A comparison of Roxolid with Ti Grade 4 implants
A one-year follow-up report on a randomized double-blind multi-center study

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Small diameter implants are beneficial in daily practice but they 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 by Straumann. This material shows better tensile and fatigue strength as compared to pure titanium and possesses excellent osseointegration properties in combination with the SLActive surface.

Based on the results of previous studies, a clinical multi-centre study was initiated with the aim of a direct comparison between pure titanium and Roxolid implants (Fig. 1).

Materials and methods
A randomized, controlled, double-blind, split-mouth study was started in the beginning of 2008 in eight centres.

- 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

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

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

After full analysis of all parameters the data was unblinded.

Results
One year after surgery, the study was unblinded and the data of 89 patients or 178 implants were evaluated respectively. Three early implant failures were recorded. The implant failures occurred in both implant material groups (one test implant and two control implants) and in three different study centres.

Crestal bone change
Implant surgery was the baseline for the crestal bone loss evaluation. The evaluation was made for the per protocol population. No statistically significant differences were found between the two groups (Table I).

Table I: Bone loss of both materials is around 0.3 mm 12 months after surgery for both groups (per protocol population).

<table>
<thead>
<tr>
<th>Material</th>
<th>Bone Loss (mm)</th>
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<tr>
<td>Roxolid®</td>
<td>0.31 ± 0.45 mm</td>
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<tr>
<td>Ti</td>
<td>0.34 ± 0.54 mm</td>
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Fig. 3: Distribution of the crestal bone loss.

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

Plaque index and sulcus bleeding
The plaque index and sulcus bleeding data was taken from the intent-to-treat population. No differences were found between study implant and control implant (Figs. 4a & b).

Conclusions
This study did not show any statistically significant differences (bone change, sulcus bleeding, plaque) between Roxolid and titanium implants. High very low bone loss (0.3 mm control and study group) was observed one year after surgery. Higher mechanical strength and uneventful one-year follow-up indicate that small diameter Roxolid implants are a valid alternative to pure titanium implants and may offer a wider spectrum of clinical applications.

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)

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