

## Blog June 5-9, 2006: Bone loss reported with NobelDirect & fractures reported with Nobel Replace

### Comments

Do you think there will be any major repercussions from the recent Nobel Direct dental implant saga, which heated up this past week?

As you may already know, two professors, Tomas Albrektsson and Lars Sennerby, had issued allegations concerning Nobel BioCare dental implant NobelDirect back in May 2005. This seemed somewhat innocuous. However, last Tuesday, Par-Olov Ostman, a Swedish dentist, said his clinic would withdraw from Nobel study, which the company is conducting to monitor the Nobel Direct dental implant.

The reason for Ostman's withdrawal? Ostman's clinic had reported that over 30 percent of the dental implants were accompanied by more than 2 millimeters of bone loss during the first year. Ostman said six implants had had to be removed due to bone loss. **"Nobel keeps telling television and newspapers that there's nothing unusual about this implant, and I cannot agree with that," Ostman told Reuters.**

**Nobel was quick to fight back against this recent accusation.** According to the company, *"The information is anecdotic; there are no indications of this material being part of a systematic review and by no means as complete as requested. They contain no scientifically or statistically relevant evidence supporting the allegations."* With regards to Ostman's dental implant findings, Nobel was quick to point out that Ostman has a strong professional relationship with Tomas Albrektsson and Lars Sennerby and more importantly, *"the performance of Dr.*

*Ostman's implants is significantly below the average performance of the other participants of the studies.*" Finally, Nobel reiterated that based on clinical studies the NobelDirect dental implant, " is a safe and reliable product." "Since the Swedish Medical Products Agency is investigating these allegations upon Nobel Biocare's request and since Nobel Biocare fully supports and trusts the Agency's procedures, the Company expects the opinion by the Agency."

**Interestingly, the Nobel Direct dental implant accounted for only 2 percent of Nobel's sales, so the economic impact to Nobel should be limited. However, the key question is whether there will be any impact from this on the marketability of other Nobel dental implant product lines. What are your thoughts?**

Posted by: | Jan 10, 2006 2:24:26 PM

This absolutely makes me apprehensive about their up and coming product lines.

Posted by: Spain | Jan 10, 2006 3:29:43 PM

First they blasted roughened surfaces, then TiUnite was the second coming, Nobel Perfect was marketed with more marketing muscle than anything before with so many promises made, and what? Nobel Direct is now under fire.... And Nobel Guide is not as easy as they say. Meanwhile training GPS to place implants in 2 days. Buyer beware is one person opinion.

Posted by: | Jan 10, 2006 4:05:37 PM

I have been placing implants for over 21 years. I have experienced problems with SteriOss rough TPS coated surface that broke down after 3 to 7 years. They lied to us. They claimed that the TPS was the 1st coming. Then they claim Ti-Unite as the 2nd coming. Will this surface break down also? They use us as guinea pigs to test their products. Now they are trying to copy the Astra system with the Groovy and again we are the field test. I also think that the company made a big mistake marketing the 2 day surgical course to GPs and now I don't do Nobel

any more. They were my #1 company before but not now. I think the dollars blinded them and the direction of the company makes me very uncomfortable.

Posted by: | Jan 10, 2006 4:39:27 PM

Where 10 years ago, before the merge with SteriOss and before the Canepa story, it was difficult to be "allowed" with the Brånemark system.

Now it has become the implant K-mart Company where they look afterwards if the implant succeeds or fails. One can trust people such as Sennerby and Albrektsson, they earned their good names in research!

Implantologists all over the world should mistrust the money greed from this Swiss lady! All the new products they tore out of the ground so quickly, promise more than their performance right now. There was a day that nothing left this Nobel Company before well tested. Even P.I. Brånemark took his name away from Nobel Biocare since he did not believe in this aggressive marketing strategy. Nowadays there are several good implant-companies performing at least as successful, or even better with less circus!

Posted by: | Jan 10, 2006 7:13:27 PM

In my opinion, we are watching the downfall of a great company right before our eyes! Greed is readily apparent. All you have to do is read Barron's magazine article last year to see the unashamed announcement of greed and proud of it! No mention of quality leader or anything like that.

I find it quite interesting that at the Astra World Congress in April that president of the scientific committee is Albrektsson and other names like Tarnow are on the committee and I heard from the Astra rep even Brånemark is involved.

Add this to Carl Misch even using Astra and selling BioHorizons, the way NB is treating their reps, it is the cycle of large companies.

We'll see how Astra, Straumann, and 3i and Dentsply (the next biggest market share companies) respond or if some "upstart" like blue sky bio at \$95 each

starts gaining market share. If you get ignored at \$300 and implant, why not get paid attention to at \$95 per implant?

Posted by: [fmn](#) | Jan 11, 2006 3:27:44 PM

I totally agree with you Albert, the implant Industry, especially Nobel, has done a lot of damage to the profession. The lack of evidence, the fact that our patients are the lab pigs of their products, the marketing strategies stating that it is simple, easy, predictable and highly esthetic, and that anyone could do it, has done a lot of harm. They got the money, hence they are running the show, but as long as a few of us are critical and objective, we can still deliver a message to the dental community. I just hope it is not too late. How many failures will be accounted with this Nobel direct lie? We will never know, but hey they will always have an explanation....our fault.

Posted by: | Jan 16, 2006 7:03:21 AM

I have placed approximately 150 Nobel Replace Select and just a few Direct with good results...However, I have begun to use the Groovy lately and have had several complications...Three implants failed to integrate and two implants actually fractured at the head...one could not be retrieved (one 4.3 and one 3.5).... I have been told by NB that they had not heard of this happening before.... Has anyone else has this experience?

Posted by: [LF](#) | Jan 30, 2006 10:34:23 PM

It is interesting to note the number of responses to this negative focus of one of the major players in implant dentistry. What I do agree with here is that being a major player, like Wal-Mart, doesn't equal premium product or service. I would be embarrassed to continue using a product if I had these same feelings or experiences represented here. Implant dentistry is a boutique service and should be controlled by boutique players.

Posted by: | Jan 31, 2006 1:00:05 PM

Stay calm Chausse.

I have had 2 fractures on the 3.5 mm. It is happening often and I really question a company like NB that is still having a fracture issue 40 years after inception.

Posted by: | Jan 31, 2006 6:40:37 PM

Interesting.! I am not a user of the Nobel Direct. I will watch to see how all of this unfolds, however please don't give all "the Big Names" so much credit! Thomas Albrektsson, when still with Nobel was speaking at our study club in San Francisco, he was adamant- only machined implant, only external hex. and only his buddy in Sweden would do an implant for him! I asked about internal connection,(tri channel), immediate load he was against everyone and everything! I called him on it and I also suggested that this guy should never be asked to lecture with the study club-and he has not! Funny, he surfaces with a new look - Astra. It is a fine implant but if they are serious at all they will soon have a tapered option! Yes, and he will move to were ever he can find a job; I would, but you don't fool anyone Thomas! At least no one that heard you only a few years ago.

Posted by: | Feb 7, 2006 9:38:04 AM

Fine - all companies have their head up their own....Nobel is no different. They have lost several excellent practitioners because of tri-channel fractures in the 3.5 series. All companies can have complications but only Nobel develops a fantastic Retrieval Kit and never tells those placing implants that it even exists! That is B.S. Unfortunately it is what we all expect from this company today.

Posted by: | Feb 7, 2006 1:33:30 PM

I had also a fracture of the three channel 3.5 mm NP implant. but just ONE. I was among the first user. after that, Nobel started advising on the package not to torque over 45 Ncm to avoid fracture. no reason now to break a second one !

Posted by: L. Chaussé | Feb 7, 2006 4:01:49 PM

Chausse,

so you deal with a company that has known faults on the NP 3.5. You continue to use the product event though there is a different protocol for a fracture issue!!!!

Is there any other company out there that tells you to do this?

It is like driving a high-end sports car but be careful on the hairpin turn as the wheel might break off!!!

Posted by: | Feb 9, 2006 9:40:31 AM

I have also experienced fracture at the fixture head with two 4.3 mm Groovy implants and I had placed many Replace Selects prior to that without any fractures. The company rep said they had never had any reports of fractures.

Posted by: RG | Apr 19, 2006 10:48:58 PM

The Paragon Implant booth in the late 1990's had a rotating sign on the top. Intelligent Design for Discerning Dentists. I use to say that I had a niche market...Discerning Dentists. Based on the intelligence shown in the comments above in this long blog, I think that discerning dentists are no longer a niche but a growing force in the industry.

Here is the reason Nobel Replace implants fracture. The wall thickness of the 3.5mmD implant is only .009" thick and when they made the 4.3mmD implant, which one would expect to be made stronger because wider implants are used in the posterior more, and therefore subject to more load, they also made the cross-section of the tri-lobe larger, leaving only .012" of wall thickness. That is just a little larger than 1/4mm (.010") and a human hair is measured at .004" so it is 3x wider than a human hair. But that is not all.... TiUnite can not bond to Titanium alloy, so while the HA coated Replace implants are made of alloy, the TiUnite coated implants are made of CP Titanium, which is weaker. There were reports of Screw-Vents fracturing when they were first introduced in CP titanium in 1986. It then had a wall thickness of .016". I quickly widened it to .020 (twice what a 3.5 Replace is today) and introduced the implant in Titanium alloy. By 1990 I stopped selling CP Titanium Screw-Vents. Another contributing factor in solving the fracture problem, was the introduction of the 4.7mmD and 6.0mmD Screw-Vents in the early 1990's, keeping the same 2.5mmD hex but thickening the walls by .020" with each succeeding increase in size. Therefore, the wall thickness of a 4.7mmD Screw-Vent was .040" or 1mm vs. .012" with the 4.3mmD Replace

today. These are the dimensions I have followed along with the same taper as Zimmer's Screw-Vent, for my ScrewPlant and ScrewPlus implants but my new RePlant is designed to match the platform and body diameter/taper of the Nobel Replace. I only use alloy to add strength. The big differences between the Replace and the RePlant are the thread design (RePlant has double lead and mini-threads) and the cost (\$150 vs. \$367 including cover screws). If you are going to get screwed, at least don't overpay for it.

Posted by: [Jerry Niznick](#) | May 31, 2006 12:14:51 AM

The reason for pressure necrosis with a tapered body design like the Nobel Replace is that the taper is not even all the way up the implant. The taper widens quickly from the apex to the midpoint of the implant where the major diameter is reached. This is in contrast to an implant like the Tapered Screw-Vent where the implant tapers from the apex to within 3mm of the top, or the ScrewPlant (Implant Direct) with the taper extending over the entire length of the implant.

When I developed the Tapered Screw-Vent in 1999, I introduced it with a soft bone and hard bone protocol using straight step drills that allows for bone expansion in soft bone, and with ample bone removal so that in dense bone the implant can be inserted without a bone tap.

If you are "comfortable" using the Nobel Replace implant, now that you know how to vary the drill diameters for dense bone consider moving from your comfort zone to your profit zone by using the RePlant implant which is 60% less expensive, while being inserted with the same Nobel Drills, and has the same tri-lobe platform.

Posted by: [Jerry Niznick](#) | Jul 11, 2006 2:51:41 PM