# STUDY OVERVIEW ON STRAUMANN® BONE LEVEL IMPLANT

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**STRAUMANN® BONE LEVEL IMPLANT**

**Property Tests**

**Study**

**Mechanical testing of ultimate strength**

**Principal investigators**

M. Wieland, H. Hornberger, Switzerland

**Setup**

According to fatigue test for endosseous dental implants (ISO 14801). A total of 19 implants were measured.

**End-point**

Static compression tests were performed for Ø 3.3 mm, Ø 4.1 mm, and Ø 4.8 mm Straumann® Bone Level implants as well as for different competitor implants until ultimate implant strength was reached.

**Key findings**

Straumann® Bone Level implants reach ultimate strength of competitor implants with smaller diameters tested in this study.

**Study**

**Mechanical testing of fatigue strength**

**Principal investigators**

M. Wieland, H. Hornberger, Switzerland

**Setup**

According to fatigue test for endosseous dental implants (ISO 14801). A total of 142 implants were measured.

**End-point**

Load-cycle diagrams were performed for Ø 3.3 mm, Ø 4.1 mm, and Ø 4.8 mm Straumann® Bone Level implants and for 13 competitor implants. In this evaluation, average measured fatigue strength of 3 Straumann® Bone Level implants was higher than the average failure strength of 13 competitor implants.

**Study**

**Microgap measurements on polished micrograph sections**

**Principal investigator**

M. De Wild, Switzerland

**Setup**

Measurement of microgap between implant and abutment using polished micrograph sections and scanning electron microscopy.

**End-point**

Microgap measurements were performed.

**Key findings**

The mean microgap is below 1 µm.

* Data on file
The influence on non-matching implant and abutment diameters on radiographic crestal bone in dogs.

RE. Jung, AA. Jones, FL. Higginbottom, TG. Wilson, J. Schoofield, D. Buser, CHF. Hämmerle, DL. Cochran
J Periodontol 2008; 79: 260–270

Introduction
An important factor in crestal bone loss around two-piece implants appears to be the position of the implant-abutment interface relative to the bone crest. A second relevant factor seems to be the abutment diameter relative to the implant diameter. A smaller abutment diameter may help to reduce bone loss by displacing the implant-abutment interface, and the inflammatory cell infiltrate, away from the crestal bone (Figure 1). The aim of this study was therefore to evaluate radiographic crestal bone changes around Straumann Bone Level implants with smaller abutment diameters placed at different levels relative to the alveolar crest.

Materials and Methods
In five dogs, a total of 60 bone level implants with smaller abutment diameters were placed bilaterally, either submucosally or transmucosally. In each side of the mandible, the implants were randomly placed with the implant shoulder either at the level of the alveolar bone crest or 1.0 mm above or 1.0 mm below (Figure 2). In the transmucosal group, the healing abutments were different lengths so that the final occlusal height was the same for each implant. Healing abutments were placed on the submucosal implants after 4 weeks. Prostheses (gold crowns) were placed on titanium meso abutments on all implants 12 weeks after implant placement. Radiographic analysis was performed at implant placement, crown placement and every month for up to 6 months.
Results

Very small changes of the crestal bone level were detected in the X-rays for both groups (Figures 3 and 4). For implants placed submucosally, the mean bone loss at 6 months after loading was +0.17 mm (slight bone gain), -1.32 mm and -0.15 mm for implants placed above, below or at the crestal bone level, respectively (Figure 5). Corresponding bone loss for transmucosal implants placed above, below and at the crestal bone level was -0.20 mm, -1.40 mm and -0.47 mm, respectively (Figure 6). No significant differences in bone loss or the level of bone-to-implant contact (BIC) were noted between submucosal or transmucosal implants. Bone loss was greatest at implants placed below the level of the crestal bone; however, the distance from the implant shoulder to the first BIC with these implants was similar to that for implants placed at the level of the crestal bone (mean 0.19 mm and 0.26 mm for submucosal implants, mean 0.14 mm and 0.44 mm for transmucosal implants).

Conclusions

- Straumann® Bone Level implants did not show radiographic differences in the crestal bone level after 6 months of loading in an animal model.
- There is no significant difference between submucosal and transmucosal approaches in this canine study.
Changes in crestal bone and soft tissue at two adjacent Straumann Bone Level implants with different inter-implant distances.

N. Elian, M. Bloom, G. Cardaropoli, B. Ehrlich, M. Dard, D. Tarnow

Introduction
Bone loss around implants has both a lateral as well as a vertical component, and studies have shown that implants placed too close together can reduce the height of the inter-implant bone crest.\textsuperscript{1,2} Platform-switching may help to reduce the inter-implant bone loss, so it was therefore suggested that platform switching in combination with a bone level implant that shows minimal bone loss may allow the closer placement of implants without compromising the inter-implant bone and soft tissue.

Materials and Methods
The mandibular premolars and the first molar from 12 minipigs were extracted. After 3 months of healing 72 implants were placed using a template guide. Three bone level implants with SLActive\textsuperscript{®} surfaces were placed at bone crest level on one side of the mandible with an inter-implant distance of 3 mm while on the contralateral side the distance was 4 mm. One stage procedure was used with abutment placement at time of surgery utilizing a transmucosal abutment healing cap. Radiographic measurements of the bone levels were done at placement and after 8 weeks. The following histomorphometric measurements were performed in a defined region of interest (ROI): first bone to implant contact (fBIC), length of barrier epithelium (lBE), length of junctional epithelium (lJE) and length of connective tissue in contact with the implant surface (lCT).

Results
Of the 72 implants placed, one implant was lost (in the 4 mm group) after 8 weeks.

Radiographic analysis: A mean bone gain of 0.2 mm ± 0.6 mm adjacent to the implants was recorded in the 3 mm inter-proximal distance group while a bone gain of 0.2 mm ± 0.3 mm in the 4 mm inter-proximal distance group was measured. There were no significant differences between the groups for the bone level measurements.

Histological results were referenced in figure 1.

Conclusions
- Mean bone gain of 0.2 mm was observed radiographically adjacent to implants in both the 3 mm and 4 mm groups
- Bone was maintained in the inter-proximal areas in both groups
- Soft tissue remained stable over 8 weeks in both groups
- There were no significant differences between 3 mm and 4 mm inter-implant distances for any of the parameters
- Results from this study suggests that Straumann Bone Level implants can be placed as close as 3 mm apart without compromising the inter-implant bone and soft tissue


Introduction

Early implant placement following extraction of a single tooth is a procedure used by many clinicians in the maxillary anterior zone, but there is a lack of documentation on esthetic outcomes. Four studies for single-tooth implant placement reported mucosal recessions in post-extraction sites. The aim of this study, therefore, was to prospectively assess esthetic outcomes of early implant placement in single-tooth gaps in the esthetic zone with Straumann® Bone Level implants.

Materials and Methods

A total of 20 patients requiring single-tooth replacement in the anterior maxilla were entered into the study. Exclusion criteria were systemic diseases that could alter the tissue integration of dental implants, pregnancy, or smoking > 10 cigarettes per day. After tooth extraction the socket was allowed to heal for 4–8 weeks. Bone level implants were subsequently placed, sealed with healing caps, with simultaneous contour augmentation using GBR with deproteinized bovine bone mineral and a collagen membrane. Reopening was performed 8–12 weeks later (Day 0). Within 7 days, provisional crowns were placed, which were gradually enlarged if necessary to optimize soft tissue contours. Final all-ceramic restorations were placed after 6 months.

The clinical parameters measured were modified plaque index (mPLI), modified sulcus bleeding index (mSBI), probing depth (PD), width of keratinized mucosa (KM), distance from mucosal margin to implant shoulder (DIM), distance from implant shoulder to first bone-to-implant contact (DIB), and mid-facial height of implant crown and contralateral tooth. Pink esthetic score and white esthetic scores were evaluated as primary endpoint.

Results

All implants were successfully integrated at 12 months, with no sign of implant mobility. The peri-implant soft tissues revealed little tendency to bleed following probing and were clinically healthy. The implants fulfilled successful tissue integration, and the results were in line with those from other prospective studies with the same parameters. Mean mPLI, mSBI, and PD values at 12 months were 0.36, 0.21, and 4.43 mm, respectively (Table 1). A wide KM band was seen at 3 months, which remained stable at 6 and 12 months (Table 1).

Mean DIB values at 3, 6, and 12 months were 0.09, 0.14, and 0.18, respectively (Table 1). The radiographic analysis indicated that 15 of 20 implants showed minimal bone resorption (Figure 1), and only one implant showed bone loss > 0.5 mm, with minor mucosal recession of 0.5–1.0 mm. Mean DIM values at 12 months were -6.68, -6.00, -3.53, and -3.84 for mesial, distal, facial, and oral, respectively.

Predictable contour augmentation with an anorganic bovine bone mineral therefore showed a reduced risk of mucosal recession, compared to other studies that have shown mucosal recession of 30–40%.

Table 1: Clinical and radiographic parameters at 3, 6, and 12 months

<table>
<thead>
<tr>
<th></th>
<th>3 mos</th>
<th>6 mos</th>
<th>12 mos</th>
</tr>
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<tbody>
<tr>
<td>mPLI</td>
<td>0.08 ± 0.24</td>
<td>0.08 ± 0.20</td>
<td>0.36 ± 0.33*</td>
</tr>
<tr>
<td>mSBI</td>
<td>0.26 ± 0.29</td>
<td>0.16 ± 0.23</td>
<td>0.21 ± 0.17</td>
</tr>
<tr>
<td>PD</td>
<td>3.69 ± 0.62</td>
<td>3.75 ± 0.46</td>
<td>4.43 ± 0.57*</td>
</tr>
<tr>
<td>KM</td>
<td>4.06 ± 1.43</td>
<td>4.10 ± 1.41</td>
<td>4.50 ± 1.54</td>
</tr>
<tr>
<td>DIB</td>
<td>0.09 ± 0.16</td>
<td>0.14 ± 0.25</td>
<td>0.18 ± 0.20*</td>
</tr>
</tbody>
</table>

*Values are statistically significant compared to values at previous measurements

Mean pink and white esthetic scores were 8.10 and 8.65, respectively (total score = 16.75), indicating favorable esthetic outcomes. The maximum for both pink and white esthetic scores is 10, and the threshold for clinical acceptability is 6/10 for each index.

Conclusions

- Minimal crestal bone resorption was demonstrated
- Good esthetic and clinical results were seen over 12 months
- The risk of mucosal recession was low
- Strict success criteria were fulfilled, resulting in 100% success and survival rates at 12 months
- The 20 implants from this study showed an average bone loss of 0.18 mm between the day of loading and 12 months of follow-up

Fig. 1: The majority of patients (75%) showed < 0.25 mm bone loss

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Randomized, controlled clinical study comparing submerged versus transmucosal placement of bone level implants in the anterior maxilla or mandible by evaluation of the change in bone level between first stage surgery and 12 months post-surgery

CHF Hämmerle, M. Sanz, St. Chen, W. Martin, J. Jackowski, L. Cordaro, Cj Ivanoff, J. Ganeles, R. Jung

Introduction

The surgical procedure and implant design both influence esthetic outcomes. For example, a submerged technique may be preferred to establish esthetics and function in anterior sites, and implants where the metallic shoulder is reduced may help to improve the esthetics of the restorations. The marginal bone change over time is another important factor,1,2 with a historical success criterion being bone loss of no more than 0.5 mm in the first year and < 0.2 mm annually thereafter.

This investigation was designed to evaluate the amount of bone level change with submerged and transmucosal healing, and to assess any difference in bone level change between the two procedures with Straumann® Bone Level SLActive® implants.

Materials and Methods

Implants to replace single teeth in the anterior region (maxilla or mandible) were placed in a total of 146 patients in 12 centers in seven countries. A temporary crown was placed between 8 and 14 weeks, and the final reconstruction was placed after 26 weeks. The primary parameter was evaluation of change in bone level, measured by standardized radiographs taken at the surgery (baseline), provisional placement (approx. 14 weeks), final crown placement (6 months) and 12 months, with annual follow-up intended for up to 5 years. Secondary parameters included soft tissue recession, implant survival and success and prosthesis success.

Results

The Intent-To-Treat (ITT) population for the 1-year results included 127 patients (60 and 67 in the transmucosal and submerged groups, respectively, with a mean age of 45.5 and 47.3 years, respectively).

Based on the 12 month ITT population data, the mean change in bone level after 6 months, was -0.30 ± 0.47 mm (-0.32 ± 0.47 mm and -0.29 ± 0.35 mm for the submerged and transmucosal groups, respectively), while after 12 months the mean change in bone level was -0.47 ± 0.64 mm (-0.47 ± 0.64 mm and -0.48 ± 0.65 mm for the submerged and transmucosal groups, respectively) (Fig. 1). There was therefore no significant difference in bone level change between the two groups. Almost two-thirds of implants (64.8 %) showed less than 0.5 mm bone loss over 12 months (Fig. 2). The implant survival and success rate was 99.2 %.
Patient satisfaction with the final prosthesis was extremely high; 99% of patients reported their level of satisfaction as excellent or good (Fig. 3).

**General patient satisfaction with final prosthesis**

<table>
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<th>ITT population at 1-year visit</th>
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<tr>
<td><strong>excellent</strong> 77%</td>
</tr>
<tr>
<td><strong>good</strong> 22%</td>
</tr>
<tr>
<td><strong>fair</strong> 1%</td>
</tr>
<tr>
<td><strong>poor</strong> 0%</td>
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Fig. 3: General patient satisfaction with final prosthesis at 12 months

**Discussion**

Traditional implant success criteria include an acceptable bone loss of ≤ 0.5 mm in the first year and < 0.2 mm annually thereafter. Recently, however, there have been suggestions for these criteria to be revised, indicating that a more acceptable bone loss for modern implant systems would be 0.3 mm over 5 years. However, many of the studies on which this suggestion is based use placement of the temporary or final prosthesis rather than placement of the implant as the baseline measurement for bone level change.

Studies that use implant placement as the baseline measurement for bone level change have shown relevant bone loss before loading, therefore, using prosthesis placement as the baseline may give an inaccurate reflection of the real amount of bone loss. A more accurate picture can be obtained by measuring bone levels at implant placement and at regular intervals thereafter (Fig 1). Knowledge of the amount of bone level change to expect has a huge clinical relevance in treatment planning to achieve an optimum esthetic outcome; for example, unexpected bone loss can cause substantial soft tissue recession, resulting in an esthetic failure.

**Conclusions**

- Marginal bone level change was small and not significantly different between submerged and transmucosal treatment groups.
- The marginal bone level change from implant placement (baseline) to 12 months was -0.47 mm (mean). The marginal bone level change from implant loading (6 months) to 12 months was -0.17 mm (mean).
- Extremely high survival and success rates were observed (99.2% for both).
- Patient satisfaction with the outcome was extremely high (99%).

A non-interventional study to document the implant success and survival rate of Straumann® Bone Level implants in daily dental practice.

Interim report
P. Bullon, A. Filippi, J. Kälber, M. Roccuzzo, D. Weingart, F. Higginbottom

Introduction
Results from clinical studies with dental implants can be affected by a number of factors, including the choice of center and the patient inclusion/exclusion criteria. It may therefore be difficult to extrapolate the high success and survival rates achieved in formal clinical trials, with a specifically defined group of patients, to an everyday clinical practice setting.

The aim of this study therefore was to document the success and survival rate of Straumann® Bone Level implants in daily practice for up to 3 years.

Materials and methods
Patients were enrolled at 123 centers in nine countries. There were no specific inclusion or exclusion criteria for patients enrolled in the study. In addition, no specific loading protocol was defined, and implants were allowed to be placed at the discretion of the clinician in accordance with the product labeling. The study was initiated in November 2006.

The primary objective of the study is implant survival rate 1 year after abutment placement. Secondary objectives include implant success and survival rate over 3 years, change in crestal bone level, loading protocol, type of restoration, and performance of prosthetic components.

Interim results
As of July 2008, 843 patients had been treated with 1501 implants. Dental risk factors (e.g., bone defects, bruxism, periodontitis, insufficient oral hygiene) were noted in 38.3% of patients, while systemic risk factors (e.g., controlled diabetes, metabolic disease, osteoporosis) were noted in 13.8%. Most patients received one or two implants; the mean number of implants per patient was 1.8.

Almost half (47%) of the implants were placed in the esthetic zone (Figs. 1 and 2).

Interim conclusions
- The excellent success of the Straumann® Bone Level implant in daily practice can be demonstrated
- The results are comparable to those achieved in controlled clinical studies
- The Straumann® Bone Level implant is successful in a variety of treatment options