ORIGINAL ARTICLE

Cutaneous Complications in Osseointegrated Implants: Comparison Between Classic and Tissue Preservation Techniques

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KEYWORDS
Osseointegrated hearing aids; Surgical procedures; Cutaneous complications; Tissue preservation

Abstract
Introduction and objectives: The standard surgical technique for osseointegrated hearing aids involves removing a large area of subcutaneous tissue down to the periosteum. Recently, the industry has designed a new range of abutment lengths for less invasive surgery with soft tissue preservation. This study compared and evaluated the complications in the standard and the tissue preservation techniques.

Material and methods: This was a prospective study including 29 adult patients who underwent single-stage osseointegrated hearing aids insertion between February 2009 and February 2013. We performed the standard technique in 14 patients, and the tissue preservation technique in 15. Soft tissue complications were graded according to the Holger’s classification.

Results: No patient required removal of implant or revision surgery. Although the Holger’s grade was always worse in the standard technique (reaction score of 3 or higher was 28% versus 7% at a month), the complication rate was not statistically significant between the 2 groups at any postoperative time a week ($P= .233$), a month ($P= .470$) and a year ($P= .401$).

Conclusion: In our experience the tissue preservation technique, without soft tissue reduction, is the procedure of choice for bone anchored implant surgery. The preservation technique is easier, faster and possible with local anaesthesia and has similar postoperative outcomes.

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PALABRAS CLAVE
Implante oseointegrado; Técnica quirúrgica; Complicaciones cutáneas; Preservación de tejido

Complicaciones cutáneas en los implantes oseointegrados: comparación entre la técnica clásica y la de preservación de tejido

Resumen
Introducción y objetivos: La técnica quirúrgica clásica de los implantes oseointegrados tiene como principio fundamental la extirpación del tejido celular subcutáneo hasta la capa perióstica. Recientemente se han diseñado pilares de mayor longitud, lo que ha permitido el desarrollo de la técnica de preservación de tejido, es decir, sin eliminación de los tejidos blandos. Este estudio evalúa las complicaciones cutáneas postquirúrgicas a corto, medio y largo plazo, comparando la técnica clásica con la técnica de preservación de tejido.

Material y métodos: Estudio prospectivo de pacientes a los que se les ha colocado un implante oseointegrado desde febrero de 2009 hasta febrero de 2013. Se realizaron un total de 29 cirugías, 14 según la técnica clásica y 15 con cirugía de preservación de tejido. Las complicaciones cutáneas fueron evaluadas según la clasificación de Holgers en revisiones a la semana, al mes, y al año.

Resultados: En ningún paciente se registraron complicaciones cutáneas de grado 4 que precisaran la retirada del implante oseointegrado o cirugía de revisión. Aunque la puntuación en la clasificación de Holgers fue siempre más desfavorable en la técnica clásica, sobre todo a corto plazo (a la semana reacción de grado 3 en el 28% de los pacientes versus 7% con técnica de preservación), no se alcanzaron diferencias estadísticamente significativas entre los 2 grupos a la semana (p = 0,233), al mes (p = 0,470) o al año (p = 0,401).

Conclusión: En nuestra experiencia, la técnica mínimamente invasiva sin reducción de tejido es la técnica de elección para la cirugía de los implantes oseointegrados por ser más sencilla, más rápida, poder realizarse con anestesia local y resultados postoperatorios iguales.

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Introduction
The first bone-anchored hearing implant was accomplished in 1977, the result of a technological development from the former bone conduction prostheses, such as headbands or glasses.1 The BAHA has the advantage that, as it allows direct bone conduction of sound, it prevents a loss of 15–20 dB due to the interposition of tissues, and improves hearing quality.

The classic surgical technique for BAHA placement is described as the removal of subcutaneous tissue down to the periosteum before setting the implant in the bone. This technique, although simple, is associated with a high complication rate resulting from the devascularisation of the skin flap, which occasionally requires surgical revision.2 BAHA which offers longer abutments has been on the market since 2011; this has enabled the surgical implantation technique to be modified through what is termed tissue preservation. This modification avoids the removal of subcutaneous soft tissue and therefore the skin flap is less vascularly compromised.3 The possible benefits of this technique would be fewer cutaneous reactions and complications.

The objective of this study was to assess the development of complications in relation to BAHA placement, comparing the classic technique with the tissue preservation technique.

Material and Methods
A prospective cohort study was undertaken which included patients fitted with a BAHA in our hospital between February 2009 and February 2013, with a minimum follow-up of 12 months after surgery.

A total of 29 patients were included; the classic technique was used in 14 (group 1) and the tissue preservation technique was used in 15 (group 2). All the operations were performed by the same surgeon (JRG). The interventions on group 1 were performed under general anaesthetic and those on group 2 were performed using local anaesthetic and sedation.

Data were collected concerning the patients’ demographic characteristics, previous otological pathology, presurgical assessment, surgery time, possible complications and patient follow-up. The follow-up protocol was a review in the surgery 1 week, 1 month and 1 year after the operation. The cutaneous complications were assessed according to Holger et al.’s classification (Table 1).4

We used SPSS software, version 20.0 for the statistical analysis. The differences between the cutaneous complications in the 2 groups was analysed using Fisher’s exact test, considering P<.05 as statistically significant.

Surgical Technique
In order not to introduce variables which might affect the results with the 2 surgical techniques, it was decided to use a very similar technique for all cases and in both groups, only differentiated by the reduction in subcutaneous tissue. In both the classic technique and the tissue preservation technique, the pedestal of the BAHA was situated in the retro auricular region at 50–55 mm from the posterosuperior edge
of the external auditory canal. In the tissue preservation technique and before infiltrating the skin, a needle was used to measure the thickness of the scalp and to select the length of the implant. The skin was infiltrated with a solution of 2% mepivacaine and epinephrine at 1:100 000. In both techniques, a 3 cm linear incision was made 1 cm in front of the site where the pedestal was to be placed. In the classic technique, all the subcutaneous cellular tissue was removed in an area about 5 cm in diameter. After making the skin incision which extended to the periostium (and removing the subcutaneous tissue in the classic technique), a posterior skin flap was lifted until the periostium of the area where the implant was to be placed was exposed. The periostium was opened and a 4 mm implant inserted, provided the thickness of the bone allowed (if not, an implant of 3 mm was placed). The skin flap was replaced over the abutment of the implant and an island of skin removed using a 4 mm skin biopsy punch as the outlet for the abutment of the implant. The subcutaneous plane was sutured with 2/0 Vycril and the skin sutured with 4/0 silk. The Baha® (Cochlear™) system was implanted in all the patients in the study. Fig. 1 illustrates the immediate post-operative period of a patient implanted with a Baha using the tissue preservation technique.

Results

The demographic and clinical characteristics of the population are shown in Table 2, where it can be observed that both groups have similar characteristics.

The average operation time was 42 min (range 34–52 min) in group 1 and 27 min (range 19–36 min) in group 2. No intra-operative complications were observed in either of the 2 groups.

Table 1  Holger’s Classification.

<table>
<thead>
<tr>
<th>Grade</th>
<th>Clinical characteristics</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>No reaction</td>
</tr>
<tr>
<td>1</td>
<td>Erythema, mild inflammation</td>
</tr>
<tr>
<td>2</td>
<td>Erythema, exudate, moderate inflammation</td>
</tr>
<tr>
<td>3</td>
<td>Erythema, exudate, moderate inflammation, granulation tissue</td>
</tr>
<tr>
<td>4</td>
<td>Signs of infection (pus) with the need for extraction of the implant</td>
</tr>
</tbody>
</table>

Figure 1  Immediate post-operative period after Baha using the tissue preservation technique.

The surgery was tolerated well by all the patients, without complications presenting in the immediate post-operative period. All the patients were discharged from hospital on the same day if the surgery had been performed under local anaesthetic (preservation technique), or 24 h after surgery when it had been performed under general anaesthesia (classic technique). No home-based antibiotics were prescribed, and NSAID every 6–8 h orally was sufficient as analgesia.

No patient in either of the 2 groups recorded cutaneous complications of grade 4 according to Holger’s classification which required the abutment or the implant to be removed during the follow-up period. In the grade 3 cases, treatment with topical antibiotics was sufficient and cauterisation of the area with silver nitrate if the granulation tissue was very profuse.

Table 3 shows the classification in Holger’s grades of the patients in group 1, corresponding to the Baha which were implanted using the classic technique (Figs. 2A and 3A). At the first review 1 week after surgery, the patients were distributed almost equally between grade 1, 2 and 3 reactions. At the second review, performed 1 month after surgery, a

Table 2  Demographic and Clinical Characteristics.

<table>
<thead>
<tr>
<th></th>
<th>Classic technique (n=14)</th>
<th>Preservation technique (n=15)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gender</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>5 (36%)</td>
<td>1 (7%)</td>
</tr>
<tr>
<td>Female</td>
<td>9 (64%)</td>
<td>14 (93%)</td>
</tr>
<tr>
<td>Mean age (range)</td>
<td>51 (13–68)</td>
<td>53 (11–77)</td>
</tr>
<tr>
<td>Diagnosis</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Congenital malformation/agenesis of the EAC</td>
<td>3 (21%)</td>
<td>3 (20%)</td>
</tr>
<tr>
<td>Operated uni/bilateral cholesteatoma</td>
<td>7 (50%)</td>
<td>11 (73%)</td>
</tr>
<tr>
<td>Fibrous EAC stenosis</td>
<td>2 (14%)</td>
<td>1 (7%)</td>
</tr>
<tr>
<td>Sudden hearing loss</td>
<td>2 (14%)</td>
<td>0 (0%)</td>
</tr>
</tbody>
</table>
notable overall improvement was found in that 64% of the patients presented a grade 1 reaction and 21% a grade 2 reaction. At the annual review, 64% of the patients showed no cutaneous reaction, although 36% continued to have redness and slight inflammation. One patient had to be treated for the growth of granulation tissue.

Table 4 shows the results of group 2, referring to the BAHA implanted using the tissue preservation technique (Figs. 2B and 3B). At the review 1 week after surgery, most of the patients already presented low-grade cutaneous reactions, 93% with Holger’s grade 1 or 2. And at the review after the 1st month, only 2 patients presented a grade 2 cutaneous reaction, and 33% already showed a grade 0. This evolution was confirmed after 1 year, since the percentage of patients with a grade 0 reaction increased to 73%.

Despite the improved clinical practice in favour of the preservation technique, no significant differences were found between either group in the cutaneous reactions observed after 1 week (P=.233), after 1 month (P=.470) or after 1 year (P=.401).

**Discussion**

The most usual indication for placing a BAHA is conductive or mixed hearing loss, where a hearing aid cannot be adapted and medical-surgical treatment cannot be given. Most of
these patients present otitis media with chronic otorrhoea and middle or outer ear malformations.\textsuperscript{1,2} In our series most of the patients had been operated for unilateral or bilateral chronic cholesteatomatosus otitis media (58%), followed by patients with congenital malformations such as agenesis of the EAC (19%), or fibrous stenosis of the EAC (10%). There were also 2 patients included with unilateral cophosis due to sudden loss of hearing, 1 patient with Shprintzen syndrome and another with CATCH22 syndrome.

In both groups, there were more females than males; 74% of the patients in the study; most of the articles also present more females, although not as many as in our case. This could be explained by the aesthetic result of the BAHA; women often have long hair and the strategies for hiding the implant are easier, whereas men often have short hair or are bald and therefore the BAHA is much more visible.

Although the surgical technique for placing BAHA is relatively simple, the procedure is not without risk and complications. This study compares the rate of cutaneous and postoperative complications between two of the techniques used to place BAHA. Both groups of patients present similar clinicopathological characteristics.

In a review of references made in 2010 which included more than 600 patients and 16 implanting centres,\textsuperscript{7} a 24% complication rate was found, the great majority related to soft tissue overgrowth, cutaneous infection, loss of the screw or the abutment, or trauma. These complications occasionally involved major aesthetic sequelae, such as alopecia, and 12% even required surgical revision. To date, studies have focused on describing the best technique for the management of soft tissues,\textsuperscript{8,9} maintaining 2 basic principles: removal of the subcutaneous tissue below the skin flap down to the periosteal layer and the reduction of subcutaneous tissue below the edges, with a minimum of 1 cm.\textsuperscript{7}

The first operation which used a tissue preservation technique was described in 2011, without skin flap and without removal of subcutaneous tissue.\textsuperscript{1} This surgical technique is based on a new generation of abutments, whose main difference is their greater length in order to adapt to the thickness of the patient’s skin and better integration with the subcutaneous tissue.\textsuperscript{3}

Although there are still a few published articles on this new technique, those that there are, describe very good results. In their series, Husseman et al.\textsuperscript{9} found 34 cases of BAHA where only 15% presented a reaction which was higher than a Holger’s grade 2, but they do not compare with a reference group. As in our study, Wilson and Kim\textsuperscript{10} compared the complications in 2 homogenous groups of patients implanted with a BAHA; in the control group, the skin flap was lifted and the soft tissue reduced (classic technique) and in the second group a biopsy punch was used without tissue reduction (preservation technique), without encountering differences between both groups. However, in this study, the postoperative time in which possible complications would be assessed is not specified, the groups were not balanced in the number of subjects, and follow-up of the development of the Holger’s grade was not pursued over time.

This is the first article on the technique for implanting an BAHA to compare the classic technique with the tissue preservation technique between homogeneous groups implanted consecutively, thus eliminating the learning curve factor, and to evaluate complications in the post-operative period short term (at 1 week), medium term (at 1 month) and long term (at 1 year).

No significant differences were found between either group in our series of patients, perhaps because of the small sample size. However, we did observe a clear reduction in early cutaneous reactions, i.e., at the review after 1 week. While in group 1 (classic technique) 28% of the patients presented a grade 3 and therefore required treatment, in group 2 (tissue preservation technique) only 7% of the patients developed a grade 3 cutaneous reaction. Therefore, 93% of the grade 2 patients had a mild or moderate grade, compared to the previous 72%. However, these differences disappear on medium to long-term follow-up.

We also found a tendency towards better and faster recovery, since 86% of the patients in group 2 (tissue preservation technique) presented grade 0 or one after 1 month, compared to 75% of group 1 (classic technique). Even in group 1 after 1 year, 1 patient required treatment because they had developed granulation tissue around the implant.

In future it will important to reassess the results of these new BAHA long term, as their greater length could imply poorer osseointegration and less stability, or even a greater tendency to develop biofilms due to pathogenic micro-organisms on the hydroxyapatite surface\textsuperscript{9} that some of these implants have in order to aid adhesion to the soft tissues.

In conclusion, from the results obtained and review of the literature, our group considers the minimally invasive technique without tissue reduction to be the technique of choice for BAHA surgery as it is simpler, faster and has fewer short to medium term complications.

Conflict of Interests

The authors have no conflict of interests to declare.

References

7. Tamaiti Conejeros JM, Dalmau Galofre J, Murcia Puchades V, Pons Rocher F, Fernández Martínez S, Extrems Navas P. Comparison of skin complications between dermatome and U-
