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Multi-phosphonate treated dental implants: comparison of clinical outcome in maxilla, mandible, smokers and non-smokers

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Background: SurfLink® surface treatment consists of a molecular monolayer of multi-phosphonate molecules covalently bound to the implant surface. Pre-clinical *in vitro* and animal studies have shown that this novel surface treatment increases the implant wettability, resulting in faster bone cell adhesion and colonisation. Once on the implant surface, bone cells quickly spread improving osseointegration on the short and long term. SurfLink® has been clinically validated in a randomised controlled trial. The aim of the study was to test the null hypothesis that there was no difference in the clinical outcome between the SurfLink® treated and control implants against the alternative hypothesis of a difference. Preliminary 1 year data was previously reported and showed excellent clinical outcome for both SurfLink® treated and control implants.

Aim / Hypothesis: The effect of SurfLink® surface treatment of dental implants at 1 year post-loading was further analysed in respect to implant surface (SurfLink® treated vs control implants), implant position (maxilla vs mandible), patient characteristics (smoker vs non-smokers, gender, age), implant dimensions and bone augmentation.

Material & Methods: The clinical study was conducted in a private Swiss clinic according to GCP and ISO 14155. Prior to the study, no clinical data was available on SurfLink® treated implants and sample size calculation was therefore not conducted. Twenty three patients were enrolled in the study (Ethics Committee Lausanne, approval n° 214/07 and SwissMedic, approval n° 2008-MD-0024) with broad inclusion criteria. Patients requiring at least 2 single implant-supported crowns were randomised according to a split-mouth design to receive one SurfLink® treated implant and one non-treated control implant. Cylindrical titanium grade IV roughened implants with internal connection (SPI® Element, Thommen Medical) were used. Single implants were loaded after 3 months in mandibles and 6 months in maxillae. If more than 2 implants were needed, SurfLink® treated implants

Table 1: Comparison of mean changes in peri-implant marginal bone levels at 1 year post-loading between implant types, position and patient characteristics.

	Baseline to 1 year post-loading		
	Number of Patients	**Implant Type**	**Mean±SD**
Surface	21	SurfLink®	-1.09±0.76
		SurfLink®[a]	-1.04±0.72
		Control	-1.36±0.87
		p / p[a]	0.057 /0.033
Maxilla	9[b]	SurfLink®	-1.32±0.79
		Control	-1.70±0.59
		p	0.070
Mandible	9[b]	SurfLink®	-0.92±0.83
		Control	-0.95±1.08
		p	0.914
Smokers	6	SurfLink®	-0.77±0.82
		Control	-1.24±0.82
		p	0.062
Non smokers	15	SurfLink®	-1.22±0.72
		Control	-1.41±0.90
		p	0.285

(a) The total number of patients included in the analysis is 21. Three patients had one additional SurfLink® treated implant each. For these three patients, the average values of the two SurfLink® treated implants were used in the statistics.
(b) Three patients had 1 implant placed in the mandible and 1 implant placed in the maxilla. These patients were excluded from the analysis.

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were placed and restored with single crowns. The study has been un-blinded. The implants were assessed for implant failure, marginal bone level changes, marginal bleeding and other complications. Mesial and distal bone heights were evaluated using x-rays and the changes in bone level were analysed by a Two-Paired-Samples, two-sided, Student *t*-test with $P < 0.05$ for significance (RealStatistics plugin for MS Excel 2013). The comparison was carried out as described in the aim.

Results: Twenty three patients were recruited. At 1 year post-loading, there was one drop-out and one patient missed the baseline time point. No implant failures or other complications related to the implants occurred. No marginal bleeding was observed. Marginal bone levels were analysed up to 1 year post-loading. Some of the results are summarised in Table 1, for the 21 patients. When the additional SurfLink® treated implants are included in the analysis, a statistically significant difference in marginal bone level changes between the 2 groups is observed ($P = 0.033$).

Conclusion & Clinical implications: SurfLink® treated dental implants showed statistically significant ($P = 0.033$) improvement in maintaining marginal bone levels when compared to untreated control implants. This seems to particularly benefit patients with compromised (i.e. smokers) or poor (i.e. maxilla) bone quality.

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