White Paper WP-7
SurfLink® Dental Clinical Trials in progress

1. Introduction

Stable bone-to-implant interface and strong fixation are essential requirements for successful implant integration and patient prognosis.

Through a series of experimental studies, SurfLink® Dental surface treatment by NBMolecules® was shown to increase osseointegration, bone fixation, and long-term implant stability [1-8].

SurfLink® binds covalently to titanium. By virtue of SurfLink®'s biomimetic phosphate-like groups the treated implant is highly hydrophilic resulting in enhanced biocompatibility. In the clinical situation, such enhanced biocompatibility can be expected to result in increased osseointegration and long-term implant stability, significantly reducing the risk of micromotion and increasing implant success.

Two major prospective Randomised Clinical Trials (RCTs) have been designed and launched with the aim of evaluating safety and effectiveness of the SurfLink® Dental surface treatment.

2. Pilot Clinical Trial

The Pilot Clinical Trial has enrolled 23 patients in a RCT with broad inclusion criteria at one Swiss dental clinic. In this split mouth trial, patients received commercially available titanium dental implants with and without SurfLink® Dental surface treatment. Only single implants are being loaded (i.e. single crowns). The trial is blinded, with the submerged healing time before loading set to three months for mandibular implants, and six months for maxillary implants. Each patient will be subjected to four different clinical assessments (A, B, C and D) during the five year post-loading period (Figure 1):

A. Implant failure rate
B. Marginal bone level changes (mean of distal and mesial) measured on periapical X-rays (Figure 2)
C. Marginal bleeding
D. Other complications and adverse events

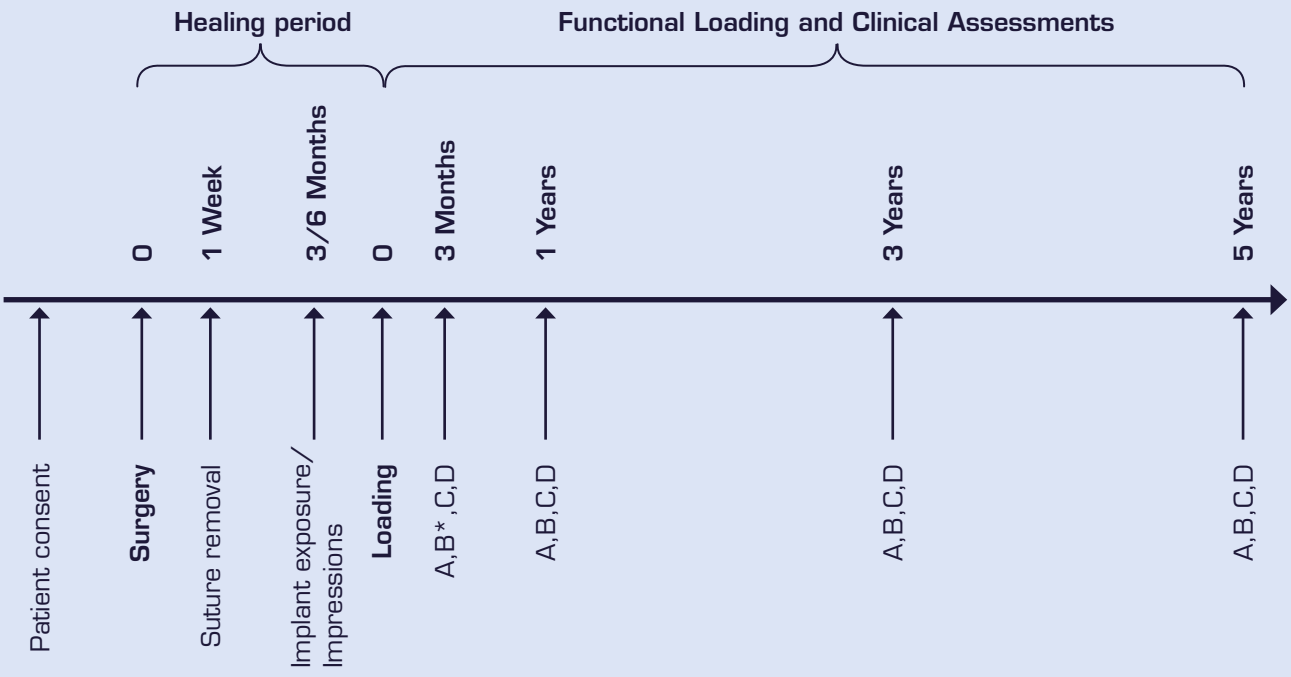

Figure 1: Timelines and assessments of the Dental Clinical Trials.
* Assessment B at 3 months is carried out for the Pilot Clinical Trial only.

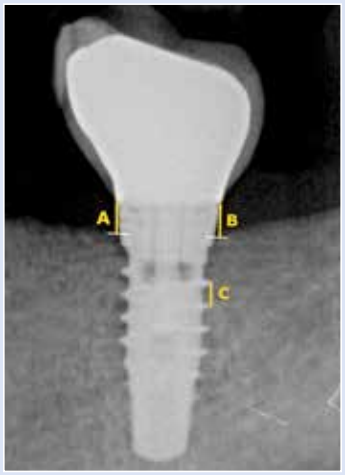

Figure 2: Measurement of distal and mesial Marginal Bone Levels.

Digitalised intraoral periapical X-rays are processed by using Image J software (National Institute of Health, USA). The measurement of the mesial (A) and distal (B) marginal bone crest levels adjacent to each implant is taken from the coronal margin of the implant collar to the most coronal point of bone-to-implant contact [9].

The measurement are calibrated (mm) by measuring a straight line between two adjacent threads (C) with a known distance.

3. Multicentre Clinical Trial

The design of the Multicentre Clinical Trial follows the same design as the Pilot Clinical Trial but aims to recruit up to 120 patients with implant loading for both maxilla and mandible occurring at 3 months after implant placement (Figure 1). The study involves three centres in Switzerland (two universiteis and one private clinic) and three private clinics in Germany.

4. References

[1] C. Viornery et al., J. Biomed. Mater. Res., **2002**, 62, 149–155.
[2] R. Dayer et al., Bone, **2005**, 36, S389 (P561).
[3] NBMolecules®' internal reports, unpublished.
[4] NBMolecules®' White Paper WP-4 Pre-clinical experimental study with SurfLink® Dental treated implants: Histology, **2011**.
[5] NBMolecules®' White Paper WP-5 Pre-clinical experimental study with SurfLink® Dental treated implants: SEM, **2011**.
[6] NBMolecules®' White Paper WP-6 Pre-clinical experimental study with SurfLink® Dental treated implants: Biomechanics, **2011**.
[7] C. Viornery et al., Langmuir, **2002**, 18, 2582-2589.
[8] NBMolecules®' White Paper WP-9 Pre-clinical experimental study with SurfLink® Dental treated implants: Fluorescence Analysis, **2012**.
[9] F. Galli et al, Clin.Oral Implant Res.,**2008**, 19, 546-552.