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Clinical Outcome of a Wide-diameter Bone-anchored Hearing Implant and a Surgical Technique With Tissue Preservation

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Objective: To investigate the clinical outcome of a surgical technique with tissue preservation for a wide bone-anchored hearing implant concerning postoperative complications, skin reactions, implant loss, and implant stability.

Study Design: Consecutive, prospective case series.

Setting: Tertiary referral center.

Patients: Twenty-four adult patients with normal skin quality were enrolled.

Intervention(s): Implantation of bone-anchored implant was performed using a one-stage linear-incision technique with tissue preservation surgery.

Main Outcome Measures(s): Skin and soft tissue reactions according to Holgers grading system. Pain and numbness measured according to visual analogue scale. Implant stability quotient values were recorded using resonance frequency analysis. Follow-up at 10 days, 6 weeks, 6 months, and 1 year after surgery.

Results: Primary implant stability was good and a significant increase in implant stability quotient occurred during the first 10 days and continued to be stable throughout the 1-year observation period. No implants were lost. Skin and soft tissue reactions were few, no reaction (Holger grade 0) was observed in 88% of the follow-up examinations and no grade 4 reactions occurred. Pain and numbness were minimal.

Conclusion: The wide implant showed good stability initially and throughout the observation period. Skin and soft tissue reactions were rare and minor. No implants were lost. **Key Words:** Bone-anchored hearing systems—Holgers grading system—Implant stability quotient—Osseointegration—Resonance frequency analysis—Skin reactions—Tissue preservation surgery—Wide-implant.

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Bone-anchored hearing implant surgery was introduced in 1977 by Tjellström et al. (1). Over 30 years later more than 150,000 implantations have been made. The principle of bone-anchored hearing system (BAHS) is that sound vibrations are led directly to the inner ear via the mastoid bone, hereby bypassing the middle ear. This is achieved by an osseointegrated implant and a skin-penetrating abutment, which is coupled with a sound processor.

Traditionally, the surgical technique for installing BAHS includes thinning of the skin, or more precisely removal of dermal and subcutaneous tissue, hair follicles and musculature, surrounding the abutment. The aim of this technique is to achieve a thin hairless skin that is well fixated to underlying periosteum to hinder skin movement

around the abutment and to facilitate cleaning. The most common forms of soft tissue reduction techniques in use are the pedicle skin flap, Dermatome and linear techniques. In recent years, promising results with modified surgical techniques with tissue preservation have been presented (2–8). This minimally invasive technique has several benefits compared with more traditional surgical techniques. It is fast, can lead to less numbness and post-operative pain, and no increase in soft tissue reactions compared with techniques with skin thinning (2,9).

Recently, implants with wider diameter have been introduced. The diameter has increased from 3.75 to 4.5 mm (Fig. 1). This provides larger initial surface-to-bone contact, leading to higher stability, and thereby the possibility of loading the implant with the hearing aid at an early time point after surgery. Successful, early loading has been shown in several studies (8,10–13). The broader implant also allows for longer abutment (12 mm), which is important when new surgical techniques without subcutaneous thinning are performed (2). The longer abutments can increase the force transferred to the fixture with higher demand on osseointegration and stability.

The objective of this study was to assess skin reactions and implant stability with the use of the 4.5-mm Wide

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Wide Ponto Implant

Ponto Implant

FIG. 1. The Wide Ponto Implant ($\varnothing$ 4.5 mm) has 72% more initial contact surface than the previous model ($\varnothing$ 3.75 mm).

Ponto Implant from Oticon Medical and a surgical technique with tissue preservation.

METHODS

The study is a consecutive, prospective case series of patients operated at our tertiary referral center (Copenhagen University Hospital, Rigshospitalet).

The patients were operated from January 18, 2013 to March 19, 2014. To be included in the study, the patients had to be at least 18 years and eligible for bone conduction implant surgery. Prespecified exclusion criteria were skin disease in the operation area and inability to participate in follow-up.

Twenty-four patients were enrolled. The study was reviewed by the regional ethical committee (H-4-2013-FSP).

Intervention

All patients were operated by either of the two senior authors on an outpatient basis using local anesthesia. A thin needle and a ruler were used before local anesthesia to measure skin thickness.

Surgical technique used was minimally invasive using a one-stage linear-incision technique without removal of subcutaneous tissue (2,14). Skin incision was approximately 4-cm long and to the periosteum, which was removed using a raspatory. A hole was drilled and widened with a 3.8-mm-diameter countersink. The implant was placed in a single stage with application of 50-Ncm torque. The incision was sutured in the epidermal layer only and a separate hole was made with a biopsy punch 0.5 to 1 cm from the incision line, allowing the abutment to penetrate the skin. Finally, the implant stability quotient (ISQ) was measured.

Implant

The implant used was a Wide Ponto Implant (diameter, 4.5 mm; length, 4 mm). The implant has a greater diameter (4.5 mm versus 3.75 mm) and a different cutting geometry and threading when compared with the previous generation model. Depending on skin thickness, abutments of lengths 6, 9, and 12 mm were used. The implant is equipped with a traditional Brånemark-type machined titanium implant surface, and the abutments are titanium abutments without coating.

Postoperative Care and Fitting

A healing cap was fixed to the abutment and gauze imbibed with antibiotic-steroid ointment (hydrocortisone 10 mg/g with oxytetracycline 30 mg/g) circulated around the abutment, under

the cap. A pressure head dressing was applied overnight to prevent hematoma. The healing cap and gauze were removed after approximately 10 days. The sound processor was fitted from approximately 6 weeks after surgery.

Prospective Follow-up Examinations

Follow-up was performed after 10 days, 6 weeks, 6 months, and 12 months. Implant stability and soft tissue reactions, numbness, and pain around the abutment were registered at all the above scheduled visits. Skin reactions were classified according to Holgers grading system (15).

Implant stability was measured using resonance frequency analysis (RFA) obtained by Osstell ISQ (Osstell, Göteborg, Sweden). This is a portable, handheld instrument that includes the use of a magnetic SmartPeg (Osstell) attached to the abutment. The resonance frequency is calculated from the response signal and the result is displayed as ISQ, which is scaled from 1 to 100. The greater the number, the greater the stability.

The measurements were performed manually in two perpendicular directions, which result in two different ISQ values: ISQ high and ISQ low. The same SmartPeg was used on the individual patient throughout the study to minimize the measurement variability. The Osstell ISQ instrument has an accuracy of ± 2 ISQ points.

Statistics

For comparisons over time, the Wilcoxon signed rank test was used for continuous variables. A significance level of 0.05 was adopted.

RESULTS

The baseline patient characteristics and implants used are represented in Table 1. The most common reason for implantation was conductive or mixed hearing loss and single-sided deafness. Two patients were previously irradiated, one patient had diabetes and two patients

TABLE 1. Baseline characteristics of the study population ($n = 24$)

Parameter	Proportion
Sex	58% woman 42% man
Age, mean (range)	59.2 yr (27–75)
Indication for BAHİ	Acquired cond/mixed hearing loss: 54% ($n = 13$) Single-sided deafness (SSD): 46% ($n = 11$) Congenital cond/mixed hearing loss: 0%
Smokers	13% ($n = 3$)
Relevant diseases/treatments	Irradiated: 8% ($n = 2$) Diabetes: 4% ($n = 1$) Chronic steroid use: 8% ($n = 2$) Other conditions known to compromise the bone: 0%
BMI, mean (range)	25.9 (17.9–37.2)
Implant length	3 mm: 0% 4 mm: 100% ($n = 24$)
Abutment length	6 mm: 8% ($n = 2$) 9 mm: 79% ($n = 19$) 12 mm: 13% ($n = 3$)

BAHİ indicates bone-anchored hearing implant.

TABLE 2. Skin reactions (Holgers grading system) at follow-up

Visits (days after surgery)	10	42	180	365	Unplanned visits
Total number analyzed	20	22	24	22	2
Holgers grade					
0 (no irritation)	19 (95%)	20 (90.9%)	20 (83.3%)	20 (90.9%)	0
1 (slight redness)	1 (5%)	0	2 (8.3%)	1 (4.5%)	0
2 (red and slightly moist tissue)	0	1 (4.5%)	1 (4.2%)	1 (4.5%)	1
3 (reddish and moist, granulation tissue)	0	1 (4.5%)	1 (4.2%)	0	1
4 (infection requiring removal of abutment or implant)	0	0	0	0	0

Numbers in parentheses are percentages of the total number analyzed.

received per oral steroid treatment, because of Mb, Addison, and nasal polyposis, respectively. The most common used abutment length was 9 mm (19 patients). All of these patients had skin thickness between 5 and 6 mm, except one (skin thickness 7 mm). The abutment length was changed from 9 to 12 mm in this patient because of contact between the processor and the skin. Three patients received 12-mm abutments because of thick subcutaneous tissue, and these had skin thickness of 8, 8, and 9 mm respectively.

There was no major surgical complication, but in one patient a minor bleeding occurred because of drilling into a vein. Surgery time was on average 22.5 (range, 13–30) minutes.

Loading of the implant with the sound processor was done on average after 8.3 weeks (range, 4.0–14.6 wk) after operation (n = 24).

Distributions of skin reactions according to Holgers grading system are summarized in Table 2. The total number of follow-up visits was 90, hereby 88 planned visits and 2 unplanned because of infection. Eight patients missed one follow-up visit and 91.7% of the study group attended the rest of their scheduled follow-up visits. In 87.8% of the visits, there was no skin irritation (Holgers grade 0). Four patients had adverse skin reactions (Holgers ≥ 2) corresponding to 14% of the patients. In general, these complications were treated successfully with local antibiotics, and granulation tissue was removed with lapis 50%. One patient had three adverse skin reaction (Holgers ≥ 2) at three out of six follow-ups. This was treated as mentioned above, though supplemented with systemic antibiotics as well. This patient had comorbidity in the form of Waldenströms macroglobulinemia, which may affect the blood circulation because of hyperviscosity of the blood. No infections that required removal of implant or abutment were observed (Holgers grade 4).

Results for numbness and pain at follow-up are presented in Table 3. Grading of pain and numbness around the implant is achieved by visual analogue scale (VAS). The scale is from 0 to 10. Zero is no pain and no numbness respectively, and 10 is worst possible, unbearable pain and numbness, respectively. This 10-point scale was converted to a 4-point scale for more convenient and reader-friendly publishing; none (VAS 0) limited (VAS 1–3), moderate (VAS 4–7), and extensive (VAS 8–10).

As illustrated in the table, there were few complaints of pain and numbness at follow-up.

The total number analyzed differs in Tables 2 and 3. Unfortunately, there were a few patients who were not registered according to pain and numbness at follow-up.

ISQ high and ISQ low for the different abutment lengths are presented in Figure 2A and B, respectively. The patient who changed abutment was excluded from both figures. There is a significant increase in mean ISQ high and mean ISQ low the first 10 days after surgery, and this continues after loading of the implants and at 6 months and 1 year after surgery ($p = <0.0001$). No implants were lost. ISQ was registered in total 111 of possible 120 registrations. Eight of these missed registrations were because the patient did not show up, and one was because of oversight.

DISCUSSION

The main objective of this study was to monitor the clinical outcome of a wide-diameter bone-anchored hearing implant (BAHI) and tissue preservation surgery. This surgical technique was first discussed in 2009 (16,17) and

TABLE 3. Distribution of pain and numbness at follow-up

Visit (days)	10	42	180	365
Total number analyzed	18	20	22	23
Pain				
None	15 (83.3%)	18 (90.0%)	18 (81.8%)	23 (100%)
Limited (VAS 1–3)	3 (16.7%)	2 (10%)	3 (13.6%)	0
Moderate (VAS 4–7)	0	0	1 (4.5%)	0
Extensive (VAS 8–10)	0	0	0	0
Total number analyzed	18	20	22	22
Numbness score				
None	18 (100%)	18 (90%)	22 (100%)	22 (100%)
Limited (VAS 1–3)	0	2 (10%)	0	0
Moderate (VAS 4–7)	0	0	0	0
Extensive (VAS 8–10)	0	0	0	0

Numbers in parentheses are percentages of the total number analyzed.

FIG. 2. A, ISQ high for individual patients and mean interindividual ISQ high for patients with 6-mm abutment (bold, dotted line; $n=2$), 9-mm-long abutment (bold, dashed line; $n=19$) and 12-mm-long abutment (bold, large dashed line; $n=3$). Bold solid line represents mean ISQ high across all abutment lengths. B, ISQ low for individual patients and mean interindividual ISQ low for patients with 6-mm abutment (bold, dotted line; $n=2$), 9-mm-long abutment (bold, dashed line; $n=19$), and 12-mm-long abutment (bold, large dashed line; $n=3$). Bold solid line represents mean ISQ low across all abutment lengths. ISQ indicates implant stability quotient.

several studies are showing promising results (2–8). This surgical procedure is quick, can be performed under local anesthesia, and gives good cosmetic results with no bald spot around the abutment and less scar tissue (18) (Fig. 3). In addition, several studies have shown less postoperative pain, shorter healing time, and less numbness around the abutment compared with more traditional surgical techniques with soft tissue reduction (2,7,9).

Over the past few years several new transcutaneous BAHÍ have been introduced to the market. These are either passive or active components, which are completely covered by skin. Hence there is no skin-penetrating coupling. Instead of a skin-penetrating coupling, these transcutaneous devices use magnetic coupling between the implant and the sound processor. Advantages of this system are that it may reduce the risk of

FIG. 3. Implant/abutment 6 months after surgery showing good cosmetic result.

infection, that it has good postoperative cosmetic results, and that it reduces the necessity of cleaning around the coupling. The latter is especially an interesting alternative with patients who for medical or other reasons have difficulties with cleaning routines (19). Disadvantages with this system compared with percutaneous BAHÍ can be temporary pain around the implant because of a powerful magnet. In several studies however, the pain disappeared when a magnet with less strength was chosen (19,20). Furthermore, the risk of accidentally loosening the external device is higher with magnetic coupling compared with a skin-penetrating coupling. In addition, some studies have shown better hearing thresholds for the percutaneous solution with direct coupling compared with the transcutaneous devices, especially in the high frequencies (20). This is because of soft tissue attenuation and energy loss in the intervening skin layer (19).

The ISQ value represents the resonance frequency of the mechanical arrangement fixated in the bone. Despite its use in research for over a decade, RFA is more a tool for clinical studies and implant research, rather than of clinical and therapeutic importance. There is, for example, no specific ISQ value that has been documented as an acceptance value for loading the implant (21). Loading of the implant is not only depending of ISQ alone, but also bone quality and postoperative wound healing. Nevertheless, ISQ value is very useful following the stability of one specific implant over time (22). On the other hand, it is difficult to compare absolute ISQ measurements between studies, because of different reporting standards. Recently, practical

recommendations regarding RFA in scientific clinical studies were published (22).

Several factors influence ISQ, for example, bone quality, design of transducer (i.e., SmartPeg), and the length of implants and abutments. A well-integrated implant in a soft bone can give lower ISQ than an insufficiently integrated implant in a hard bone (23). Comparing the present wide implant stability directly with older more narrow ones is difficult since the SmartPeg for testing ISQ does not fit the older abutments (18). Nevertheless, ISQ in the earlier narrow version (3.75 mm) has shown statistically significant lower values than the present Wide Ponto Implant (13). Furthermore, the use of a wider implant has several advantages. The larger diameter of this wide implant increases initial bone-to-implant contact surface. This is increased by 72% compared with previous narrow versions (3.75 mm) and by 10% compared with other wide implants on the market (also 4.5 mm) (18,24). The larger radius of the implant and increased surface area improve stability (10,25). Second, the Wide Ponto Implant allows smaller drilling hole (3.8 mm versus 4.0 mm for the other available implants), thus reducing the surgical trauma. This is because of a new cutting geometry of the threaded area.

Basic studies in the laboratory with the same implant but different abutment lengths give an estimation of stability loss of 3 to 4 ISQ for each millimeter of longer abutment (23). This was also the case in the present study. Both mean high and low ISQ values are clearly lower in the longer abutments. The average data for the 6- and 12-mm abutment length are only based on two and three patients respectively, and should be interpreted with caution.

After loading of the implant on average 8.3 weeks after surgery we did not observe a fall in ISQ. With the initially high ISQ, and quick wound healing, earlier loading seems feasible. Successful, early loading of wide implants has been documented in several studies where loading was performed after 2, 3, and 4 weeks (8,11,12), as well as 3 weeks with the previous 3.75-mm implant (13). We registered a significant increase in ISQ throughout the 1-year follow-up period and the values remained above baseline values. This is also shown in other studies of wide implants (10,11,13,18,26).

In this study four patients (14%) had Holgers ≥ 2 . This is consistent with previously presented material with the same surgical technique without soft tissue reduction (2,3,20). On the other hand, there are several studies showing no difference regarding frequency of infections when comparing surgical techniques with or without soft tissue reduction, respectively (2,9).

The most common complication in BAHS surgery is soft tissue reactions around the skin-penetrating coupling. The majority of skin inflammation and infection are grade 1 reactions, and can be treated locally with topical treatment. No revision surgery was performed within the 1-year follow-up, and a single abutment change was made to a longer abutment. No other soft-

tissue-related complications that have been reported for tissue reduction techniques, such as skin overgrowth or skin necrosis, were encountered. In our group, the only soft-tissue-related complications were Holgers scores, which were all successfully treated. At the 12-month visit, two patients experienced a skin reaction corresponding to Holgers grades 1 and 2 respectively.

Pain and numbness were a subjective evaluation made by the patient and hence subject to a substantial degree of variability. Nevertheless, it is worth taking notice that there were only very few reports of numbness and pain related to the surgical procedure. At the end of the study (12-month follow-up), no patient reported either numbness or pain around the implant. In similar, several studies have shown less pain and numbness around the implant after tissue preservation surgery compared with other surgical techniques with soft tissue reduction (2,4,9).

Limitations of this study were the small number of patients and no control group for comparison.

CONCLUSION

The present prospective, 1-year follow-up study, concerning a wide BAH in combination with a surgical technique with tissue preservation, reveals ISQ values with good stability as a sign for good osseointegration and no decrease in ISQ after implant loading. In addition, we observed few skin reactions, minimal pain, and numbness. We believe that linear incision with tissue preservation technique is a simple, safe, and reliable method and should be taken into consideration when assessing the patient in the need for bone conductive hearing aid.

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