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# Use of ITAP implants for prosthetic reconstruction of extra-oral craniofacial defects

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## KEYWORDS

Bone anchor;  
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**Summary** We report the outcomes of a single-stage, surface-mounted implant used as a bone-anchor for prosthetic reconstruction of complex facial defects. The implant used differs from other designs of osseointegrated bone-anchor because it was designed to be implanted in one-stage with the added intention of integrating with the adjacent soft-tissue. Our aim was to extend the principles underlying the intraosseous transcutaneous amputation prosthesis (ITAP) into the design of infection-free implants suitable for direct skeletal attachment of a prosthesis to the craniofacial skeleton. The implants were manufactured incorporating a porous flange structure coated with hydroxyapatite to encourage soft-tissue integration. These were inserted into the cranial facial skeleton at a number of different sites in 6 adult patients.

A total of 16 implants were inserted using a one-stage procedure and implants were followed up for periods of 18 months – 7 years. One implant loosened at 3 months. This implant experienced multiple episodes of infection and was replaced with another ITAP implant 4 years later. The replacement is now stable and has never been infected at 18 months after insertion. One other patient experienced a few minor episodes of superficial infection (not requiring antibiotics) in the first year but no episodes thereafter. One patient died during follow-up (death unrelated to implant surgery).

Patients were asked for their personal opinions using a structured questionnaire. All the patients were either very satisfied, or satisfied with their ITAP implants. Two patients reported problems with skin irritation under their prosthesis. All would be happy to undergo this type of surgery again.

We conclude that a single-stage, surface-mounted implant designed to incorporate the principles of ITAP can be used to produce an effective bone-anchor for an external prosthesis in the reconstruction of complex craniofacial defects.

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## Introduction

Prosthetic replacement of complex facial deficits is often a better option compared to surgery because of its simplicity and realism.<sup>1,2</sup> It is especially useful for patients undergoing extensive surgery<sup>3</sup> and/or those who are unsuitable for extensive reconstructive procedures. However, securing the prosthesis to the face/head and neck can be difficult. This has prompted the development of bone-anchored implants which allow a prosthesis to be fixed directly to the facial skeleton without using adhesives or adjuncts (e.g. spectacle frames). A number of different types of bone-anchor are in routine use in the craniofacial skeleton. The best known are the two-stage implants pioneered by Branemark.<sup>2</sup> These have been spectacularly successful in the intra-oral environment with many thousands of dental implants inserted annually.<sup>4</sup> Another is the EPITEC system<sup>5-7</sup> which relies on flat plates and can be used as a one-stage implant (Figure 1).

Despite the undoubted value of bone-anchored implants, some reports have suggested that problems with the skin-implant interface continue to limit their usefulness in the extra-oral environment.<sup>8,9</sup> Problems arise when the skin around the transcutaneous component of the bone-anchor remains mobile with respect to the implant (Figure 2). When this occurs, the skin at the interface with the surface of the implant continues to behave like a freshly created open wound and the inflammatory process persists. Granulation tissue forms at this site resulting in a chronic and troublesome discharge. Epithelial cells then migrate downwards at the interface to create a pocket in which debris and bacteria accumulate creating the milieu for persistent infection. To avoid this scenario, the soft-tissues around the implant need to be immobilised with respect to the surface of the implant. This is normally achieved by thinning the soft-tissues around the implant down to dermis or replacing them with a split-thickness skin

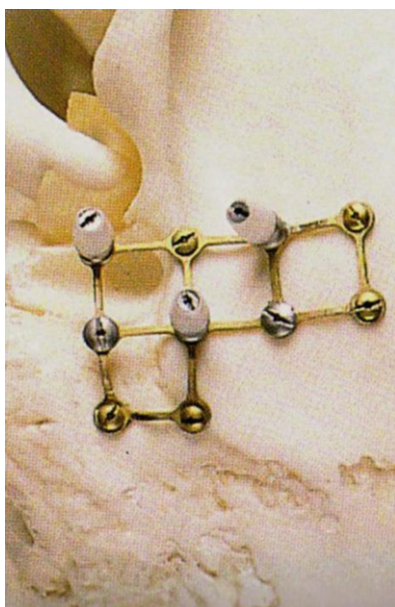


Figure 1 EPITEC system for cranio-facial bone-anchor.

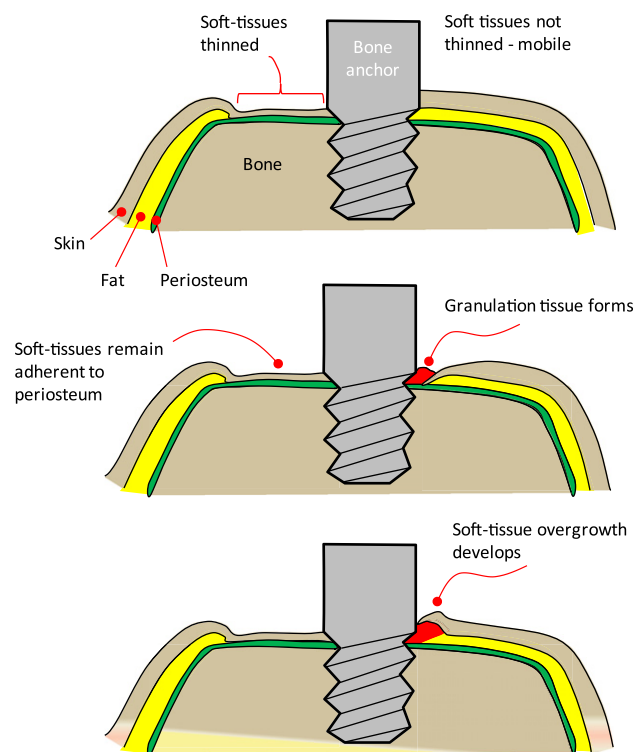


Figure 2 Possible outcomes at the skin-implant interface comparing thinned with unthinned skin.

graft (SSG) so that the epithelium is directly adherent to bone/periosteum.<sup>10,11</sup> However, despite following this recommendation, soft-tissue problems still persist in some case series.<sup>12-14</sup> This experience prompted a search for an alternative design to tackle the soft-tissue problems and to avoid the need for a two-stage procedure.

We now report the outcomes of a single-stage, surface-mounted implant used as a bone-anchor for prosthetic reconstruction of complex facial defects. The implant was designed to incorporate the principles of the intraosseous transcutaneous amputation prosthesis (ITAP).<sup>15</sup> ITAP represents a new approach to the design of bone-anchored implants and is the first implant specifically designed to achieve osseo-cutaneous integration whereby the skin is encouraged to adhere directly to the implant. Theoretically, this would address the problem of excessive soft-tissue mobility at the skin-implant interface and would provide a better biological seal preventing the entry of bacteria. The design of ITAP is based on the work of Pendergrass et al.<sup>16</sup> who studied the interface between the skin and deer antlers (a bone-anchored structure). Subsequent animal studies have confirmed the effectiveness of this approach *in vivo*.<sup>17</sup>

## Patients and methods

This was a retrospective case series. A total of 6 patients were included. All the patients were recruited from the patient population seen in the clinics of the senior author. All patients with loss or absence of part of their face were considered for treatment with an ITAP implant. Patients who smoked cigarettes were asked to discontinue this habit

before surgery. All patients spoke English and were able to give their written consent to undergo treatment.

## Outcomes

All patients were photographed before, during and after treatment. The following outcome measures were also recorded; (a) length of procedure (averaged per implant), (b) revision rates, (c) infection rates, (d) patient satisfaction using a Likert scale questionnaire (scale of 1–5 for each question). Total score of 1–5 (excellent), 5–10 (good), 10–15 (fair), 15–25 (poor).

## Implants

The ITAP implants were manufactured by Stanmore Implants Worldwide Ltd (Century Park, Watford, UK). Each implant was custom-built for a named patient under the requirements of the Medical Devices Directive (MDD) of the UK which is regulated by the Medicines and Health Regulatory Authority (MHRA). Each implant was manufactured for the particular needs of the patient following the instructions of the senior author. The implants were made of titanium alloy and consisted of a vertical, transcutaneous component attached to a flat, subcutaneous plate (Figure 3). The transcutaneous component was designed with an internal diameter of 1.3 mm. This allowed some degree of cross-compatibility with the retention system designed for the Branemark system (e.g. attachment of magnets). The plate was coated with hydroxyapatite (HA) to encourage osseointegration. Initial designs for the transcutaneous component were coated entirely in HA. However, for subsequent designs, the HA coating was restricted to the subcutaneous parts while the transcutaneous parts were coated with a diamond-like-coating (DLC) to reduce bacterial adhesion to the implant. The plate was porous to allow the soft-tissues to grow through the implant with the specific intention of encouraging the overlying skin to become tightly adherent to the surface of the ITAP implant. The implants were secured to the

underlying bone with a minimum of two, self-tapping, titanium screws.

The variables for each implant included; differences in the thickness and shape of the base-plate (maximum thickness – 1 mm), length of the transcutaneous component, angle of the transcutaneous component in relation to the base plate, number of perforations in the base plate and coatings diamond-like-coating (DLC) and hydroxyapatite (HA). These differences are summarised in Table 1.

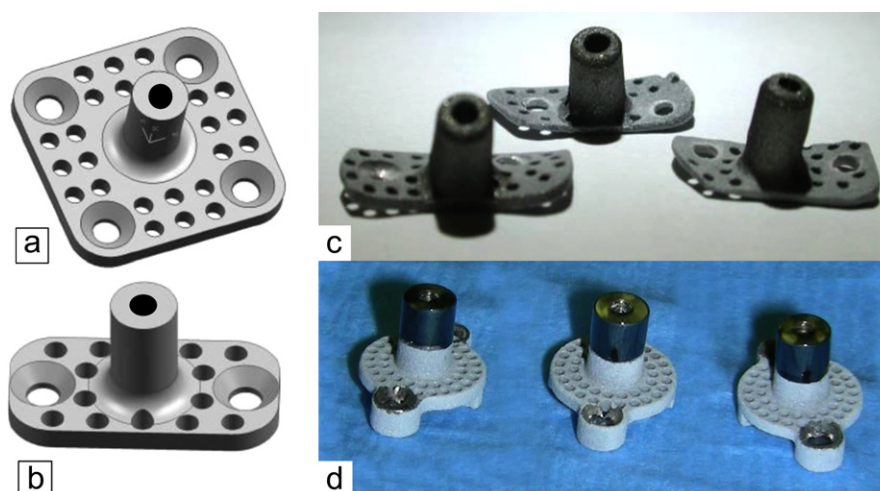
## Surgical technique

All ITAP implants were inserted in a one-stage procedure. All surgery was performed as a day case under local or general anaesthesia according to patient preference and depending on their fitness for anaesthesia. In all cases, decisions on where to place the implants were made after consultation with a prosthetist.

In planning the surgery, CT-scans and/or plain X-rays were obtained pre-operatively. This allowed the manufacturer some leeway on the design of the implant based on thickness and surface contour of the bone at the sites selected for insertion.

All incisions were made approximately 1–3 cm from the site for insertion (Figure 4b). A skin flap was raised down to the periosteum (Figure 4c). The periosteum was incised and raised as a flap or simply pushed away to expose the underlying bone (Figure 4d). The ITAP implant was placed directly onto the exposed bone and the orientation of the base plate was determined on-table to allow for optimum orientation of the transcutaneous component. Two to four (depending on the size of the implant) titanium screws (1.5 mm, self-tapping) were then inserted. The length of the screws used depended on the thickness of the bone. In the periorbital area, screw length varied between 2 and 3 mm. In the temporal bone, screw length varied between 5 and 8 mm.

Once the ITAP was secure, the overlying skin flap was thinned by removing excess fat and/or muscle leaving just



**Figure 3** (a) glabellar implant for Case 2 (b) maxillary implant for Case 2 (c) implants for Case 1 – thin plates which are fully coated with hydroxyapatite (HA) (d) Implants for Cases 3, 4, 5 and 6 showing diamond like coating (black) and HA coating (grey).



**Table 1** Details of implants used.

Patient No.	Site of defect	Number of implants	Operating time (min per implant)	LA/GA	Base plate (shape)	Transcutaneous component	Number of perforations (per implant)	Coatings
Patient 1	Orbit	3	35	GA	Rectangular	3 mm	20	HA
Patient 2	Perinasal	2	40	GA	Rectangular and square	5 mm	24 – glabella 14 – maxilla	HA/DLC
Patient 3	Ear	2	30	GA/LA	Circular	5 mm	45	HA/DLC
Patient 4	Ear	3	30	GA	Circular	5 mm	45	HA/DLC
Patient 5	Ear	3	43	GA	Circular	7 mm	45	HA/DLC
Patient 6	Ear	3	35	LA	Circular	5 mm	45	HA/DLC

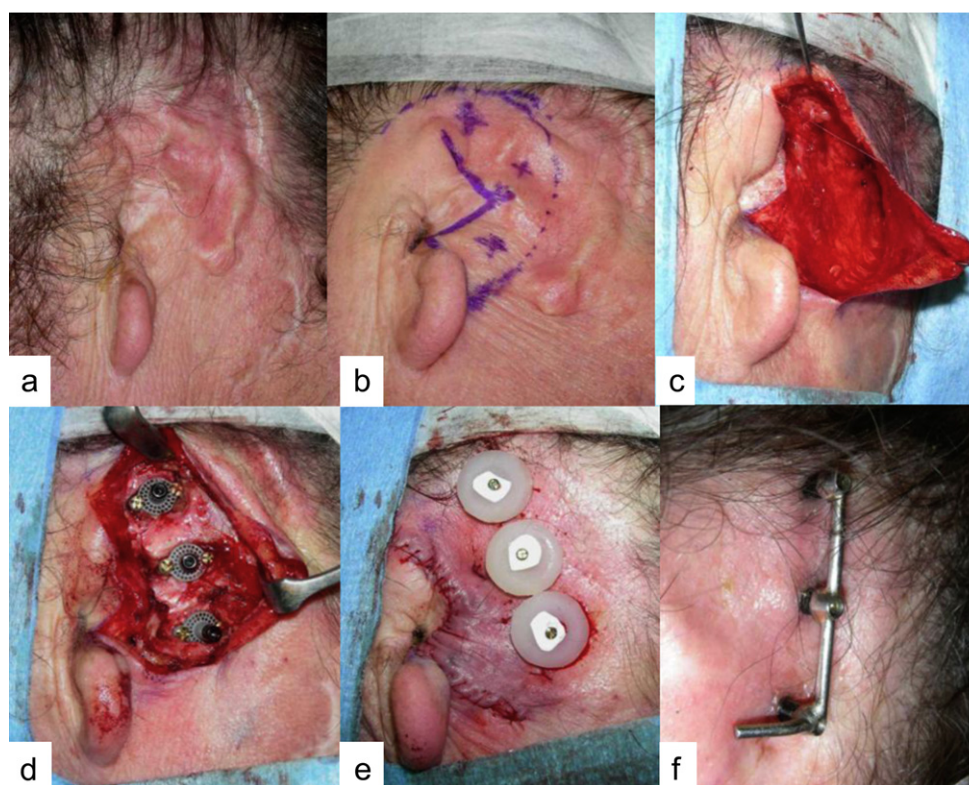
LA: local anaesthetic; GA: general anaesthetic; HA: hydroxyapatite; DLC: diamond like coating.

dermis in contact with the base plate of the implant. A 3 or 4 mm punch biopsy tool was used to perforate the flap directly over the transcutaneous component to allow it to come through the skin. No attempt was made to suture the skin flap directly to the implant.

Once the transcutaneous component was through the skin and haemostasis was satisfactory, the skin was closed with absorbable 5/0 monocril™ and/or 5/0 vicryl rapide™. A healing cap was then screwed into the transcutaneous component (Figure 4e). This was used to hold a petroleum jelly-impregnated gauze dressing in place for the next 5–7 days. The dressing pushed the skin down at the base of the

transcutaneous component and assisted in the process of allowing a tight seal to form between the implant and the overlying skin. The patient was then discharged home on a 1 week course of oral antibiotics.

The skin was inspected after 1 week. If healing appeared to be progressing satisfactorily, then the patient was advised to wash and shower normally. The skin was redressed with a petroleum jelly-impregnated gauze dressing for another 1–2 weeks. After this, the patient was advised to stop all dressings and instructed to apply chloramphenicol ointment (1%) or Savlon™ ointment to the interface between the implant and the skin for another 4–6 weeks.



**Figure 4** (a) pre-op (b) position of incision and ITAP implants marked (c) skin flap raised and thinned to dermis (d) periosteum cleared and three ITAP implants fixed to temporal bone (e) silicone healing caps in place (f) with retention bar at 19 months post-op.

## Prosthesis

The facial prosthetics were custom-built according to the particular needs of the patients. All prostheses were manufactured from silicone and secured to the bone-anchors by either magnets or a retention bar (Figure 4f). This could be attached as soon as skin healing was complete (within 6 weeks).

## Case series

### Case 1

32 year old female (Figure 5). Loss of right eye due to recurrent infections of an orbital cystic hygroma. Previous Branemark retention system – frequently infected. Therefore, removed and replaced with three ITAP implants located on medial orbital wall and orbital rim. Magnetic retention system fitted within 6 months. The patient continues to be unhappy with the cosmetic quality of the prosthesis and does not wear it. No problems with the skin-ITAP interface after 7 years.

### Case 2

74 year old male (Figure 6). Basal cell carcinoma treated by excision and radiotherapy. Recurrence led to partial loss of nose and maxilla. One ITAP implant secured to glabellar area. Second ITAP implant secured to maxilla. Skin healed within 6 weeks and magnetic retention system fitted within 6 months. The patient was very satisfied with his appearance and wore his prosthesis regularly. At 18 months after insertion of the ITAP implants, he went on holiday to Spain and developed pneumonia from which he died.

### Case 3

40 year old male (Figure 7). Absence of right ear due to microtia. Previous prosthetic reconstruction of ear using two

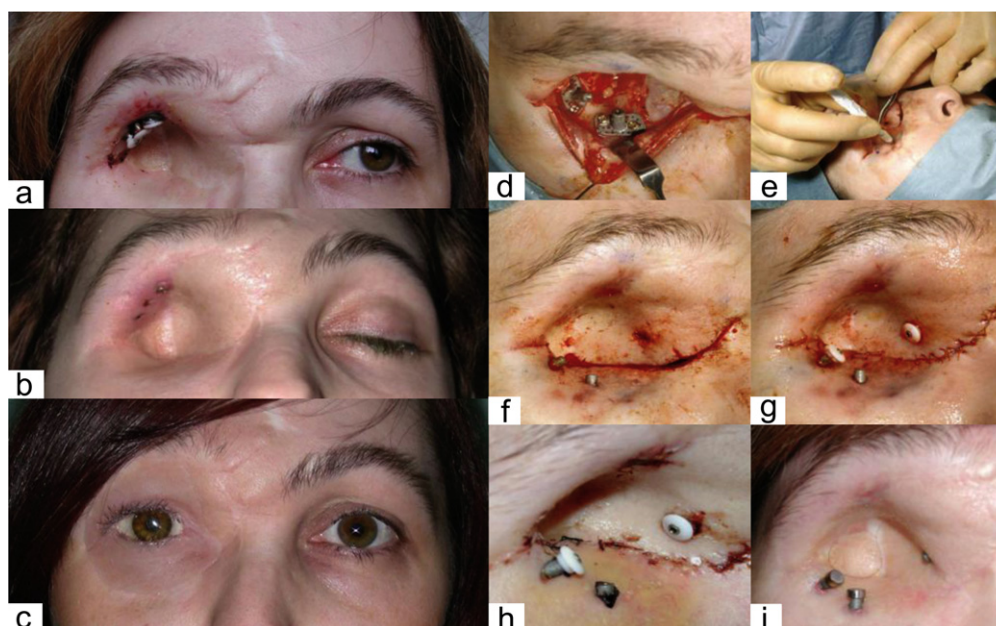
Branemark bone-anchors. Frequent episodes of infection from one of the Branemark implants. Therefore, implant removed and replaced with single ITAP implant. Developed loosening of the ITAP implant after 3 months with minor episodes of infection every 3–4 months; self-treated with topical chloramphenicol ointment. Patient declined revision for 4 years. Eventually, ITAP implant removed and replaced with another ITAP implant. This has now been stable for 18 months with no further episodes of infection. The patient is very happy and wears his prosthetic ear daily.

### Case 4

21 year old male. Absence of left ear due to Goldenhar's syndrome; failed multiple attempts at autologous reconstruction. Three ITAP implants attached to temporal bone in one-stage under general anaesthetic. Skin healed within 6 weeks. Magnetic retention system attached after 6 months. External auditory meatus (EAM) in abnormal position created difficulties with attaching a prosthetic ear. Therefore, EAM repositioned closer to the implants. The patient is very happy and wears his prosthesis daily. No problems with skin-ITAP interface at 5 years after insertion.

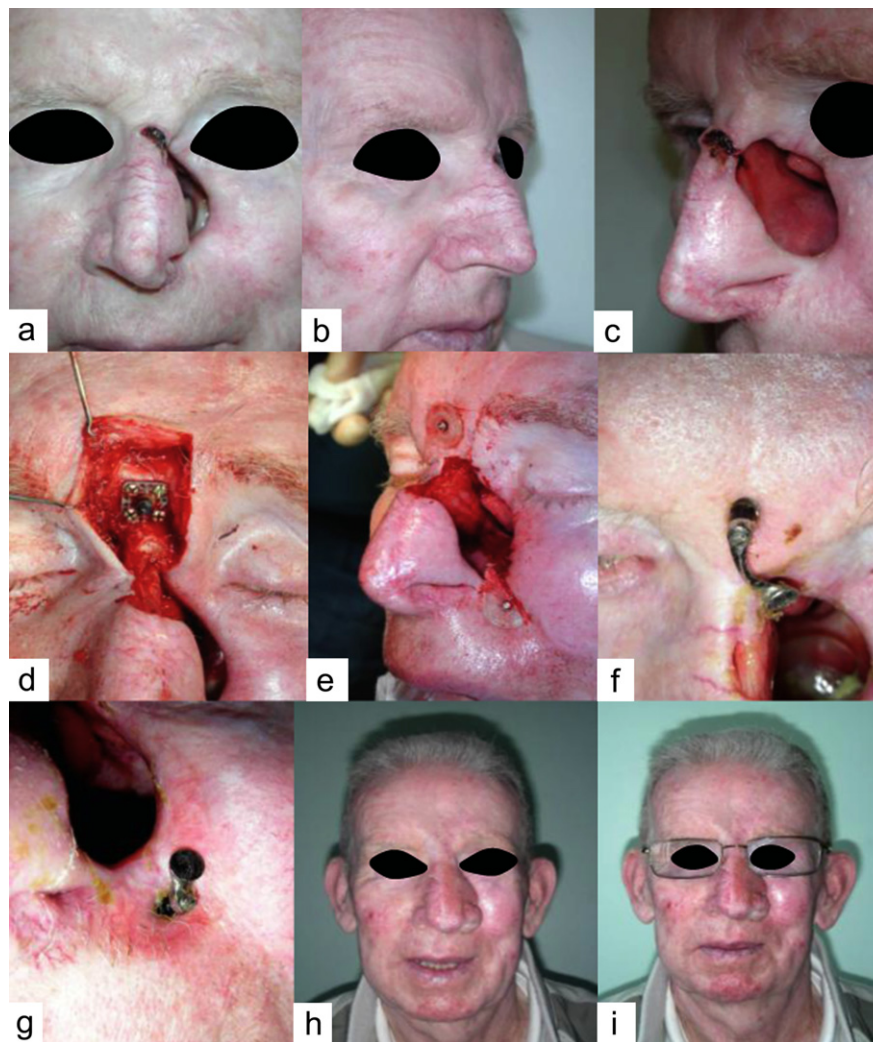
### Case 5

57 year old female. Loss of right ear in house fire aged 15 years. She wanted a short reconstructive procedure. Three ITAP implants secured to right temporal bone. Skin healed within 6 weeks and magnetic retention system fitted within 6 months. The patient developed minor episodes of infection every 3–4 months for first year but nothing thereafter. She also noticed improved hearing after surgery which may have been due to greater bone conduction. She is not happy with the cosmetic quality of the ear prosthesis, therefore, it is only worn occasionally. No problems with skin-ITAP interface after 3 years.



**Figure 5** (a) Three Branemark implants in place (b) Branemark abutments falling out after attempted salvage with skin graft (c) with prosthesis in place 5 years after ITAP (d) ITAP in place on orbital floor (e) punch biopsy tool used to allow transcutaneous component to come through (f) & (g) ITAP implants in place with healing caps (h) at 1 month (i) at 5 years post-op.





**Figure 6** (a), (b), (c) with recurrent BCC on dorsum of nose after previous partial maxillectomy and radiotherapy (d) ITAP in place at glabella (e) two ITAPs in place with healing caps (f) & (g) appearance at 13 months post-op (h) & (i) appearance with prosthesis and spectacles at 13 months.

#### Case 6

57 year old male (Figure 4). Total loss of left ear after alleged assault aged 36. Hair thinning, therefore loss of ear more visible. Not fit for autologous reconstruction due to atrial fibrillation and hypertension. On regular warfarin. Three ITAP implants attached to temporal bone under local anaesthetic in one-stage. Skin healed within 6 weeks. Bar retention system attached after 6 months but converted to magnets a few months later. Does not wear ear prosthesis due to continuing problems with poor fitting of his prosthesis to the magnets. No problems with skin-ITAP interface at 3 years after insertion.

## Results

### Patient demographics

6 patients were recruited for the study including 4 men and 2 women. All the patients were adults ranging in age from 71 to 23 years with an average age of 55 years on entry into the study.

### Implant characteristics

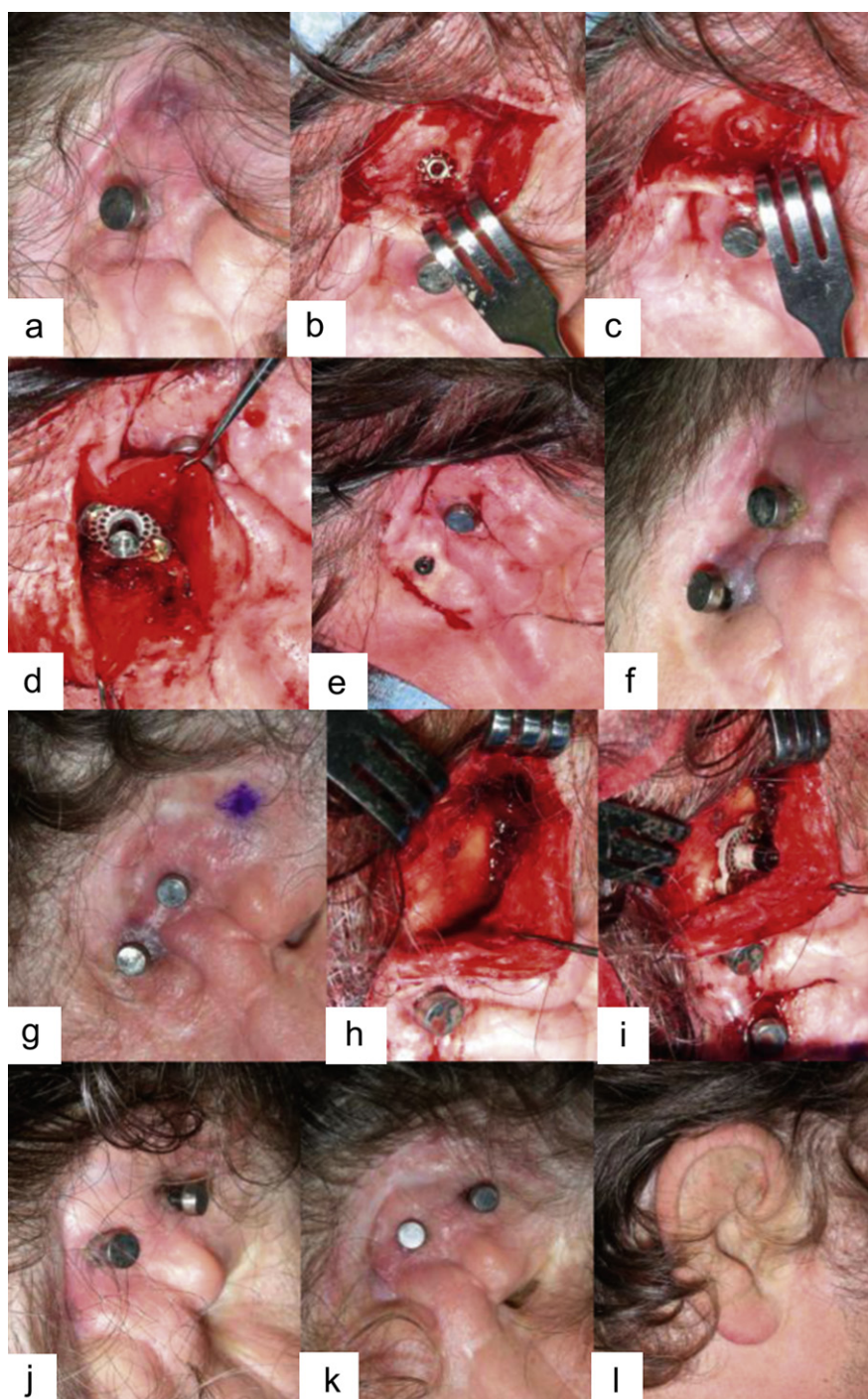
A total of 16 implants were used (average of 2.6 per patient).

### Infections/revisions

Only one patient developed significant problems with infection (defined as needing repeated courses of antibiotics). This was associated with loosening of the ITAP implant. After revision, the new ITAP implant was stable and the patient experienced no further episodes of infection up to 18 months after insertion. Minor (and infrequent) episodes of superficial infection occurred in one other patient during the first 12 months after insertion but not thereafter. There were no episodes of infection and no revisions for the rest of the study group.

### Operating time

Operating times were short, averaging 35 min per implant.



**Figure 7** (a) two Branemark implants in place (b) & (c) upper abutment removed due to recurrent infection (d) first ITAP implant in place (e) transcutaneous part of implant (lower) (f) ITAP loose and infected at 3 months post-insertion (g) pre-op removal of ITAP and re-insertion of second implant at position marked with blue dot (h) site of previous Branemark implant (i) new ITAP implant in place (j) & (k) at 18 months after insertion (j) with prosthesis in place.

### Patient satisfaction

The patient satisfaction questionnaires were completed by 5 of the patients. Patients were either very satisfied or satisfied with the ITAP implants (total score 6). The implants caused little in the way of any pain, discomfort or skin problems. Unfortunately, when asked whether they actually used the prosthesis that was supplied, only two out

of the six patients reported regular use of their prosthesis. This appeared to be directly related to unhappiness about the cosmetic quality of the prosthesis (total score of 11) itself rather than the ITAP implants or the retention system for the prosthesis (i.e. magnets, bars). In fact, the retention system was described by all patients as being either easy or very easy to use (total score 9) and stable or very stable (total score 8).



## Discussion

This study has shown that a single-stage, surface-mounted, bone-anchor can be used successfully to secure a craniofacial prosthesis in a variety of extra-oral sites. Length of follow-up for this study varied between 18 months and 7 years with only one revision. The only patient that needed revision also experienced significant infection. Following revision, this patient experienced no further episodes of infection suggesting that the initial episodes of infection were the result of loosening of the implant rather than the other way around (i.e. infection causing loosening).

None of the patients experienced problems with formation of granulation tissue at the skin-implant interface or soft-tissue overgrowth around or over the transcutaneous component of the implants. Once healed, attempts to move the skin in clinic also showed that the skin around the implants was firmly adherent to the underlying structures in every case. Although it was not clear what the skin was actually adhering to, there was nothing other than the porous flange directly under the skin adjacent to the percutaneous component of the implant (i.e. no periosteum). Therefore, the assumption must be that the skin was adhering to the flange or at least to scar tissue over the flange. This suggests, but does not prove, that one of the principles of ITAP was working i.e. adhesion of the skin to the surface of the implant. To prove our claim, we would clearly need to repeat the same study using the same implants but without a coating of HA and constructed without a porous flange.

There were additional advantages from our approach. Using a surface-mounted implant meant that it could be placed on any thickness of bone. No complex equipment was needed to fix the implants to the bone making it more flexible and easier to apply. Surgery was quick and could also be performed under local anaesthesia. This was a definite advantage in a patient population that commonly suffers from multiple medical co-morbidities. The one revision performed demonstrated that the loosened implant was easy to remove and replace (again under local anaesthetic) with a successful outcome.

There were a number of significant problems encountered in this study. The first was the cost of the implants (approximately £1300 each) although this might be expected to fall with mass production. The second was the provision of a prosthesis. When planning the design of the implant, insufficient thought was given to the nature of the interface between the ITAP implant and the prosthesis. Essentially, the prosthetist was not given enough of a role in the final design. As a result, once the implants were inserted we found that the prosthetist had a great deal of difficulty in trying to attach magnets or retention bars to the transcutaneous component of the implant. This led to long delays in fitting of the final prosthesis in all cases. Moreover, problems related to funding the prostheses used by our six patients have had a direct effect on the quality of the prostheses that have been supplied.

Although the implants used in this case series were custom-built, the principles demonstrated could easily be converted into a simple, standardised, off-the shelf design. This would create a quick, easy and flexible system for providing bone-

anchors suitable for use in a wide variety of situations in the craniofacial skeleton. The EPITEC system has many features in common with the design of the ITAP implant (e.g. can be used in one-stage, surface-mounted, flexible) and perhaps wider use of such a system coupled with more careful attention to the soft-tissue implant interface should be encouraged.

Currently, we have no plans to continue using craniofacial ITAP implants. However, the information gained from the use of the implants in this case series may be of use in the design of similar bone-anchored implants in the future. As our understanding of how these implants work increases, it seems clear that prosthetists should be given a more central role in any future design. Although it would appear that we can create implants that work reasonably reliably as a bone-anchor, the final measure of success should be a patient who is able to return to normal social interaction with a high quality prosthesis secured to their face. Sadly, we were unable to achieve this for every patient in this case series despite the success of the bone-anchors themselves.

## Conflicts of interest

Dr Pendegress and Professor Blunn receive some funding support from Stanmore Implants Worldwide (SIW) – makers of the implants used in this study.

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