

Bone-Anchored Hearing Aid Implant Location in Relation to Skin Reactions

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Objective: To evaluate the effect of implant location and skin thickness on the frequency and degree of adverse skin reactions around the abutment.

Design: Retrospective multivariate analysis of implant position related to skin thickness and clinical variables.

Setting: Tertiary referral center.

Patients: Random sample of 248 patients with bone-anchored hearing aids.

Interventions: Bone-anchored hearing aid implant placement by means of the linear incision technique.

Mean Outcome Measures: Type and number of skin reactions and implant loss.

Results: The mean (SD) distance from the external auditory ear canal to implant was 48.8 (8.0) mm (range, 29-84 mm). The mean skin thickness was 5.5 (1.9) mm. Severe skin reactions (Holgers classification, 2-4) were seen in 46 of the 248 patients (18.5%). Implant loss occurred in 4 patients (1.6%). Three implants were lost owing to failed osseointegration (1.3%), and another implant was removed because of deterioration of cochlear function (0.9%). No implant was lost as a result of infection.

Conclusion: Implant location and skin thickness were not correlated with implant loss or the frequency or degree of adverse skin reactions around the abutment.

Arch Otolaryngol Head Neck Surg. 2009;135(8):742-747

BRÅNEMARK ET AL¹ FIRST DESCRIBED the principle of osseointegrated implantation in the dental region. On the basis of osseointegration between bone and titanium, a new hearing device was introduced, the bone-anchored hearing aid (BAHA).² Tjellström et al³ initiated the first clinical application of a BAHA device coupled to a skin-penetrating, bone-anchored titanium implant (anchored to the temporal bone of the skull). The implant in the skull enables sound vibrations to be transmitted to the cochlea via bone conduction. Since 1987, the BAHA system has been successfully introduced in many countries. In the Netherlands, the BAHA program was established at the University Medical Center in Nijmegen in 1988. In patients with conductive or mixed hearing loss, the BAHA has been a well-established treatment for over 25 years.^{4,5}

One of the main concerns in BAHA surgery is to achieve a stable implant with a

zone of reaction-free skin around the percutaneous abutment. It has been reported that movement of the tissue around the percutaneous implant it is a risk factor for skin reactions.⁶ Surgical thinning of the skin around the abutment reduces the chance of epithelial debris or crusts being trapped between the abutment and the skin and acting as foreign bodies.

Regular cleaning is the most effective way to prevent skin reactions. If skin reactions occur, they can usually be treated successfully with a medicated ointment. Skin reactions should be avoided because they can have a more serious outcome, such as skin overgrowth, implant extrusion, and severe wound infection.⁷⁻⁹ The probability of losing an implant as a result of adverse skin reactions is fairly low. However, if left untreated, a skin reaction may eventually lead to implant loss or withdrawal.¹⁰ Also, preexisting skin impairment, such as dermatoses, thick skin, previous radiotherapy, and poor hy-

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giene, can impair the clinical outcome.^{6,11,12} Other factors that might influence the long-term results are soft-tissue reduction during BAHA surgery and the implant location on the skull, which might also influence soft tissue in the long term. We evaluated the effect of the implant location and skin thickness on the frequency and degree of adverse skin reactions around the abutment.

METHODS

PATIENTS

Patients who were scheduled for their regular (yearly) follow-up visit to the BAHA outpatient clinic were invited to participate in the study. Inclusion criteria were age older than 17 years, implant using the Nijmegen linear incision technique, unilateral application, and at least 1 year of BAHA use. Patients with syndromic features and skull deformities were excluded. The patients were informed about the study, including the skin thickness measurement using a needle and the lateral skull radiograph. A random sample of 248 patients agreed to participate in the study. They had undergone implantation during the period of January 1, 1992, through December 31, 2006.

BAHA SURGERY

All the patients had received their BAHA using the Nijmegen linear incision technique. In general, the Nijmegen linear incision technique consists of a longitudinal incision approximately 3 cm long, 50 to 55 mm posterosuperiorly to the ear canal. After removal of the periosteum, the titanium implant was placed according to the 1-stage technique described by Tjellström and Granström.¹³ Subcutaneous tissue was reduced extensively over an area of approximately 2 cm around the incision. After wound closure, a pressure dressing provided hemostasis. The handling of the soft tissue is described by de Wolf et al¹⁴ and was not modified during the study period.

SKIN THICKNESS MEASUREMENTS

Skin thickness at the implant site was estimated by using a needle to penetrate the skin up to the bone on the contralateral side at the matching position (relative distance of the implant from the ipsilateral rim and pinna). The procedure was performed by 2 otolaryngologists (E.A.M.M. and M.K.S.H.). Measurements were recorded as the number of millimeters the needle penetrated the skin during the regular checkups.

IMPLANT POSITION

A standardized digital lateral conventional radiograph of the whole skull (Siemens, Erlangen, Germany), taken of the ipsilateral side of the implant, was used to determine the position of the implant on the skull. The side of the implant was always positioned nearest to the x-ray detector to avoid differences in the magnification factor. The distance from the upper center of the external auditory ear canal to the implant was measured using the ruler function in a radiological program, with the Frankfurter horizontal plane (FHP) as a baseline (adopted at the 1884 Craniometrical Conference in Frankfurt am Main, Germany, cited in 1958 by Moorrees and Kean¹⁵). It consists of a straight line between the most superior point on the upper margin of the external auditory ear canal and the most inferolateral point in the orbital cavity (**Figure 1**). The position of the

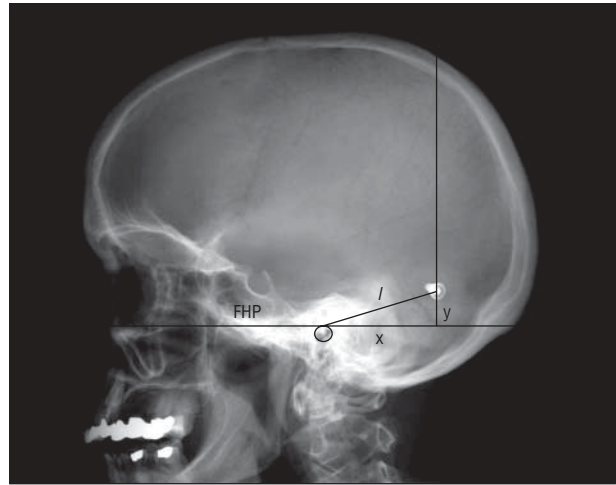


Figure 1. Frankfurt horizontal plane (FHP) coordinates of the implant (x- and y-coordinates) used to measure the distance from the upper center of the external auditory ear canal to the implant (l). x indicates the distance from the upper center of the external auditory ear canal (EAEC) to implant along the FHP; and y , the distance from the upper center of the EAEC to the implant vertically perpendicular to the FHP.

implant was recorded as x- and y-coordinates (horizontal and vertical, respectively) using the FHP as the x-axis.

CASE ANALYSIS

Data were retrieved from the medical records. These include age, sex, indication for a BAHA, surgical method, type of implant (3 or 4 mm), type of abutment (5.5 or 8.5 mm), type of tissue at the end of the drilled hole, implant loss, duration until loss, skin reactions (according to the classification published by Holgers et al,¹⁶ hereinafter Holgers classification), time of implantation, and duration of follow-up.

FOLLOW-UP

The tissue reactions around the abutment were evaluated according to the Holgers classification: grade 0, no reaction; grade 1, reddish discoloration of the skin around the implant; grade 2, red and moist surface of the skin around the implant; grade 3, formation of granulation tissue around the implant; and grade 4, extensive soft-tissue reaction that requires implant removal or leads to implant loss.¹⁶ The state of the skin around the implant was also observed. Thick skin around the implant was noted when it was level with the top of most of the abutment. At each follow-up visit, the implant stability was checked manually with a torque wrench. All these data were entered into the medical files by means of a standardized stamp. Initially, the patients attended the checkups at least once every 4 months. Later, the interval was prolonged to 6 months, and currently, once a year is the standard interval.

STATISTICAL ANALYSIS

Comparisons of categorical variables were made using multivariate correlation tests, 1-way analysis of variance, and independent sample t tests. Time-to-event analyses were conducted using Kaplan-Meier curves. The analyses controlled for age at surgery, sex, duration of follow-up, and tissue type at the end of the hole drilled for the abutment. SPSS software (version 16; SPSS Inc, Chicago, Illinois) and Prism Graph Pad 5 (GraphPad Software, La Jolla, California) were used to perform statistical analysis. The level of significance was set at $P = .05$.

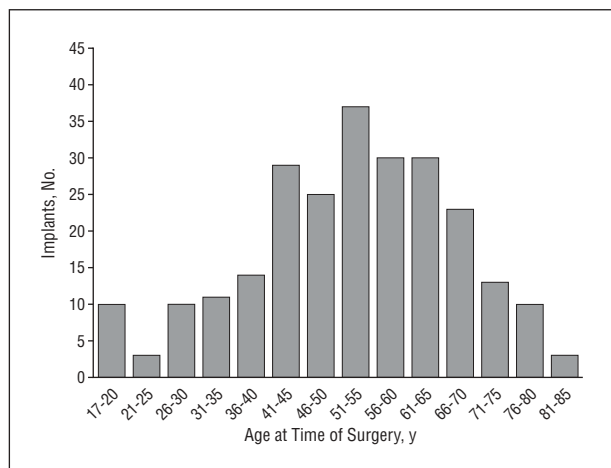


Figure 2. Age at time of surgery per implant (N=248 patients) and number of implants.

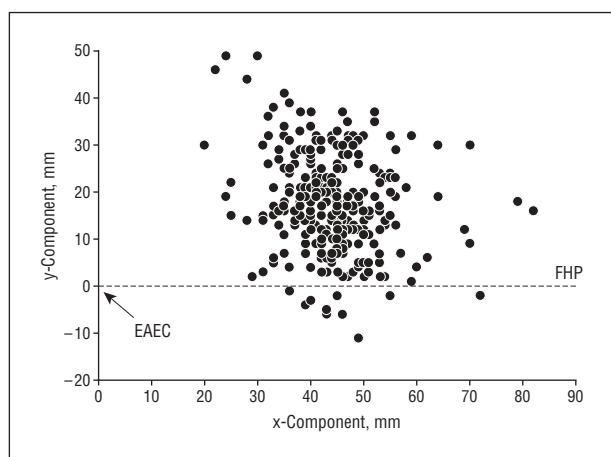


Figure 3. Scatterplot of the implant locations. The coordinates (0,0)=external auditory ear canal (EAEC); x=distance from the upper center of the EAEC to implant along the Frankfurt horizontal plane (FHP); y=the distance from the upper center of the EAEC to implant vertically perpendicular to the FHP.

RESULTS

DESCRIPTION OF POPULATION

Our population comprised 100 men and 148 women with a unilateral percutaneous titanium implant. The mean (SD) age at implantation was 52.5 (14.7) years. **Figure 2** shows the age distribution. Implants had been placed on the left side (n=128) and on the right side (n=120). Indications for BAHA fitting were bilateral acquired conductive or mixed hearing loss (n=209 patients [86.7%]), congenital conductive hearing loss (n=8 [3.8%]), and unilateral inner ear deafness (n=31 [12.5%]). The latter group comprised 30 cases of acoustic neurinoma and 1 case of intracranial rhabdomyoma. The etiology of the hearing loss in 1 patient (0.4%) was trauma. A total of 12 patients were classified as having mental retardation.

A 1-stage surgical procedure had been used to place 247 implants (99.6%). In 1 patient, the second stage (abutment placement and tissue reduction) was performed separately.

During surgery, the drilled hole had ended in bone in 213 cases (85.9%), at the dura mater in 21 cases (8.5%), and in the sinus in 8 cases (3.2%). Only 6 observations were missing (2.4%). All of the implants were 4 mm except for 1. In 2 cases, the length of the implant was not noted in the medical records. All the abutments were 5.5 mm except for 1. This patient did not report any adverse skin reactions or thick skin. The mean duration of follow-up was 67.7 (39.4) months (range, 12-215 months) with a mean of 7.4 (4.9) observations per implant.

IMPLANT LOCATION MEASUREMENTS ON THE LATERAL RADIOGRAPHS

The mean (SD) distance from the upper center of the external auditory ear canal to the implant was 48.8 (8.0) mm (range, 29.0-84.0 mm), the mean distance of the x-component was 44.8 (8.5) mm (range, 22.0-82.0 mm), and the mean distance of the y-component was 18.6 (10.6) mm (range, -13.0 to 48.0 mm). **Figure 3** shows a lateral representation of the scatter of implant positions.

In patients with congenital atresia (n=8), the mean distance of the y-component was 21.3 mm. Compared with the mean distance of the y-component in the other patients (18.5 mm) this was not a notable difference. Their x-component was 46.3 mm compared with the other patients, which was not clinically significant. The mean distance between the upper center of the external auditory ear canal and implant was 51.5 mm. This difference (0.3 mm) was not clinically significant compared with those of the other patients. The measurements in the patients with congenital atresia did not notably affect the distances in the total group of patients. In the patients who had undergone translabyrinthine schwannoma surgery, the x-component of the implant location did not differ from that in the patients who underwent "regular" BAHA surgery.

IMPLANT LOSS

A total of 4 of the 244 implants (1.6%) were lost: 3 owing to failed osseointegration (1.3%) and 1 that was removed owing to deterioration of cochlear function (0.9%). No implants were lost as a result of infection. Statistical analysis did not show any relationship between implant loss and the distance from the upper center of the ear canal to the implant, the mean distance of the x-component, and the y-component.

SKIN REACTIONS

Skin reactions were observed in 130 patients (52.4%): in 84 patients the most severe skin reaction was Holgers grade 1 (33.9%), in 32 patients this was Holgers grade 2 (12.9%), in 12 patients this was grade 3 (4.8%), and only 2 patients had a grade 4 skin reaction (0.8%). In this group, 46 patients (18.5%) had a skin reaction that required treatment (classified as Holgers grade 2-4). This type of reaction occurred only once in 33 of the 46 patients (71.7%) (**Table 1** and **Table 2**).

The mean intervals in months between implantation and the skin reactions were 42.5 months for grade 1, 37.8

Table 1. Clinical Data on Skin Reactions and Revision Surgery

Scale (Skin Reaction)	No. (%)	
	Distribution per Observation	Most Severe Skin Reaction per Implant
0 (No irritation)	1505 (84.7)	118 (47.6)
1 (Slight redness)	206 (11.6)	84 (33.9)
2 (Red and moist tissue)	52 (2.9)	32 (12.9)
3 (Granulation tissue)	12 (0.7)	12 (4.8)
4 (Infection leading to removal of abutment)	2 (0.1)	2 (0.8)
Total	1777 (100)	248 (100)

^aAccording to the scale described by Holgers et al.¹⁶

months grade 2, 37.8 months for grade 3, and 76.5 months for grade 4 (**Table 3**). The mean interval until the first skin reaction, irrespective of the grade, was 24.3 months (range, 0-129 months).

The distance from the upper center of the external auditory ear canal to the implant was not correlated with Holgers grade 1 to 4 skin reactions or the total number of skin reactions. Furthermore, there was no correlation between skin reactions or implant loss and the x- and y-components of the distance from the upper center of the ear canal to the implant.

SKIN THICKNESS, MEASUREMENTS, OBSERVATIONS, AND REVISION SURGERY

In 204 patients (82.3%), skin thickness was measured on the side contralateral to the percutaneous implant. Skin thickness varied from 2.0 to 11.0 mm, with a mean (SD) thickness of 5.5 (1.9) mm. Analyses did not show any statistically significant correlations between skin thickness and implant loss ($P = .58$), or skin reactions of Holgers grades 1 and 2 ($P = .48$ and $.65$, respectively; there were too few cases of Holgers skin reactions of grades 3 and 4 for statistical comparison), or with the total number of skin reactions ($P = .39$). There was no significant correlation between skin thickness and the vertical component (y) ($P = .57$). However, skin thickness was significantly correlated with the horizontal component (x) (0.2 mm; $P < .002$) and the mean distance from the implant to the ear canal (0.2 mm; $P < .001$).

Next to the measurements of the thickness of the skin at the contralateral side to the implant, the state of the skin level around the abutment was recorded during follow-up in 192 patients. Thick skin, that is, skin reaching to the top of the 5.5-mm abutment, had been noted in 81 patients (42.2%), with a mean rate of 2.4 observations (range, 1-12 observations). Only 40 patients (16.1%) had 1 single observation of thick skin. The latter once-only events accounted for 49.4% of all the observations of thick skin. The mean (SD) interval until the first observation of thick skin was 47.0 (33.6) months. In most of the cases, the thick skin was treated successfully with antibacterial and steroid ointment or watchful waiting.

Tissue reduction surgery was performed on 23 implants (9.4%) at a mean period of 34 months after im-

Table 2. Frequency of Skin Reaction and Most Severe Skin Reaction Around the Implant

Frequency of Skin Reactions Follow-up, No.	No. (%)	
	Total Adverse Skin Reactions per Implant	Total Skin Reactions Rated as 2-4 per Implant ^a
0	118 (47.6)	202 (81.5)
1	68 (27.4)	33 (13.3)
2	27 (10.9)	9 (3.6)
3	15 (6.1)	2 (0.8)
4	7 (2.8)	2 (0.8)
5	7 (2.8)	0
6	2 (0.8)	0
7	4 (1.6)	0
Total	248 (100)	248 (100)

^aAccording to the scale developed by Holgers et al.¹⁶

Table 3. Interval Between Implantation and Skin Reaction

Time to Skin Reaction Type, mo	Implants		
	No.	Range	Mean (SD)
1	111	0-179	42.5 (34.0)
2	37	0-119	37.8 (35.5)
3	12	1-127	37.8 (39.8)
4	2	48-105	76.5 (40.3)

plantation (range, 4-119 months) when thick skin persisted. One patient required 1 subsequent tissue reduction surgery.

COMMENT

We evaluated the effect of the implant location and skin thickness on the frequency and severity of skin reactions around the abutment. To evaluate this correlation, the position of the implant (the mean distance from external auditory ear canal to the implant) was measured (48.3 mm). This corresponds with the ideal site according to the Nijmegen BAHA surgical procedure because it leaves enough space to accommodate the BAHA transducer behind the auricle.¹⁴ No correlation could be found between implant location and the frequency and severity of skin reactions in this study.

To our knowledge, no previous studies have investigated a possible correlation between implant location and skin reactions. Eeg-Olofsson et al,¹⁷ however, described the position of the implant in relation to the external auditory ear canal. Their study was set up to determine the extent to which bone dampened sound transmission to the cochlea. They found that moving the vibrating stimulus closer to the cochlea increased the velocity at the cochlear promontory. Combined with the results of our study, the ideal implant site in terms of optimal sound transmission and low incidence of skin reactions would be as close to the cochlea as possible.

It should be noted that skull dimensions can vary among individuals. Skull dimensions also change with

advancing age (eg, progressive decrease in the height of the neurocranium).^{18,19} Patil and Mody²⁰ described significant differences in 10 cephalometric dimensions between men and women. In the current study, we adjusted the statistical analyses for sex and age to address the differences in skull dimensions.

In BAHA surgery, special attention must be given to the handling of the soft tissue in order to obtain thin hairless skin with optimal reduction of mobility. The soft-tissue reduction technique used results in a gentle slope of the soft tissue in an area of approximately 15 to 20 cm² around the percutaneous implant, depending on the length of the incision. At the basis of the abutment, postoperatively the skin thickness varies from approximately 1 to 1.5 mm. Unfortunately, because skin thickness measurements at the implant location were not performed in a structural manner, a prospective analysis was not possible.

Implant loss is one of the major clinical outcome measures in BAHA surgery. In our study, the total implant loss was 1.6% (4 of the 248 implants). Recent studies by the Nijmegen BAHA team reported a 9.3% implant loss (14 of 150 implants) in a consecutive series of 142 patients who had undergone BAHA surgery and in 6.5% (14 of 248 implants) in 224 elderly patients who had undergone BAHA surgery.^{14,21} In the literature, implant loss caused by failed osseointegration ranged from 0.4% to 7%, whereas loss caused by infection ranged from 0.4% to 2.7%.^{5,7,9,10,22,23} The mean (SD) duration of follow-up in the current study was 78.4 (48.3) months (range, 12-220 months) compared with a range of 6 to 141 months in the literature.^{5,7,10,22} Rates of implant loss in these Nijmegen series are substantially lower than those described in literature.

An explanation for the differences in implant loss might lie partly in the exclusion of children from this study. Compared with the adult skull, the infant skull is less thick and has less mineral content and more water content. This is believed to be one of the causes of the higher risk of failed osseointegration in the younger population.⁷ In the study by Proops,²² implant loss occurred in 19 of 188 patients (10.1%); 10 of these 19 (52.6%) occurred in children. In the Nijmegen consecutive series of children,²⁴ implant loss in children also accounted for a relatively large part of the percentage. Overall implant loss in the Nijmegen series²⁴ was 16.3% (21 of 129).

Another major clinical outcome measure in the follow-up after BAHA surgery is skin reactions. Our data showed that 46 of the 248 patients (18.5%) had a severe skin reaction (Holgers grade, 2-4) at least once during follow-up. In this group of patients, 33 (71.7%) had a severe skin reaction only once. The rates of severe skin reactions in the current study conform with those in the literature (3.4%-39.6%).^{5,10,16,25-27} These data are also in line with those of previous studies performed within the BAHA program at the University Medical Centre. de Wolf et al¹⁴ found an incidence of 26.7% (40 of 150) in a consecutive series of patients with BAHA implants.

Besides implant location, another potentially relevant variable is skin thickness. Measurements found in this study varied from 2.0 to 11.0 mm, with a mean (SD) thickness of 5.5 (1.9) mm. No correlations were found

between skin thickness and implant loss, Holgers grade 1 to 4 skin reactions, the y-component, or the total number of skin reactions. Measurements of the skin thickness were taken on the side contralateral to the implant. Skin thickness was significantly positively correlated with the x-component and the distance between the implant and the ear canal (0.22 mm, $P < .002$; and 0.24 mm, $P < .001$, respectively). Thus, the greater the distance between the implant and the ear canal, the thicker the skin. The procedure used for skin thickness measurements was based on the assumption that the skin is of equal thickness on both sides.

In conclusion, no correlations were found between the distance from the superior part of the external auditory ear canal to the implant nor between the horizontal and vertical positions of the implant and the type and number of skin reactions. Skin thickness measured on the contralateral side was not correlated with the type and number of skin reactions. Comparatively, implant loss was not correlated with the distance from the superior part of the upper center of the external auditory ear canal to the implant, the position of the implant, or skin thickness.

Submitted for Publication: December 15, 2008; final revision received January 30, 2009; accepted March 2, 2009.

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Author Contributions: Mr Faber and Dr de Wolf contributed equally to this study. All of the authors had full access to all the data in the study and take responsibility for the integrity and the accuracy of the data analysis. *Study concept and design:* Faber, de Wolf, de Rooy, Hol, Cremers, and Mylanus. *Acquisition of data:* Faber, de Wolf, Hol, and Mylanus. *Analysis and interpretation of data:* Faber, de Wolf, Cremers, and Mylanus. *Drafting of the manuscript:* Faber, and Mylanus. *Critical revision of the manuscript for important intellectual content:* de Wolf, de Rooy, Hol, Cremers, and Mylanus. *Statistical analysis:* Faber and Mylanus. *Administrative, technical, and material support:* de Wolf and Mylanus. *Study supervision:* de Wolf, de Rooy, Hol, Cremers, and Mylanus.

Financial Disclosure: None reported.

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