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MAIN ARTICLE

Bone-anchored hearing aids and chronic pain: a long-term complication and a cause for elective implant removal

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Abstract

Objectives: To report a case series of elective removal of bone-anchored hearing aid implants, and reasons for removal.

Design: Retrospective review of a prospectively collected database.

Setting: Two tertiary referral centres in the Manchester area: Manchester Royal Infirmary and Salford Royal University Hospital.

Participants: A series of 499 adults and children who had undergone a total of 602 implant insertions (1984–2008).

Main outcome measures: Implant removal rates, and reasons.

Results: Twenty-seven of the 602 implants (4.5 per cent) required removal. Of these, 12 were due to pain (2.0 per cent), seven to persistent infection (1.2 per cent), three to failure of osseointegration (0.5 per cent), three to trauma (0.5 per cent) and two to other reasons (0.4 per cent).

Conclusion: Chronic implant site pain represents the main reason why implants are removed electively, and affects 2 per cent of all implants. This complication has important medico-legal implications and should be discussed when obtaining informed consent for implantation.

Key words: Adult; Child; Hearing Aids; Hearing Loss; Postoperative Complications; Prostheses And Implants; Retrospective Study; Pain, Intractable; Surgical Wound Infection

Introduction

Bone-anchored hearing aids (BAHAs) are bone conducting hearing devices comprising a vibration transducer, microphone and power source in a single housing, directly coupled to the skull by a titanium fixture implanted in the mastoid bone. This allows sound to be transmitted to the cochlea via the cranium, thereby bypassing the tympanic membrane and ossicular chain. This therefore circumvents any middle-ear pathology. Thus, BAHAs were initially used in cases of conductive and mixed hearing loss in which the use of conventional hearing aids was contraindicated.[1]

Bone-anchored hearing aids confer more efficient bone conduction compared with the transcutaneous coupling of conventional bone conduction devices, by up to 15 dB, particularly at the higher frequencies.[2]

Direct bone conduction also requires less energy and is a more comfortable option for patients.[3]

Since the procedure was first developed in the 1980s by Tjellstrom *et al*, the indications for BAHA have changed.[1] The devices were first used in patients with conductive and mixed hearing loss, particularly those with chronically discharging ears.[1] Later usage was expanded to include adults and children with congenital ear malformations in whom fitting a mould was not possible, and also patients whose previous ear surgery rendered them unable to wear conventional hearing aids.[1] Most recently, BAHAs have been used in patients with unilateral sensorineural hearing loss to achieve contralateral routeing of sound from the opposite side of the cranium, improving directional hearing and sound recognition.[4,5]

The Greater Manchester region BAHA programme was established in 1984, and our database dates from its inception. The aim of this paper is to describe our case series of elective BAHA implant removals

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within the Greater Manchester region, and to explore the reasons for these removals.

The original two-stage BAHA technique was described by Tjellstrom *et al.* in 1989. It involved an initial step of implanting a titanium screw in the temporal bone, with the periosteum in situ. After a period of three months, the titanium fixture was uncovered, its osseointegration checked and subcutaneous soft tissue reduction of the skin flap carried out prior to attachment of the abutment. The transduction aid was fitted after one month, at which stage the implantation site would be sufficiently healed to allow this.[6]

Some centres still employ this technique, specifically for groups at higher risk of failure of primary integration, in part due to increased risk of abutment trauma and the tendency for the use of the shorter 3 mm fixtures for thinner, immature skulls.[7]

In 1993, Tjellstrom and Ganstrom described a one-stage technique for BAHA insertion whereby both the fixture and abutment were inserted simultaneously.[8] They went on to show that both techniques had similar rates of success.[9] Kohan *et al.* reported similar findings, and also showed that the one-stage procedure was more cost-effective and enabled earlier hearing rehabilitation.[10] This helped reduce the risk associated with two general anaesthetics; this was especially important as a significant proportion of these patients had syndromes with cranio-facial deformities which were associated with higher anaesthetic risk. This one-stage technique could be carried out effectively under local anaesthetic.

More recently, the FAST single-stage technique (FAST is the name given by the manufacturer for this new motor dermatone technique) has been described by BAHA manufacturers Cochlear Bone Anchored Solutions AB (Mölnlycke, Sweden). This technique has similar soft tissue reduction steps to previously described techniques, but utilises a motorised dermatome, a 3 or 4 mm drill, and a motorised abutment inserter in order to simplify BAHA implantation surgery. A biopsy punch is then used to accurately expose the abutment through the skin flap.[11]

Materials and methods

The cohort consisted of patients with BAHAs implanted at Manchester Royal Infirmary or Salford Royal University Hospital between 1984 and 2008. Patient records were compiled by the respective hospital audit departments. Patients were identified and their records reviewed to obtain information pertinent to their BAHA implantation and, where applicable, BAHA explantation. This information included surgical indications, grade of operating surgeon, method of anaesthesia, operative technique, and whether implantation was performed as a one- or two-stage procedure. Information on any complications was also sought, particularly ones leading to explantation of the titanium fixture.

A literature search was conducted using the PubMed, Medline and Cochrane electronic databases, with the following key words: 'bone-anchored hearing aid', 'postoperative complications', 'pain', 'removal', 'explantation', 'titanium' and 'cranio-facial implants'. Articles in English published up to January 2010 were included in the search. The literature search was expanded by utilising the 'related articles' feature of the above databases, to locate any other articles deemed relevant.

During the aforementioned study period, 602 BAHAs were implanted in 499 patients. These procedures were conducted by 32 surgeons; 284 cases were performed by two consultant surgeons and the remainder by their higher surgical trainees in the North West Deanery training scheme.

Results and analysis

Between 1984 and 2008, 602 BAHAs were implanted at the two centres, in 499 patients. Patient age ranged from four to 87 years.

Twenty-seven implants were removed electively, representing 4.5 per cent of total implants.

Three hundred and sixty-six procedures were performed at Salford Royal University Hospital, of which 15 were removed (4.1 per cent). Two hundred and thirty-six procedures were performed at the Manchester Royal Infirmary, of which 12 were removed (5.1 per cent). The difference in removal rates was not statistically significant (see Table I).

Table II shows the reasons for implant removal.

A total of 12 BAHAs required removal due to persistent pain lasting more than six months and not associated with any soft tissue reactions or infection (referred to hereafter as chronic pain). This pain was mostly described as 'burning' in nature. Pain scores were not recorded, but the pain was reported as moderate to severe. Eight of these BAHAs were implanted by consultant surgeons, four by their trainees. These 12 BAHAs represented 2.0 per cent of all implants. The mean time interval between implantation and pain onset was 3.67 years, with a range of one to seven years. Patient age at onset of pain ranged between 31 to 65 years. Chronic pain accounted for almost half (48 per cent) of all elective implant removals. Female patients comprised the majority, with a female to

TABLE I
BAHAs IMPLANTED AND ELECTIVELY REMOVED

Site	Implanted (*n*)	Removed	
		n	%
SRUH	366	15	4.1
MRI	236	12	5.1
Total	602	27	4.5

BAHAs = bone-anchored hearing aids; SRUTH = Salford Royal University Hospital; MRI = Manchester Royal Infirmary

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TABLE II
REASONS FOR ELECTIVE BAHA REMOVAL

Reason	Site (*n* (%))		Total (*n* (%))
	SRUH	MRI	
Chronic pain	8 (2.2)	4 (1.7)	12 (2.0)
Chronic infection	1 (0.3)	6 (2.55)	7 (1.2)
Failed OI	3 (0.8)	0 (0)	3 (0.5)
Trauma	2 (0.1)	1 (0.4)	3 (0.5)
Pt choice*	1 (0.3)	0 (0)	1 (0.2)
Recurrent VS†	0 (0)	1 (0.4)	1 (0.2)
Total	15 (4.1)	12 (5.1)	27 (4.5)

Data represent bone-anchored hearing aids (BAHAs). *Implant not considered useful. †To enable radiotherapy for recurrent vestibular schwannoma (VS). SRUH = Salford Royal University Hospital; MRI = Manchester Royal Infirmary; OI = osseointegration; Pt = patient

male ratio of 2:1. Chronic pain was the indication for 4.0 per cent of all implants removed in female patients, compared with only 1.1 per cent in male patients. The reason for this discrepancy is unclear.

None of these patients had any clinical manifestations of infection, inflammation or scar formation at the site of the implant. Treatment administered prior to removal of the implants included antineuralgics, topical application of antibiotic and steroid creams (TAC ointment, combination of betnesol and mupirocin), and local infiltration with bupivacaine and hydrocortisone. However, these patients' symptoms only resolved after their implants had been removed.

Of the 12 patients who underwent BAHA explantation due to chronic pain, six chose to have a new implant inserted on the same side, while the other six abandoned the idea of further BAHA use. Of the six patients who had a second BAHA inserted, three (50 per cent) required subsequent removal due to chronic pain.

One of the latter three patients developed chronic pain four years after her second implant had been inserted. This implant was removed, and the patient requested that a third implant be inserted on the same side. At the time of writing, she had not experienced any further problems with her third implant.

Chronic infection unresponsive to topical and systemic antibiotic treatment accounted for seven removals (1.2 per cent). Thirty-one patients reported skin infections at the implant site, seven (22.6 per cent) of whom eventually required explantation. Of these seven patients, three abandoned the idea of further BAHA use, while four had subsequent reinsertion which did not result in removal.

Failure of osseointegration accounted for three removals (0.5 per cent), and loosening secondary to trauma accounted for a further three (0.5 per cent). One patient found their BAHA unhelpful and requested implant removal (0.2 per cent), while another patient required BAHA removal to enable subsequent radiotherapy for recurrent vestibular schwannoma (0.2 per cent).

Discussion

At the time of writing, the Greater Manchester region BAHA programme had been implanting patients for over 20 years, and has a series of 602 implants.

A number of published studies have assessed general BAHA complication rates, including one using our current database.[12] However, none has assessed specific reasons for implant removal, particularly idiopathic chronic pain, and most studies have involved relatively small patient numbers from a single centre (i.e. from 32 to 218 patients).[7,10,13–16]

Chronic pain is a known complication of titanium implantation in the head and neck, but little is known about the incidence, onset and management of this problem. Our large case series highlights the incidence of idiopathic chronic pain as a long-term complication and a cause for removal of approximately 2 per cent of BAHA implants. The incidence was consistent across the two study centres and the two surgeon grades, so was unlikely to be due solely to local factors. Of the 27 BAHA removals, chronic pain accounted for approximately half (48 per cent), followed by persistent infection, failure of osseointegration and trauma. Our overall implant failure rate was comparable to other published series.[12]

To our knowledge, the only other published case series of BAHA removal due to pain was reported by Badran *et al.*[17] Seven out of 167 patients developed persistent pain, resulting in four implant removals (2.3 per cent).

In addition, Mylanus *et al.* reported that 10 out of 500 (2 per cent) titanium cranio-facial implants (BAHA and non-BAHA) were removed due to chronic pain resistant to conservative measures.[18]

It is unclear why this complication has not been reported more frequently in other series. Our figures suggest that this may have been due to under-reporting.

In our series, the onset of persistent pain occurred between one and seven years after implantation. This varied quite significantly from Mylanus and colleagues' series, in which seven temporal bone implants were retrieved from four patients who developed chronic pain.[18] One patient had had four different auricular prosthesis implants (two on each side), and the other three had required unilateral BAHA explantation. Mylanus *et al.* found that the onset of chronic pain ranged from immediately post-operative up to 27 months after the procedure. However, unlike our cohort, these authors recorded associated skin reactions for five of the seven implants involved. They did not offer an explanation for this finding.

Thus far, there has been no clear explanation for the aetiology of chronic pain associated with BAHA implants. Mylanus *et al.* performed histological analysis of percutaneous titanium implants removed due to pain, and demonstrated varying densities of inflammatory cells present at the interface between bone and metal.[18] In contrast to these findings, Tjellstrom *et al.* analysed explanted implants which had not been

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associated with pain; one difference was that there were very few inflammatory cells at the bone–metal interface.[19] However, Mylanus *et al.* believed that the density of inflammatory cells at the bone–metal interface was not sufficient to explain the pain experienced by the patient.[18]

In the Mlynski and colleagues' series, one of the five patients who required removal of their BAHA implant had experienced intractable pain; in this patient, computed tomography demonstrated contact between the implant and the underlying sigmoid sinus dura.[20] Mlynski *et al.* and Granstrom demonstrated similar degrees of bone–metal contact, which tended to increase with increasing loading times; however, neither showed any relationship with chronic pain symptoms.[20,21]

Of the patients in our series who underwent BAHA reimplantation after removal for chronic pain, 50 per cent developed further chronic pain necessitating removal of the second implant. This suggests that intrinsic patient factors rather than surgical factors were responsible, possibly due to a reaction to the titanium unique to this subgroup of the population.

Removal secondary to persistent infection around the implant site constitutes 1.2 per cent of all BAHA explantations. In our series, 5 per cent of patients reported implant site infection at some stage. This is consistent with single institute studies, which have reported incidences ranging from 4 to 33 per cent.[10,13–15] Of these patients, close to a quarter (22.6 per cent) went on to require explantation due to intractable infection.

- **A series of 602 bone-anchored hearing aids implanted in 499 patients over 24 years is presented**
- **Elective removal was needed in 4.5 per cent**
- **This was due to chronic pain in 2 per cent**
- **Chronic pain was the most common cause of elective removal**
- **Removal was due to chronic infection in 1.2 per cent**

Interestingly, in our series 70 BAHAS were implanted because of chronic discharging mastoid cavities. Of these 70, six were removed due to a combination of persistent pain and chronic implant site infection, representing a removal rate of 8.5 per cent in this group. This rate is almost double the overall removal rate for our whole series. We did not find an increased removal rate in any other subgroup, including patients with chronic serous otitis media, congenital ear abnormalities and sensorineural hearing loss. We are as yet unsure of the reasons for this difference.

Conclusion

Our study highlights idiopathic chronic pain as a significant potential complication of BAHA implant surgery, which in our series resulted in 2 per cent of all implants being removed. Our figures suggest that this complication may previously have been underreported. We believe this finding has important medico-legal implications. When obtaining informed consent for BAHA implantation, we strongly recommend that patients be appropriately counselled about the risk of chronic pain and of possible consequent implant removal.

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