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Media release

Leading researchers present scientific proof that SLActive surface technology significantly cuts implant healing time

Scientific evidence from completed preclinical trials and ongoing clinical studies indicate:

- *Faster osseointegration*
- *60% more bone with SLActive 2 weeks after placement*
- *Reduced healing times from 6 to 3-4 weeks*
- *Higher predictability and reduced risk with earlier loading*

compared with SLA®, the current gold standard.

Munich, 20 June 2005: At the ITI (International Team for Implantology) World Symposium in Munich, which began on Saturday and concludes today, leading researchers presented the initial body of scientific evidence to support SLActive, Straumann's innovative implant surface technology, which promises to set a new standard in tooth replacement and patient care. Some 2600 congress participants heard presentations on preclinical studies and initial reports from the ongoing clinical (human-trial) program. SLActive is supported by more scientific studies than any other dental implant technology at the point of market launch because it is based on - and goes beyond - the scientific, clinical data for the current SLA surface.

When Straumann developed the SLA implant in 1994, it dramatically reduced healing times from 12 to 6 weeks. With its roughened, acid-etched surface, the osseoconductive macro and microstructure of SLA became the gold standard in implant dentistry. Although other manufacturers have imitated the roughened surface, SLA has hitherto remained the scientifically proven benchmark. With SLActive, the next generation of implant technology, Straumann has once 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.

SLActive uses the same initial manufacturing process as SLA, involving Sand-blasting with Large grit followed by Acid etching to achieve an optimal topography for bone cells to attach themselves. Using an innovative manufacturing process, 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 chemical reaction with the atmosphere. SLActive's chemical activity gives it remarkable hydrophilic properties and high surface energy. On the basis of preclinical results, these properties accelerate the healing process of osseointegration with the result that early bone-to-implant contact is significantly increased. This in turn results in greater implant stability, especially in the critical early stage of healing.

Professor David Cochran (University of Texas Health Science Center, San Antonio, USA) explained why conventional implants are most at risk in the period of 2 to 4 weeks after

placement. At this time, there is a temporary decrease in implant stability. This is because the primary mechanical stability achieved by screwing the implant into the bone has begun to erode as osteoclasts perform the process of resorbing bone around the implant. The bone-forming process, in which osteoblasts make new and replacement bone, is not far enough advanced to provide sufficient secondary stability.

Professor Jürgen Geis-Gerstorfer (Tübingen University, Germany) presented the concept of hydrophilicity, explaining how conventional titanium surfaces are hydrophobic and thus repel fluids such as blood or serum. The chemical purity and retained surface energy of SLActive give it marked hydrophilic properties. As a consequence, it quickly attracts blood to the implant surface, potentially promoting the process of bone formation around the implant to give it long-term stability.

The work presented by Professor Barbara Boyan (Georgia Institute of Technology, Institute of Bioengineering and Bioscience, Atlanta, USA) expands on the practical implications of this theory and illustrates the importance of both surface topography and chemistry working together to achieve exceptional results. Her studies showed for the first time that the chemically-active, hydroxylated SLActive surface exhibits significantly improved cell response in vitro compared with conventional SLA and control surfaces. Moreover, the osteoconductive properties associated with the complex microtopography of the SLA surface were enhanced by the SLActive technology. Cells on SLActive showed to be much more active bone cells. Importantly, these in-vitro studies revealed that, in addition to an elevation in markers for bone formation, the SLActive surface also showed a reduction in bone resorbtion regulators.

Professor David Cochran also reviewed 4 preclinical studies investigating bone apposition against the SLActive surface. Results showed that there was 60% more bone formation around the SLActive surface after 2 weeks compared with SLA. Furthermore, strength of bone to implant was also significantly higher with SLActive at the same very early stage of 2 weeks after implant placement. Histological examinations revealed that the quality of bone formation was more advanced with SLActive after 2 weeks. Professor Cochran also presented a dual-center prospective randomized controlled clinical trial (RCT) in patients. This study is underway to evaluate the comparative stability of SLActive and SLA over the first 6 weeks of healing using a special resonance-frequency-measuring device (Osstell™) to assess implant stability. Preliminary findings point towards an increase in early implant stability with SLActive. Summarizing, Professor Cochran noted that SLActive technology has the advantage of faster healing with greater early stability. This in turn allows for earlier restorations and reduces the risk of interference during the healing process. He concluded that SLActive would bring practitioners closer to the goal of providing the best possible care to patients.

Associate Professor Dean Morton (Center for Implant Dentistry, University of Florida, USA) presented first results from an ongoing clinical study conducted by the Universities of Bern and Florida. In this study, implants were early loaded after 3 weeks in 60 patients. Preliminary results suggest that early loading of SLActive implants just 21/22 days after placement does not increase risk or implant loss when compared to conventional implant loading protocols (between 6 weeks and 3 months). Additional field and multicenter trials are ongoing to confirm the results of this study. Professor Morton concluded that SLActive may lower treatment risk in a variety of clinical indications.

Dr Kerstin Fischer (Consultant in oral-maxillofacial surgery, Falun, Sweden) presented the first clinical results from a multicenter study of SLActive in 17 centers around the world. Demanding indications, for example multiple implant sites, were included in this study.

Patients are randomized to receive the provisional restoration either immediately or 4 weeks (early) after implant placement. So far, 209 patients have been randomized and 174 have undergone surgery. To date, final prosthetic restorations have been completed in 103 patients. In total, the study plans to include more than 240 patients. So far, 249 implants have been placed with an implant survival rate of 98.4%, which is very promising in view of the challenging indications and protocol. Dr Fischer concluded that immediate and early loading with SLActive is working well and the level of patient satisfaction is high.

To date, more than 500 SLActive implants have been placed and further clinical results will be presented at the European Association for Osseointegration (EAO) meeting in September. The stepwise introduction of SLActive is underway and the product will be available to customers in Europe and Asia in September, and in the USA in March 2006.

Further information

Further information about SLActive is published in the current edition of *Starget*, Straumann's customer magazine, and on the SLActive web page: www.straumann.com/slactive.

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 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. Over the past ten years, several million Straumann implants have been placed, providing patients with 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 approximately 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.

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