

# STRAUMANN® SLActive SCIENTIFIC EVIDENCE FIFTH EDITION (2011)



Straumann® Dental Implant System

COMMITTED TO SIMPLY DOING MORE FOR DENTAL PROFESSIONALS



## Contents

2	Innovation: SLActive®
3	Study overview
4	Preclinical studies
20	Clinical studies
30	References

### Innovation: SLActive®

#### The clinical challenge

Most implant failures occur in the critical early period between week 2 and 4<sup>1</sup>. This is the pivotal "dip" (stability dip), present in the transition period between primary and secondary stability in the bone formation process (Fig. 1). This trend, linked with the need for **greater security and higher predictability in early treatment, was the primary motivating factor in the development of SLActive®2**. Thus, the goal was to enhance treatment predictability and security for clinician and patient.

#### The innovation: "Activation of full healing potential"

To reach this goal, the research team focused on understanding the biologics of the healing process in the initial phase of up to four weeks after implant insertion. The purpose of this research and development process was at the **full and immediate activation** of the human body's natural healing potential.

The result is the new SLActive® surface. SLActive® is based on the scientifically proven SLA® topography. In addition, it has a **fundamentally improved surface chemistry**. The chemically active, hydrophilic SLActive® surface promotes the initial healing reaction, allowing for direct cell interaction at the initial stage of the osseointegration process. Bone formation is immediately initiated resulting in earlier secondary stability, therefore reducing the critical dip (Fig. 2).

#### The next generation in implant technology

Since the first study conducted in 1994, the macro- and microstructured, osseoconductive SLA® surface has become the industry standard for dental implant surfaces (Fig. 3). With the **new chemically active and hydrophilic SLActive® surface**, Straumann has now established a **new standard in oral implantology**, further reducing healing times down to 3–4 weeks.

#### The patient's benefit

Comparative measurements taken 2 weeks after the placement of implants with SLActive<sup>®</sup> illustrate that the **bone-to-implant contact** with SLActive<sup>®</sup> was 60 % higher than with SLA<sup>®</sup> (D. Buser et al. 2004). The significantly improved implant stability in the critical treatment phase between week 2 and 4 thus provides new treatment options and maximizes treatment security and predictability for the challenges in daily practice.



Fig. 3: SLA® vs. SLActive® preparation; SLActive® is prepared under protective gas conditions followed by liquid instead of dry storage.



**Fig. 1:** The decreasing primary stability and increasing secondary stability result in a decrease in overall stability (dip) between week 2 and 4 after implant placement.



**Fig. 2:** The optimized ossecintegration process with SLActive<sup>®</sup> leads to a higher implant stability between week 2 and 4.



<sup>1</sup> Raghavendra S., Wood MC, Taylor TD. Int J Oral Maxillofac Implants. 2005 May-Jun;20(3):425-31.

<sup>2</sup> SLActive® is the commercial name for modSLA or modified SLA® which are sometimes used in scientific publications

## Study overview

	PRECLINICAL STUDIES									
#	ТОРІС	AUTHORS	REFERENCE	PAGE						
1	Comparison of bone apposition at the surface of SLA® and SLActive® implants	D. Buser et al.	J. Dent. Res. 2004;83:529-533.	04						
2	Effects of molecular and cellular interactions on various treated titanium surfaces	L. Scheideler et al.	Poster #870, 83rd General Session and Exhibition of the International Association for Dental Research (IADR), March 9–12 2005, Baltimore, MD, USA	05						
3	Comparison of early cellular activity at hydrophilic and hydrophobic surface	G. Zhao et al.	J. Biomed. Mater. Res. A. 2005;74A:49–58.	06						
4	Evaluation of surface free energy (SFE) and hydrophilicity of different titanium surfaces	F. Rupp et al.	J Biomed Mater Res A 2006;76(6):323-334.	07						
5	Comparison of biomechanical properties of SLA® and SLActive® implants	S.J. Ferguson et al.	J. Biomed. Mater. Res. A. August 2006;78(2):291–297.	08						
6	Effects of surface hydrophilicity and microtopography on early stages of soft and hard tissue integration	Schwarz F. et al.	J Periodontol 2007;78(11):2171-2184.	09						
7	Evaluation of Initial and early subepithelial connective tissue attachment to SLA® and SLActive® implants	Schwarz F. et al.	Clin Oral Investig 2007;11(3):245–255.	10						
8	Assessment of initial and early osseous integration at SLA® and SLActive® implants	F. Schwarz et al.	Clin. Oral Impl. Res. 2007;18:481–488.	11						
9	Proliferation of MG63 and primary cells on various treated titanium surfaces	X. Rausch-Fan et al.	Dental Materials 2008;24:102–110.	13						
10	An experimental comparison of two different clinically used implant designs and surfaces	J. Gottlow et al.	Gottlow J., Barkarmo S., Sennerby L. Clin Implant Dent Relat Res. 2012 May; 14 Suppl 1:e204–12.	14						
11	Comparison of bone apposition around SLA® and SLActive® implants	M. Bornstein et al.	Clin. Oral Impl. Res 2008;19:233–241.	15						
12	Bone regeneration with $SLActive^{\circledast}$ in dehiscence-type defects	F. Schwarz et al.	Study 1: J Clin Periodontol 2007;34:78–86. Study 2: J Clin Periodontol 2008;35:64–75.	16						
13	Comparison of bone apposition around SLA® and SLActive® implants at sites with coronal circumferential defects	Lai H-C et al.	Clin Oral Implants Res 2009;20(3):247-253.	17						
14	Influence of titanium implant surface characteristics on bone regeneration in dehiscence-type defects	F. Schwarz et al.	J Clin Periodontol 2010;37(5):466–473.	18						
		CLINICAL STUDIES								
#	ТОРІС	AUTHORS	REFERENCE	PAGE						
15	Comparison of $SLA^{\textcircled{B}}$ and $SLActive^{\textcircled{B}}$ implant stability	T.W. Oates et al.	Int J Oral Maxillofac Implants 2007;22:755-760.	20						
16	Immediate and early loading of SLActive® implants in the posterior mandible and maxil	J. Ganeles et al.	Clin. Oral Impl. Res 2008;19:1119–1128.	21						
17	3 weeks loading of SLActive® implants in the maxillary molar region	M. Roccuzzo/ T.G. Wilson	Int J Oral Maxillofac Implants 2009;24:65-72.	22						
18	Stability change of palatal implants with SLActive® surface	M. Schätzle et al.	Clin. Oral Implants Res. 20, 2009;489–495.	23						
19	Early loading of nonsubmerged SLActive® implants	Bornstein M. M. et al.	Clin Implant Dent Relat Res 2009;11(4):338-347.	24						
20	Early loading at 21 days of non-submerged SLActive® implants	Bornstein MM. et al.	J Periodontol 2010;81(6):809-818.	25						
21	Early loading after 21 days of healing of nonsubmerged SLActive® implants	D. Morton et al.	Clin. Implant Dent. Relat. Res., 2010, 12(1), 9-1.	26						
22	A multicenter prospective 'non-interventional' study about Straumann® SLActive implants	G. Luongo et al.	J Oral Implantol 2010;30(4):305–314.	27						
23	Early osseointegration to hydrophilic and hydrophobic implant surfaces in humans	NP Lang et al.	Clin. Oral Implants Res. 2011;22:349-356	28						

### Enhanced bone apposition to a chemically modified SLA® titanium surface

D. Buser, N. Broggini, M. Wieland, R. K. Schenk, A. J. Denzer, D. Cochran, B. Hoffmann, A. Lussi, S. G. Steinemann J. Dent. Res. 2004;83:529–533.

**Abstract:** The degree of bone apposition at the implant surface was compared between SLA® and SLActive® implants in miniature pigs. After 2 and 4 weeks, there was a significantly greater percentage (up to 60 %) of bone-to-implant contact with SLActive®.

#### Introduction

Enhanced bone apposition has been evaluated and demonstrated on rough surface implants, including SLA®. However, more recently, it has been recognized that surface chemistry is another key factor in influencing bone-to-implant contact (BIC). Increased wettability and surface free energy both have a positive influence on bone apposition. The purpose of this study, therefore, was to evaluate the degree of bone apposition with the chemically modified SLActive® surface versus the SLA® surface, which has the same surface micro- and macrotopography.

#### **Material and Methods**

SLA® and SLActive® implants were placed in circular bone defects created in the maxillae of miniature pigs at least 6 months after tooth removal. Three or four implants were placed on either side of the maxilla in a split-mouth design and allowed to heal in a submerged position. The implants and implant sites were examined after 2, 4 and 8 weeks.

#### Results

PRECLINICAL STUDIES

Evidence showed that the amount of BIC was significantly greater with SLActive® after 2 and 4 weeks of healing. At 2 weeks, the BIC on SLActive® was 60 % greater than that on SLA® (49.30 % ± 7.49 versus 29.42 % ± 7.58; p < 0.02). Moreover, the typical pattern of new bone formation with a scaffold of woven bone was observed. (Fig. 1a). At 4 weeks, the BIC for SLActive® was 81.91 % ± 3.59, compared to 66.57 % ± 8.14 (p < 0.02) for SLA®. Bone density increased, as indicated by the reinforcement of woven bone trabeculae (Fig. 1b). Both surfaces showed similar results after 8 weeks (Fig. 1c), where early signs of bone remodeling were apparent. Thus, SLActive® promoted enhanced bone apposition during the early stages of bone regeneration.



**Fig. 1a:** At 2 weeks, bone is deposited upon the bony wall of the tissue chamber and upon the implant surface. Both layers are connected by a scaffold of tiny trabeculae. Waven bone is characterized by the intensive staining of the mineralized matrix and the numerous osteocytes located in large lacunae (undecalcified ground section, surface stained with toluidine blue and basic fuchsin. bar = 500 µm).



**Fig. 1b:** At 4 weeks, the volume density of this scaffold has increased both by the formation of new trabeculae and by deposition of more mature, parallel-fibered bone upon the primary scaffold. Woven bone is mainly recognized by the numerous large osteocytic lacunae (bright). The gap between bone and implant surface is an artifact (bar = 500 μm).

# Comparison of percentage of bone-to-implant contact (BIC) between SLA® and SLActive®

Period	Implant surface		Mean in %	St. dev.
2 weeks	SLActive®	8	49.30	7.49
	SLA®	8	29.42	7.58
4 weeks	SLActive®	8	81.91	3.59
	SLA®	8	66.57	8.14
8 weeks	SLActive®	7	78.47	11.14
	SLA®	7	75.45	7.66

- Bone apposition is significantly enhanced in the early osseointegration stages with SLActive®
- 60 % more bone (BIC) after 2 weeks with SLActive<sup>®</sup> compared to SLA<sup>®</sup>
- Earlier formation of more mature bone
- SLActive® further reduces the healing period following implantation



Fig. 1c: At 8 weeks, growth and reinforcement result in a further increase in bone density and an almost perfect coating of the implant surface with bone. Remodeling has started, replacing the primary bone by secondary osteons (bar =  $500 \mu m$ ).

# Storage conditions of titanium implants influence molecular and cellular interactions

L. Scheideler, F. Rupp, M. Wieland, J. Geis-Gerstorfer Poster #870, 83<sup>rd</sup> General Session and Exhibition of the International Association for Dental Research (IADR), March 9–12 2005, Baltimore, MD, USA

**Abstract:** The effects of protein and cellular interactions were compared on a variety of treated titanium surfaces, including SLA® and SLActive®. The chemically modified surface of SLActive® was found to increase osteoblast proliferation and significantly increase protein adsorption.

#### Introduction

The initial hydrophobicity of sandblasted and acid-etched titanium implant surfaces is a result of the microtopography and atmospheric contamination, which can influence initial surface conditioning by blood components, and thus affect cellular interactions. Protein- and cell-surface interactions and cellular proliferation were therefore investigated on the hydrophilic SLActive® surface compared to a variety of other surfaces.

#### **Materials and Methods**

Various disks of grade II titanium were prepared:

- Polished (Ti)
- Acid etched (A)
- $\bullet$  SLA® (SLA)
- SLActive® in NaCl with ph of 3-4 (modA)
- SLActive<sup>®</sup> in NaCl with ph of 4–6 (modSLA)

Fibronectin adsorption was determined by ELISA, and the initial osteoblast proliferation rate was determined by BrdU-incorporation (DNA synthesis rate).



#### Results

All surface treatments increased the amount of fibronectin conditioning the surface. On SLA- and A-surfaces the mean amount of fibronectin increased to 187 % (p<0.01) and 242 % (p<0.01), respectively, compared to the reference surface Ti. Storing of SLA-specimen in NaCl pH 4–6 resulted in a significantly further increased fibronectin-adsorption (162 %, compared to unmodified SLA®, p<0.01). Storing of acid-etched samples in NaCl pH 3–4 or pH 4–6 increased osteoblast proliferation to 121 % (p=0.06) and 117 % (p=0.15), resp., compared to A-samples stored at room atmosphere.

- SLActive<sup>®</sup> surface enhances osteoblast-surface and cellsurface interactions compared to SLA<sup>®</sup>
- SLActive® shows a significantly higher fibronectin adsorption (162 %) compared to SLA® and other surface types
- Effects may be due to increased hydrophilicity and surface free energy, and may improve clinical healing *in vivo*

### High surface energy enhances cell response to titanium substrate microstructure

G. Zhao, Z. Schwartz, M. Wieland, F. Rupp, J. Geis-Gerstorfer, D. L. Cochran, B. D. Boyan J. Biomed. Mater. Res. A. 2005;74A:49–58.

**Abstract:** The early cellular activity at the hydrophilic SLActive® surface was evaluated and compared with the hydrophobic SLA®. The cell reaction (osteoblast differentiation) was enhanced with SLActive®, and production of osteogenic factors, such as osteocalcin, alkaline phosphatase, PGE<sub>2</sub> and TGF-B1, was significantly increased.

#### Introduction

Investigations of osteoblast response to titanium surface chemistry have shown that osteogenesis is enhanced by hydrophilic surfaces. However, until recently, conventional titanium surfaces currently available have had low surface energy and distinct hydrophobic properties due to the microtopography and to adsorbed hydrocarbons. The purpose of this investigation was to compare the cellular response to different titanium microstructures, including SLActive®.

#### **Material and Methods**

Various disks of grade II titanium were prepared:

- Pre-treated titanium
- $\bullet \ \mathsf{SLA}^{\mathbb{R}}$
- SLActive<sup>®</sup>

Plastic discs were also prepared. Osteoblasts were then cultured on these surfaces and cellular response evaluated by measurement of alkaline phosphatase, osteocalcin, PGE<sub>2</sub> and TGF- $\beta$ 1.

#### Results

Osteoblasts cultured on SLActive® showed a more differentiated phenotype than those on the other surfaces tested. Compared to SLA®, there was a 3-fold increase of cell layer alkaline phosphatase activity on the SLActive® surface. In addition, osteocalcin (a late differentiation marker) was significantly increased (Fig. 1) and there was a higher production of the local growth factors PGE<sub>2</sub> (10-fold increase) and TGF-β1 (2.5-fold increase), creating a highly osteogenic microenvironment (Fig. 2). The effect of 1,25-dihydroxyvitamin D3, an osteotropic hormone that increases osteoblast differentiation, was also enhanced with SLActive®, in a manner synergistic with high surface energy.



**Fig. 1:** Osteocalcin production by MG63 cells during culture on plastic or Ti disks. Values are the mean ± SEM of six cultures.

\* p<0.05, Ti disks vs. plastic.

# p<0.05, treated vs. untreated control for a particular surface.

p<0.05, 10°M 1 α, 25(OH), D3 vs. 10°M 1 α, 25(OH), D3.</li>

The results suggest that the increased bone formation observed with SLActive<sup>®</sup> *in vivo* is partly due to stimulatory effects of the increased surface free energy (chemical activity) on osteoblasts.

#### Conclusions

- Osteocalcin production with SLActive<sup>®</sup> is significantly increased
- Osteoblast activity was clearly enhanced as a result of the chemically activated SLActive<sup>®</sup> surface
- A significantly enhanced production of local growth factors up to 10-fold is present
- Osteogenic properties are optimized



Surface partially covered with carbons from atmosphere



56 % reduction of carbons on the surface



Fig. 2: Latent TGF- $\beta$ 1 production by MG63 cells during culture on plastic or Ti disks. Values are the mean  $\pm$  SEM of six cultures.

\* p<0.05, Ti disks vs. plastic.

# p<0.05, treated vs. untreated control for a particular surface.

p<0.05, 10°M 1 α, 25(OH), D3 vs. 108M 1 α, 25(OH), D3</li>

3

4

# Enhancing surface free energy and hydrophilicity through chemical modification of microstructured titanium implant surfaces

Rupp F, Scheideler R, Olshanka N, de Wild M, Wieland M, Geis-Gerstorfer J. J Biomed Mater Res A 2006;76(6):323-334.

**Abstract:** The hydrophilicity and surface free energy (SFE) of different titanium surface preparations, including SLActive®, were evaluated. Both SFE and hydrophilicity were found to be increased with the SLActive® surface, and reduced atmospheric contamination was observed.

#### Introduction

Roughness-induced hydrophobicity, a well-known phenomenon from natural plant surfaces, has been identified on microstructured titanium implant surfaces. Since this hydrophobicity may inhibit primary interactions with the aqueous biosystem, a novel titanium surface modification was developed with increased wettability that prevents contamination and retains a more active titanium surface. The hydrophilicity and surface free energy of the modified surface was therefore evaluated.

#### **Methods**

Titanium specimens with six different surface preparations (SLA®, SLActive®, sandblasted with large grit [SL], acid-etched [A], modified acid-etched [modA], polished [P]) were characterized for roughness and topography, and dynamic contact angle analysis, surface free energy evaluation and x-ray electron spectroscopy were performed.

#### Results

The SLActive<sup>®</sup> surface modification increased surface free energy and increased hydrophilicity with initial water contact angles, as assessed by the Wilhelmy electrobalance method, of 0° compared to 139.9° for the SLA<sup>®</sup> surface (Table 1). Hydrophilicity was also maintained even after drying of the surface. Reduced hydrocarbon contamination was identified as having a possible role in the altered surface thermodynamics. Comparable initial hydrophilization was observed with SLA® stored in water after N2 drying, but the effect was completely reversed by subsequent vacuum drying, which had no effect on the hydrophilicity of SLActive®. The stability of the hydrophilic behavior of SLActive® was demonstrated by the difference in the hysteresis loops (Fig. 1), where neither ultrasonic cleaning nor vacuum drying of SLActive® could reach the advancing force loop of SLA®.



**Fig. 1:** 10-fold hysteresis loops of SLA® and SLActive® (modSLA) showing the stability of the SLActive® hydrophilicity (F = force, L = length, F/L denotes hysteresis), indicating that ultrasonic cleaning (US) and vacuum drying (vac) of SLActive® did not reach the advancing force loop of SLA®.

n = 6	SLA®	ModSLA	А	ModA	SL	Р
θ <sub>l.adv</sub> (°)	139.88	0	122.40	0	106.58	91.31
Mean (SD)	(8.69)		(7.39)	0	(4.18)	(7.30)
$\theta_{2.adv}$ (°)	0	0	0	0	<5	82.32
Mean (SD)						(11.79)
$\theta_{1,\text{rec}}$ (°)	<5	0	8.85	0	15.35	42.99
Mean (SD)			(2.70)		(3.01)	(11.37)
θ <sub>2.rec</sub> (°)	<5	0	8.63	0	14.25	40.83
Mean (SD)			(3.03)		(2.79)	(10.71)

Table 1: Dynamic wettability of titanium surface modifications by first and second loop advancing (adv) and receding (rec) water contact angles

- SLActive<sup>®</sup> is highly hydrophilic (water contact angle of 139.9° versus 0° for SLA<sup>®</sup>)
- The SLActive® surface shows reduced atmospheric contamination
- Surface free energy is much higher with SLActive<sup>®</sup>

# Biomechanical evaluation of the interfacial strength of a chemically modified sandblasted and acid-etched titanium surface

S. J. Ferguson, N. Broggini, M. Wieland, M. de Wild, F. Rupp, J. Geis-Gerstorfer, D. L. Cochran, D. Buser J. Biomed. Mater. Res. A. August 2006;78(2):291–297.

**Abstract:** The biomechanical properties of SLActive® and SLA® implants were compared in a split-mouth study in adult miniature pigs. After 2, 4 and 8 weeks of healing, removal torque and interfacial stiffness values were significantly higher for SLActive®.

#### Introduction

The capacity of osseointegrated dental implants to bear load depends largely on the bone-to-implant interface, which can be greatly influenced by the characteristics of the implant surface. The hydrophilic, chemically activated surface of SLActive® implants has been shown to enhance bone apposition and promote rapid bone-to-implant contact. One might suggest, therefore, that the enhanced osseointegration could lead to greater initial implant stability. In order to assess this, the biomechanical characteristics of the SLActive® surface were compared with those of SLA®.

#### **Materials and Methods**

SLActive® and SLA® implants 4.8 mm in diameter were placed in a splitmouth design (three implants per side) in nine adult miniature pigs following at least 6 months of healing after tooth removal. After 2, 4 and 8 weeks, the implants were evaluated by removal torque testing using a torque rotation curve to assess the interfacial shear strength and removal torque of each implant.

#### Results

Both the healing period and the implant surface type were shown to be significant factors affecting the biomechanical performance. Overall, removal torque for both SLA® and SLActive® implants increased to a peak value at 4 weeks, and then decreased (Fig. 1). Removal torque values for SLActive® were significantly higher (8– 21 %; p = 0.003) than those for SLA® at each individual time point (1.485, 1.709 and 1.345 Nm for 2, 4 and 8 weeks, respectively, compared to 1.231, 1.585, and 1.143 Nm for SLA). Interfacial stiffness values were approximately 9–14 % higher for SLActive® implants than for SLA® implants (p = 0.038). Changes in the biomechanical characteristics of the interface may reflect the natural process of bone apposition and remodeling, as the interface is transformed from a purely mechanical to a biologically integrated system. The evidence therefore suggests superior bone anchorage with the SLActive® implant surface.

#### Conclusions

- Bone apposition is enhanced with the SLActive® surface
- Interfacial mechanical stiffness and strength is significantly greater with SLActive®
- SLActive® gives higher implant stability during the critical early weeks of osseointegration



Fig. 1: 3 Animals per timepoint & 3 implants (3+3) per animal [3].

### 6

Schwarz F, Ferrari D, Herten M, Mihatovic I, Wieland M, Sager M, Becker J. J Periodontol 2007;78(11):2171-2184.

**Abstract:** SLA® or SLActive® implants with different transmucosal surface preparations were placed in dogs and evaluated by histomorphometry and immunohistochemistry for up to 28 days. Surface hydrophilicity was found to have a greater effect on soft and hard tissue integration.

#### Introduction

Long-term outcomes of implants may be influenced by marginal soft tissue integration, which seals the adjacent alveolar bone from the oral environment. This study therefore investigated early stages of soft and hard tissue integration at non-submerged implants in dogs.

#### Methods

SLA® implants with either a machined or SLA® transmucosal part (M-SLA or SLA-SLA) or SLActive® implants with either a modified acidetched or SLActive® transmucosal part (modA-SLActive or SLActive®. SLActive®) were placed bilaterally in the mandibles and maxillae of 15 dogs. Tissue reactions were analyzed histomorphometrically and immunohistochemically after 1, 4, 7, 14 and 28 days.

#### Results

Day 1: Some localized transmucosal areas showed an intimate junction with adjacent fibroblasts and collagen fibers for both SLActive® implant types, and stabilization of the coagulum was most commonly observed with these implants.

Day 4: Connective tissue adjacent to the SLActive® implant types showed a dense network of vascular structures.

Day 7: Subepithelial connective tissue was in close contact with the SLActive<sup>®</sup> implant types, and attached fibroblasts and collagen fibers were generally perpendicular to the implant surface.

Day 14: Epithelial cells were in close contact with the modA-SLActive implants, and well vascularized connective tissue with collagen fibers extending and attaching perpendicularly to the implant surface were observed with both SLActive<sup>®</sup> groups (Figure 1).

Day 28: Histology was similar to day 14 for all groups, but collagen fibers appeared as filaments perpendicular to the surface in the SLActive® groups (Figure 1).

Mean BIC was significantly greater in the maxilla and mandible for the SLActive<sup>®</sup> groups at days 7 and 14, and was significantly greater in the maxilla for the SLActive<sup>®</sup> groups at days 7, 14 and 28.



Fig. 1: Attached fibroblasts and collagen fibers in a partially perpendicular direction to the implant surface at day 14 (left: modA-SLActive, magnification x 400) and supracrestal connective tissue with numerous collagen fibers extending and attaching perpendicularly to the implant surface at day 28 (right: SLActive®, SLActive®, magnification x 400)

#### Conclusions

• Soft and hard tissue integration was influenced mainly by surface hydrophilicity rather than microtopography

# Histological and immunohistochemical analysis of initial and early subepithelial connective tissue attachment at chemically modified and conventional SLA® titanium implants. A pilot study in dogs

Schwarz F, Herten M, Sager M, Wieland M, Dard M, Becker J. Clin Oral Investig 2007;11(3):245-255.

**Abstract:** Subepithelial connective tissue attachment to SLA® and SLActive® implants was evaluated in dogs for up to 14 days. The results indicated that the SLActive® surface may have the potential to enhance attachment of the connective tissue, with well organized collagen and blood vessel formation.

#### Introduction

Marginal soft tissue integration plays an important role in the healing process following implant placement. The aim of this investigation was to evaluate initial and early subepithelial connective tissue at tachment to the transmucosal portions of SLA® and SLActive® implants, both of which were submerged to prevent bacterial contamination.

#### **Methods**

Four dogs each received eight SLA® implants and eight SLActive® implants (five of each in the mandible and three of each in the maxilla) in a split-mouth design. The implants were RN  $\oslash$  3.3 mm with a length of 8 mm. Histological and immunohistochemical analyses were performed after 1, 4, 7 and 14 days (one animal at each time point).

#### Results

The submerged implant surgical procedure resulted in an artificial gap in the transmucosal area of both implant types at day 1. By day 4 the gaps were minimized in both implant types to a width of approximately 80 µm, but the collagen fibers at the SLActive® surface appeared to be replaced by loose connective tissue, whereas the density of collagen fibers at the SLA® surface appeared to increase. The newly formed connective tissue bridged the gap and was in close contact with the SLActive® implant surface at day 7, with fibers organized perpendicular to the surface. In contrast, dense connective tissue with collagen fibers parallel to the surface was observed at the SLA® implants, with no direct adhesion to the surface (Figure 1). Well organized collagen and blood vessel formation was observed at the SLActive® implants at day 14, and the subepithelial connective tissue could not be separated into different zones. SLA® implants, however, were still separated by a dense connective tissue capsule at day 14 (Figure 2), and blood vessel formation was rare.



Fig. 1: Histological views of connective tissue reactions to SLA® (left) and SLActive® (right) implants at day 7  $\,$ 



Fig. 2: Histological view of connective tissue reactions to SLA® (left) and SLActive® (right) implants at day 14

- The SLActive<sup>®</sup> surface may have the potential to promote subepithelial connective tissue attachment at the transmucosal part of implants
- The results underscore the biological impact of the SLActive® surface

# Histological and immunohistochemical analysis of initial and early osseous integration at chemically modified and conventional SLA® titanium implants: preliminary results of a pilot study in dogs

F. Schwarz, M. Herten, M. Sager, M. Wieland, M. Dard, J. Becker Clin. Oral Impl. Res. 2007;18:481–488.

**Abstract:** Early tissue reactions around SLA® and SLActive® implants were assessed. During a period of 14 days, faster and more structured bone formation was observed around the SLActive® implants, with greater vascularization and increased osteocalcin activity.

#### Introduction

Assessment of bone-to-implant contact (BIC), an essential factor for successful osseointegration, is usually performed via conventional histological staining. However, this method may not be suitable for the investigation of very early tissue responses that begin with protein adhesion to the implant surface, which may in turn affect tissue development, depending on the type of proteins present. Osteogenic cells and osteoblast differentiation may also be important for osseo-integration, and may also be associated with early angiogenic activity. The aim of this investigation was therefore to assess early tissue reactions to SLA® and SLActive® implants (up to 14 days) using conventional and immunohistochemical techniques.

#### **Material and Methods**

SLA® or SLActive® was placed in a split-mouth design 4 months following tooth extraction in four fox hounds; six implants (three of each type) were placed in the maxilla and ten implants (five of each type) were placed in the mandible of each animal. Specimens were retrieved for immunological and immunohistochemical assessment after 1, 4, 7 and 14 days of healing. Toluidine blue was used to assess the extent of new bone formation, and Massner Goldner Trichrome was used to assess the quality and quantity of collagen and new bone formation. Unlike conventional stains, this allows the differentiation of changes to be observed over a very short time period (e.g. days rather than weeks).

#### Results

Vascular infiltration of the blood clot adjacent to the implant was apparent for both implant types after 1 day, contacting the surface of SLActive® implants but not SLA® implants. The blood clot around SLActive® implants appeared to be stabilized, whereas the clot around SLA® implants appeared to be partially collapsed (Fig. 1). Infiltration of the clot by macrophages was also apparent.

At day 4, collagen-rich dense connective tissue was apparent around SLActive® implants and the first indications of osteocalcin synthesis, which reached the implant surface, were observed (Fig. 2 and 3). Both of these suggest more rapid osseointegration processes. In contrast, SLA® implants were surrounded by newly formed granulation tissue and some provisional connective tissue, with no osteocalcin synthesis (Fig. 2 and 3). The tissue around both implant types contained vascular structures, but these appeared to be of a higher density around SLActive® implants.

At day 7, dense fibrous connective tissue, with collagen fiber bundles, blood vessels surrounded by newly formed trabeculae of woven bone and osteocalcin, indicating bone remodeling, were all apparent around SLActive® implants (Fig. 4, 6 and 7). In contrast, unstructured connective tissue with smaller blood vessel density and decreased osteocalcin concentration was observed around SLA® implants (Fig. 4 and 6). SLA®





Fig. 1: Histology at Day 1; collapsed blood clots (SLA®) versus stabilized blood clots (SLActive®).

SLA®

**SLActive**<sup>®</sup>



Fig. 2: Histology at Day 4; no osteocalcin synthesis (SLA®) versus first indications of osteocalcin synthesis (SLActive®).



Fig. 3: Histology at Day 4; granulation tissue (SLA®) versus collagen-rich connective tissue (SLActive®).

After 14 days, newly formed trabecular bone was formed around the SLA® implants, whereas firmly attached, mature, parallel-fibered woven bone was present around the SLActive® implants (Fig. 5 and 8). The formation of primary osteons was seen in the bone surrounding SLActive® implants, with a radical deposition of lamellar bone around the core of connective tissue surrounding the blood vessels, whereas newly formed trabecular bone was observed around the SLA® implants.



Fig. 6: Osteocalcin, an indicator of bone remodeling, is synthesized faster and was consistently higher with SLActive®.





Fig. 8: Transglutaminase levels consistently higher with SLActive®.

SLA®

**SLActive®** 



Fig. 4: Histology at Day 7; not yet structured bone (SLA®) versus mineralized and organized bone (SLActive®).



Fig. 5: Histology at Day 14; newly formed trabeculae (SLA®) versus firmly attached, mature, parallel-fibered woven bone and primary osteons (SLActive®).

- Significantly increased proliferation of vascular structures with SLActive® throughout days 1–14
- Significantly increased activity of osteocalcin at the bone-to-implant interface, and enhanced bone formation processes with SLActive<sup>®</sup>
- Quantitative and qualitative analysis showed significant differences in bone formation

# Proliferation of MG63 and primary cells was highest on controls, followed by A surfaces, modA and SLA® surfaces being almost the same level and lowest on modSLA (SLActive®) surfaces

X. Rausch-fan, Z. Qu, M. Wieland, M. Matejka, A. Schedle Dental Materials 2008;24:102–110.

Abstract: Early cellular processes were assessed on various treated titanium surfaces. Initial results show substantially increased production of osteocalcin and local growth and vascularization factors with SLActive®.

#### Introduction

Implant surface properties such as topography or chemistry play a key role in the establishment of cell-biomaterial interfaces. Wettability and surface charge both play an important role in protein adsorption, which can be modulated according to changes in the physico-chemical characteristics of the surface, subsequently affecting cell attachment. Based on this, the process of cell attachment, time lapse motion, contact guidance and cell proliferation were assessed on titanium surfaces with different topographical and chemical attributes, in order to obtain a deeper understanding of how these different surfaces influence cell behavior.

#### **Material and Methods**

Four types of titanium disks were used: Acid-etched, SLA®, modified acid-etched and modified SLA® (SLActive®). Human primary cells (osteoblasts, gingival fibroblasts and gingival epithelial cells) were used in order to mimic the in vivo situation as closely as possible. In addition, appropriate cell lines were also used: MG-63 (human osteoblastic cell line), HGF-1 (gingival fibroblast cell line), HSC-2 (epithelial cell line) and an endothelial cell line. Growth on the titanium surfaces was monitored by fluorescence cell staining and time-lapse photography (Fig. 1).

#### Results

Initial results, from MG-63 cells and alveolar osteoblasts, show that succinate dehydrogenase activity (indicative of cellular mitochondrial function), alkaline phosphatase synthesis (Fig. 2), and production of osteocalcin, osteoprotegerin (Fig. 3), TGF- $\beta$ 1 and VEGF (an important vascularization factor) were all increased with SLActive® compared to the SLA®, acid-etched or modified acid-etched surfaces.

#### Conclusions

- A significantly enhanced early cell reaction can be seen as a result of the chemically activated SLActive® surface
- There is a substantially increased production of osteocalcin and osteoprotegerin with SLActive<sup>®</sup>
- Substantially increased production of local growth and vascularization factors with SLActive<sup>®</sup>



Fig. 1: Living MG-63 cells, grown for 24 h on a mod. SLA® surface (SLActive®).



Fig. 2: Alkaline phosphatase synthesis of MG-63 cells grown on SLA® and SLActive®.



**Fig. 3:** Osteoprotegerin production of MG-63 cells grown on SLA® and SLActive<sup>®</sup>.

### An experimental comparison of two different clinically used implant designs and surfaces

Gottlow J., Barkarmo S., Sennerby L. Clin Implant Dent Relat Res. 2012 May;14 Suppl 1:e204–12.

#### Introduction

The aim of the present animal study was to compare the bone tissue responses and implant stability of two principally different implant designs and surfaces after 10 days, 3 and 6 weeks of healing.

#### **Materials and Methods**

The two implants compared were Straumann® Standard Plus (Ø 4.1 mm, RN, SLActive®, 10 mm) and Replace® Select Taper (Ø 4.3 mm, TiUnite®, 10 mm) from Nobel Biocare®. A total of 30 adult rabbits were chosen for the study. Three implants of both SLActive® and TiUnite® groups were placed in the distal femur, the proximal tibia and the distal tibia of each rabbit using a rotational scheme. Each ten animals were sacrificed at 10 days, 3 weeks and 6 weeks after surgery and the histology and the removal torque were measured. Removal torque values were normalized by the implant design to calculate the shear strength.

#### Results

The normalized values of the shear strength displayed in Figure 1 showed that after 10 days the shear strength of both implants was similar, however, at 3 and 6 weeks after surgery the mean shear strength values for the SLActive® implants were significantly higher in comparison to TiUnite® implants. The histology showed a statistically significantly higher bone-to-implant contact (BIC) for SLActive® after 10 days, similar for both implant types after 3 weeks and statistically significantly higher for TiUnite® after 6 weeks (see Figure 2).

#### Conclusion

In this study, done in rabbit tibiae and femur, both implant types were found to be well integrated in the bone and showed increased stability from placement to 6 weeks. When looking at these two implants, no single factors such as design or surface can be isolated and compared independently. The SLActive<sup>®</sup> implants demonstrated significantly higher removal torque after 3 weeks and significantly higher shear strength after 3 and 6 weeks. BIC was higher for SLActive<sup>®</sup> implants after 10 days and significantly higher for TiUnite<sup>®</sup> implants after 6 weeks. The authors indicated that the results may be due to differences in surface roughness and hydrophilic properties.







10

# Bone apposition around two different sandblasted and acid-etched titanium implant surfaces: A histomorphometric study in canine mandibles

M. M. Bornstein, P. Valderrama, A. A. Jones, T. G. Wilson, R. Seibl, D. L. Cochran Clin. Oral Impl. Res 2008;19:233-241.

**Abstract:** The degree of bone apposition around SLActive® compared to SLA® implants was compared in foxhounds. Early results suggest greater and more mature bone growth 2 weeks after implant placement.

#### Introduction

The present study evaluates bone apposition to a modified SLA® implant surface (SLActive®) in the canine mandible as compared to the standard SLA® surface. Test and control implants had the same surface topography, but the modSLA surface has a different chemistry with improved hydrophilic characteristics. The hypothesis of the study was that implants with a modSLA surface would promote faster bone apposition in comparison to implants with the standard SLA® surface.

#### **Material and Methods**

**SLA**®

The foxhound model was chosen to allow in vivo evaluation of SLActive® in a higher animal species biologically similar to humans. Initially, all premolars and first molars from five animals were removed bilaterally to create edentulous ridges. After a healing period of six months, the ridges were re-entered, and six randomly assigned implants (three with the SLA® surface, three with the modSLA surface) were inserted per mandible and left unloaded. The implants were evaluated by histological and histomorphometric analysis (VIS software package, Visiopharm A/S, Horsholm, DK) after 2 and 4 weeks after implant placement.

**SLActive**<sup>®</sup>

#### Results

In the present study, both implant surfaces tested – SLA® and SLActive® – demonstrated excellent osseointegration over the fourweek healing period. Distant and contact osteogenesis was seen simultaneously after two weeks of healing and were ongoing throughout the four-week observation phase. Contact osteogenesis, as seen in the histologic sections through the "osteo-coating", is especially considered to be a crucial phase in the osseointegration process. Since no bone was present on the implant surfaces upon insertion of the devices, the implant surfaces must become colonized by a population of osteogenic cells before initiation of bone matrix formation, thus enabling a contact osteogenesis. However, the bone to implant contact length (BIC) of newly formed bone with the surface of SLActive® implants showed more than 25 % greater values after 2 weeks of healing compared to with SLA.



Fig. 2: Insertion of a dental implant with a SLActive® surface. The hydrophilic properties of this surface are evident by the ascending blood in the threads.



**Fig. 3:** Newly formed bone-to-implant contact length (BIC) 2 and 4 weeks after implant placement. Results are shown as percentages  $\pm$  standard deviation. Statistically significant differences (P< 0.05) are indicated by an asterisk (\*).

Fig. 1: Two examples of histological slides of SLA® and SLActive® implants after two weeks of healing.

- Pronounced increase of bone formation around SLActive<sup>®</sup> compared to SLA<sup>®</sup> in the early stage of implant integration in vivo
- Significant increase of bone formation in the period between 2 and 4 weeks of healing both for SLA® and SLActive® implants

## Bone regeneration with SLActive® in dehiscence-type defects in dogs: histological, histomorphometric and immunohistological analyses

Study 1: F. Schwarz, M. Herten, M. Sager, M. Wieland, M. Dard, J. Becker. Bone regeneration in dehiscence-type defects at chemically modified (SLActive®) and conventional SLA® titanium implants: a pilot study in dogs. J Clin Periodontol 2007;34:78-86. Study 2: F. Schwarz, M. Sager, D. Ferrari, M. Herten, M. Wieland, J. Becker. Bone regeneration in dehiscence-type defects and non-submerged and submerged chemically modified (SLActive®) and conventional SLA® titanium implants: an immunohistochemical study in dogs. J Clin Periodontol 2008;35:64-75.

Abstract: The aims of the present studies were to evaluate bone regeneration in dehiscence-type defects at titanium implants with SLActive® and SLA® surfaces. The results indicated that SLActive® promotes bone regeneration in dehiscence-type defects.

#### Introduction

The achievement of direct bone-to-implant contact without connective tissue between the implant and bone is a pre-requisite for osseointegration. However, bone defects, particularly bone dehiscences and fenestrations, can compromise the establishment of osseointegration. Although guided bone regeneration techniques can be successful in these situations, implant survival tends to be lower, suggesting that augmenting bone where there are exposed implant threads introduces additional risk factors. The bone formation at such defects may, however, be improved by the hydrophilic properties of the SLActive® surface.

These two studies therefore evaluated the effect of implants with the SLActive® surface compared to SLA® in dehiscence-type defects in dogs. In the second study, the potential effect of surgical procedure was also assessed, using submerged or non-submerged implants.

#### **Material and Methods**

Standardized dehiscence defects were created in the upper and lower jaws of four dogs (Study 1) and 12 dogs (Study 2), and SLA® or SLActive® implants were placed. Dissected blocks were obtained after 2 and 12 weeks (Study 1) or 1, 2, 4 and 8 weeks (Study 2). In both studies, new bone height (NBH), percent linear fill (PLF), percent of bone-to-implant contact (BIC-D) and area of new bone fill (BF) were assessed histomorphometrically, with additional immunohistochemical analysis in Study 2.

#### Results

PRECLINICAL STUDIES

Study 1: After 12 weeks, the defects around SLActive® implants were completely filled with new bone. Newly formed trabeculae of woven bone were observed after 2 weeks, originating from the walls and bottom of the defects, and the implants were surrounded by mature, parallel-fibered woven bone by 12 weeks (Fig 1a). There were significant increases in NBH, PLF, BIC-D and BF. In contrast, wound healing at the defects with SLA® implants was characterized by poorly vascularized, dense connective tissue at both 2 and 12 weeks, with only small amounts of bone formation in the apical part of the defect and no significant increases in NBH, PLF. BIC-D or BF (Fig 1b).

**SLActive**®



Fig. 1a: Histological evaluation of the defects around SLActive® implants, showing complete filling of the defect with new parallel-fibered woven bone; BIC = 80%





Fig. 1b: Histological evaluation of the defects around SLA® implants after 12 weeks, showing limited new bone formation only in the most apical part of the defect; BIC = 5 %.

Study 2: After 8 weeks, values for NBH, PLF, BIC-D and BF were significantly higher with SLActive® implants compared to SLA® implants (Figs 2a and 2b), therefore confirming the results of the previous study.



Fig. 2a: Histological view of wound healing at non-submerged (A) and submerged (B) SLActive® implants.

Fig. 2b: Histological view of wound healing at non-submerged (C) and submerged (D) SLA® implants, showing partial collapse of mucoperiosteal flap compromising bone regeneration.

- SLActive<sup>®</sup> promotes bone regeneration in dehiscence-type defects
- SLActive® promotes the production of significantly greater and more mature bone than SLA®
- Significant increases in new bone height, bone fill and bone-to-implant contact are seen with SLActive®
- Complete bone fill can be obtained with SLActive®

# Bone apposition around two different sandblasted, large-grit and acid-etched implant surfaces at sites with coronal circumferential defects: an experimental study in dogs

Lai H-C, Zhuang L-F, Zhang Z-Y, Wieland M, Liu X. Clin Oral Implants Res 2009;20(3):247-253.

**Abstract:** SLA® and SLActive® implants were placed in the premolar and molar positions in the mandibles of dogs, with or without a gap around the coronal part of the implant. Greater early bone apposition was observed with the SLActive® surface, and the results indicated that small gaps may not require a regenerative procedure.

#### Introduction

The SLActive® surface has been shown to enhance bone apposition in standard implant sites, and may also improve bone formation at defect sites. This study was therefore designed to evaluate bone apposition around SLA® and SLActive® implants in different sizes of circumferential defects.

#### **Methods**

Mandibular premolars and first molars were extracted from six dogs and implants with SLA® and SLActive® surfaces (three of each; length 10 mm) were placed after 3 months; SLA® and SLActive® implants were randomly assigned to either side. Implants were placed with a 0.5 mm gap, 1.0 mm gap or no gap (control) around the coronal 5 mm of the implant (Figure 1). Histological and histomorphometric analyses were performed after 2, 4 and 8 weeks.

#### Results

A similar pattern of bone apposition was observed around implants with both surfaces, but the percentage of BIC and new bone fill, and the distance from the most coronal position of the BIC to the bottom of the defect was significantly greater for the SLActive® surface at 2 and 4 weeks (Table 1). By 8 weeks, the differences were not significant and the defects were almost entirely filled with new bone, regardless of defect size. No differences were observed between the two defect sizes at any time point.



Fig. 1: Photograph (left) and radiograph (right) showing the implant sites after defect preparation and implant placement

	Control		P-value	Type 1 defect		P-value Type 2 defect		P-value	
	SLA	modSLA		SLA	modSLA		SLA	modSLA	
2 weeks	37.61 (12.78)	58.32 (13.54)	<0.05	35.83 (13.13)	60.15 (14.12)	<0.05	36.53 (14.12)	59.82 (13.69)	<0.05
4 weeks	64.58 (14.76)	76.43 (15.21)	<0.05	65.23 (13.78)	74.57 (14.38)	<0.05	63.78 (15.01)	78.05 (14.52)	<0.05
8 weeks	78.41 (24.69)	80.54 (23.21)	n.s.	79.11 (23.43)	81.62 (24.91)	n.s.	77.89 (24.67)	83.45 (24.98)	n.s.

\*Non-defect area: Control, all the 10-mm bony part of the implants; Type 1 and Type 2 defect, the apical 5-mm part of the implants.

Table 1: Percentage of BIC within the non-defect area [mean (SD)]

- Greater bone apposition was observed in the early stages of healing for the SLActive® surface compared to the SLA® surface
- The surface characteristics of the SLActive® surface may therefore enhance bone apposition in coronal circumferential defects at non-submerged implants
- A defect gap size < 1 mm may not require a regenerative procedure

# Influence of titanium implant surface characteristics on bone regeneration in dehiscence-type defects: an experimental study in dogs

Schwarz F, Sager M, Kadelka I, Ferrari D, Becker J. J Clin Periodontol 2010;37(5):466-473.

**Abstract:** Implants with either an SLActive<sup>®</sup> or a NanoTite<sup>®</sup> surface were placed in dehiscence-type defects in dogs and underwent submerged healing for 2 or 8 weeks. Histomorphometric analysis showed greater new bone height and bone-to-implant contact for SLActive<sup>®</sup>, possible indicated a greater potential to support ossecintegration in dehiscence-type defects.

#### Introduction

The aim of the present study was to evaluate and compare bone regeneration in standardized dehiscence-type defects at implants with the SLActive® surface or with a calcium phosphate nanoparticle-modified dual acid-etched surface (NanoTite® Certain Prevail, Biomet 3i, FL, USA).

#### **Methods**

Standardized buccal dehiscence-type defects (height 4 mm, width 4 mm, depth 2 mm) were surgically created following implant site preparation in both upper and lower jaws of 12 dogs. Both SLActive® and NanoTite® implants were randomly assigned in a split-mouth design and left to heal in a submerged position. After 2 and 8 weeks, dissected blocks were processed for histomorphometric analysis (new bone height [NBH], percentage of bone-to-implant contact [BIC], area of new bone fill [BF], and area of mineralized tissue [MT] within BF). For the statistical evaluation of changes within groups, the paired ttest was used.

#### Results

Wound healing in both groups at 2 weeks was characterized by woven bone formation in the defect area. However, differences were observed in the bridging of the implant surface and defect margin by newly formed bone; woven bone was in close contact with the surface at SLActive® implants, while BF areas were commonly separated from NanoTite® implants by non-mineralized tissue (Figure 1).

After 8 weeks, continuous filling of the intertrabecular spaces was observed in both groups, with slight-to-moderate superficial contour resorption (Fig. 2), which appeared to be more pronounced in the NanoTite® group, resulting in a significant decrease in mean BF.



Fig. 1: Histological analysis of wound healing at 2 weeks, showing new trabecular bone in close contact with the SLActive® surface (a: mandible, b: maxilla) and the interposition of non-mineralized tissue at the NanoTite® surface (c: mandible, d: maxilla) (magnification × 12.5)



Fig. 2: Histological analysis at 8 weeks, showing ongoing bone formation and signs of remodeling (a and b: SLActive®, lower jaw; c and d: NanoTite®, lower jaw) (magnification x 12.5)

Mean BF and MT were comparable between the groups, but NBH and BIC were significantly higher at the SLActive® implants. Percent linear fill (PLF), defined as NBH divided by defect length (DL), was also significantly greater at SLActive® implants (Table 1 and Table 2).

Groups	Weeks	DL	NBH	PLF	BF	MT	BIC	
	2	4.1 ± 0.2	$2.6 \pm 0.8^{\dagger}$	$63.3 \pm 19.6^{\dagger}$	$2.4 \pm 0.6$	31.1 ± 14.3	55.8 ± 9.7‡	
modsla	8	4.2 ± 0.1	$3.6 \pm 0.3^{\dagger}$	$86.8 \pm 0.3^{\dagger}$	$2.3 \pm 0.5^{\dagger}$	$81.3 \pm 9.4$	78.2 ± 14.5	
DCD/CaP		n.s.	p <0.05	n.s.	n.s.	p <0.001	p <0.05	p value*
	2	$4.2 \pm 0.2$	$0.9 \pm 0.8$	21.4 ± 19.0	$2.0 \pm 0.6$	38.9 ± 15.9	20.3 ± 16.7	
	8	4.2 ± 0.1	1.8 ± 1.4	$43.0 \pm 34.9$	$1.6 \pm 0.4$	82.7 ± 8.8	47.2 ± 30.7	
		n.s.	n.s.	n.s.	p <0.05	p <0.01	n.s.	p value*

Table 1: Mean values for histomorphometric measurements in the maxilla after 2 and 8 weeks for SLActive® (modSLA) and NanoTite® (DCD/CaP) implants \*Comparison within the groups (paired, Hest).

Comparisons between groups (unpaired t-test): †p< 0.05, ‡p < 0.01

Groups	Weeks	DL	NBH	PLF	BF	MT	BIC	
modSLA	2	4.2 ± 0.1	$2.4 \pm 0.8^{\dagger}$	57.8 ± 19.9 <sup>†</sup>	$2.3 \pm 0.6$	32.3 ± 7.3	$53.5 \pm 11.3^{\ddagger}$	
	8	$4.2 \pm 0.2$	$3.4 \pm 0.3^{\dagger}$	$82.5 \pm 9.2^{\dagger}$	$2.5 \pm 0.6$	83.2 ± 8.2	$79.5 \pm 6.6^{\dagger}$	
DCD/CaP		n.s.	p <0.05	p <0.05	n.s.	p <0.001	p <0.001	p value*
	2	4.1 ± 0.2	$0.8 \pm 0.7$	17.9 ± 17.6	$2.1 \pm 0.6$	42.1 ± 11.0	19.3 ± 16.4	
	8	4.1 ± 0.1	1.7 ± 1.4	$42.1 \pm 34.4$	$1.4 \pm 0.5$	$84.4 \pm 6.3$	$43.3 \pm 22.1$	
		n.s.	n.s.	n.s.	p <0.05	p <0.001	n.s.	p value*

 Table 2: Mean values for histomorphometric measurements in the mandible after 2 and 8 weeks for SLActive® (modSLA) and NanoTite® (DCD/CaP) implants

 \*Comparison within the groups (paired, Hest).

Comparisons between groups (unpaired t-test):  $^{t}p$  < 0.05,  $^{t}p$  < 0.01





It should be noted that both types of implants revealed potential differences with respect to the macrodesign; therefore, the influence of individual design features on the outcome of healing cannot be estimated.

- New bone height and bone-to-implant contact were significantly higher for SLActive® implants
- SLActive<sup>®</sup> implants may have a higher potential to support osseointegration in dehiscence-type defects than NanoTite<sup>®</sup> implants

## Enhanced implant stability with a chemically modified SLA® surface: a randomized pilot study

T. W. Oates, P. Valderrama, M. Bischof, R. Nedir, A. Jones, J. Simpson, H. Toutenburg, D. L. Cochran Int J Oral Maxillofac Implants 2007;22:755-760.

**Abstract:** Implant stability, measured by resonance frequency analysis, was compared for SLA® and SLActive® implants over the first 12 weeks following implant placement in humans. After an initial decrease in stability for both groups, stability increased with SLActive® implants at a much earlier stage than with SLA® implants (2 weeks versus 4 weeks).

#### Introduction

Advances in understanding the influence of implant surface properties on osseointegration have led to shorter healing times from implant placement to permanent restoration. More recently, investigations into the effects of alterations of the surface chemistry have also translated into potential clinical benefits. The chemically modified hydrophilic SLActive® surface has been shown to increase bone-toimplant contact during the first 4 weeks of healing, compared to SLA®. This suggests an enhancement of osseointegration that may translate into an improvement in initial implant stability. The aim of this clinical study, therefore, was to measure and compare the implant stability over the first 3 months following implant placement using resonance frequency analysis.

#### **Material and Methods**

In a total of 31 patients with at least 2 missing teeth in the posterior mandible or maxilla, 62 implants were placed (one SLA® and one SLActive® implant in each patient). No bone grafting or guided bone regeneration was used; implants were placed only into healed ridges (> 4 months post-extraction) with sufficient bone. Resonance frequency analysis, by use of an Osstell device, was measured at 0, 1, 2, 3, 4, 5, 6 and 12 weeks after implant stability quotient over a range from 1 to 100. Statistical analysis was performed by means of the Chow test, which makes the assumption that data can be represented by two straight lines and then identifies the break point in the data.



#### Results

All 62 implants were successfully restored and ossecintegrated within the 6-week time frame. Both SLA® and SLActive® implants showed a similar initial level of stability, decreasing initially and then increasing within the first 6 weeks. Within this 6-week period, however, SLActive® implants demonstrated a significantly different change in stability patterns compared to SLA® implants. The break point, i.e. the change from decreasing to increasing stability, occurred after 2 weeks with SLActive® (p < 0.001), compared to the change with SLA® implants, which occurred at 4 weeks. Significance was not seen in the maxilla. However, the much smaller implant numbers for the maxilla may be an important factor.

The identification of the breakpoint suggests a change in the overall bone remodelling from predominantly resorptive to predominantly formative. The shift in this transition point from 4 weeks with SLA® to 2 weeks with SLActive® therefore suggests accelerated bone healing on the SLActive® surface compared to SLA®.

#### Conclusions

- Significant improvement in the stability pattern with SLActive®
- Increased stability at an earlier stage with SLActive<sup>®</sup> (break point after 2 weeks with SLActive<sup>®</sup> versus 4 weeks with SLA<sup>®</sup>)
- $\bullet$  Results suggest faster healing and osseointegration with SLActive^\*
- SLActive<sup>®</sup> has the potential for reduced risks and more predictability in early/immediate loading procedures

		Number of implants	Breakpoint	Significance
tive®	maxilla	6	3 weeks	< 0.001*
SLAct	mandible	25	2 weeks	< 0.001*
A	maxilla	6	3 weeks	0.643 (n.s.)
SL	mandible	25	4 weeks	< 0.001*

= significant n.s.= no significance

16

# Immediate and early loading of Straumann implants with a chemically modified surface (SLActive®) in the posterior mandible and maxilla: 1-year results from a prospective multicenter study

J. Ganeles, A. Zöllner, J. Jackowski, C. ten Bruggenkate, J. Beagle, F. Guerra Clin. Oral Impl. Res 2008;19:1119-1128.

**Abstract:** 383 SLActive<sup>®</sup> implants were placed in the mandible and/or maxilla of 266 patients and restored immediately or after 28–34 days. Survival rates after 12 months were high and were not significantly different between the two groups. Similarly, the change in mean bone level was not significantly different between the groups, after adjusting for implantation depth, and several cases of bone gain were observed.

#### Introduction

In the continuing effort to simplify treatment and increase patient satisfaction, researchers have designed a multicenter randomized controlled trial to evaluate the survival rates as well as changes in bone level in connection with immediately and early loaded Straumann implants using the Straumann<sup>®</sup> SLActive surface.

#### **Material and Methods**

For the study a total of 266 patients received 383 implants in the posterior mandible and/or maxilla. 186 implants were placed in the early loading group, while 197 implants were placed in the immediate loading group. Patients were randomized to receive a temporary restoration (single-crown or 2–4 unit fixed partial denture) out of occlusal contact on the day of implant placement (immediate loading group) or 28–34 days later (early loading group). Permanent restorations were placed 20–23 weeks after surgery. The primary variable was crestal bone level from baseline (surgery) to 12 months; the secondary variable included success and survival rates.

#### Results

Implant survival rates in the early loading group were 97 %, whereas survival rates in the immediate loading group were 98 % after 12 months. This shows that there was statistically no significant difference. The survival rates compare favorably with those from other studies of early and immediate loading. The immediate loading procedure may be more technique-sensitive than early or delayed loading. Radiographs were available for both baseline and 12 months from 323 implants (168 immediately loaded and 155 early loaded). Missing radiographic data was attributed to implant failures, patient drop-outs and late analysis.

Mean bone level was  $0.90 \pm 0.90$  mm in the immediate group versus  $0.63 \pm 0.95$  mm in the early group. This difference is statistically significant. However, further analysis revealed that the mean implantation depth for immediately loaded implants was 0.30 mm lower than for early loaded implants. When this is taken into account, the treatment group no longer had a significant influence. The results confirm the findings from the interim 5-month analysis. Bone gain was observed in 16 % of the implants.

The bone loss in this study compares well with the bone resorption in other immediate and early loading studies, and within the reported limits of <1 mm in the first year. While it is known that bone loss leads to gingival recession, it is expected that the relatively low bone loss in this study will produce good esthetic results. In addition, the bone loss is less than that observed in another recent study, where mean marginal bone resorption of 1.24 mm for immediate loading and 1.19 mm for early loading with fixed partial dentures were observed after 1 year.

Analysis revealed that bone quality had no significant effect on implant survival or bone loss. No implant failures in Type IV bone were recorded. Approximately 41.5% of the implants in the current study were placed in poorer quality (Type III/IV) bone, therefore showing the beneficial effects of SLActive® even in situations of poor bone quality.

- Immediate and early loading with Straumann® SLActive implants yields excellent survival rates (98 % and 97 % after 1 year)
- Immediate loading is as successful as early loading with Straumann® SLActive implants
- Successful implant treatment is possible with Straumann<sup>®</sup> SLActive even in poor quality bone
- No implant failures were evident in Type IV bone
- Bone gain was observed in 16% of the implants



## 17

# A prospective study on 3 weeks loading of chemically modified titanium implants in the maxillary molar region: 1-year results

M. Roccuzzo, T.G. Wilson Int J Oral Maxillofac Implants 2009;24:65–72.

**Abstract:** SLActive<sup>®</sup> implants were placed in the posterior maxilla, which tends to have lower bone density, and loaded after 3 weeks. Preliminary results suggest no complications and no early implant failures in this challenging indication.

#### Introduction

Implants with the SLA® surface can be loaded early (6 weeks instead of the conventional 12 weeks) with highly predictable results.<sup>1,2,3,4,5</sup> Early loading in the posterior maxilla, where bone density tends to be lower, has also been shown to be successful.<sup>6</sup> The greater and earlier bone apposition with the SLActive® surface, and the biomechanical bone anchorage properties,<sup>7,8</sup> suggested that even earlier loading may be possible with suitable stability and without increased risk of failure, even in low density bone.

#### **Material and Methods**

The study included 35 healthy non-smoking patients, each with one implant designated for evaluation. Site preparation was by the use of osteotomes, with drilling kept to a minimum; screw tapping was never performed. The abutments were connected (at 15 Ncm) and provisional restorations loaded 21  $\pm$  2 days after surgery, with further abutment tightening (at 35 Ncm) 4–6 weeks later for the final restoration.

At abutment connection, several measurements were taken, which will be re-evaluated after 1, 3 and 5 years post-surgery. These were: probing depth, plaque index, bleeding on probing and standard peri-apical radiographs.

#### Results

Of the 35 patients, 7 were male and 28 female; the mean age was 54.9 years. For all patients, there were no adverse events or complications during surgery or healing, and there was minimal discomfort. Good soft tissue healing was observed at the time of abutment connection (21  $\pm$  2 days; Fig 1).



Fig. 1: Soft tissue healing at 3 weeks post op.

Primary implant stability was always achieved. For six of the implants, there was slight rotation at abutment connection; in these cases, protective caps were placed and the implants left to heal for an additional 4 weeks. Following this period, the abutments were re-tightened and the prosthetic reconstruction placed. After 12 months, there were no patient drop-outs, and the implant survival rate was 100%. Mean bone loss after 12 months was 0.22  $\pm$  0.35 mm, and there were no significant differences for presence of plaque, bleeding on probing or probing depth (Table 1).

	Baseline	12-month follow-up	Statistical difference
₫	14 %	17 %	n.s.
BOP	16 %	18 %	n.s.
G	$3.5 \pm 0.9 \text{ mm}$	3.4 ± 1.0 mm	n.s.

 Table 1: Clinical parameters at baseline and one year after placement

 (PI = plaque index, BOP = bleeding on probing, PD = probing depth)

- Successful functional loading is possible in the maxillary molar region after 3 weeks with SLActive® implants
- Implant survival was 100 % after 12 months in low density bone
- The procedure represents an important step towards faster healing and increased treatment predictability

# Stability change of chemically modified sandblasted/acid-etched titanium palatal implants. A randomized controlled clinical trial

M. Schätzle, R. Männchen, U. Balbach, C.H.F. Hämmerle, H. Toutenburg, R.E. Jung Clin. Oral Implants Res. 20, 2009;489–495.

**Abstract:** This randomized-controlled clinical study was designed to examine stability changes of palatal implants with the SLActive<sup>®</sup> surface, compared to the standard SLA<sup>®</sup> surface, during the early stages of bone healing.

#### Introduction

Most clinical studies of implants deal with surrogate biological endpoints. However, palatal implants are temporary anchorage devices and are therefore subsequently removed after therapy. Consequently, they have a shorter loading time, which is defined by the preexisting treatment plan and the end of the need for additional anchorage. Palatal implants are therefore the only implants in which explantation is performed after clinical success. The implants are removed with a trephine along with a small amount of adjacent bone; therefore, these implants may offer the potential of studying the early pattern of osseointegration, including later histological analysis.

#### Materials and methods

The study recruited 40 adult volunteers, who were randomly assigned to the test group (SLActive® surface) and control group (SLA® surface). Resonance frequency analysis (RFA) was performed to evaluate implant stability changes. RFA values were expressed as implant stability quotient (ISQ).

#### Results

The ISQ values were not significantly different between the groups (mean ISQ 73.8 +/- 5 and 72.7 +/- 3.9 for SLA® and SLActive®, respectively), with only small changes seen in the first 2 weeks and a decreasing trend in mean ISQ levels thereafter. For the SLActive® implants, a tendency towards increasing ISQ values was observed after 28 days, with ISQ values corresponding to those following implant placement after 42 days. For SLA® implants, the trend changed after 35 days and yielded ISQ values corresponding to the baseline after 63 days (Fig 1). After 12 weeks (n=10), significantly higher ISQ values were observed for the SLActive® implants (77.8 +/- 1.9 versus 74.5 +/- 3.9 for SLA® implants, respectively).



Fig. 1: Mean ISQ value changes in SLA® and SLActive® implants

- The results indicate that chemical modification of the SLA® surface can have a positive influence on the biologic of osseointegration and can decrease the healing time.
- Straumann concludes that the outcome of this study confirms the previous study results<sup>1</sup> for the early increase of the implant stability with SLActive<sup>®</sup> as compared to SLA<sup>®</sup>.

### Early loading of nonsubmerged titanium implants with a chemically modified sand-blasted and acid-etched surface: 6-month results of a prospective case series study in the posterior mandible focusing on peri-implant crestal bone changes and implant stability quotient (ISQ) values

Bornstein MM, Hart CN, Halbritter SA, Morton D, Buser D. Clin Implant Dent Relat Res 2009;11(4):338-347.

**Abstract:** Forty patients received 56 SLActive<sup>®</sup> implants, which were functionally loaded after 3 weeks. Implant stability (ISQ) was measured at various time points for up to 26 weeks and showed a steady increase from implant placement to week 26.

#### Introduction

Preclinical studies have demonstrated that the SLActive® surface may allow a further reduction of the healing period over that provided by rough surfaces. The aim of this investigation was to assess the shortterm clinical and radiographic performance of SLActive® implants loaded after 3 weeks and monitored using the implant stability quotient (ISQ) method.

#### **Methods**

A total of 56 implants were placed in healed sites in the posterior mandibles of 40 partially edentulous patients. Functional loading with screw-retained crowns or fixed prostheses was performed after 3 weeks. Clinical and radiological parameters, including implant stability as measured by ISQ were evaluated after 4, 7, 12 and 26 weeks.

#### Results

Although there were no osseointegration failures, two implants were considered 'spinners' after 3 weeks so were left unloaded for a longer period. The soft tissue was found to be suitably healed after 3 weeks. Clinical and radiographic measurements were favorable for all implants at 6 months. ISQ increased steadily from 74.33 at the time of implant placement to 83.32 at week 26 (Figure 1). The 6-month survival and success rate was 100 %.



Fig. 1: Box plots of the ISQ values at implant placement (day 0) and after 3, 4, 7, 12 and 26 weeks

- Early loading with SLActive® implants 3 weeks after placement in then posterior mandible has a low risk for early failures
- Definitive functional restoration after 3 weeks is possible
- The soft tissue is ready 3 weeks after implant placement

### Early loading at 21 days of non-submerged titanium implants with a chemically modified sandblasted and acid-etched surface: 3-year results of a prospective study in the posterior mandible

Bornstein MM, Wittneben J-G, Brägger U, Buser D. J Periodontol 2010;81(6):809-818.

**Abstract:** SLActive<sup>®</sup> implants were placed in patients and functionally loaded after 21 days; clinical and radiographic parameters were evaluated for up to 36 months. No implants were lost and clinical attachment levels and probing depths were improved versus historical SLA<sup>®</sup> controls.

#### Introduction

Preclinical studies have demonstrated that the SLActive® surface may allow a further reduction of the healing period over that provided by rough surfaces. The aim of this prospective study was to assess the clinical and radiographic performance of SLActive® implants placed in the posterior mandible of partially edentulous patients and loaded after 3 weeks.

#### **Methods**

A total of 56 implants were placed in healed sites in the posterior mandibles of 39 partially edentulous patients and were functionally loaded with provisional crowns after 21 days. Clinical parameters regarding soft tissue (e.g. modified plaque index [mPL], modified sulcus bleeding index [mSBI], probing depth [PD], distance from implant shoulder to mucosal margin [DIM], clinical attachment level [CAL]) and radiographic parameters (e.g. distance from implant shoulder to first BIC [DIB]) were measured at different time points between implant placement and 36 months and the results compared to results from historical controls of SLA® implants loaded after 6 weeks).

#### Results

Although there were no osseointegration failures, two implants were considered 'spinners' after 21 days so were left unloaded for a longer period. All implants showed favorable clinical and radiographic findings after 3 years, and all were successfully osseointegrated; the implant survival and success rate was therefore 100 %. Significantly improved clinical attachment level values and probing depths were found for the SLActive® implants versus historical SLA® controls (Figure 1). Mean DIB was 2.43 mm at baseline, increasing to 2.67 mm after 1 year, with a slight reduction to 2.55 mm after 3 years (Figure 2). No implants showed bone loss > 1 mm, and most showed bone loss between 0 and 0.3 mm.

Examination	mPLI	mSBI	PD (mm)	DIM (mm)	CAL (mm)
3 mo (n = 54)	0.23 (± 0.06)	0.23 (± 0.03) <sup>a,b</sup>	3.09 (± 0.10) <sup>a,b,c,d</sup>	-0.78 (± 0.10) <sup>a,b,c</sup>	2.30 (± 0.09)
6 mo (n = 54)	0.37 (± 0.07)	0.25 (± 0.04)	3.40 (± 0.11)°	-1.02 (± 0.11)°	2.36 (± 0.08)
12 mo (n = 54)	0.24 (± 0.03)	0.13 (± 0.03)°	3.65 (± 0.10) <sup>b</sup>	-1.51 (± 0.12) <sup>b</sup>	2.12 (± 0.09)
24 mo (n = 54)	0.30 (± 0.05)	0.23 (± 0.04)	3.76 (± 0.11)°	-1.40 (± 0.13)°	2.36 (± 0.08)
36 mo (n = 54)	0.23 (± 0.04)	$0.11 (\pm 0.02)^{b}$	$3.53 (\pm 0.09)^d$	-1.01 (± 0.11)	2.53 (± 0.07)

Fig. 1: Peri-implant soft tissue parameters evaluated at 3, 6, 12, 24 and 36 months



Fig. 2: Box plots of the mean DIB values from implant placement to 3 years

- Early loaded SLActive® implants can achieve and maintain osseointegration successful tissue integration over 3 years
- The procedure offers rehabilitation with a definitive restoration after 3 weeks, increasing cost-effectiveness for the patient
- Loading after 3 weeks can be recommended in defined clinical situations for standard sites without bone defects

### Early loading after 21 days of healing of nonsubmerged titanium implants with a chemically modified sandblasted and acid-etched surface: 2-year results of a prospective two-center study

D. Morton, M.M. Bornstein, J.-G. Wittneben, W.C. Martin, J.D. Ruskin, C.N. Hart, D. Buser Clin. Implant Dent. Relat. Res. 2010, 12(1), 9-17.

Abstract: Results from early loading of SLActive<sup>®</sup> implants after 3 weeks suggest that successful integration can be achieved without increasing the risk of implant loss.

#### Introduction

This was a prospective multi-center clinical study in partially edentulous patients requiring implant intervention in posterior sites to evaluate implant integration and tissue response to implants that received full occlusal loading 21 days after placement.

#### **Material and Methods**

All 56 patients, who presented with a single-tooth gap, extended edentulous space or a distal extension situation in the posterior jaw, met strict inclusion criteria and provided informed consent. A total of 89 SLActive® tissue level implants were with undisturbed healing for 21 days, after which time the implants were provisionally loaded in full occlusion, with definitive metal ceramic restorations fabricated and placed after 6 months of healing. Measurements were taken to assess soft tissue parameters and radiographs were obtained for up to 24 months after implant placement.

#### Results

Of the 89 implants placed, two (2.2 %) implants failed to integrate and were removed during healing, while two (2.2 %) more implants required a prolonged healing time. A total of 85 (95.6 %) implants were therefore loaded 21 days after placement. One implant was lost and therefore excluded from further analysis. The remaining implants all exhibited favorable clinical and radiographic findings (Tables 1 and 2). Based on strict success criteria, the implants were considered successfully integrated 2 years after insertion, resulting in a 2-year success rate of 97.7 %. 

Exam	mPLI	mSBI	PD (mm)
3 Months (N=84)	0.23 (±0.04)	0.22 (±0.03)	2.69 (±0.09) <sup>a.b.c</sup>
6 Months (N=84)	0.27 (±0.05)	0.20 (±0.03)	2.93 (±0.10)°
12 Months (N=84)	0.20 (±0.03)	0.15 (±0.02)	3.07 (±0.11) <sup>b</sup>
24 Months (N=84)	0.32 (±0.04)	0.28 (±0.03)	3.21 (±0.11)°

Statistically significant differences are marked with the same letters (alpha level of 0.05).

Example: a, statistically significant between 3 months and 6 months. mPLI = modified plaque index; mSBI = modified sulcus bleeding index; PD = probing depth.

Table 2: Mean	radiographic	parameters from	baseline to 2	years
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Exam	0 Months	3 Months	6 Months	12 Months	24 Months
Mean	2.37	2.57	2.63	2.60	2.57
SEM	±0.06	±0.04	±0.04	±0.04	0.05
Significance	a, b, c	а	b	С	

SEM = standard error of the mean.

#### Conclusion

- Tissue level implants with the SLActive® surface can predictably achieve successful tissue integration when loaded with full occlusion after 21 days.
- This study indicates that early loading of SLActive<sup>®</sup> implants in the posterior mandible has a reasonably low risk for early failures (2.3 %).
- The concept of early loading offers a straightforward treatment with definitive restoration after a 3-week healing period and accordingly offers good cost-effectiveness.



**CLINICAL STUDIES** 

22

# A multicenter prospective 'non-interventional' study to document the use of and success of Straumann<sup>®</sup> SLActive implants in daily dental practice

Luongo G, Oteri G.

24th Annual Meeting of the Academy of Osseointegration, February 26-28, San Diego, CA, USA; poster P220. J Oral Implantol 2010; 36(4):305-314.

**Abstract:** A multicenter non-interventional study was conducted, in which 276 SLActive® implants were placed and documented in 218 patients according to situations where implants would normally be placed. After 1 year the survival and success rate was 98.2 %, similar to that observed in strictly controlled clinical trials.

#### Introduction

Results from clinical trials have indicated excellent outcomes with SLActive® implants; however, clinical trials are normally performed under controlled conditions with strict patient inclusion/exclusion criteria. The aim of this investigation, therefore, was to evaluate SLActive® implants in a large patient population in a private practice setting and compare the success and survival rates to those from controlled clinical trials.

#### **Methods**

This was a 1-year prospective, non-interventional cohort study at 30 private practices in Italy. A total of 226 patients were treated, and up to five visits were scheduled for each patient: screening, surgery, temporary restoration (optional), final restoration and 1-year follow-up. SLActive® implants were placed according to the recommended indications in situations where the dentist would normally place implants. Treatment decisions were left to the discretion of each individual practitioner according to the patient's situation and requirements.

	Patients n (%)	
Oral hygiene		
Excellent	17	(17.8)
Good	127	(58.3)
Fair	62	(28.4)
Poor	12	(5.5)
Risk factors		
Smoking	52	(23.9)
Untreated gingivitis, periodontitis	19	(8.7)
Bruxism	14	(6.4)
Osteoporosis treatment	4	(1.8)
Other*	10	(4.5)

Table 1: Oral hygiene and risk factors

\* Uncontrolled diabetes, post-extraction bone infection, rheumatoid arthritis, previous myocardial infarction, atherosclerosis, hypertension, microcytemia and mild depression



#### Fig. 1: Position of implants in the maxillae and mandibles according to FDI nomenclature

#### Results

Eight patients were lost to follow-up, making a total of 218 patients with 276 implants documented. Risk factors in the patient population included smoking, untreated gingivitis or periodontitis, bruxism and osteoporosis. And most patients had good or fair oral hygiene (Table 1). Distribution of implants was similar between the mandible (46 %) and maxilla (54 %), and the majority was placed in the posterior region (Figure 1). Early (48.4 %) or conventional (34.1 %) loading was most commonly performed. Bone augmentation procedures were performed for 31.1% of implants, either alone (22.8 %) or with a membrane (8.3 %). Five implants failed, all of which were associated with a simultaneous sinus augmentation procedure, giving an implant survival and success rate of 98.2 %.

- The 1-year cumulative survival and success rate was 98.2 %
- All failed implants were associated with a simultaneous sinus floor augmentation procedure
- The success rate of SLActive® implants in daily practice is similar to that observed in formal clinical trials with strictly controlled patient populations



# Early osseointegration to hydrophilic and hydrophobic implant surfaces in humans

Lang NP, Salvi GE, Huynh-Ba G, Ivanovski S, Donos N, Bosshardt DD. Clin. Oral Implants Res. 2011;22:349–356.

**Abstract:** This is the first study to demonstrate histologically the osseointegration process with SLActive<sup>®</sup> in humans. 49 titanium implants with either a SLA<sup>®</sup> or SLActive<sup>®</sup> surface were placed and documented in 28 healthy volunteers. The rate and degree of osseointegration during the early phases of healing were evaluated and osseointegration (BIC) was significantly greater after 28 days for SLActive<sup>®</sup>.

#### Introduction

The surface characteristics of titanium implants influence the rate and degree of osseointegration. Moderately rough surfaces such as SLA® have demonstrated superior bone-to-implant contact (BIC) than surfaces such as titanium plasma-sprayed (TPS),  $Al_2O_3$ -blasted or machined surfaces. Chemical modification, such as with the hydrophilic SLActive® surface, can further enhance the osseointegration process.

Investigations comparing osseointegration with various implant surfaces have been performed, but tend to be in vivo animal studies. No data are available from human studies, and the healing sequence of the early osseointegration process in man and how it compares to the process – seen in other in vivo investigations – is relatively unknown.

The aim of this investigation, therefore, was to evaluate the rate and degree of osseointegration at two different implant surfaces (SLA® and SLActive®) during the early phases of healing in a human model.

#### Materials and methods

A total of 49 specially designed titanium implants (length 4 mm, outer diameter 2.8 mm) with either a SLA® or SLActive® surface were placed in the retromolar region of 28 healthy volunteers. A healing cap with an internal screw assembly was attached to the coronal part of the implant. After submerged healing periods of 7, 14, 28 and 42 days, the implants were removed using a specially designed trephine, which removed the implant and circumferential tissue of 1 mm thickness.

Histological sections were prepared and histometric analyses performed for amounts of new bone, old bone, bone debris, soft tissue and BIC.

#### Results

Healing was uneventful at all sites. Of the 49 implants placed, 30 were available for histological/histometric analysis; difficulty in harvesting the biopsies resulted in the loss of some specimens.

Artifacts were present on a number of specimens – these areas were excluded from analysis so that only artifact-free regions were evaluated. The percentages of new bone-to-implant contact after 7, 14, 28 and 42 days are shown in table 1.



% mean value (SD)	7 days	14 days	28 days	42 days
SLActive <sup>®</sup>	6.14	14.80	48.34	61.62
	(10.63)	(15.37)	(14.91)	(4.98)
SLA®	6.47	12.19	32.38	61.53
	(6.02)	(10.62)	(16.21)	(5.79)

Table 1: Percentage of BIC after 7, 14, 28 and 42 days

After 7 days, no differences were observed between the SLA® and SLActive® specimens. BIC was approximately 6%, and some early bone apposition was noted in places where existing bone was in close contact with the implant surface; bone therefore bridged a gap between old bone and implant in these situations. The majority of the space between bone and implant was filled with soft tissue comprising primitive matrix with various bone debris particles. BIC increased to 12.2% and 14.8% for SLA® and SLActive®, respectively, after 14 days. Bone formation was noted on the existing bone, extending partly onto the implant surface. The beginning of new bone apposition was evident over large areas of the surface of the SLActive® implants. Larger bone particles were seen to be surrounded by osteoid, which helped trabecula formation.

BIC increased in both sample types by day 28, but was significantly higher with SLActive® (48.3%) than with SLA® (32.4%). A bony coating was observed with both specimen types (Fig. 1 and Fig. 2), but almost complete BIC was observed within some threads of the SLActive® implants (Fig. 2), and new mineralized bone trabeculae were observed extending into the provisional matrix.



**Fig. 1:** Light micrograph of the implanttissue interface at a SLA<sup>®</sup> surface after 28 days (arrows indicate new bone)



**Fig. 2:** Light micrograph of the implant-tissue interface at a SLActive<sup>®</sup> surface after 28 days (arrows indicate struts of woven bone trabeculae extending from old bone (OB) towards implant surface)

After 42 days, BIC increased further to 62% for both SLA® and SLActive®. An advanced stage of bone maturation was observed with both surfaces, and the formation of osteons was observed away from the implant surface. The osteocoating was noted to be thick and extensive, and was frequently connected via trabeculae, extending onto new bone.

- Similar healing patterns were observed for both SLA<sup>®</sup> and SLActive<sup>®</sup> implants
- Osseointegration (BIC) was greater after 14 days and significantly greater after 28 days for SLActive<sup>®</sup>
- The rate of osseointegration was substantially slower (approximately double the healing time) in humans than that observed in animal studies
- This is the first study to demonstrate histologically the osseointegration process with SLActive<sup>®</sup> in humans

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