A prospective two-year clinical trial of titanium-zirconium alloy implants (Roxolid® Straumann®) with hydrophilic surface (SLActive®) in patients with controlled Type 2 Diabetes Mellitus.

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Abstract

Background: The prevalence of Type 2 Diabetes Mellitus is increasing. By affecting the healing of the wounds can alter the osseointegration process of the implants. Recent short-term studies have shown how narrow diameter implants are useful in patients with type-2 diabetes mellitus patients (DM2).

Aim/Hypothesis: To evaluate prospectively the long-term (2-years) of the performance of the Titanium-Zirconium alloy implant (Roxolid® Straumann®) with a narrow diameter (3.3 mm) and with hydrophilic surface (SLActive®) in DM2 in unitary restorations.

Methods and Materials

28 patients, 14 DM2 (test group) and 14 without diabetes mellitus (control group). With a unitary tooth absence was rehabilitated in incisors, canines or premolars with a titanium-zirconium alloy implant of narrow diameter (3.3 mm) Standard RN (2.8 mm high platform) SLActive® Roxolid®, (Institut Straumann AG, Basel, Switzerland). Implants were placed in healed bone (more than 8 weeks post-exodontia), non-submerged healing and loaded 2 months after surgery. The success and survival rate was assessed according to the criteria of Buser et al., 1991. Implant follow-up was performed at 2 years, with standardized radiographs evaluating marginal bone loss and by measurement of glycemic control of patients over time (glycosylated hemoglobin -HbA1c-).

Results

With our study sample, the power of the study is 93 -99%. There was statistically significant (p<0.05) more diabetics men than woman's in our sample. We find a correlation between the presence of hypertension and DM2 with statistically significance (p<0.05) and with same significance was found more thick biotype of soft tissues in the DMG group (p<0.05).

The success and survival rate of the implants was 100% in both groups. No marginal bone loss appeared in any of the groups at two years. Being the bone tissue located with respect to the 2.8 mm polished neck of our implant without significant differences between the two groups and equally with no significant difference in the variation of it as described in the tables.

Conclusions

Strawmann® Roxolid® SLActive® narrow diameter (3.3 mm) titanium-zirconium alloy implants, are placed in both well-controlled DM2 and healthy patients, have the same behavior and outcome. Given the lower surgical trauma to DM2, the indications for this type of narrow-diameter implants could be widened. Although short- and long-term results are already known, more controlled clinical trials are necessary to corroborate these results. The results demonstrate that with good glycemic control, narrow implants with a hydrophilic surface could be useful in the treatment of DM2 patients.

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