

Media release

Leading clinicians present research observations and results on Straumann's new generation Bone Level Implant

- *Data from large pre-launch research and development program presented at EAO in Barcelona and at AAP in Washington D.C.*
- *Highly positive responses from clinicians regarding flexibility and simplicity of system*
- *6 and 12-month results from a clinical study confirm predictable osseointegration and crestal bone preservation, with excellent esthetics*
- *Preclinical studies show excellent and predictable results in terms of crestal bone preservation*
- *Mechanical tests show superior strength of new implant-abutment system*

Basel, 31 October 2007: At two of implant dentistry's most prestigious scientific congresses, the 16th Annual Scientific Meeting of the European Association for Osseointegration (EAO) in Barcelona and the 93rd Annual Meeting of the American Academy of Periodontology (AAP) in Washington, D.C., eleven internationally renowned clinicians and researchers have just presented the latest findings in an extensive research program assessing the Straumann® Bone Level Implant – the new generation bone level implant that Straumann is currently launching in Europe, North America, Australia and New Zealand.

Scientific pedigree with well documented design elements

The Straumann Bone Level Implant combines new and innovative concepts with well-documented design elements such as the unique SLActive surface. Backed by a wealth of completed clinical and pre-clinical studies, together with a large ongoing clinical program, this is one of the best investigated implant surfaces on the market^{1,2,3,4,5,6,7,8,9,10,11,12,13,14,15}. Another scientifically proven and well-documented design element is the implant thread, which comes from Straumann's Tapered Effect Implant. Launched in 2002, this has been documented in several large studies, including multicenter trials, which have shown the implant's outstanding success and survival rates in clinically challenging situations^{16,17,18,19,20}.

To test the overall design and performance of the new bone level implant a preclinical and clinical research program was put together by Straumann in close collaboration with internationally renowned experts.

Biomechanical / property tests

The program started with a range of exacting biomechanical tests, the outcomes of which were presented by Dr Stephen Chen²¹ at the EAO and Dr Frank Higginbottom²² at the AAP.

High precision conical connection

As the microgap between an implant and the abutment is an important element in bone control design, the connection was subjected to rigorous examination. The results demonstrated the very high manufacturing precision of the conical connection, which is used in preference to a flat-top design in order to achieve a tighter seal against bacteria and to minimize micro-movements. Scanning electron microscopy showed the microgap to be just $0.6 \pm 0.3\mu\text{m}$, which puts Straumann Bone Level Implant among the very best in class.

Exceptional biomechanical stability

Extensive mechanical testing was performed to assess ultimate strength and to simulate the effects of prolonged and intense chewing under extreme conditions (fatigue strength). The results show that both the fatigue and ultimate strength of all Straumann Bone Level Implants (\varnothing 3.3mm, \varnothing 4.1mm and \varnothing 4.8mm) is well above the average of tested competitors. In fact, Straumann Bone Level Implants showed higher ultimate and fatigue strengths than larger diameter implants made by leading competitors²³.

Preclinical studies

The preclinical program was summarized by Dr Stephen Chen at the EAO and Prof. David Cochran²⁴ together with Prof. Guiseppe Cardaropoli²⁵ at the AAP. The latest results of the various studies show excellent and predictable bone preservation with the Straumann Bone Level Implant.

Excellent results in terms of predictable crestal bone preservation²⁶

The aim of the first preclinical trial, which was conducted by Prof. Cochran's group and Dr Ronald Jung²⁷, was to evaluate radiographically and histologically the crestal bone changes around the Straumann Bone Level Implant placed either submerged or non-submerged at three different levels relative to the bone crest (1mm above, 1mm below, and level with bone crest). In total 60 implants were placed.

Excellent and predictable bone preservation was reported 6 months after implant loading. Radiography revealed no or only very little bone loss (between zero and 0.5mm relative to the implant-abutment connection in each case). Remarkably, 75% of the implants placed 1mm above bone crest showed positive bone gain after 6 months. Histological specimens were prepared after six months and show excellent osseointegration, confirming the results from the x-ray examinations²⁸.

At the AAP, Professor Cochran noted: "The Bone Level Implant incorporates an abutment diameter that is smaller than the implant diameter and fits inside the implant with a conical connection. On the outside of the implant is the highly osteoconductive SLActive surface. Our pre-clinical study evaluated the reaction of the crestal bone to the implant placed at different levels in relationship to the bone margin. Impressively the bone after 6 months of loading was located in some instances on the bevel of the implant. Additionally, the epithelium and the connective tissue in these cases were located on the abutment surface. This is a remarkable finding and one I have never seen before when the implant configuration includes implant and abutment diameters that are matched resulting in a butt joint connection."

Inter-proximal bone preserved

The aim of a second preclinical study²⁹ was to investigate the bone and soft tissue changes at two adjacent implants that were set either 3 or 4mm apart from each other. The study, which involved 72 implants, recorded a mean radiographic bone gain of 0.2 ± 0.6 mm in the 3mm interproximal distance group (a situation in which crestal bone is difficult to maintain). In the 4mm inter-proximal distance group, the mean radiographic bone gain was 0.2 ± 0.3 mm. The results thus revealed only minimal bone changes and no statistically significant differences between the 3mm and 4mm groups. The radiographic results have been confirmed by histology and μ CT data. Further investigations are underway to evaluate what happens when the distance between the implants is reduced further to 2mm.

Clinical studies

Following the promising pre-clinical results, a broad clinical program was started, including a prospective pilot study, a multicenter study and a non-interventional field trial. To date, some 1500 implants have been clinically documented in over 800 patients by more than 130 centers around the world.

Pilot clinical study

The pilot study³⁰ was conducted to assess the performance, bone level preservation and esthetic outcome of the new implant in single-tooth gaps in the upper front region of the mouth. Data from the study were presented at the EAO by Prof. Urs Belser³¹.

In total, 20 patients were treated and have been followed for a minimum of 12 months after loading of the implant. Straumann Bone Level Implant was shown to offer predictable osseointegration and crestal bone preservation. Three implants showed a change in bone level of more than 0.3 mm, and only one implant demonstrated slight (approximately 0.9 mm) bone loss at 6 months. However, the situation in this particular case had improved at 12 months. No soft tissue complications (such as gingival recession) have been reported, i.e. stable peri-implant soft tissues have been observed.

Randomized controlled clinical study

A randomized, controlled clinical study is also underway and was presented in Barcelona by the principal investigator Prof. Christoph Hämmerle³². It compares submucosal with transmucosal placement of Straumann Bone Level Implants in single tooth gaps. Interproximal bone levels, soft tissue parameters and the influence of the healing protocol on esthetic outcomes are also being evaluated.

The study involves 134 patients in 12 centers in 7 countries. To date, more than 110 implants have been placed, with one loss reported. No adverse events and no major complications have been reported. As the study is still ongoing, the results will become available in due course. However, the feedback from study centers so far is very positive.

Non-interventional clinical study

A non-interventional study³³ was set up to document the success and survival rates of Straumann Bone Level implants in everyday practice in all approved indications for up to 3 years after implant placement. 'Non-interventional' means that clinicians are free to include all indications and apply their preferred treatment approach with minimal intervention by the study organizer. The patient-dentist interaction is therefore not influenced by protocol or other interventions. As a result, the study provides a realistic picture of actual patient pools and treatment protocols. It also provides insight into how the implant is used and how it performs in clinical situations, with the intention of validating the data from controlled trials.

Professor Juan Blanco-Carrion³⁴ presented data from this study at the EAO. To date, 118 international centers have placed and documented more than 1370 implants in 729 patients. Of these, just 5 implant losses have been reported, indicating a very high success rate. Over 440 implants have been observed for more than 6 months, the timeframe in which early implant failure in general is most likely to occur. Up to now, no major adverse events or complications have been reported. Overall, the data show that clinicians perceive the new implant as an excellent solution for a wide range of indications.

Summary

Very positive responses from clinicians

In general the investigators have highlighted the following attributes:

- Reliability: the implant respects all 5 key biological principles and is thus designed to optimize crestal bone preservation (Bone Control Design™). Scientific data on the Straumann Bone Level Implant confirm the positive effect of this concept.
- Ease of handling: here a number of features were noted: for example the fact that the CrossFit™ connection, gives the restorative doctor confidence that the abutment has seated correctly, and the fact that the same instrument kit can be used. The latter benefit translates into time savings for the practice staff with regard to cleaning and sorting.
- Increased versatility and flexibility of the new implant line extension: the Straumann Dental Implant system now offers the dental professional unmatched flexibility, as all Straumann's implants use one instrument kit and the same procedures.

Confidence at every level

The combination of its design features, together with the current body of scientific and clinical data, provides dental professionals with a completely new level of confidence at bone level. This will be further strengthened through the addition of new data as the ongoing clinical program progresses.

Straumann is the only company that offers a full range of tissue- and bone-level implant options combined with state-of-the-art CAD/CAM prosthetics and regenerative solutions.

Further information

More details about the Straumann Bone Level Implant are published in the current edition of *STARGET*, Straumann's customer magazine, and at www.straumann.com.

Presentation slides, pictorials, and other information can be downloaded from www.straumann.com.

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About Straumann

Headquartered in Basel, Switzerland, the Straumann Group (SWX: STMN) is a global leader in implant and restorative dentistry and oral tissue regeneration. In collaboration with leading clinics, research institutes and universities, Straumann researches, develops and manufactures dental implants, instruments, prosthetics and tissue regeneration products for use in tooth replacement and restoration solutions or to prevent tooth loss. Straumann currently employs approximately 1790 people worldwide and its products and services are available in more than 60 countries through its broad network of distribution subsidiaries and partners.

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- ²³ Summarized in *STARJET* 2007/4 pp. 24-25.
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