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MAIN ARTICLE

Initial experience of a rapid-insertion bone-anchored hearing system: series of 20 consecutive implants

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Abstract

Objective: The loading of bone-anchored hearing system sound processors usually occurs two to three months after surgical implant. This study examined a new bone-anchored hearing system coupling mechanism that permits loading at two weeks post-implantation without compromising osseointegration.

Methods: Twenty implants were implanted into 15 patients. The interval between operation and time of processor loading was recorded, along with the cause of any delay and any late complications.

Results: Two patients were fitted with implants at seven and nine weeks. The delay was a result of administrative errors; the patients reported no skin problems. Of the remaining 17 implants, 8 processors were fitted at 2 weeks, 1 at 3 weeks, 4 at 4 weeks, 3 at 7 weeks and 1 at 8 weeks. For those nine implants fitted later than two weeks, the delay was because of incomplete skin healing.

Conclusion: The Oticon Medical Xpress system allowed processor loading at two weeks post-operatively, providing skin healing was adequate. Early loading occurred in approximately half of the patients. All patients were fitted within the two to three months traditionally allowed. Prolonged skin healing time was the main reason for the delayed fitting of sound processors.

Key words: Osseointegration; Hearing Loss; Hearing Aid; Surgical Procedures, Operative

Introduction

Bone-anchored hearing systems have been proven successful for hearing rehabilitation in patients unable to wear conventional hearing aids, such as those suffering from recurrent aural discharge.[1,2] Additionally, bone-anchored hearing systems have been demonstrated to improve the quality of life of patients with unilateral profound hearing loss via contralateral cochlea stimulation.[3] Bone-anchored hearing systems work by transforming an auditory stimulus into a vibratory stimulus; this is transmitted to the cochlea via a titanium fixture within the temporal bone. For this process to be successful, osseointegration of the titanium prosthesis into the temporal bone is required.[4]

Satisfaction rates with bone-anchored hearing systems have been reported to be as high as 98 per cent.[5] Although implants are generally well tolerated, a recent study with an 18-year follow up of bone-conducting implants revealed that 70 per cent of patients reported annoyance with wind noise.[6] Bone-anchored hearing systems have developed rapidly in the past few years with the introduction of fitting software and signal processing enhancements, such as directional microphones, digital feedback cancellation, and noise and wind noise reduction. Studies have shown increased speech intelligibility and improved subjective patient satisfaction ratings.[7]

There is still debate regarding the optimum time for processor loading; a balance between ensuring osseointegration has occurred and minimising the patient's wait to use the bone-anchored hearing system has to be made. There appears to be little difference in the risk of osseointegration failure for those patients loaded at less than 6 weeks or more than 12 weeks, or even at 4 weeks post-operatively.[8–10] Recent advances in fixture technology include a wider diameter fixture to increase the bone-fixture contact area and novel fixture coatings to speed up osseointegration.[11] Both of these may permit earlier loading than has traditionally been performed.

The Ponto implant system (Oticon Medical, Askim, Sweden) consists of fixtures with two different widths and a range of abutment lengths. In this study, the Ponto 3.75 mm fixture with a 6 mm abutment was used together with the Xpress coupling. The Oticon Medical Xpress external component is attached to the

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abutment via a clip-on mechanism, without the usual lever action required to attach and remove a classic sound processor (Figures 1 and 2). It is hypothesised that the lever action of coupling and decoupling the bone-anchored hearing system to the abutment may compromise the integrity of fixture fixation during the initial crucial period of osseointegration, and lead to extrusion of the implant. The Xpress fitting system was developed to permit early loading of bone-anchored hearing systems without compromising the integrity of osseointegration. In this study, 20 bone-anchored hearing systems were fitted with the intention of early loading with the Oticon Xpress external component.

FIG. 2
The Oticon Medical Xpress bone-anchored hearing system attachment.

Materials and methods

Ethical approval for the study was prospectively granted by our institutional ethics board.

Surgical procedure

All procedures were performed under local anaesthetic and involved single-stage insertion of fixture and abutment. A split skin graft was harvested with an electric dermatome, and the soft tissues were appropriately undermined. Loose periosteum was removed and a punch performed in the periosteum at the intended location of the implant. A standard 4 mm guide drill and countersink were used before the implant was inserted, with up to 40 Ncm torque. The split skin graft was secured in place with size 4.0 Vicryl sutures (Ethicon, Somerville, New Jersey, USA). Jelonet (Smith and Nephew, Hull, UK), Inadine (Johnson and Johnson, New Brunswick, New Jersey, USA) and gauze dressings were then applied before the healing cap was attached. All patients wore a head bandage overnight; this was removed at home the following day.

Patients

Fifteen adult patients (6 males and 9 females, aged 16–70 years) were initially recruited via the out-patient otology service at the Queen Elizabeth Hospital, Birmingham (a regional teaching hospital). Twenty implants were subsequently implanted into these 15 patients. Demographic data are shown in Table I. All patients were implanted with the intention of using the Oticon Medical Xpress coupling system (Oticon Medical).

The patients underwent surgery between March 2009 and January 2012 in a single UK teaching hospital. All procedures were performed by one of two surgeons experienced in bone-anchored hearing systems. Patients were followed up at one week by a bone-anchored hearing system clinical nurse specialist for removal of dressings, and patient and relative abutment care education. The patients were seen at two weeks by an audiologist for potential fitting of sound processors. If suitable, fitting occurred at two weeks post-surgery; if not, patients were reviewed weekly until fitting was appropriate. The interval between the operation and time of processor loading was recorded for all patients, along with the cause of any delays. Late complications were also recorded, regardless of whether or not these resulted in the removal of the bone-anchored hearing system. Patients were seen by their surgeon in the out-patient department, at four weeks post procedure.

Surgical procedure and out-patient follow-up data were retrospectively retrieved from the electronic note system and cross-referenced with clinical records from the audiological service.

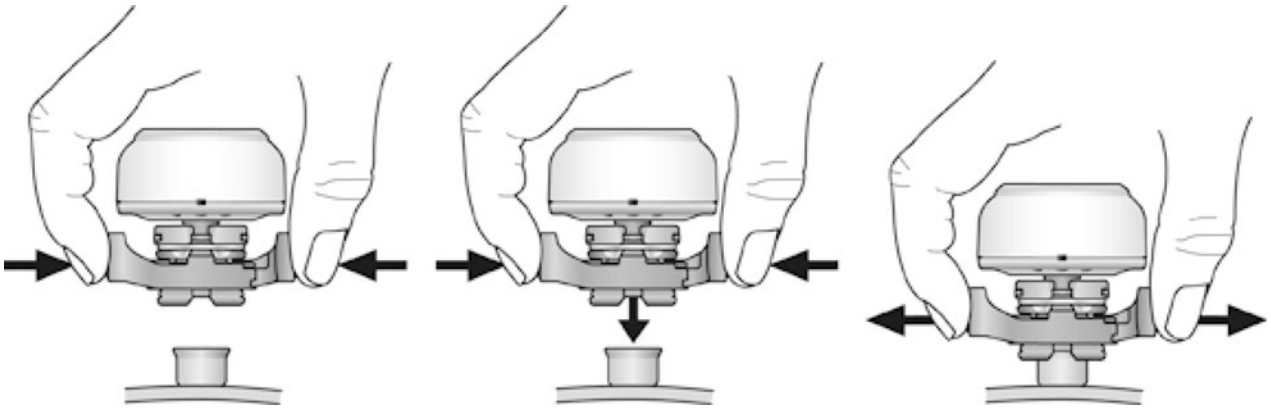

FIG. 1
Mechanism of the Oticon Medical Xpress bone-anchored hearing system attachment.

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TABLE I
RESULTS

Pt no	Sex	Age (y)	Side	Surgery date	Fitting date	Loading wait (weeks post-op)	Xpress fitted?	Complications	Outcome
1	M	66	L	10/03/2009	28/04/2009	7	Yes	Fitting delayed due to skin inflammation	
2	F	27	R	10/03/2009	31/03/2009	3	Yes	None	
3	M	57	R	10/03/2009	06/05/2009	8	No	Fitting delayed due to skin inflammation, R implant fell out	
			L	10/03/2009	28/04/2009	7	Yes	Fitting delayed due to skin inflammation, longer abutment used	L abutment removed
4	M	59	R	10/03/2009	25/03/2009	2	Yes	None	
			L	10/03/2009	28/04/2009	7	Yes	Fitting delayed due to skin inflammation	
5	F	36	R	10/03/2009	25/03/2009	2	Yes	None	Hearing not as good as hoped
6	M	59	R	13/03/2009	25/03/2009	2	Yes	None	
7	F	70	L	13/03/2009	24/03/2009	2	Yes	None	
8	F	55	L	22/05/2009	03/06/2009	2	Yes	None	
9	F	58	L	09/07/2010	20/07/2010	2	Yes	None	
			R	16/08/2011	31/08/2011	2	Yes	None	
10	F	39	L	09/07/2010	20/08/2010	4	Yes	Fitting delayed due to skin inflammation	
11	M	16	R	14/09/2010	13/10/2010	4	Yes	Abutment removed 16/12/10	Removed following looseness after revision mastoid surgery
12	F	29	L	02/11/2010	08/12/2010	7	No	Admin error (fitting not picked up until 6 weeks post-op)	
13	F	40	L	10/09/2010	16/11/2010	9	No	Audiology not notified that surgery had occurred	
			R	10/09/2010	16/11/2010	9	No	None	
14	F	46	R	07/12/2010	22/12/2010	2	Yes	None	
15	M	69	R	03/01/2012	01/02/2012	4	Yes	Fitting delayed due to skin inflammation	
			L	03/01/2012	01/02/2012	4	Yes	None	

Pt no = patient number; y = years; post-op = post-operation; M = male; L = left; F = female; R = right

Results

Two patients were fitted with a total of three implants at seven and nine weeks because of administrative errors; no skin problems were reported by these patients. Of the remaining 17 implants, 8 processors (47.1 per cent) were fitted at 2 weeks post procedure, 1 at 3 weeks (5.9 per cent), 4 at 4 weeks (23.5 per cent), 3 at 7 weeks (17.6 per cent) and 1 at 8 weeks (5.9 per cent). In those (non-administration error) patients who were fitted later than two weeks, the delay was due to incomplete skin healing. The devices were loaded as soon as complete skin healing had occurred.

Two implants were subsequently removed because of complications. One implant was removed as a result of persistent skin site inflammation. This implant had been loaded at seven weeks; the delay was due to on-going skin inflammation. The other implant became loose during subsequent revision mastoid surgery and was removed; the implant had originally been loaded at four weeks and had caused no problems before the mastoid surgery. Further details are shown in Table I.

Discussion

Skin site complications are a recognised cause of processor loading delay following bone-anchored hearing system implantation. Skin complications occur with greater frequency in people of African origin, though there appears to be no correlation with diabetes mellitus, immunosuppression or tobacco usage.[12] Initial skin problems may be reduced by utilising a linear incision rather than a split skin graft.[13] The feasibility of early loading protocols for a variety of bone-conducting hearing aids appears to be increasing, with new wider implant designs and less invasive surgical procedures.

The results of a recent study using linear incision and a wide implant (Cochlear BAI300) suggested complete skin healing in an average of 8 days, with a steady implant stability quotient at 3 weeks, implying that osseointegration had occurred.[14] Use of the same implant processor with loading at four weeks has also been shown to be viable.[9] In a study of a linear incision surgical technique with no skin thinning, using both Cochlear and Oticon Medical implant systems, healing time was reported to be significantly shorter for the test group than for a control group who underwent surgery with a dermatome procedure. The skin of all patients in the test group healed within 10 days.[15]

Our study demonstrated that the Oticon Xpress system enables the loading of sound processors as soon as two weeks after insertion of the titanium implant. In this study, approximately half of the patients were loaded two weeks after surgery. In common with other implanted bone-conducting systems, prolonged skin healing time was the main reason for the delay in fitting sound processors. We were reluctant to load the processor before complete healing, and it may well be the case that many of the patients who waited longer than two weeks could have been fitted sooner. All patients in the study underwent sound processor fitting within the three months traditionally allowed according to national standard practice (nearly all patients had the fitting within two months, which is the standard practice at our institution).

- **Bone-anchored hearing systems are effective for hearing rehabilitation in a variety of conditions**
- **A new sound processor system attachment (Oticon Medical Xpress) can be loaded as early as two weeks after surgery**
- **Problems with skin healing are the main reason for delayed loading of sound processors**

In one of the two patients whose implant was extruded or removed, the delayed loading of the Xpress system was due to skin problems. We do not believe that the use of the early loading system was a factor in the implant loss. Interestingly, this patient requested the continued use of the Xpress system at two months (when the patient was to be converted to a classical fitting system) as they found it simpler to attach and remove. This patient was elderly, with reduced dexterity. The alternative attachment mechanism of the Xpress system may therefore benefit patients struggling with a conventional device.

Conclusion

Whilst our series is of modest size, it does illustrate the feasibility of early sound processor fitting using the Oticon Medical Xpress system. This system allows processor loading as soon as two weeks after the surgical procedure, provided skin healing is adequate. All patients were fitted within the three months traditionally allowed. Prolonged skin healing was the major reason for the delayed fitting of sound processors.

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