A one-year follow-up report on a randomized, controlled, double-blind multi-center clinical study comparing Roxolid® and Ti Grade 4 implants in edentulous mandibles in a split mouth design

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Introduction

Small diameter implants are beneficial in the daily practice but have limits based on the choice of implant material or surface. In order to increase confidence and enhance the treatment options for narrow diameter implants, an alloy composed of titanium and zirconium (Roxolid®) has been developed. This material shows better tensile and fatigue strength as compared to pure titanium[1,2] and possesses excellent osseointegration properties[3] in combination with the SLActive® surface.

Based on the results of previous studies, a clinical multi-center study has been initiated with the aim of a direct comparison between pure titanium and Roxolid® implants.

Materials and methods

A randomized, controlled, double-blind, split-mouth study was started in the beginning of 2008 in eight centers.

- Indication: Fully edentulous mandible
- Test: BL implant Ø 3.3 mm SLActive® Roxolid®
- Control: BL implant Ø 3.3 mm SLActive® Ti
- Solution: Removable denture on 2 LOCATOR® abutments
- Specific: Double-blind study for the first year

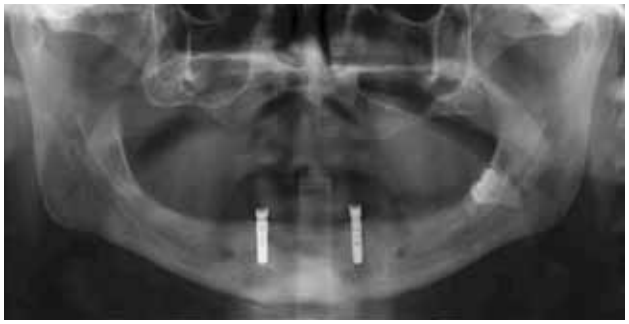

Figure 1: X-ray picture showing one test and control implant after placement. There is no visible difference between test and control implant

Each patient was treated with two implants (one test implant, one control implant), which were placed intraforaminally. Abutment and prosthesis placement was performed 8–10 weeks after surgery (Figure 2). Twelve months after surgery, the following parameters were analyzed:

- Crestal bone loss (standardized X-rays)
- Bleeding on probing
- Plaque index

After full analysis (one-year follow-up) of all parameters the data was un-blinded.

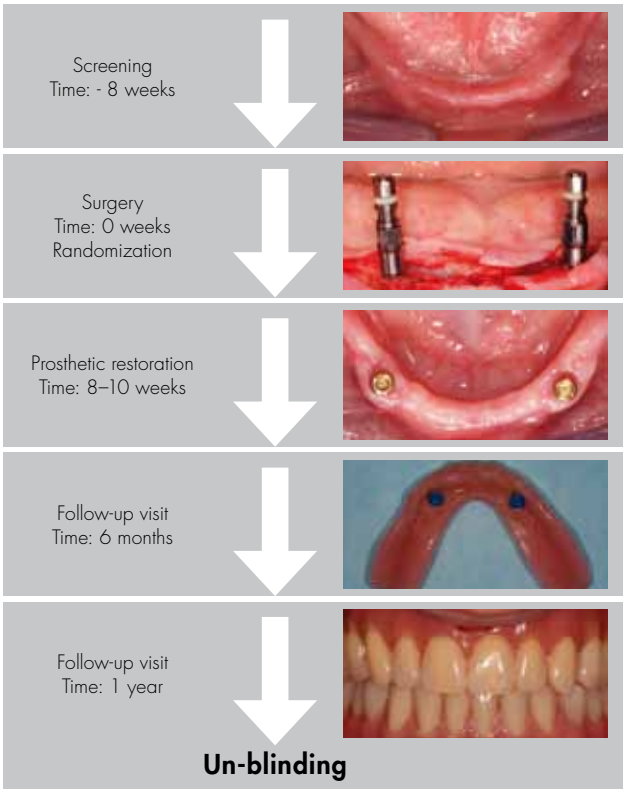

Figure 2: Treatment plan before un-blinding procedure

Results

One year after surgery, the study was un-blinded and the data of 89 patients with 178 implants were evaluated. Three early implant failures were recorded. The implant failures occurred in both implant material groups (one test implant, two control implants) and in three different study centers.

Crestal bone change

Implant surgery was the baseline for the crestal bone loss evaluation. The evaluation was made for the per protocol population (n=70). No statistically significant differences were found between the two groups (table 1).

	Roxolid®	Ti
Average bone loss	0.31 mm	0.34 mm
Standard deviation	±0.45 mm	± 0.54 mm

Table 1: Bone loss of both materials 12 months after surgery (per protocol population)

Frequency analysis of the crestal bone change did not show any statistically significant difference between the two groups (Figure 3).

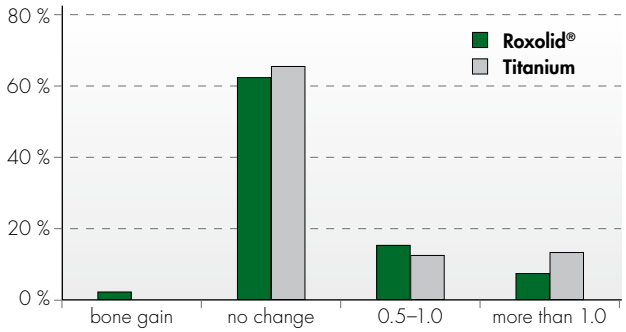

Figure 3: Distribution of the crestal bone loss

Plaque index and sulcus bleeding

The plaque index and sulcus bleeding data were taken from the intent-to-treat population (n=85 Ti, n=87 Roxolid). No differences were found between study implant and control implant (figures 4a and 4b).

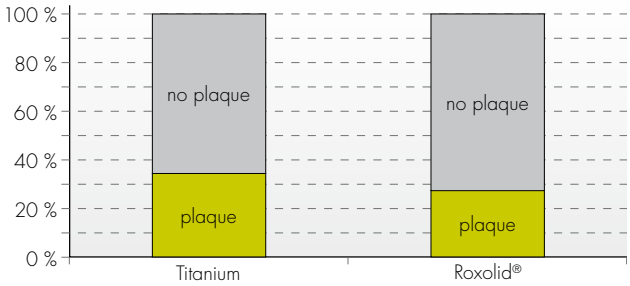

Figure 4a: Not statistically significant in the plaque index between the groups

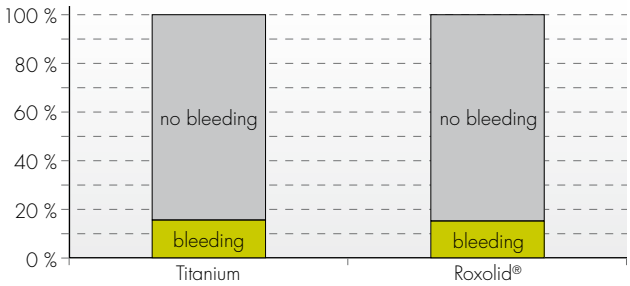

Figure 4b: Not statistically significant in the sulcus bleeding between the two groups

Conclusions

- This study did not show any statistically significant differences (bone change, sulcus bleeding, plaque) between Roxolid® and titanium implants.
- Minimal bone loss (0.34 mm control and 0.31 mm study group) one year after surgery was observed.
- Higher mechanical strength and uneventful one-year follow-up indicate that small diameter Roxolid® implants are a valid alternative to pure titanium implants and offer more treatment options

References

1) Data on file, tensile strength of material used for all Straumann® titanium and Roxolid® implants

2) Norm ASTM F67 (states min. tensile strength for annealed titanium)

3) Gottlow J, Dard M, Kjellson F, Obrecht M, Sennerby L 'Evaluation of a New Titanium-Zirconium Dental Implant: A Biomechanical and Histological Comparative Study in the Mini Pig' Clin Implant Dent Relat Res. 2010 Jun 25

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