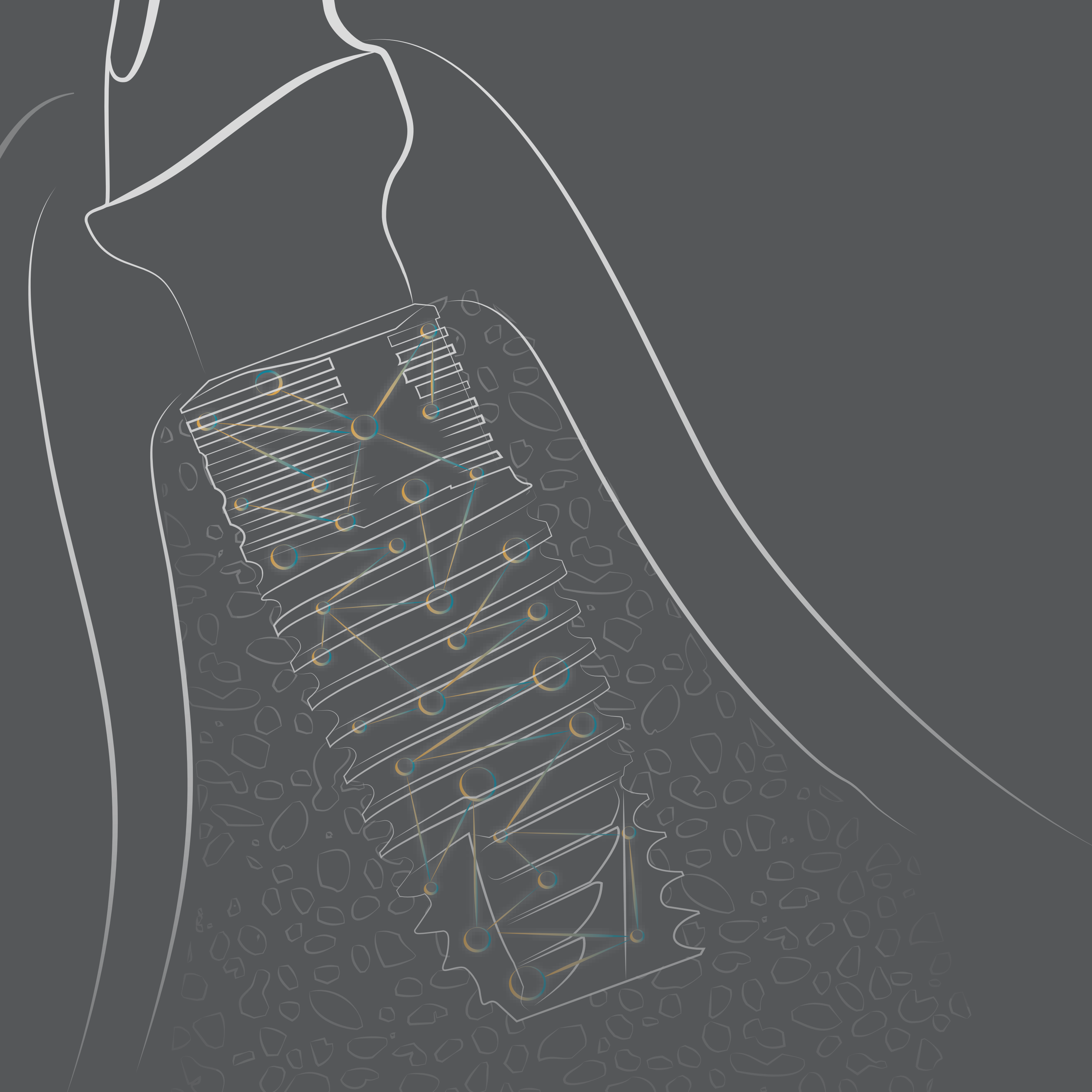
Biological Organic Contact

B+ surface on MIS Website

The MIS Quality System complies with international quality standards: ISO 13485: 2016 - Quality Management System for Medical Devices and Medical Device Directive 93/42/EEC. Please note, not all products are registered or available in every country/region.

IFUs for MIS products may be found at: https://ifu.mis-implants.com. Adobe Acrobat is required to view the IFU file on the website. This software may be freely downloaded from the Adobe website



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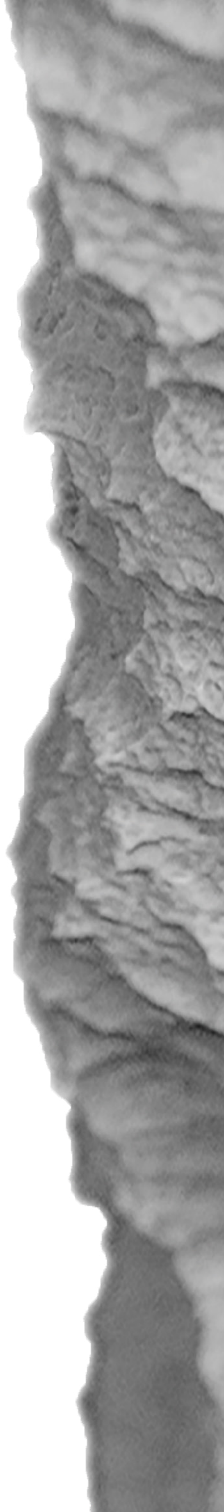
MIS Surface Quality

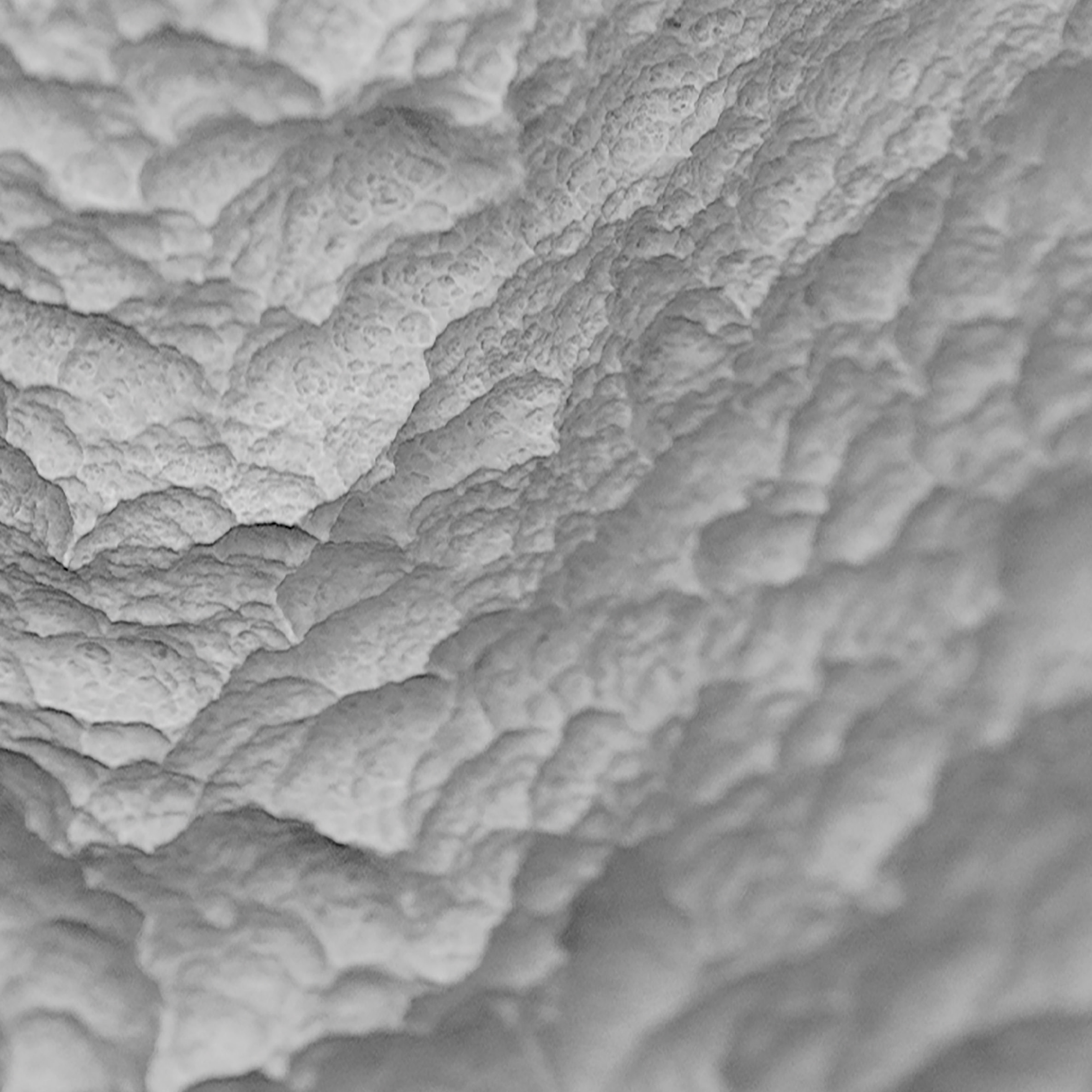
During the first stages following implant placement, BIC (Bone to Implant Contact), is a critical factor for the osseointegration process and for long term biological stability, success and survival of the implant. Osseointegration is defined as the process by which living bone integrates with the surface of an implant. Osseointegration is determined by the raw material of the implant, its morphology and the chemical composition of its surface.

MIS surface treatment is a combination of sand blasting and acid-etching, which induces micro and nano-structures that significantly increase the surface area of the implant body for optimal osseointegration. The roughened surface may improve bone adhesion, as well as the proliferation and differentiation of osteoblasts.

MIS is one of only a handful of companies worldwide using electron microscopy on a daily basis for implant quality inspection. Sand-blasted and acid-etched surfaces have been substantially proven to maximize BIC (Bone-to-Implant Contact), designed to achieve immediate and long-lasting osseointegration. Acid-etching and packaging processes are performed inside a controlled environment clean-room to ensure sterility and quality. Implants are inspected by scanning electron microscope (SEM) and X-ray photoelectron spectroscopy (XPS), to ensure surface morphology, roughness and cleanliness level.

Current literature demonstrates a linkage between improved bone healing and early osseointegration with the hydrophilicity of the implant surface. MIS surface treatment ensures surface purity.





MIS Surface Quality

SURFACE ANALYSIS OF STERILE-PACKAGED IMPLANTS

Dr. Dirk Duddeck and Dr. Jörg Neugebauer, PhD

For the third time in a row, the Quality and Research (Q&R) Committee of BDIZ EDI is examining sterile packaged implants under the scanning electron microscope for the more than 5,500 members of the association. In cooperation with the University Hospital of Cologne, extensive qualitative and quantitative elemental analyses are performed on each of the implants studied. In 2008/2009, the surfaces of 23 implants were analyzed, a number that had grown to 54 different implants from manufacturers in nine countries by 2011/2012. Here, isolated implants showed residue from the manufacturing and/or packaging process, pecularities in the external threading or residual filings inside the implant. 65 dental implants from different leading manufacturers underwent topographical and chemical composition analysis. The protocol included the use of a Scanning Electron Microscope (SEM), which enabled the topical evaluation of each implant surface. The high sensitivity backscattered electron detector generates images in compositional and topographical modes to a magnification of up to X5,000 for this study. The BSE detector also allows researchers to draw conclusions about the chemical nature and allocation of remnants or contaminants on the sample material. Qualitative and quantitative analyses of implant surfaces were done using Energy Dispersive X-ray Spectroscopy (EDX). This element identification software even allows the identification of elements deep within the sample. Testing on MIS implants revealed percentages of Titanium, Oxygen, Aluminum and Vanadium.

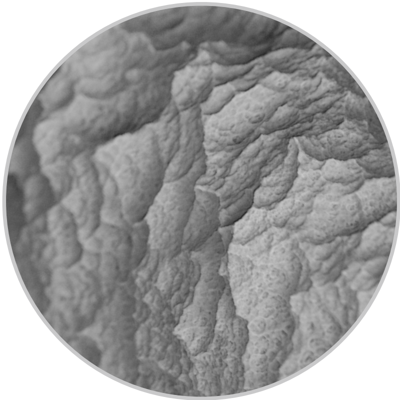
Conclusions reached in the study state:

"The C1 implant and the Seven implant (both MIS) stood out positively in the current study. Whereas during the 2011/2012 study, the Seven implant still exhibited blasting material on up to seven per cent of the surface, the current study did not even find isolated spots with residue on the two MIS implant types of grade 23 titanium (Ti 6Al-4V ELI)".

The study is available for download from the MIS Website: Surface Analysis of Sterile-Packaged Implants: EDI Journal, Issue 1/2015:
https://www.mis-implants.com/research-and-development/research-library?categories=Published%20Articles

Residue-free surface,
MIS C1 implant (x 1,000)

MIS C1 implant surface with
micro-nano-structure (x 2,500)



MIS C1 implant side-view
of a thread (x 2,000)

MIS Surface Quality

POSEIDO Journal
Periodontology, Oral Surgery, Esthetic & Implant Dentistry Open

IDENTIFICATION CARD AND CODIFICATION OF THE CHEMICAL AND MORPHOLOGICAL CHARACTERISTICS OF 62 DENTAL IMPLANT SURFACES. PART 3: SAND-BLASTED/ACID-ETCHED (SLA TYPE) AND RELATED SURFACES (GROUP 2A, MAIN SUBTRACTIVE PROCESS).

David M. Dohan Ehrenfest[1,2*], Marco Del Corso[3,4], Byung-Soo Kang[5], Philippe Leclercq[6], Ziv Mazor[7], Robert A. Horowitz[8], Philippe Russe[9], Hee-Kyun Oh[10], De-Rong Zou[11], Jamil Awad Shibli[12], Hom-Lay Wang[13], Jean-Pierre Bernard[2] and Gilberto Sammartino[3].

Background and Objectives: Dental implants are commonly used in dental therapeutics, but dental practitioners only have limited information about the characteristics of the implant materials they take the responsibility to place in their patients. The objective of this work is to describe the chemical and morphological characteristics of 62 implant surfaces available on the market and establish their respective Identification (ID) Card, following the Implant Surface Identification Standard (ISIS). In this third part, surfaces produced through the main subtractive process (sand-blasting/acid-etching, SLA-type and related) were investigated.

Materials and Methods: Eighteen different implant surfaces were characterized: Straumann SLA (ITI Straumann, Basel, Switzerland), Ankylos (Dentsply Friadent, Mannheim, Germany), Xive S (Dentsply Friadent, Mannheim, Germany), Frialit (Dentsply Friadent, Mannheim, Germany), Promote (Camlog, Basel, Switzerland), Dentium Superline (Dentium Co., Seoul, Korea), Osstem SA (Osstem implant Co., Busan, Korea), Genesio (GC Corporation, Tokyo, Japan), Aadva (GC Corporation, Tokyo, Japan), MIS Seven (MIS Implants Technologies, Bar Lev, Israel), ActivFluor (Blue Sky Bio, Grayslake, IL, USA), Tekka SA2 (Tekka, Brignais, France), Twinkon Ref (Tekka, Brignais, France), Bredent OCS blueSKY (Bredent Medical, Senden, Germany), Magitech MS2010 (Magitech M2I, Levallois-Perret, France), EVL Plus (SERF, Decines, France), Alpha Bio (Alpha Bio Tec Ltd, Petach Tikva, Israel), Neoporos (Neodent, Curitiba, Brazil). Three samples of each implant were analyzed.

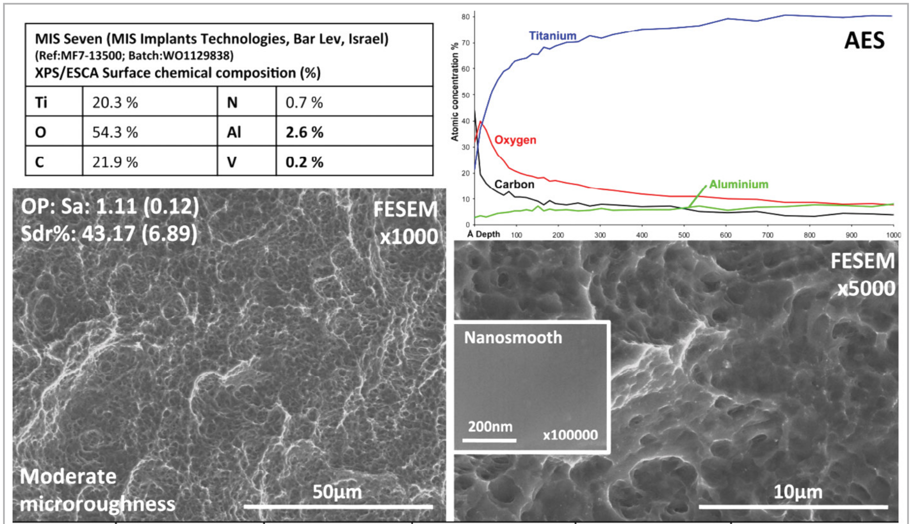
Superficial chemical composition was analyzed using XPS/ESCA (X-Ray Photoelectron Spectroscopy/Electron Spectroscopy for Chemical Analysis) and the 100nm in-depth profile was established using Auger Electron Spectroscopy (AES). The microtopography was quantified using optical profilometry (OP). The general morphology and the nanotopography were evaluated using a Field Emission-Scanning Electron Microscope (FE-SEM). Finally, the characterization code of each surface was established using the ISIS, and the main characteristics of each surface were summarized in a reader-friendly ID card.

Results: From a chemical standpoint, in the 18 different surfaces of this group, 11 were based on a commercially pure titanium (grade 2 or 4) and 7 on a titanium-aluminium alloy (grade 5 or grade 23 ELI titanium). 4 surfaces presented some chemical impregnation of the titanium core, and 5 surfaces were covered with residual alumina blasting particles. 15 surfaces presented different degrees of inorganic pollutions, and 2 presented a severe organic pollution overcoat. *Only 3 surfaces presented no pollution (and also no chemical modification at all): GC Aadva, Genesio, MIS SEVEN®.*

From a morphological standpoint, all surfaces were microrough, with different microtopographical aspects and values. All surfaces were nanosmooth, and therefore presented no significant and repetitive nanostructures. 14 surfaces were homogeneous and 4 heterogeneous. None of them were fractal.

Discussion and Conclusion: The ISIS systematic approach allowed to gather the main characteristics of these commercially available products in a clear and accurate ID card. The SLA-type surfaces have specific morphological characteristics (microrough, nanosmooth, with rare and in general accidental chemical modification) and are the most frequent surfaces used in the industry. However they present different designs, and pollutions are often detected (with blasting/etching residues particularly). Users should be aware of these specificities if they decide to use these products.

Identification card of the MIS SEVEN surface, following the 'Implant Surface Identification Standard' codification



Surface	Core Material (Core)	Modification (Mod)	Microtopography (Micro)	Nanotopography (Nano)	Global Architecture (Archi)
MIS Seven (MIS Implants Technologies, Bar Lev, Israel)	Ti-6Al-4V ELI Grade 23 Titanium (G23Ti)	None	Rough (R). Moderate (Mo). Flat (Fl)	Smooth (S)	Non Fractal (NF). Homogeneous (Ho)
	Core.G23Ti		Micro.R.Mo.Fl	Nano.S	Archi.NF.Ho

ISIS (MIS Seven) = Core.G23Ti / Micro.R.Mo.Fl / Nano.S / Archi.NF.Ho

Fig. 1
Identification Card of the MIS SEVEN® surface:

MIS SEVEN®(MIS Implants Technologies, Bar Lev, Israel; Figure 1) was a sandblasted/acid-etched surface on a grade 23 ELI (Extra Low Interstitials) titanium core. No pollution or chemical modification was detected. The surface was moderately microrough, nanosmooth, and homogeneous all over the implant.

1LoB5 unit, Research Center for Biomineralization Disorders, Chonnam National University, South Korea. 2Department of Stomatology, School of Dental Medicine, University of Geneva, Switzerland. 3Department of Oral Surgery, Faculty of Medicine, University Federico II of Naples, Italy. 4Private Practice, Turin, Italy. 5Department of Physics, Seoul National University, Seoul, South Korea. 6Private Practice, Paris, France. 7Private Practice, Ra'anana, Israel. 8Department of Periodontology and Implant Dentistry, College of Dentistry, New York University, New York, USA. 9Private Practice, Reims, France. 10 Department of Oral and Maxillofacial Surgery, School of Dentistry, Chonnam National University, South Korea. 11 Department of Stomatology, Shanghai Sixth People's Hospital, Shanghai Jiao Tong University, China. 12 Department of Periodontology and Oral Implantology, University of Guarulhos, Sao Paulo, Brazil. 13 Department of Periodontics and Oral Medicine, School of Dentistry, University of Michigan, Ann Arbor, USA. *Corresponding author: David M. Dohan Ehrenfest.

B for Biology

B+ is a mono molecular layer of multi-phosphonates. It is permanently bound to the surface of the implant and is perceived as bone-like by the body.

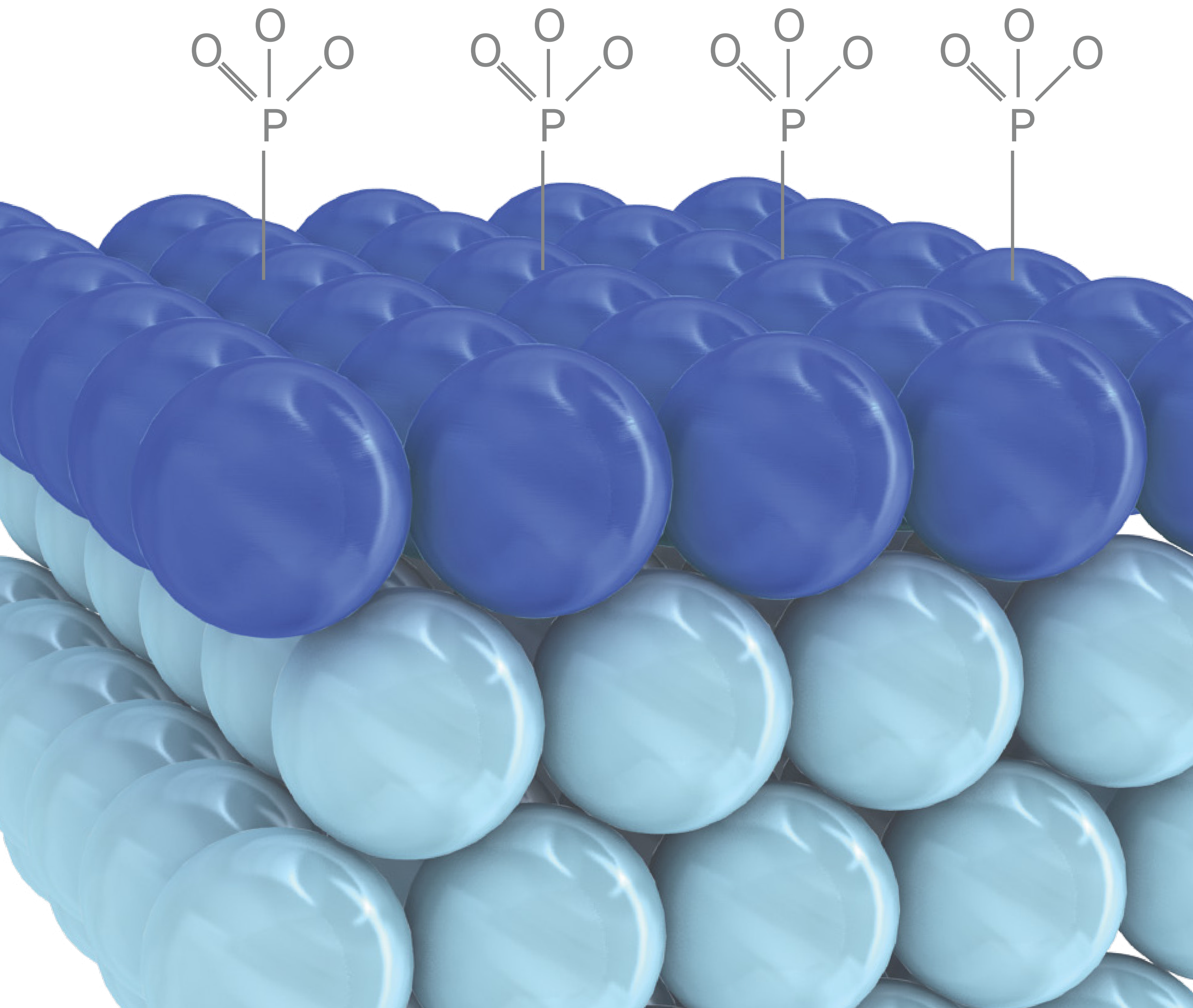
The technology has been clinically demonstrated to result in visible bone growth directly on the surface of the B+ implant in sheep. The characteristics of B+ promote enhanced clinical performance and better preservation of bone levels around the implant as observed in a study with sheep. This may potentially lead to longer term implant survival, even in patients with compromised bone healing situations.

Molecules of B+ chemically bind to the implant surface, creating a hydrophilic surface and remain stable throughout the life span of the implant. The phosphonated molecules of B+ have demonstrated high stability in terms of chemical degradation. These properties prevent the molecules from detaching from the implant surface, which allows them to remain present for the lifespan of the implant.

This novel, phosphonate rich surface is designed to mimic one of the main constituents of bone, which may provide more favorable environment for implant integration. It has also been observed to accelerate the healing process, eliminate the "micro gap" between the bone and implant surface, and increase the fixation of the implant in bone.

* A Novel Multi-Phosphonate Surface Treatment of Titanium Dental Implants: A Study in Sheep. Marcella von Salis-Soglio et. Al. J. Funct. Biomater. 2014, 5, 135-157.

B+ provides a chemical connection between bone and implant surface, in addition to mechanical interlocking due to roughened topography.



Advantages

Hydrophilicity

Current literature demonstrates a linkage between improved bone healing and early osseointegration with the hydrophilicity of surface. MIS implant surface treatment combines sand-blasting and acid-etching. These treatment types increase the potential for surface purity and hydrophilic properties. B+ enhances the wettability of the implant surface, and this may attract water, proteins, and cells from the blood, and possibly enable quicker cell adhesion and colonization, which may result in faster bone matrix formation and osseointegration.

Biomechanical Fixation

Once on the implant surface, a new bone matrix may be formed quickly, maturing to organized mineralized bone. The biomimetic characteristics of B+ may allow for greater implant integration at earlier stages, which may lead to long-term optimal osseointegration. The increased number of bone cells in contact with the B+ implant may result in enhanced biomechanical implant fixation very early on in the healing process. Increased fixation with B+ has been observed to reduce healing time.

Elimination of the “Micro-Gap”

In addition to possible mechanical interlocking resulting from the implant’s roughened topography, B+ may also provides a chemical connection between bone and implant surface, eliminating the “micro-gap”. This may result in early functional implant stability and fixation.

Stability in a Physiological Environment

The B+ molecule was shown to remain permanently bound to the implant surface throughout osseointegration. Furthermore, unlike phosphates, phosphonated molecules such as B+ are chemically stable, ensuring that B+ will remain attached to the implant and will not be released into the body over time.

In the following study the B+ molecule was referred to as SurfLink, a patented Surface Technology under license from NBMolecules.

B+ Clinical Studies

Journal of Functional Biomaterials

A NOVEL MULTI-PHOSPHONATE SURFACE TREATMENT OF TITANIUM DENTAL IMPLANTS: A STUDY IN SHEEP

Marcella von Salis-Soglio, Stefan Stübinger, Michéle Sidler, Karina Klein, Stephen J. Ferguson, Käthi Kämpf, Katalin Zlinszky, Sabrina Buchini, Richard Curno, Péter Péchy, Bjorn-Owe Aronsson and Brigitte von Rechenberg J. Funct. Biomater. 2014, 5, 135-157; doi:10.3390/jfb5030135

Abstract: The aim of the present study was to evaluate a new multi-phosphonate surface treatment (SurfLink®) in an unloaded sheep model. Treated implants were compared to control implants in terms of bone to implant contact (BIC), bone formation, and biomechanical stability.

The study used two types of implants (rough or machined surface finish) each with either the multi-phosphonate Wet or Dry treatment or no treatment (control) for a total of six groups. Animals were sacrificed after 2, 8, and 52 weeks. No adverse events were observed at any time point.

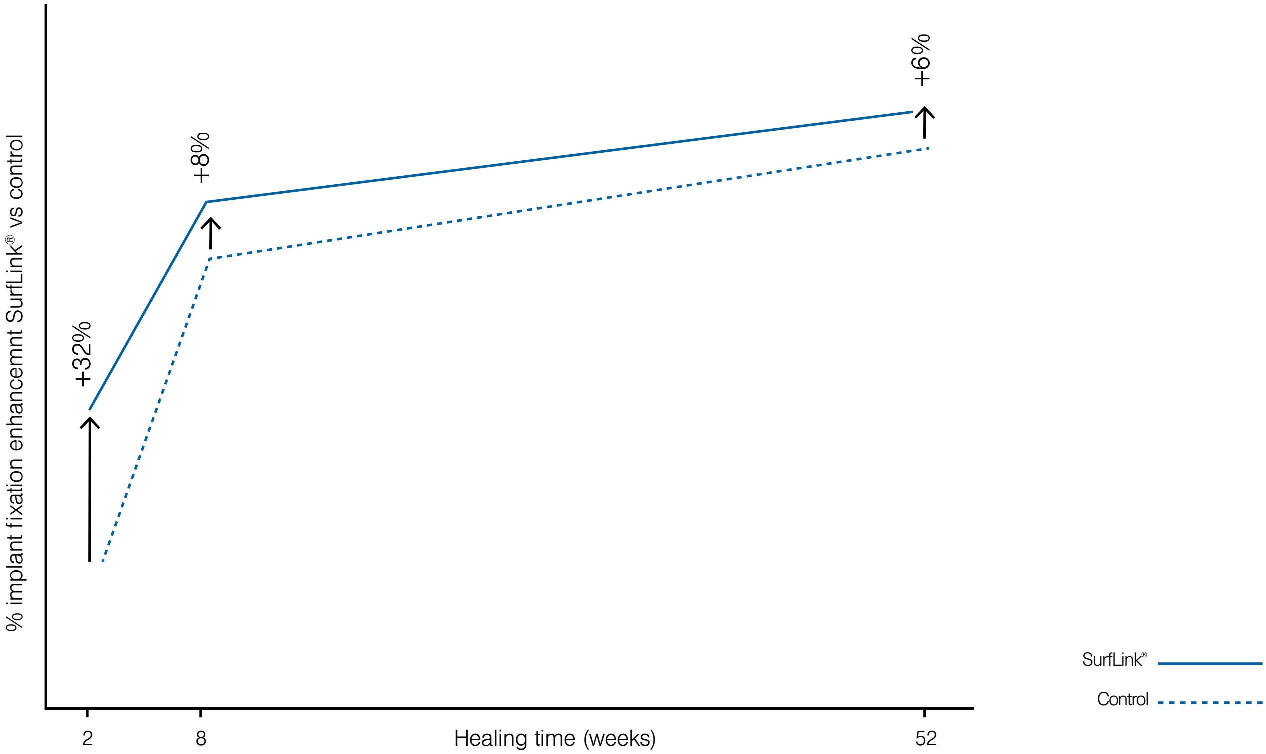
At two weeks, removal torque showed significantly higher values for the multi-phosphonate treated rough surface (+32% and +29%, Dry and Wet, respectively) compared to rough control.

At 52 weeks, a significantly higher removal torque was observed for the multi-phosphonate treated machined surfaces (+37% and 23%, Dry and Wet, respectively).

The multi-phosphonate treated groups showed a positive tendency for higher BIC with time and increased new-old bone ratio at eight weeks.

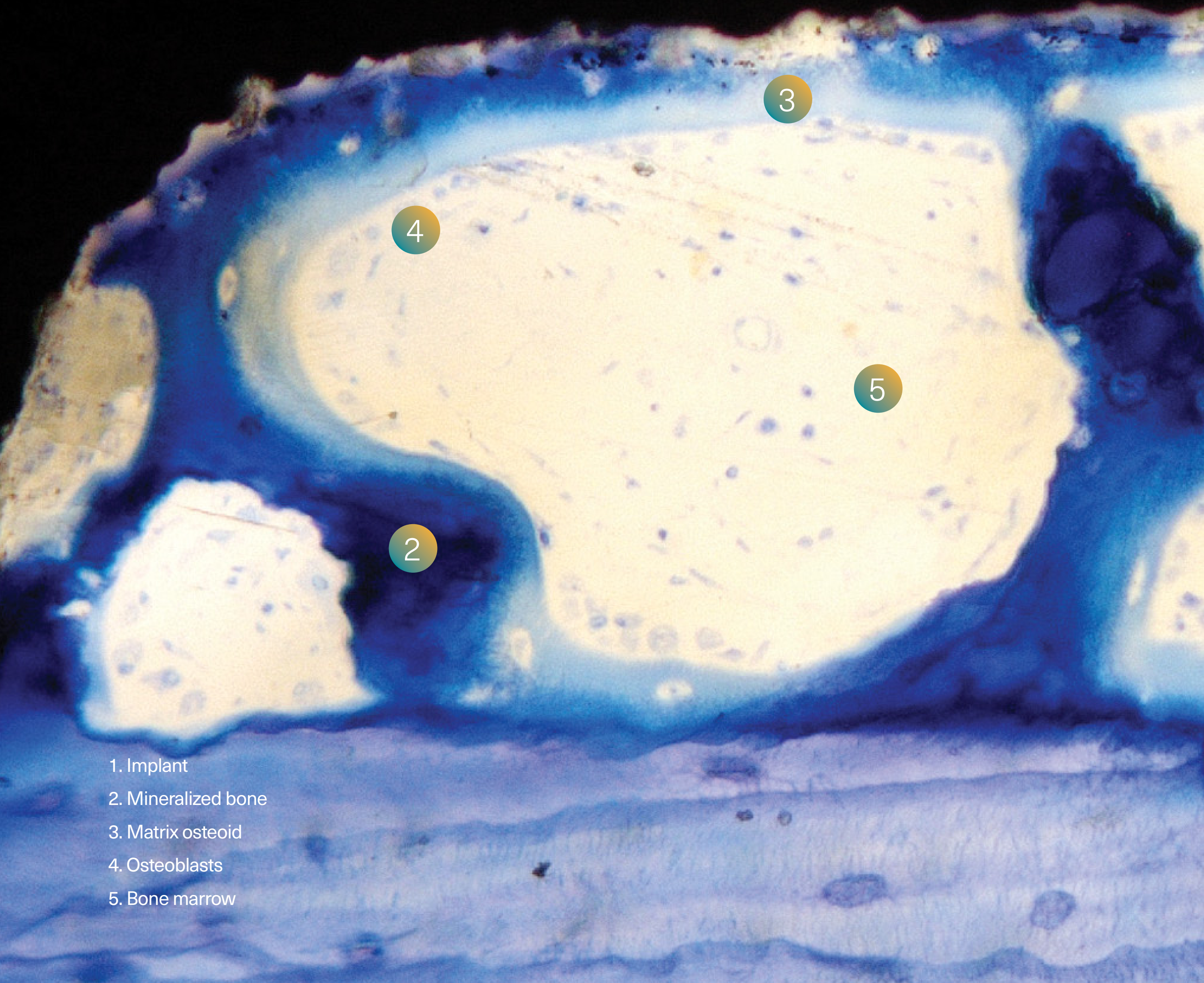
SEM images revealed greater amounts of organic materials on the multi-phosphonate treated compared to control implants, with the bone fracture (from the torque test) appearing within the bone rather than at the bone to implant interface as it occurred for control implants.

Mean pairwise relative difference in removal torque values of roughened dry multi-phosphonate (SurfLink®) treated versus control roughened dry implants by time.

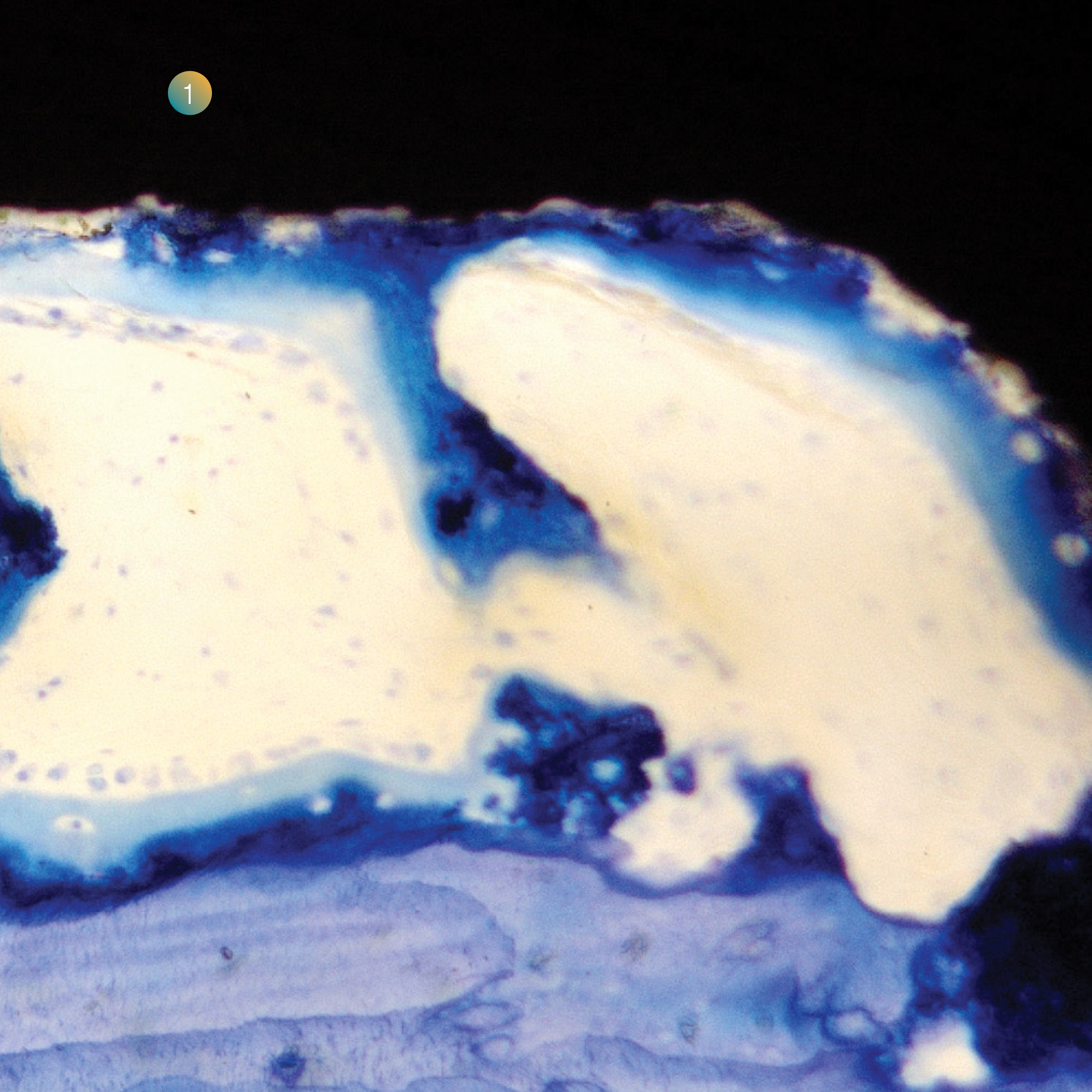


J. Funct. Biomater. 157-135 ,5 ,2014; doi:10.3390/jfb5030135

Process of bone formation on a multi-phosphonate treated implant at 2 weeks healing in sheep.



1. Implant
2. Mineralized bone
3. Matrix osteoid
4. Osteoblasts
5. Bone marrow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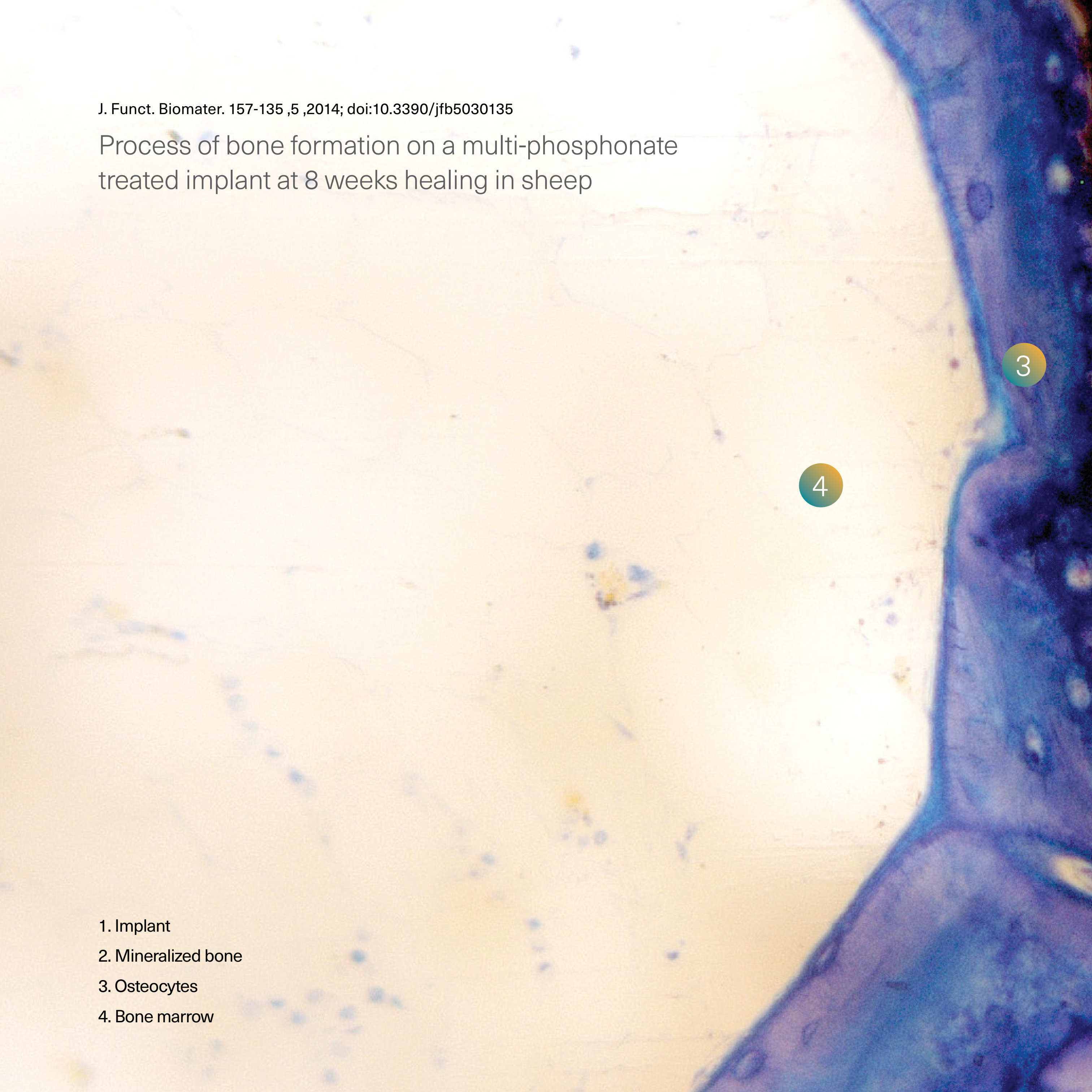
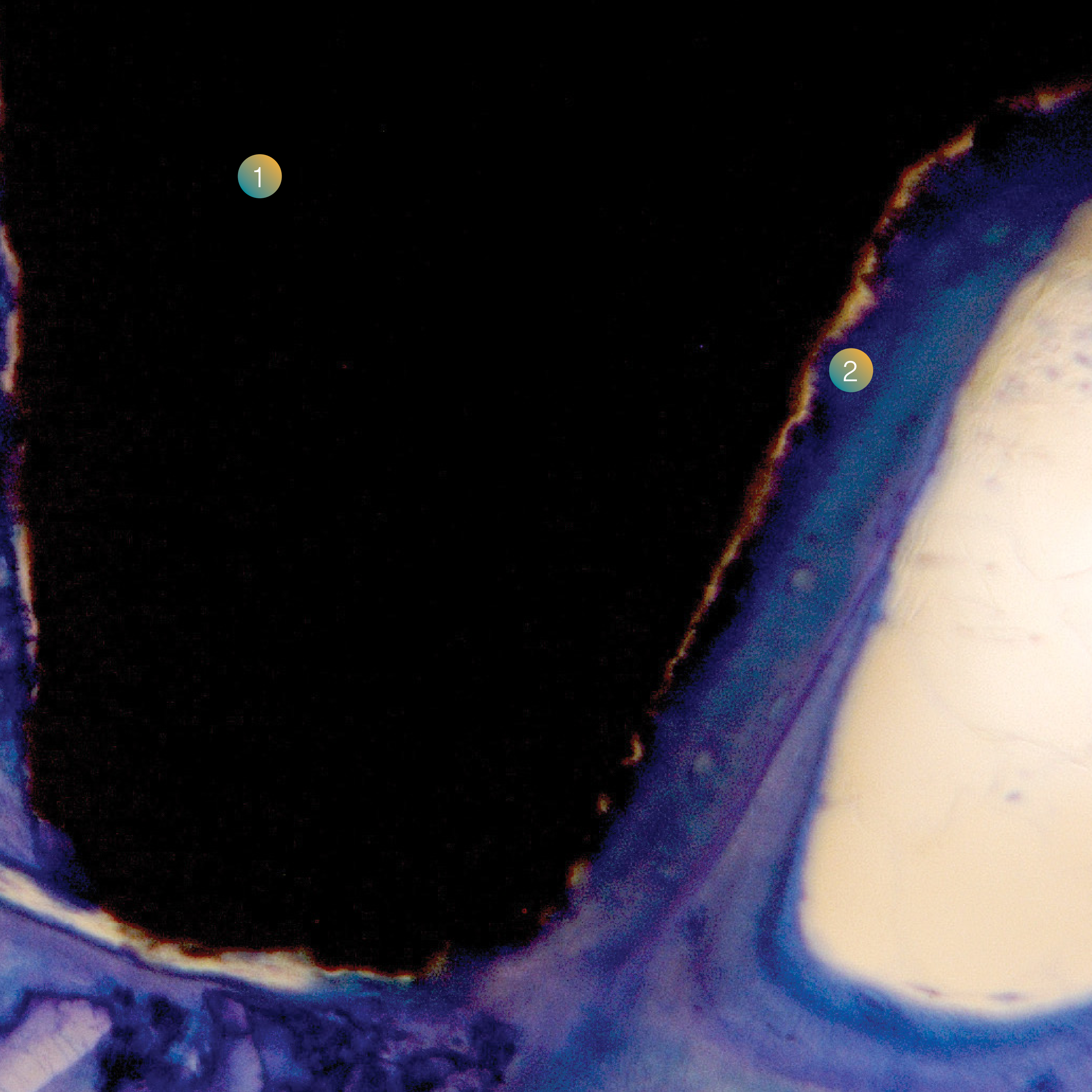
J. Funct. Biomater. 157-135 ,5 ,2014; doi:10.3390/jfb5030135

Process of bone formation on a multi-phosphonate treated implant at 8 weeks healing in sheep



1. Implant
2. Mineralized bone
3. Osteocytes
4. Bone marrow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2

In the following study the B+ molecule was referred to as SurfLink, a patented Surface Technology under license from NBMolecules.

B+ Clinical Studies

EUROPEAN JOURNAL OF ORAL IMPLANTOLOGY

SAFETY AND EFFICACY OF A BIOMIMETIC MONOLAYER OF PERMANENTLY BOUND MULTI-PHOSPHONIC ACID MOLECULES ON DENTAL IMPLANTS: 1 YEAR POST-LOADING RESULTS FROM A PILOT QUADRUPLE-BLINDED RANDOMISED CONTROLLED TRIAL

Marco Esposito, Ivan Dojcinovic, Laurence Germon, Nicole Levy, Richard Curno, Sabrina Buchini, Peter Pechy, Bjorn-Owe Aronsson Eur J Oral Implantol, 2013, 6(3), 227–236

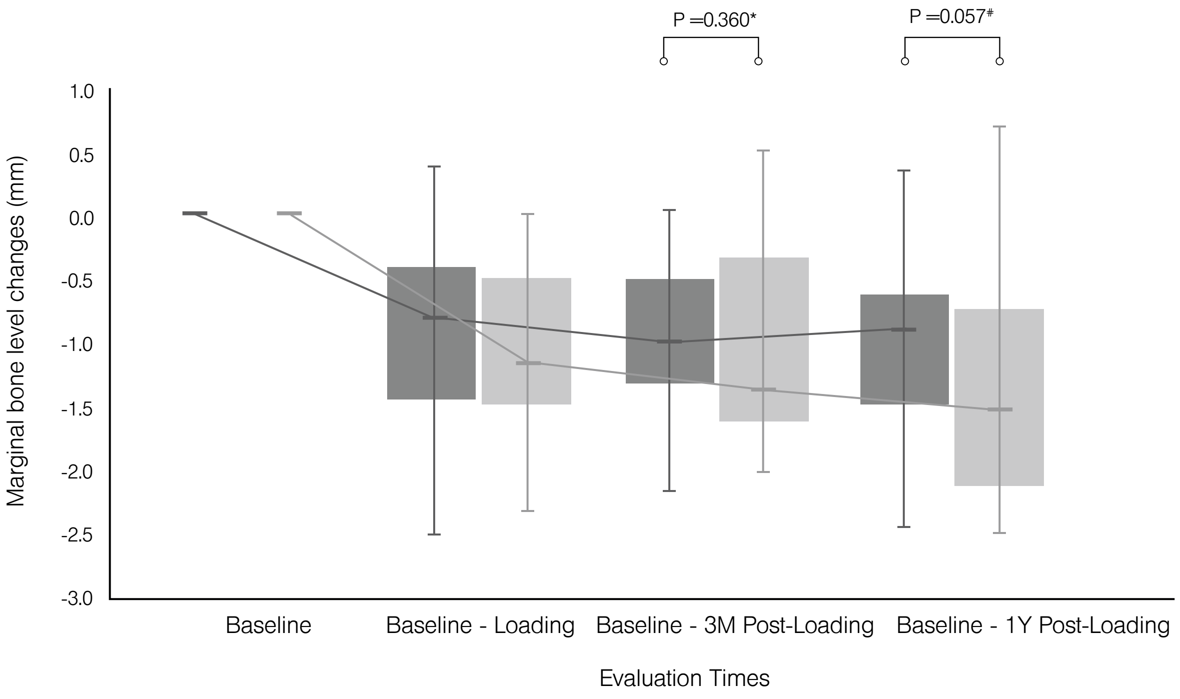
Purpose: To evaluate the safety and clinical efficacy of a novel surface treatment (SurfLink®, Nano Bridging Molecules, Gland, Switzerland) on titanium dental implants. SurfLink consists of a monolayer of permanently bound multi-phosphonic acid molecules, which mimics the surface of naturally occurring hydroxyapatite.

Materials and methods: Twenty-three patients requiring at least two single dental implants had their sites randomised according to a split-mouth design to receive one titanium grade 4 implant treated with SurfLink and one untreated control implant. Additional SurfLink-treated implants were placed if needed. Implants were submerged for 3 months in mandibles and 6 months in maxillae, were loaded with definitive metal-ceramic crowns, and followed up for 1 year after loading. Outcome measures were crown/implant failures, any complication, radiographic peri-implant marginal bone level changes and marginal bleeding.

Results: One patient dropped out after abutment connection. All remaining patients were followed up to 1 year post-loading. No implant failed and only 1 postoperative complication (pain) occurred, but it may not have been related to the implant treatment. No bleeding was observed when a periodontal probe was used to examine the peri-implant soft tissues around the implants. There were no statistically significant differences in marginal bone level changes between the two groups (P = 0.057, mean difference = -0.27, SE= 0.13; 95% CI -0.55 to 0.01).

Conclusions: Preliminary short-term data (1 year post-loading) of implants with a biomimetic monolayer of permanently bound multi-phosphonic acid molecules (SurfLink surface treatment) presented no safety issues. Clinical healing in both the control and SurfLink-treated implant group was uneventful and did not differ significantly between groups. More challenging clinical situations need to be investigated to evaluate the real effectiveness of this surface treatment.

Box plot representing peri-implant bone loss at different times for SurfLink-treated and untreated control implants (N = 21). P values (#paired *t* test; *Wilcoxon test) between time intervals are indicated.



In the following study the B+ molecule was referred to as SurfLink, a patented Surface Technology under license from NBMolecules.

B+ Clinical Studies

University of Cologne

SEM ANALYSIS OF OSSEOINTEGRATED PHOSPHOROUS RICH IMPLANTS AFTER 52 WEEKS IN SHEEP PELVIS

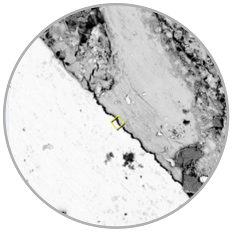
D.U. Duddeck, S. Buchini, R. Curno, B.-O. Aronsson Poster presentation at DIKON conference in Berlin, 2015

Aim: The surface of dental implants determines the initial phases of the biological response and affects its ability to integrate into the surrounding tissue. Covalently binding a monolayer of phosphorous rich molecules (SurfLink) to well established surface modifications (sandblasting, acid-etching) offers new dimensions of osseointegration. The aim of this study is to present the surface analysis of SurfLink implants using Scanning Electron Microscopy (SEM) and elemental analysis (EDX).

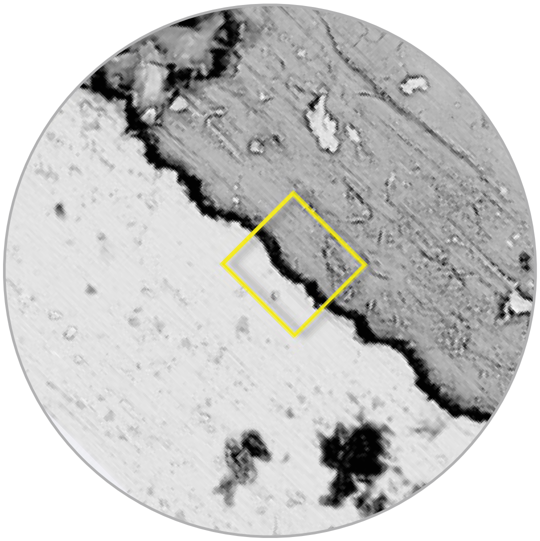
Material and Methods: Machined and roughened dental implants with either SurfLink treatment or no treatment (control) were placed in the pelvis of 24 sheep. Selected implants, retrieved after 52 weeks healing, previously used for removal torque testing, were analyzed by SEM and EDX (Phenom ProX SEM, high-sensitivity backscattered electron detector for topographical mode and thermoelectrically cooled Silicon Drift Detector for EDX).

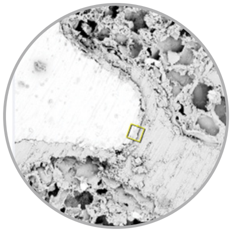
Results: SurfLink implants showed increased bone coverage on the machined and roughened surfaces compared to control implants. The presence of mineralized fibrous structures was evidenced by significant Ca and P peaks detected by EDX, with bone cells on the SurfLink implant surface. The machined control implant showed a nearly bare titanium surface. Fracture lines after torque testing occurred at the bone-implant interface in the control group, while the SurfLink implants showed a fracture line within the bone, indicating the absence of the typical proteoglycan layer.

Conclusion: SEM images of SurfLink implants showed fractures within the bone and not at the bone-implant interface. This suggests a significant increase in bone adhesion on SurfLink surfaces. Clinically this results in improved implant stability especially in the early phases of osseointegration.

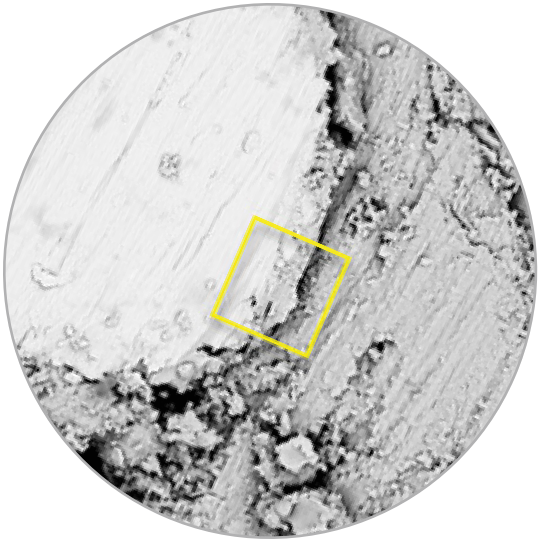


Fractures at the interface (control) after implant removal

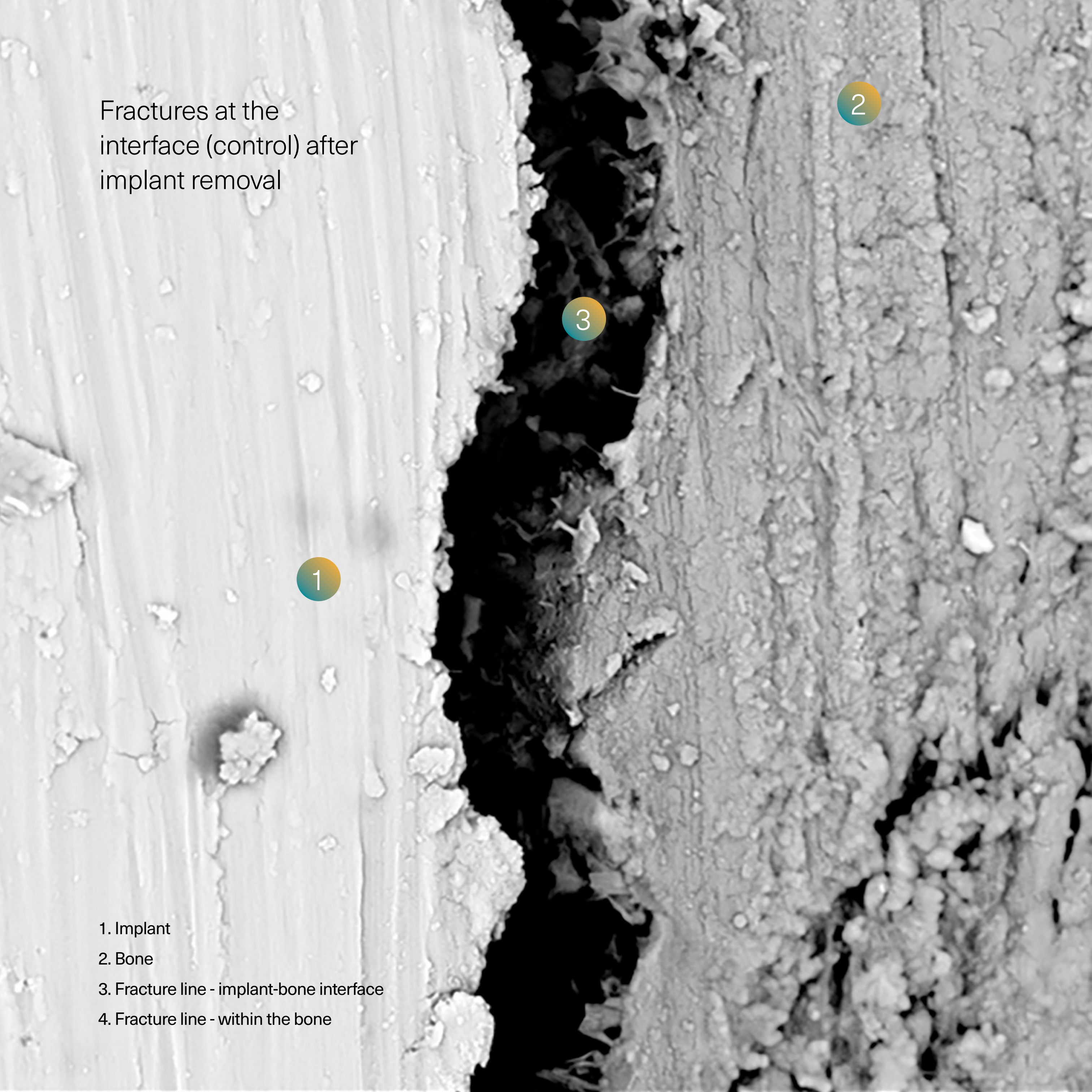




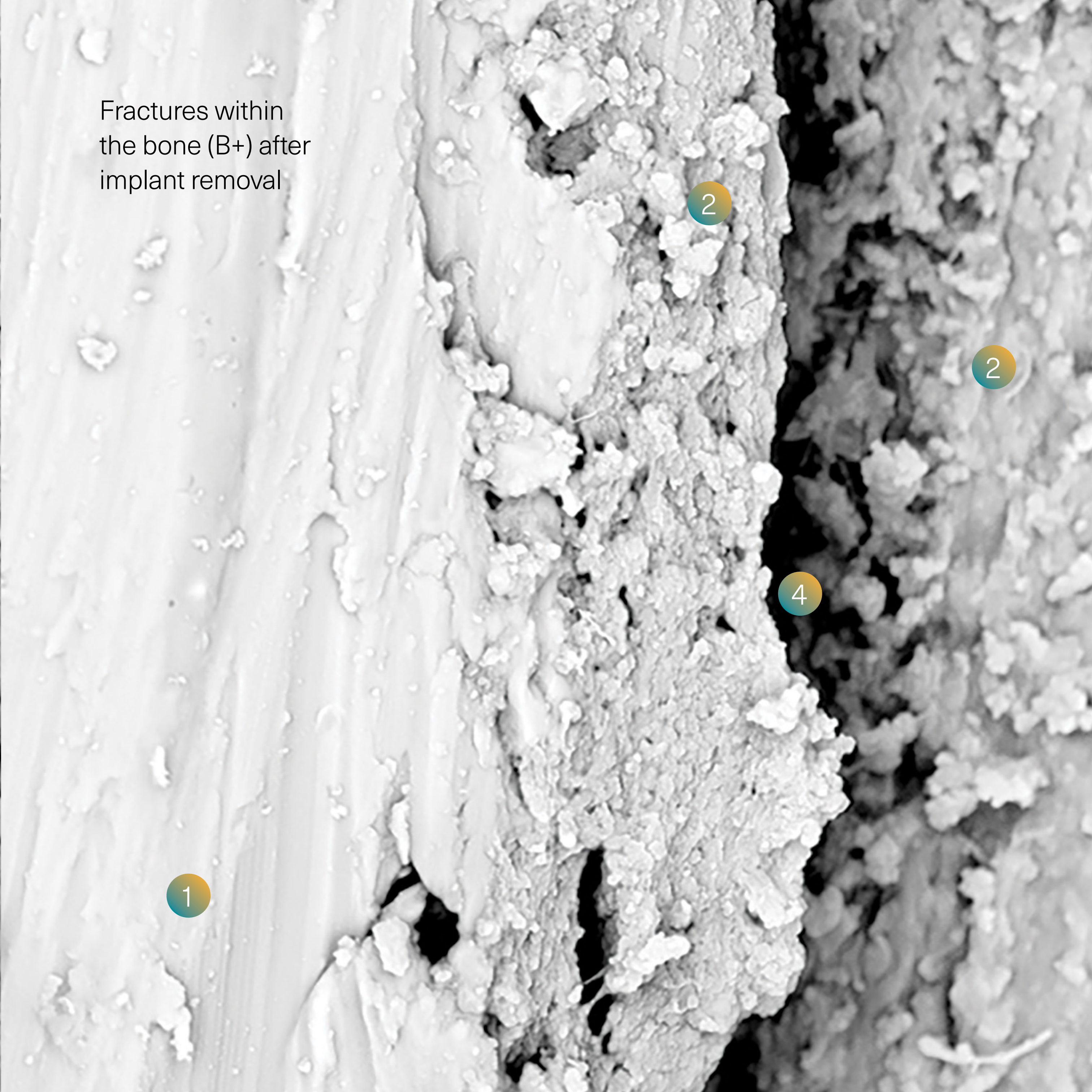
Fractures within the bone (B+) after implant removal



Fractures at the interface (control) after implant removal



1. Implant
2. Bone
3. Fracture line - implant-bone interface
4. Fracture line - within the bone



Fractures within the bone (B+) after implant removal

In the following study the B+ molecule was referred to as SurfLink, a patented Surface Technology under license from NBMolecules.

B+ Clinical Studies

Published in:

2014 | CLINICAL ORAL IMPLANTS RESEARCH

MULTI-PHOSPHONATE TREATED DENTAL IMPLANTS: COMPARISON OF CLINICAL OUTCOME IN MAXILLA, MANDIBLE, SMOKERS AND NON-SMOKERS

B. Aronsson,I. Dojcinvic, L. Germon, N. Levy, R. Curno, S. Buchini, P. Pechy,Nano Bridging Molecules SA, Gland, Switzerland, Private Dental Clinic, Morges, Switzerland Clin. Oral Impl. Res., 2014, 25 (Suppl. 10), 229-230

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 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 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 xrays 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).

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. 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.

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

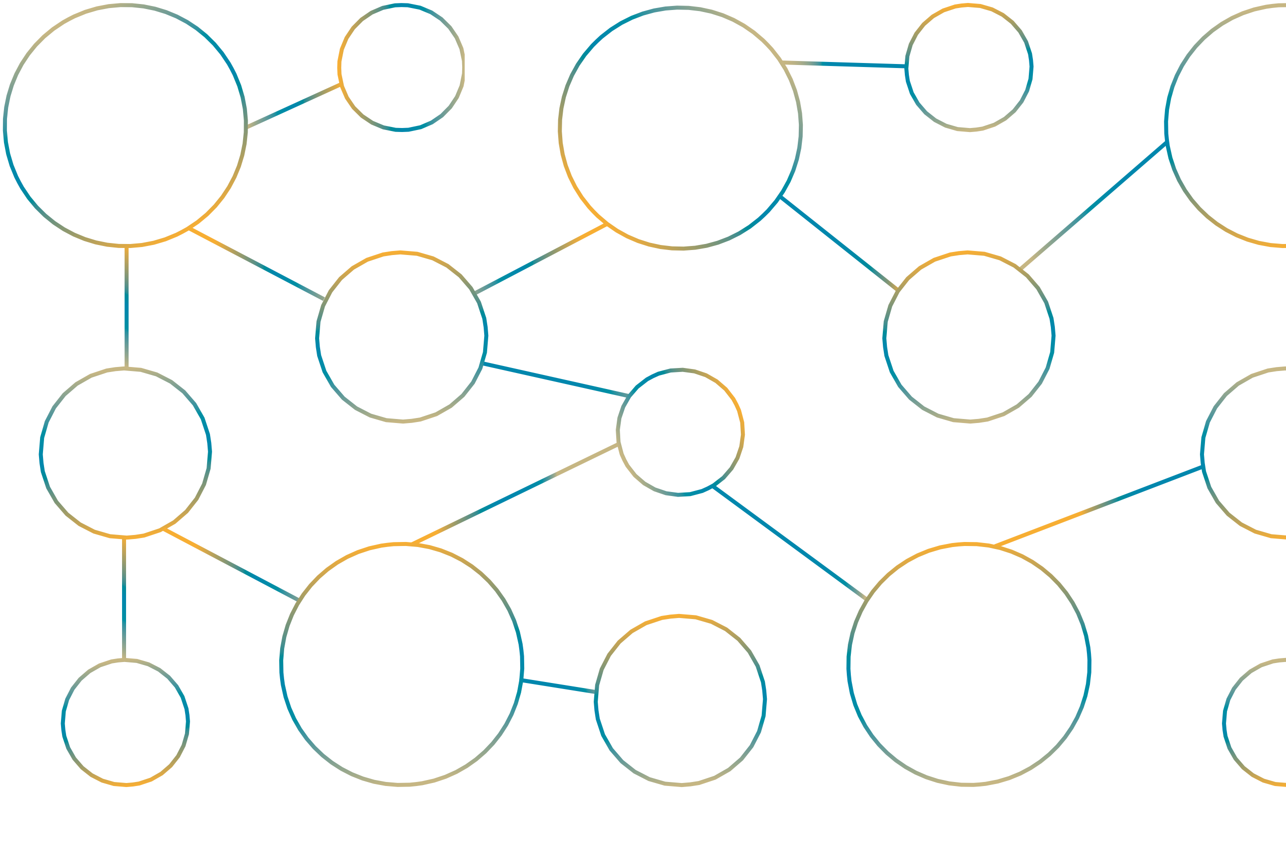
	Baseline to 1 year post-loading		
	Number of Patients	Implant Type	Mean ± SD
Surface	21	SurfLink®	-1.09±0.76
		SurfLink® (a)	-1.04±0.72
		Control	-1.36±0.87
		p / *p* (a)	0.057 /0.033
Maxilla	9(b)	SurfLink®	-1.32±0.79
		Control	-1.70±0.59
		p	0.070
Mandible	9(b)	SurfLink®	-0.92±0.83
		Control	-0.95±1.08
		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.

B+ Product Line

B+ implants are available in all MIS lengths and diameters for V3 and C1 implant systems.

B+ label on inner tube
for simple identification.



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