Poster Number 300

A 5-year randomized pilot study with chemically modified SLA implants

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Topic: Tissue augmentation and engineering

Abstract

Aim: Until now, no study was performed to compare long-term success rates of implants with chemically modified, sandblasted, large grit and acid-etched (mod-SLA) and SLA surface. This study evaluates the 5-year clinical performances of mod-SLA and SLA implants and compares crestal bone levels around implants.

Material and methods: This randomized controlled trial was conducted with 14 patients. Each patient randomly received one mod-SLA (SLActive®) and one SLA implant (Straumann AG) in either posterior mandible or maxilla. Clinical and radiographic parameters were assessed at 5 years after loading. Crestal bone losses and gains were measured at the mesial and distal implant sides.

Results: All 28 implants were successfully integrated and restored after 3.1 ± 0.3 months of healing. After 5 years, they were clinically stable. The mean overall crestal bone change was a moderated bone loss of -0.28 ± 0.70 mm. Seventeen sides of mod-SLA implants showed crestal bone loss (mean -0.81 ± 0.74 mm) and 11 sides showed bone gain (mean 0.54 ± 0.22 mm). Also 17 sides of SLA implants displayed bone loss (mean -1.08 ± 0.84 mm) whereas 11 sides displayed bone gain (mean 0.54 ± 0.36 mm). The difference in bone loss and gain between mod-SLA and SLA implants was not statistically significant (p>0.05).

Conclusions: This study showed that implants with mod-SLA surface could be placed using an early loading protocol and could achieve tissue integration over a period of 5 years. Crestal bone loss was limited with no significant difference between both implant types. The 5-year success rates were 100% for mod-SLA.

Background and Aim

Mod-SLA implant surface demonstrated significant bone-to-implant contact during the first four weeks of bone healing (Ferguson 2006, Buser 2004). By fostering the healing process at the implant-bone interface, this surface could shorten the healing period with short-term clinical success similar to those observed for SLA (Oates 2007, Schätzle 2009). Furthermore, experimental animal studies suggested that it might promote bone regeneration and osseointegration in presence of large bone defects (Schwarz 2007, 2010). Recently, a human trial has shown that the osseointegration degree after 2 and 4 weeks was higher for the mod-SLA compared with the SLA surface (Lang 2011) .

The 5-year control of this presented randomized controlled pilot trial was set-up to gather data and to compare implants with mod-SLA and SLA surfaces in terms of survival rate, success rate, clinical parameters and radiographic crestal bone level measurements.

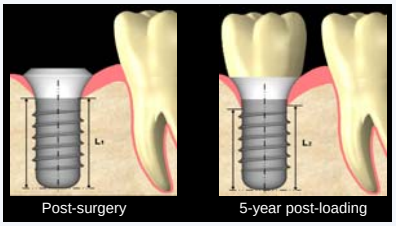
Methods and Materials

Ethics Committee: approved by Lausanne University (Switzerland, n°06-089)
Number of patients: 14 (57.3 ± 11.9 years)
Sites: 28 healed sites; 2 sites/patient, either in the posterior mandible or maxilla

Treatment (Oates 2007): Two endosseous standard implants (Ø 4.1 mm, length 8 or 10 mm, Straumann AG, Basel, Switzerland) were randomly placed without bone augmentation and according to standard procedure using a non-submerged technique; one implant had a mod-SLA surface (SLActive®) and the other a standard SLA surface.
Healing period: 3.1 ± 0.3 months
Restorations: fixed single crowns

Five-year post-loading clinical examination:
- modified plaque index (mPI): score 0 (no plaque) to 3 (abundant soft matter);
- bleeding index (BI): score 0 (no bleeding) to score 3 (heavy or profuse bleeding);
- probing pocket depth (PD, mm);
- distance between implant shoulder and mucosal margin (DIM, mm);
- width of the keratinized gingival mucosa (KG, mm).

Five-year post-loading radiographic analysis:
The distance parallel to the implant axis between the most coronal bone-implant contact and the implant apex was measured on post-operative (L_1) and 5-year (L_2) non-standardized peri-apical radiographs. A negative value of the subtraction L_2 - L_1 indicated crestal bone loss whereas a positive one suggested crestal bone gain.



Statistical analysis: The non-parametric Wilcoxon signed-rank test was used to compare implant group behavior. Success rates were tested with the Student-t test. The threshold value for statistical significance was set at p<0.05.

References

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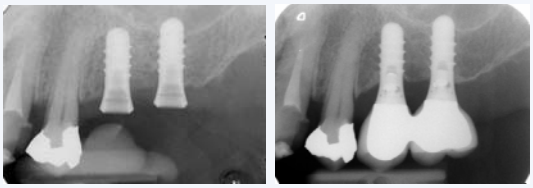
Results

All implants were successfully integrated and restored. At the 5-year control, all patients expressed good satisfaction in terms of comfort, appearance, ability to chew and ability to taste. The implant survival rate was 100%.

patient	mod-SLA surface						SLA surface					
	site	mPI	BI	PD (mm)	DIM (mm)	KG (mm)	site	mPI	BI	PD (mm)	DIM (mm)	KG (mm)
# 1	25	0.00	0.00	1.00	-0.25	3.00	24	0.00	0.00	1.50	0.50	3.00
# 2	46	0.25	0.25	1.75	1.50	2.00	47	0.75	0.25	2.25	1.75	2.00
# 3	46	0.50	0.00	2.50	0.63	3.00	44	0.50	0.25	2.50	1.00	4.00
# 4	47	0.00	0.00	1.00	0.25	1.00	46	0.00	0.00	1.00	-0.50	3.00
# 5	36	0.00	0.50	3.00	1.25	3.00	46	0.00	0.50	2.00	0.75	2.00
# 6	24	0.00	0.00	1.75	0.00	3.00	26	0.00	0.00	2.25	1.00	3.00
# 7	15	0.50	0.25	3.75	0.75	5.00	25	0.75	1.00	3.50	0.75	3.00
# 8	47	1.25	0.25	4.00	2.25	3.00	46	0.25	0.00	3.25	1.75	4.00
# 9	25	0.00	0.25	2.50	0.00	1.00	26	0.25	0.25	2.25	0.50	1.50
# 10	36	0.50	1.00	2.00	-0.25	1.00	34	0.25	1.00	2.25	0.50	3.00
# 11	44	0.00	0.00	2.50	-0.25	4.00	46	0.25	0.25	3.00	0.00	2.00
# 12	36	0.00	0.25	3.00	-0.50	1.00	46	0.00	0.25	3.25	0.25	0.00
# 13	46	0.00	0.00	3.25	2.00	3.00	36	0.00	0.25	3.25	1.75	3.00
# 14	36	0.00	0.25	3.75	0.50	2.00	37	0.00	0.00	1.75	0.25	1.00
Mean value		0.21	0.21	2.55	0.56	2.50		0.21	0.29	2.43	0.73	2.46
Std deviation		0.37	0.27	0.97	0.88	1.22		0.27	0.34	0.74	0.68	1.12

Complete overview of 5-year clinical results.



Post-operative and 5-year post-loading radiographs (Patient #9).
Site 25: mod-SLA implant. Site 26: SLA implant

patient	mod-SLA surface				SLA surface			
	site	crestal bone level (mm)			site	crestal bone level (mm)		
		mesial	distal	mean		mesial	distal	mean
# 1	25	-0.15	0.72	0.28	24	-1.37	1.05	-0.16
# 2	46	0.60	0.40	0.50	47	-2.34	0.20	-1.07
# 3	46	-0.10	0.58	0.24	44	0.18	0.81	0.49
# 4	47	-0.29	0.58	0.14	46	-0.29	-0.29	-0.29
# 5	36	0.38	-2.20	-0.91	46	0.80	1.10	0.95
# 6	24	-0.46	0.81	0.18	26	0.09	-0.19	-0.05
# 7	15	0.01	0.61	0.31	25	-1.25	0.58	-0.34
# 8	47	0.72	0.50	0.61	46	-0.29	-1.73	-1.01
# 9	25	-0.56	-0.28	-0.42	26	0.41	-0.22	0.09
# 10	36	-1.47	-0.65	-1.06	34	-1.15	-3.15	-2.15
# 11	44	-1.37	-1.06	-1.22	46	-0.63	-0.86	-0.74
# 12	36	-2.27	-0.01	-1.14	46	0.55	-0.36	0.10
# 13	46	-0.07	-0.23	-0.15	36	-1.00	-1.80	-1.40
# 14	36	-1.00	-1.54	-1.27	37	-0.60	0.20	-0.20
Mean value		-0.43	-0.13	-0.28		-0.49	-0.33	-0.41
Std deviation		0.84	0.93	0.70		0.87	1.21	0.80

Complete overview of 5-year radiographic results. A negative value expresses crestal bone loss; a positive one means crestal bone gain.

Conclusions

Implants were successfully integrated five year after loading. No significant differences in clinical and radiographic behavior were observed between mod-SLA and SLA implants. Around the implants, soft tissues were healthy and the marginal soft tissue recession around implants was limited. All mod-SLA implants exhibited a CBL>-2.3 mm on their both sides (mesial and distal implant sides) whereas 2 SLA implant exhibited one side with a CBL<-2.3 mm. Success rates were 100.0% for the mod-SLA implant group and 92.9% for the SLA implant group; there was no statistical difference in success rates between the two surfaces (p=0.69).

The mean bone level loss was limited along 5 years. Eleven sides of mod-SLA implants showed crestal bone gain (mean 0.54 ± 0.22 mm) and 17 mod-SLA implant sides showed crestal bone loss (mean -0.81 ± 0.74 mm). Also 11 SLA implant sides displayed crestal bone gain (mean 0.54 ± 0.36 mm) whereas 17 sides of SLA implants displayed crestal bone loss (mean -1.03 ± 0.84 mm). The difference in gain and loss between the two implant groups was not statistically significant (p=0.32 and p=0.92, respectively).

The study has demonstrated that the use of mod-SLA implants is predictable and allows treating edentulous posterior region with reliable long-term results. The mod-SLA implants could successfully achieve tissue integration over 5 years. This study is the first report of a long-term follow-up of implants with mod-SLA surface.

Presented at the 20th Annual Scientific Meeting of the European Association of Osseointegration
3-15 October 2011, Athens, Greece