

Media release

Straumann launches SLActive implant technology, setting new standards in implant dentistry

- *Latest clinical results show highly significant difference in implant stability between SLActive and the current gold standard*
- *Innovative oral bone ceramic launched in US sooner than expected*

Munich, 22 September 2005: At the 14th Scientific Meeting of the European Association for Osseointegration (EAO) in Munich today, Straumann, a global leader in implant dentistry and dental tissue regeneration, announced the European and Asian launches of its new-generation implant surface technology SLActive, which reduces implant healing times by half. The US launch of SLActive will follow in March.

Also at the EAO, important clinical results were announced for SLActive, adding to the formidable body of scientific evidence supporting the new surface. In particular, results from a dual-center, prospective, randomized, controlled trial (RCT) in patients show a statistically significant improvement in stability with SLActive implants, compared with the gold standard SLA surface, during the critical early treatment period - when patients are most at risk to implant failure.

The company also announced the US launch of its innovative bone ceramic for treating patients with insufficient bone for implant therapy. Originally the product introduction had been slated for next year as part of the global roll-out. Straumann said that clinicians had reacted overwhelmingly positively in pre-market testing, prompting the company to launch the product fully in US.

SLActive

Straumann's SLActive implant surface technology promises to set a new standard in tooth replacement and patient care and is supported by more scientific studies than any other dental implant technology at market launch.

Healing times halved to 3-4 weeks

When Straumann developed the SLA implant surface in 1994, it dramatically reduced healing times from 12 to 6 weeks. SLA consequently became the gold standard in implant dentistry and has hitherto remained the scientifically proven benchmark. With SLActive, the next generation of implant technology, Straumann has again cut healing times by half, bringing them down to 3 to 4 weeks. The implications of this are: shorter treatment protocols, higher predictability and reduced risk with earlier loading, resulting in better patient care.

Greater implant stability in critical stage of healing

SLActive uses the same initial manufacturing process as SLA, involving Sandblasting with Large grit followed by Acid etching to achieve an optimal topography for bone cells to attach themselves. SLActive is then conditioned in nitrogen and immediately preserved in an isotonic saline solution. This maintains its high surface activity, which would otherwise be lost due to reaction with the atmosphere.

Conventional titanium surfaces are hydrophobic and thus repel fluids, whereas the chemical purity and retained surface energy of SLActive give it remarkable hydrophilic properties. As a consequence, it quickly attracts blood and proteins, potentially promoting the process of bone formation around the implant to give it increased early stability.

On the basis of preclinical results, these properties accelerate the healing process of osseointegration so that early bone-to-implant contact is significantly increased around the whole surface – not just the thread contours. This in turn results in greater implant stability, especially in the critical early stage of healing.

Implants most at risk 2-4 weeks after placement

Conventional implants are most at risk between 2 and 4 weeks after placement. This is when the primary mechanical stability, achieved by screwing the implant into the bone, has begun to erode as osteoclasts perform the process of resorbing the contact bone around the implant. At the same time, the bone-forming process, in which osteoblasts make new and replacement bone, is not far enough advanced to provide sufficient secondary stability. Preclinical studies investigating bone apposition against the SLActive surface have shown 60% more bone formation after 2 weeks compared with SLA.

The current clinical results build on and confirm preclinical observations.

Clinical trials

Randomized, controlled, clinical trial shows highly significant increase in implant stability during critical loading period

A team led by Professor David Cochran of the University of Texas Health Science Center, San Antonio, USA, has just completed a dual-center, prospective, randomized, controlled, clinical trial to evaluate the comparative stability of SLActive and SLA in patients over the first 6 weeks of healing. To do this, the investigators used a special resonance-frequency-measuring device (Osstell™) to measure the implant stability non-invasively in the jaw. The results demonstrate a highly significant difference in stability patterns between SLActive and SLA implants during the critical early treatment period between weeks 2 and 4. This outcome suggests that osseous healing (osseointegration) occurs much faster around the hydrophilic SLActive implant surface than around conventional, hydrophobic surfaces. The change in stability pattern of the SLActive implant was twice as fast (2 weeks vs. 4 weeks) relative to SLA, which is consistent with preclinical results. The findings prove in patients that SLActive offers accelerated healing and greater implant stability in early healing periods and therefore offers increased safety. A scientific publication is in preparation and the results of the study will be presented in detail at the 2006 Academy of Osseointegration meeting in Seattle.

Early loading, three weeks after placement in patients

A clinical study is also being conducted by the Universities of Bern and Florida to investigate the effect of early loading of SLActive implants in 60 patients. The results suggest that the risk of implant loss is not increased by early loading of SLActive implants just 21/22 days after placement, in comparison with conventional implant loading protocols (between 6 weeks and 3 months after placement). The first scientific publication is planned for 2006.

Immediate and early loading working well; high patient satisfaction

New results of the multicenter study of SLActive in 19 centers around the world were presented at the EAO by Prof. Zöllner (University of Witten/Herdecke, Germany). In this study, which focuses on critical indications - including immediate and early loading, patients are randomized to receive the provisional restoration either immediately or 4 weeks (early) after implant placement. So far, 288 patients have been randomized and 260 have undergone surgery. To date, final prosthetic restorations have been completed in 142 patients. 363 implants have been placed with an implant survival rate of 98%, which is very promising in view of the challenging indications and aggressive protocol. At this stage, the investigators conclude that, despite the aggressive protocol, immediate and early loading with SLActive achieves excellent survival rates - well above the average mean results of comparable representative clinical studies. The interim results are also in line with the conclusions from pre-clinical studies and the aforementioned RCT study. Furthermore, the immediate and early loading protocols showed equal survival rates, proving once more that SLActive enhances implant stability during the critical loading period between weeks 2 and 4.

Straumann Bone Ceramic launched in the US

Approximately one in five patients needing tooth replacement do not have adequate bone to provide sufficient stability for a dental implant. Such cases are most commonly treated with a bone graft, although the process of harvesting/removing bone from the donor site in the patient can be painful and is associated with risks. One alternative is to use materials from another human source or from animals, which may be associated with a potential risk for disease transfection. Fully synthetic bone graft materials provide a solution to these obstacles, but available products are limited by their absorption or handling characteristics.

Straumann Bone Ceramic is a novel, fully synthetic bone-graft substitute with improved resorption properties and outstanding handling convenience. Its composition of hydroxyapatite (HA) and tricalcium phosphate (β -TCP) gives it two-phases of activity: firstly it supports the formation of new vital bone and maintains mechanical stability, and secondly it enhances the subsequent replacement of new tissue with mature laminar bone.

Straumann Bone Ceramic has already gained CE certification in Europe and clearance from the Food and Drug Administration in the USA. The overwhelming positive reaction in the clinical program has prompted Straumann to broaden its selective introduction by fully launching the product in the USA. Straumann will present the product at key dental meetings in the US in the course of the next few days.

Further information

More details about SLActive are published in the current edition of *Starget*, Straumann's customer magazine, and at www.straumann.com/slactive.

Presentation slides, pictorials, and other information can be downloaded from www.straumann.com. A selection of **photographs** is available for a limited period at http://straumann.imagedirector.net/album?album_code=lbrac5dix5td

About Straumann

Straumann is a global leader in implant dentistry and dental tissue regeneration. Since its foundation in 1954, the Swiss-based company has been driven by a passion for scientific discovery and belongs to the pioneers of modern dental implantology.

Straumann researches, develops, produces and distributes dental implants, instruments and tissue regeneration products. It works closely with the International Team for Implantology (ITI), an independent international network of eminent clinicians and researchers, as well as leading clinics, research institutes and universities.

With its roots in Swiss precision and clinical excellence, the Straumann® Dental Implant System is renowned for its exceptional quality and is one of the most extensively scientifically documented implant systems in the world. Several million Straumann implants have been placed, providing dental replacement solutions that are widely regarded as the closest thing to natural teeth.

Straumann also develops and manufactures products that help to heal periodontally compromised teeth or to support implant procedures. These include innovative products such as Emdogain®, a convenient protein-based gel which regenerates the periodontal tissue that supports the teeth. Its indications include the treatment of tissue recession due to periodontitis.

In 2004, the Straumann Group generated sales of CHF 420 million of which approximately 6% are re-invested in research and development, making Straumann one of the leading contributors to research and development in the field. With its global business expanding at a compound average rate of 20% over the past 4 years, Straumann has created a number of new employment opportunities, increasing its staff to more than 1200 employees worldwide. From its headquarters in Basel, Switzerland, Straumann's products and services are available in more than 60 countries through the company's subsidiaries and broad network of distributors.

Disclaimer

This press release contains certain "forward-looking statements", which can be identified by the use of terminology such as: "healing time", "initial", "promises", "potentially", "will", "suggest", "may", "risk" or similar wording. Such forward looking and other statements include statements regarding trial outcomes and statements that reflect the current views of independent researchers and/or of management and are subject to known and unknown risks, uncertainties and other factors that may cause actual results, performance or achievements to differ materially from those expressed or implied. These include risks related to the success of and demand for the Group's products, the potential for the Group's products to become obsolete, the Group's ability to defend its intellectual property, the Group's ability to develop and commercialize new products in a timely manner, the dynamic and competitive environment in which the Group operates, the regulatory environment, changes in currency exchange rates, the Group's ability to generate revenues and profitability, and the Group's ability to realize its collaboration projects in a timely manner. Should one or more of these risks or uncertainties materialize, or should underlying assumptions prove incorrect, actual results may vary materially from those described in this release. Straumann is providing the information in this release as of this date and does not undertake any obligation to update any forward-looking statements contained in it as a result of new information, future events or otherwise.

Contact

Mark Hill
Straumann Corporate Communication
+41 (0)61 965 13 21 (office)
+41 (0)79 320 24 77 (mobile)
mark.hill@straumann.com

Straumann Holding AG, Peter Merian-Weg 12, 4002 Basel, Switzerland.
Phone: +41 (0)61 965 11 11 / Fax: +41 (0)61 965 11 01
E-Mail: corporate.communication@straumann.com
Homepage: www.straumann.com