Long-term stability and survival rates of a novel Oticon Medical bone conduction device implant

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The overall aim of the study is to investigate the Ponto wide implant considering; initial implant stability, stability over time, skin reaction and long term success when loaded at 3 weeks post surgery. Patients* quality of life improvements...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Hearing disorders
Study type	Interventional

Summary

ID

NL-OMON37464

Source
ToetsingOnline

Brief title
wide implant BCD study

Condition

- Hearing disorders
- Skin and subcutaneous tissue disorders
- Head and neck therapeutic procedures

Synonym
implant stability, local skin reactions

Research involving
Human

Sponsors and support

Primary sponsor: Oticon Medical AB

Source(s) of monetary or material Support: bedrijf (derhalve eigenlijk 4e geldstroom): Oticon Medical Systems;Sweden

Intervention

Keyword: BAHA/BCD, novel implant, stability, survival rates

Outcome measures

Primary outcome

The primary objectives consider the implant stability, skin reactions and effects of early loading of the BCD processor. Both implant stability and the effects of early loading on the implant stability will be measured by RFA and valued in ISQ. ISQ values can be used to see the evaluation of the stability of the implant during time.

Skin reactions will be assessed using the scale developed by Holgers:

Grade 0: no irritation; epidermal debris removed if present.

Grade 1: slight redness; temporary local treatment.

Grade 2: redness and slightly moist tissue, no granulation; local treatment, extra follow up.

Grade 3: red and moist, sometimes granulation; surgical revisions is indicated.

Grade 4: removal of skin-penetrating implant necessary due to infection.

Long-term effects of the new implant and the early loading will be easily conducted from all parameters described, when followed over a course of time.

Furthermore there will be subjective outcome measurement using the GBI.

Secondary outcome

When implant stability show the lowest values, the initial mechanical stability is gradually replaced by biological stability. To assess this moment, there

will need to be established an average value of all ISQ data. When plotted in a graphic as a function of time, the lowest point in the graph will be the time implant stability is the lowest (and the initial mechanical stability is gradually replaced by biological stability).

Study description

Background summary

Bone conduction hearing systems was introduced in 1977 and has now been used clinically for over 30 years. More than 75,000 patients have been fitted with the system worldwide and long-term clinical follow-up studies have shown an overall implant survival rate of more than 90%. However higher failure rates have been reported to occur in patients with compromised bone and in children. With the aim to improve outcomes for all patient groups and also to reduce the loading times and enable the patient to benefit from the device earlier a new implant design was developed by Oticon Medical based on known technology of bone anchored hearing aids as well as knowhow from the dental industry. This clinical prospective study will investigate the clinical outcomes of this new implant.
With the aim to improve outcomes for all patient groups and reduce the loading times a new implant design was developed by Oticon Medical based on known technology of bone anchored hearing aids as well as knowhow from the dental industry. As a general concept it has been found that screw shaped implant design develops higher mechanical retention as well as greater ability to transfer compressive forces. The screw design not only minimizes micromotion of the implant but also improves the initial stability. In addition there is evidence in the literature that stability may be improved by increasing the implant diameter and/or decreasing the drill diameter. The implant length has also been shown to influence the outcome of immediate loading of dental implants. This is primarily due to the fact that increase in length, equals increase in surface area. Micro threads at the upper part of the implant have been shown to limit or delays bone resorption and the literature also suggests that marginal bone loss tend to stop at the first tread. Skin reactions have been found to be caused by movement of the skin, thick skin, or poor skin condition around the implant. The literature also suggests that the accumulation of bacteria in the skin penetration and skin movement in relation to the abutment is a cause for skin reactions. Based on this knowledge the screw shape of the Ponto wide implant is designed with a maximized implant surface and a conical flange for increased support. The treads extend all the way up to the implant flange and the implant is further equipped with a micro

groove under the flange. In addition the diameter is increased and by optimizing the cutting abilities the drill diameter has been decreased. The design of the new Ponto implant has also a unique new cutting geometry which means it cuts more efficiently and gentle in to the bone tissue. Except for offering a high initial bone contact and stability, it means that the diameter of the drilled hole in the bone can be reduced without making it harder for the implant to engage and be inserted in the hole. With the new design, the drill diameter was reduced to 3,7 mm compared to a 4,0 mm drill diameter that is required for a traditional implant design of a 4,5 mm diameter implant. It is the final countersink drilling that prepares the hole in the living bone that will interact with the implant in the osseointegration process. The Ponto abutment has been designed with a tight seal to the implant to avoid micro gaps for bacteria to grow and be transported in. The Ponto abutment design allows the skin to be supported by the underlying bone and periost all the way up to the abutment without having it to go into a groove or lying more unsupported on top of the implant flange. In addition to that the abutment interface against the skin is smooth without any grooves for dirt and bacteria to be collected in.

Study objective

The overall aim of the study is to investigate the Ponto wide implant considering; initial implant stability, stability over time, skin reaction and long term success when loaded at 3 weeks post surgery. Patients* quality of life improvements following implantation will also be surveyed.
More specifically the primary objective of this clinical study is to test the hypothesis;
1. The new Ponto wide diameter implant offers increased implant stability measured as ISQ compared to the previous generation Ponto implant.
2. Loading of the sound processor at 3 weeks after surgery does not affect the stability of the implant.
And the secondary objective is to investigate when in time implant stability is the lowest as the initial mechanical stability is gradually replaced by biological stability.

Study design

The clinical investigation is an open, randomized, prospective, controlled, study enrolling 60 adult patients. Patient inclusion 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 patients will be randomized to either of the two implants in proportions of 2:1 (test *control). The randomization will be blinded to patients and investigators until the time of surgery. Both study groups will come for check-ups at 7 days, 14 days, 21 days, 28 days, 6 and 12 weeks, 6, 12, 24 and 36 months following implant insertion. At each visit a clinical evaluation will

be made where implant stability is measured using ISQ. At each visit skin status is also assessed. 3 weeks after surgery the patients will be fitted with the sound processor. To determine benefit of implantation of the Ponto device, each patient will be surveyed, using the Glasgow Benefit Inventory. The Glasgow Benefit Inventory (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. The GBI is an 18-item, post-surgical questionnaire given to patients.

Intervention

The intervention is surgical placing of a new type of titanium implant to connect a BCD. 60 patients will participate in the study, of which 40 will receive the test, wide implant, while the other 20 patients will receive the conventional implant. Distribution will be drawn by lot. Besides the different implant type, both groups will be treated exactly the same.

Study burden and risks

The risk of participating in the study is low and comparable with corresponding rehabilitation outside the study. The implant surgery is identical to the regular surgery and will not contribute to any additional risk. By following the patients over time this will give an indication on the design modifications contribution to increasing overall implant survival rate. The patients will be fitted with their sound processor 3 weeks before regular practice which will speed up the rehabilitation. No complication other than those that might occure when rehabilitating patients with a bone anchored hearing aid oustide 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 result of the study in finding timing of the lowest implant stability will give important direction for further research within this field. Participation in the study will require more frequent follow-ups for the patient than what is normally required. This will require an extra effort for the patient however the patient will have the opportunity to more frequently interact with the treating physician.

Contacts

Public
Oticon Medical AB

Ekonomivägen 2
SE-436 33 Askim

SE
Scientific
Oticon Medical AB

Ekonomivägen 2
SE-436 33 Askim
SE

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

The subject is/has:
1. 18 years or older;
2. given written informed consent to participate in the study;
3. eligible for the BCD system;
4. eligible for implantation with a BCD implant (bone thickness at implant site at least 4mm).

Exclusion criteria

The subject is/has:
1. age below 18 years;
2. longer abutment (>6mm) required;
3. inability to participate in follow-up;
4. psychiatric disease in the medical history;
5. mental disability;
6. presumed doubt, for any reason, that the patient will be able to show up on all follow ups;
7. disease or treatment known to compromise the bone quality at the implant site: radiotherapy, osteoporosis, diabetes mellitus.

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	08-06-2012
Enrollment:	60
Type:	Actual

Medical products/devices used

Generic name:	bone conduction (hearing) device
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	11-05-2012
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	NL38556.091.11

Study results

Date completed:	27-09-2017
Actual enrolment:	60