

Detailed Feedback from AO



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AO Largest U.S. Dental Implant Congress

In this note we provide detailed feedback from the 21st **Annual Meeting of the Academy of Osseointegration (AO)**, which kicked off on 16 March in Seattle. Specifically we highlight clinician feedback on Nobel Biocare, observations relating to Straumann as well as other market developments.

Nobel Biocare - Risk Profile Increasing?

Based on feedback during Nobel Biocare's corporate forum, we got the impression from attending clinicians, that they felt that the **company's focus has changed significantly over the past three years**, away from the an institution that made science a priority to an organization that is more concerned about launching new products more quickly without having long-term data. In addition, they showed concern about what they believe is an **overly simplified or aggressive marketing strategy** that may encourage the overuse of difficult concepts such as 'flapless surgery' in conjunction with one-piece NobelDirect, amongst new or recent adopters of dental implants.

While we acknowledge that this may have allowed Nobel Biocare to grow faster than the market over the past 2 years, we are concerned that this may have **increased the company's risk profile**, by its products potentially achieving lower implant success rates in the future compared to industry benchmarks. This may explain some of the controversies that have recently emerged on some of its recently launched products of NobelDirect and NobelPerfect. Moving forward we believe the market would be happy to accept slightly slower top line growth rates for a less aggressive management style; we believe this is the key reason why the financial market has re-assigned a premium rating to Straumann. We retain our **'Neutral'** recommendation.

Straumann - Probably The Safer Bet

During the AO meeting, Straumann launched its new SLActive implant in the U.S. market. Interestingly, Straumann's **marketing materials for the U.S. appear to have become a little broader** since the technology was first launched at the ITI World Congress in September 2005. Rather than marketing it only for 1/3rd of indications (i.e. the less predictable), Straumann is now suggesting it is suitable for all indications. We welcome this broader labelling from a financial perspective, as we felt that the company was unnecessarily limiting the penetration of its new technology. Furthermore, we believe Straumann should also benefit from Germany, which our dental field checks suggest is performing well. Nevertheless, we continue to believe that **FY06E will be a transition year for the company**, driven by an infrastructure expansion cycle in the U.S. which will negatively impact margins and thus not deliver the earnings growth necessary to get the incremental investors excited. As a result we retain our **'Neutral'** recommendation.

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Detailed Feedback from AO

On 16 March 2006 the 21st Annual Meeting of the Academy of Osseointegration (AO) kicked off in Seattle, U.S., which incorporated the corporate forum day, during which companies highlighted their latest products, including industry leader Nobel Biocare, Straumann, 3i, Dentsply, Zimmer Dental, Astra Tech as well as Jerry Niznick's internet based company, Implant Direct. In addition, with attendance of over 1,000 delegates, we believe it provided the first good opportunity for gauging clinicians' experiences and opinions surrounding NobelDirect and NobelPerfect, following recent claims by the University of Gothenburg and University of Southern California, that they can cause excessive bone loss. In addition, we performed an informal survey on clinicians, to get a better understanding of their willingness to use a low cost internet based dental implant selling approach.

Nobel Biocare - Neutral Recommendation

Provided below is a summary from the Nobel Biocare corporate forum, which included an update on the safety and efficacy of its NobelDirect and NobelPerfect implant, its push into the short implant segment as well as its NobelGuide technology.

NobelDirect & NobelPerfect Implants

During the forum Nobel Biocare released a synopsis of forthcoming scientific publications on NobelDirect and NobelPerfect. According to the company, all publications demonstrate that the marginal bone average stabilizes at the level of the first implant thread and consequently shows no unusual bone loss. Nobel Biocare has made reference to four data sets, which stem from a worldwide call for data on its one-piece implant systems that generated 1,722 implants of which 1,475 could be evaluated. It should be noted that the majority is **retrospective data** which is less powerful than prospective, but nevertheless provide useful insights:

Data Set 1: NobelDirect - 25 Centers with 1,009 Implants

Nobel Biocare has highlighted a forthcoming publication titled "**Multiple Center Clinical and Radiographic Evaluation of One-Piece Implants – A Retrospective 6-Year Evaluation**" by T. Siepenkothen et al. This study includes data obtained from 25 clinics in Germany on 1,009 one-piece implants, which were consecutively placed in 544 patients. Follow-up was between 6 months and 6 years with an overall survival rate of 98.2% with the marginal bone level remaining stable.

We are looking forward to seeing the finer details of this study, particularly as the implant in question is the recently launched NobelDirect implant which contains the TiUnite surface all the way up the implant. Given that this implant was only launched in 1H CY04, the **data greater than 1.5-2 years must logically equate to a previous generation one-piece implant.**

Data Set 2: NobelDirect - 1 Center with 37 Implants

Nobel Biocare has highlighted another forthcoming publication titled “**Clinical Evaluation of One-Piece Implants used for Immediate Function – A Preliminary Report of Bone Level Up-To 2-Years**” by J. Hahn. This retrospective study includes radiographic evaluation of 37 one-piece implants in 22 patients followed up to 2 years. According to Nobel Biocare, the outcome demonstrates an implant survival rate of 97.3% with a mean marginal bone level located well above the first implant thread, corresponding to results in Nobel Biocare’s own multicenter study.

Data Set 3: NobelDirect - 49 Centers with 429 Implants

Nobel Biocare has highlighted a further publication titled “**Worldwide radiographic evaluation of Nobel Biocare one-piece implants**”. The summary report contains 429 implantations in 49 clinics in the U.S., Japan and Europe. The data according to the company shows a stabilization of the marginal bone level slightly above the first thread after 1 year of loading corresponding to the results of Nobel Biocare’s own multicenter study.

Data Set 4: NobelPerfect - 5 Centers with 106 Implants

Nobel Biocare has also provided insight into a pending report from 5 clinics, corresponding to 80 patients and 106 implants. According to the company the data shows a stabilization of the marginal bone slightly above the first thread after 1 year of loading. The mean marginal bone level for all implants that have passed 12 months was located 0.44mm (Standard Deviation 1.0) below the reference point, (i.e. the lower corner of cylindrical part.)

Professor Nowzari Data Pending - University of Southern California

We understand this week the journal of Clinical Implant Dentistry and Related Research is expected to publish a peer reviewed paper by Professor Hessam Nowzari (Chairman of Advanced Periodontics Department, University of Southern California) on his findings surrounding Nobel Biocare’s recently introduced NobelPerfect implant. As a reminder NobelPerfect, which like NobelDirect is an innovative design and is indicated for the aesthetic zone through its unique scalloped shape. Following a MedLine literature review, Professor Nowzari believes this the first and only non-sponsored study.

Although the finer details of the study are yet to be published, the results of 17 NobelPerfect implants in 6 patients demonstrates/suggests the following:

1. **Bone loss** around NobelPerfect implants was equal to or greater than, what has been reported around non-scalloped implants. **Average bone loss was ~4mm at 18 months;**
2. Although the implants remained stable, patients treated may be at **risk of further complications such as implant exposure**. This may require implant removal in the future due aesthetic reasons; and
3. NobelPerfect provided **no advantages** over traditional dental implant design.

Professor Lars Sennerby Data Pending - University of Gothenburg

We understand that Professor Lars Sennerby from the University of Gothenburg is expected to publish a paper, which includes data from Nobel Biocare's own prospective randomized trial as well as data from their own retrospective study of approximately 300 dental implants. We understand that to date the professors have completed their calculations of the first 222 consecutive implants, which show:

- A failure rate (i.e. implant loss) of 5.2%, which is high compared to the industry average of 2-3%; and
- Bone loss of > 3mm in 30% of cases at 1year follow-up.

We understand that these results will be submitted as a scientific paper for peer review and if accepted should be published mid 2006.

Dr. Antonio Rocci - Italy

As we highlighted in previous research, Nobel Biocare suggested reading materials incorporated a case report, which was published on the "Esthetic outcome of immediately loaded scalloped implants placed in extraction sites using flapless surgery. A 6 month report of 4 cases" by Antonio Rocci & Jan Gottlow, Applied Osseointegration Research – Volume 4, 2004.

In the study, 11 teeth were extracted in four patients for periodontal or endodontic reasons and were directly replaced with NobelPerfect implants, which were immediately loaded. At 6 months all implants remained stable. It was concluded that early experiences from four patients showed that scalloped margin design of the implant combined with flapless surgery and immediate loading resulted in an aesthetic clinical outcome with a scalloped soft tissue profile and papillae filling the available interproximal space. The successful papilla fill seemed unrelated to the height of the interproximal bone. It was also concluded, that prospective long-term data from more patients are needed to confirm preliminary findings.

After reading this study we contacted Dr. Rocci of Italy, to get an update on the results of the aforementioned four patients at post 12-months. **While the aesthetic results continue to look pleasing, radiographic follow-up suggests excessive bone loss**, which according to Dr. Rocci, substantially raises the likelihood of implant failure. In addition to these 4 implants, subsequent placement of ~80 NobelPerfect implants in different patients, suggest similar high levels of bone loss compared to conventional implants. Furthermore, it appears Dr. Rocci has also placed over 100 NobelDirect implants, which according to him also showed excessive bone loss in approximately 1/3rd of patients and may jeopardize the long-term stability of the implant. We understand the data is currently being compiled and will be published once Dr. Rocci's confidentiality agreement with Nobel Biocare expires.

Clinician Feedback from AO

General Comments from Longer-term Nobel Biocare Users (> 5 years)

Based on feedback during Nobel Biocare's corporate forum, we got the impression from our discussions with longer-term clinicians, that they felt that the company's focus has changed significantly over the past three years, away from an institution that made science a priority to an establishment that is more concerned about launching new products more quickly without having long-term human clinical data.

Some of the attendees during Nobel Biocare's forum regarded the company's aforementioned AO press release on NobelDirect and NobelPerfect as another example, where the company is trying to retrospectively accumulate clinical evidence for a product that was launched before long-term data on its one-piece NobelDirect (which for the first time carried the rough TiUnite surface all the way into the soft tissue) became available. Clinicians felt the same way about the potentially new and appealing concept of NobelPerfect, where equally no long-term is available; while at the same time the company is making very strong esthetic product claims and charging high prices. Interestingly, one long-term Nobel Biocare user of 12 years felt that Nobel Biocare customers are becoming the experimental "guinea pigs" for new product concepts, that really should be tested over a 3-5 year period in a controlled clinical setting.

However, when asked whether they have considered switching to another manufacturer, the answer was generally no, on the basis that Nobel Biocare's legacy products such as the traditional Bränemark and Replace system achieve good long-term and predictable results. The clinicians however also indicated that they generally would not use Nobel Biocare's recently launched dental implant products.

The final clinician comments related to, what they believe is an aggressive marketing campaign by Nobel Biocare which labels dental implant procedures as simple and easy. Specific clinician comments related to the concept of flap-less surgery in combination with a one-piece implant, which according to the experienced clinicians should be classified as a niche indication, particularly for new dental implant users. Although Nobel Biocare gives their customers freedom of product choice, they feel that this oversimplified marketing approach of flap-less surgery with NobelDirect is too persuasive and thus may result in overuse by new or recent adopters of dental implants.

General Comments from Short-term Users (< 2 years)

The feedback from Nobel Biocare's users which have recently moved into dental implantology (i.e. less than 2 years), is that they felt generally comfortable with the company's new product launches, on the basis of its strong reputation as the market leader. They also indicated that their limited knowledge of dental implants specifically meant that they did little work themselves to understand the clinical data supporting new products; we believe one new clinician summarized the view of the short-term user quite well - ". . . in the end it is just a matter of trust."

Comments from AO Opening Symposium - Dr. Konrad Meyenberg

Dr. Konrad Meyenberg, who does self-supported research, gave an interesting presentation during AO Opening Symposium on “Recent Developments in the Implant Abutment Complex”. While there were many interesting components to the presentation such as new concepts for abutment designs, we thought there were two interesting comments on taking the rough surface all the way to the top of the implant as well as NobelPerfect. These comments have been highlighted below:

1. **Rough surface to top of implant** - Meyenberg indicated that taking the rough surface all the way to the top of the implant (i.e. into the soft tissue area as with NobelDirect and NobelPerfect) is potentially an attractive concept but really requires 3-5 years of data, to gain comfort on the longer-term implications. Without this data it is impossible to predict the long-term implications of the implant both on function as well esthetics on the patients’ soft and hard tissue, driven by possible negative side effects concerning chronic periimplant inflammations compared to standard protocols and control of pretended effect on stabilization of coronal soft tissue; as a result the well established machined dental implant head, should remain the technology of choice until relevant clinical data becomes available; and
2. **NobelPerfect** - Meyenberg, in his work of comparing different implant systems noticed periodically more bone remodeling in NobelPerfect compared to other dental implant systems; similar results were also observed by his colleagues. Furthermore, the implant was more difficult to use and more challenging for following the prosthetic steps, with esthetic results that are **no better** compared to non-scalloped implant designs that cost half the price.

Chart 1: NobelSpeedy Groovy & Shorty



Source: Nobel Biocare

Short Implants vs. Bone Regeneration

An interesting lecture was given by Dr. Frank Renouard (France) during the Nobel Biocare corporate forum on the topic of “Managing Complex Surgical Situations Using Minimally-Invasive Treatment Solutions”. It was highlighted, that a good candidate for implant treatment was defined as a healthy patient, with plenty of dense bone and no parafunctional problems. All clinical situation which diverged from this reference was considered as a more risky patient. As a result surgical procedures such as bone grafts and sinus lifts were developed in order to modify the patient so as to allow the surgeon to place the longest possible implant. Dr Renouard indicated that it is time to reconsider this dogma by using much shorter implants (i.e. 4-5mm) compared to traditional implant designs of greater than 10mm. Amongst other things it was highlighted that short implants such as Nobel Biocare’s recently launched “Shorty range” could be used in routine practice with a high success rate with, maybe, a better biomechanical prognosis. Furthermore, this technology could reduce the need to use expensive bone grafting procedures on many patients and provide an attractive alternative for many dentists / dental surgeons. However, it should be noted that implant placement for short implants is highly important as the lack of bone stock may increase the risk of interfering with nerves. As a result this technology may only be useful for highly experienced clinicians or clinicians who have access to computer assisted surgery technology, such as NobelGuide.

Chart 2: NobelGuide


Source: Nobel Biocare

Short-Implants May Result In Higher Risk

While this could be interesting technology for Nobel Biocare, it should be noted that “short-implant” technology is not new, with U.S. based Bicon being one of the early pioneers with the technology available since 1997, offering both 5.7mm x 6.0mm and 5.0mm x 6.0mm implants. The importance of keeping this technology in the hands of very experienced surgeons, was recently highlighted by a lecture from Dr. Michael Ragan a dentist/attorney who only does malpractice defense cases; he highlighted that his biggest rise in malpractice cases relates to mini or short implants; chances are that the dentist who uses these and gets sued is more than likely to lose. As a result we hope that Nobel Biocare encourages the use of its “Shorty” implant range to only its experienced customers.

NobelGuide - Great Technology

Dr. Thomas Balshi provided an interesting lecture on NobelGuide, which we continue to believe is an important area of production differentiation for Nobel Biocare. As a reminder the product was effectively launched over the last 12-months and is a treatment modality that uses virtual surgical computer planning to treat patients with a less invasive protocol (i.e. flapless surgery). Improvements in CT scanning technology such as I-Scan have made it possible to fully recreate the surgical site in three dimensions. The company’s robotics factory either in Sweden or the U.S. uses CAD-CAM technology to create a surgical template that is based on the surgical template that is based on the virtual planning. A prefabricated definite prosthesis can be fabricated from the planning files.

As we highlighted in previous research, **we continue to believe that computer guided dental implant placement will become a much bigger theme in dental implantology moving forward.** In our view it will help to expand the market, by broadening the indications for dental implants (i.e. patients with poor quality bone) as well as attracting more general practitioners, who will find additional comfort in doing dental implant procedures with the support from this technology. However, the additional cost to the patient, which we estimate at \$1,000 or more per procedure, may be prohibitive, as it raises the total procedure cost by as much as 50% for a single tooth replacement.

Nevertheless, at the list price of +US\$6,000 for the planning software (which includes the Procera platform and conversion software), we feel the company’s top line may continue to benefit from some “capital sales” over the shorter-term, while longer-term sales will benefit from NobelGuide “consumable revenues.”

Chart 3: I-CAT


Source: Xoran Technologies

Conclusion - Company Risk Profile May Increase

Based on further feedback from the AO, it is difficult to judge as to whether there is anything intrinsically faulty with NobelDirect or NobelPerfect. However, further short-term evidence published by Nobel Biocare during the AO may suggest there is nothing wrong with the implant design itself. Instead, cases which may have observed greater than normal bone loss and/or unaesthetic outcomes are more likely to be driven by dentist/surgeon error, perhaps through inexperience, over-use or not following the procedure manual correctly. While this clearly has no direct implications on Nobel Biocare (at the end of the day it is the surgeons' problem), we are concerned that this may have negative long-term ramifications on the company in other ways. **Specifically, we feel that the market leader not only has the responsibility of producing innovative implant designs backed-up by long-term clinical data, but to incorporate these into a complete package/program to ensure predictable outcomes. This is especially important for Nobel Biocare as the company's strategy includes expanding its customer base beyond specialists into the general dentist population.**

While we acknowledge that Nobel Biocare's more aggressive management style relative to its competitors has allowed the company to grow faster than the market over the past 2 years, we are concerned that this may have increased the company's risk profile, by its products potentially achieving lower implant success rates compared to industry benchmarks.

Straumann - Neutral Recommendation

Provided below are our Straumann findings from the AO meeting, which include details on SLActive, some competitive product launches as well as clinical updates on its Emdogain product, which makes up the majority of its biologics sales.

SLActive - Now With Broader Marketing Claims?

During the AO meeting, Straumann launched its new SLActive implant for the U.S. market, which as planned, is 6 months behind Europe. Interestingly, Straumann's marketing materials for the U.S. have become a little broader than when the technology was introduced at the ITI World Congress in Munich in September of 2005. Rather than marketing it for 1/3rd of the indications, it seems that Straumann is now suggesting it is suitable for all indications. We welcome this broader indication from a financial perspective, as we felt that STMN was unnecessary limiting the penetration of its new SLActive implant product.

Chart 4: Straumann's SLActive Implant



Source: Straumann

European Marketing Text

"Although implants with SLActive surface are suitable for all indications, the high treatment-security they provide render them especially beneficial to advanced and complex treatment protocols in challenging indications."

U.S. Marketing Text

"Implants with the SLActive surface are suitable for all indications, and are especially beneficial in advanced and complex treatment protocols in challenging indications such as immediate loading."

SLActive Reception in Europe

It appears that the SLActive reception is doing well in Europe, with the price premium of +30-40% crystallizing compared to its older SLA technology. We suspect SLActive will garner more momentum over the coming 12-months in Europe with a lag effect in North America, due to the later launch. Furthermore, the surface enhancement should also provide Straumann with useful product differentiation from new competition such as MIS Implant Technologies.

New Implant Design Pending?

We are of the opinion that Straumann has been working on a new dental implant design that may either replace or work side-by-side with its current but ageing ITI design, that perhaps may be more suitable with the concept of platform switching (more on this later). However, with Straumann's strong track record for clinical research, we suspect a new system may be 2 years before it becomes commercial.

New Implant Competition

Although Israel based MIS Implant Technologies is not new discount competition, we understand that in the coming two weeks they will launch Mistral (in addition to its older platform of Seven). Mistral is a copy of Straumann's core single stage ITI system incorporating the same internal connection and will be offered for US\$189 with cover screw, abutment and impression mount; this compares ~US\$300 for just the Straumann implant without the abutment. However, with only 5 sales people in the U.S. attempting to sell 20,000 -30,000 implants in 2006, we do not regard this as a material threat. Furthermore, with SLActive we feel Straumann has a competitive advantage over its lower cost competition.

Emdogain - Bone Growth Does Not Look That Hot

A number of papers were presented on STMN's Emdogain (Enamel Matrix Protein) product, which it acquired through the Biora acquisition in mid 2003 for ~CHF60m. As a reminder, part of the acquisition was driven by the belief that Emdogain has the potential to stimulate bone growth and thus provide a useful adjunct to its core dental implant business.

"A Comparison Between Enamel Matrix Derivative and Resorbable Membrane to Enhance Healing Around Transmucosal Immediate Post-Extraction Implants - A Case Series" - M. Soyster et al

Thirty-two adult patients scheduled for tooth replacement with dental implants accepted to participate. Following insertion of a transmucosal implant into the extraction site, the subjects were assigned to one of 2 treatment alternatives of the remaining bone defect around the implant: 1) the residual bone defects were filled in Enamel Matrix Derivate (EMD); or 2) the residual bone defects were covered with an absorbable membrane. At 12-month follow-up the membrane group showed a significantly lower mean probing attachment level than the EMD group at proximal, buccal and lingual site, which was statistically significant. It was **concluded** that the membrane group obtained more favorable results in terms of both probing attachment level and per-implant position of soft tissues compared to EMD group. The use of bioabsorbable membrane around immediately placed transmucosal implants was able to enhance soft and hard tissue healing and might be the advisable treatment choice particularly in areas with high esthetic demands.

Chart 5: Straumann's Emdogain



Source: DentalInsurance

"The Effect of Enamel Matrix Derivative (Emdogain) as Grafting Material Around Immediate Post-Extraction Transmucosal Dental Implants - A Case Series" - F. Cangini et al

This clinical study evaluated the use of an Enamel Matrix Derivative (Emdogain) as a grafting material around immediate placement of transmucosal implants in extraction sockets. Thirty-two adult patients scheduled for tooth replacement with dental implants participated. Following the implant insertion (STMN's ITI implant system) into the extraction site, the subjects were assigned to one of two treatment alternatives: 1) Emdogain (test) or 2) mucoperiosteal flap closure (control). It was **concluded** that use of Emdogain seems to be able to support healing around immediately placed implants in shallow probing depth and attachment level compared to control sites, but the results are unconvincing.

New Competition - GEM21S

In November 2005, Biomimetic Therapeutics of the U.S. received FDA approval for GEM 21S[®] growth-factor Enhanced Matrix, for the treatment of bone loss associated with advanced periodontal disease. GEM 21S combines the tissue growth factor rhPDGF-BB with the synthetic bone matrix, Beta-tricalcium phosphate (β -TCP). Under the exclusive agreement with Osteohealth Company, a division of Luitpold Pharmaceuticals, Inc. which is a group company of Sankyo Co., Ltd., Osteohealth is responsible for the worldwide marketing, sales, distribution, and post-approval development of GEM 21S for additional indications including the repair or reconstruction of cranio-maxillofacial osseous defect indications. We understand that the price in the U.S. is US\$329 (3-9 units), US\$299 (10-19 units) and US\$279m (+20 units).

Based on our discussions with Straumann, it appears that the company has so far not seen any negative impact on its Emdogain product. Although it is likely to be superior with respect to growing bone, we do not expect a major impact on Straumann's Emdogain over the coming 12-months.

Implant Direct - Jerry Niznick

Dr. Jerry Niznick used the AO meeting to launch his newly found Implant Direct company, which will use the internet as the primary selling tool. Furthermore, the internet web-site has now gone live allowing customers to submit their orders using their credit card; it is important to note however that orders can not be processed until Implant Direct receives FDA approval.

FDA Product Approval / Launch Timetable

We understand the product approval and launch time table is expected to incorporate the following dates, as set-out below:

Table 1: Product Launch Time Table

Product	Expected Launch Date
Zimmer Compatible Abutment	April 2006
Spectra System Launch	July 2006
Replant (Nobel Biocare Compatible System)	September 2006

Source: Implant Direct, Merrill Lynch estimates

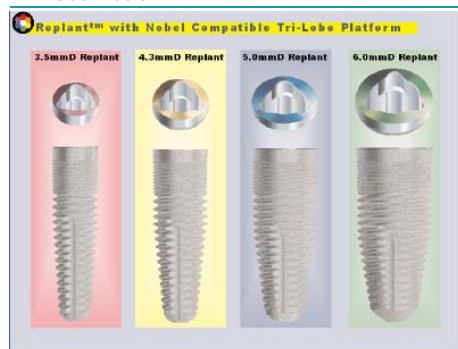
The Spectra dental implant system is expected to be FDA approved in July 2006, followed by the Nobel Biocare compatible system, Replant in September 2006.

Competitive Impact - Likely To Be Low

Following our attendance at the AO, we continue to believe that Implant Direct's low cost business model is unlikely to result in a meaningful impact on the dental implant industry, which includes Nobel Biocare and Straumann. Although our clinician field checks indicate that an internet based ordering approach is not a limitation (many clinicians actually prefer this method compared to placing an order by phone), they made the following comments:

1. **Referral based model reduces implant system flexibility** - clinicians felt that it is getting more difficult to switch to a new implant system under a referral based model. Specifically, in the U.S. where the placement of an implant is referred to a surgeon and then re-referred to the referring dentist for the restorative work (i.e. attaching the abutment and prosthetic). While the concept of a cheaper implant system is highly attractive, the switch to a new dental implant system requires a group decision (typically 20-30 people) between the surgeon and his restorative dentists. To the credit of Implant Direct, clinicians did indicate that the apparent internal connection compatibility to Zimmer and Nobel Biocare implants does reduce this challenge, as it allows the restorative dentist to continue to use the premium priced products they have become accustomed to. Nevertheless, in a European context a system switch is more likely as a referral based model is significantly less common; and
2. **After sales service** – although most experienced clinicians agreed that they need very little help from their sales representative, they did acknowledge that there is the odd occasion where essential technical assistance or after sales service is required. This may include advice on the use of recently launched components, the return of products that were sent in error as well as complaints/questions on faulty or fractured products. The convenience of being able to deal with a responsive sales rep or customer help line, compared with Implant Direct's on-line internet service portal may just be more important than price.

Chart 6: Replant – Nobel Biocare Compatible Tri-Lobe Platform



Source: Implant Direct

Nevertheless, many clinicians we spoke to thought that a business model offering quality implants at heavily discounted prices through an internet based approach was an interesting concept and would be willing to perhaps look into it at a later stage. We will be monitoring this space with great interest over the coming 12-months.

Medtronic - Moving into Dental

For the first time we have seen Medtronic Sofamor Danek participate at the AO meeting with a small booth, highlighting their unique rhBMP2 technology, which currently is only FDA approved for spinal fusion indications. We understand Medtronic is clearly interested in expanding the rhBMP2 label into dental implant indications. Specifically, it appears the company has filed its rhBMP2 PMA (requiring two year follow-up) with the FDA for two indications:

1. Sinus lift; and
2. Extraction socket with buckel defect.

If everything goes well we think it is realistic that Medtronic could get FDA approval in 2H CY06. Initially the focus will be on large bone defects, primarily because the price point of \$3,000-5,000 will be similar as it is for orthopedic spine. Moving forward however, we would not be surprised to see a focus also on smaller defects, which will naturally attract a lower price point. We suspect rhBMP2 will have a niche market segment due to its price and thus will not compete with Straumann's Emdogain.

Other Tid Bits Company Updates

Astra Tech

During Astra Tech's world congress in New York in April 2006, the company is likely to launch a number of new products, geared towards simplifying the restorative process of its dental implants from 3 to 2 lines. In addition, a significant amount of focus will also be given to their recently acquired Cresco Ti Systems, which holds about a 30% share of the dental implant bridge market in Sweden and also strong positions in central Europe.

We understand that AstraTech is growing their dental implant business at +40%, helped by strong investments from its parent AstraZeneca, particular over the past 2 years. A key focus appears to be the lower penetrated U.S. market and more recently Canada, in which they have a total of over 105 sales representatives.

Biomet (3i) - Some Potential Product Issues with Osseotite NT

Based on our field checks it appears that Biomet (3i) did not launch any new products at the AO, with the exception of a temporary abutment system, which in our view is low key. We believe the company's sales continue to suffer from potentially higher implant failure rates on its Osseotite NT implant line, which was launched in 2003. Interestingly, over the past 9 months, an updated version of the aforementioned implant was launched with the Osseotite surface all the way to the top of the implant. Our discussion with a number of clinicians during 3i's corporate forum presentation, highlighted some unhappy customers.

An interesting presentation was given by Dr. Davies (Canada) on the topic of “New Osseotite Surface Enhancements”, which provides a detailed overview of a pending new implant surface that may be released by 3i in 2007. This surface is based on the company’s Osseotite technology, which incorporates a tiny layer of calcium phosphate. Experimental results have demonstrated a 160% increase in mean bone contact area compared to other dual acid etched titanium surfaces.

Dentsply - Some Price Increases

Based on our field checks it appears that Dentsply did not launch any new products during the AO, but did raise prices in January 2005 by 7-9%. This appears to be the first material price increase over the past 5 years.

Zimmer Dental - Logistical Challenges

Based on our field checks it appears that the move of out Zimmer’s old facility in 2005, which is owned by Jerry Niznick, caused logistical issues and resulted in back-orders. We suspect that resulted in the loss of a number of dental implant accounts, which was partly offset by their very strong biologics franchise.

During the AO the company only launched a contoured abutment, which should be followed by a one-piece implant in Q3 2006. In addition a contoured abutment in ceramic will also be launched by Zimmer in 2006, which will be manufactured by Atlantis.

Other Companies

Discount operator **BioHorizons** is expanding its operations into Europe by opening up a sales office in Germany. We understand sales growth currently stands between 20-30%. **Innova**, which forms part of the Sybron group appears to be experiencing sales growth in the 15-20% range. Finally we have noticed an increasing number of Korean manufacturers entering the U.S. market at discount prices including Implantum and ExFeel.

German Market - Recovering Strongly

Our field checks suggest that the German dental market, the world’s second largest, has recovered strongly from the healthcare reforms which were introduced in Q1 2005. We suspect this development will add to our thesis that the dental implant will grow strongly in 2006, at an estimated rate of 18% in constant currency. With 25% of its sales coming from Germany, we feel that Straumann should be a healthy beneficiary in 2006.

Platform Switching - The New Buzz Word

Over the past 12-months we have seen the emergence of new product trend and ‘buzz word’ in the dental implant industry, referred to as ‘platform switching’. This concept, which is being aggressively being pushed by companies such as Biomet (3i) and AstraTech, incorporates the attachment of a smaller diameter or narrower abutment to the dental implant. Although it is not yet clear, early results may suggest a greater chance of maintaining bone around the head of the implant. Based on our observations, it appears that both Nobel Biocare and Straumann do not have a dedicated product offering.

Rough Surface to Top of Implant - Good or Bad?

A paper was published on the topic of “**The Implant Collar and Crestal Bone Levels**” by S. Botos et al. In our view this is a relevant paper to provide a better insight into the issues that were raised surrounding Nobel Biocare’s recent product launches of NobelDirect and NobelPefect, in which the rough TiUnite surface was taken all the way to the top of the implant.

The paper noted that loss of 1.0 to 1.5mm of crestal bone has been observed around implant fixtures. Suggested causes include trauma, excessive loading, stress shielding, microgap infection and reestablishment of biological width. The **purpose** of this study was to compare crestal bone adjacent to the laser microtextured (LMT) and machined collars (MC) fixtures utilizing two different implant systems.

The **method included** four implants with MC and LMT collars (i.e. implant heads), which were placed in the anterior mandible and immediately loaded with prefabricated dentures. Radiographs were taken, scanned into the computer and quantitatively evaluated for bone loss using Autocad 2000.

The **results** with the BioLok machined collars and Nobel's Replace Select (also machined collars) were compared to the BioLok rough surface collar implants. The data showed with respect to crestal bone height that there was no difference between BioLok machined and BioLok rough surface collars. However Nobel Biocare's Replace Select had lower bone levels than the BioLok Laser Lock (i.e. rough collar). It was **concluded** that a rough surface collar such as BioLok of 12 micron grooving for osteoblastic cells and 8 micron grooving for fibroblasts had demonstrated greater crestal bone (but not bone height) and hence soft tissue stability. Although this data is not directly applicable to Nobel Biocare's decision to take its rough TiUnite surface all the way to the top implant of NobelDirect and NobelPerfect, we believe the data suggests that there is no early harm in doing it. However, we would also like to stress that many clinicians we spoke to, said more research needs to be done on this topic to evaluate the long-term impact on soft and hard tissue.

Flapless Surgery

An interesting paper was presented on the dental implant treatment concept of "flapless surgery" by J.M. Kang *et al* on the topic of "**Flapless Surgery – Advantages, Indications and Complications**".

The authors noted that dental implant treatment has been reported to be a reliable and predictable treatment modality for the restoration of fully and partially edentulous patients. Various surgical techniques have been developed since the publication of the original work by Professor Bränemark to decrease the number and duration of surgery and to minimize patient pain and discomfort. Implant placement has been with flapless surgery has been recently advocated in selected cases and perhaps more broadly by Nobel Biocare. However, it was noted that there are only a few reports concerning survival and complications of flapless surgery. The **purpose** of this study is to evaluate the survival of implants placed with flapless surgery and present potential complications of the procedure.

The **method** included patient information in this retrospective study will be obtained from New York University anonymous data base, a pool of patients who were treated at the Ashman Department of Implant Dentistry, New York University.

It was **concluded** that this data will be analyzed and published following the New York University Institutional Board of Research Associates approval. In our view this data, when published, will be reasonably influential in determining whether proponents of flapless surgery, in particular Nobel Biocare with their NobelDirect implant can demonstrate a healthy risk / benefit relationship.

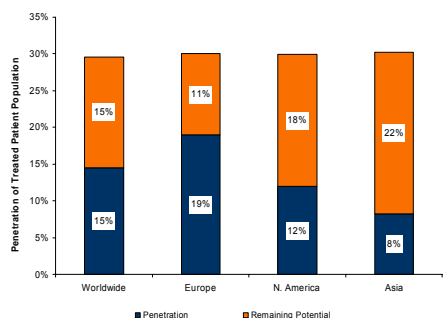
Immediate Loading of Implants in Edentulous Patients

Given that we continue to see the use of dental implants in fully edentulous patients as a very healthy growth opportunity (particularly for Nobel Biocare who with its more aggressive immediate loading marketing concept is more likely to attract more customers), we have decided to provide a summary of paper presented by C. Alpha et al on ***“Immediate Load of the Edentulous Maxilla and Mandible: The All-on-Four Protocol”***.

The paper noted that patients desire immediate replacement of their existing removable prosthesis with a fixed prosthesis. The **method** included 20 patients were treated with 8 Nobel Biocare Bränemark System Mark IV, Mark III and Speed Groovy implants. All prosthesis were fully loaded following surgery.

The **results** showed that all the patients which received the Nobel Biocare “all on four concept” could be loaded immediately. Furthermore, all implants were osseointegrated (attached to bone) and all prosthesis were intact and functional. It was **concluded** that this study compliments previous reports of the success of immediate loading of implants in edentulous patients.

Chart 7: WW Dental Implant Penetration Rates



Source: Merrill Lynch estimates

Investment Conclusion

Following our attendance at the AO meeting in Seattle, we continue to believe in the attractive nature of the dental implant market due to its low penetration rates in Europe, U.S. and Asia, which we currently estimate at 19%, 12% and 8% respectively or ~15% worldwide. It should be noted that our definition of penetration equates to patients treated with dental implants divided by patients who have received conventional technology such as crowns and bridges; this in itself is a conservative definition, as yearly new patients with missing teeth are added to the pool, driven by an ageing population or incidents of trauma.

Fast Growing Market - Many Good Years Left

Provided below is our worldwide dental implant market model, which suggests a constant currency growth rate of 18% for CY06E. We also remain comfortable with our 16% growth rate for CY07E, which could prove to be conservative.

Table 2: Worldwide Dental Implant Market Model

Dec Y/E (US\$m)	CY01E	CY02E	CY03E	CY04E	CY05E	CY06E	CY07E	CY08E
Nobel Biocare	226	256	329	420	523	645	755	863
Growth (%)	12%	13%	28%	28%	24%	23%	17%	14%
LC Growth (%)	17%	12%	19%	22%	25%	23%	17%	14%
Straumann	137	165	249	320	372	426	490	555
Growth (%)	22%	20%	51%	29%	16%	14%	15%	13%
LC Growth (%)	24%	23%	24%	21%	15%	19%	15%	13%
Biomet (3i)	136	158	194	238	270	310	357	410
Growth (%)	15%	16%	23%	23%	13%	15%	15%	15%
LC Growth (%)	15%	16%	18%	19%	12%	15%	15%	15%
Zimmer (Centerpulse)	71	78	98	116	139	152	175	199
Growth (%)	111%	10%	25%	18%	20%	9%	15%	14%
LC Growth (%)	5%	18%	16%	22%	18%	14%	15%	14%
Dentsply (Friadent)	49	56	64	75	87	100	114	130
Growth (%)	18%	15%	15%	18%	15%	15%	14%	14%
LC Growth (%)	18%	15%	15%	18%	15%	15%	14%	14%
Lifecore Biomedical	22	24	29	34	39	45	52	59
Growth (%)		12%	19%	18%	14%	15%	15%	15%
LC Growth (%)	9%	12%	17%	15%	14%	14%	15%	15%
Other	57	66	76	87	100	115	133	153
Growth (%)	-38%	15%	15%	15%	15%	15%	15%	15%
LC Growth (%)	-38%	15%	15%	15%	15%	15%	15%	15%
Total	698	803	1039	1291	1530	1793	2075	2369
Growth (%)	16%	15%	29%	24%	19%	17%	16%	14%
LC Growth (%)	13%	16%	19%	20%	18%	18%	16%	14%

Source: Merrill Lynch estimates. LC = local currency sales growth

For instance, we would not be surprised if the dental implant can continue to grow in the high-teens compared to FY07E and FY08E forecast of 16% and 14% respectively.

Investment Recommendations for Stocks Under Coverage

As highlighted above, we continue to believe that the dental implant market can grow in the high-teens over the intermediate term and thus consider this one of more exciting growth areas in European MedTech. Nevertheless, everything has its price and we feel that the strong investor interest in dental implants over the years has rightfully pushed up the valuations sharply for Nobel Biocare and Straumann. While we continue to see positive returns of the aforementioned companies over the long-term, we feel the current CY06E P/E valuation range of 29-31x does not allow for any material uncertainties.

Nobel Biocare (NBCHF, B-2-7, EUR295.75) - Neutral (Risk Profile Increasing?)

Based on further feedback from the AO, it is difficult to judge as to whether there is anything intrinsically faulty with the NobelDirect or NobelPerfect implant. However, further short-term evidence published by Nobel Biocare during the AO may suggest there is nothing wrong with the implant design itself. Instead, cases which have observed greater than normal bone loss and/or unaesthetic outcomes are more likely to be driven by dentist/surgeon error, inexperience, over-use or not following the procedure manual correctly. While this clearly has no direct implications on Nobel Biocare (at the end of the day it is the surgeons' problem), we are concerned that this may have negative long-term ramifications on the company in other ways.

Specifically, we feel that the market leader not only has the responsibility of producing innovative implant designs backed-up by long-term clinical data, but to incorporate these into a complete package/program to ensure predictable outcomes. This is especially important for Nobel Biocare as the company's strategy includes expanding its customer base beyond specialists into the general dentist population. While we acknowledge that Nobel Biocare's more aggressive management style relative to its competitors has allowed the company to grow faster than the market over the past 2 years, we are concerned that this may have increased the company's risk profile, by its products potentially achieving lower implant success rates in the future compared to the industry benchmarks. We reiterate our 'Neutral' stance.

Straumann (SAUHF, B-2-7, CHF300) - Neutral (Slower Grower But Less Risk)

For highly rated dental implant stocks, such as Straumann, we believe **the valuation requires both high-teens sales growth and margin expansion of 100 basis points, to result in +20% EPS growth.** STMN is likely to approach the required high-teens sales growth through new product launches (i.e. SLActive) as well as easy comparatives in its key market of Germany, but is unlikely to show meaningful margin expansion, due to a strong infrastructure expansion cycle in North America and new product launch costs. These developments are likely to equate to a transition year for STMN in CY06E; the margin dilution of the aforementioned products may also impact 1H CY07E. We retain our **'Neutral'** stance and can understand why the financial market has recently re-assigned a premium rating to Straumann relative to Nobel Biocare, which in our **view is driven by a lower risk rating, which more than offsets the slower top line growth.**

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