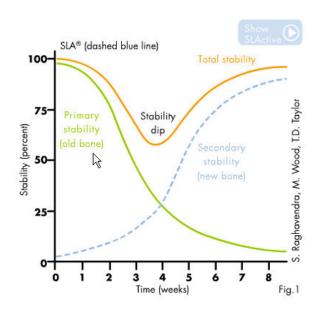
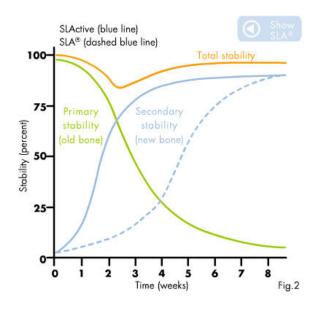


June 19, 2006: Blog on Straumann's SLActive Surface - Does Research prove any real Clinical Advantages?





Dr. Niznick,

SLActive is SLA, which has 8-10 years of data regarding the stability and performance of the surface. Straumann did not change the thread pitch or the location of the roughened surface, which allows for at the very least a 1:1 comparison of past performance of the SLA surface. New claims on SLActive are in the process of being published and appear to be in the 2-3 year range.

I have noticed that you try to lump all companies under the same umbrella. Nobel is having some problems with the Direct and the scalloped implant but you try and Tar, Straumann, 3I and Zimmer etc. with the same lack of research brush. In life you get what you pay for. Which is why most dentists don't drive Hugo's, or listen to "me to claims" in their personal purchasing life.

NIZNICK RESPONSE

When SLA (Sand blasted with large grit followed by acid etching to remove the aluminous oxide particles) came out in the late 1990's Straumann claimed in its advertisements that its new surface cut healing time in half. They based this not on comparative clinical studies, but on their claims that with the new surface, you could load the implant in 6-8 weeks instead of 3-4 months that was then recommended by Nobel for unloaded healing. 3i played the same marketing game with its Osseotite surface. You may remember the Straumann advertisement with a Samurai cutting a clock in half with a sword. I think the real reason Straumann introduced SLA was that when the porous TPS surface became exposed from any bone loss, it caused soft tissue problems. Of course Straumann had to give a reason for its change in surface other than saying they screwed up for over a decade with putting too rough a surface right at the crest of the bone when everyone was keeping a relatively smooth neck to allow for bone loss. Straumann's TPS screws were used for immediate load and their other implants could just as easily be loaded in 6 weeks as the SLA implants. Straumann never did any clinical comparison clinical studies showing the that SLA implants could be loaded in 6 weeks while the same implant with TPS surfaces needed 12 weeks. They just took what everyone knew... that you can load implants in good quality bone earlier than 12 weeks, or even immediately, and then claimed that the shorter healing time was attributable to the change in surface from TPS to SLA. Now Straumann is doing it all over again, packaging the SLA implants in sterile saline, raising the prices by about \$50 per implant, and claiming that now you can load them in 3-4 weeks. Where are the side-by-side clinical studies comparing SLA to SLActve and showing a statistically significant difference in success? They cannot do it because they know that in good quality bone, both implant surfaces can be loaded even immediately, and heal with an osseointegrated interface. A clinical study of about 300 Straumann SLA (old) surface implants presented by Wilson at this year's AO meeting in Seattle, showing 98% success with immediate load in extraction sockets. I asked him from the audience if he would expect to get 99% success with SLA active... he did not answer this

rhetoric question, because the answer shows the fallacy in Straumann's claims of earlier loading with SLActive. Conducting an animal study in miniature pigs (Buser et al. J. Dental Research: Vol 83, 7, July 2004) showing a significant different in implant bone contact between SLActive and SLA at 2 weeks (before the bone is mature enough to carry load) and at 4 weeks, but with less bone contact at 8 weeks with the new SLActive surface compared to the original SLA surface, hardly justifies Straumann's claim that SLActive cuts the healing time needed prior to loading a dental implant, in half. I will give Straumann more credit for doing research before it brings a new product out, than I would give Nobel but Straumann's SLActive surface studies primarily serve to create marketing sound-bites rather than prove any clinical significance to their new surface. In that regard, I do not see any difference between the exaggerated claims of Nobel and the exaggerated claims of Straumann, both serve the single purpose of justifying exaggerated prices.

Your posting claims: "In life you get what you pay for. Which is why most dentists don't drive Hugo's, or listen to 'me to' claims in their personal purchasing life." This statement does not happen to be true when purchasing implants from Nobel, Straumann, 3i and any other company with large marketing budgets and huge profits. Yes, you do not get a Mercedes car for the price of the Hugo, but to paraphrase Lloyd Benson in the VP debate against Dan Quayle, I drive a Mercedes and the Straumann, Nobel and 3i products are not the Mercedes of the dental implant industry. They are not a Hugo either but more like a Buick selling for Bentley prices. Implant Direct's marketing strategy is not based on "listen to me" claims, but to say listen to your own good judgment and common sense. For every dollar they spend with Straumann or Nobel, about \$.17 goes for cost of goods, \$.33 for sales and marketing expenses, and \$.33 for profits. That equates to about \$200,000,000 in profit for Nobel and around \$100,000,000 in profit for Straumann every year. That is great if you are a shareholder but not so great if you are the dentist paying Nobel \$46 for a cover screw that other companies include free with their implant, or paying an additional \$50 to get your implant delivered in a sealed container of sterile saline. At Implant Direct, the savings in marketing expenses are passed on to the consumer for 60-70% savings over the list prices charged by the major implant companies. Dentists going to Implant Direct's web site to view 24/7 operations on 5 live cameras will reach the same conclusion Merrill Lynch did in its June 10, 2005 published report to investors in medical industry after visiting our factory. ML published report, concluded that Implant Direct is a "Serious and Dynamic operation" further stating that they were "impressed with the precision engineering and the attention to detail."

Posted by: Jerry Niznick | Jun 19, 2006 12:20:34 PM

You have posted over an over about SLActive and it is clear that you do not understand what Straumann is claiming or the technology behind the innovation. Sterile Saline protects what has been accomplished with the surface; it is not what makes the implant hydrophilic or chemically active. In addition, you talk about roughened surfaces as if they existed in a vacuum. Implant surfaces have improved over time as have implant designs. Your Internal Hex design, for example, that is currently got to have the folks at Zimmer wondering what they paid for. TPS was an additive surface while SLA is subtractive. Straumann researched the morphology that osteoblasts cells seemed to prefer and came up with a design that was supported by that research. Right or wrong they documented outcomes and published those results for everyone to read and agree or disagree. 3i did the same with Osseotite, although maybe not with as much attention to publishing. Machined surfaces gave way to HA coated surfaces or roughened additive surfaces which gave way to subtractive surfaces. Each time improvement regarding healing times occurred. Giving that once all implants recommended 6 months prior to final prosthesis. Once again you bring up the rather simplistic immediate load argument, which as I stated in another post is like saying if your car works you should drive it. What happens when you do not have the bone quality for an immediate is a far better question? That is in keeping with the reality of the situation that implants are being placed into. If it doesn't matter then why not go back to machined surfaces and make everybody wait 6 months for prosthesis?

The same Buser study you quote shows new bone replacing old bone in the first week of implant placement. There is no statistical difference of bone to implant

contact in the 8th week. But there is a huge difference in week 4 when you consider that we are talking about secondary stability and not primary stability.

Posted by: | Jun 19, 2006 3:54:51 PM

"ANONYMOUS" POSTED QUESTION:

What happens when you do not have the bone quality for an immediate is a far better question? That is in keeping with the reality of the situation that implants are being placed into.

NIZNICK RESPONSE:

Now you have asked the right question, not that you or Straumann will like the answer. In type 1 and 2 bone, where the density requires 35Ncm of torque or more to insert the implant, then any rough surface implant can be immediately loaded. In Type 4 bone, which is so porous that the implant can be inserted using finger force alone, it is best to wait the full 8 weeks it takes for maximum bone attachment. At 8 weeks, the Buser Study I cited and Straumann relies on for its claims of faster healing with SLActive, show that SLA has a higher bone contact than SLActive, although not significantly so. That leaves type 3 bone that may or may not require 35Nc of torque because it is subjective as to what you call type 3 bone. On Straumann's web site, under the histology picture of the bone at 4 weeks healing with SLActive surface, it states: "Woven bone is mainly recognized by the numerous large osteocytic laculae." This hardly sounds like bone well suited to loading at that time and Straumann has no side-by-side clinical studies showing success with SLActive loaded at 4 weeks with failure of SLA surface implants in the same quality bone when loaded at 4 weeks.

THE ANSWER TO YOUR QUESTION ABOUT WHAT TO DO IF YOU DO NOT HAVE GOOD QUALITY BONE, SUITABLE FOR IMMEDIATE LOADING (i.e. can not achieve 35Ncm of torque) IS FOUND IN TWO ARTICLES. One was written by me in 2000 and is posted on www.implantdirect.com under Research on the home page. It is entitled "Achieving Osseointegration in Soft Bone: The Search for Improved Results." That describes the technique I developed and even patented of placing a tapered implant into an undersized socket to increase the initial stability.

The Tapered Screw-Vent and the straight step-drills I developed for inserting that implant (also used for my new Spectra-System Implants with the same body dimensions and taper), were used in that study and show a doubling of the torque required to insert an implant in soft bone. So if the bone is too soft to achieve 35Ncm using a straight implant like the ITI, or a tapered implant inserted using tapered drills like Nobel's Tapered Replace Implant, the threshold stability for immediate load may be achieved by varying the surgical technique. If by using my surgical technique of inserting a tapered implant into an undersized straight socket, one could achieve the 35Ncm minimum initial stability and therefore allow immediate load that would be 4 weeks shorter than with the ITI implant with its \$50 premium SLActive surface. My study and surgical technique are backed up by a recent study by Shalabi et al. COIR Vol17. #2, April 2006. Pg 172-178. In that study, Shalabi compared Tapered implants with a machined surface to the same implants with a "grit-blasting and additional acid etching"... sound familiar? The researchers looked at Bone to Implant Contact (BIC), Peak insertion and removal torque, and SEM of bone morphology. "RESULTS: Insertion and removal torque values were significantly higher for etched implants inserted with the undersized technique... Also the average BIC value was higher for the etched implants placed with the undersized technique, which was statistically significant, compared with machined and etched implants inserted by conventional technique.

CONCLUSION: This study shows that the surgical technique has a decisive effect on implant fixation (represented in this study by installation torque values/removal torque values and histomorphometric evaluation) in trabecular bone."

Straumann would have been better advised to taper the ITI implant, develop a set of drills to allow inserting it into an undersized socket, and then drink the saline.

Posted by: Jerry Niznick | Jun 20, 2006 12:25:59 AM