrated that a general surgery practice did not meet the basic criteria recommended by the General Medical Council[4]. It is also well known that the majority of operation records in the United Kingdom (UK) continue to be hand written[5] and that operation records frequently lack basic or critical elements yet may often include irrelevant details[5-7]. This may be the result of a number of factors including: lack of training, time constraints, complexity, limited awareness and tiredness. It is likely that similar factors also apply at the consultation and planning stages before surgery.

Ideally, medical records should be of the highest standard to protect the patient and facilitate good quality care and clinical governance, audit, research, education, and the management of medico-legal litigation. The aim of this audit was to assess the quality of documentation both before and after the introduction of a novel planning proforma designed to facilitate the process and documentation of obtaining informed consent. The authors are not aware of any similar studies using a template based approach for organising the complex information provided to maxillofacial oncology patients.

Planning proforma:

The proforma is kept in the case record and acts as a focus for reviewing and documenting the clinical management by the surgical team. Additional written entries and treatment summary letters are created in the usual manner. The proforma is composed of 14 sections and provides a comprehensive analysis of tumour site and stage, investigations required, treatment plan for surgical resection and reconstruction, general advice on the principles of management and potential complications, specific advice about the surgical procedures and any associated morbidity, and additional multidisciplinary support. Finally it acts as a record of the length and frequency of the consultations and to ensure that the staff member entering the information is readily identifiable. (Figure 1).

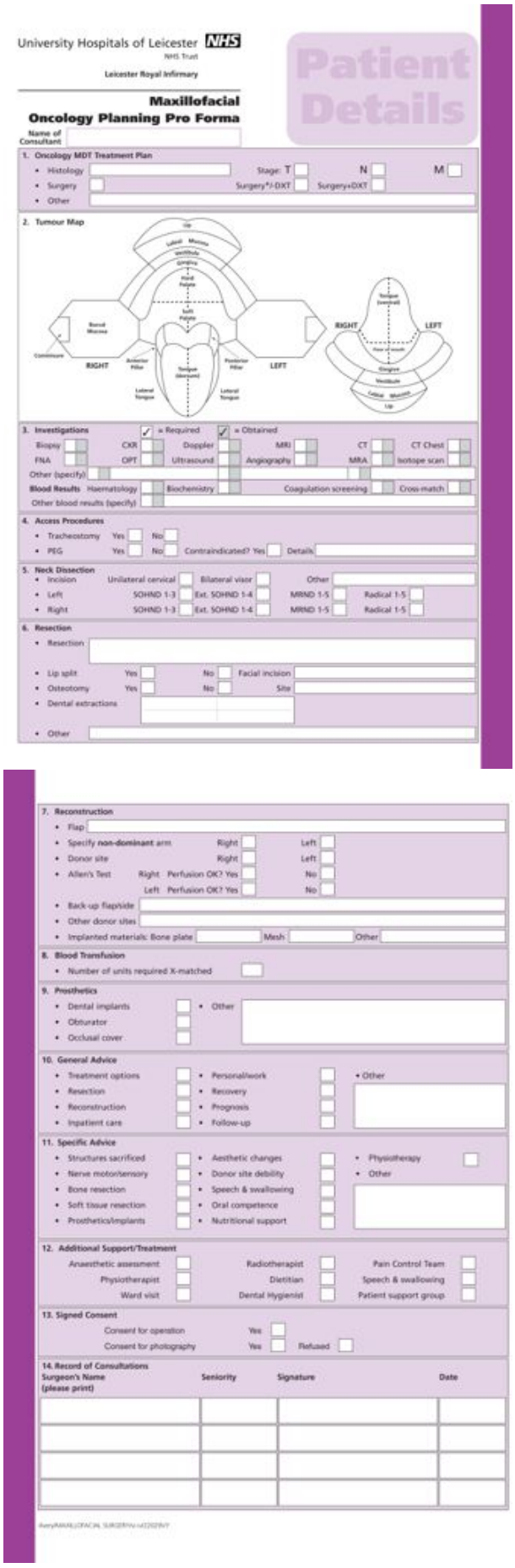
Methods

Data was collected from a retrospective analysis of randomly selected records from a contemporaneous oncology database at the University Hospitals of Leicester (UK) between December 1998 and December 2009. Only patients undergoing major maxillofacial oncology surgery and reconstruction with a free or pedicled flap were included. A total of 90 case records, comprised of 3 groups of 30 records, were analysed. Each group was selected from one of 3 time periods. The first group included patients treated before the use of the proforma (non-proforma 1999 - 2002), the second group was from soon after the introduction of the proforma (early proforma 2003 - 2006) and the third group was from when use of the proforma should have become established (late proforma 2007 - 2009).

The proforma was constructed by a senior member of staff. The RCSE Good surgical Practice was used for assistance with construction[3]. Other standards employed were clinical experience, expert opinion and local hospital protocols.

Examination of the case records included; the proforma if present, handwritten entries, consent forms and clinic letters. Sixty variables were identified and subdivided in to 5 domains; initial management (15), operation plan (10), complications (15), postoperative care (8) and specialist support (12).

Figure 1. Planning proforma


University Hospitals of Leicester NHS
NHS Trust
Leicester Royal Infirmary

Maxillofacial
Oncology Planning Pro Forma

Patient Details

Name of Consultant

1. Oncology MDT Treatment Plan
- Histology
- Surgery
- Other

Stage: T N M
Surgery*/-DXT Surgery+DXT

2. Tumour Map

RIGHT LEFT

3. Investigations ✓ = Required ✓ = Obtained
Biopsy CXR Doppler MRI CT CT Chest
FNA OPT Ultrasound Angiography MRA Isotope scan
Other (specify)
Blood Results Haematology Biochemistry Coagulation screening Cross-match
Other blood results (specify)

4. Access Procedures
- Tracheostomy Yes No
- PEG Yes No Contraindicated? Yes Details

5. Neck Dissection
- Incision Unilateral cervical Bilateral visor Other
- Left SOHND 1-3 Ext. SOHND 1-4 MRND 1-5 Radical 1-5
- Right SOHND 1-3 Ext. SOHND 1-4 MRND 1-5 Radical 1-5

6. Resection
- Resection
- Lip split Yes No Facial incision
- Osteotomy Yes No Site
- Dental extractions
- Other

7. Reconstruction
- Flap
- Specify non-dominant arm Right Left
- Donor site Right Left
- Allen's Test Right Perfusion OK? Yes No
Left Perfusion OK? Yes No
- Back-up flap/side
- Other donor sites
- Implanted materials: Bone plate Mesh Other

8. Blood Transfusion
- Number of units required X-matched

9. Prosthetics
- Dental implants
- Obturator
- Occlusal cover
- Other

10. General Advice
- Treatment options
- Resection
- Reconstruction
- Inpatient care
- Personal/work
- Recovery
- Prognosis
- Follow-up
- Other

11. Specific Advice
- Structures sacrificed
- Nerve motor/sensory
- Bone resection
- Soft tissue resection
- Prosthetics/implants
- Aesthetic changes
- Donor site debility
- Speech & swallowing
- Oral competence
- Nutritional support
- Physiotherapy
- Other

12. Additional Support/Treatment
Anaesthetic assessment Radiotherapist Pain Control Team
Physiotherapist Dietitian Speech & swallowing
Ward visit Dental Hygienist Patient support group

13. Signed Consent
Consent for operation Yes
Consent for photography Yes Refused

14. Record of Consultations
Surgeon's Name (please print) Seniority Signature Date

Statistical Methods

Baseline characteristics and individual proforma variables were compared between cohorts using the Chi-squared or Fisher's Exact test as appropriate. Percentage completion rates of all applicable variables as well as of relevant grouped domains, within each proforma, were compared using the Mann-Whitney U test.

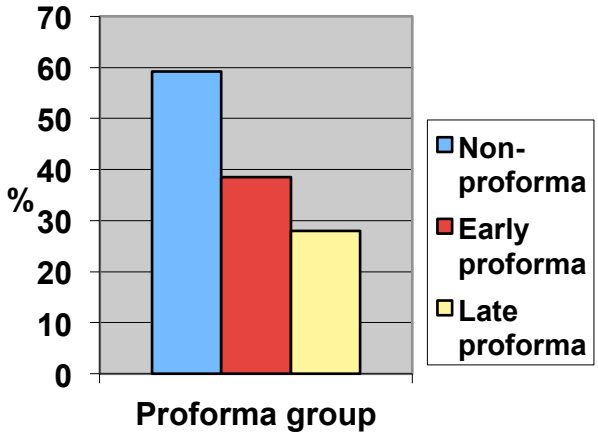
Results

There was no significant difference between the 3 groups in terms of age, gender or rate of 'not applicable' variables.

Rates of omission

There were 8 (27%) missing proformas in the early proforma group and 4 (13%) in the late proforma group. In these cases the records were less complete but the numbers too small to demonstrate a statistical difference. A significantly lower omission rate for applicable variables was noted when comparing the early (mean 38.5%, range 5.0-68.3%) and non-proforma (mean 59.2%, range 35.0-80.0%) groups (P<0.001). The late proforma group demonstrated a significantly lower overall omission rate (mean 28.0%, range 10.2-58.3%) than both the non-proforma (P<0.001) and early proforma (P =0.003) groups (Figure 2).

Figure 2: Percentage of applicable variables omitted in case records.



Documentation of variables

There was a substantial improvement in documentation for 24 variables (40%) when comparing the non-proforma and early proforma groups and 38 variables (63.3%) when comparing the non-proforma and late proforma groups. This included variables such as; grade of surgeon, tumour map, dental extractions, pain, swelling, infection and recurrent disease (P<0.001). When comparing the early and late proforma groups there was significantly improved documentation for 16 variables (26.7%) including; investigation results, speech impediment, donor site morbidity and physiotherapy (P<0.001) but poorer documentation for two variables; lymphoedema (P = 0.005) and pain team (P = 0.001) (Tables 1-5).

Table 1: Individual variables analysed for the planning stage with statistical comparison between groups (P Value). Initial Management

Variable	Non-Proforma vs. Early Proforma [1999-2002]	Non-Proforma vs. Late Proforma [2003-2006]	Early Proforma vs. Late Proforma [2007-2009]
Disease Status			
Stage of disease	0.424	0.706	1.00
Histology	0.026	0.026	1.00
Tumour map	<0.001	<0.001	1.00
Consultant name	0.353	0.488	0.103
Investigations			
Radiology	1.00	0.492	1.00
Haematology	1.00	0.237	0.492
Other specified	0.410	<0.001	<0.001
Results	0.424	0.492	0.052
Blood transfusion	0.108	0.002	0.095
ASA grade	0.584	0.787	0.781
Allen's test	0.382	0.037	0.297
Treatment options			
Surgery	1.00	0.237	0.492
Radiotherapy	0.421	0.260	0.062
Palliative	0.719	1.00	0.703
Treatment plan	0.371	0.184	0.028

Table 2: Individual variables analysed for the planning stage with statistical comparison between groups (P Value). Surgical Procedures

Variable	Non-Proforma vs. Early Proforma [1999-2002]	Non-Proforma vs. Late Proforma [2003-2006]	Early Proforma vs. Late Proforma [2007-2009]
PEG	1.00	1.00	1.00
Tracheostomy	0.611	0.611	1.00
Neck dissection	1.000	0.663	0.659
Classification of neck dissection	0.670	1.00	1.00
Resection	0.889	0.012	0.021
Lip split	0.30	<0.001	0.010
Osteotomy	0.097	0.010	0.355
Extractions	<0.001	0.051	0.079
Type of flap	1.00	1.00	1.00
Flap complications	0.003	<0.001	0.234

Table 3: Individual variables analysed for the planning stage with statistical comparison between groups (P Value). Complications

Variable	Non-Proforma vs. Early Proforma [1999-2002]	Non-Proforma vs. Late Proforma [2003-2006]	Early Proforma vs. Late Proforma [2007-2009]
Swelling	<0.001	0.020	0.091
Pain	<0.001	<0.001	0.317
Immobility	0.197	<0.001	0.002
Prolonged hospitalisation	0.011	<0.001	<0.001
Infection	<0.001	<0.001	0.152
Scar	0.067	0.020	0.602
Lymphoedema	0.080	0.492	0.005
Disfigurement	0.706	<0.001	<0.001
Speech impediment	0.100	<0.001	<0.001
Eating impediment	0.002	<0.001	0.011
Donor site morbidity	0.012	<0.001	<0.001
General morbidity	0.002	<0.001	0.145
Altered sensation	0.002	<0.001	0.038
Recurrent disease	<0.001	0.001	0.771
Secondary surgery	0.001	<0.001	0.004

Table 4: Individual variables analysed for the planning stage with statistical comparison between groups (P Value). Post Operative Care

Variable	Non-Proforma vs. Early Proforma [1999-2002]	Non-Proforma vs. Late Proforma [2003-2006]	Early Proforma vs. Late Proforma [2007-2009]
Access procedures			
Lines	0.009	<0.001	0.153
Tracheostomy	0.849	0.004	0.002
Repeated venepuncture	0.472	1.00	0.254
PEG feed/Nil by mouth	0.630	0.007	0.002
Rehabilitation			
Prosthetics	0.127	0.001	0.045
Physiotherapy	0.599	<0.001	<0.001
Wound care	0.045	0.006	0.506
Implants	0.401	0.001	0.013

Table 5: Individual variables analysed for the planning stage with statistical comparison between groups (P Value). Specialist Support

Variable	Non-Proforma vs. Early Proforma [1999-2002]	Non-Proforma vs. Late Proforma [2003-2006]	Early Proforma vs. Late Proforma [2007-2009]
Consultations			
Anaesthetist	0.004	0.020	0.559
Oncologist	0.902	0.887	0.792
SALT	<0.001	<0.001	0.825
Dietician	<0.001	<0.001	0.434
Physiotherapist	<0.001	<0.001	0.683
Pain team	0.005	1.00	0.001
Specialist nurse	0.353	0.003	0.067
Palliative care	0.011	<0.001	0.149
Surgical leaflet	0.002	<0.001	0.284
Staff Identity			
Signature	1.00	1.00	1.00
Printed name	0.424	0.424	1.00
Grade surgeon	0.001	0.006	0.706

There was significantly improved documentation within all five domains when comparing the non-proforma with the early ($P < 0.05$) and late ($P < 0.001$) proforma groups. There was further improvement in the domains of complications ($P < 0.001$) and postoperative care ($P < 0.001$) when comparing the late and early proforma groups.

Discussion

The introduction of a structured proforma at the planning stage has resulted in a substantial improvement in the documentation of both a wide range of individual variables and the overall percentage of variables recorded. These variables represented only a selection of the myriad of potential events that could have been chosen. The improvement was most marked soon after the introduction of the proforma and was progressive, with further improvements seen over a prolonged period of time. The proforma was particularly effective at documenting advice given on potential complications and outcomes of surgery. Whilst this advice may have been given in the non-proforma group it was not documented and this has important implications for the quality of the informed consent obtained and in the event of medico-legal litigation. However, there is still room for improved compliance with completion of the proforma as new staff remain unfamiliar with the concept.

A proforma based system is convenient as most of the information is consolidated in one accessible document which is usually legible. At the planning stage a wide variety of health professionals may quickly identify the management plan and status of the investigations. The proforma is also a potentially valuable educational tool as it provides a logical framework within which the surgical trainee may be guided through considering all the important aspects of care. The topics covered in each consultation are noted in a tick box fashion with further clarification on the proforma, clinical notes or clinic letter as necessary. The frequency and length of consultations, together with the grade of surgeon, are recorded. This document supports the operation consent form, which cannot alone represent the complexity of the consenting process and myriad of potential complications.

The use of templates for collecting basic data at admission has become more acceptable but has not been widely reported[8]. At the stage of the operation note the shortcomings of the conventional handwritten record have been well documented and the introduction of a structured template has been demonstrated to increase both the quantity and quality of information recorded[7,9]. Although dictated operation notes are easier to read they also suffer from similar shortcomings and there is an additional delay before the corrected record reaches the notes[10]. Increasingly the use of computer based operation templates or electronic synoptic records have been shown to be superior to dictated records[11-14]. In 2010 Park[14] demonstrated good interobserver agreement, a significantly higher level of completed data collection and the records were quick to complete and rapidly available. The level of data completion is substantially higher than in standard notes which often omit 40-50% of the fields whilst synoptic notes may achieve capture rates of over 90%[9,11]. Even though not all fields are mandatory it is likely the synoptic template acts as a reminder.

The scope of electronic synoptic records need not be restricted to just the operative record and the next stage for our project will be to introduce the planning proforma in an electronic format as part of an integrated care pathway. Once on an electronic platform the proforma may be flexibly designed to cover common scenarios and include free text boxes for additional comments[13]. The high degree of completeness and conformity offers an opportunity to standardise the quality of records. Additional potential advantages include the option of including operation coding information and the data is unlikely to be lost. The high quality of the data should facilitate research, education and audit. However, as the amount of potential information is limitless the system should remain easy to navigate and quick to complete to ensure compliance remains high.

Conclusion

The use of a structured planning proforma has led to a sustained and statistically significant improvement in the quality of documentation prior to complex maxillofacial oncology surgery. The format of the proforma continues to evolve and the concept will be developed as an electronic version. The application of a proforma can be integrated into any aspect of the patient journey.

The use of a proforma is particularly encouraged amongst the junior members of staff as it ensures no areas of importance are overlooked during pre-operative planning, and serves as a useful aid memoir. We would encourage all trainees to adopt a proforma based practice and to ensure continuation throughout their career.

Sources of Support – None

Conflict of Interest Statement - None declared

Ethical Approval - Not required

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