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Clinical evaluation of a new laser-ablated titanium implant for bone-anchored hearing in 34 patients: 1-year experience

1 | INTRODUCTION

Successful bone-anchored hearing implantation requires good osseointegration of the titanium implant in the temporal bone and low skin-related complication rates. The introduction of wider diameter implants, providing an enlarged bone-implant interface and thus a larger interface for osseointegration, has resulted in up to 3-year survival rates of >96% in healthy adult patients.¹⁻³ Despite the low incidence of implant loss in healthy adults, in certain patient groups, ie patients with compromised bone quality or in children, the incidence is much higher, varying between 3.5%-10.5% even with these wider diameter implants.⁴⁻⁶ To improve implant survival in these populations as well, further optimisation of implant material, design and surgical technique remains needed.

Based on dental research, modifications of the implant surface, eg physical topography and chemical properties, could play a pivotal role in further optimising the integration in the recipient's bone.⁷ As such, a new implant for bone conduction hearing was developed in 2015. This implant is, in contrast to currently used implants, selectively laser-ablated within the thread valley. Combined with modified chemical properties, this has shown improved biomechanical anchorage in pre-clinical animal testing.⁸ In our clinical practice, before this implant is tested in patients with a higher risk of implant loss, it first has to be proven effective to use in healthy adults. This study, therefore, assesses retrospectively the performance of the new laser-ablated implant by reviewing implant survival, stability and soft tissue tolerability in healthy adults 1 year after surgery.

2 | METHODS

2.1 | Ethical considerations

The ethics committee has passed a positive judgement on the study.

2.2 | Study population

The study was designed as a retrospective chart review approximately 1 year after implantation of patients who previously participated in a completed 4-week controlled market release (CMR) testing conducted at Radboudumc (Nijmegen, The Netherlands),

Queen Elizabeth University Hospital (Birmingham, England) and James Cook University Hospital (Middlesbrough, England). In these centres, patients eligible for bone-anchored hearing implantation test all available hearing restoration options in daily life situations to determine which system they prefer. Patients preferring the Ponto system were then asked whether they would like to participate in a CMR-testing of the new laser-ablated implant.

To be included in the CMR-testing, patients had to be ≥ 18 years old and have no disease or treatment known to compromise the bone quality at the implant site. Exclusion criteria included inability to follow investigational procedure and any factor, at the discretion of the investigator, that was considered to contraindicate participation. As such, 34 healthy adult patients consented and received the laser-ablated implant between September 2015 and January 2016. In all patients, a single-stage surgical procedure using a linear incision technique was performed under either local or general anaesthesia. Subcutaneous soft tissue reduction during surgery was applied in one hospital, whilst subcutaneous soft tissue was preserved in the other two hospitals.

2.3 | Implant

The implant used was the wide Ponto BHX-implant (diameter, 4.5 mm; length, 3 or 4 mm)(Oticon Medical AB Askim, Sweden). This implant is, in contrast to traditional Brånemark type machined titanium implant surface, selectively laser-ablated within the thread valley to produce a microtopography with a superimposed nanotexture and a thickened surface oxide layer. Pre-mounted Ponto abutments of lengths 6, 9 and 12 mm were used, in case of tissue preservation depending on skin thickness measured during surgery.

2.4 | Follow-up evaluations and outcomes

Standard follow-up visits were performed 1 week, 4-6 weeks and approximately 1 year after implantation. An additional standard 3-month visit was performed in one of the 3 participating hospitals. Implant survival and the degree of adverse skin reactions, according to the Holgers scale,⁹ were noted at each visit. Holgers ≥ 2 were considered as adverse skin reactions, in which medical treatment was needed. Extra visits, revision surgery and, if available, stability

over time measured as Implant Stability Quotient (ISQ) were also noted. ISQ was assessed using resonance frequency analysis (RFA) at abutment level, using the Osstell ISQ and a SmartPeg (type 55) (Osstell AB, Göteborg, Sweden).¹⁰ The highest and lowest values obtained from perpendicular measurements were recorded.

2.5 | Statistical analyses

All data were analysed using Descriptive Statistics in the Statistical Package for Social Sciences (IBM SPSS Statistics for Windows, Armonk, NY: IBM Corp), version 22.0. For continuous variables, means and ranges are reported; for dichotomous variables, frequencies are reported. For comparison over time, the Wilcoxon signed-rank test was used for continuous variables. A significance level of 0.05 was adopted.

3 | RESULTS

All 34 subjects were eligible for review. However, in three patients, the last visit was performed by phone due to travelling issues. For these visits, only implant survival data were used in the analysis. Demographics and baseline characteristics are summarised in Table 1. Only one patient needed a 3 mm implant due to insufficient bone thickness for placing a 4 mm implant and did not experience complications during the follow-up. In the entire cohort, no major perioperative complications were observed. The median clinical

TABLE 1 Demographics and baseline characteristics (N = 34)

Parameter	Number (%)
Gender	
Male	16 (47.1)
Female	18 (52.9)
Age group	
18-49 years	11 (32.4)
50-74 years	17 (50.0)
>75 years	6 (17.6)
Hospital	
Radboudumc	14 (41.2)
James Cook University Hospital	10 (29.4)
Queen Elizabeth University Hospital	10 (29.4)
Surgical technique	
Tissue reduction	14 (41.2)
Tissue preservation	20 (58.8)
Implant length	
3 mm	1 (2.9)
4 mm	33 (97.1)
Abutment length	
6 mm	6 (17.6)
9 mm	21 (61.8)
12 mm	7 (20.6)

Keypoints

- In specific patient groups with a bone conduction hearing implant, ie children or patients with compromised bone quality, the incidence of implant loss is much higher; further implant optimisation is, therefore, needed.
- The new laser-ablated titanium implant for bone-anchored hearing implantation has an enlarged contact area for osseointegration compared to the standard implant, aiming to improve implant loss rates.
- This retrospective multicentre study is the first to assess the performance of this implant in healthy adults 1 year after surgery.
- With excellent survival rates, good soft tissue tolerability and few complications, the implant is safe to use in healthy adults.

follow-up was 15 months (range: 7-17 months); only one patient had less than 12 months of follow-up.

In this one patient, a spontaneous implant loss occurred 3 months after surgery, but the patient did not present until almost 5 months after the event. No clinical signs of infection were reported to be present prior to the implant loss. The patient was re-implanted shortly after, outside this study. Data from the patient up to the moment of implant loss were included in the analysis. For the entire cohort, a median 15-month implant survival of 97% was observed. Another patient spontaneously lost an abutment after 3 months, whilst being abroad. On the patient's return, the skin had grown over the remaining implant necessitating a skin punch to re-insert a new abutment. No other skin revision surgery was performed.

Figure 1 presents an overview of soft tissue reactions per visit. Overall, Holgers grade 0 was observed in 72.4% of the visits; Holgers grade one in 23.3% of the visits; Holgers grade two in 3.4% of the visits; Holgers grade three in 0.1%. No Holgers grade four was observed. During follow-up, an adverse skin reaction (Holgers grade two-4) was observed in four (8.8%) subjects. Interestingly, all events were observed in the tissue preservation group. All have been successfully treated with locally applied medication.

Pain was reported by 9 subjects (27%) during any of the visits. In 2 patients, this was reported at the first visit 1 week after surgery without signs of infection and was resolved at the second visit. In 5 other patients, pain was reported combined with certain signs of infection (Holgers > 0), but was resolved at the next visit. The last two patients reported pain at the latest visit without any signs of infection (Holgers = 0). Numbness was also reported by 9 subjects (27%) during any of the visits. In 8 patients, it resolved during the follow-up; the other patient reported numbness at the latest visit, however without prior reported numbness. The presence of pain and numbness were independent of surgical techniques being used, ie tissue reduction or preservation.

Implant Stability Quotient was measured in two hospitals, resulting in 23 patients with complete ISQ-data. ISQ over time can be

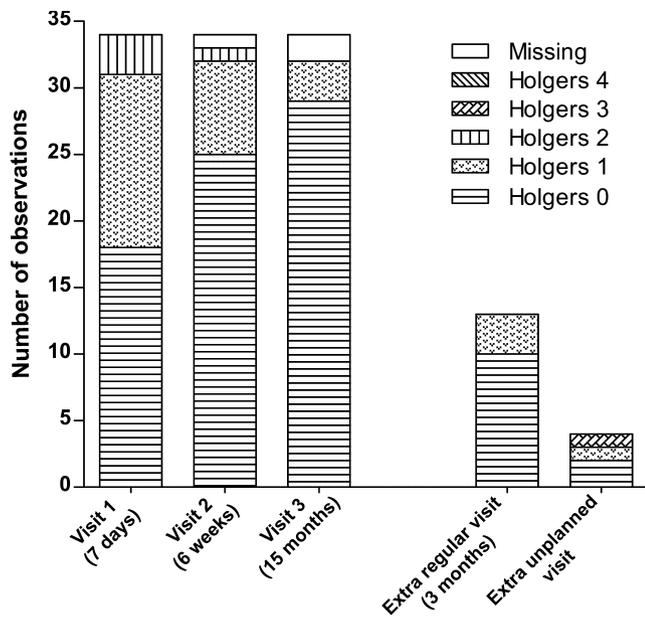


FIGURE 1 Holgers score per visit. The median follow-up for each visit (entire cohort) is stated in the round brackets. Missing data were caused by visit performed by phone or implant loss prior to visit

observed in Figure 2. Overall, a significant decrease in 3.4 ISQ-low points was observed at the first visit compared to at surgery. ISQ-low significantly increased thereafter until the last visit. At this visit, ISQ-low surpassed per-operative values by a significant 2.1 points. No clinical instability was observed during the ISQ-dip.

4 | DISCUSSION

4.1 | Synopsis of key/new findings & strengths of the study

The current study is the first to report clinical outcomes and performance data—ie implant survival, ISQ, soft tissue tolerability and

other complications—of the new laser-ablated titanium wide-diameter implant for bone conduction hearing. With only one spontaneous implant loss, the laser-ablated implant displays an excellent (median) 15-month implant survival in this patient group. The soft tissue tolerability is good with only few adverse skin reactions observed. Due to this population size, the multicentre nature of the study and no loss-to-follow-up outcomes can be considered reliable.

4.2 | Comparisons with other studies

Implant survival and soft tissue tolerability seem comparable to the standard wide-diameter implants used in healthy adults.¹⁻³ However, due to the retrospective, multicentre nature of this study, using multiple surgical techniques, caution is needed in drawing conclusions especially regarding soft tissue tolerability.

The use of ISQ to measure osseointegration has been discussed extensively and remains questionable.¹⁰ If we compare 1-year ISQ of the 5 patients in this cohort with a 6 mm abutment to patients with the standard wide-diameter implant and identical 6 mm abutment, using the same surgical technique, no differences seem present (66.0 vs 66.0). [Kruyt et al submitted at O&N, under review] This was also found in pre-clinical animal testing of this implant; however, removal torque measurements showed a 153% higher biomechanical anchorage of the laser-modified implants.⁸ This underlines that ISQ might not reliably reflect actual osseointegration and that this implant might be beneficial for using in high-risk patients.

4.3 | Clinical applicability of the study

Despite these excellent results in terms of survival, prospective, long-term comparative research, using only one surgical technique, is needed to determine clinical usefulness of this implant. In addition, incremental cost-effectiveness has to be assessed, as the (head) room for improving implant survival compared to the standard wide-diameter implants seems to be limited. However, more headroom is present in high-risk patient groups. The current (retrospective) study

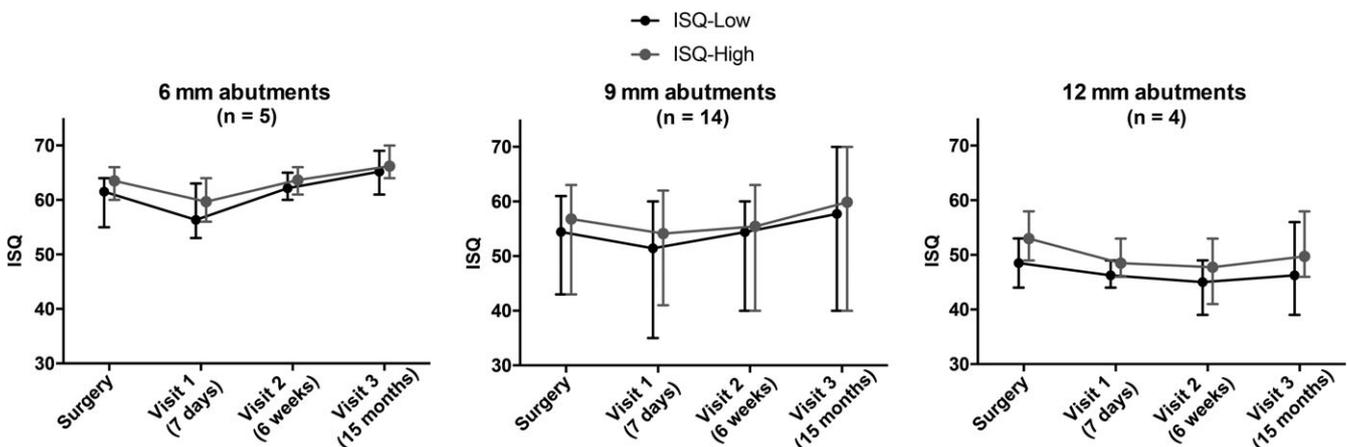


FIGURE 2 Implant Stability Quotient (ISQ)-low & ISQ-high over time per abutment length. The median follow-up for each visit (entire cohort) is stated in the round brackets

does suggest that this implant is safe to use in healthy adults. On the basis of these outcomes, in our clinical practice, we believe it justified to test this implant in higher-risk patients and concomitantly assess the possible additional benefit in this specific patient group.

5 | CONCLUSION

The new laser-ablated titanium implant for bone-anchored hearing implantation showed excellent survival rates and soft tissue tolerability, with few complications. These results indicate that the new implant is safe to use in healthy adults.

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CONFLICT OF INTEREST

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