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Three-week loading of the 4.5 mm wide titanium implant in bone anchored hearing systems☆

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ABSTRACT

Purpose: The purpose of this study is to assess implant stability, implant loss, adverse skin reactions and quality of life benefit following surgical implantation and early processor loading (3-weeks post-implantation) of the Oticon Ponto 4.5 mm osseointegrated auditory implant. This study also investigates the relationship between the type of post-operative skin reactions and the gender, BMI and medical co-morbidities of participants.

Materials/Methods: Using a prospective, multicenter design, thirty adult patients 18 years or older who met medical and audiological candidacy for an osseointegrated auditory bone-anchored hearing device were evaluated. They underwent simultaneous implantation of the Oticon 4.5 mm wide implant and a 3.75 mm sleeper implant. Sound processor loading occurred at three weeks post-implantation. Implant stability was measured using Radio Frequency Analysis (RFA) at surgery, 1, 3, 6, 12, 26 and 52 weeks. The Glasgow Benefit Inventory was used to assess quality of life benefit at 12 and 52 weeks following implantation.

Results: The results show a positive linear trend in implant stability measures in all subjects over time. There have been no implant losses with early 3-week loading. Skin reactions were limited to grade 0 and 1 of the modified Holger's grading scale.

Due to the limited incidence of complications, no conclusion can be made regarding the relationship between patient demographic data and soft tissue reaction.

Conclusion: Our findings confirm the safety and efficacy of early loading of the Oticon 4.5 mm wide implant. Participants showed satisfaction with the earlier use of their processor with no added complications after one year post-implantation.

1. Introduction

The application of the Titanium Osseo Integrated implants in the temporal bone was introduced by Tjellstrom in 1977 [1] and has been successfully used since. The evolution of the techniques, results, and complications has been extensively published [2–5]. The amount of time necessary for osseointegration was empirically chosen at three months post-implantation in adults.

The purpose of this paper is to confirm the efficacy and safety of early loading of the titanium implant with the

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Table 1 – Baseline descriptive statistics (qualitative variables).

Variable	Frequency	%
Gender		
Male	8	27
Female	22	73
Site		
MEI	10	33
FL	20	67
Smoking status		
Yes	1	3
No	29	97
Diabetes		
Yes	3	10
No	27	90
Abutment length		
6 mm	20	67
9 mm	7	23
12 mm	3	10

Table 2 – Baseline descriptive statistics (quantitative variables).

Variable	N	Mean	Std Dev	Minimum	Maximum
Age (yrs)	30	60.83	16.07	20.00	87.00
Weight (kg)	30	76.72	19.61	48.10	124.50
Height (cm)	30	163.79	8.89	152.40	188.00
BMI	30	28.56	7.09	19.90	50.10

processor at three weeks postoperatively. Earlier studies have confirmed safety in loading at six weeks [6], three weeks [7–9] and even two weeks postoperatively [10].

2. Materials and methods

A prospective multi-institutional study was designed to include 30 adult patients implanted with the wide titanium implant (Oticon Medical, Askim, Sweden). Following institutional review board (IRB) approval, 20 patients were enrolled at the Silverstein Institute (Sarasota, FL) and 10 patients were enrolled at the Michigan Ear Institute (Farmington Hills, MI). There were 22 females and eight males. Twenty-nine of the 30 patients were non-smokers, and 27 were non-diabetics. The average age was 60.83 years; the average weight was 76.72 kg with an average BMI of 28.56 ranging from 19.90 to 50.10 (Tables 1 and 2). All patients were provided with a sleeper implant to be exteriorized in case of loss of the activated implant.

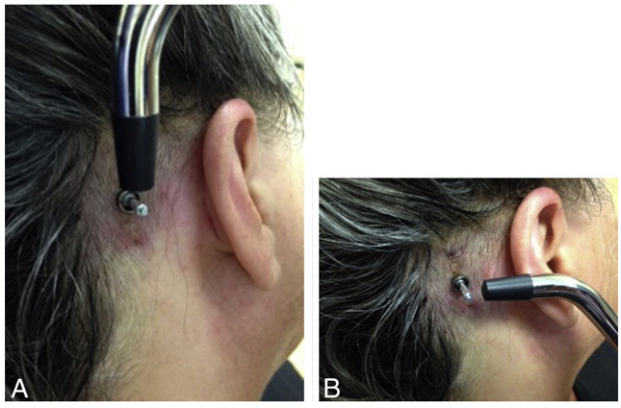

Fig. 1 – (A) Vertical radio frequency measure. (B) Horizontal radio frequency measure.

Table 3 – Modified Holger's soft tissue reaction grading system.

Grade	Clinical description
0	No irritation: epithelial debris removed if present
1	Slight redness: temporary local treatment indicated
2	Red and slightly moist; no granulation tissue present
3	Red and moist with granulation tissue, skin overgrowth, or scar formation: Local treatment indicated
4	Extensive granulation, skin overgrowth, or scar formation requiring revision surgery
5	Removal of skin-penetrating abutment necessary to control infection

The implant stability was measured using the Osstell® implant stability quotient (ISQ) instrument (Osstell, Göteborg, Sweden), a non-invasive tool that measures the resonance frequency of the implant in bone in the vertical and horizontal directions. Measurements were obtained at surgery, one week, three weeks, six weeks, three months, six months, and 12 months postoperatively (Fig. 1A, B).

Twenty (20) of the patients received a 6 mm abutment, seven patients received a 9 mm abutment, and three received a 12 mm abutment. All patients were loaded with the processor at three weeks postoperatively. The skin reactions were graded according to the modified Holger's scale as seen in Table 3.

SAS 9.4 was used for all statistical analyses. Descriptive statistics were calculated for all relevant variables. Estimates with 95% confidence interval for ISQ measurements were calculated for each of the following points: at surgery, one, three, and six weeks, and three, six and 12 months postoperatively.

3. Results

ISQ measurements in the vertical and horizontal planes plotted over time are shown in Table 4, demonstrating progressive

Table 4 – ISQV and ISQH over time (from surgery to 12 months after surgery).

Variable/ Time	N	Mean	Std Dev	LCL [a]	UCL [b]	Min	Max
ISQV							
At surgery	30	58.43	8.01	55.44	61.42	30.00	70.00
1 week	30	59.70	7.03	57.07	62.33	37.00	70.00
3 week	30	60.53	7.14	57.87	63.20	37.00	70.00
6 week	30	61.28	5.81	59.11	63.45	48.50	70.00
3 months	30	61.97	5.91	59.76	64.17	48.00	71.00
6 months	30	63.62	5.26	61.65	65.58	50.00	72.00
12 months	30	63.73	5.31	61.75	65.72	48.00	72.00
ISQH							
At surgery	30	58.58	7.42	55.81	61.35	35.00	70.00
1 week	30	59.77	7.88	56.82	62.71	37.00	71.00
3 week	30	60.30	7.78	57.40	63.20	37.00	71.00
6 week	30	61.02	6.56	58.57	63.47	48.00	70.00
3 months	30	62.00	6.07	59.74	64.26	48.50	70.00
6 months	30	63.27	5.48	61.22	65.31	49.00	72.00
12 months	30	63.62	5.26	61.65	65.58	49.00	72.00

[a] Lower 95% confidence limit for the mean.
[b] Upper 95% confidence limit for the mean.