# Dr. Daniel Buser's Presentation to the Titanium Society, April 9, 2013

Dr. Buser's presentation adds insight into the relationship between and credibility of researchers funded exclusively by a single commercial entity, in his case, Straumann. One of Buser's slides details his personal "Recipe for a successful Academic Career" which included establishing "a good collaboration with top MedTech companies" and "Stay Independent." Buser slide on Current Concerns of Implant Dentistry sounds like the complaints voiced by overpriced implant companies, losing market share to companies selling on value rather than "research".

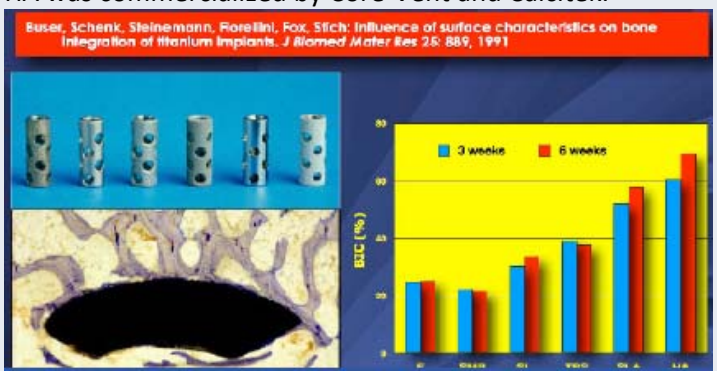

*Dr. Buser fails to understand that "independent, company funded research" is an oxymoron.*

Straumann's "Scientific Research Summaries" posted on its website, references 30 studies by Dan Buser and/or Dr. David Cochran. Many of these are the basis for Straumann's false claims that**: "The advent of the Straumann SLA surface allowed this healing time to be cut in half, from 12 weeks (for TPS) to 6 weeks for SLA, and then 3-4 weeks with the advent of Straumann SLActive surface."** None of the research reports cited proves that SLA or SLActive surface treatments were the single factor that "allowed" the implants to be loaded earlier than the 12 weeks recommended for TPS Straumann Implants. In order to prove this, comparative clinical studies using TPS plus SLA implants, loaded after 6 weeks, and SLA plus SLActive Implants loaded in 3-4 weeks, would have had to be done, with the control implants (TPS) demonstrating higher failure rates. Merely by loading SLA implants at 6 weeks and SLActive implants at 3-4 weeks with acceptable success rates, does not prove that the success was attributable to the surface treatments. It is well documented in the literature that successful osseointegration can be achieved with immediate loading of implants having a wide selection of surfaces if an initial stability of 35+Ncm is achieved. **Buser's presentation supported Straumann's false premise that its SLA/SLActive surfaces alone "allowed" healing time to be cut in half." One of his slides contained the following: "Progress in Implant Dentistry": "We can offer our patients much shorter healing periods with early loading or even immediate loading ... due to modern micro-rough implant surfaces."** TPS (Straumann 1980), $AlO_2$ blasted and etched (Core-Vent 1982) and HA (Calcitek 1985) are not "modern micro-rough surfaces" and yet have proven successful with healing times shorter than 12 weeks. To claim shorter healing times merely because the implants were loaded earlier than some historically recommended time is as ludicrous as claiming instant bone healing for implants that achieve high enough initial stability to withstand immediate loading.

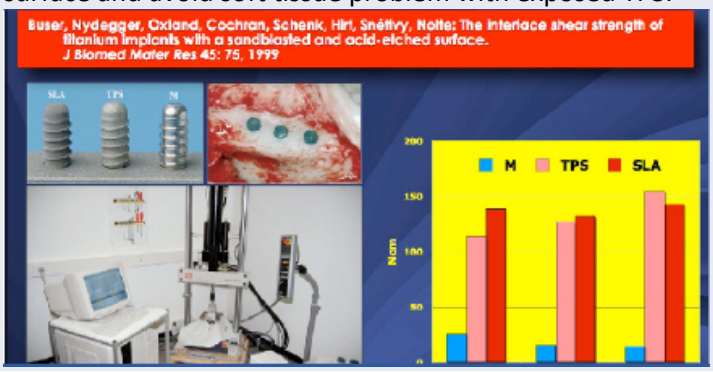
Buser is the immediate past president of ITI, and Cochran is the immediate past president of the AO and the current president of ITI. ITI is the organization exclusively funded by Straumann to promote its products through "research" and education. This raises questions about the selection process of the recipients of the Branemark Award by the Titanium Society. The three recipients that preceded Buser's selection, Prof. George Zarb, Prof. Daniel Van Steenberghe and Prof. Ulf Lekholm where all academics directly or indirectly funded by Nobel Biocare. All three had published reports supportive of Branemark Implants that have been questioned for objectivity and/or validity. The Titanium Society may think that it has made a bold move away from Nobel Biocare, the source of Award's funding, by giving its annual award to Dr. Buser, a Straumann paid opinion leader rather than another Nobel Biocare advocate paid opinion leader. Whose next....Aibrektsson and Sennerby with a long history of misleading articles critical of implants that were a commercial threat to whatever implant company was paying them to lecture, first Nobel and then Astra? The Titanium Society Members should select candidate whose contributions have positively impacted the field of Implantology through research, education, product development or treatment philosophy.

Straumann's 1st False Claim: **"The advent of the Straumann SLA surface allowed the healing time to be cut in half from 12 weeks (for TPS) to 6 weeks for SLA…"** As can be seen from the Buser 1991 and 1999 invitro surface studies below, there were slight difference between TPS and SLA with regard to BIC and torque removal with TPS actually showing a higher torque removal at 12 weeks.

Buser's 1991 Study comparing 6 different surfaces – HA coated implants demonstrated the highest BIC at 3 and 6 weeks. Buser dismissed further study of HA claiming it showed signs of resorption. While this was true of HA produced in the 1980's, by the late 1980's, high crystalline HA was commercialized by Core-Vent and Calcitek.

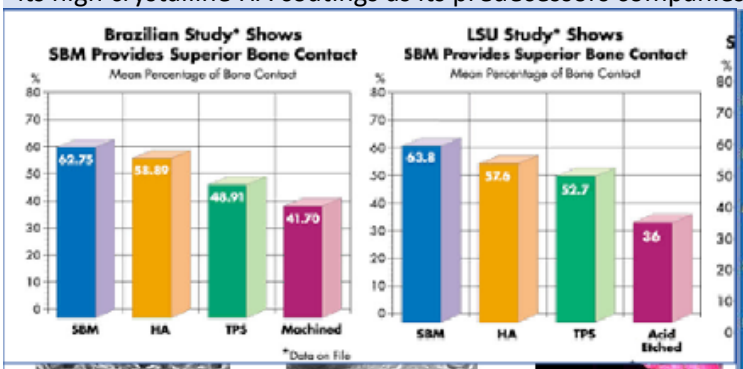


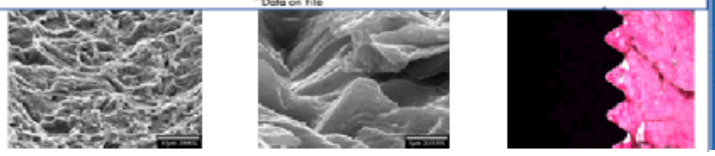

Buser's 1999 torque study compared machined, TPS and SLA surface with no significant difference between TPS and SLA, (TPS higher at 12 weeks), Straumann claimed in ads that SLA cut healing time in half when in fact they just advocated earlier loading as a way to justify the new surface and avoid soft tissue problem with exposed TPS.

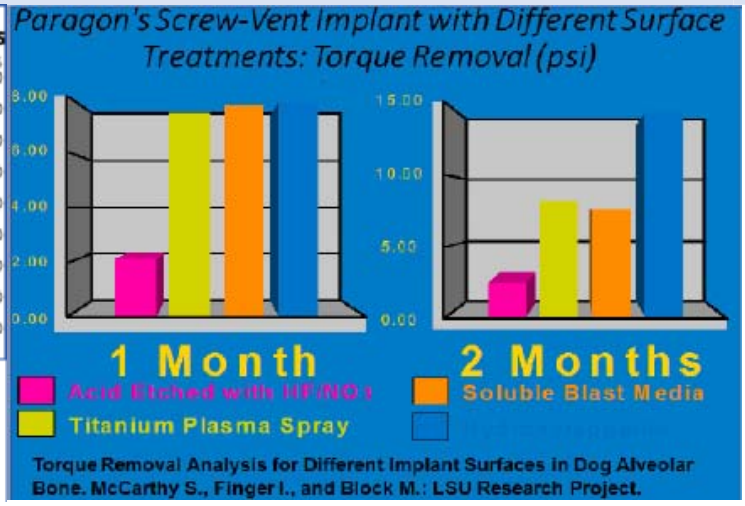



The 1991 Buser study (top left) evaluated BIC with 6 different surface treatments at 3 and 6 weeks. Although HA produced the highest results, Buser did not pursue further studies citing potential resorption of the HA surface. From studies conducted in the 1990's on Core-Vent Corporation's Screw-Vent implants (below) with 4 surfaces [acid etched (smooth), TPS (rough), SBM (blasted with HA particles - medium rough) and HA (bioactive/medium rough)], the SBM demonstrated a higher % bone contact than both HA and TPS. Torque removal study for SBM, TPS and HA were similar at 1month but the HA exhibited double the attachment strength at 2 months, confirming a faster and more complete osseointegration.

Implant direct uses the same vendor today to provide surface texture (blast with HA soluble crystals called SBM) and for its high crystalline HA coatings as its predecessors companies did since 1991.






***Straumann Retreat from TPS to SLA due to Soft tissue complications when TPS became exposed to soft tissue.***

In 1982, the Core-Vent hollow-basket implant was introduced with a surface that was $AlO_2$ blasted followed by an acid etch passivation process. Straumann implants pioneered the use of Titanium Plasma Sprayed (TPS) surface to create a rough, textured surface with micro-pores. Buser's and Cochran's research studies in the 1990's focused on animal and clinical studies to justify the efficacy of this type of surface and many companies followed applying the same surface treatment. The design of the Straumann tissue level implants brought this rough surface to the crest of the ridge, with the increased potential of exposure and soft tissue complications. It took Straumann, and its IT/ group, almost 10 years to realize that a surface treatment using $AlO_2$ followed by an acid etching to remove the imbedded Al particles would provide a micro-textured surface conclusive to osseointegration, with less soft tissue complications if exposed. In order to sell this retreat from TPS to a blasted surface as a scientific advance, Buser, Cochran and Straumann spend the better part of the next decade conducting studies to justify claims that SLA cut healing time in half compared to TPS.

**Straumann bases its claim of faster healing with SLA compared to TPS on a 2002 study by Cochran DL, Buser D, et al.** entitled "The use of reduced healing times on ITI implants with sandblasted and acid-etched (SLA) surface" (Clin Oral Implants Res 2002; 13: 144-153). The study "evaluated restoration of Straumann **SLA implants 6 weeks after placement in patients with bone quality 1-3**" – (implant in patients with Type 4) bone quality were restored after 12 weeks). The success rate of 329 implants at 12 months was 99.1% and 138 implants were followed for 24 months post-loading evaluation with no change in results. **If the researchers were serious**, *they would have also used TPS implants with the shorter healing time protocol to see if there was any difference in success rates. Attributing a "reduced healing time with SLA vs. TPS, without including TPS implants in the study reveals an obvious bias if the researchers. Straumann's advertisements promoting SLA showed a Samani soldier with a sword above a clock, claiming to cut healing time in half." I challenged Cochran at the time whether TPS could also be loaded at 6 weeks in Type 1-3 bone. He responded "probably".*

Journal of Periodontology Online
official publication of the American Academy of Periodontology



## Abstract

Journal of Periodontology
June 2007, Vol. 78, No. 6, Pages 974-982 , DOI 10.1902/jop.2007.060294
(doi:10.1902/jop.2007.060294)

# Clinical Field Trial Examining an Implant With a Sand-Blasted, Acid-Etched Surface

**David Cochran,[*] Thomas Oates,[*] Dean Morton,[†] Archie Jones,[*] Daniel Buser,[‡] and Francoise Peters[§]**

**Methods:** A prospective, multicenter, human clinical observational study was initiated with the goal of recruiting a minimum of 500 patients and 800 implants. The implants were to be placed and restored in predominantly private-practice settings around the world. Ninety-two practitioners in 16 countries agreed to participate, and 86 followed the study design. Patients had to be in good health, have sufficient bone to encase the implant, and agree to return for recall appointments. Exclusion criteria included heavy smoking (>10 cigarettes a day) and bone augmentation procedures at the implant site. All implants were two-piece (an abutment was to be placed after 6 weeks of healing) and were characterized by the presence of a transmucosal polished collar. Each implant had an SLA surface. All implants were positioned using a non-submerged (single-stage) surgical technique. Survival and success rates were calculated by life-table analyses.

**Results:** A total of 706 patients were enrolled and 1,406 implants were placed. In the final analyses, 590 patients with 990 implants (70.4% of those enrolled) met all inclusion criteria, including placement of an abutment and provisional restoration within 63 days of surgical placement. The majority of implants were 10 and 12 mm long (78.7%) and were placed in type II and III bone (87%). Seventy-three percent of the implants were placed in the mandible, and 27% were placed in the maxilla. The cumulative survival rate was 99.56% at 3 years and 99.26% at 5 years. The overall success rate was 99.12% at 3 years and 97.38% after 5 years.

**Conclusions:** Under private-practice conditions, implants with an SLA surface could be placed and restored predictably within 6 to 8 weeks. Data from this prospective, multicenter, human observational study reinforced the results of more formal clinical studies and demonstrated that implants with the SLA surface can be restored in patients in approximately half of the time of conventional healing periods.

***Straumann's Scientific Research Summary cites several studies to support its claim that healing time was reduced "to 3-4 weeks with the advent of SLActive surface."*** The Cochran study below comparing stability between SLA and SLActive using resonance frequency measurements showed only a small improvement at week 2-4 **in type 4 bone between these two surfaces**. The research protocol could have included an SLA implant inserted into an undersized socket to determine if that achieved and maintained higher stability than the SLActive implant (see Shalabi study)

Enhanced Implant Stability with a Chemically Modified SLA Surface: A Randomized Pilot Study Omas W. Oates, David L. Cochran DDS, PhD et. al: Int. J Oral Maxillo fac implants 2007; 22: 755-760

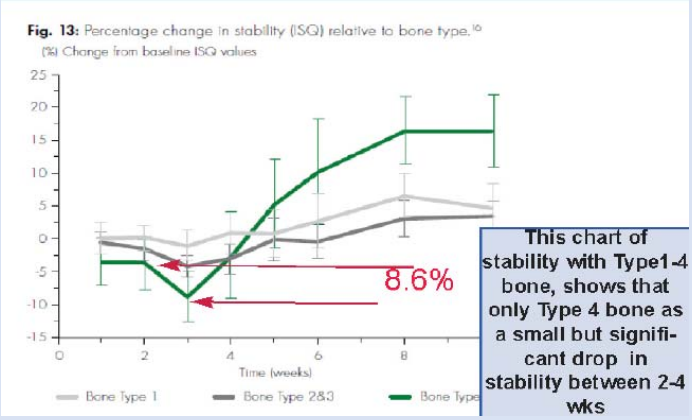
**Purpose:** Chemically modification to a sandblasted, large-grit, acid-etched (SLA implant surface has been own to enhance the rate of Osseointegration **(this is just building on an unproven claim - enhanced rate compared to what?)**. The goal of the present study was to examine changes in stability for implants with a chemically modified SLA surface (SLActive) and to compare their outcomes to those of control implants.

Materials and Methods: A randomized controlled trial was conducted with 31 patients. Each patient received 2 with the same physical properties but with surfaces that were chemically different. The control implants had a standard SLA surface, while the test implants had a chemically modified surface. Resonance frequency analysis was assessed weekly over the first 6 weeks following implant placement.

**Results:** All implants proved clinically successful, allowing for restoration. Most implants were placed in the mandible (50 to 62). A shift in implant stability from decreasing stability to increasing stability (P<.001), occurred after 2 weeks for the test implants and after 4 weeks for the control implants.

Conclusion: The findings from this pilot study provide clinical support for the potential for chemical modification the SLA surface to alter biologic events during the Osseointegration process and demonstrate levels of short-term clinical success similar to those observed for implants with an SLA surface.

The Barewal/Cochran 2003 study evaluated stability in all bone types and noted only an 8.6% drop at 2-4 weeks with Type 4 bone, with no difference in Type 1 bone and only a slight difference in Type 2-3 bone. This study indicates factors that increase initial stability, such as increased density of bone (or insertion into an undersized socket) will reduce the drop at 2-4 weeks.

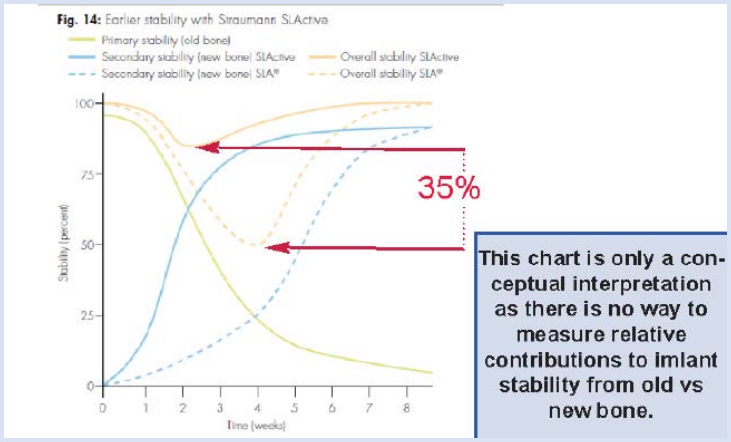



This chart of stability with Type1-4 bone, shows that only Type 4 bone as a small but significant drop in stability between 2-4 wks

Implant stability in all bones types, assessed by resonance frequency analysis (RFA) using the OsstelIR device, initially decreased and then increased after 3 weeks (Fig. 13); the biggest stability decrease at this time was in Type 4 bone (8.6% decrease). There were no differences in stability between the various bone types from week 5 onwards. Implants in Type 1 bone exhibited no significant change in stability for the whole 10-weeks period.

16 Barewal RA, Oates TQ, Meredith N, Cochran DL. Resonance frequency measurement of implant stability in vivo on implants with a sandblasted and acid-etched surface. Int J. Oral Maxillofac Implants 2003; 18: 641-651.

The Oates/Cochran 2007 study in mini-pigs showed a 35% difference in stability measurements at 2-4 weeks healing but no difference at 6 weeks. The researcher's conclusion that this "suggest greater predictability in earlier loading procedures" is unfounded given the Barewal/Cochran 2003 study invivo showed once could only expect a drop in soft bone. If clinical cases, if the initial stability is inadequate for immediate load (35Ncm+), it would not wise to load early.




This chart is only a conceptual interpretation as there is no way to measure relative contributions to imlant stability from old vs new bone.

In another study comparing implant stability between Straumann SLActive and SLA implants increased stability has been shown at an earlier stage, with the change in stability pattern (from primary to secondary stability) occurring earlier with SLActive (Fig. 14). These results suggest greater predictability in earlier loading procedures. This is the type of sound bite Straumann uses to justify it charging $55 more to SLActive.

#107 Oates TW, Valderrama P, Bischof M, Nedir R, Jones A, Simpson J, Toutenburg H, Cochran DL, Enhanced implant stability with a chemically modified SLA surface: a randomized pilot study. Int J. Oral Maxillofac Implant 2007; 22: 755-760.

## HA Coated Implant Surfaces discounted by Buser in spite of highest invivo and invitro results.

*While there was some complications with Pre-1990 low (35%) crystalinity HA coatings by Calcitek, they were primarily due to the fact that Calcitek's HA coating extended to the top of the implant. The implant had no internal anti-rotational features so the 1-piece abutment's butt joint right against the HA surface was not conducive to marginal seal. By 1990, the crystalinity of the HA for most implants approximated 90% Implants. Implant companies like Steri-Oss and Core-Vent distanced the HA from the top of the implant with a non-coated collar and Calcitek took a license on Core-Vent's internal connection patent (Niznick US #4,960,381). Clinical studies documenting very high success rates with HA coated implants proved the efficacy and safety of using HA coated implants, with significant improvements in success in types 3 & 4 bone. Unfortunately, Buser and Cochran were more intent on only conducting studies that showed the Straumann products in the best light and ignored the potential advantages of HA coated implants. Below are two very large clinical studies documenting high success with HA:*

1. HA-coated implant surfaces in one clinical study, documented a cumulative 5-year survival rate of 99.3% for almost 4,000 Calcitek Dental Spline® implants. Pikos MA, et. al.: International retrospective multicenter study of 8130 HA-coated cylinder implants: 5-year survival data. International Magazine of Oral Implantology 2002:3(1):6-15
2. Multi-center (32 Universities and VA Hospitals- 1990-1993), prospective, controlled, randomized, double blind, double peer reviewed study including approximately 1000 patients receiving about 3000 implants. The study included 1802 HA coated implants with a 96.1% success rate over 36 months. The success rate by quality of bone showed "no major difference in survival was found for HA coated implants placed in each bone quality." (Type 1: 108/97.3%; Type 2: 750/96.4%; Type 3: 748/95.9; Type 4: 196/95.1%). The VA Study generated over 100 research papers including those found in a Special Issues in both JOMFS and J Perio. The study also demonstrated for implants followed for up to 5 years, no greater soft-tissue complications with HA coated implants and no evidence that the HA coating dissolved or delaminated. Richard S, Morriss H, Ochi S: Implant Surface Coating and Bone Quality-Related Survival Outcomes through 36 Months Post-Placement of Root-Form Endosseous Dental Implants. Ann Periodontal 2000; 5:109=118.

## Initial Stability in soft bone, independent on design and surgical protocol, critical to success.

# Achieving Osseointegration in Soft Bone:

## *The Search for Improved Results*

*by Gerald A. Niznick, DDS, MSD*

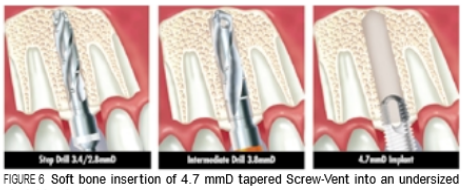
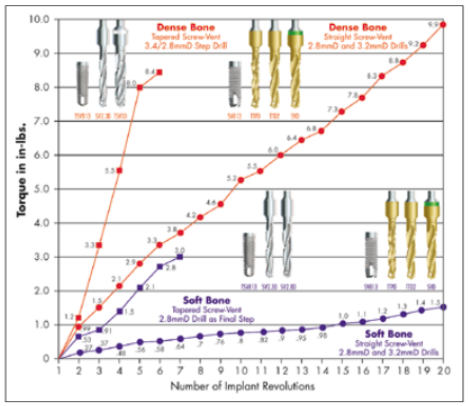


FIGURE 6 Soft bone insertion of 4.7 mmD tapered Screw-Vent into an undersized straight osteotomy.




*Shalabi MM, et al. The effects of implant surface roughness and surgical technique on implant fixation in an in vitro model. Clin. Oral Impl. Res. 17, 2006 172-178*

# The effects of implant surface roughness and surgical technique on implant fixation in an *in vitro* model

**Abstract**

**Objectives:** The aim of the present study was to determine the relationship between implant surface parameters, surgical approach and initial implant fixation.

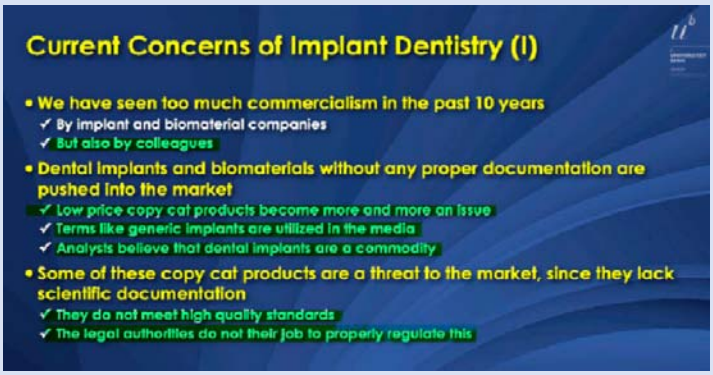
**Material and methods:** Sixty tapered, conical, screw-shaped implants with machined or etched surface topography were implanted into the explanted femoral condyle of goats. The implant sites were prepared either by a conventional technique, by undersized preparation, or by the osteotome technique. Peak insertion & removal torque, bone-to-implant contacts (BIC) and morphological bone appearance were assessed by scanning electron microscope (SEM) and micro-computer tomography. (micro-CT).

**Results:** Insertion and removal torque values were significantly higher for etched implants inserted with the undersized technique (115.2 ± 31.1, 102.9 ± 36.4 N cm) respectively. Also, the average BIC value was higher for the etched implants placed with the undersized technique (87.5 ± 5.6), which was statistically significant compared with machined and etched implants inserted by conventional technique.

**Conclusion:** In conclusion, this study shows that the surgical technique has a decisive effect on implant fixation (represented in this study by installation torque value/removal torque value and histomorphometric evaluation) in trabecular bone. Nevertheless, additional *in vivo* studies have to be done to prove the importance of surgical protocol for the final implant–bone response.

**CONCLUSION: Straumann funded studies designed to support claims of "faster healing" with SLA vs. TPS and with SLActive vs. SLA were biased by the failure to the researchers to include surgical protocol variables that would have demonstrated much higher initial stability with a more dramatic improvement in maintaining the original stability during the first 12 weeks of healing than Straumann's straight implants with SLActive.**

Buser expressed concerns about "too much commercialism" from companies and "colleagues." He complains about the use of term like "generic" and claims that "these copycat products are a threat to the market" and "some do not meet high quality standards. "He has no documentation to support this so he just exposing Straumann's commercial concerns about lower priced compatible implants.




Buser attributes “much shorter healing periods with early loading or even immediate loading” to “modern micro-rough implant surfaces”. Buser’s study showed reduced stability dip in early healing only in type 4 bone where early loading is generally contra-indicated. He ignores the significance of studies such as Shalabi, which showed inserting an implant into an undersized socket increased BIC as well as higher initial and post insertion on torque removal.


| Straumann’s Conclusions from its Scientific Research Summaries contain unsubstantiated claims not supported by the research in the report. | Straumann’s conclusion offer speculation to justify higher prices for SLActive such as: “may offer greater confidence” and “may improve survival” |
|---|---|
| SLA has biologically friendly topography and **optimum** roughness with **demonstrated benefits** for the clinician. | SLA studies did not test SBM (HA blasted) or HA coating so it was not proven to be "optimum." There were not studies showing higher success with SLA vs. TPS |
| The proven SLA topography is the basis for Straumann SLActive, the **next generation in implant surface** technology. | SLActive and SLA are both still sold by Straumann. Other than to justify an additional $55 charge, SLActive has no proven clinical advantage. |
| When compared to SLA, **faster osseointegration with SLActive** reduces the stability dip in the early healing period and there with **may offer greater confidence**. | Study showed "reduced stability dip" in Type 4 bone. Without initial stability of >35Ncm, no knowledgeable clinician is going to load an implant between 2-6 week |
| SLActive surface technology **may improve the implant survival rate** by reducing the failure rate in the early phase. | Initial stability will "improve the implant survival rate" and that is best achieved by inserting a self-tapping, tapered implant into an undersized socket |

## Implant Direct’s SwishPlus™ is not a Clone of Straumann’s tissue level implant.

It offers surgical and prosthetic compatibility with progressively deeper threads
for increased surface area, self-tapping features for increased initial stability and improved packaging.