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Main Article

Long-term complications of bone-anchored hearing aids: a 14-year experience

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Abstract

Objectives: To report cases of long-term surgical complications, implant failure and revision surgery, within a large bone-anchored hearing aid programme.

Study design: Retrospective, case–cohort study.

Setting: Tertiary referral centre.

Patients: One hundred and sixty-five adults and children who had undergone a total of 177 bone-anchored hearing aid implantations.

Intervention: Diagnosis and explanation of adverse events and device failure.

Main outcome measures: Operative complications and survival analysis, surgical challenges related to revisions, and causes of failure.

Results: Twenty-one per cent of patients (3.4 per cent of those observed) suffered from skin reactions; this rate did not increase over time. Seventeen per cent had loss of osseointegration at a median interval of 6.3 months. Loss of osseointegration was observed more frequently in patients with a 3 mm compared with a 4 mm fixture ($p < 0.001$). Intra-operatively, the only complication was bleeding, occurring in 3 per cent of patients. Post-operative complications included: primary bleeding (2 per cent); severe skin reactions requiring intravenous antibiotics, cautery or grafting (8 per cent); thickening or overgrowth of skin requiring excision (8 per cent); failure of osseointegration requiring a new fixture (18 per cent); and graft necrosis requiring revision (1 per cent). In two patients, it was necessary to explore the area to remove overgrowth of bone. In 16 patients (10 per cent), the bone-anchored hearing aid had to be abandoned due to failure of osseointegration ($n = 4$), dissatisfaction with the aid ($n = 6$), intolerable pain ($n = 4$), hair growth around the abutment ($n = 1$) or recurrent infections ($n = 1$). In 12 of these patients, the bone-anchored hearing aid was removed surgically. Overall, 57 patients (34 per cent) underwent revision surgery.

Conclusion: Awareness of complications is becoming increasingly important in bone-anchored hearing aid programme. A substantial workload of device maintenance should be anticipated, and patients should be appropriately counselled beforehand. Ninety per cent of our patients chose to persevere with this form of hearing rehabilitation.

Key words: Implants and Prostheses; Hearing Aids; Deafness; Complications

Introduction

The principle of titanium implants within human bone originated from dental work (i.e. the 1966 Branemark implant system) and has shown long-term success.[1] In order to maintain good osseointegration (bonding) between the implant and the bone, it is of paramount importance to apply good basic clinical principles. This can be achieved through ensuring: gentle and meticulous technique during surgical installation; a direct connection between vital bone and titanium implants; the absence of interposed tissue between the fixture and the bone; an adequate period of healing; and proper distribution of stress over the implant.[1] It has been almost three decades since this technology was first applied to the temporal bone for the application of a bone-anchored hearing aid (BAHA) (in Gothenburg, Sweden, in 1977). In these initial procedures, a titanium screw was placed in the mastoid process and a transducer was attached to a skin-penetrating coupling. This allowed sound vibration to be transmitted to the cochlea via the implant and the skull bone, bypassing atresia or disease in the external and middle ear.[2–5]

The first official description of a BAHA was by Hakansson *et al.* (of Nobel Biocare, Gothenburg, Sweden) in 1985. This innovation in the rehabilitation

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of patients with impaired hearing had a high success rate initially.[2,6] The implantation of a screw directly into bone made it possible to obtain permanent, rigid, reaction-free penetration of the skin, without intervening soft tissues to attenuate sound transmission (especially in the high frequency range) or pain due to pressure and skin irritation, compared with conventional bone conduction hearing aids.[2–4,6–9]

The BAHA programme was established at the Countess of Chester Hospital in early 1991. Since then, this hospital has been the referral centre for the Merseyside region and parts of north Wales. We have experienced most of the early and late stages of this rapidly developing technique. The aim of this study was to evaluate the long-term results of osseointegration of BAHA implants in the mastoid process, with particular emphasis on the frequency and degree of adverse skin reactions close to the region of skin penetration.

Materials and methods

The case notes of all patients who had undergone BAHA insertion were retrospectively reviewed, and information regarding demographics, indication for surgery, previous hearing aids and audiograms was extracted. Any documented peri- or post-operative complication was recorded, and the total length of follow up was noted. Patients who had undergone fixture placement for an auricular prosthesis were excluded from the study.

The pure tone average (PTA) of the pre-operative bone conduction threshold in the operated ear was calculated at 0.5, 1.0, 2.0 and 4.0 kHz.

Results

We identified 167 patients who had undergone a total of 178 BAHA procedures between January 1991 and December 2004. Two patients who had been lost to follow up or had moved out of the geographical area soon after the operation were excluded from the study. There were 68 males and 97 females. The age of the patient at the time of operation ranged from four to 85 years, with a mean of 49.7 years and a median of 53.5 years. Twelve patients (two bilateral) were aged 16 years or under. Nine patients had a BAHA inserted on each side of their head at separate times (i.e. bilateral BAHA). Two patients had their BAHA changed from one side to the other. In most cases, the BAHA was fitted on the hearing side that had the best bone conduction thresholds; this was on the left side in 75 procedures and on the right side in 100 procedures.

Patients in this study underwent a BAHA fitting for the indications outlined in Table I.

One child and one adult with anotia had an abutment inserted alongside the fixtures for an artificial pinna, during the same operation. One hundred and five patients had undergone previous operations on the ear on the side in which the BAHA was inserted (Table II). The majority had undergone mastoid surgery for control of disease (90 per cent successfully) but were hearing aid users and could not maintain a dry cavity. Those who had undergone middle-ear surgery had associated otitis externa as the main indication for BAHA implantation, although one patient had persistent perforation. Patients who had undergone reconstruction of the external canal for hearing benefit or correction of a narrow canal (for chronic otitis externa) had restenosis. One patient had failed stapedectomy and required BAHA for unilateral sensorineural hearing loss (SNHL).

TABLE I

DIAGNOSIS OF 165 TREATED PATIENTS

Diagnosis	*n*	%
Chronic otitis media	112	64
Chronic otitis externa ± acquired stenosis	38	21
Congenital atresia	12	7
Single-sided neural deafness	4	2
Otosclerosis	5	3
Ossicular disease	2	1
Dissatisfaction with old hearing aid	3	2

The hearing loss in the operated ear was conductive on 55 occasions (54 patients), and mixed on 117 occasions (107 patients). A BAHA was fitted to a 'dead ear' on four occasions (four patients). In line with the original criteria for BAHA implantation,[3] most of our patients had a PTA threshold of 45 dB or better (Figure 1). Those with bone conduction better than 45 dB also fared well (11 patients had pre-operative bone conduction of 45–60 dB; only one abandoned their BAHA, due to persistent pain around the abutment). Six patients had a dead ear, four had unilateral SNHL, one had recurrent loss of osseointegration of a fixture originally fitted on the good hearing side, and one patient's audiologist recommended fitting another BAHA on the non-diseased deaf ear in order to increase spatial awareness.

Although most patients had used hearing aids previously, 15 had the BAHA as their first hearing aid (Table III). In the second half of this series, all patients had a two-month trial period with a bone conduction hearing aid prior to their BAHA fitting.

One hundred and sixty of the procedures were performed by a consultant (90 per cent) and the rest by specialist registrars. Due to technical reasons, we chose to perform the majority of procedures under general anaesthesia (83 per cent). The remainder was performed under local anaesthesia, at the patient's choice or due to unfitness for general

TABLE II

PATIENTS' PREVIOUS EAR SURGERY

Procedure	*n*
Mastoidecomy	78
Tympanoplasty or tympanotomy	18
Reconstruction of external canal*	7
Stapedectomy	1
Fenestration	1

*For congenital or acquired stenosis.

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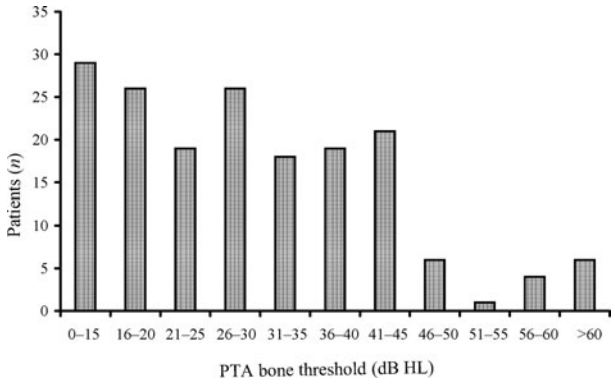

FIG. 1

Patients' pre-operative pure tone average bone conduction thresholds in the operated ear.

anaesthesia. However, this provided less operator control, particularly when drilling the bone. The majority of procedures ($n = 131$) were performed as day cases. In-patient stay was required when there were concerns over the patient's fitness or the distance of their home from the hospital. Three patients planned as day cases had to stay overnight because of bleeding.

The main problem encountered during the procedure was bleeding from the temporalis and sternocleidomastoid muscles. It was found that this was minimised if the muscles were divided with cutting diathermy. Bleeding from the bone occurred in five patients (3 per cent); this was controlled with bone wax to allow a further hole to be drilled in an adjacent site. In one case, there was a very small mastoid process and elevation of the sternocleidomastoid muscle resulted in incision of the internal jugular vein. This was sealed with a fibromuscular plug from the vastus lateralis and the operation was abandoned. The operation was subsequently completed with the placement of the fixture and the abutment somewhat more superiorly than usual. The dura was exposed on three occasions, but this did not prevent the insertion or the osseointegration of the flange fixtures.

Follow-up time ranged from three months to 161 months (13.4 years), with a mean of 50 months (4.2 years) and a median of 36 months (three years). The first post-operative visit was two weeks after the operation, at which the healing cap and sutures were removed and the condition of skin around the abutment was monitored. The next visit was around 2.5 months post-operatively, when the BAHA was attached. Patients were reviewed three months later (six months from the operation date) and thereafter at six-monthly intervals.

For 42 operations, incomplete healing of the graft was observed during the first follow-up visit. This was usually at the graft's anterior edge, as our flaps were posteriorly based. No treatment was required, and there was no delay to the provision of the hearing aid. However, partial failure of the graft was observed for three procedures; these grafts healed over within one month without further complication. In one case, there was total necrosis of the skin flap, which was closed by a rotation flap. This healed by primary intention and did not delay the provision of the hearing aid.

We recorded skin reactions around the abutment, using the system first described by Holgers *et al.*[10] Only symptomatic skin reactions were recorded (i.e. skin reaction type two or worse). Seventy-two per cent of our patients did not experience any symptomatic skin reactions. Skin reactions were categorised as early (i.e. within one year post-operatively), intermediate (one to three years) or late (more than three years). The majority of skin reactions tended to occur early (37/624 observations); of these, type two reactions were the commonest (26/37, 70 per cent). Skin reactions were less likely to occur as time progressed (intermediate reactions were noted in 12/403 observations (3.0 per cent) and late reactions in 12/646 observations (1.9 per cent)). Type two skin reactions were managed with local ointments and oral antibiotics. Type three skin reactions were observed in 11 patients, and were managed with silver nitrate cautery to the granulations in five cases; however, in six patients, granulation tissue was excised under general anaesthesia, followed by grafting in three patients. Two patients were admitted to hospital for intravenous antibiotic treatment due to severe infection of granulations. Type four skin reactions were observed in three patients during three clinic visits. Such a severe reaction necessitated temporary removal of the abutment. After one such experience, one patient decided to completely abandon their BAHA.

No BAHA complication showed an increasing rate of incidence with time.

Eighty-one per cent of patients did not suffer from loss of osseointegration at any stage (Figure 2). Loss of osseointegration occurred in 31 fixtures (24

TABLE III

PATIENTS' HEARING AID USAGE PRIOR TO BAHA

Aid type	Ears	
	n	%
Air conduction	93	53
Bone conduction	37	21
Air & bone conduction	11	7
None	15	9
Data unavailable	20	11

BAHA = bone-anchored hearing aid

TABLE IV

PERCENTAGE LOSS OF OSSEOINTEGRATION VERSUS PATIENT AGE

Reason	Occasions (*n*)
Poor sound quality	6
Pain at BAHA site	4
Loss of osseointegration	4
Recurrent infection	1
Uncontrolled hair growth	1

BAHA = bone-anchored hearing aid

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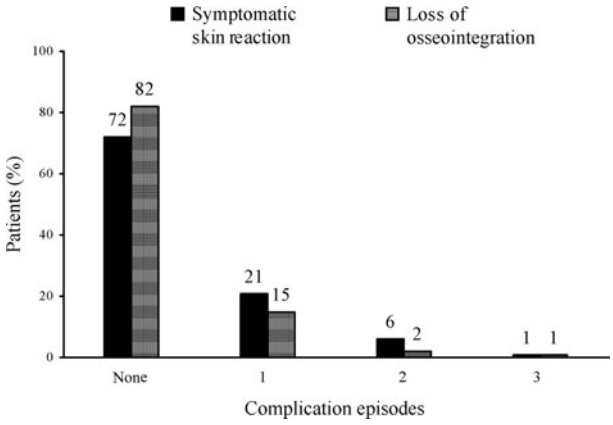

FIG. 2
Percentage of patients suffering episodes of complications.

spontaneous and seven traumatic cases), amounting to almost one-fifth of our population (18 per cent). Four patients decided to abandon their BAHA, while 27 patients requested reinsertion of the fixture (Table IV). Data for loss of osseointegration, stratified by age and fixture size, are shown in Table V. In total, the median interval from the time of operation to loss of osseointegration was 6.3 months.

The incidence of common complications (i.e. symptomatic skin reactions and loss of osseointegration) over the follow-up period is shown in Figure 2. There was no tendency for loss of osseointegration to increase with time. Loss of osseointegration did not increase with the age of the patient.

Thickening or overgrowth of skin and soft tissue around the abutment occurred in 15 patients, leading to an inability to fit the aid to the abutment. This required surgical removal of subcutaneous tissue. In two of these patients, there was also overgrowth of bone surrounding the flange fixture, which required removal of the excess bone by drilling.

Seven patients suffered persistent pain in the BAHA region. In four patients, removal of the abutment and the flange fixture was required.

In three patients, bleeding occurred within 24 hours of the operation, and in two cases the patient required admission. Recurrent bleeding around the abutment at a later date occurred in 23 cases. This was due to excessive rubbing of the area while cleaning, or due to the presence of loose, mobile skin.

TABLE V
FIXTURE FAILURE BY PATIENT AGE AND FIXTURE SIZE

Factor	Failed fixtures/total (*n* (%))
Patient age (yrs)	
<16	5/14 (36)
>16	26/162 (16)
Fixture size	
3	25/90 (28)
4	6/86 (7)

Yrs = years

Fifty-seven patients underwent a total of 73 revision operations (under general or local anaesthetic), as follows (some patients had more than one revision procedure): insertion of a new fixture after loss of osseointegration (29 patients, 34 procedures); removal of the abutment with or without the flange fixture (12 patients, 12 procedures); exploration of the abutment and excision of granulations or an abscess (four patients, six procedures); and removal of skin growth or soft tissue thickening around the abutment (14 patient, 21 procedures). Some of the patients in the last two groups required removal of bone and/or a skin graft.

The BAHA was abandoned in 16 patients (9.7 per cent). This occurred spontaneously following loss of osseointegration in four patients. The BAHA had to be removed in the remaining 12 patients.

Discussion

The introduction of the BAHA has enabled patients who cannot use conventional hearing aids to enjoy better hearing, due to the BAHA's safety, low incidence of complications and high efficacy in transmitting sound energy.[2–5]

In the earlier years of BAHA insertion procedures, surgeons were recommended to perform a two-stage procedure (described in detail elsewhere).[11] This technique was subsequently replaced with a one-stage procedure (described elsewhere),[2] which has been proved to be as effective.[12,13] In our series, the two-stage technique was applied in 17 procedures (17 patients), 83 per cent of which were performed before 1994. In the remaining 159 procedures (150 patients), a one-stage procedure was performed (two patients with bilateral BAHAs underwent both techniques).

In our early experience, we used a postauricular (Thiersch) graft for skin reconstruction at the BAHA site, as described by Tjellstrom.[12] Subsequently, we moved to using a split skin graft, harvested from the BAHA insertion area (using a hand-held dermatome), in a similar manner to that described later by Woolford *et al.*[14] As our experience developed, we began to use a local, split

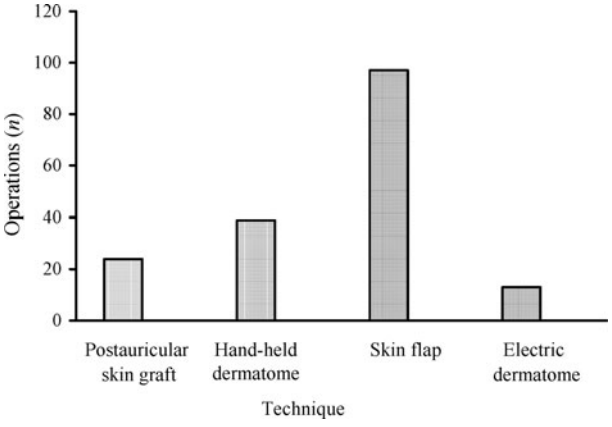

FIG. 3
Operative techniques used for bone-anchored hearing aid implantation.

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thickness skin flap technique, using a number 15 blade, which was becoming popular in the UK at that time (??, personal communication). More recently, the electric dermatome has been introduced in our department (Figure 3).

Previous reports comparing the original two-stage procedure with the more recent one-stage procedure concluded that the clinical results of the two techniques were statistically comparable.[11,13] Mylanus and Cremers showed that the frequency of adverse skin reactions following the two techniques was similar, 12 months after the operation.[13] Although the one-stage technique showed a higher incidence of early skin reactions (possibly due to early loading of the abutment), these authors mentioned that the results of this technique were encouraging as regards a reduced number of operations. However, they admitted that their follow-up time was too short to make a general statement about the possibility of replacing the two-stage technique.[13] We had exactly the same results in our first 12 months. However, after compiling data from a longer follow-up period, we observed that skin reactions in the two-stage procedure were more frequent four years after the operation, compared to a one-stage procedure (Figure 4). Although the significance of this finding is unclear (it should be noted that the number of patients under follow up (i.e. the denominator) declines with time in longitudinal studies, which magnifies the effect of those surviving in subsequent intervals (i.e. the numerator)), this finding generally supports the move towards a one-stage procedure. In our department, the one-stage technique was introduced in 1993, just two years after the BAHA programme was started.

The survival curves for the different techniques used for skin reconstruction are presented in Figure 4. For the two-stage technique, the initial results were good; however, deterioration tended to occur with time. Closure by skin graft resulted in fewer skin complications than skin flap closure. We also observed fewer skin reactions when the skin

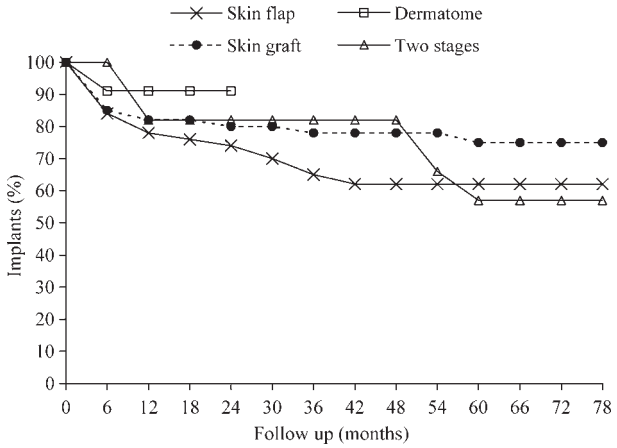

FIG. 4

Cumulative proportion of bone-anchored hearing aid implants remaining free from symptomatic skin reactions over the follow-up period (six-monthly assessment).

flap was raised using an electric dermatome, although the follow-up period was short.

Inadvertent penetration of the internal jugular vein, encountered in our series, has been reported before. Similar to our management, this has been reported to be easily controlled by placing a muscle flap over the bleeding site.[15] In our series, the dura was exposed in three cases, but this did not lead to adverse events. One previous study reported a patient whose implant was in contact with the sigmoid sinus but caused no complication.[4] Inadequate bone thickness while drilling has also been mentioned as a hazard, especially in young children.[15] Thinness of bone should not hinder implantation, as in many cases the implant can still be made stable.[3] In our series, such a situation was encountered only once, in a nine-year-old child. In this case, we used a 3 mm fixture, which at the time of writing had lasted almost two years.

Our first post-operative evaluation of the graft was performed 10 to 14 days after the operation. Although we noted that a significant number had incomplete healing at that time, all had healed within one month with conservative treatment. This has also been observed by Proops,[15] who stressed that such an event was not a disaster as the skin heals well within the three months required for osseointegration to occur.[15]

In 96.2 per cent of the observations in our series, no symptomatic skin reaction was noted. Our results are similar to those of previous studies, which reported a rate of 96.6–98.3 per cent (these results included grade one reactions).[2,4] Extensive soft tissue reduction at the time of the operation was deemed necessary, as it was thought to lessen the incidence of skin reactions.[2] Seventy-two per cent of our patients did not experience a single episode of skin reaction during their follow up. Other studies have reported a rate varying from 68 to 81 per cent.[2,4,13,15]

In assessing skin reactions (Gothenborg classification by Holgers),[4–14] some authors have reported no apparent increase in the rate of skin reaction over time.[3,4,8,10] Hakansson *et al.*[3] used a score obtained by dividing the sum of the skin reactions (calculated according to their severity) by the total number of implants for each month of follow up. They found a range of 0.01 to 0.21 during the first 60 months, with no clear tendency to increase. They also calculated the score for implants that were followed for longer than 42 months, and found that this score was almost identical to the average result of all observations. Our results were quite similar; the range was 0.02–0.22 in the first 60 months, and the scores for implants followed for longer than 42 months were almost identical to the total average for all implants ($\pm$1.7 per cent).

Subcutaneous tissue around the BAHA implant can increase in thickness over time, requiring excision with or without grafting.[2] This observation was noted to be more apparent around puberty.[15] In our series, soft tissue reduction (excluding excision of overgrowth) was required in 10/176 cases (5.7 per cent).

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In our series, 31 patients (18 per cent) lost their BAHA implant. Out of these, 24 patients immediately requested replacement with a new implant. This is in concordance with other published series in which patients immediately requested a new implant when the first was lost.[4,15] However, other published series reported lower rates of implant loss. It should be noted that our series included seven traumatic displacements of the abutment, accounting for the higher overall rate of implant loss. Initially, the flange fixture and the abutment were separate. On 27 visits (22 patients), the attachment of the abutment to the flange fixture was observed to have become loose. The screw attaching these two pieces was tightened in the clinic. In four patients, there was loss of osseointegration, seen after tightening, which may have been either cause or effect. Since the introduction of the pre-mounted fixture (i.e. both the abutment and the flange fixture inserted as one unit) in late 2003, this procedure has not been required.

The overall loss of osseointegration following the one-stage procedure (25/159 observations) was less than that observed following the two-stage procedure (six of 17 observations). This was noted despite early loading of the flange fixture in the one-stage procedure. However, the significance of this observation is unclear, due to the substantial difference in group sizes. Only one study in the literature compared the two techniques, and found no differences regarding loss of osseointegration.[2]

- **This paper reports rates of long-term surgical complications, implant failure and revision surgery for a large bone-anchored hearing aid (BAHA) programme**
- **Thirty-one patients (18 per cent) lost their implant; of these, 24 immediately requested replacement with a new implant**
- **One in three patients will require some form of revision surgery during the lifetime of their BAHA implant**
- **A substantial workload for maintaining the device should be anticipated, and patients should be appropriately counselled beforehand**

We observed that loss of osseointegration does not increase with the age of the patient. As has been previously suggested,[4] this implies that osteoporosis in the mastoid process is not a factor leading to BAHA implant loss. It has been established that the length of the BAHA implant is related to its stability, as more threads distribute the load better.[4] In our series, it was noted that loss of osseointegration was more often seen with the 3 mm fixture. However, such loss occurred at a later stage (Table V).

Conclusions

Our experience with BAHA implants has been largely positive, and replicates the Swedish experience. However, it must be appreciated that one in three patients will require some form of revision surgery during the lifetime of their BAHA. A substantial workload for maintaining the device should be anticipated, and patients should be appropriately counselled beforehand.

One-stage surgery was associated with earlier skin reactions and two-stage surgery with later reactions. Skin grafts resulted in fewer skin reactions, compared with skin flaps, and the former are recommended. Dermatome surgery resulted in a promisingly low rate of skin complications. There was no significant increase in skin reactions over time. Loss of osseointegration may be reduced by using the 4 mm fixture and by adopting a one-stage technique. Intra-operative complications are mainly minor and predictable. Sixteen patients chose to abandon their BAHA. Despite this, 91 per cent of patients in our series continued to use their BAHA with satisfaction.[16]

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