TECHNICAL NOTE

Simplified technique without skin flap for the bone-anchored hearing aid (BAHA®) implant

Tecnica semplice senza lembo cutaneo per l'impianto di protesi BAHA®

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SUMMARY

Aim of this report is to present a new surgical technique for the BAHA[®] system implant and to discuss the operational techniques and complications related to this type of surgery. The common technique for the positioning of the Bone-Anchored Hearing Aid (BAHA[®], Cochlear Limited, Englewood, CO, USA) titanium implant into the temporal bone is based on the use of either a free or a pedunculated skin flap. Reported complications of this type of surgery include skin flap necrosis with healing by second intention, infection of the flap, skin growth over the abutment, failure of osseointegration and implant extrusion. In order to reduce the incidence of these problems, different types of surgery have already been presented over the years. Herewith, a new technique is proposed for implanting a BAHA[®] screw in the temporal bone, that is simple, rapid to perform, and does not require the use of a flap. This technique appears to offer two main advantages: i) the speeding up of the procedure; ii) the low risk of complications, such as infection and necrosis, within the skin surrounding the implant.

KEY WORDS: Hearing loss • Osseointegrated implants • BAHA® • Surgery

RIASSUNTO

Con il presente lavoro l'Autore presenta una nuova metodica chirurgica utilizzabile per l'impianto di protesi BAHA[®]. A tal fine viene comunemente impiegata una vite in titanio, alloggiata a livello della squama del temporale, e viene allestito un lembo cutaneo che può essere sia libero che peduncolato. Complicazioni derivanti da questo tipo di chirurgia sono: necrosi e/o flogosi del lembo cutaneo, crescita del lembo cutaneo al di sopra della vite, estrusione della vite per mancata osteointegrazione. Proprio al fine di ridurre l'incidenza delle suddette complicanze, sono state già presentate, da vari Autori, delle modifiche alle tecniche chirurgiche tradizionali utilizzate per l'impianto delle protesi BAHA[®]. L'Autore propone una nuova tecnica chirurgica, semplice e veloce per tale tipo di intervento, che non necessita dell'allestimento del lembo cutaneo.

PAROLE CHIAVE: Ipoacusia • Protesi osteointegrate • BAHA® • Chirurgia

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Introduction

Positioning of the Bone-Anchored Hearing Aid (BAHA[®], Cochlear Limited, Englewood, CO, USA) titanium implant, into the temporal bone, is usually based on the use of a free or pedunculated skin flap. However, following this procedure, complications have frequently been reported, including skin flap necrosis with healing by second intention, flap infection, skin growth over the abutment, failure of osseointegration and extrusion of the implant ¹⁻⁴.

The original method of Bone-Anchored Hearing Aid (BAHA[®], Cochlear Limited, Englewood, CO, USA) implantation consists of a two-stage procedure in which the titanium fixture is placed under a subperiosteal flap and allowed to osseo-integrate for at least 3 months without any skin preparation. Then, at the second stage, a circular section of scalp overlying and surrounding the implant is removed and a full-thickness skin graft is positioned ⁵⁻⁷.

Use of either a free or a pedunculated skin flap has been

proposed in the past ⁶⁻⁹. Among the free flap techniques, Tjellstrom ⁶ used a free split thickness non-hair bearing graft harvested from the post-auricular sulcus; Browning ¹⁰ designed a transposition flap using a Z-plasty technique, while Mylanus & Cremers ¹¹ published their results on a one-stage procedure for BAHA using a longitudinal incision behind the ear and a free skin graft from the retro-auricular fold, reporting an incidence of 21% of skin necrosis. Mainly for this reason, the high incidence of necrosis, a pedunculated skin flap is nowadays preferred when implanting a BAHA system.

Rectangular, pedunculated and very thin flaps are generally recommended and can be obtained with a manual technique or with the use of a dermatome especially designed for this purpose. In order to obtain a clean, hairless and non mobile flap, it must be < 1 mm in thickness and fixed to the skull bone with compressive packaging which is maintained under the healing cup for at least one week. Proops ⁸, in particular, recommended a thin pedicle flap, while Reddy et al.

described a radial four-flap technique ¹². Recently, with the aim of reducing the risk of flap ischemia, the use of a very large flap ¹³ has been proposed. Most studies emphasize the importance of precise surgery, use of sharp tools when reducing soft tissues in order to minimize tissue trauma, and reducing the incidence of infection and skin necrosis related to this surgical procedure.

Complications of this type of surgery (implant with pedunculated flap) have been reported in the literature: skin flap necrosis with healing by second intention, infection of the flap, skin growth over the abutment, failure of osseo-integration and implant extrusion, with an overall incidence that ranges from 3.4% to 39.6% ⁷⁹¹¹¹⁴⁻¹⁸. Adverse skin reactions seem to be the main complication with a variable incidence, from 5 to 30%, of the reported cases ⁶⁻⁹¹¹¹⁴⁻¹⁷¹⁹, while failure of osseo-integration and implant extrusion have been reported in 3-9% of cases ¹²⁰²¹.

Thus, in order to achieve a healthy medium between periosteum and abutment and preventing complications, surgeons' efforts are still necessary to modify the technique ⁹¹²²².

Herewith, a surgical technique for implanting a BAHA screw in the temporal bone is presented, that is simple, fast and does not require the drawing of a flap. This technique has two main advantages: i) a more rapid procedure, ii) very low risk of infection and necrosis within the skin surrounding the implant.

Preliminary experience on 5 consecutive adult patients who underwent BAHA implantation, with this technique, is described.

Materials, methods and results

Between 2003 and 2007, the Author implanted 32 BAHA[®] in 30 patients, mostly young children with bilateral aural atresia. A traditional pedunculated rectangular flap was always used until February 2007, when the Author introduced the technique reported below. Since then, this new technique has been carried out in 5 consecutive adults. Nonetheless, the traditional technique is still preferred in children when a two-stage procedure is required: in fact, a large rectangular flap allows the screw to be covered with intact skin.

The 5 adult patients had a mixed hearing loss due to bilateral chronic otitis and were either unable to tolerate traditional bone-conduction hearing aids, or had not gained sufficient benefit from open-ear devices.

The patients were 2 men and 3 women, age range 53-84 years (mean 69.7). A retrospective review of clinical charts was conducted to analyse the results and complications (skin infection, necrosis, haematoma, loss of screw).

Six weeks after the surgical implantation, patients were

fitted with BAHA Divino (cases n. 1, 2 and 3) and with $BAHA^{(B)}$ Intenso (cases 4 and 5). Data from all patients are outlined in Table I.

Description of surgical procedure

In adults, BAHA[®] surgery is generally performed under local anaesthesia, while in children, a general anaesthesia is preferred. In young children or in those with very thin cranial bones, BAHA[®] system implantation may require two operative steps, one for placement of the mounting device and a second for maturation of the surrounding skin. In older children or in those with well-developed cranial bones, a one single-stage procedure may be preferred.

The implant is placed at a distance of 5.5 cm from the outer ear canal, at the level of a line drawn posteriorly from the supra-meatal crest. At this point, a suitable bone thickness can be found and a good sound conduction to the cochlea is achieved. The point is marked together with the circular border of a surrounding area of 3-4 cm diameter (Fig. 1). This skin area of the skull is injected with local anaesthetic. A 4-5 cm incision of the skin, penetrating into the subcutaneous and muscular tissue, perpendicular to the above-mentioned line is carried out using an electrosurgical scalpel. The periosteal membrane can be completely removed from the circled area with no risks, thus further reducing the thickness of the skin around the fixture. The implant site is now prepared as described by Tjellstrom ⁶. First, a guide drill, on high speed, is used. An adequate irrigation is essential in order to avoid bone heating and the irrigation should be directed at the point where the drill penetrates the bone surface. Drilling then continues using the exact diameter drill. The titanium fixture is then inserted using a low speed setting (Fig. 2).

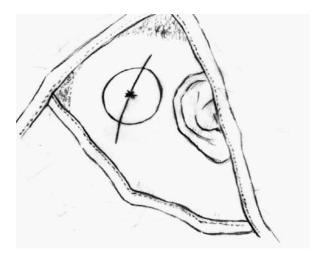


Fig. 1. Pre-operative marks.

Table I. Data from patients who underwent titanium screw implantation with the technique described

Patient #	Sex	Age (yrs)	Associated medical factors	PTA air threshold, (best ear)	PTA bone threshold, (best ear)	Follow-up (mos)
1	М	53	Smoker (1 packet/day)	75	30	13
2	М	69	None	62	28	9
3	F	63	None	68	37	5
4	F	79	None	82	42	5
5	F	84	Mild hypertension	85	45	2

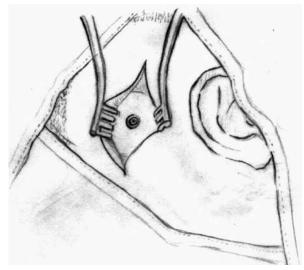


Fig. 2. After incision, titanium implant is fixed using a low speed setting.

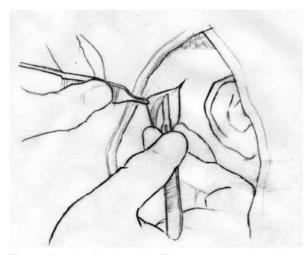


Fig. 3. Muscular flap is peeled off from cutaneous plan and then harvested.

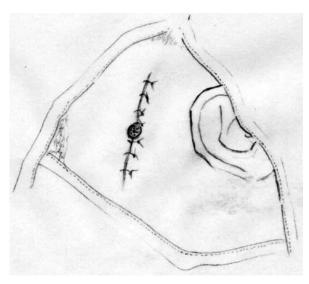


Fig. 4. A circular lodging site is obtained; cutaneous plan is sutured.

Subcutaneous and muscular tissues are peeled off the skin and the skull bone, and then harvested performing a circular incision (Fig. 3). This procedure is carried out on both sides of the initial incision, in order to obtain a circular lodging site. The surgical incision is then sutured (Fig. 4) and packed with ointment gauze under the healing cup. Six weeks later, the external processor can be loaded for regular use.

In all 5 adult patients who underwent BAHA[®] implantation with the technique described, healing was uneventful and no other problems were encountered at regular follow-up.

Discussion and conclusions

The surgical success of a BAHA[®] implant depends upon percutaneous implant which must be surrounded by thin, hairless and immobile skin in order not to cause an adverse soft tissue reaction at the interface between skin and screw, thereby remaining stable over a long period of time ⁹.

Several different techniques/procedures have already been proposed over the past few years, since the original method of BAHA® implantation was described 68 10-13. At present, BAHA® titanium implantation and exteriorisation are generally carried out using a one-stage technique and using pedunculated skin flaps. Rectangular, pedunculated and very thin flaps are generally recommended. As reported by Proops, there are several different techniques with which to carry out these flaps, particularly for making the skin reduction. Nevertheless, flap necrosis may still occur in 2-5% of cases 8. For this reason, the periosteal layer is always preserved around the titanium implant, since in cases of flap necrosis, it guarantees a second intention healing. In the absence of the periosteum, the bone is not completely covered with skin and revision surgery is necessary.

This preliminary small series of 5 patients appears to demonstrate that with the technique described, the risk of skin necrosis is negligible. Manual thinning of the skin requires a minimum of surgical skill and accuracy, but no more than would be required in thinning the pedunculated flap. Removal of subcutaneous and muscular tissue can be carried out with an electrosurgical scalpel thus reducing bleeding. The periosteal layer can be safely removed thus further reducing flap thickness. At the same time, skin growth over the abutment was not observed in any of these cases.

Another advantage is represented by the fact that in cases of bleeding from the bone after the drilling (i.e., from a diploic vessel) a second or even third hole can be made along the line corresponding to the skin incision without any risk. On the contrary, with the conventional pedunculated flap, changing the position of the bone drill may lead to further difficulties. Finally, the surgical procedure is less time consuming with the present technique and the implant can be loaded after a 6-week period without failure of osseointegration of the titanium implants, thus meeting the recommendations of Wazen et al. regarding the timing of loading and activation ²³. This earlier activation resulted in enhanced patient satisfaction.

In conclusion, the BAHA[®] has now become a well-accepted method of auditory rehabilitation and should be part of every otologist's background. The technique presented offers the opportunity to improve the surgical procedure.

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