Clinical survey of Oticon Medical Ponto implants and a surgical technique with tissue preservation

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Hearing disorders
Study type	Observational non invasive

Summary

ID

NL-OMON38035

Source
ToetsingOnline

Brief title
Oticon tissue preservation study

Condition

- Hearing disorders

Synonym
Bone Anchored Hearing Aid, Bone Implant

Research involving
Human

Sponsors and support

Primary sponsor: Oticon Medical AB
Source(s) of monetary or material Support: Oticon Medical AB

Intervention

Keyword: Oticon, Surgical technique, Tissue preservation

Outcome measures

Primary outcome

Numbness around implant, specifically mean Total sensibility 36 months after surgery.

Sensibility of the skin directly around the implant is an important outcome measurement to establish a possible difference between surgery with or without skin thinning. Two different sensibilities will be tested by means of a broken wooden cotton swab/bud (q-tip): gnostic (with cotton side) and vital (with broken, sharp wooden side) sensibility. The measurement locations are standardized and conducted at standardized moments to assure comparability. The sequence of gnostic/vital stimuli are randomly applied by the investigator, to rule out any chance of habituation by the patient. Scoring will be done to three measures

* Gnostic sensibility: 0%-100% (number of sensitive locations [0-6] / number of locations tested [6])

* Vital sensibility: 0%-100% (number of sensitive locations [0-6] / number of locations tested [6])

* Total sensibility: 0%-100% (number of sensitive locations [0-12] / number of locations tested [12])

Secondary outcome

- Compare the Surgical time between test and control group

Length of surgery as measured from incision to placement of healing cap (in minutes).

- Investigate the effect of soft tissue around the abutment on audiometric thresholds

For all patients (test and control group) we will measure and calculate the individual difference between bone conduction audiometric thresholds with test band and on abutment for frequencies 250Hz, 500Hz, 750Hz, 1kHz, 1.5kHz, 2kHz, 3kHz, 4kHz, 6kHz and 8kHz. The Individual threshold difference is calculated for separate frequencies, and overall. The difference between mean Individual threshold difference for the test and control groups reflect the potential dampening effect of the tissue thickness surrounding the abutment. By using the same sound processor for the individual patients, device effects are reduced.

- Investigate and compare the number of unplanned visits, unplanned surgical procedures and other treatments for the test and control group.

Sum of number of unplanned visits, revision surgeries, medications related to implant, and other treatments requiring medical staff per patient during 0-6 months, 0-12 months and 0-36 months

- Investigate and compare the rate of adverse skin reactions

Evaluation of local reactions at the site of implantation will be performed from visit 2 and onwards. If local reactions occur between scheduled visits, the subjects will be encouraged to contact the clinic for follow-up and

treatment. For assessment of local reactions the Holgers classification will be used (Holgers et al 1998)

- Investigate implant loss and implant stability

Implant stability will be assessed at each visit using resonance frequency analysis (RFA). The measurement will be performed at abutment level, by attaching a single-use SmartPeg (Osstell, Gothenburg, Sweden) to the abutment and activating the SmartPeg with an Osstell Mentor (Osstell, Gothenburg, Sweden) handled RFA instrument. The RFA measurement results in an Implant Stability Quotient (ISQ) value reflecting the stability of the implant. ISQ values range from 1 to 100, where a higher value reflects a more stable implant. The RFA measurement shall be performed in accordance with the procedures recommended by the manufacturer of the Ostell Mentor.

- Investigate and compare subjective benefit as measured by APHAB, GBI and GHSI questionnaires

To determine benefit of implantation of the Ponto device, each patient will be surveyed, using 3 questionnaires: the Abbreviated Profile of Hearing Aid Benefit (APHAB), Glasgow Health Status Inventory (GHSI), and the Glasgow Benefit Inventory (GBI). The APHAB is a 24-item self-assessment inventory in which patients report the amount of trouble they are having with communication or noises in various everyday situations. Benefit is calculated by comparing the patient's reported difficulty in the unaided condition with their amount of difficulty when using amplification. The GHSI assesses health state, can be

used at any point in time and measures the general quality of life the person experiences and how health problems affect this. The GBI is a measure of patient benefit developed especially for otorhinolaryngological (ORL) interventions. Patient benefit is the change in health status resulting from the intervention. While the GBI is maximally sensitive to a change in health status brought about by a specific event (e.g. an operation), the GHSI gives a general measure of the health status of the person at any specific time. Both questionnaires contain 18 questions.

- Investigate and compare scar assessment, by the Patient and Observer Scar Assessment Scale (POSAS)

The POSAS is a standardized rating that deals with the most commonly described scar characteristics from a patient and observers perspective:

* Vascularity
* Pigmentation
* Relief/texture
* Thickness
* Pliability
* Surface area
* Pain
* Itching / Pruritus

The POSASv2.0 consists of two parts: a Patient Scale and an Observer Scale. Both scales contain six items that are scored numerically on a ten-step scale. Together they make up the *Total Score* of the Patient and Observer Scale.

Furthermore category boxes are available to score nominal parameters (e.g. type

of colour). Moreover, the patient and observer also score their *Overall

Opinion*.

Study description

Background summary

Percutaneous bone anchored hearing systems were introduced in 1977 and have now been used clinically for over 30 years. Today, more than 100.000 implantations have been made around the world. The long-term success rate is high, with a low rate of major complications [Dun et al 2012].
The most common complication is soft tissue reactions around the skin-penetrating coupling [Holgers et al 1988]. Recently, promising modifications related to the surgical approach have been suggested [Hultcrantz 2011, Shin et al 2012, Singam 2010, Soo 2009]. The result is minimal scar tissue formation and skin with natural thickness around the abutment. In combination with recent abutment developments introduced by Oticon Medical [Westerkull 2012] this has the potential to offer significant benefits for the patients and the success of percutaneous bone anchored hearing devices.
The aim of the traditional surgical procedure is to achieve a thin hairless skin that is well fixated to the underlying periosteum to hinder skin movement around the abutment and to facilitate cleaning. The preparation is usually performed either through a straight incision or with the help of a dermatome. Although this approach is well established and works very well for the majority of patients [Dun et al 2012, Holgers et al 1988], there are a number of drawbacks such as the large amount of scar tissue formation and numbness in the area around the abutment, and for many patients the cosmetic aspect of being left with a bald spot [Hultzcrantz 2011] is unattractive. In addition, skin can thicken up so that the abutment becomes too short with resulting skin irritation [Hultzcrantz 2011]. In recent years, promising results with modified surgical techniques with tissue preservation have been presented [Hultzcrantz 2011, Shin et al 2012, Singam 2010, Soo 2009]. With this technique no soft tissue reduction is performed, except in specific cases where the longest abutments are still too short. For instance, Hultcrantz has reported less numbness in the area around the abutment and no increase in skin complications with tissue preservation surgery. This technique can also significantly shorten the time of the surgery.

In the original procedure, introduced by Tjellstrom in 1977, no soft tissue reduction (or skin graft) was performed, but surgery was a two stage procedure. No subcutaneous tissue was removed, and in the second stage of the procedure,

only a hole was punched through the skin to allow for the attachment of the abutment to the implant. In the discussion, they note that *a few patients complained of minor skin irritation during the first weeks after the second surgical procedure [the placement of the abutment]. This problem was noted among those patients who had a thick subcutaneous layer and a skin rich in sebaceous glands*, but no adverse skin reactions or removal of abutments was noted. In a subsequent paper, long-term follow-up of the same patients was published. Here it is noted that soft tissue had to be trimmed to avoid tissue movement around the abutment in a few cases. A free skin graft is also mentioned as a solution for cases where there are hair follicles in the area around the implant. Again it is noted that *problems with slight skin irritations were only found in patients with thick soft tissue layers over the mastoid. After surgical reduction of the subcutaneous layers the problems disappeared. This kind of surgical soft tissue reduction has, in selected patients, since been included at the first clinical operation [in a two stage procedure]. After this change of clinical routine there has been no skin irritation at the abutment penetration site*. Reduction of soft tissue has since been a part of the standard bone-anchored hearing system surgery.
It should be noted that the early abutment design had a sharp 90 degree edge facing the skin, which possibly can have contributed to skin irritation. It could be postulated that a thicker skin would come in contact with the sharp edge of the abutment whereas there was no contact with the sharp edge for patients with a thin skin. The Ponto implants and abutments does not feature a sharp edge, and compes in a varity of different lengths to accommodate different skin thickness.

Very recently, a number of studies have reported results using a surgical technique with minimal soft tissue removal [Goldman et al 2013, Hawley et al 2013, Husseman et al 2013, Lanis et al 2013, Wilson et al 2013, Shin et al 2012], also called minimal invasive surgery (MIS). Allocating the result from Hawley, Husseman, Hultcrantz, Lanis, and Shin (which all used a version on linear incision surgery with soft tissue preservation) yields a total of 97 patients with 98 implants (of which 15 children) having their bone anchored hearing aids installed without or with limited skin thinning. The mean follow-up time in these studies is between 12-18.5 months (minimum 0.3 months). Implant extrusion occurred in three patients (incidence between 0 to 2.7 %) and revision surgeries were needed for totally four patients, all in the same study [Hawley et al 2013] (incidence between 0 to 10.8%). The incidence of skin reactions in four of the five reported studies ranges between 0 to 28% for adult and 0 to 60% for children. (A single study [31] reported the highest incidences for both children and adults
Excluding this study, reported ranges were 0 to 14.7% for adults and 0 to 10% for children.) Skin reactions were defined as Holgers scale *2 for all but one study, where it was defined as peri-implant infection yielding an incidence of 10% (n=1/10) [Lanis et al 2013]. These results are comparable or better than the data reported in the systematic review by Kiringoda et. al.

Further, other positive outcomes reported were:
* Better cosmetic outcomes were mentioned in all studies including a control
* Shorter surgery time was reported in all studies including a control
* Faster wound healing was mentioned in three studies considering MIS [Hultzcrantz et al 2011, Husseman et al 2013, Lanis et al 2013], two of which were controlled
* Less numbness was mentioned in three [Hultzcrantz et al 2011, Hawley et al 2013, Lanis et al 2013] of the five studies, two of which were controlled studies.

The risk of losing an implant due to adverse skin reaction when using a tissue preservation technique at installation of the system is in the same region or better than the general data previously reported in the literature. The incidence of skin reactions is better or equal to the data previously reported in the literature and an increased risk for trauma resulting in loss of implant has not been reported. In addition, new risk factors and other potential effects (beneficial and harming) have not been reported in the currently published studies.
Another weakness of these studies is that they often mix different types of implant and/or abutment geometries. Further, several of the studies are either retrospective in nature, or controlled studies but with a limited number of patients. The follow-up times are generally relatively short.
The justification for this study is therefore to collect data in a prospective study, including a larger number of patients. We will use a single abutment geometry and surface, so that the results only reflect the difference in surgical techniques. With this study, we will further collect long-term (three year) data. Focus will be on numbness, which has been stated as an area where tissue preservation has a positive patient impact, but where reproducible measurements have lacked until today, as well as surgery time, complications needing treatment and skin-related issues. We will further investigate the effect of this modified technique on audiometric thresholds. We will also investigate the safety of the tissue preservation surgical technique with regard to implant survival and stability data.

Study objective

The primary objective of the study is to investigate the difference in numbness around the implant between after a surgical procedure with soft tissue preservation (test) and a surgery with soft tissue reduction (control) for implanting using Oticon Medical Ponto implants and abutments with regard to:
- Numbness around implant

The primary hypothesis is that there is less numbness is lower, surgery time is shorter, and there is little to no loss of sound quality after surgery with soft tissue preservation than after surgery with a procedure with soft tissue reduction.

The secondary objectives are
- Compare the Surgical time between test and control group
- Investigate the effect of soft tissue around the abutment on audiometric thresholds
- Investigate and compare the number of unplanned visits, unplanned surgical procedures and other treatments for the test and control group.
- Investigate and compare the rate of adverse skin reactions
- Investigate implant loss and implant stability
- Investigate and compare healing time after surgery
- Investigate and compare subjective benefit as measured by APHAB, GBI and GHSI questionnaires
- Investigate and compare scar assessment.

Study design

Patient inclusion for the test group of this clinical investigation will be performed among patients that already have been audiologically and otologically evaluated and found suitable candidates for treatment with a bone anchored hearing aid. The test group will be consecutively included in the study, and includes 25 patients. The control group will consist of the last 25 patients (all patients for which 12 month follow-up visit takes place after Jan 1st , 2014) that have already undergone surgical intervention in the prospective clinical study C33 (CMO 2011/497), and that have received the same wide Ponto implant with 6 mm abutment and soft tissue reduction as a part of that study. The test group will come for check-ups at 7 days, 21 days, 12 weeks, 6, 12, 24 and 36 months following implant insertion, approximately the same amount number of follow-up moments visits patients undergo in regular clinical practice. At each visit a clinical evaluation will be made where implant stability is measured using resonance frequency analysis, and a range of outcome measured related to skin status are collected including the standardized Holgers score. Three weeks after surgery the patients will be fitted with the sound processor. The control group has undergone an extensive follow-up programme with special focus on implant stability measures. For the last 25 participants of this study, a few study variables need to be added at the 1, 2, and 3 year follow-up visits for comparative reasons .

All data is to be registered in the paper based Case Report Forms.

Study burden and risks

The risk of participating in the study is low and comparable to corresponding rehabilitation outside the study. The implant and abutment are identical to the ones used in a regular surgery and will not contribute to any additional risk. The patients will be fitted with their sound processor at 3 weeks, which is nowadays regular practice and will speed up the rehabilitation. No type of complications other than those that might occur when rehabilitating patients

with a bone anchored hearing aid outside the study is anticipated. Treatment of possible complications for patients in the study will be the same as for regular implant patients. All adverse events will be registered and taken into consideration when compiling the final report.
The subcutaneous tissue reduction, that is a part of the standard surgical technique, is omitted in this study. The reports published so far indicate positive patient benefits in terms of less numbness around the implant, faster healing time after surgery and a cosmetically more attractive result.
If long-term results are not as anticipated, subcutaneous tissue reduction can be performed after the initial surgery if needed. This will require an additional surgery, but the end result should be the same as for patients undergoing the regular surgery. (Two-stage surgeries are already today used is some patients, and revision surgeries are a possible treatment for patients suffering from e.g. skin overgrowth.)
Participation in the study requires follow-upvisits for the patient with approximately the same frequency, but with longer duration, than what is normally required. This will require an extra effort for the patient however the patient will have the opportunity to interact more with the treating physician.
We conclude that the risks of this modified surgical technique are acceptable when weighted against the user benefits of the technique and the gain in terms of research results in a field important for long-term patient outcomes.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Inclusion criteria:
* 18 years or older
* Patient indicated for an ear level bone anchored sound processor
* Bone thickness at the implant site of at least 4 mm
* Written informed consent

Exclusion criteria

Exclusion criteria:
* Inability to participate in follow-up
* Psychiatric disease in the medical history
* Mental disability
* Presumed doubt, for any reason, that the patient will be able to show up on all follow ups
* Diseases or treatments known to compromise the bone quality at the implant site, e.g. radiotherapy, osteoporosis, diabetes mellitus.
* Patients with natural skin height of >10 mm (as there will be additional skin reduction needed)

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)

Control:	Active
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	22-01-2014
Enrollment:	25
Type:	Actual

Ethics review

Approved WMO

Date:	04-12-2013
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL46793.091.13

Study results

Date completed:	01-10-2018
Actual enrolment:	25