ORIGINAL ARTICLE

Bone-Anchored Hearing Device Surgery: Linear Incision Without Soft Tissue Reduction. A Prospective Study⭐

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KEYWORDS
Osseointegration; Hearing aids; Surgical procedures

Abstract

Introduction and objectives: The classic surgical procedure for percutaneous bone-anchored hearing devices involves removal of a large area of subcutaneous tissue down to the periosteum. This leads to alopecia and raises the risk of devascularization of the overlying skin with the potential for infection and scarring.

The objective of this study was to determine the results of implant placement using a single, linear incision with no underlying soft tissue reduction.

Material and method: A prospective study was conducted in our hospital over a period of 14 months in all consecutive surgeries performed using this technique in adults. Patients were reviewed regularly (week 1, week 3, weeks 4–6 and months 3, 6 and 12) to assess wound healing including evaluation with the Holgers scale.

Results: Corresponding to 34 patients, 34 cases were consecutively enrolled in this study. We found that 15% of the patients had minor skin reactions during the first visit (Holgers grade 1 or 2); this number raised to 20% in week 3, but at week 4 only 1 patient had a reaction score of 1 (which was solved by week 6). None of the cases required revision surgery and all skin reactions were treated topically.

Conclusions: Our results suggest that the tissue preservation technique is a simple and effective insertion technique with a favourable healing process and cosmesis.

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Introduction

Bone-anchored hearing devices have become a widely-used and well-established solution for various forms of hearing loss.

Although the surgical technique for these devices is not complex, it can involve complications and adverse effects, most commonly in relation to soft tissue reduction and inflammation around the device. The incidence of these complications is variable and we observe complication rates of between 5% and 50% according to the series studied.1-5 Although the majority of these reactions respond to conservative topical treatment, problems with the surrounding soft tissue can give unfavourable cosmetic results (Fig. 1), cause sensitive changes around the implant and, in some cases, necessitate revision surgery, and also result in a delay in fitting the processor and consequent delay in hearing benefits for the patient.

The “traditional” or standard surgical procedure or technique for fitting these devices involves creating a skin flap and the removal of subcutaneous tissue down to the periosteum. This soft tissue reduction, in particular, produces a relatively large area of alopecia around the device (Fig. 1) and compromises the revascularisation of the skin flap with a potential risk of infection and scarring.4 More recent techniques have advocated less “invasive techniques” to improve healing and aesthetic result and to reduce local complications. These techniques use linear incisions instead of skin flaps with removal of subcutaneous cellular tissue and longer standard abutments.2,6 The fact that only short abutments of around 6 mm were available proved a limitation to this surgery in the past. Surgery without the reduction of soft tissue has been made possible with the introduction of longer percutaneous abutments.7-9

In this article we describe our experiences using a linear incision technique without removing subcutaneous tissue and using longer percutaneous abutments which prevent the hearing processor coming into contact with the surrounding skin tissue.

Cirugía del implante osteointegrado: estudio prospectivo empleando incisión lineal sin reducción de tejido subcutáneo

Resumen

Introducción y objetivos: La técnica quirúrgica clásica para la colocación de los implantes osteointegrados percutáneos implica la reducción del tejido subcutáneo hasta el periostio y esto ocasiona algunas alteraciones estéticas y sensitivas en el área del implante además de las no poco habituales complicaciones infeccioso-inflamatorias locales.

El objetivo de este estudio es el análisis de los resultados empleando una técnica de incisión lineal sin reducción de tejido subcutáneo.

Material y método: Se realiza un estudio prospectivo de los pacientes de edad adulta intervenidos por medio de esta técnica en nuestro hospital en un periodo de 14 meses. Se realiza un seguimiento anotándose los hallazgos en la zona periimplante según escala de Holgers en la semana 1, semana 3, semanas 4-6 y a los 3 meses, 6 meses y 12 meses poscirugía.

Resultados: Treinta y cuatro casos consecutivos fueron intervenidos que corresponden a 34 pacientes. Respecto a la irritación periimplante, se aprecia que un 15% de los casos presentan un Holgers 1 y 2 en la primera semana, un 20% en la semana 3 y a partir de la semana 4 solo un paciente presentaba un Holgers 1 que se resolvió en la semana 6. Todos los casos de irritación respondieron a medidas tópicas y no se requirió reintervención en ningún caso.

Conclusiones: Nuestros resultados indican que esta técnica quirúrgica, además de simplificar la cirugía, favorece la cicatrización y disminuye el número de reacciones colaterales que pueden verse en los casos operados con la técnica tradicional.

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Material and Method

A prospective study was undertaken of all consecutive cases operated using this technique in our hospital over a period of 14 months (January 2013 to February 2014). The two available commercial manufacturers for percutaneous bone-ancreased devices were used, Oticon® and Cochlear®.

Surgical Procedure (Fig. 2)

The patients are operated under local anaesthetic and sedation under a major outpatient surgery regime with antibiotic prophylaxis using cefazolin 2 g, provided they are not allergic to the drug.

The necessary amount of hair is shaved around the area for the implant and the thickness is measured of the subcutaneous tissue in the site chosen for the implant and pre-assembled abutment (around 55 mm from the external auditory canal and at the level of the upper end of the auditory chamber). To this measured thickness we add 3 mm, and this measurement is used for the abutment. In other words, for a thickness of 6 mm, an abutment of 9 mm or 10 mm is selected. After this measurement, local anaesthetic (2% lidocaine with adrenaline 1:100 000) is infiltrated. A linear incision is made down to the periosteum which is dissected on the subperiosteal plane to expose about 1 cm bone diameter. Reaming and countersinking are performed and the selected implant and abutment are placed in the usual way. The subcutaneous tissue is sutured with Vicryl® 3/0 absorbable suture and the skin with Vicryl Rapid® 4/0 covering over the abutment, which is brought to the exterior eccentrically to the incision through an opening behind it made using a punch. Finally, the abutment cap is placed and gentle pressure applied over the surgical wound and below the cap with a dressing impregnated with antibiotic ointment (Tulgrasum®) and then a headband-type bandage is applied for 48 h. The patients are discharged shortly after the procedure.

The patients are reviewed as outpatients one week after the operation, and the cap and impregnated dressing are removed at this time. The patients are instructed how to clean the wound and the skin around the implant and are given the cleaning kit with the processor. The next review is 3 weeks after surgery and the processor is activated or placed between the 4th and 6th week post implantation. A further review is made at 3 months, at 6 months and the patients are offered an annual review.

The findings in the area around the implant are noted according to Holger’s scale12 in these reviews.

Any irritation and granulation appearing in the area around the implant are treated with antibiotic and anti-inflammatory ointment and cauterised with silver nitrate if the surgeon considers this necessary during the outpatient consultation.

Results

During this period, between January 2013 and February 2014, a total of 36 bone-ancreased hearing devices were implanted and all except 2 (due to excess subcutaneous tissue) were operated using the technique described above (a total of 34 patients).

All the patients had a minimum of 6 months’ follow-up and 60% were followed up for at least one year.

The surgery was well-tolerated in all cases under local anaesthesia and sedation and all the patients were discharged on the day of the operation. No immediate intra- or postoperative complications were recorded; there was no local bleeding, fever or early infection in any of the patients.

Table 1 shows the relevant demographic and surgical details. It can be seen that the mean thickness is around 6 mm and therefore the most frequently used abutment is 9 mm. The length of the incision is around 2 cm on average, and the surgical time is only 20 min in most cases.

On average, the processor was activated 30 days after surgery (21 days minimum and 60 days maximum). The implant was removed due to poor performance and lack of use in 2 of the 34 patients, one year after the implantation in both cases. Both patients had suffered unilateral deafness after acoustic neuroma surgery via a translabyrinthine approach. At the final review the remaining patients were still regularly using the processor.

Holger’s scale was used to quantify the degree of cutaneous and subcutaneous skin reaction around the implant.12 This scale measures the skin reaction from 0 to 4 and is widely used for measuring these reactions in the case of percutaneous implants.

Table 2 shows our patients’ irritation grade according to this scale on each of their visits.

Only 15% of the patients had some minor irritation at the wound site one week after intervention. This percentage was the same at the third week, however, at this review skin growth over the abutment was observed in one patient. When the time came for the processor to be activated, weeks 4–6, only one patient presented irritation of Holger’s grade 1 (this constitutes rather less than 3%), which had resolved by week 6.

No case required surgery; there were no implant or abutment failures. All the minor reactions, and even the skin

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>No. of patients</td>
<td>34</td>
</tr>
<tr>
<td>Patient gender (male/female)</td>
<td>13/21</td>
</tr>
<tr>
<td>Age (mean and range)</td>
<td>49 (33-72)</td>
</tr>
<tr>
<td>Anatomical side (right/left)</td>
<td>25/9</td>
</tr>
<tr>
<td>Subcutaneous tissue thickness in mm (mean and range)</td>
<td>5.8 (4–8)</td>
</tr>
<tr>
<td>Implant length 4 mm</td>
<td>34</td>
</tr>
<tr>
<td>Abutment length</td>
<td></td>
</tr>
<tr>
<td>8 mm</td>
<td>4</td>
</tr>
<tr>
<td>9 mm</td>
<td>19</td>
</tr>
<tr>
<td>10 mm</td>
<td>3</td>
</tr>
<tr>
<td>12 mm</td>
<td>8</td>
</tr>
<tr>
<td>Incision length in cm (mean and range)</td>
<td>2.3 (1.5–3)</td>
</tr>
<tr>
<td>Surgical intervention time in minutes (mean and range)</td>
<td>21 (15–35)</td>
</tr>
<tr>
<td>Activation date of the processor in days (mean and range)</td>
<td>30 (21–60)</td>
</tr>
</tbody>
</table>
Bone-Anchored Hearing Device Surgery

Figure 2 Key surgical steps in the surgical technique without reduction of subcutaneous tissue. (a) Measurement of soft tissue thickness. (b) Implant and percutaneous abutment placed without reduction of subcutaneous tissue. (c) Percutaneous abutment eccentric to the incision using a 4 mm punch.

Table 2 Holger’s Grade in Successive Visits.

<table>
<thead>
<tr>
<th>Week</th>
<th>Holger’s 0</th>
<th>Holger’s 1</th>
<th>Holger’s 2</th>
<th>Holger’s 3</th>
<th>Holger’s 4</th>
<th>Overgrowth</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>29</td>
<td>3</td>
<td>2</td>
<td>–</td>
<td>–</td>
<td>–</td>
</tr>
<tr>
<td>3</td>
<td>28</td>
<td>3</td>
<td>2</td>
<td>–</td>
<td>–</td>
<td>1</td>
</tr>
<tr>
<td>4–6</td>
<td>33</td>
<td>1</td>
<td>–</td>
<td>–</td>
<td>–</td>
<td>–</td>
</tr>
<tr>
<td>12–24</td>
<td>34</td>
<td>–</td>
<td>–</td>
<td>–</td>
<td>–</td>
<td>–</td>
</tr>
<tr>
<td>&gt; 24</td>
<td>34</td>
<td>–</td>
<td>–</td>
<td>–</td>
<td>–</td>
<td>–</td>
</tr>
</tbody>
</table>

overgrowth, were treated topically until they completely resolved.

In 2 cases the abutment was changed for a longer one (from 6 to 9), and this procedure took place during consultation, without the need to cut the skin at all.

It is worth mentioning that the punch used in 29 of the 34 cases was 4 mm in diameter. Although it is rather more difficult and laborious to bring the abutment to the exterior through the hole created by this punch, we noticed that the skin around the abutment remains completely sealed during and after the operation. In the 5 remaining cases where the punch was used, there was no major irritation, however the skin in very close contact with the implant took rather longer to seal and to heal completely.

Finally, in terms of aesthetic result, Fig. 3 shows some examples of the area around the implant, there are no areas of alopecia, the scar cannot be seen and there is no tissue defect in the area.

Discussion

34 patients were included for their prospective participation during the period of this study. This technique has already been published by other authors with similar results to ours as shown in Table 3.

We considered this technique better compared to the traditional technique, with or without dermatome, with removal of subcutaneous cellular tissue, during both the operation and the post-operative period. Aesthetic defects disappear or are almost completely minimised, healing is faster, which enables the hearing device to be fitted rapidly and early, and the likelihood of infection and inflammation around the implant is significantly less. Moreover, the technique is becoming simpler and faster, which means it can be suitable for a wider range of patients and the surgery will become increasingly popular with all ENT specialists.

Most of the complications with bone-anchored hearing devices relate to tissue complications around the implant, infections, skin overgrowth, and inflammation, and ultimately to loss of bone anchor. The most likely hypothesis

Figure 3 Aesthetic appearance of the area around the implant 4 weeks after surgery.
to explain infection and inflammation in the area around the implant is revascularisation of the skin caused by the removal of subcutaneous cellular tissue.\textsuperscript{14}

Performing this conservative technique with subcutaneous tissue was limited by the lack of longer abutments. The introduction of new and longer abutments (initially 8.5 mm/9 mm and later even longer, up to 12 mm) allowed some hospitals to perform surgery involving less subcutaneous tissue removal, they then removed no tissue and became completely conservative in this regard.\textsuperscript{15} The results were very positive in terms of healing and the technique became popular. The results showed various advantages such as: no regional hyposthesia, no alopecia and minimal scarring and more rapid recovery.\textsuperscript{5,7,9,10,15,16} It has been postulated that the hydroxyapatite layer on some of these abutments encourages skin tissue to adhere to the abutment, thus preventing skin overgrowth and promoting subcutaneous tissue repair. No comparative study has been made in this series between abutments with and without this material.

There are different ways of measuring subcutaneous tissue thickness before selecting the most appropriate abutment. Wröbel et al.\textsuperscript{7} measured this thickness by ultrasound in 100 adult patients. They concluded that more than 80% of the patients had a thickness of 3–6 mm. Taking this into account, most of these patients would be candidates for abutments of 8 mm or 9 mm. Only one of the 100 patients had a thickness of less than 3 mm and therefore would have been a candidate for an abutment of 6 mm; the remaining patients were candidates for abutments of more than 10 mm. Before infiltrating local anaesthesia, we used a needle to take this measurement in order to add 3 mm later. It is better to have some margin above rather than below this measurement, i.e., it is better to fit an abutment which is 1 mm longer rather than 1 mm shorter. Changing the abutment in the consultation clinic is a very simple procedure which can be performed if the abutment chosen intra-operatively is not the most appropriate or the tissue thickness beneath the skin increases or reduces over time, however cost should be considered before opting for this technique and selecting the abutment intra-operatively. This procedure was necessary in 2 cases in this series.

The abovementioned technique was not performed in another 2 cases during the study period; a linear incision was made instead, with reduction of soft tissue, because it was observed that the tissue was excessively thick. This constitutes 6% during this period, therefore we consider that the technique described in this article should not be considered universal and we should always be prepared to remove tissue when required.

### Conclusions

Surgery without the removal of subcutaneous tissue for placing percutaneous bone-integrated hearing devices is not only possible, it is recommended. It facilitates surgery and reduces operating time. It improves aesthetic results and sensitivity around the implant site and reduces the amount of skin complications. Thus, recovery is faster and results in early hearing rehabilitation for these patients.

### Conflict of Interests

The authors have no conflict of interests to declare.

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