

Two-year results of a human pilot study evaluating success and survival rate of Roxolid® implants

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Introduction

Narrow diameter implants are often chosen for cases where there is a reduced availability of alveolar ridge width or interdental space. However, the reduced surface area for osseointegration^{1,2} and the increased risk for implant fracture^{3,4} in such cases may speak against the usage of narrow diameter implants. In order to increase confidence in narrow diameter implants, an alloy composed of titanium and zirconium (Roxolid®) has been developed. Mechanical tests have shown higher tensile and fatigue strength of the Roxolid® material compared to pure titanium.^{5,6} Osseointegration has been demonstrated in animal studies.^{7,8} This performance must now be verified in the human model.

The aim of the study was to investigate the performance of implants made of Roxolid® in human subjects.

Materials and methods

This pilot clinical study was designed as a single-cohort, prospective case series in two centers (UK). The clinical study was approved by the National Ethics Committee. Patients who were partially edentulous in the mandible or maxilla with an opposing dentition were eligible for the study. Implants were placed at least 8 weeks after any tooth extraction. Each patient received a Straumann® Standard Plus Regular Neck Ø 3.3 mm SLActive® Roxolid® implant (study implant) splinted to at least one supporting titanium SLActive® implant (Ø 4.1 or Ø 4.8 mm). After a healing phase of 10 to 14 weeks, successfully integrated implants received their final prosthesis (Figure 1).

The patients were recalled for several follow-up visits at various points in time. During these visits, various parameters were assessed including:

- Implant survival and success
- Bone level change
- Pocket Probing Depth (PPD)
- Prosthetic restoration

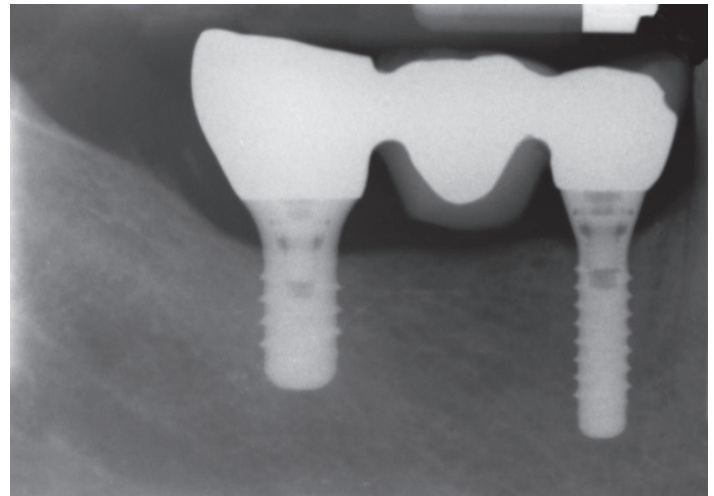


Figure 1: Radiographic picture showing the Roxolid® implant (Mesial) splinted with a wider titanium implant

Results

22 patients were entered in the study and received a study implant. 20 had the implant still in position approximately 2 years after implant placement. One patient did not complete the 2-year assessment and another patient experienced implant loss after 80 days (prior to prosthesis placement) due to an infection arising from an adjacent tooth. All surviving study implants were considered to be successful at all assessment intervals up to 2 years.

Radiographic Evaluation

Standardized radiographs were taken to assess bone level change, measured from implant loading (baseline). The mean values of bone level changes after 1 year and 2 years were -0.16 mm, and -0.33 mm (Table 1) respectively. Overall, the radiographic mean loss of bone 2 years post-surgery was less than 1 mm.

	Baseline	1 year	2 years
Mean	0	-0.16	-0.33
SD	0	± 0.42	± 0.54

Table 1: The mean bone level changes from the baseline (in mm)

Probing Pocket Depth (PPD)

Mean PPD values were assessed at mesial, distal, bucal and lingual positions. Mean PPD values did not substantially change from baseline (prosthesis placement) to 2-year follow-up. The values ranged from 1.43 to 1.95 mm at baseline and from 2.21 to 2.89 mm at 2 years.

Prosthetic restoration

All 20 patients assessed at 2 years had a stable and functional prosthetic restoration. One patient reported a pulsing sensation shortly after the loading visit. This sensation remained at the 6-month and 1-year visit but had resolved without sequelae before the 2-year visit. For this patient, the study implant was considered successful at all visits.

Conclusions

- First human study showing performance and tolerability of the new Roxolid® implants over 2 years
- Minimal crestal bone change was observed 2 years after implant loading
- Roxolid® combines high implant stability and good osseointegration properties while still retaining adequate mechanical strength with a reduced implant diameter, thus increasing confidence when using small diameter implants

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