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Indications and methods of care for aspects of extraoral osseointegration

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Abstract. The introduction of percutaneous osseointegration biotechnology in 1979 to head and neck reconstruction permanently revised the long held view that a facial prosthesis was a last resort for the patient and surgeon alike. Since that time, the use of extraoral osseointegration has expanded considerably. The present review of the literature considers indications and methods of care for aspects of extraoral osseointegration as it relates to facial prosthetics. The clinical literature reviewed was graded for hierarchy of strength of evidence according to the Bandolier system. Almost all literature reviewed was of the lowest level of strength of evidence. Consequently, clinicians are advised to be cautious in applying the evidence to patients.

Key words: facial prosthetics; epithesis; extraoral osseointegration; craniofacial osseointegration.

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Introduction

The history of facial prosthetics provides a remarkable example of the ingenuity of mankind in dealing with facial disfigurement[18,63]. Facial prostheses were limited in their usefulness by technological limitations and these limitations frequently placed facial prostheses as the last resort for patient and surgeon alike. The introduction of percutaneous osseointegration biotechnology to head and neck reconstruction has permanently revised this long held view.

Prior to the introduction of osseointegration, methods of retaining facial prostheses remained as their primary limiting factor. Mechanical retention and the use of adhesives were the essential methods of retaining facial prostheses. As an example, extrinsic mechanical retention might typically involve spec tacle frames to support a nasal or an auricular prosthesis. The use of adhesives persists but remains controversial[21,60]. Mechanical and adhesive retention are disadvantages since they do not provide specific positioning and the retention they provide is not reliable[37].

Based on the concept of osseointegration, in 1975 Brånemark considered that maintaining a permanent percutaneous implant may be possible[1]. In 1977 the first osseointegrated implants were installed in the temporal bone for connecting a percutaneous abutment to support a bone conduction hearing processor. In 1979, the first implants were placed in the mastoid region to retain an auricular prosthesis[71]. Since that time osseointegration has been employed internationally in facial reconstruction with facial prostheses. The loss or absence of a facial structure may be due to acquired or congenital conditions. The resulting facial defect may be treated with a facial prosthesis, by autogenous reconstruction or a combination of approaches.

The expansion of autogenous surgical techniques in facial reconstruction provides a remarkable diversity of options for hard and soft tissue reconstruction. However, reconstruction of facial defects by autogenous means is not always possible, may at times be undesirable or may need to be delayed. Facial prosthetic reconstruction becomes the treatment of choice in these situations. Consequently, it is important that clinicians undertaking facial reconstruction do not view autogenous reconstruction and osseointegration as competing approaches, but rather as being complementary. For this reason, it is

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important for clinicians to have a sound understanding of the two approaches.

The purpose of this paper is to review the indications, planning, surgical and prosthetic methods of care for aspects of extraoral osseointegration.

Indications

General indications

Any condition that influences the ability of the bone to remodel may presumably influence the integrity of the bone-implant interface in osseointegration. The literature cites numerous potential local and systemic factors that may negatively influence osseointegration. Of these local and systemic factors, relatively few are objective contraindications[25,26]. It appears there is consensus that smoking reduces implant survival although well designed trials are reported lacking[26]. The literature on smoking and implant survival addresses dental implants and not extraoral osseointegrated implants. When considering craniofacial osseointegration, age alone does not appear to be a contraindication since patients 2 to 3 years of age[44] and as old as 80 years of age have been treated[77]. Patients with psychiatric conditions need to be considered carefully as candidates for craniofacial osseointegration. Patients also need to be compliant with homecare regimes and be willing to return for follow-up visits. Patients also need to possess adequate dexterity to manipulate the prosthesis and to carry out hygiene procedures[77]. Combined modality cancer therapy may influence individual implant success rates. Radiation therapy has been associated with craniofacial implant failure[42,43] but is not seen as an absolute contraindication[77]. Implant loss in the irradiated patient is highest in the zygoma and frontal bone, followed by the maxilla, temporal bone and then mandible[42]. The use of hyperbaric oxygen therapy (HBO) to counter the effects of therapeutic radiation on bone remains controversial[52]. A recent case-controlled study provides compelling evidence in favour of the use of HBO[40]. This study found a statistically significant difference between the irradiated group and the two other groups: non-irradiated versus irradiated and HBO treated. Furthermore, in 10 irradiated patients who had lost implants, new implants were installed after HBO treatment. HBO treatment statistically significantly improved implant survival in this group from 34 out of 43 implants previously being lost to 5 out of 42 of the reinstalled and HBO treated implants being lost.

Chemotherapy at the time of implant placement has been reported to be associated with implant loss. If a period had elapsed before and after implant installation, it appeared not to influence implant loss[82]. Where tumour surveillance is considered important, a facial prosthesis is indicated[67].

Indications for orbit reconstruction

Autogenous options may be limited when the contents of the orbit have been exenterated or severely anatomically disrupted. Flaps may be used to provide coverage of the orbit but provide poor aesthetic results. Likewise, reconstruction of severe enophthalmos in the presence of a visually compromised eye seldom produces an acceptable result. For tumour surveillance, coverage of the orbital defect precludes self-examination by the patient and makes clinical examination challenging. Craniofacial osseointegration is indicated in all the above situations involving the orbit[77]. Care should be taken to fully understand the patient's needs and that they are fully informed so that they have appropriate expectations of the treatment modality selected.

Nose and midface reconstruction

In limited defects of the midface, autogenous options might exist but patient preference, medical status and tumour surveillance may result in the selection of craniofacial osseointegration as the treatment of choice. Where the defect extends to the oral cavity or orbit, osseointegrated implants may offer the most appropriate treatment option. Alternatively, autogenous reconstructive procedures in conjunction with craniofacial osseointegration may be the treatment of choice[24,47,67].

When considering nasal defects alone, craniofacial osseointegration may also be considered as a treatment option. An algorithm for selection of treatment for nasal reconstruction has been presented[76]. In common with aspects of ear reconstruction, if the patient's medical status precludes surgery, residual tumour is present, there are no suitable donor sites, the patient will not tolerate the donor sites or by the patient choice, autogenous reconstruction may be precluded. In these situations, craniofacial osseointegration becomes the treatment of choice. Where there has been severe loss of facial contour this may be best reconstructed with an implant retained facial prosthesis[76].

Indications for ear reconstruction

The relative roles of autogenous and osseointegrated ear reconstruction remain controversial. Indications for selecting an autogenous or craniofacial osseointegrated implant approach are becoming accepted[78]. An osseointegration approach is indicated where ear loss has been due to cancer resection[79]. Cancer resection patients will frequently be irradiated and this will add further compromise to the local tissue. Radiation therapy, scarring due to trauma or burns may compromise local tissues so that autogenous reconstruction may be contraindicated and craniofacial osseointegration is the only realistic treatment option. Anatomically, the lower half of the ear is the most challenging to reconstruct. Consequently, where the lower half of the ear has been lost, an osseointegration approach may be preferred. Calcification of the costal cartilage progresses with age but may be encountered in younger adults as well. Constructing the cartilaginous framework for autogenous reconstruction may not be possible in such cases and so osseointegration will become the treatment of choice. In ear reconstruction, it appears that patient preference is an important factor as patients appear to favour either osseointegration or autogenous reconstruction and reportedly seldom reverse their decision[77]. Where attempts at autogenous reconstruction have failed, craniofacial osseointegration provides a valuable salvage option[78]. A particularly controversial aspect of treatment selection in ear reconstruction is in the paediatric patient with microtia. It is possible to place osseointegrated implants in the young but the question remains as to what is appropriate. If an autogenous reconstruction fails, the craniofacial osseointegration option remains. However, if an osseointegration reconstruction fails or is rejected by the patient, an autogenous option might not be available to the patient. With the installation of implants, the microtic area is scarred and this may limit potential for satisfactory autogenous reconstruction if this becomes necessary at a later time. Consequently, it is important to ensure that the patient and/or their family is well informed of their options before embarking on treatment[78].

The question has been raised as to whether an adhesive retained prosthesis can be used first to determine if the patient will benefit from an auricular prosthesis. It has been stated that this should not be considered since the adhesive retained prosthesis provides none of the advantages of the implant retained auricular prosthesis[77].

Indications for treatment of alopecia

Where significant areas of hair loss have occurred, the osseointegrated implants have been used to retain a hairpiece[75,81]. While this is not a widely used application of craniofacial osseointegration, it may provide an option where wearing of a conventional hairpiece, tissue expansion or hair transplantation is not possible.

Methods

Treatment planning

The need for an interdisciplinary approach to treatment planning, treatment and long term follow-up for craniofacial osseointegration care is widely agreed upon[67,73,80]. The team may consist of a nuclear structure or be more broadly based[67,80]. Planning craniofacial osseointegration treatment is a multifactorial process and requires tailoring for each patient. Craniofacial osseointegration is however a stepwise protocol driven process and an algorithm for treatment planning has been proposed[80]. This algorithm suggest treatment specific charting, preoperative photographs, pretreatment moulages, psychological profiling, planning implant positions and available bone volume assessments where indicated. Preoperative education, counseling and obtaining procedure specific informed consent should be considered essential[67,77,80].

Assessment of the area should include the nature and the mobility of the skin overlying the potential implant sites. Hairless skin that is thin and immobile is preferred. The positions of the implants are planned on the skin surface. This may be achieved by use of biometric landmarks and planning templates[84] or trial prostheses[24]. Where concerns exist regarding available bone volume, CT scanning with radiographic templates may be used. Radiographic templates carrying barium markers are constructed. The barium markers locate planned implant positions and allow for navigation in the image. A CT scan is recorded with the template in position and then the image data is manipulated in an information technology implant planning application. The implant planning software allows bone volumes and densities to be assessed. Implant installation can be simulated, depth of soft tissues overlying the area can be assessed and emergence profiles can be considered. Indications for implant installation simulation planning have been cited as: under 10 years of age; severe trauma; major resections; altered morphology; syndromic patients; a history of problems with implant installation[77]. A more sophisticated approach to craniofacial implant planning has been described. This technique makes use of overlaying laser scanning of soft tissues that is digitally overlaid on CT scanning and then CNC milling is used to locate desired implant positions[74]. Rapid prototyping with stereolithography has been used in patients with dysostosis of the cranial region. The rendered acrylic model of the splanchno- and neuro-cranium assists in siting the implants in accordance with goals of facial prosthetic treatment[38].

In the early experience with single endosseous implants, three to four implants were placed for an auricular prosthesis. By 1990 it was confirmed clinically that only two implants were required to retain an auricular prosthesis[71]. In the orbit, typically three implants are used to retain the prosthesis. Higher implant loss in the frontal bone, zygoma and in particular in irradiated patients[51], has led to the placing of additional implants to compensate for potential implant loss. The lateral and superior orbital rims are the suggested sites of implant placement[24], although the lateral aspect of the inferior orbital rim may also provide adequate bone volume. In the case of nasal prostheses, two implants are placed into the maxilla that forms the inferior border of the piriform aperture. Care needs to be taken in siting these implants if teeth are present[24,76]. Additionally, if the superior aspect of the nose is involved, an implant may also be positioned in the naso-ethmoid area[76]. If the facial defect is extensive then clinical judgement must be used to determine potential implant sites. In such cases, it is particularly important to undertake interdisciplinary planning so that implant sites are planned to be appropriate for prosthesis construction.

In the case of implant installation in the cranium, such as for retention of hairpieces, little is reported in the literature. Based upon the history of the condition, it may be wise to undertake CT scanning and use implant installation simulation software to confirm available bone volume and soft tissue thickness at potential sites. This will allow for planning not only implant installation, but also planning of soft tissue management.

Surgery

Implants that are screw-shaped[6,77], cylindrical[6,57,59] or plate-like[27,28,30,31,57,59] have been used for retaining facial prostheses.

The surgical installation of screw-shaped osseointegrated implants is well described in the literature[70,77]. The original surgical technique used a two-stage approach with three to four months healing between the stages of surgery. More recently, a one-stage approach in the mastoid has been described although a two-stage approach continues to be advocated for paediatric patients, the orbit, midface applications and patients who have been irradiated[70]. One-stage procedures in the orbit have been reported[6]. In this study, both pre-cut threaded and self-tapping threaded implants were used in one- and two-stage procedures with reported success. With appropriate treatment planning using CT scanning and implant installation simulation applications, the site of implant installation can be preoperatively determined. This means that in both one- and two-stage approaches, periosteal reflection may no longer be necessary.

The surgical installation of cylindrical implants for facial prostheses has been described as a two-stage procedure[57]. This procedure advocates a 3-month healing period between implant installation and percutaneous connection. It has been reported that cylindrical implants produced microfracture of the orbital bone and so were not advocated for use in the orbit[6].

The surgical installation of the plate-like implant system differs from that of the screw-shaped or cylindrical systems. In certain conditions and some anatomical locations, bone availability may be limited for screw or cylindrical implant installation. While the screw-shaped or cylindrical systems are typical osseointegration systems, the plate-like system is retained with mini-screws. The process of installing the plate-like system is similar to typical bone plate installation. The

plate houses threads into which percutaneous posts of varying length can be screwed. These percutaneous posts provide the sites for connection of the retentive elements. As the posts can be connected to various sites on the plate, opportunity to establish optional positioning exists[37]. A period of 4 weeks healing has been used prior to prosthesis construction[6]. The plate-like system has been advocated for use in the mastoid, orbit and nasal region[11]. It has been preferred where bone availability is limited such as where the nasal bones are intact and only cartilage and soft tissue have been lost[57]. Comments of the plate-like system are that periosteal reflection is required, the plates need to be bent before installation and hygiene maintenance was considered more demanding[57]. The use of the plate-like system is well described for use in the auricular, orbital and nasal regions. Its use has also been described in maxillary resections[27,28,30,31]. The principles associated with the use of the plate-like system has been described in relation to plate fixation[29].

Regardless of the system used, it appears there are several fundamental principles that are important[24,27,57,70,77]. The bones into which implants for facial prostheses are installed rely upon periosteal blood supply; minimizing periosteal reflection is considered important particularly where the bone has been compromised; the surface of the implant must not be compromised and nor must the surface of titanium instruments used to manipulate titanium components be compromised; bone drills must be sharp and used with ample irrigation to prevent damage to the bone that would render it non-vital; for the same reason, drill speeds and torques should be controlled to the protocol for the drills used; implants should not be placed too closely together as this creates problems for hygiene control; electrocoagulation should be used sparingly, particularly in the midface, orbit, one-stage and irradiated patients; the skin should be thinned to limit relative motion between the skin and the percutaneous connector; the skin surrounding the abutment should be hair free; where cartilaginous vestiges remain, these should not be removed without thorough discussion with the patient or family; cartilage vestiges should only be removed at the second stage of a two-stage procedure when it is established that osseointegration has been achieved; care must be taken to consider the placement of the aesthetic margin of the prosthesis; in auricular prostheses, the tissue bed should be flat and the tragus maintained where possible; in the orbit, ptosis of the brow should not be produced when closing the incision line; steep contour changes between the tissues surrounding the abutment and the surrounding tissue should not be created.

Bone volume availability may be a limiting factor in the installation of osseointegrated implants to support a facial prosthesis. This may be encountered particularly in patients with congenital malformations[70,74] and in the midface[57,70]. Bone volume availability may be expanded in certain situations with the use of membranes and guided tissue regeneration. This has been described for use in the mastoid region[41]. In the orbit, ablative surgery, trauma or unfavourable anatomy may limit available sites for implant installation. To overcome this limitation, a technique has been described where a non-vascularized iliac crest is placed in the posterior orbit and implants can then be inserted in the saggital plane[66]. Patients with facial defects may present with complex deformities that require management by a combination of both autogenous and osseointegration techniques. Typically, these patients have both bony and soft tissue deficits that must be addressed in conjunction with the osseointegration procedure. Fourteen of 27 patients treated with extraoral osseointegration required ancillary procedures[47]. This approach involved a wide variety of procedures such as soft tissue expansion, facial slings, ectropion repair, skin grafts, non- and vascularized procedures amongst others. The objective of the ancillary procedures is to reduce the defect volume, thereby decreasing the size of the prosthesis, placing the prosthesis margins at the junction of facial aesthetic units, improving facial contour and bringing viable bone into the area of implant placement. Where bone needs to be brought into the treatment site for implant placement, a comparative study of bone dimension in four vascularized bone flaps reported that iliac crest, scapula, fibula and radius all had adequate bone volume in males for implant placement[35]. Scapula and radius in elderly females were found to have inadequate bone volume to install osseointegrated implants. More recently, the DCIA free flap was advocated where osseointegrated implants are to be considered in complex defects involving the maxilla[13]. Where there is communication between the oral cavity and face, a stated objective is to separate the oral cavity from the facial defect. To achieve this both non- and vascularized techniques are employed[10,48,50,67].

Prosthetic treatment

The methods of constructing a facial prosthesis that is retained by extraoral osseointegrated implants is well described in terms of general principles[7,8,10,80] and more specifically for the ear[10,33,34,80] orbit[9,10,62,73] and nose[10,36].

Biomechanics is considered important to the future understanding of modulating the bone-implant interface. In an extensive review of the biomaterials and biomechanics of oral and maxillofacial implants, Brunski et al.[14] stated that while implants have made an undisputed contribution to patient's lives, fundamental principles underlying design issues are still missing. This review also stated that it cannot be assumed to implants in different bones or implants loaded under differing conditions will have identical bone healing sequences, rates or interfaces. It appears to be frequently assumed that loads delivered to extraoral osseointegrated implants retaining facial prostheses are trivial and insignificant when compared to intraoral implants. In a general discussion on biomechanics of implant supported orbital prostheses, attention was drawn to considering bending moments, force levels delivered by retentive elements, number of implants, connecting implants for load sharing and lone-standing implants[61]. Del Valle et al.[21] undertook a mechanical evaluation of craniofacial osseointegration retention systems. It was found that the adhesive systems tested were less predictable than the mechanical retention systems. Within the mechanical systems, magnets were more predictable than mechanical systems. Magnets were thought to be more useful in situations where lateral forces are less likely to be encountered. Ball and clip attachments were also found to deliver adequate retention. Mechanical arrangement of the components did not influence mechanical performance as much as expected although clips were not activated. Where clip-bar systems were activated, even clip adjustments of only 0.15 mm resulted in load delivery increases of 25%. Given the level of clip adjustment typically used in clinical situations, the loads delivered with clip-bar systems are expected to be

very significantly increased over those reported in the study. It was also found that preformed bars were preferable to cast bars in terms of retention performance. The loads measured in the study showed that the loads delivered by the retention systems should not be considered trivial.

In a numerical study using the finite element method, strain distribution at the interface was studied for axial and moment loads for extraoral osseointegrated implants[20]. This was studied for three implant designs in three bone conditions. It was found that bone strains three to seven times higher were encountered with moment loads. In designing retention systems, thought may need to be given to limiting moment loads. In reviewing the literature, a wide variety of designs of superstructure are encountered. It appears that these designs are developed in an intuitive fashion, have no scientific basis and have no clinical evidencebased research to support their use.

A commonly used bar design has the bar offset to the implant[8]. This design introduces a moment and so has been considered biomechanically poor and a centre-to-centre design has been advocated[83]. Bar and clip designs are widely advocated for auricular[8,10,34,83], orbital[18,62] and nasal[10,36] prostheses. Positioning prosthetic components in the orbit is difficult due to radial alignment of the implants. To provide options in these situations, an abutment that offsets the retentive components was introduced. The loads delivered by this design of abutment was considered[32]. It was found that a 10 N load on a 30° offset abutment could be predicted to deliver approximately 29 N lateral load at the neck of a 3 mm implant. It was also shown that a 10 mm cantilever on the same implant would deliver 31 N lateral load to the neck of the implant. The 30° offset abutment produced strains 5 times higher for 4 mm implants and 5.6 times higher for 3 mm implants than for axial loading of these implants. These results would indicate that, in the absence of more conclusive information, axial loading, avoiding offset designs where feasible and placing retentive components as close to the abutment as possible are desirable design features.

In more extensive defects, designs of superstructure that appear rigid or flexible are found[48]. The adoption of either rigid or flexible designs appears arbitrary and no scientific justification or evidence-based research is noted to justify either design. Anderson & Kasra[3] have used engineering principles to design a superstructure for an extensive midfacial defect. An engineering approach was used to attempt control of forces and moments on the implants supporting and retaining the facial prosthesis.

The use of magnets to retain facial prostheses appears to have gained renewed interest. This is attributed in part to improved retention strength and reduced corrosion[69]. Magnetic retention has been promoted for use with auricular prostheses[11], orbital prostheses[6,38,66] and nasal prostheses[11]. Magnetic retention leaves the implants lone standing which is simpler for maintenance of hygiene and it is suggested that they allow for stress breaking[69]. The use of telescope magnet abutments has been suggested for auricular and nasal prostheses. It has been suggested that two freestanding telescope magnet abutments provide adequate retention with limiting of rotational and dislodging forces. Divergence of the telescope abutments is thought to further enhance these effects. The telescope abutment technique omitted the use of bars, clips and resin substructures. The silicone prosthesis is retained on the abutments without blockout[37]. Magnetic retention has been associated with statistically significantly higher implant losses in irradiated patients[43]. While the interface between the magnetic components is closed, the system is mechanically passive. If the interface opens during functional loading of the prosthesis, the magnetic flux will contribute to the implant-bone interface strain history. No reference to this subject was noted in the literature reviewed.

It appears that current understanding of biomechanics in relation to extraoral osseointegrated implants is very limited. Much of contemporary belief emerges from concepts such as Frost's Mechanostat theory[56]. The theory proposes that in long bones, below 200 $\mu\varepsilon$ bone loss occurs whereas equilibrium by remodelling occurs between 200 $\mu\varepsilon$ and 2500 $\mu\varepsilon$ in compression and 1500 $\mu\varepsilon$ in tension. Faulkner et al.[32] have predicted from a finite element method that a typical load to an extraoral implant would produce tensile strains of 23–155 $\mu\varepsilon$. If these predictions are reasonable, then extraoral implants in healthy bone are assumed, in the Mechanostat model, to exist in an environment of bone loss through remodelling. Clinical experience would indicate that this is not the case. However, in the extraoral experience, high implant loss rates are associated with irradiated bone where presumably the remodelling capacity is reduced. It is possible to speculate that in these situations the strain history is exceeding the remodelling capacity. It may be that the loads on extraoral implants are not trivial and that their capacity to withstand strain may have a lower tolerance in some bones and certain conditions, than is generally anticipated. The relationship of load, induced strain, strain history, remodelling capacity to retention systems and facial prosthesis design is not known at present.

Orthopaedic applications of osseointegration for limb, hand, and digit prostheses

Orthopaedic application of osseointegration for limb, hand and digit prostheses represents an interesting development for the future. It is reported that work began on lower limb prostheses in 1990 and follow-up studies are now finding osseointegration to be a viable alternative to conventional limb prosthesis approaches in selected cases[46,65]. Osseointegration has also been used in forearm amputation with implants being installed in the ulna and radius[64]. In a study of the first 16 patients with lower limb prostheses, it was found that after a 3-year follow-up, 12 patients were successfully treated[46]. Four patients lost their implants due to sepsis and in three patients implants were successfully reinstalled. Both superficial and deep infections appear to have been the most prevalent complication, although mechanical failure of implants components also occurred. It was concluded that average quality of life increased markedly for the patients. Additionally, bone resorption did not appear to create any major problems. An interesting concept arising from osseointegration and studied in the orthopaedic application of osseointegration is that of osseoperception[12]. Osseoperception is a term that refers to the restitution of some sensory and tactile function[64]. With vibrometric tests, it was shown that the normal hand extremity and osseointegrated hand prosthesis had similar threshold responses for vibrotactile stimuli[64]. By distinction, conventional hand prostheses had an average 70% of the threshold response of that of normal extremities[64]. Osseointegration has also been used for finger prostheses[55]. Currently, hand prostheses remain

primitive in function, provide no sensation and are limited to opening and closing of the hand through signals from the extensor and flexor muscles. More advanced central systems for hand prostheses are under development and involve a range of technologies, including microchips implanted in peripheral nerves[55].

The future

There are several areas of development that appear important to the future of extraoral osseointegration and its application to facial prosthetics. A remaining challenge is that the soft tissues do not attach to the percutaneous abutment. Early work has been undertaken to understand how soft tissue attachment to the abutment may be promoted[22,53]. Advanced manufacturing technologies will also become increasingly important to this field of endeavour[38]. Conventional prototyping, rapid prototyping and image data acquisition systems are seen to be likely to play an increasingly important role in treatment planning and treatment[5,16,17,19,23,38]. Of the current rapid prototyping technologies, stereolithography and fused deposition modelling are thought to be important but appropriate technology selection for head and neck reconstruction applications is yet to be defined. Colour matching of facial prosthetic elastomers to skin colour with portable spectrophotometry and computerized colour formulation have been developed and deployed clinically with reported success[68,72]. Fascinating challenges to the field are provided by robotics in the development of active prostheses. Both blinking[49,54] and moving eye[44] orbital prostheses have been considered. Many of these and other areas of innovation are under consideration or development but have not yet been brought to clinical application.

An evidence-based approach

An evidence-based approach to care requires '. . . integrating individual clinical experience with the best available external clinical evidence from systematic research'[15]. In considering an evidence-based approach, the evidence in the literature is assessed on the degree to which the observed results are likely to be attributable to the intervention. As part of an evidence-based approach, one method is to simply rank the literature on hierarchy of strength of evidence[15].

Table 1. Hierarchy of strength of evidence (Moore et al.[58] as cited by Bury T[15])

I.	Strong evidence from at least one systematic review of multiple well-designed randomized controlled trials
II.	Strong evidence from at least one properly designed randomized controlled trial of appropriate size
III.	Evidence from well-designed trials without randomization, single group pre-post, cohort, time series or matched case-controlled studies
IV.	Evidence from well-designed non-experimental studies from more than one centre or research group
V.	Opinions of respected authorities, based on clinical evidence, descriptive studies or reports of expert committees

In 1990, Anderson considered implants in the treatment of the maxillofacial patient[4]. In this work, it was pointed out that if only randomized controlled clinical trials or case series were examined in the literature, then in the case of the maxillofacial implant patient, a very short biography would result. Largely, comments in the publication had to rely on clinical reports. In 2000, Anderson[2] again returned to the subject of considering evidence-based practice in prosthodontics. In a search of the literature on 'maxillofacial prosthesis' from 1995–1998 only 4% of papers were controlled studies. Consequently, Anderson concludes that the clinician, in considering this literature, should '. . . be cautious in applying the evidence to patients.'

In the literature considered in the present review, clinical papers were graded for hierarchy of strength of evidence by simply assigning them to Grade I–Grade V according to the Bandolier system[15]. This system is shown in Table 1[15]. The ranking of the hierarchy of strength of evidence is provided after each reference in the reference list. The majority of the clinical references were case reports or book chapters and consequently, almost all the literature was considered to be of the lowest level of hierarchy of strength of evidence (Class V—opinions of respected authorities, based on clinical evidence, descriptive studies or reports of expert committees).

It would appear that, amongst certain clinician groups, there is a perceived strong treatment effect with regard to aspects of facial prosthetic care with extraoral osseointegrated implants. While the available literature should not be disregarded, it must be considered with caution since even with the empirical evidence-based approach applied to the literature reviewed, the scientific basis for indications and methods discussed is not strong. Consequently, in the absence improved evidence, it is perhaps wise to avoid dogma and to heed Anderson's[2] advice that clinician's should '. . . be cautious in applying the evidence to patients'.

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Note: Entries in parentheses following each reference provide the authors' grading for hierarchy of strength of evidence according to the Bandolier system. The letters (NC) indicate that the reference was judged to be non-clinical.

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