SAFETY AND EFFICACY OF MULTI-PHOSPHONATE TREATED DENTAL IMPLANTS (RANDOMISED TRIAL): 1 YEAR POST-LOADING REPORT

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BACKGROUND AND AIM

Improving biocompatibility of an implant surface is a long standing challenge. Several approaches have been developed over the years ranging from mechanical (e.g. blasting, machining) to chemical (e.g. anodisation and acid etching) treatments.

SurfLink® Dental implant surface treatment produces a monolayer of permanently bound multi-phosphonate molecules on the surface of an implant[1]. This novel phosphonate-rich surface mimics one of the main constituents of bone, hydroxyapatite, providing a favourable environment for cell colonisation[2].

Through a series of in vivo studies of SurfLink® treated dental implants, it has been shown that biocompatibility can be increased[3].

This clinical study tested the null hypothesis that there was no difference in the clinical outcomes between the SurfLink® treated and control implants against the alternative hypothesis of a difference.

MATERIALS AND METHODS

In a Pilot Clinical Trial, 23 patients were enrolled in a RCT (Ethics Committee Lausanne, approval n° 214/07 and SwissMedic, approval n° 2008-MD-0024) at one Swiss dental clinic. In this split mouth trial, patients received 2 commercially available moderately rough (sand blasted and acid etched) cp titanium, grade 4, dental implants (SPI® Element, Thommen Medical AG, Waldeburg, Switzerland) with either SurfLink® treatment or no treatment (control). Single implants were loaded after 3 months in mandibles and 6 months in maxillae. Figures 1, 2, and 3 describe the experimental details.

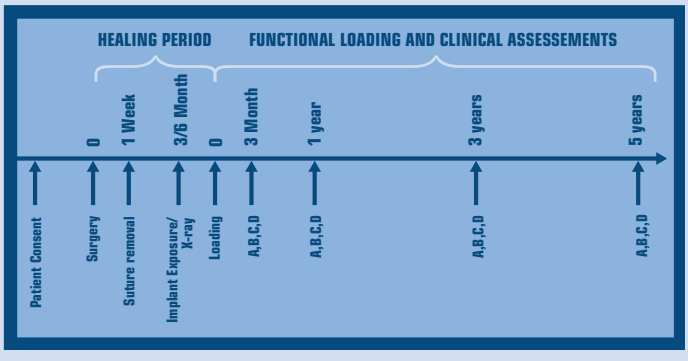
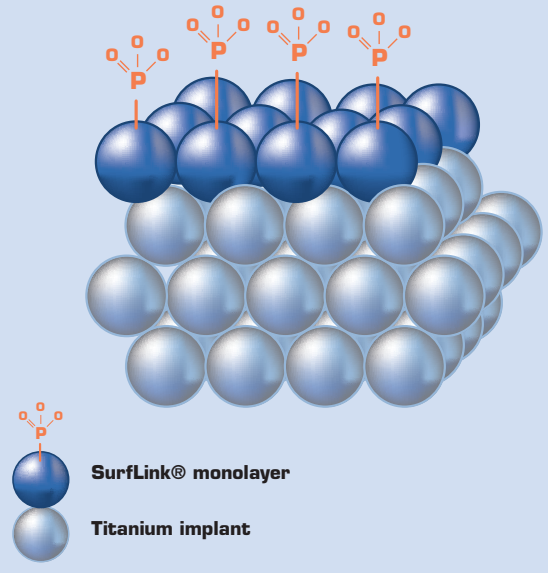


FIGURE 1. Outcome measures: A) Failure, B) Marginal Bone, C) Marginal Bleeding, D) Other Complications.

SurfLink®

CONCEPT



- **Assure successful aesthetics**
- **Promise predictable marginal bone levels**
- **Improve patient satisfaction**
- **Enable early bone formation directly on the implant surface**
- **Enhance early and long-term biomechanical fixation**
- **Promise long-term implant stability and true osseointegration, even in patients with compromised bone quality**

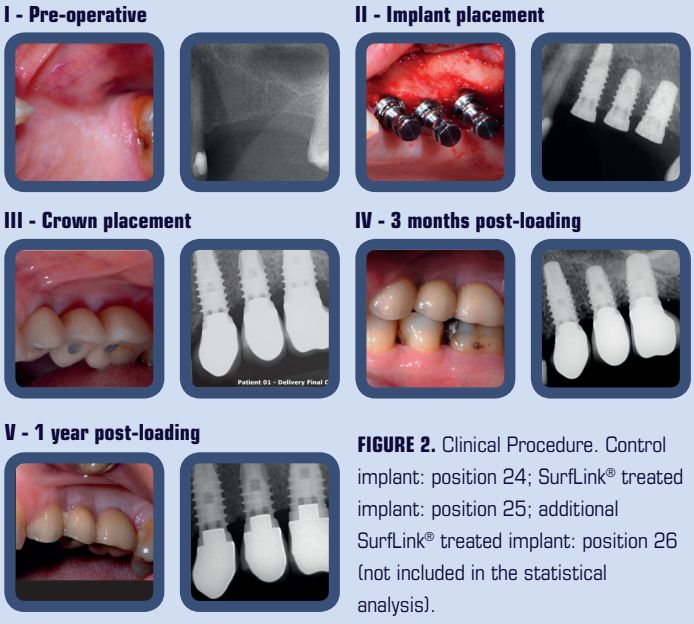


FIGURE 2. Clinical Procedure. Control implant: position 24; SurfLink® treated implant: position 25; additional SurfLink® treated implant: position 26 (not included in the statistical analysis).

RESULTS

This is the first follow-up report from a pilot study designed to clinically evaluate the safety and efficacy of SurfLink® treated dental implants. At 1 year post-loading, the clinical outcome was excellent: no implant failures, complications or adverse events occurred with the exception of one post-operative complication which appears to be unrelated to implant treatment. No bleeding was observed when running a periodontal probe in the peri-implant soft tissues around any of the implants.

Peri-implant marginal bone loss at 1 year post-loading was 1.4 mm for control implants and 1.1 mm for SurfLink® treated implants, which is in the normal physiologic range for implants having 1 mm of polished neck.

Although mean peri-implant marginal bone loss was lower for SurfLink® treated implants when compared to control implants, the result was not statistically significant (figure 4. P = 0.057, mean difference=-0.27, SE=0.13; 95% CI: -0.55 to 0.01 at 1 year).

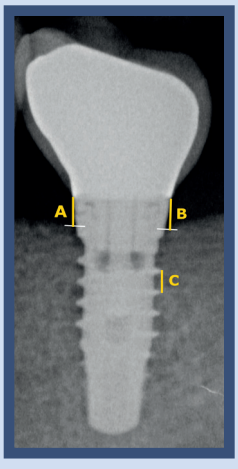


FIGURE 3. Marginal Bone. Measurements of mesial and distal marginal bone levels (A and B) using ImageJ software after length calibration (C) before each measurement. The height of the cover screw (in this case 1 mm) was subtracted from the baseline measurements. Mean value of the mesial and distal bone crest levels adjacent to each implant (A and B) were used for statistical analysis.

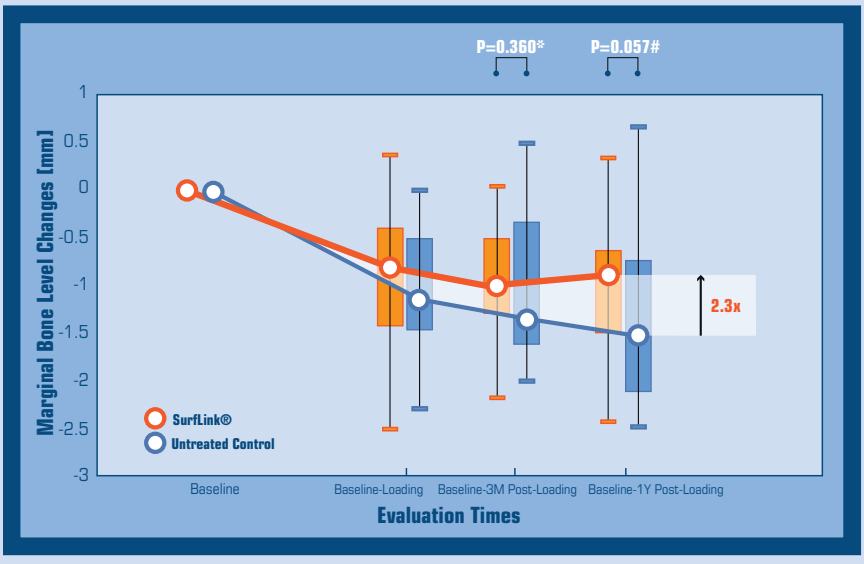


FIGURE 4. Box plot representing peri-implant bone loss at different times for SurfLink® treated and control implants. Control implants lost 2.3 times more bone from loading to 1 Year follow-up. N=21; P-values (#paired t-test; *Wilcoxon test). (Median, 1st quartile, 3rd quartile, MIN, MAX).

CONCLUSIONS

One year post-loading data of SurfLink® treated implants presented no safety issues. Clinical healing in both control and SurfLink® treated implant groups was uneventful. Although mean peri-implant marginal bone loss was lower for SurfLink® treated implants when compared to control implants, the result was not statistically significant (P = 0.057).

REFERENCES

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