Bone anchored hearing implant surgery with tissue preservation – A systematic literature review

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Objective: To summarize the peer-reviewed literature on bone anchored implant surgery with limited or no skin thinning, and compare complication rates from these procedures with published data on traditional techniques involving soft tissue reduction around the implant.
Methods: A systematic literature review was performed by searching PubMed. The search strategy aimed to find all peer-reviewed articles discussing clinical outcomes of the installation of percutaneous bone anchored hearing implants with limited or no soft tissue reduction. In total, the search resulted in 251 papers.
Results: After excluding articles not adhering to the inclusion criteria, eight papers were left for review. The total number of implants installed with tissue preservation techniques in these articles was 147.
Conclusion: Based on this systematic review, we conclude that tissue preservation techniques are a safe way to install percutaneous bone anchored hearing aid implants with titanium abutments. Complication rates are as low or lower compared to the traditional skin thinning methods. In addition, several other important patient improvements, such as less peri-abutment numbness, better cosmetic outcome, and shorter surgery time have been identified. Importantly, no new intra- or post-operative risk factors or complications were indentified or reported.

INTRODUCTION

In 2009, implantation of percutaneous bone anchored hearing implants without the traditional skin thinning was discussed for the first time at a scientific conference. The first clinical results were published by Hultcrantz in 2011. Since then, surgery with tissue preservation has rapidly gained popularity among surgeons. The early results were very promising, and recently a five-year follow-up study on the first patients undergoing this surgery was published. Several other reports discussing the details of the procedure as well as patient outcomes have also recently been published.

Traditionally, the surgical procedure for installing a bone anchored hearing implant included thinning of the skin surrounding the abutment. This step in the process has its origins in the belief that minimizing the relative movement between the surrounding skin and the percutaneous post was necessary (von Recum & Park, 1981; Brånemark & Albrektsson, 1982) and that reducing the subdermal tissue – leaving only epidermis, dermis, and the periosteum in contact with the abutment – was the ideal way to obtain this result.

However, reducing the skin thickness is associated with its own set of adverse outcomes, including infection, hair loss, and scarring. Also, the natural immune host defense is diminished since much of the soft tissue is removed.

A recent meta-analysis of 2,310 device installations provides the best overview of outcomes with this traditional approach (Kiringoda & Lustig, 2013). The authors excluded procedures that used minimal tissue thinning and the longer abutments now available. In this paper, the reported incidence of skin reactions (Holgers grade ≥2, Holgers et al., 1988) in adults was 2.4% to 38.1%. The reported incidence of peri-implant infection was 1.0% to 50.0%, and incidence of soft tissue overgrowth of the abutment was 9.5% to 28.6%.

Researchers have recently been documenting favorable results for bone anchored hearing implants installed without skin-thickness reduction. This technique was first discussed at the Second International Symposium on Bone Conduction Hearing – Craniofacial Osseointegration (OSSEO) meeting in Gothenburg (Hultcrantz, 2009; Soo, 2009). This paper will provide a systematic literature review of subsequently published studies on surgical approaches for installing bone anchored hearing systems that preserve the soft tissue.

METHOD

To evaluate the clinical safety and efficacy of installing percutaneous bone anchored hearing implants with minimal or no soft tissue reduction around the abutment, a search in the database of the National Library of Medicine (http://www.ncbi. nlm.nih.gov) up to November 1, 2013, was carried out. Publications in any language were considered, and non-English publications were translated by an authorized professional translator.

The search strategy applied was: (((bone-anchored hearing aid[All Fields] OR bone-anchored hearing aids[All Fields] OR bone anchored hearing aid[All Fields] OR bone anchored hearing aids[All Fields] OR bone-anchored hearing aid system[All Fields] OR bone anchored hearing aid system[All Fields] OR baha[All Fields] OR bone anchored hearing system[All Fields] OR bahs[All Fields])OR((“Prostheses and Implants”[Mesh] OR “implant” [All Fields] OR “implants” [All Fields] OR “Medical device”[All Fields] OR “biomaterial”[All Fields] OR “biomaterials”[All Fields] OR “device”[All Fields]) AND (“osseointegration”[MeSH Terms] OR “osseointegration”[All Fields] OR osseointegrated[All Fields]) AND(“hearing”[MeSH Terms] OR “hearing”[All Fields] OR hearing aid)))) AND (Skin OR skin thinning OR tissue preservation OR soft tissue). Furthermore, a manual search in the Oticon Medical company database was performed and the reference lists of publications selected for inclusion in this review were systematically screened.

Inclusion criteria were defined as:

- evaluation of the placement of percutaneous osseointegrated hearing implants with minimal or no soft tissue reduction;
- articles published in any language since 1945 that described clinical investigations of any design or methodology;
- adult and pediatric subjects;
- comparison of implants to any currently or previously available device with an equivalent use, or equivalent device currently under investigation.

Outcomes of interest were performance variables (surgical complications related to device installation, pain, numbness, local infection or bone loss, skin reactions, Holgers score, soft tissue or bony overgrowth, revision surgery rate, loss of fixture and loss of osseointegration) and safety variables (intra- and post-operative adverse events).

RESULTS

The search resulted in 251 articles. After excluding papers that failed to meet inclusion criteria, 12 papers remained. Four of these were duplicated in the PubMed and Oticon databases, leaving 8 papers included in the review (Figure 1).

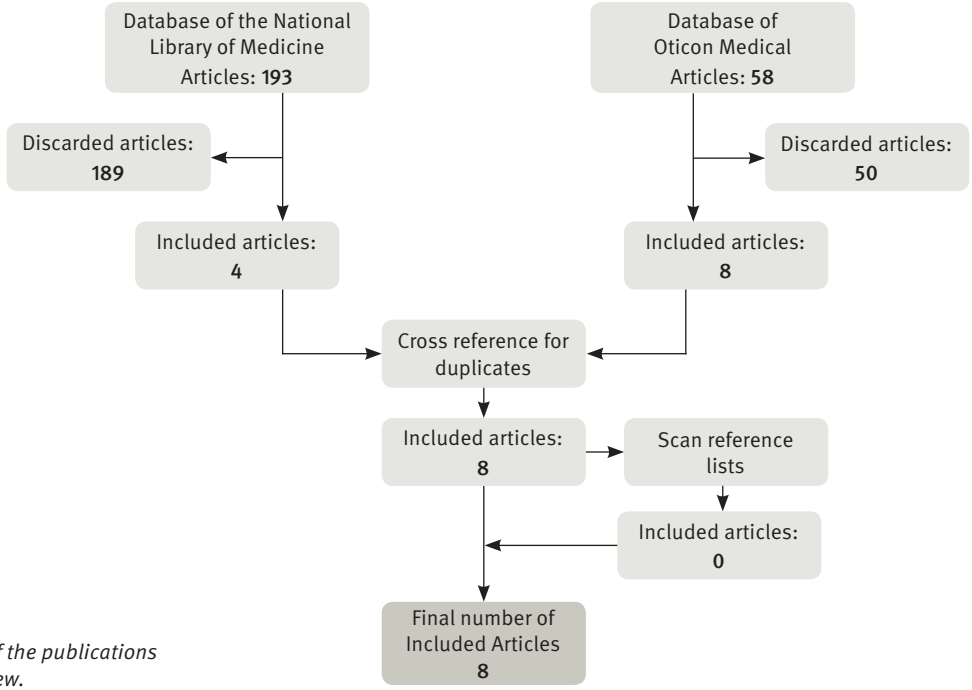

Figure 1.
Selection process of the publications included in the review.

Surgical approaches in tissue preservation

The tissue preservation surgeries discussed in this review can be divided into two categories, defined by whether or not the procedure is performed with a linear incision. The surgery with a linear incision, first described by Hultcrantz for tissue preservation, is the most commonly used type in the review (Hultcrantz, 2011). A second approach, using only a biopsy punch but no incision, has been described by Goldman et al. (2013) and Wilson & Kim (2013). The papers are summarized in Table 1.

Reference	n (total)	n TPS*	Adult/ Children	Follow-up months	Surgical Method	Incidence of soft tissue reaction	Revision rate	Fixture Loss
Goldman et al. (2013)	15	15	A	Mean 14.8 (9-20)	TPS/Punch	0%	0%	0%
Hawley & Haberkamp (2013)	37	37	A/C	Mean 18.5 (3-45)	TPS	Adult: Holgers ≥2: 28% implants Children: Holgers ≥2: 60% implants	10.8%	2.7% (n=1)
Hultcrantz (2011)	18	7	A	12	TPS	Holgers 1-3: 14% patients	14.3% (n=1)	0%
Hultcrantz & Lanis (2014)	36	12	A	60	TPS	Holgers ≥2: 16.7% patients (n=2)	8.3% (n=1)	0%
Husseman et al. (2013)	34	34	A	85% >6	TPS	Holgers ≥2: 14.7%	0%	0%
Lanis & Hultcrantz (2013)	33	10	C	Mean 15.6	TPS	10% patients	0%	10% (n=1)
Shin et al. (2012)	15	10	A	Mean 13.0	TPS	0% patients	0%	0%
Wilson & Kim (2013)	40	29	A	≥ 12	TPS/Punch	Holgers ≥2: 13.8% patients	3.4%	0%
Kiringoda & Lustig (2013)	2310	–	A/C	Mean 36.9	Standard techniques with full tissue reduction and short (5.5-6mm) abutments	Adult: Holgers ≥2: 2.4 – 38.1% Children: N/A	Adult: 1.7 – 34.5% Children: 0.0 – 44.4%	Adult: 1.7 – 34.5 % Children: 0.0 – 25.0%

*Table 1. Overview of the eight studies adhering to the inclusion criteria of the systematic review. *n TPS=number of implants installed with tissue preservation surgery (TPS). The results shown only refer to the implants installed with TPS, i.e. not including control groups. Outcome from a meta-analysis of 2,310 implants installed with traditional skin-thinning technique is included in the table for reference (Kiringoda & Lustig, 2013).*

Linear incision with tissue preservation

The steps of this procedure include measuring the skin depth, marking the implantation site with dye, injecting local anesthesia, then making a straight incision through the skin down to the periosteum. After the periosteum is opened, a hole is drilled into the skull. Based on the skull's thickness, a hole is drilled for either a 3mm or 4mm long implant. The implant – with an abutment of 6 to 12 mm depending on the patient's skin thickness – is then screwed into place. The abutment is externalized by punching a hole through the skin adjacent to the incision (Figure 2). Alternatively, the implant and abutment are placed in the incision line (Figure 3). In this case, half-circle shaped portions of the skin are excised around the abutment, either using a biopsy punch or a blade. The incision is then closed, and a healing cap with dressing applied. The procedure can be performed as a single-stage procedure or a two-stage procedure. A large majority of the implantations in this review were single-stage, with staged surgeries only used in some of the pediatric patients.

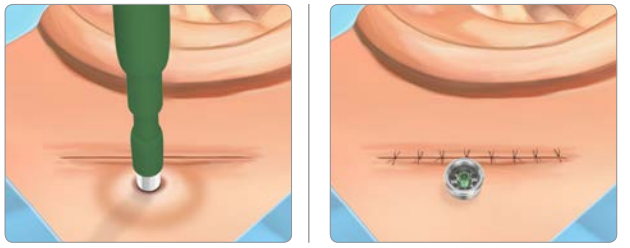

Figure 2. Linear incision with tissue preservation according to Hultcrantz, where the implant is positioned alongside the incision. In this approach, an incision is made through the skin, through which a hole is drilled into the skull and the implant is installed. A hole is punched approximately 10mm from the incision, the skin is then pulled over the abutment and the incision closed.

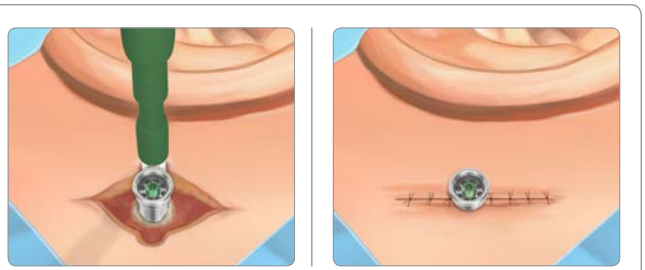

Figure 3. Tissue preservation technique with the implant positioned in the incision line. A single straight incision is made and the implant is installed in line with the incision. Skin is excised around the abutment, and the incision is closed.

Biopsy punch technique

The second approach represented in the literature is to mark the implant site, then use a biopsy punch to remove soft tissue down to the skull surface (Goldman et al., 2013; Wilson & Kim, 2013). The periosteum within the resulting circle is excised. A hole is drilled for the appropriate implant (3 or 4mm length). The thickness of the scalp determines the length of the abutment that is used. Various techniques are used to ensure enough space for drilling and to improve visibility (see below for details). The biopsy punch approach is illustrated in Figure 4.

Study overview

The eight studies are summarized in Table 1. The complications listed in the table are related only to the implants that were installed using a tissue preservation technique (thus, not including control groups). The study provided in the bottom row (Kiringoda & Lustig, 2013) was included to give a comparison of complication rates using traditional techniques with skin thinning.

Adult patients undergoing procedure with linear incision

Hultcrantz (2011) – The author reports the results of a prospective controlled study including 18 adults, mean age 64.1, with 12 month follow-up time. Nine patients were intended to be treated without soft tissue reduction (test group). The technique used was a linear incision placed alongside the abutment position. Two patients were excluded from the test group because of a skin thickness of more than 10 mm. Nine patients underwent the traditional approach with skin-thinning (control group) using a dermatome technique, but two were excluded due to age-matching of the test group. All surgery was performed under local anesthesia. The test group (n=7) showed faster wound healing compared to the control group (≤ 10 days vs. ≤ 2 months) and less infection (14% vs. 43%). Local numbness at 12 months was also less likely in the test group (1 vs. 6 patients). The surgery time was reduced in the procedures without soft tissue reduction (28.1 vs. 44.6 minutes). No implant loss was reported for the test group, and one minor revision was made due to a skin wrinkle interfering with the sound processor.

The author concluded that the approach without soft tissue reduction is preferable, though it warrants further study.

Husseman et al. (2013) – This paper included results from a prospective study of 34 adults who underwent bone anchored hearing aid placement with minimal or no soft tissue reduction.

The linear incision was placed across the implant position. In this study, the longest abutment available was 9 mm. Because of this, the authors aimed to achieve a final scalp thickness not greater than 6 mm around the abutment.

Subjects had a mean follow-up period of 494 days (range, 164 to 1056 days). The authors noted no implant failures. They also reported that 14.7% of the patients had a Holgers score of 2 (marked by redness, moistness, and moderate swelling) or 3 (those symptoms with the addition of granulation tissue). All resolved with conservative treatment.

The authors concluded that this approach is "simple and effective," leading to "excellent cosmetic results."

Hultcrantz & Lanis (2014) – This paper reported five-year follow-up data from 36 adults. The study design was a retrospective follow-up study with age-matched control groups. The test group did not undergo skin thinning. In the first control group a flap technique was used, whereas in the second control group a dermatome technique was used. Seven of the patients in the test group were also included in the test group of another paper (Hultcrantz, 2011), where 12-month results were reported.

The installation technique for the test group of 12 patients was the same as previously described by Hultcrantz (2011). Results show that complications, in terms of skin reactions, revision surgeries, and overgrowth, were lower in the test group. The rate of patients suffering an adverse skin reaction (Holgers ≥2) during the five year follow-up was 16.7% in the test group, and 50% and 97% respectively in the control groups. Numbness was reported by all patients (100%) in the first control group (flap) and in 50% of the second control group (dermatome), whereas only 22% of the test group suffered from this problem. The healing time after surgery was also significantly shorter for the test group.

Based on the five-year follow-up data, the authors concluded that the "non-thinning technique provides improved aesthetics, minimized numbness, fewer peri-implant infections, and fewer abutment removals."

Adult patients undergoing procedure with punch method

Goldman et al. (2013) – This paper reviewed the cases of 15 adults who all received a bone anchored hearing aid without soft tissue thinning. The punching was performed with a 12 mm biopsy punch, and the opening was sutured at the end of the surgery. The average surgical time was 15.2 minutes. Minimal skin thinning was done selectively on male patients, since abutments with a maximum length of 9 mm were used. Over an average of 14.8 months of follow-up, the authors noted no skin overgrowth, no revisions, and no need for topical or injected steroids. No subjects developed infection or a skin reaction of Holgers grade 2 or higher. The authors concluded that their result "calls into question the necessity of more complicated methods".

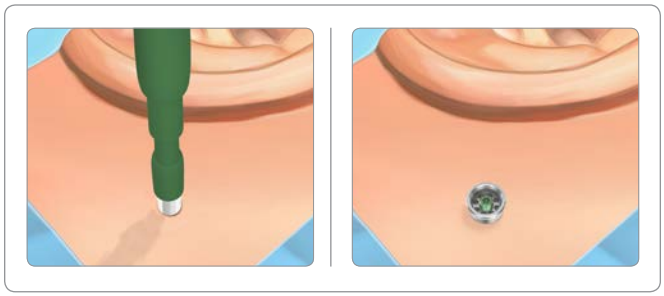

Figure 4. Biopsy punch technique. A hole is punched through the scalp, and drilling and installation of the implant is performed through the hole. Suturing is only needed if a large biopsy punch is used.

Wilson et al. (2013) – This retrospective case series included 40 patients, 11 of whom underwent implantation with tissue reduction (control group) and 29 of whom had implantation with minimal tissue reduction (test group). For the latter group, a 4-mm diameter biopsy punch was used. A small amount of subcutaneous tissue was also cut away from the edge of the hole, giving the opening a conical shape that improved visualization of the skull. The test group had a shorter surgical time (mean 32.3 vs. 56.1 minutes). They were also more likely to have local anesthesia with sedation compared to general anesthesia. The rate of complications was similar between the groups. The control group had two cases of skin complications of Holgers score 2 or 3, while the test group had four such cases. The authors note that implantation with minimal skin thinning can lead to successful outcomes with shorter surgical times and comparable safety.

Study populations containing pediatric patients

Hawley & Haberkamp (2013) – The authors evaluated the outcomes of 31 adults and five children who underwent a procedure with minimal tissue removal and a short incision across the implant site. Children under 10 years of age underwent a two-stage procedure to install the implant and later attach the abutment. Mean follow-up was 18.5 months. The study was performed retrospectively.

No patient had intraoperative complications. Seven adults had one to two soft tissue complications that resolved within two months. Five adults had more than two episodes of skin reaction or chronic implant-related problems, three of whom required surgical revision. Two patients had hearing problems; in one patient, the abutment was replaced with a longer version, and in the other patient, soft tissue revision was performed. It should be noted that abutments longer than 8.5 mm were not utilized in this study, and limited tissue reduction thus had to be made in several patients.

Of the children, one had minor soft tissue overgrowth that was treated in the office. Another needed soft tissue revision during surgery, and a third required explantation.

The authors concluded that their results support continued investigation into this approach, as complication rates were similar to or lower than current techniques. However, they felt that this approach may have limited suitability for pediatric patients. It should be noted that only five children were included in this study.

Lanis & Hultcrantz (2013) – The authors included 33 children in this retrospective chart review. Ten patients received implants without soft tissue reduction, and the remaining 23 underwent the traditional procedure with tissue reduction. The surgery was performed in one or two stages, depending on patients' skull thickness.

The group that did not undergo skin thinning had a shorter operation time; faster healing time (all healed in 7 to 10 days vs. most healed ≤ 30 days); less infection (11% vs. 36%); less skin overgrowth (0 vs. 6); and less numbness after 12 months (0 vs. 12). The authors conclude that the approach with tissue preservation appears "beneficial for children".

Shin et al. (2012) – The authors evaluated the outcomes of 15 children and adults; five underwent a procedure with soft tissue reduction (with a dermatome) and 10 were implanted without tissue reduction. The surgical procedure was a linear incision with the abutment in the incision line.

Surgery time was shorter without skin thinning (mean 25 vs. 55 minutes), as was wound healing time (mean 28 vs. 56 days). Patients in the group without tissue removal were less likely to have infection (0 vs. 2 cases) or tissue overgrowth (0 vs. 2 cases). However, in two cases, the abutment separated from the fixture, requiring outpatient repair.

The authors note an improved outcome in appearance in patients who did not undergo tissue removal. They conclude that "the single vertical incision technique without skin thinning has many benefits when compared with the BAHA dermatome."

DISCUSSION

This review has summarized the results from eight studies of bone anchored implants installed with limited or no reduction of the skin. The number of unique implants installed with tissue preservation was 147, spread over six different centers. (In total, 154 implants were included in review, however results from seven patients were reported in two studies with different follow-up times.)

Shorter surgery time was reported in all studies including a control group. Further, Wilson & Kim also reported shorter overall time in the operating room. Another benefit reported in two studies is the convenience of performing the tissue-preserving procedure under local anesthesia (Wilson & Kim, 2013; Hultcrantz & Lanis, 2014). This is also possible for older children, as well as patients with diseases that make them poor candidates for general anesthesia. Local anesthesia further allows the procedure to be performed as an outpatient procedure.

Importantly, no intra-operative complications were reported. The simplified nature of tissue preservation compared to previous techniques should theoretically reduce the risks for intra-operative complications. However, the relative benefits and risks of the linear incision technique versus the punch technique require further investigation. One obvious shortcoming of the punch technique is that it provides limited visibility of the implant site, which could conceal intra-operative complications that may arise. In addition, drilling though a small opening may damage soft tissue and inhibit irrigation during the drilling sequence.

Based on this review, we conclude that healing time after surgery is considerably shorter with tissue preservation surgery compared to traditional techniques that include skin thinning. Faster wound healing was reported in five of the studies (Hultcrantz, 2011; Husseman et al., 2013; Lanis & Hultcrantz, 2013; Hultcrantz & Lanis, 2014; Goldman et al., 2013), three of which were controlled. The inflammatory and wound healing responses after insertion of a biomaterial in tissue are generally dependent on the extent of injury or defect created by the implantation procedure (Anderson, 2001). Hence, reducing the surgical trauma may affect the extent of granulation tissue formation, foreign body reaction, and fibrosis development. In addition, by preserving the soft tissue surrounding the implant site, much of the natural immune response is kept intact.

Overall, the tissue preservation approach is associated with post-surgical outcomes that are at least as good as those seen with previous techniques. In terms of skin inflammation or infection, the rate of Holgers scores ≥ 2 ranged from 0% to 14.7% in seven of the papers. In the remaining paper, the rate was 28% in adults and 60% in children. It is noteworthy that no new types of complications have been reported in any of the studies. The lower incidence of infection and faster healing may be due to improved blood supply, better immune response, and less scar tissue resulting from decreased trauma in the absence of skin-thinning. In four of the eight papers, no patients required revision. In the remaining four articles, revision rates varied between 3.4% and 14.3%. It can be noted that in three of those articles, a single revision was reported, and the revision rate therefore was somewhat arbitrary. Similarly, six of the papers described no fixture loss. In the remaining two papers, fixture loss occurred in 2.7% and 10% of cases (one implant loss in each of the studies). Calculated across all implants in all studies, the average revision rate was 4.8% and the implant loss rate was 1.4%. Elective removal of abutments due to patients perceiving no benefit was not included, but was reported in two studies (Hultcrantz & Lanis, 2014; Husseman et al., 2013).

Better cosmetic outcomes were reported in all studies that included a control group. Patients had an improved appearance around the surgical site, with minimal or no hair loss. Two examples of outcomes one year after surgery using Ponto implant and abutments and tissue preservation are shown in Figure 5 (Hultcrantz, unpublished data). Appearance is an important factor for deciding on the type of bone conduction device. Although a majority of patients wear the sound processor daily, and therefore the appearance with the sound processor connected should be the more important factor, it's also important to consider how the percutaneous implant and the area around the abutment will look. In a recent prospective study of patients eligible for a bone anchored hearing implant (most were children), the most common reason for parents' refusal was their concern about social acceptance related to cosmesis (Zawawi et al., 2014).

The growing popularity of tissue preservation surgery has also highlighted a rarely discussed adverse reaction linked to bone anchored hearing implants: the numbness around the implant that many patients report. According to this review, patients are less likely to experience local numbness after a procedure without skin thinning. Less numbness was reported in four (Hultcrantz, 2011; Hawley & Haberkamp, 2013; Lanis & Hultcrantz, 2013; Hultcrantz & Lanis, 2014) of the eight studies, three of which were controlled studies.

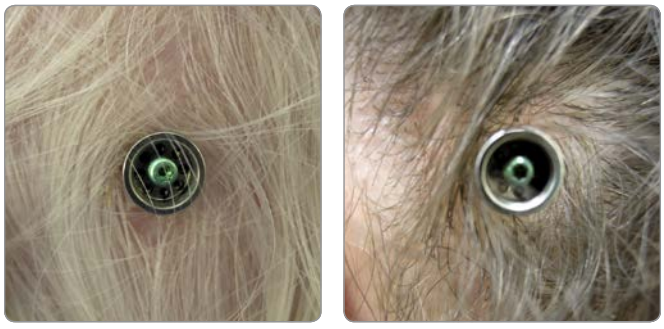

Figure 5. Patient outcomes for implants installed ad modum Hultcrantz 12 months after surgery (Hultcrantz, unpublished data)

It is worth noting that all studies that met the inclusion criteria for this review reported results using abutments with the traditional titanium surface. Preclinical results have been reported using other surfaces in this application (Larsson et al., 2012) but no clinical results are available in the research literature. Studies investigating new abutment surfaces would benefit from having a relevant control group, in order not to confuse the improvements achieved by a tissue preservation technique, as documented in this review, with the potential improvements from altering the abutment-skin interface.

One conclusion that can be drawn from the reviewed studies is that abutments longer than 6 and 9 mm are required for tissue preservation. The data included in this review is not sufficient to give preference to a specific design of implants and abutments. Various implant and abutment designs, including devices from both manufacturers of bone anchored hearing implants, were included in the review. Future randomized controlled studies comparing designs would be beneficial. This type of research has been reported from several centers regarding sound processor performance to help guide clinical choices (Olsen et al., 2011; Bosman et al., 2013; Hill-Feltham et al., 2014).

Long-term follow-up data continue to support the safety of titanium abutments for tissue preservation installation of bone anchored hearing devices. The longest follow-up reported in the literature is the study by Hultcrantz and Lanis, where the average follow-up time was more than five years. It should be noted that the average onset of skin reactions in the tissue preservation group in this study was approximately 36 months. As a result, when evaluating new developments in this area, a long time horizon is fundamental before making firm conclusions. Several studies are ongoing that will provide even more long-term data on outcomes of procedures performed with tissue preservation.

SUMMARY AND CONCLUSION

Taken as a whole, this literature review points to a number of advantages associated with bone anchored hearing systems implanted with tissue preservation, without revealing any new safety concerns.

Implant survival rates were at least as high as the published rates using skin thinning techniques. In addition, soft tissue outcomes were comparable or better than those seen in a systematic review of procedures using skin thinning methods. All published data on bone anchored hearing system implantation with tissue preservation have involved titanium-surfaced abutments.

Importantly, this review of the literature also indicates other patient benefits: reduced surgery time, faster healing, less perceived local numbness, and a more attractive cosmetic result. Hence, we conclude that using a tissue–preserving approach when installing bone anchored hearing implants with titanium abutments is clinically safe. Performance outcomes are comparable or better than published data from procedures that utilize a skin thinning technique. Given the positive patient outcomes, we recommend preserving the surrounding tissue when installing these implants.

Scan this code to watch a video of Prof. Hultcrantz performing the linear incision technique with tissue preservation

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Oticon Medical is a global company in implantable hearing solutions, dedicated to bringing the magical world of sound to people at every stage of life. As a member of one of the world's largest groups of hearing health care companies, we share a close link with Oticon and direct access to the latest advances in hearing research and technologies. Our competencies span more than a century of innovations in sound processing and decades of pioneering experience in hearing implant technology.

By working collaboratively with patients, physicians and hearing care professionals, we ensure that every solution we create is designed with users' needs in mind. We share an unwavering commitment to provide innovative solutions and support that enhance quality of life for people wherever life may take them. Because we know how much sound matters.

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