PB 61

IMPLANT THERAPY OUTCOMES, PERI-IMPLANT BIOLOGY ASPECTS

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, compared to a control group of patients without diabetes mellitus, and to analyse the success rate and survival, the marginal bone loss and the influence of the glycemia level of the patients in the osseointegration, by measuring the glycosylated hemoglobin (HbA1c).

Materials and Methods: 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: The study power is 87%. The success and survival rate of the implants was 100% in both groups. The mean marginal bone loss from implant placement to 2 years was -0.53 ± 0.54 mm. There were no significant differences between the two groups (-0.48 ± 0.50 mm, in the test group (DM2) and -0.43 ± 0.47 mm in the control group). No marginal bone loss appeared in any of the groups measured from the implant platform to the bone tissue at two years. The values of HbA1c were maintained on average in 7.10% in patients with DM2. Moreover, no significant correlation between HbA1c levels and obtained results was observed.

Conclusions/Clinical Implications: Straumann® Roxolid® SLActive® narrow diameter (3.3 mm) titanium-zirconium alloy implants, 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 would be 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.

Background and Aim

The prevalence of Type 2 Diabetes Mellitus is increasing. By affecting the healing of the wounds can alter the osseointegration process of the implants.[1, 2] Recent short-term studies have shown how narrow diameter implants are useful in patients with type-2 diabetes mellitus patients (DM2).[3]

The aim of this study was 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®) [4] in DM2 in unitary restorations, compared to a control group of patients without diabetes mellitus, and to analyse the success rate and survival, the marginal bone loss and the influence of the glycemia level of the patients in the osseointegration, by measuring the glycosylated hemoglobin (HbA1c).

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.[5] 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 between 87-90%. There was with statistically signification ($p<0,05$) more diabetics mans than woman's in our sample. We find a correlation between the presence of hypertension and DM2 with statistically signification ($p<0,05$) and with same signification was found more thick biotype of soft tissues in the DM2 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 level 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:

MBL (2 years follow up)

	Diabetes	Control	All	*p*
Mesial	-0,50 ± 0,48	-0,58 ± 0,53	-0,52 ± 0,50	
Distal	-0,36 ± 0,60	-0,49 ± 0,68	-0,41 ± 0,62	
Mean	-0,43 ± 0,47	-0,53 ± 0,54	-0,47 ± 0,50	

MBL CHANGE (from base line to 2 years follow up)

	Diabetes	Control	All	*p*
Mesial	0,81 ± 0,74	0,87 ± 0,68	0,84 ± 0,70	
Distal	0,54 ± 0,75	0,62 ± 0,46	0,58 ± 0,62	
Mean	0,68 ± 0,67	0,75 ± 0,49	0,71 ± 0,58	

MBL=marginal bone level.
p=statistical significance.

The values of HbA1c were maintained on average in 7.10% in patients with DM2 in the 2 years follow up and during all the study in 6.8%. Moreover, no significant correlation between HbA1c levels and obtained results was observed, although in the initial reviews there appeared to be a tendency to have it.

CORRELATION MBL and HbA1c

	Final restoration		6 months follow up		1 year follow up		2 years follow up	
	Corr.	*p*	Corr.	*p*	Corr.	*p*	Corr.	*p*
Mesial	-0,4571		-0,5286	quasi	-0,5073	quasi	-0,4248	
Distal	-0,1943		-0,5146	quasi	-0,4411		-0,3399	
Mean	-0,3607		-0,5790	*p*<0,05	-0,5262	quasi	-0,4242	

MBL=marginal bone level. HbA1c= glycosylated hemoglobin. Corr.=correlation.
p=statistical significance.

Conclusions

Straumann® Roxolid® SLActive® narrow diameter (3.3 mm) titanium-zirconium alloy implants, 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 would be 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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