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TECHNICAL NOTE

BAHA implant: Implantation technique and complications

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KEYWORDS

BAHA;
 Hypertrophic scar;
 Skin complications;
 Surgical technique;
 Skin graft;
 Skin flap

Summary

Objectives: BAHA implants have been shown to be effective in certain forms of conductive hearing loss, but the presence of the titanium abutment is responsible for sometimes severe skin reactions. The objective of this study was to compare two operative techniques: skin flap, and full-thickness skin graft.

Material and methods: Between January 2004 and January 2011, 72 patients were treated by BAHA implant and 32 of these patients (total of 41 implants) were included in the study. Two surgical techniques were used: full-thickness skin graft ($n=21$) and skin flap ($n=20$).

Results: Four types of skin complications were observed: necrosis, inflammation/infection, hypertrophic scar, and fixture loss due to inadequate osseointegration. Complications requiring surgical revision were observed in 20% of cases with the skin flap method and 38% of cases with the skin graft technique, with no significant difference between the two groups ($P=0.31$).

Conclusion: The skin graft technique appears to be associated with a higher rate of major complications. The most common complication is hypertrophic scar. The apparently high complication rate in this series can be explained by a selection bias (exclusion of a large number of complication-free patients).

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Introduction

Bone-anchored hearing aids (BAHA) are indicated in patients with conductive or mixed hearing loss unsuitable for conventional air conduction hearing aids and ineligible for surgical rehabilitation. The indications for BAHA have been more recently extended to unilateral sensorineural hearing loss, as several studies have demonstrated improved speech understanding in noise and improved hearing comfort

related to attenuation of the “screen” effect of the head in these patients, under certain conditions.

These hearing aids, initially developed by Tjellström and Carlsson (Göteborg) in 1977, are based on the concept of osseointegration described by Branemark several years previously. Branemark demonstrated, in animals and then in man, perfect integration of titanium prostheses implanted in the maxilla and mandible.

Due to the presence of a foreign body in contact with the scalp, skin reactions are commonly observed and can sometimes lead to severe complications [1]: skin necrosis, infection, hypertrophic scar, and defective osseointegration possibly responsible for fixture loss. Holgers et al. proposed a 5-stage classification of increasing severity of implant (from

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grade 0: no reaction, to grade 4: infection requiring removal of the implant).

The BAHA surgical implantation procedure is simple, but requires compliance with certain basic principles to minimize the postoperative complication rate. Many surgical variants concerning the skin incision have been described, all designed to reduce these complications. However, no technique has been clearly demonstrated to be superior and the technique used essentially depends on the team's usual practice.

Our team in Strasbourg has been implanting BAHAs since 1992. The technique initially used consisted of creating an anterior- or superior-based U-shaped skin flap, but this technique appeared to be associated with a high postoperative skin complication rate. Since 2005, we have simplified our technique by performing a thinned circular full-thickness skin graft raised directly at the site of implantation. The objective of this study was to compare these two techniques in terms of complications and to compare our results with those of the various published series.

Material and methods

Patients

The study design consisted of retrospective review of the medical charts of 72 patients included on the basis of the following criteria: unilateral or bilateral BAHA implant placement, patients of all ages, operated between January 2004 and January 2011. Forty cases were excluded from this study (22 skin grafts and 18 skin flaps) because of missing data in the medical charts or the most recently operated patients with less than 1 year of postoperative follow-up. Thirty two patients satisfying all of these criteria were therefore included in the study. Twenty-nine of these 32 patients presented unilateral/bilateral conductive or mixed hearing loss and three presented unilateral cophosis. Several BAHAs were implanted in six patients because of skin complications. Two patients received bilateral BAHA implants: this series therefore comprised a total of 41 BAHA implants.

Twenty one of the 41 implants were implanted according to the skin graft technique and 20 were implanted according to the skin flap technique. In the first group, the mean age at the time of implantation was 35.3 years and the sex ratio was 0.48. In the second group, the mean age at the time of implantation was 36.3 years and the sex ratio was 0.55. Both groups comprised a similar proportion of children under the age of 16 years: eight on 21 in the skin graft group, and seven on 20 in the skin flap group ($P=1$). Comorbidities likely to affect healing were investigated (diabetes, long-term corticosteroid therapy, obesity, smoking, atopy). These risk factors were identified in 29% (6/21) of patients of the skin graft group and 15% (3/20) of patients of the skin flap group, with no significant difference between the two groups ($P=0.45$). Mean follow-up was 4 years (range: 1–11 years).

Surgical technique

Four senior surgeons perform BAHA implantation in our institution. The skin flap technique was gradually abandoned from 2005 onwards. Only the skin graft technique is used at

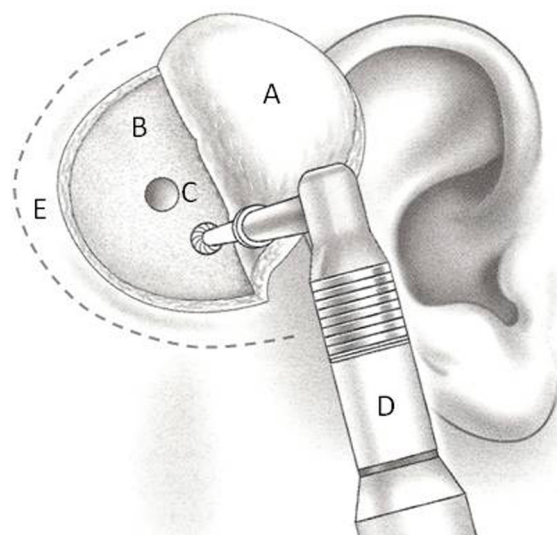


Figure 1 Anterior-based skin flap technique. A. Anterior-based flap. B. Periosteum. C. Countersink. D. 2 or 3 mm long cutting drill. E. Zone of thinning of the subcutaneous tissue around the implant.

Portmann M, Manuel pratique de chirurgie otologique, Elsevier Masson, 1997.

the present time. No bias related to learning of a new surgical technique was observed, as this is a simple procedure used in other indications. Two techniques were therefore used: anterior-based U-shaped skin flap and, more recently, the circular full-thickness skin graft raised from the implantation site.

Both techniques are performed under local or general anaesthesia. The procedure starts with identification of the implantation site, which must be extensively shaved, situated posteriorly and slightly superiorly to the external ear, generally 5.5 cm from the external auditory canal. Implantation may be facilitated by using a phantom implant, which must not be in contact with the ear. After antisepsis and placement of sterile drapes on the operative field, the subcutaneous tissue is infiltrated with local anaesthetic, preferably with adrenaline.

In the skin flap technique, a 3 to 4 cm rectangular or semicircular incision centered on the implant position is performed (Fig. 1). The scalpel is not placed perpendicular to cortical bone, but at an angle in order to harvest a maximum of subcutaneous tissue present underneath the edges of the skin around the implant. The flap is then reclined anteriorly, sparing the periosteum which must be simply perforated over the site of implantation of the screw. The fixture is then inserted according to the principles described by Branemark: a countersink, 3 or 4 mm long depending on the thickness of the bone, is drilled using a high speed cutting drill. This countersink is then enlarged with a bone rasp to the shape and diameter of the implant. Finally, a 3 or 4 mm self-tapping fixture is screwed at low speed perpendicularly to the bone. All these procedures must be performed under abundant irrigation to prevent heating of the bone that can interfere with osseointegration. The skin flap is subsequently thinned with a scalpel blade, in a subdermal plane removing the hair follicles: the flap must be hairless

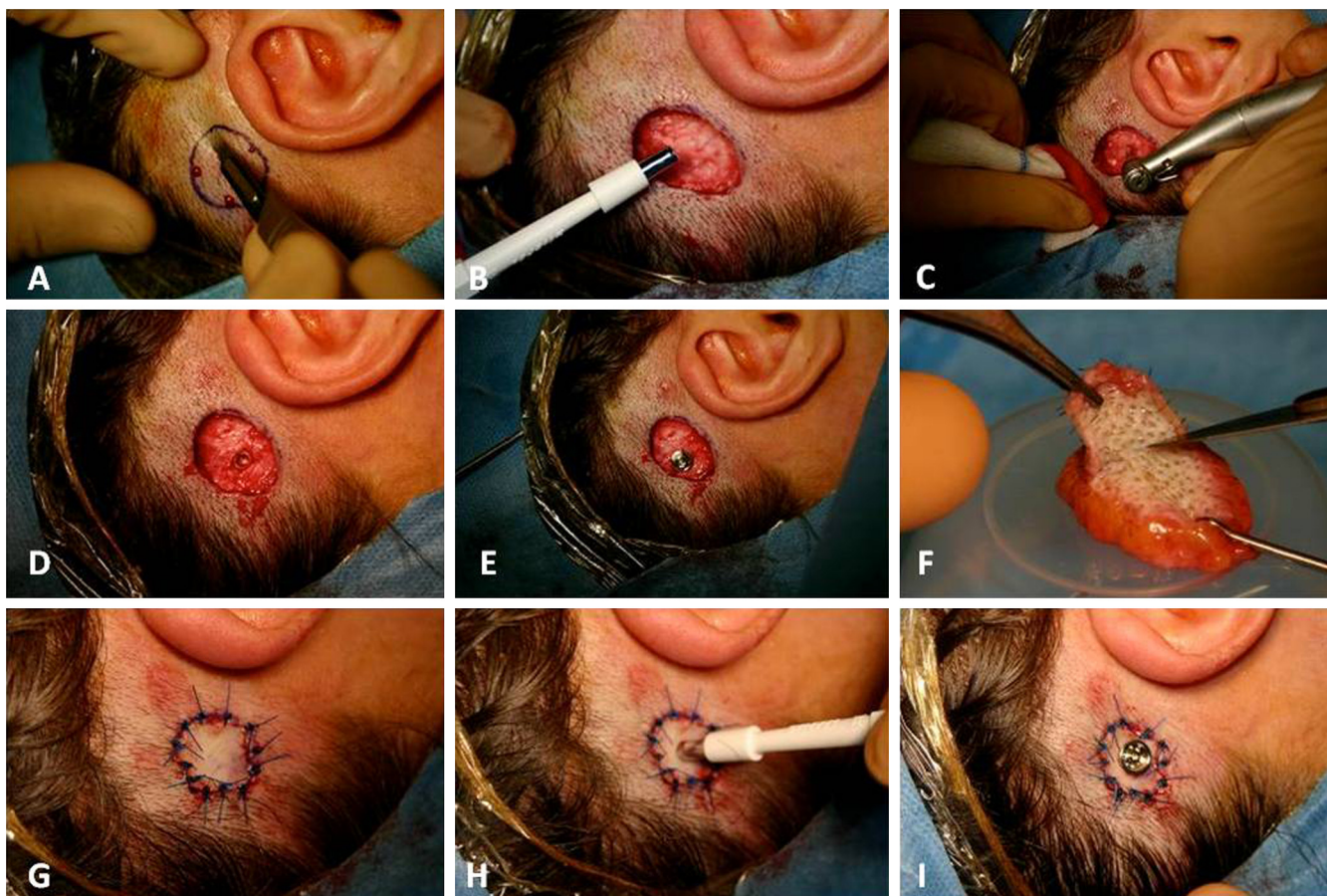


Figure 2 Circular full-thickness skin graft technique. A. Oblique circular incision. B. Creation of a periosteal window using the punch scalpel. C. High-speed drilling of the countersink. D. Reaming of the countersink. E. Placement of the fixture. F. Subdermal thinning of the graft. G. Suture of the graft. H. Perforation in the centre of the graft. I. Placement of the abutment.

to facilitate subsequent cleaning, and must be as thin as possible. Removal of part of the subcutaneous tissue of the peri-implant skin achieves a gently sloping junction with the implantation site. Finally, the flap is placed over the fixture, sutured with 5.0 monofilament, and perforated over the fixture with a punch scalpel, and the abutment is then screwed onto the fixture.

The skin graft technique is similar to the skin flap technique except that the incision is circular (3 to 4 cm in diameter) (Fig. 2). Implantation of the fixture and abutment is performed according to the same principles. The skin graft is thinned in the same way as the flap, with removal of all hair follicles. At the end of operation, a healing cap is clipped onto the abutment, underneath which a piece of tulle gras is placed to act as a compressive dressing. This cap and the sutures are removed on the 10th postoperative day. The processor is installed 6 to 8 weeks after the operation.

Data collected

The following parameters were recorded for each patient: operative indication, surgical technique, development of complications, time to onset and management of these complications. Complications were classified into four categories:

- flap/graft necrosis;
- inflammation/infection;
- hypertrophic scar;
- and primary or secondary defective osseointegration of the fixture.

Complications were either minor (requiring conservative local treatment) or major (requiring surgical revision). Statistical analysis was performed using Fisher's exact test, in view of the sample size. A *P* value less than 0.05 was considered to be statistically significant.

Results

The causes of hearing loss are summarized in Table 1. The most common cause of conductive or mixed hearing loss was cholesteatoma (secondary to chronic otitis media or surgery). Three of the six patients with minor or major atresia presented a congenital malformation syndrome (Goldenhar, Pierre Robin and Franceschetti). Two cases of unilateral sensorineural hearing loss were iatrogenic (translabyrinthine approach to a petroclival meningioma; vestibular neurectomy for disabling Ménière's disease).

Table 1 Causes of hearing loss.

Conductive/mixed hearing loss		Unilateral sensorineural hearing loss	
Chronic otitis	20		
Otospongiosis	2	Iatrogenic	2
Minor/major atresia	6	Congenital sensorineural hearing loss	1
Bilateral fracture of the petrous temporal bone	1		
Total	29	Total	3

Table 2 Complications according to surgical technique.

Complication	Skin flap technique (n=20)		Skin graft technique (n=21)		P=
	n	%	n	%	
Graft/flap necrosis	0	0	0	0	1
Inflammation/infection	1	5.00	4 (1)	19 (4.7)	0.34
Hypertrophic scar	9 (3)	45 (15)	7 (7)	33.3 (33.3)	0.53
Fixture loss	1 (1)	5% (5)	0	0	0.49
Total	11	55	11	52.4	1
Minor	7	35.00	3	14.30	0.16
Major	4	20.00	8	38.00	0.31

In parentheses: major complications (requiring surgical revision).

In this series of 41 BAHA implants, the surgical technique was skin graft in 21 cases and skin flap in 20 cases. Four types of postoperative complications were observed:

- total or partial graft or flap necrosis;
- inflammation or infection, characterised by more or less severe erythema of the flap or graft, sometimes associated with localized suppuration, granuloma, or even systemic signs of infection;
- hypertrophic scar around the abutment, interfering with placement of the hearing aid;
- and fixture loss related to a primary or secondary defect of osseointegration (with or without infection).

All complications are presented in [Table 2](#).

All complications requiring surgical revision were considered to be major complications. Posttraumatic fixture loss (two patients) was excluded from the analysis, as it does not constitute an inherent complication of the surgical technique. In patients experiencing several complications, only the most serious complication is shown in the table, allowing comparison with published series also based on this principle.

The complication rate was 55% (11/20) for skin flap and 52.4% (11/21) for skin graft. Graft or flap necrosis is an early postoperative complication, generally occurring during the first 2 weeks after implantation. This complication was not observed in the present series. Inflammatory or infectious complications were observed in one (5%) of the 20 implants in the skin flap group, and four (19%) of the 21 implants in the skin graft group with a mean time to onset of 12 months (range: 1 week–24 months). This complication always resolved in response to local wound care, except for one case in the skin graft group which

required excision of a granuloma under local anaesthesia. The most common complication was hypertrophic scar, which occurred an average of 14 months after implantation (range: 1–36 months). Hypertrophic scar was observed in nine (45%) of the 20 implants of the skin flap group, requiring surgical revision in three (15%) out of 20 cases, and in seven (33.3%) of the 21 implants of the skin graft group that all required surgical treatment. Three patients presented recurrent hypertrophic scar (at least two episodes). One 16-year-old patient with psychomotor retardation (trisomy 21) required six surgical revisions (skin flap group). Fixture loss was observed for three implants (two in the skin flap group and one in the skin graft group). Fixture loss was secondary to trauma in two cases (not shown in [Table 2](#)), while the third case was due to a primary defect of osseointegration without infection, in a patient implanted according to the skin flap technique. Another implant was placed on the same side, 2 months after the first attempt, with no subsequent complications.

Overall, 35% of patients of the skin flap group and 14.3% of patients of the skin graft group experienced minor complications ($P=0.16$). Major complications were observed in 20% patients of the skin flap group and 38% of patients of the skin graft group ($P=0.31$) with no significant difference between these two groups.

Discussion

BAHA clearly provide better hearing comfort for patients with conductive hearing loss after failure of conventional hearing aids or in patients unsuitable for rehabilitation surgery. However, skin complications frequently occur around the implant abutment and are a source of discomfort for patients (repeated visits, surgical revision, delayed

Table 3 The various published series.

Year	Author	Implants	Technique	Minor complications (Holgers I, II, HS) (%)	Major complications (Holgers III, IV, HS) (%)
2011	Kraai et al. [1]	27	Dermatome	12/27 (44)	12/27 (44)
2009	Tamarit Conejeros et al. [2]	27	Dermatome	13/27 (48.1)	7/27 (25.9)
		26	Skin flap	4/26 (15.4)	5/26 (19.2)
2009	Van De Berg et al. [3]	30	FTSG	NS	2/30 (6.7)
		45	Skin flap	NS	10/45 (22.2)
		47	Dermatome	NS	6/47 (12.7)
		21	Vertical incision	NS	1/21 (4.7)
2008	Falcone et al. [4]	26	Skin flap	18/90 (20)	7/90 (7.8)
		64	Dermatome		
2008	Wazen et al. [5]	223	Dermatome	17/223 (7.6)	17/223 (7.6)
2008	Stalfors and Tjellström [6]	25	Dermatome	4/25 (16)	
		45	Skin flap	16/45 (35.5)	
2008	De Wolf et al. [7]	150	Vertical incision	56/150 (37.3)	20/150 (13.3)
2007	House and Kutz [8]	149	Dermatome	NS	15/149 (10)
2005	Lekakis et al. [9]	11	Dermatome	5/11 (45.4)	6/11 (54.5)
		11	Skin flap	4/11 (36.3)	0/11 (0)
1999	Woolford et al. [10]	25	FTSG	4/25 (16)	1/25 (4)

FTSG: full-thickness skin graft; HS: hypertrophic scar; NS: not specified.

installation of the processor). Many surgical variants of the skin incision have been described in the literature, designed to reduce these complications to a minimum. Table 3 presents the results of 10 series published in the international literature [1–10].

A disadvantage of the classification proposed by Holgers, used by some authors, is that it does not include hypertrophic scar, which is nevertheless one of the main complications of this procedure. Consequently, in order to compare our results with those reported by other authors, we classified complications into two categories: minor and major.

Minor complications (erythema = Holgers grade 1, maceration or minimal infection = Holgers grade 2, hypertrophic scar) require regular wound care, antisepsis, application of eosin to dry the lesion in the case of maceration, and sometimes application of topical antibiotics. Corticosteroid ointment or silver nitrate cauterization are sometimes necessary to treat granulation tissue. Local corticosteroid injections are sometimes effective to treat hypertrophic scar nodules.

Treatment of major complications (granulomas = Holgers grade 3, primary or secondary defect of osseointegration = Holgers grade 4, hypertrophic scar refractory to conservative treatment) ranges from simple excision under local anaesthesia to removal of the abutment followed by primary healing then excision-regraft of the implant zone under general anaesthesia.

The skin complication rate, all stages combined, was very variable in the 10 published series (15.2 to 88%). The major complication rate ranged between 0 and 54.5% with a mean

of 16.7% (excluding the series by Tjellström and Stalfors in which the complication rate was not reported).

No technique appears to be superior in terms of efficacy, as the lowest major complication rates in the various series are reported for full-thickness skin graft (6.7%) [3], vertical incision (4.7%) [3], dermatome (7.6%) [5], and skin flap (0%) [9].

According to other authors, use of the dermatome can be responsible for a high major complication rate: 44% [1], 25.9% [2], and 54.5% [9]. Van de Berg et al. [3] were the only authors to compare four different methods (retroauricular skin graft, skin flap, dermatome and vertical incision). In this series, vertical incision was associated with a significantly lower complication rate than the other three techniques. This technique consists of performing a 4 cm vertical incision and resecting all of the subcutaneous tissue, including hair follicles, for at least 2 cm under each edge of the incision, sparing the periosteum. According to these authors, the lower complication rate would be due to the better blood supply of these large-based “flaps”. Several authors who used a full-thickness skin graft, according to a method similar to our own have reported low major complication rates [3,10].

In our personal experience, the skin graft technique appears to be associated with a higher major complication rate (38%) than the skin flap technique (20%), although the difference between the two techniques was not statistically significant ($P=0.31$). Furthermore, in the presence of hypertrophic scar, 100% of patients of the skin graft group required surgical revision versus 33% of patients in the skin flap group ($P=0.21$). However, our series presents an obvious

selection bias: a large number of complication-free patients were excluded from the study because of missing data, which explains why the complication rate in this series appears to be relatively high compared to the literature.

A review of the literature does not demonstrate one technique to be superior to the others in terms of complications. However, the three largest series provide interesting results. Wazen et al. [5] reported a large series ($n = 223$ implants) with a very low complication rate using the dermatome (7.6% of major complications). House et al. used the same technique in a series of 149 patients and reported a major complication rate of 10% [8]. The third series described use of the vertical incision technique in 150 patients with equally good results (13.3% of major complications). In order to ensure an optimal postoperative course, these authors highlighted the need to comply with certain rules during the surgical procedure, regardless of the technique used: the skin around the abutment must be as thin as possible, with removal of all hair follicles and must be firmly immobilized; resection of subcutaneous tissue must be extended 1 to 2 cm beyond the limits of the flap to ensure a gently sloping junction between the adjacent skin and the zone of implantation. The periosteum must be thoroughly dissected to avoid any residual tissue between the skin graft and the periosteum. Skin margins must be immobilized by suturing them to the periosteum before placement of the flap or skin graft [4]. Surgical instruments must be precise and sharpened, drilling of the countersink and placement of the fixture must be performed under continuous irrigation [2,5,8,9]. Resection of the subcutaneous tissue around the implant site must be even more extensive in obese patients or patients with a thick scalp [5]. At the end of the procedure, the skin graft must be firmly maintained in place: some authors [4] prefer to use a bolster dressing as an alternative to the healing cap provided by the manufacturer.

The skin incision technique therefore appears to have a minimal influence on the postoperative course. Strict compliance with a certain number of rules during the procedure, regular postoperative follow-up, and optimal patient hygiene conditions in relation to the implant are essential factors to ensure the best possible results [6].

Conclusion

BAHA implants have been demonstrated to be effective in some patients with conductive hearing loss and, to a lesser extent, unilateral cophosis. BAHAs can be implanted according to several techniques, mainly dermatome, skin flap, skin

graft or a single vertical incision. Skin complications, especially hypertrophic scar around the abutment, are frequent and represent the main disadvantage of these implants. Very variable results concerning complications have been reported in the literature and no technique has been clearly demonstrated to be superior. The present study did not reveal any significant difference between the two groups, but the skin graft technique appeared to be associated with a higher major complication rate.

Disclosure of interest

The authors declare that they have no conflicts of interest concerning this article.

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