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Long-term soft tissue outcomes for hydroxyapatite-coated bone-anchored hearing implant surgery

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Abstract

Purpose To investigate skin-related postoperative outcomes following a tissue preservation technique in percutaneous hydroxyapatite-coated bone-anchored hearing aid (BAHA) abutment implantation.

Methods A retrospective medical records review of adult patients, who underwent single-stage BAHA implantation between July 2013 and November 2017 at a tertiary centre was conducted. Surgical procedures were performed by a single surgeon using a linear incision soft tissue preservation technique. Patients were reviewed at 1 week, 4 weeks, 3 months, 6 months, and annually postoperatively and soft tissue reactions were graded using Holger's score

Results There were 102 patients included with a slight female preponderance (female:male 56:46). There were 586 follow-up episodes during the study period. From the recorded follow-up episodes, Holger's scores were documented as follows: Holger score 0 (89%); 1 (7%); 2 (2%); 3 (1.9%). Three patients (3%) required peri-abutment soft tissue excision (Holger 3) and insertion of longer abutments. One patient (1%) reported atraumatic implant loss. The BAHA was re-implanted in two patients (2%) due to traumatic dislodgement. There was a statistically significant association ($p = 0.009$) when the mean time to minor skin complications was compared with mean time to a significant skin reaction.

Conclusion Tissue preservation technique is the procedure of choice for BAHA abutment implant surgery. It confers excellent soft tissue outcomes and an excellent implant survival rate.

Keywords BAHA · Osseointegrated device · Abutment · Linear incision soft tissue preservation techniques · Minimally invasive surgery

Introduction

Since their first use in humans in the 1970s [1], bone-anchored hearing devices (BAHD) have become a propitious alternative in hearing rehabilitation for patients in whom a conventional hearing aid is inappropriate. Evidence suggests excellent outcomes, 88–93%, regarding implant stability and osseointegration [2]. Current indications for BAHD include conductive hearing loss, mixed hearing loss, and single-sided deafness, where it acts as a surgically implanted contralateral routing of signal (CROS) hearing aid [3].

Until the beginning of this decade, the central tenet for BAHD surgery was predicated on soft tissue reduction techniques (STRT). The prevailing precept was that soft tissue reduction allowed the skin to adhere to the periosteum, thereby eliminating soft tissue reactions from friction between the implant and skin [4, 5]. Further, it was also assumed that thinning of the peri-abutment skin allowed a tighter fit between the abutment and skin interface, thereby reducing the risk of infection from entrapped epithelial debris and crusts. Numerous surgical techniques, including the pedicled skin flap, dermatome, and U-graft were described to accommodate these presumptions [6–8]. Unfortunately, these soft tissue techniques were associated with a panoply of complications despite excellent audiological outcomes from the implants. Complications ranged from hair loss, asymmetry of the scalp, paraesthesia, and most importantly soft tissue reactions and implant loss. The peri-abutment skin reactions, thought to be B-cell mediated, can manifest with cellulitis, tenderness, swelling, granulation tissue, and soft tissue overgrowth [4].

Recognition of these complications precipitated a natural evolution in the surgical paradigm with a shift towards soft

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tissue preservation techniques (STPT). Results have been encouraging, suggesting superior soft tissues outcomes from STPT when compared with the STRT. Consequently, there has been a sea change in the surgical approach with STPTs essentially supplanting the STRT. Like many other institutions, we changed our own practice from using STRT and adopted a STPT in July 2013 to improve the patient's experience.

Materials and methods

Data were retrieved from medical records of all adult patients who underwent percutaneous single-stage BAHA (BIA400 DermaLock (Cochlear Bone Anchored Solutions AB, Molnlycke, Sweden) implantation in our unit, an adult tertiary referral centre, between July 2013 and November 2017 with a 6-months minimum follow-up period. Our analysis is based on recorded soft tissue complications on each respective follow-up interval graded using Holger's score [9] (0 = no irritation, 1 = slight redness, 2 = red and moist tissue, 3 = granulation tissue, and 4 = infection leading to removal of abutment).

All procedures were performed by the senior author (R.T) using a linear incision soft tissue preservation technique (LISTPT). We published our experience with this technique in Wilkie et al. [10]. Patients were reviewed routinely at 1 week, 4 weeks, 3 months, 6 months, and annually postoperatively and soft tissue reactions graded as above. We also included outcomes of those patients developing complications outside their follow-up schedule.

Statistical analysis was undertaken using SPSS (v24, IBM, Armonk, NY, USA). We analysed statistical associations between normally distributed data using Levene's test for equality of variances and the independent samples *t* test. Categorical data were examined using Pearson's chi-squared test. We set the significance level for all tests (α) at 0.05.

Surgical technique

The patient's head is positioned supine on a head ring and the hair on the surgical site is shaved. The implant site is marked 55 mm from the external acoustic meatus 45° postero–superior to the horizontal plane. Soft tissue thickness is measured using a small-gauge hypodermic needle mounted on a pair of artery forceps (Fig. 1a). A manufacturer-supplied measuring ruler is used to measure the depth of penetration of the hypodermic needle, which then guides selection of the appropriate abutment length. This is deemed to be 3 mm greater than the measured soft tissue thickness as per the manufacturer's instructions. Abutments are available in varying lengths ranging from 6 to 12 mm. The surgical site is cleaned with chlorhexidine solution and then draped. Local anaesthesia infiltration is followed by a 2–3 cm long linear incision down the periosteum of the skull. A small raspatorium is used to separate the periosteum from the cortical bone (Fig. 1b). Implant insertion is performed within the incision in a standard fashion using an Osscora handpiece and foot controller (Cochlear Bone Anchored Solutions AB Molnlycke, Sweden) (Fig. 1c–e). Tension-free skin closure is achieved with interrupted 3.0 vicryl sutures (Fig. 1f).

Results

One hundred and two patients were implanted during the study period with a slight female preponderance (female: male 56:46). Age at implantation ranged from 20 to 93 years with an average age of 58.5 years during implantation. All patients had a minimum of 6-months postoperative follow up with an overall range of 1 week–60 months.

The indication for implantation included conductive hearing loss 48% (49/102), mixed hearing loss 28% (29/102), and sensorineural hearing loss 24% (24/102) (Table 1).

Soft tissue outcomes

There were a total 586 follow-up episodes over the study period (Fig. 2). The Holger scores of 0 and 1 were recorded on 89% (524/586) and 7% (41/586) of visits, respectively. Holger 2 and 3 scores were recorded on 2% (12/586) and 1.9% (11/586) of clinic visits. There were no Holger 4 scores recorded.

Table 2 illustrates results of statistical analysis of variables associated with a "significant skin reaction", which we defined as Holger 3 at or before the 6-month outpatient review, or any implant removal due to skin reaction. There was a statistically significant association ($p - 0.009$), when the mean time to minor skin complications was compared with mean time to significant skin reaction. Further, patients with a background of CSOM were less likely to develop significant skin reactions when compared to patients with chronic recurrent otitis externa or other indications ($p - 0.003$), which was statistically significant.

There were no statistically significant association between age, gender, laterality, and severity of soft tissue infections.

Revision surgery and implant loss

Three patients (3%) required peri-abutment soft tissue excision (Holger 3) with two receiving longer abutments. Two patients (2%) elected for explantation due to recurrent low-grade soft tissue irritation (Holger 1–2) and one patient had the implant removed due to lifestyle factors. One patient (1%) reported atraumatic implant loss. Two patients (2%)

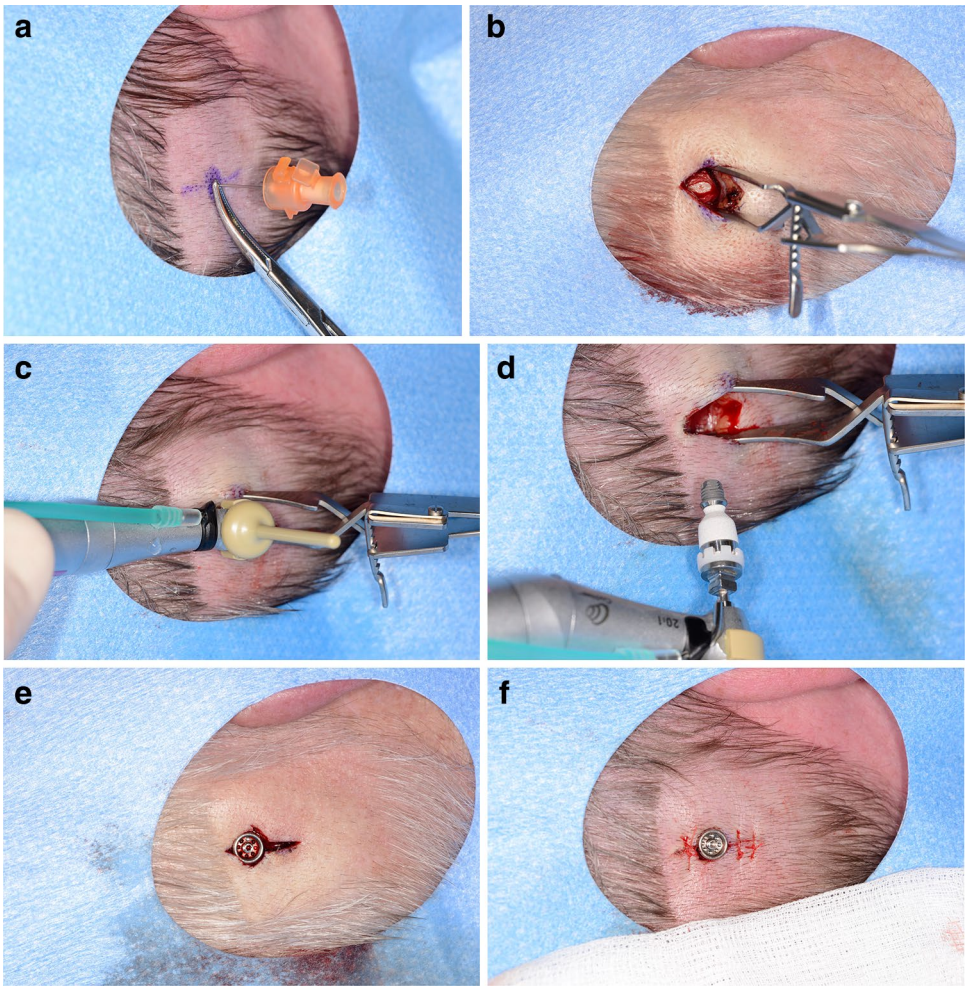

Fig. 1 **a** Skin marking and skin thickness measurement using a hypodermic needle. **b** A 2–3 cm long linear incision reaching the periosteum of the skull which is divided. **c**, **d** Preparation is made for the insertion of the implant using the Osscora handpiece and foot controller (Cochlear Bone Anchored Solutions AB). **e** The abutment is attached to the implant. **f** Tension free skin closure is achieved with interrupted 3.0 vicryl sutures

Table 1 Demographics and indications ($n = 101$)

Indications	
Mixed hearing loss	28%
Conductive hearing loss	48%
Sensorineural hearing loss	24%
Sex	
Male	45%
Female	55%

required re-insertion of their abutments due to traumatic dislodgement.

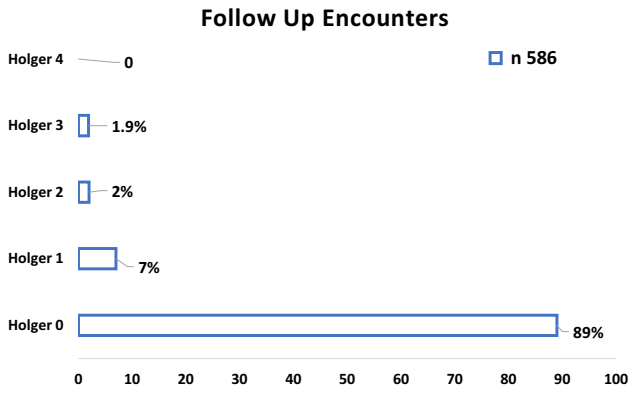

Fig. 2 Follow-up encounters

Discussion

We have evaluated soft tissue outcomes of patients, who had BAHA implantation surgery using a LISTPT between July 2013 and November 2017 in our institution. Recent systematic reviews and a meta-analysis confirm that the choice of surgical technique; STPT or STRT in their various forms, influences soft tissue outcomes in BAHD surgery and that STPT is associated with less soft tissue complications [11–13].

Table 2 Variables associated with a significant skin reaction

	No or minor skin reaction	Significant skin reaction	*p* value
Age (years)	58.1	58.3	0.979
Mean time since new technique introduced (months)	32.6	16.8	0.009*
Gender (male:female)	41:53	5:3	0.303
Indication (COSM: CROE or other)	51:43	0:8	0.003*
Laterality (left: right)	47:47	3:5	0.497

'Significant skin reaction'—Holger score 3 at or before the 6-month outpatient review, or any implant removal due to skin reaction

COM chronic otitis media, *CROE* chronic or recurrent otitis externa

As asterisk denotes statistically significant associations

STPTs result in conserved vascularity and minimal disruption of the local immune system which in turn leads to faster healing, minimal scarring, and lower incidence of soft tissue reactions [14]. Jarabin et al. evidenced that STPT is associated with better vascularity around the implant site when compared with a STRT (U shaped dermatome technique) on Laser–Doppler studies [15]. In addition to the excellent soft tissue outcomes, we believe that LISTPT is also meritorious for its simplicity, shorter surgical time, and implant stability, especially when compared to some of the techniques referenced above [6–8].

Two implant placement methods have been described—intra or extra incision. We favour implant placement within the incision and we believe, this approach is beneficial in that it avoids additional trauma to the surrounding skin. In the alternative approach, the implant is placed outside the incision through a punch incision on virgin tissue [16]. This approach is predicated on the view that implanting on minimally traumatised skin mitigates against a florid inflammatory reaction, ergo soft tissue complications [16].

However, a study comparing outcomes of the two implant placement methods illustrated that there were no statistically significant differences in long-term soft tissue outcomes or implant survival between the two approaches. Of note, patients who had the implant placed outside the incision had less soft tissue reactions in the first few weeks after implant placement [17].

Though the LISTPT is considered a minimally invasive technique, some argue that it is still associated with pronounced tissue trauma and increased surgical time is dedicated to haemostasis and suturing. Furthermore, it has also been argued that the technique is associated with increased pain and paraesthesia on the incision site, increased soft tissue complications due to tissue damage, and poor cosmetic outcomes from the scarring [18–20].

To counter these drawbacks, some surgeons have adopted an alternative technique, which involves using a skin punch, instead of an incision, for access [18–20]. This technique has been standardised more recently into the Minimally Invasive Ponto Surgery (MIPS) technique by Oticon Medical AB (Askim, Sweden) [21]. Proponents of this technique campaign its numerous benefits which include the absence of an incision and therefore a scar, shorter surgical time, and better soft tissue outcomes [18–20, 22].

Calon et al. in a prospective randomised control trial, comparing a minimally invasive drill technique and linear incision technique, evidenced that the MIPS technique confers statistically significant benefit with regard to pain, paraesthesia, cosmetic results, and shorter operating times. However, it is noteworthy that there was no statistically significant difference in terms of overall soft tissue outcomes. The study also acknowledges the potential drawbacks of this technique: reduced visibility, which might lead to drilling at an angle, and therefore affect implant placement and limited access for external irrigation, which can cause thermal damage to the skin. An interesting observation from this study, though statistically insignificant, was a slightly increased rate of implant loss. As the authors acknowledged, this warrants further investigation [22].

The dearth in high-quality head to head studies comparing long-term outcomes between the MIPS technique/punch and drill technique" and the LISTPT is noteworthy. This, in part, is explained by the fact that the punch techniques are relatively new compared to the LISPT, which is a well-established technique. Furthermore, consideration must be given to the compatibility of these techniques with the different implants available from different manufacturers. Does a punch technique affect the integrity of hydroxyapatite-coated implants? This is especially important, given some of the potential technical challenges associated with the punch technique, i.e. limited access and therefore view and the increased risk of thermal injury to the skin. Clearly, there is a need for well-designed prospective studies comparing soft tissue outcomes, implant stability and patient reported outcomes between the STPT and MIPS/ punch and drill techniques.

Soft tissue complications

Long-term success of BAHD surgery depends on full osseointegration and minimal soft tissue complications. From a patient's perspective, florid skin reactions might preclude wearing of the hearing device until the skin has healed, which can cause anxiety in those for whom the BAHD is the only viable hearing option.

Some studies suggest that skin reactions including peri-abutment infections and skin overgrowth range from 8 to 59% [11]. In our series we observed an overall Holger 0

score of 89% (524/586 observations) over the 5-year study period and a 12.2% (72/586) incidence of skin complications superior to some of the published literature.

A Holger 1 was recorded on 7% (41/586) of visits and a Holger 2 was recorded on 2% (14/586) of clinic visits. In our series, we observed a Holger 3 score of 1.9%, which compares favourably with findings from a recent systematic review which reported an overall Holger 3 score of 5.9% [12].

An interesting observation from our study is that patients with a background of CSOM were less likely to develop significant skin reactions, when compared to patients with chronic recurrent otitis externa or other indications ($p - 0.003$), which was statistically significant. A putative explanation is that the BAHA site is inadvertently contaminated with external auditory canal flora in between infections. However, this is a purely speculative explanation and one that would need exploration through well-designed clinical studies.

Consistent with findings in other studies, we have observed that topical steroid preparations on their own or combined with antibiotics are sufficient to resolve most soft tissue reactions from Holger 1–3 [11, 12, 23, 24]. Other treatment modalities we have used, particularly for Holger 3 scores which are often complicated by granulation tissue include silver nitrate cautery, ribbon gauze soaked in steroid/antibiotic ointment or antiseptic solution applied between the skin, and abutment interface and secured with a healing cap for a week.

Patient awareness of early complications is crucial. In our practice, patients go through an extensive education programme encompassing device use, day to day cleaning and recognition of soft tissue complications when candidacy for surgery is confirmed. Further, we provide an open system through which patients can arrange urgent clinical appointments with our Otolaryngology or Audiology department. Though this pathway is vulnerable to service pressures, we believe that it is crucial for the timely management of complications.

Revision surgery and device loss

Multiple factors, such as surgeon's experience, surgical technique, and patient factors like good self-care and personal hygiene, play a significant role in dictating long-term outcomes in BAHD surgery [11]. Moreover, failure to treat soft tissue complications early can result in widespread infection and soft tissue overgrowth, which might necessitate revision surgery or implant removal.

In our experience, only 3% (3/102) patients required revision surgery because of soft tissue complications. Johansson et al. in their systematic review of BAHDs implanted using a STPT observed an average revision rate of 3.5% [25]. Higher revision rates (11.3%) have also been reported [17]. In our series, two of the patients revised were managed with excision of soft tissue overgrowth and insertion of longer abutments and in the third case, excision of soft tissue overgrowth was sufficient.

Interestingly, we observed a statistically significant association ($p - 0.009$) when the mean time to minor skin complications (32.6 months) was compared with mean time to significant skin reaction (16.8 months). We could not find any plausible explanation for this finding and a review of the literature was equivocal in terms of predicting when complications occur.

Device failure is rare in adults. Rates of 0 and 5.8% have been reported in surgery using STPT, though some of these studies used a punch technique [19, 20, 26, 27]. In our series only one patient (1%) reported atraumatic device loss while asleep. He had soft tissue overgrowth on clinical review days later and it was unclear whether the implant loss had resulted from soft tissue overgrowth or failed osseointegration. The patient was managed with excision of soft tissue overgrowth and reinsertion of the abutment. He had a follow-up Holger scores of 0 at 4 weeks.

Limitations

The retrospective nature of our study leaves it vulnerable to the well-established pitfalls associated with such studies. Additionally, we have reported complications over the number of observation as documented on clinic visits as opposed to implant specific outcomes typical of some reported studies. This limits direct comparison between studies, although the overarching message will be the same. Furthermore, we did not record parameters such as pre-existing skin conditions, diabetes mellitus, and the smoking habits of our patients, which might affect skin outcomes.

Conclusion

With the continual evolution of BAHD surgical techniques towards a minimally invasive paradigm favouring soft tissue preservation, it is crucial to analyse results from large numbers of patients to inform current treatment approaches and guide the development of future techniques. Our series demonstrates that soft tissue preservation techniques using a linear incision have excellent long-term soft tissue outcomes and a low incidence of implant failure.

Future research should focus on direct comparisons between the LISTPT and the MIPS/punch and drill techniques and the relevant patient-related outcomes.

Compliance with ethical standards

Conflict of interest The authors declare that there are no conflicts of interests.

Ethical approval For this type of study formal consent is not required. We deemed this study to be service evaluation and therefore we did not seek research ethics committee approval.

Informed consent This was a retrospective records review and as such informed consent was not sought from all the patients whose records we reviewed. Furthermore, the data used in our work is anonymised and there is no patient identifiable information. Written consent for the use of clinical photographs was sought and granted by the patients whose photographs are used in the study.

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