Acta Otorrinolaringol Esp. 2009;**60(6):**422-427

Acta Otorrinolaringológica Española

www.elsevier.es/otorrino

ORIGINAL ARTICLE

Comparison of skin complications between dermatome and U-graft technique in BAHA surgery

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Received March 1, 2009; accepted June 15, 2009
Available online September 26, 2009

KEYWORDS
Bone anchored hearing aid;
Skin reactions;
Dermatome;
U-graft technique

Abstract
Introduction and objective: The most common postoperative complications related to BAHA prosthetic surgery are skin complications. In this study we compare and evaluate these reactions with 2 different surgical techniques, the BAHA dermatome and the U-graft technique.
Material and method: Fifty-three patients who underwent implantation of a BAHA at our hospital between 2001 and 2008 were studied. The comparison of the skin reactions was carried out according to Holgers' classification. We also recorded the number of cures required until skin stabilization.
Results: We used the dermatome in 27 patients and the U-graft in 26 patients. In the dermatome group there was a total of 74%of skin reactions (20 patients), in contrast with the 34%(9 patients) observed in the U-graft group. The average number of cures for patients in the dermatome group and those in the U-graft group was 4.1 and 2.7, respectively. The differences found were statistically significant and had a 95% confidence interval.
Conclusions: In our experience, the use of the electric dermatome in BAHA surgery offers a higher incidence of skin complications in comparison with the U-graft technique. Since both techniques have a number of advantages and disadvantages, selecting the technique to be employed according to the individual characteristics of each patient may offer better results in the future.

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0001-6519/$ - see front matter

PALABRAS CLAVE
Bone anchored hearing aid;
Complicaciones dermatológicas;
Dermatomo;
Colgajo en "U"

Comparación de las complicaciones dermatológicas entre el dermatomo y el colgajo en "U" en la cirugía del BAHA

Resumen
Introducción y objetivo: Las complicaciones dermatológicas son las complicaciones postoperatorias más frecuentes relacionadas con las prótesis BAHA (bone anchored hearing aid). En este estudio comparamos y evaluamos estas complicaciones con dos técnicas quirúrgicas diferentes: el dermatomo BAHA y el colgajo en "U".
Material y métodos: Se estudió a 53 pacientes intervenidos en nuestro centro entre 2001 y 2008. La comparación de las complicaciones se realizó según la clasificación de Holgers et al. Hemos registrado, además, el número de curas que se requieren hasta la estabilización de la piel.
Resultados: Hemos utilizado el dermatomo en 27 pacientes y el colgajo en "U" en 26 pacientes. En el grupo dermatomo hemos tenido el 74% de complicaciones (20 pacientes), que contrastan con el 34% (9 pacientes) con el colgajo en "U". La media de curas por paciente con el dermatomo y con el colgajo en "U" es de 4,1 y 2,7, respectivamente. Las diferencias encontradas son estadísticamente significativas para un intervalo de confianza del 95%.
Conclusiones: En nuestra experiencia, el uso del dermatomo eléctrico en la cirugía del BAHA es un método que nos ofrece un mayor número de complicaciones dermatológicas que el colgajo en "U". Dado que ambas técnicas tienen una serie de ventajas y desventajas, quizás la selección de la técnica por utilizar según las características de cada paciente de forma individualizada permita obtener mejores resultados en el futuro.

Introduction

From the first application of titanium implants in the temporal bone in 1977, the bone anchored hearing aid (BAHA) type osseointegrated implant has become a widespread, well-established method of auditory rehabilitation. This percutaneous implant provides greater performance, comfort and sound quality than conventional devices using bone conduction and osseointegrated transcutaneous systems. It also allows a significant reduction in ear infections in patients with chronic otitis using hearing aids with conduction through the airways.[1,2]

The modifications and additions that have occurred around this hearing aid are multiple, especially regarding indications and surgical technique. While the principles of the surgical technique described by Tjellstrom are maintained,[3] it has been the subject of variations and modifications by various authors, always with the goal of decreasing the number of complications and improving results.

Regarding the implantation, that is, the introduction of the implant into bone tissue, few changes have occurred. Moreover, the 2-stage technique used initially is currently used only in young children. In contrast, there has been considerable progress and new incisions have been developed in the management of skin and soft tissue.

In the first BAHA surgeries, a free, thin, autologous, cutaneous flap was transposed from the retroauricular region to the region of the osseointegrated implant in the second surgical procedure.[4] The only subcutaneous tissue reduction performed was that needed for the implant to remain above skin level.

Subsequently, an anterior-based, U-shaped, pedicled manual flap[5] was developed. However, other multiple incisions and manipulations of the skin in BAHA have been described.[6] We can cite transposition flaps (Browning, 1990), the linear incision (Mylanus and Cremers, 1994), the free flap around the implant (Rothera, 1998) and the circular island flap with four releasing incisions (Dutt, 2000), among others. The challenge of obtaining the correct cutaneous thickness took a turn in 2001 with the incorporation of a dermatome specially designed for BAHA surgery.

Whatever the incision used, it should enable generous resection of the subcutaneous soft tissue, creating a progressive depression at the edges (to avoid skin overgrowing the implant) and maintaining a fixed, immobile flap to minimize scarring and inflammation around the implant. At the same time, the careful handling of the skin tissue and its viability are very important.

Material and methods

We studied the patients implanted at our department of otolaryngology from December 2001 through November 2008. A total of 71 BAHA surgeries (19 reoperations) were carried out on the 53 patients included in the study. A total

of 27 patients were included in the "dermatome" group and 26 patients in the U flap group. Of these, 50.9% were men and 49.1%were women, with an average age of 42.8 years and a range of 12-76 years. The indications for implantation were, in most cases (96%), bilateral chronic otitis media non-susceptible to reconstructive surgery and which did not tolerate conventional hearing aids due to frequent otorrhea. One patient presented bilateral congenital ear atresia and another, unilateral anacusis.

Patients were divided into 2 groups to study the dermatological complications arising and the number of cures required until final skin stabilization, according to the type of flap employed (manual U flap vs electric dermatome). The classification used for complications was that of Holgers et al[7] (Figure 1):

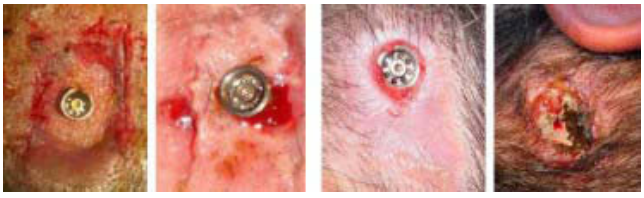

Figure 1 Examples of skin complications. From left to right: discrete redness (Grade 1), redness and discharge (Grade 2), granulation tissue (Grade 3) and extensive inflammation and infection with "buried" implant requiring removal (Grade 4).

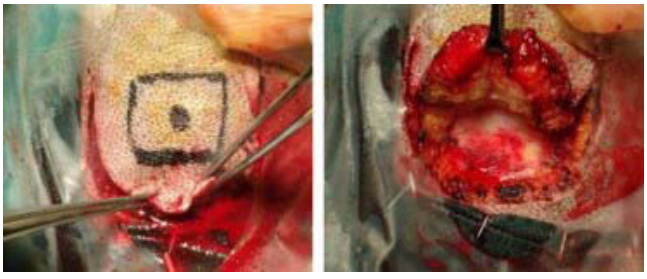

Figure 2 Manually prepared U flap.

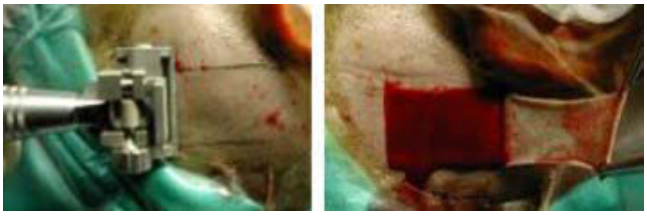

Figure 3 Flap prepared using the electric dermatome.

- Grade 0: no skin reactions. Cleaning of epithelial debris, if necessary.
- Grade 1: discrete redness or cutaneous erythema. Local treatment.
- Grade 2: mild exudate erythema without granulation tissue. Local treatment and extra checks.
- Grade 3: erythema and exudate, sometimes with granulation tissue. Review surgery indicated.
- Grade 4: extensive inflammation and infection requiring implant removal.

The surgical technique employed[5] begins with delimitating the previously-shaved surgical area with a simulator and infiltrating with local anesthesia.

Two types of flap were used in skin management, as mentioned previously. The U flap (Figure 2) measures 25-30 mm in length by 20 mm of anteriorly pedicled base. It is designed with a cold scalpel and should be thinned out as much as possible to obtain a flap free of hair follicles and with a minimum thickness. A shaver is used from the inside of the skin to aid in this process, allowing a reduction of the thickness to a minimum while being as atraumatic as possible for the skin tissue. The flap made with the electric dermatome (Figure 3) is pedicled superiorly or inferiorly for the surgeon's convenience, depending on the side to intervene: a right-handed surgeon performs it from the bottom up (that is, pedicled superiorly), while it is in the opposite direction for a left-hander (pedicled inferiorly). The flap obtained is free from hair follicles and is 25 mm wide and 0.6 mm thick. Once the flap is fashioned, it is folded down and covered with gauze soaked in physiological saline solution.

The following part, reducing the subcutaneous tissue, is of great importance. It should be fully resected from the region around the implant up to the periosteum, which must be respected. It is preferable to dissect and respect (that is, not to remove) this tissue initially, because if a complication arises, such as cerebrospinal fluid fistula (CSF) or severe bleeding, this material can serve as seal. The subcutaneous tissue should be resected even below the margins (at least 1-2 cm) of the incision to create a gradual slope towards the area of the implant. Suturing the remaining subcutaneous tissue to the periosteum is important to facilitate the formation of this slope.[8]

Review surgeries usually consist of lifting the flap, excising all subcutaneous tissue, thinning the flap and, in some cases, placing a pedestal of greater length (8.5 mm).[8]

Table 1 Dermatological complications according to the classification of Holgers et al.

Grade	Patients, No. (%)
0 (no skin reactions)	24 (45.2)
1 (discrete redness)	10 (18.8)
2 (erythema and discharge)	7 (13.2)
3 (granulation tissue)	11 (20.7)
4 (extensive inflammation and infection)	1 (1.8)

Table 2 ermatological complications according to surgical technique employed

Grade	U flap (n=26)	Dermatome (n=27)
0	17	7
1	2	8
2	2	5
3	5	6
4	0	1
Total, n (%)	9 (34)	20 (74)

The software programs SPSS version 15 and Epidat 3.1 were used for statistical analysis.

Results

Dermatological complications appeared in 52.8% of patients. Of these, 18.8% (10 patients) presented Grade 1 complications, 13.2% (7 patients) Grade 2, 20.7% (11 patients) Grade 3, and 1.8% (1 patient) Grade 4 (Table 1). Of these, 16.9% (9 patients) required surgical reviews to solve their cutaneous problems, 3 of them twice. A free skin graft of abdominal skin was used on 2 occasions.

In patients intervened with U flap, there were 9 patients with complications, in contrast to the 20 in patients intervened with dermatome (Table 2). The differences between both groups are statistically significant (P=.0091).

The classification of Holgers et al. does not include cutaneous overgrowth and there are complications that can coexist. We therefore included such complications in the degrees of Holgers et al. Partial and total flap necrosis (often associated with exudates and infection) were included in Grade 2, because in most cases they are not associated with granulation tissue. Moreover, they do not generally require review surgery for resolution, as this usually occurs over time by healing through secondary intention. Cutaneous overgrowth, often associated with granulation tissue, was included in Grade 3. These cases are also, generally, the ones that require review surgery with placement of an 8.5 mm pedestal.

In Group 3 patients, it should be noted that of the 5 intervened with U flap, 4 later presented cutaneous overgrowth and only one presented granulomas. In contrast, out of the 6 dermatome patients, 2 presented overgrowth and 4 granulomas.

The average number of cures in the patients intervened with the U flap was 2.73 per patient, while it was 4.1 treatments per patient in those intervened with the dermatome. These differences were once again statistically significant (P=.000).

Discussion

The problem we pose with skin reactions that occur in BAHA prosthesis is an issue that continues to cause changes and contributions despite three decades of experience. Regardless of the good auditory results obtained with the prosthesis, there is this potential limitation of the skin inherent to the nature of the device. Constant contact between the foreign titanium body and the skin around the implant results in a chronic inflammatory reaction around it. This decreases with time.[12] It consists of polymorphonuclear cells, B cells and plasma cells, but not T cells, suggesting a reaction to exogenous factors related to the implant rather than a chronic allergic reaction to the implant itself. An allergic reaction to contact with titanium is rare, but as we have seen, it is the cause of a local inflammatory reaction.[13]

The classification of Holgers et al is widely used in various publications and forms the basis of different comparisons. However, from our point of view, and coinciding with Wazen et al,[14] there are a number of limitations to point out. It does not include cutaneous overgrowth as a complication, one we could consider major, as it requires review surgery. We have also previously discussed the possibility of coexistence of various complications classified in different degrees, in some cases treated successfully with conservative approaches and others with the need for surgery.

We know that many patients develop granulation tissue (Grade 3 according to Holgers et al) and are successfully treated with local cures without the need for review surgery. However, there may be erythema and exudates that cause major flap necrosis, without granulation tissue (also Grade 3), which are solved without surgery. Therefore, another classification was proposed, with 5 degrees selected on the basis of the treatment required and also including skin overgrowth, which we believe to be more complete.[14] Another recently-published classification divides the minor and major complications, depending on the need or not for review surgery.[15] However, to establish comparisons with most authors, we must turn to the classification of Holgers et al.

Various publications provide very different results regarding the frequency of complications. Most of them agree on a large number of patients who have some type of skin reaction, in some series reaching 51%[1] or 33%[16] The proportion of complications in our study (52.8%) is slightly above the best of these series. In complications of Grade 2 or higher, there is also great variability in the medical literature, from 1.74% to 21%[9-12,17,18] Our series offers worse results, with 35.7% of complications at Grade 2 or higher. It should be pointed out that we had an elevated number of patients who developed granulation tissue in the skin-titanium interface (20.7%), without this entailing review surgery (only local cures) in most of them.

The 2 techniques compared in the study can be seen to have a number of advantages and disadvantages. The U flap requires more surgical time in its elaboration and gives a greater skin thickness. It is therefore difficult for it to be completely free of hair follicles and there is a higher possibility that the hair plane is sunk with respect to the skin plane. However, it offers a lower rate of complications than the dermatome (34% vs 74%), with fewer concurrent infections and necrosis, possibly due to its increased vascularization. There is also less formation of granulation tissue.

The dermatome is obtained much more quickly (it reduces surgical time) with a very thin skin thickness. However, we consider that it behaves almost as a free flap and the rate of necrosis is therefore much higher (22% vs 2.6%). This increased avascularity may make necrosis, as well as infection and granulation tissue in the skin-titanium interface, more likely. The dermatome also increases the cost of surgical materials. In a study comparing the U flap with the dermatome, more necrosis was obtained with the first than the second (9.2% vs 3%), with no significant differences between both techniques.[19] There is a hypothesis that would explain this by the lower metabolic demand of the flap obtained with the dermatome. In contrast, in our series we obtain significant differences both in the number of complications and the number of cures, which are closely related aspects.

Considering the moment of external processor adaptation, which we performed 3 months after surgery, these treatments do not prolong this period. This is because the skin is usually already stabilized, although the treatments generally require two cures. However, different authors set the time of adaptation at 6 weeks without affecting osteointegration.[14,19,20] Given this, the "dermatome group," with its greater number of cures, might not obtain sufficient skin stability to adapt the processor in that time.

We also understand that the thickness of subcutaneous cellular tissue has important implications, and that individualized patient assessment according to weight and constitution can be a factor to consider. Currently, we are focusing on establishing correlations between the U flap and the dermatome with patient BMI (unpublished data). We are using the dermatome in children, non-obese women and lean men. In contrast, we are utilizing the U flap in men in general, obese women, reinterventions, skull deformities, skin scarring and dermatitis, as well as for simultaneous mastoidectomy.

While continuing to develop different surgical techniques, we must not forget the basic principles of soft tissue management in BAHA, which are essentially 2:

- The first is the removal of the subcutaneous tissue below the skin flap to the periosteal layer (which should be respected, except in the area of implant insertion). The subcutaneous tissue that we leave allows us to stop flap movement during cures and progress towards scarring and swelling; it may eventually lead to cutaneous overgrowth above the hair plane.
- The second, more important, is to reduce the subcutaneous plane below the edges of the incision as well. At least 1 cm is considered sufficient, depending on the thickness of the cranial subcutaneous tissue.

All this must be considered in the context of meticulous surgical technique, both in skin handling and implant placement.

Conflict of interests

The authors declare no conflict of interests.

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