

## Media release

### **Results from large international clinical trials provide dentists and patients with a new level of confidence in dental implants**

**Basel, 6 August 2013:** Results from two of the largest international clinical studies performed to date with dental implants have just been published and demonstrate excellent clinical performance. Together, the studies have evaluated more than one thousand Straumann Bone Level implants in Europe, the US and Australia. The scope of these studies is particularly remarkable in view of the fact that most dental implant companies do not conduct clinical trials because they want to cut costs and do not have the capabilities.

The studies are also remarkable in that they both reported very high implant survival rates of more than 98% with practically no bone loss around the implants. The findings are considerably better than values reported in a comprehensive review of previously published studies with other implants<sup>1</sup>. The new studies add to the wealth of strong clinical evidence backing the Straumann dental implant system and thus provide very good reasons for patients and dentists to insist on Straumann implants rather than undocumented alternatives.

#### **The benchmark in clinical research**

The first study was a randomized controlled clinical trial (RCT) at 11 clinical centers in Europe, USA and Australia<sup>2</sup>. RCTs are the benchmark in clinical research because they offer the highest level of clinical evidence. However, few are performed with dental implants and very rarely on such a large scale.

This RCT has evaluated 106 patients each treated with one implant and followed for three years. The investigators compared the outcomes of two different approaches – the first involving two surgical steps, in which the implant is covered with gum tissue ('submerged') during healing, and the second involving just a single step, in which part of the implant is left exposed ('transmucosal') thus saving a second surgical operation. The most impressive highlight reported was the fact that only a single implant was lost, yielding 3-year implant-survival rates of 98.1% and 100% for the transmucosal and submerged groups respectively.

Because bone loss around implants has been documented as a common undesirable effect of implant treatment<sup>3</sup>, this study looked carefully at bone level changes. It showed that bone level was impressively stable over 3 years after implant placement, with mean decreases of less than 0.7 mm and 0.6 mm in the submerged and transmucosal groups respectively. These values are well below the data presented in previous studies with other implants. An analysis of published data showed that only three implant systems achieved mean marginal bone loss below 1 mm over a period of 5 years<sup>1</sup>.

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<sup>1</sup> Laurell L, Lundgren D.: Marginal bone level changes at dental implants after 5 years in function: a meta-analysis. Clin Implant Dent Rel Res 2011; 13, 19-28

<sup>2</sup> Sanz, M, Ivanoff, CJ, Weingart, D, Wilfgang, J, Gahlert, M, Cordaro, L, Ganeles, J, Bragger, U, Jackowski, J, Martin, WC, Jung, RE, Chen, S, Hämmerle, C: Clinical and radiologic Outcomes after Submerged and Transmucosal Implant Placement with Two-Piece Implants in the Anterior Maxilla and Mandible: 3-Year Results of a randomized Controlled Clinical trial. Clin. Impl Res, e-pub ahead of print

<sup>3</sup> Qian J, Wennerberg A, Albrektsson T.: Reasons for marginal bone loss around oral implants. Clin Implant Dent Relat Res. 2012 Dec;14(6):792-807

### **Excellent results also achieved in everyday practice**

While RCTs demonstrate that products or treatments work well, they are usually conducted by specialists in selected and strictly controlled populations. This study was performed by dental practices and University clinics that are highly specialized in dental implantology, which raises the question of whether its excellent results can be reproduced in daily dental practice. To answer this, a large study using the same implant was conducted in Europe and the US, in which the dentists had to follow the product guidelines but were able to use the implant as they would in normal daily practice. The strength of this type of investigation, which is known as 'non-interventional study' (NIS), is that it documents real-life situations, in which indications, patients and conditions all vary widely.

In this study<sup>4</sup>, a total of 908 implants were evaluated in 538 patients at more than a hundred dental practices in six countries, revealing an implant survival rate of 98.5% after one year (the risk of failure is highest in the first year after implant placement<sup>5</sup>). Besides the very high survival rates, the bone level remained very stable in the majority of cases. The investigators therefore concluded that treatment with Straumann Bone Level Implants yielded very successful outcomes in 'real life' conditions.

### **Results impress further when viewed in the context of other published data**

The survival rates reported in both studies are higher than those documented in the literature. The most recent analysis of published data on other implants showed an overall implant survival rate of 95.5% one year after implant placement<sup>5</sup>, in contrast to the 98.5% achieved in this NIS in daily dental practice conditions.

#### **About Straumann**

Headquartered in Basel, Switzerland, Straumann (SIX: STMN) is a global leader in implant, restorative and regenerative dentistry. 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 2300 people worldwide and its products and services are available in more than 70 countries through its broad network of distribution subsidiaries and partners.

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<sup>4</sup> Filippi A, Higginbottom FL, Lambrecht T, Levin BP, Meier JL, Rosen PS, Walkkamm B, Will C, Rocuzzo M: A prospective noninterventional study to document implant success and survival of the Straumann Bone Level SLActive dental implant in daily dental practice. Quintessence Int 2013;44(7):499-512.

<sup>5</sup> Hartog L, Huddleston SlaterJJR, Vissink A, Meijer HJA, Raghoobar GM: Treatment outcome of immediate, early and conventional single-tooth implants in the aesthetic zone: a systematic review to survival, bone level, soft-tissue, aesthetics and patient satisfaction. J Clin Periodontol 2008; 35: 1073-1086