Adverse skin reactions following percutaneous bone conduction implant surgery using the linear incision technique with and without subcutaneous tissue reduction

Adverse skin reactions following percutaneous bone conduction implant surgery using the linear incision technique with and without skin reduction.

Long-term outcome in 289 cases.

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ABSTRACT

Conclusions:

Adverse skin reactions were equally distributed among age groups, surgical technique or presence of a retroauricular incision. Implant loss was observed more frequently in children when compared to adults and elderly.

Objective:

A bone conduction (osseointegrated) implant can be used for rehabilitation of patients with conductive hearing loss or single-sided deafness. The surgical technique has been modified to minimize adverse skin reactions and other complications. Two commonly used techniques are the linear incision technique with skin reduction and the technique without skin reduction.

The primary aim is to compare the complication rate between the two surgical techniques.

Methods:

Retrospective study on all bone conduction implant cases implanted between April 1990 and July 2014. Skin reactions were graded by Holgers' scale (grade 0-1: "normal", grade 2-3: "adverse"). The worst follow-up available was reported.

Results:

Of the 289 bone conduction implants, 25 were implanted in children, 220 in adults and 44 in elderly. Implant loss occurred in 2.8% of all cases: 8.0% in children, 2.3% in adults and 2.3% in the elderly. Skin overgrowth was seen in 4.2%: 4% in children, 4.8% in adults and 3.5% in the elderly. We observed no differences in the amount of adverse skin reactions (16.8% versus 14.7%) or skin overgrowth (4.6% versus 2.9%) between the surgical techniques. There was no difference in adverse skin reactions if the patient had a retroauricular incision (14.4% with versus 17.8% without prior incision).

Key words: bone conduction, wound infection, wound closure techniques.

INTRODUCTION

The bone-anchored hearing aid (BAHA) or bone conduction (osseointegrated) implant (BCI) was introduced by Anders Tjellström in 1977 (1) in patients with mixed or conductive hearing loss, who were unable to wear an air conduction hearing device. François-Michel Vaneecloo extended the indications to single-sided deafness in 2001 (2), by reporting the use of BCI for contralateral routing of signals by bone conduction.

Although the surgical technique to introduce the percutaneous titanium implant into the cortical bone hasn't changed significantly, the way the overlying skin and subcutaneous tissues are handled has evolved quite significantly (3-5). Among the most frequent complications that occurred after implantation, were adverse skin reactions around the abutment (including erythema and/or granulation tissue with or without infection) and rarely implant loss. While mild adverse skin reactions can be treated with topical ointment containing mixtures of antibiotics and corticosteroids, more severe adverse skin reactions require the use of a dressing fixated by the healing cap or eventually revision surgery. The surgical techniques that are recommended nowadays are the linear incision techniques *with* and *without* skin reduction. Both techniques were designed to reduce manipulation of the skin, believing that fewer intraoperative and postoperative complications would occur.

The aim of this study is to describe the frequency of complications after implantation of the percutaneous BCI, to compare the results in different age groups and between two surgical techniques.

MATERIALS AND METHODS

Ethics.

The study was designed and conducted according to the Declaration of Helsinki (1996). Ethics committee approval for surgical outcome auditing was obtained.

Patient data

This is a retrospective study on all percutaneous BCI cases implanted in the Antwerp University Hospital between April 1990 and July 2014. We reviewed the etiology of hearing loss, type of surgical technique, presence of skin overgrowth or implant loss, and the state of the skin surrounding the abutment. Skin observation started 3 months postoperatively, followed by examinations available in the electronic patient record system with a minimal interval of 3 months. Patients where observed at least on a yearly basis or in case of skin reactions. Skin reactions were graded by the Holgers scale (Table 1) (6) and were identified as “normal” if graded 0 or 1, and “adverse” if graded 2 or 3. Implant loss is defined as grade 4. The worst follow-up available was reported. We defined age groups as “children” if younger than 17 years, “adults” between 17 and 64 years and “elderly” from 65 years.

Surgical technique

The linear incision technique *with* skin reduction was used between April 1990 and October 2012. This technique requires a linear retro-auricular incision at the site where the titanium implant will be drilled into the cortical bone. Subcutaneous tissues are resected, so only the epidermis, dermis and periosteum stay in situ. The incision is closed around the abutment with non-resorbable sutures. In October 2012, we started using the technique *without* skin reduction in all patients. In this technique the subcutaneous tissues are left untouched and the implant is placed next to the linear incision being about 1 centimeter behind the linear incision. We also used a newer implant with a hydroxyapatite coating on the abutment. The abutment is available in different heights, so after measuring the thickness of the skin, the correct implant can be chosen. A 5-mm biopsy punch is

used to make a calibrated hole in the skin and the abutment is pushed through. The linear incision is closed with resorbable and non-resorbable sutures.

Statistics

A Cox-regression was used to analyse *adverse skin reactions*. Chi Square-test was used to analyse *skin overgrowth, implant loss and prior surgery*. T-test was used to analyse *length of follow-up and revision surgery*. Log Rank test was used to analyse the *interval until an adverse event occurred*.

RESULTS

A total of 289 BCI implants were placed in 265 patients: 25 children (3-16 years), 220 adults (17-64 years) and 44 elderly (65-88 years), with a mean age of 47 years. Twenty-four patients were implanted bilaterally. Skin reduction was performed in 251 cases, while 38 cases underwent the procedure without skin reduction. Concerning comorbidity, there are two patients with Down syndrome, one with Treacher-Collins and one with Franceschetti-Klein syndrome. The mean follow-up time was 42 months in the whole study population, 47 months in the group with skin reduction (range 2-258 months) and 6 months in the group without skin reduction (range 2-18 months).

Etiology of hearing loss

Conductive hearing loss (62% of all cases) was mainly caused by cholesteatoma (33%), middle ear surgery (28%), chronic otitis media (22%) and congenital deformities (10%). The group with sensorineural hearing loss (34% of all cases) consists of patients with single-sided deafness, such as after resection of a vestibular schwannoma (36%), sudden sensorineural hearing loss (28%), Ménière's disease (11%) and congenital sensorineural hearing loss (9%). Etiology was unknown in 4%.

Skin reactions

The worst follow-up available per patient is shown in Table 2. In 15.2% of patients, the worst follow-up was Holgers grade 2 or more. Comparing the two surgical techniques, we observed no statistically significant differences in the amount of adverse skin reactions: 16.8% in the group with skin reduction versus 14.7% in the group without skin reduction, Hazard Ratio 0.583 (CI 0.222 – 1.527; $p = 0.272$) in the whole group of patients. No statically significant difference was observed between the 3 age groups (Hazard Ratio 0.576 (CI 0.219 – 1.517; $p = 0.264$). Holgers grade 2 or more was not preceded by a lower score. A Kaplan-Meier survival analysis studying the interval until an adverse skin reaction occurred, can be found in figure 1.

Skin overgrowth

In total, 4.2% of patients had skin overgrowth. There was no statistically significantly difference between the two surgical techniques (4.6% in the group with skin reduction versus 2.9% in the group without skin reduction, p = 0.548). No statically significant difference was observed between the 3 age groups (p = 0.807), with 4.0% in children, 4.8% in adults and 2.5% in the elderly.

Implant loss

Overall, 2.8% of the implants were lost spontaneously after a mean of 52 months (range 2-114 months): 8% in children, 2.3% in adults and 2.3% in the elderly. The difference between children and adults was not statistically significant (p = 0.153). The mean time to any adverse event in the overall population was 29 months; 31 months (range 2-114) in the group with skin reduction, 4 months (range 2-6) in the group without skin reduction (p = 0.000), which is statistically significant.

Prior surgery

We did not observe a statistically significant difference in adverse skin reactions if the patient already had a retroauricular incision before implantation (14.4% of patients with prior surgery in comparison with 17.8% without prior retroauricular incision, p = 0.301), such as after resection of a vestibular schwannoma or cholesteatoma. There was no statistically significant difference in skin overgrowth when patients had prior surgery (4.1% versus 4.5% in patients without prior surgery, p = 0.561). Implant loss occurred both in the groups with or without prior surgery (3.8% without versus 1.0% with prior incision, p = 0.156).

Revision surgery

Revision surgery was needed in 12.8% of overall cases, of which 14.3% in the group with skin reduction versus 2.6% in the group without skin reduction (p = 0.028). Revision surgery was performed after a mean of 40.5 months (range 2-126 months) after implantation. In most cases

(62%), revision surgery was performed to adjust the skin edges to the implant and resect necrotic skin. This type of surgery happens after a mean follow-up period of 35 months (range 2-126 months). Revision surgery that was performed to resolve skin overgrowth (19% of cases) occurs after a mean follow-up period of 63 months (range 18-96 months). Comparison of the timing of revision surgery was not statistically different between the group with skin problems or the groups with skin overgrowth ($p = 0.053$).

DISCUSSION

Over the past few years, techniques for percutaneous BCI placement have evolved. All techniques aim to further reduce adverse skin reactions and complications. Initially, surgical techniques aimed to reduce as much tissue as possible surrounding the abutment. More recently, the focus of surgery has evolved into avoiding tissue removal and introducing a longer abutment coated with hydroxyapatite (3-5, 7). In our department, we have used the linear incision technique with and without skin reduction for over 20 years. When comparing adverse skin reactions in both groups, we found no statistically significant differences in Holgers score. An overall percentage of 15.2% in adverse skin reactions is comparable with the results of another study of 185 patients with different surgical techniques (8), including a manual pedicled flap, with an overall percentage of 14.1% of adverse skin reactions. In our population, we did not observe a statistically significant difference in adverse skin reactions between age groups. This finding is in contrast to the study by Dun et al. (9) and Tzortzis et al. (10), that children are more prone to adverse skin reactions when compared to adults and the elderly. A similar study on adults by Husseman et al. (11) reported an adverse skin reaction rate of 14.7%.

Our data indicate that implant loss is observed more frequently in children. Our results are consistent with the findings of a meta-analysis where implant loss in children ranged up to 25% (12) compared with a percentage up to 17% in adults and mixed populations. Bodnia et al. (8) also found a trend toward more implant losses among children (18%), when comparing with adults (2.5%). Another study with a population of patients with an age of 60 years or older (13) shows implant loss in 6.5% of cases. Theoretically, implant loss can be the result of failed osseo-integration, which is observed more frequently in the elderly. The newer abutment with hydroxy-apatite coating can diminish this part of implant losses (14), which may be of importance for patients with thin or compromised bone. A study by Hultcrantz et al. (15) already demonstrated the reduction in duration of surgery to 10-15 minutes, which is important for organizational and financial aspects.

To our knowledge, there are no earlier studies investigating the influence of prior retroauricular surgery. By incising the skin of the retro-auricular region and loosen it from the bone, it is possible that the vascular supply is diminished and it makes the skin prone to more adverse reactions (16). Results of this study indicate that a retroauricular incision isn't worsening the outcome of the implant surgery by adverse skin reactions or implant loss. Revision surgery was needed in 12.8% of cases, comparable with 10% in a study by Singham et al. (17) and 12.8% in another study with 149 patients (18). They also noticed that skin overgrowth procedures are late complications. As stated in a study by Allis et al. (19), a longer abutment (8.5 mm, without hydroxyapatite coating) can diminish the amount of infections of the surrounding skin, skin overgrowth and the need for revision surgery. This can be an explanation why there is a trend to less revision surgery in the group without skin reduction, due to a better choice of abutment in this group.

A limitation of our study is the difference in mean follow-up time between the group with skin reduction (mean of 47 months follow-up time) and the group without skin reduction (mean of 6 months follow-up time), which can be explained because the technique without skin reduction is new and only used since 2012. Conclusions about long-term follow-up should be interpreted with caution. A larger population with longer follow-up time in the group without skin reduction is needed in further research.

CONCLUSION

We could not demonstrate a statistically significant difference in adverse skin reactions, implant loss or revision surgery when comparing the linear incision technique without skin reduction to the linear incision technique with skin reduction. Since both techniques demonstrate equivalent adverse skin reactions, we prefer the linear incision technique without skin reduction because it is easier to perform and less time-consuming.

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REFERENCES

1. Tjellstrom A, Hakansson B, Lindstrom J, Branemark PI, Hallen O, Rosenhall U, et al. Analysis of the mechanical impedance of bone-anchored hearing aids. Acta Otolaryngol 1980;89:85-92.

2. Vaneecloo FM, Ruzza I, Hanson JN, Gérard T, Dehaussy J, Cory M, et al. The monaural pseudo-stereophonic hearing aid (BAHA) in unilateral total deafness: a study of 29 patients. Rev Laryngol Otol Rhinol (Bord) 2001;122(5):343-50.

3. Stalfors J, Tjellstrom A. Skin reactions after BAHA surgery: a comparison between the U-graft technique and the BAHA dermatome. Otol Neurotol 2008;29(8):1109-1114.

4. Van Rompaey V, Claes G, Verstraeten N, van Dinther J, Zarowski A, Offeciers E. Skin reactions following BAHA surgery using the skin flap dermatome technique. Eur Arch Otorhinolaryngol 2011;268(3): 373-6.

5. Mylanus EA, Cremers CW. A one-stage surgical procedure for placement of percutaneous implants for the bone-anchored hearing aid. J Laryngol Otol 1994;108(12):1031-1035.

6. Holgers KM, Tjellström A, Bjursten LM, Erlandsson BE. Soft tissue reactions around percutaneous implants: a clinical study of soft tissue conditions around skin-penetrating titanium implants for bone-anchored hearing aids. Am J Otol 1988;9(1):56-9.

7. van de Berg R, Stokroos RJ, Hof JR, Chenault MN. Bone-anchored hearing aid: a comparison of surgical techniques. Otol Neurotol 2010;31(1):129-35.

8. Bodnia NC, Foghsgaard S, Moller MN, Caye-Thomasen P. Long-term results of 185 consecutive osseointegrated hearing device implantations. Otol Neurotol 2014;35:301-6.

9. Dun CA, Faber HT, de Wolf MJ, Mylanus EA, Cremers CW, Hol MK. Assessment of more than 1000 implanted percoutaneous bone conduction devices: skin reaction and implant survival. Otol Neurotol 2012;33:192-9.

10. Tzortzis S, Tzifa K, Tikka T, Worrollo S, Williams J, Reid AP, Proops D. A ten-year review of soft tissue reactions around percutaneous titanium implants for auricular prosthesis. Laryngoscope 2015;Feb 20 (in press).

11. Husseman J, Szudek J, Monksfield P, Power D, O'Leary S, Briggs R. Simplified bone-anchored hearing aid insertion using a linear incision without soft tissue reduction. J Laryngol Otol 2013;127 Suppl 2:S33-8.

12. Kiringoda R, Lustig LR. A meta-analysis of the complications associated with osseointegrated implants for bone conduction at 4 weeks. Otol Neurotol 2013;33:1578-82.

13. de Wolf MJ, Hol MK, Mylanus EA, Cremers CW. Bone-anchored hearing aid surgery in older adults: implant loss and skin reactions. Ann Otol Rhinol Laryngol 2009;118(7):525-31.

14. Dun CA, de Wolf MJ, Hol MK, Wigren S, Eeg-Olofsson M, Green K. Stability, survival, and tolerability of a novel baha implant system: six-month data from a multicenter clinical investigation. Otol Neurotol 2011;32(6):1001-7.

15. Hultcrantz M, Lanis A. A five-year follow-up on the osseointegration of bone-anchored hearing device implantation without tissue reduction. Otol Neurotol 2014;35(8):1480-5.

16. Jarabin J, Bere Z, Hartmann P, Tóth F, Kiss JG, Rovó L. Laser-Doppler microvascular measurements in the peri-implant areas of different osseointegrated bone conductor implant systems. Eur Arch Otorhinolaryngol 2014; Dec 12 (in press).

17. Singam S, Williams R, Saxby C, Houlihan FP. Percutaneous bone-anchored hearing implant surgery without soft-tissue reduction: up to 42 months of follow-up. Otol Neurotol 2014;35(9):1596-600.

18. House JW, Kutz JW. Bone-Anchored Hearing Aids: Incidence and Management of Postoperative Complications. Otol Neurotol 2007;28(2):213-7.

19. Allis TJ, Owen BD, Chen B, Jones DT, Moore GF. Longer length Baha™ abutments decrease wound complications and revision surgery. Laryngoscope 2014;124(4):989-92.

TABLES

Grade 0	No irritation
Grade 1	Slight redness
Grade 2	Red and slightly moist tissue
Grade 3	Red and moist; sometimes granulation tissue
Grade 4	Implant loss

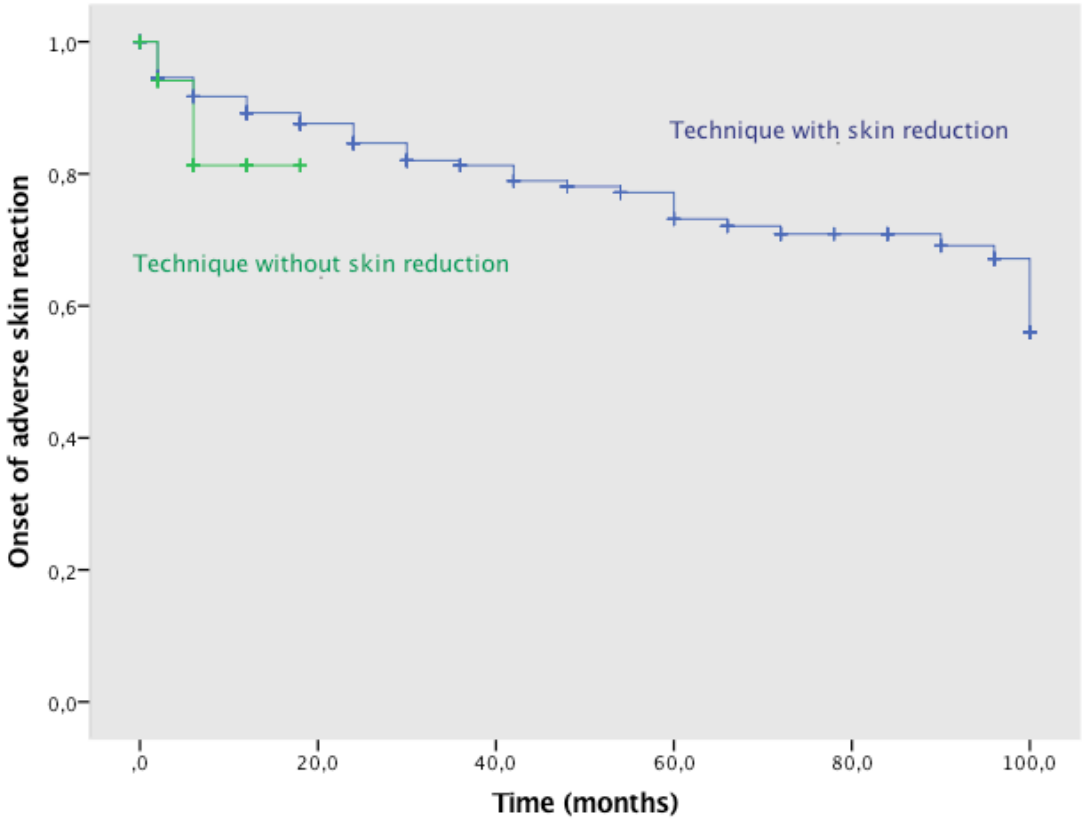
Table 1. Holgers scale (6)

	8-16y	**17-64y**	**65-91y**
Holgers grade 0	8	124	54
Holgers grade 1	4	23	9
Holgers grade 2	0	11	3
Holgers grade 3	2	20	8
Holgers grade 4	1	2	5

Table 2. Skin reactions per age group: worst follow-up available

FIGURE LEGENDS

Figure 1. Kaplan-Meier analysis shows no statistically significant difference between the two surgical techniques (Log Rank test, p = 0.256) when studying the interval until an adverse skin reaction occurred.



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