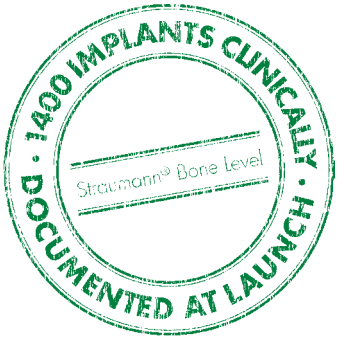
straumann®

# BONE LEVEL IMPLANT

## SCIENTIFIC OVERVIEW

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# STUDY OVERVIEW ON STRAUMANN® BONE LEVEL IMPLANT

## Pre-clinical studies

| | Topic | Objective | Study Setup, Principal Investigator |
|---|---|---|---|
| Property tests | Biomechanical stability | Ultimate strength and fatigue strength of the Straumann® Bone Level implant in comparison to competitor implants. | Hydropulser tests, ISO 14801<br>M. Wieland, H. Hornberger, Switzerland |
| | Reliability | Screw fit after cyclic mechanical load of the Straumann® Bone Level implant. | Hydropulser tests, ISO 14801<br>M. Wieland, H. Hornberger, Switzerland |
| | Microgap | Measurements of gap size. | Scanning electron microscopy on polished micrograph sections<br>M. de Wild, Switzerland |
| Animal | Bone maintenance | Bone maintenance with submerged and non-submerged implants placed at different heights. | Delayed restoration, 60 implants<br>D. Cochran, USA |
| | | Interproximal bone maintenance with adjacently placed implants. | Immediate abutment placement, 72 implants<br>D. Tarnow, USA |

## Clinical studies

| | Topic | Objective | Study Setup, Principal Investigator |
|---|---|---|---|
| Human | Basic clinical evidence | Performance and esthetic outcome in single tooth gaps in the anterior maxilla. | Single center, 20 patients<br>D. Buser, Switzerland |
| | Esthetics | Submerged vs. non-submerged placement in the anterior maxilla or mandible. | 12 centers in Europe and USA<br>134 patients, C. Hämmerle, Switzerland |
| | Various treatments | Implant success and survival rate in daily dental practice. | Over 100 active centers worldwide, over 1500 implants |
| | Immediacy | Immediate or delayed provisional restoration versus no provisional restoration in healed alveolar ridges. | Single center, 24 patients<br>N. Donos, UK |
| | Small diameter implants (3.3 mm) | Edentulous mandibles restored with a removable prosthesis on 2 small diameter Straumann® Roxolid™ Bone Level implants. | 8 international centers, 91 patients<br>B. Al-Nawas, Germany |

Clinical studies are ongoing.

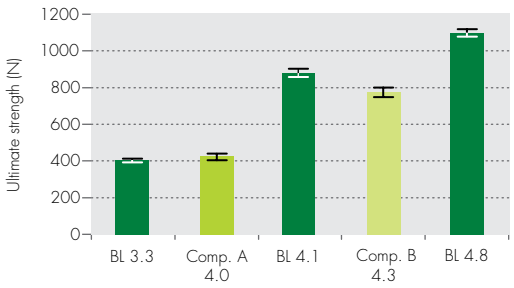
## Additional scientific evidence

| | Topic | Objective | Link to Straumann® Bone Level Implant |
|---|---|---|---|
| | Straumann® SLActive® | More than 21 published and 12 ongoing scientific studies substantiate this groundbreaking surface technology. | The Straumann® Bone Level implant is available with the Straumann SLActive surface. |
| | Thread geometry | Field study to demonstrate the performance of the Straumann® Tapered Effect thread geometry. | The Straumann Bone Level implant features the same thread geometry as the Straumann Tapered Effect implant. |

# STRAUMANN® BONE LEVEL IMPLANT

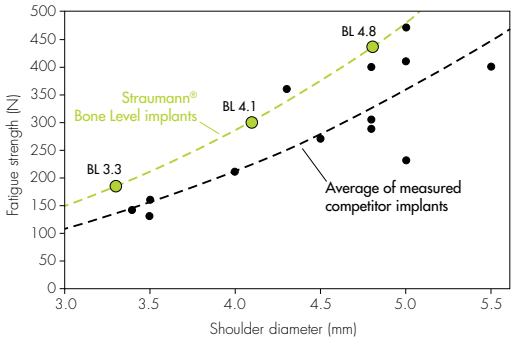
## Property Tests*

| | |
|---|---|
| **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. |



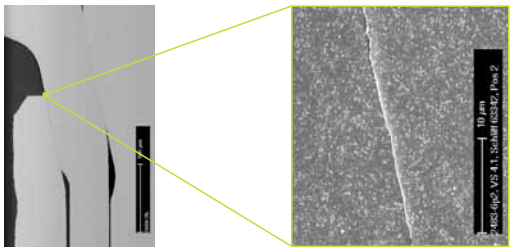

*Comparison of ultimate strength of the three Bone Level implants and two competitor implants (n = 3 – 5). Error bars show standard deviation.*

| | |
|---|---|
| **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. |
| **Key findings** | In this evaluation, average measured fatigue strength of 3 Straumann® Bone Level implants was higher than the average failure strength of 13 competitor implants. |




*Fatigue strength of Straumann® Bone Level implants (green dots and regression line) in relation to the fatigue strength of 13 competitor implants (black dots and regression line), plotted against implant shoulder diameter.*

| | |
|---|---|
| **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. |



*Representative polished micrograph section (magnification: left 50x; right 2500x)*

* 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.

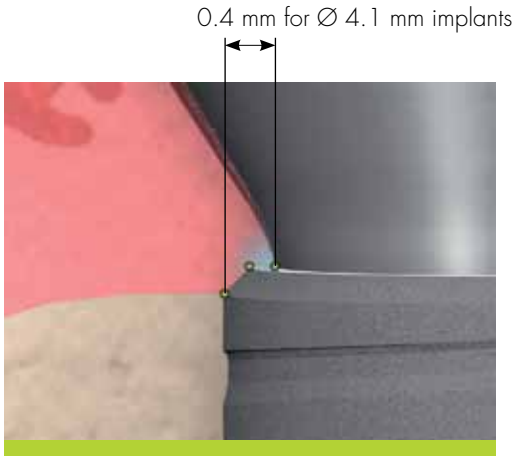



**Fig. 1:** Platform Switching with Straumann Bone Level implants.

### 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.

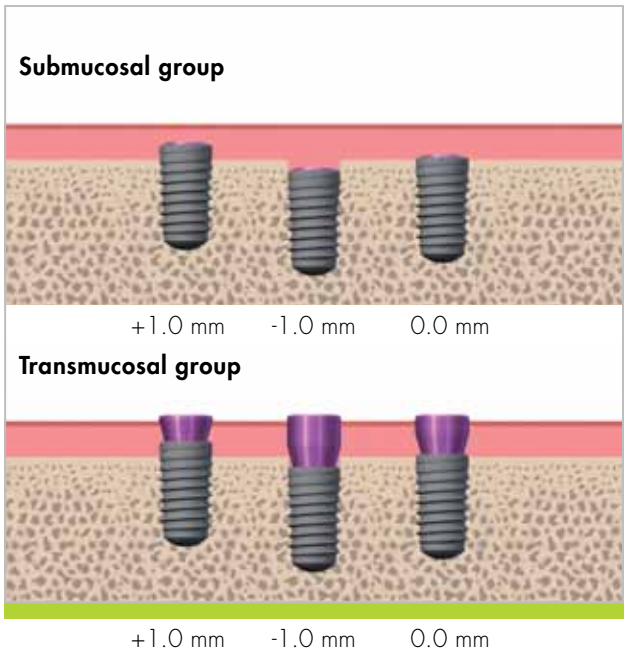



**Fig. 2:** Submucosal and transmucosal group with bone level implants placed either at the level of the alveolar bone crest or 1.0 mm above or 1.0 mm below.

## 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).

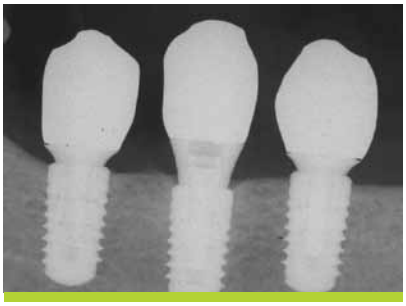


**Fig. 3:** Transmucosal implants 6 months after loading.

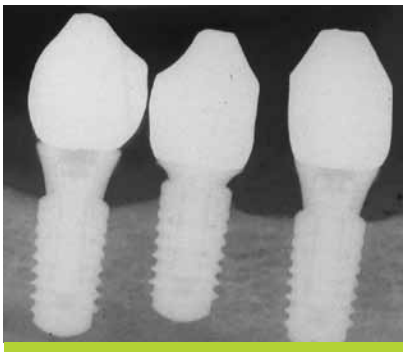


**Fig. 4:** Submucosal implants 6 months after loading. Note the slight bone growth of the middle implant between crown placement and 6-month follow-up.

## 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.

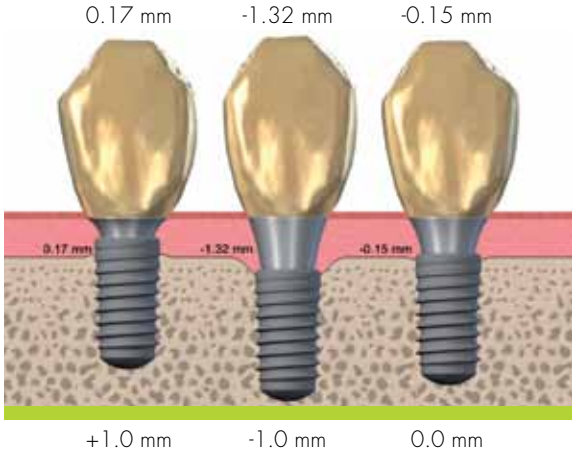



**Fig. 5:** Very little bone loss was detected in the submerged group 6 months after loading.

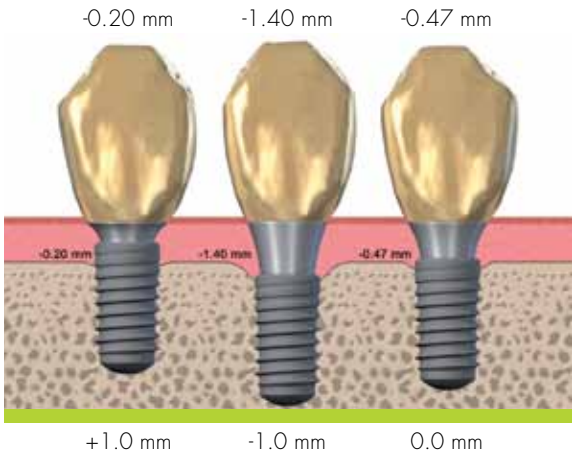



**Fig. 6:** Very little bone loss was detected in the transmucosal group 6 months after loading.

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# 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.[i,ii] Platform-switching may help to reduce the inter-implant bone loss[i], 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® 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.

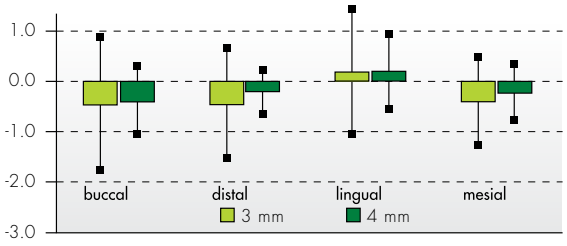


**Fig. 1:** Bone level at buccal, distal, ligual and mesial sides after 8 weeks

*Histomorphometric analysis:* The results showed that the mean overall BIC was not significantly different between the two groups (86.9 ± 7.3 % and 83.0 ± 10.2 % in the 4 mm and 3 mm groups, respectively). Similar results were obtained for BIC at the interproximal sides only. There was also no significant difference in bone density between the two groups (63.4 ± 6.1 % and 65.1 ± 5.7 % for the 3 mm and 4 mm groups, respectively). There were no significant difference in lBE, lJE, and lCT for the 3 mm and 4 mm groups, respectively.

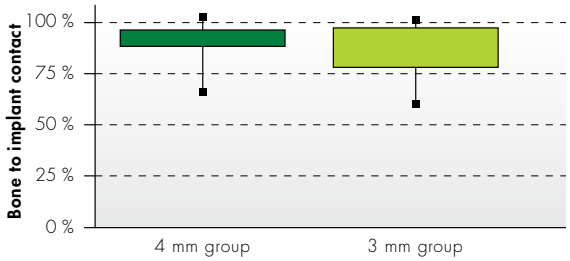


**Fig. 2:** Mean BIC in the region of interest

## 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

[i] *Tarnow DP, Cho SC, Wallace SS. The effect of inter-implant distance on the height of the inter-implant bone crest. J Periodontol 2008; 71: 546–549.*

[ii] *Kuperschmidt I, Levin L, Schwartz-Arad D. Inter-implant bone height changes in anterior maxillary immediate and non-immediate adjacent dental implants. J Periodontol 2007; 78: 991–996.*

# Early implant placement with simultaneous guided bone regeneration following single-tooth extraction in the esthetic zone: 12-month results of a prospective study with 20 consecutive patients.

D. Buser, S. Halbritter, C. Hart, MM. Bornstein, L. Grütter, V. Chappuis, UC. Belser
J Periodontol 2009;80:152-162

## Introduction

Early implant placement following extraction of a single tooth is a procedure used by many clinicians in the maxillary anterior zone,[1] 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.[3, 4, 5, 6] 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 %.[7, 8, 9]

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

| | 3 mos | 6 mos | 12 mos |
|---|---|---|---|
| **mPLI** | 0.08 ± 0.24 | 0.08 ± 0.20 | 0.36 ± 0.33* |
| **mSBI** | 0.26 ± 0.29 | 0.16 ± 0.23 | 0.21 ± 0.17 |
| **PD** | 3.69 ± 0.62 | 3.75 ± 0.46 | 4.43 ± 0.57* |
| **KM** | 4.06 ± 1.43 | 4.10 ± 1.41 | 4.50 ± 1.54 |
| **DIB** | 0.09 ± 0.16 | 0.14 ± 0.25 | 0.18 ± 0.20* |

*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

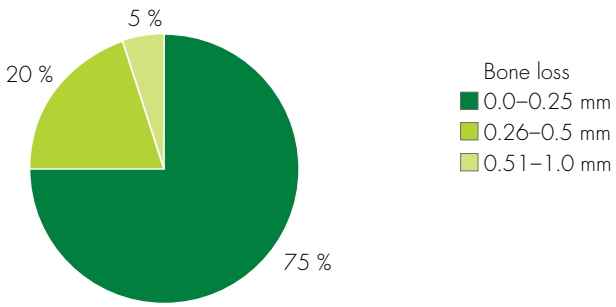


**Fig. 1:** The majority of patients (75 %) showed < 0.25 mm bone loss

# 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 %.

### Bone loss based on 12 month ITT population

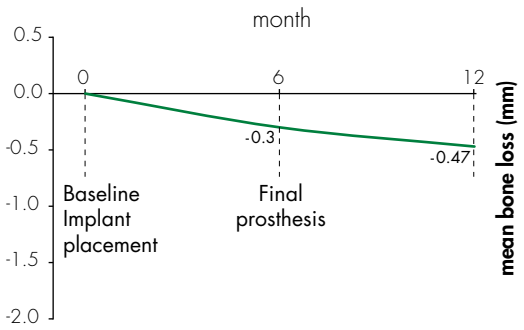


**Fig. 1:** Mean bone level change from baseline at 6 and 12 months

### Bone level change in % and mm categories

*Baseline to 12 months*

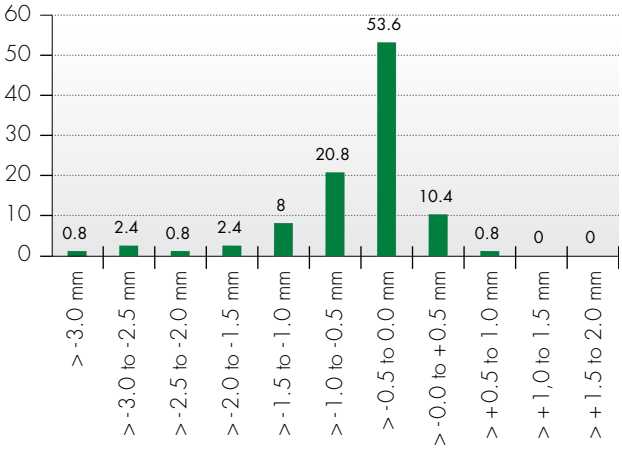


**Fig. 2:** Percentage of implants showing different categories of bone level change

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**

*ITT population at 1-year visit*

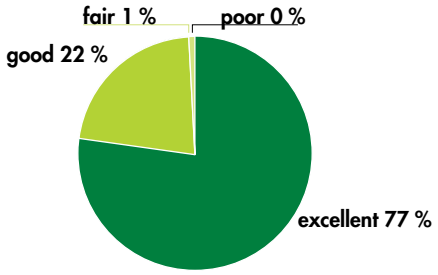


**Fig. 3:** General patient satisfaction with final prosthesis at 12 months

## Discussion

Traditional implant success criteria include an acceptable bone loss of ≤ 0.5 mm in the first year and < 0.2 mm annually thereafter.[3] 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.[4]

Studies that use implant placement as the baseline measurement for bone level change have shown relevant bone loss before loading;[4, 5] therefore, using prosthesis placement as the baseline may give an inaccurate reflection of the real amount of bone loss.[6, 7] 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 %)


[1] Hermann JS, Buser D, Schenk RK, Schoolfield JD, Cochran DL. Biologic width around one- and two-piece titanium implants. Clin Oral Implants Res 2001;12:559–571.

[2] Hermann JS, Schoolfield JD, Schenk RK, Buser D, Cochran DL. Influence of the size of the microgap on crestal bone changes around titanium implants. A histometric evaluation of unloaded non-submerged implants in the canine mandible. J Periodontol 2001;72:1372–1383.

[3] Albrektsson T, Zarb G, Worthington P, Eriksson AR. The long-term efficacy of currently used dental implants: a review and proposed criteria of success. Int J Oral Maxillofac Implants 1986;1:11–25.

[4] Engquist B, Åstrand P, Dahlgren S, Engquist E, Feldmann H, Gröndahl K. marginal bone reaction to oral implants: a prospective comparative study of Astra Tech and Brånemark System implants. Clin Oral Implants Res 2002;13:30–37.

[5] Åstrand P, Engquist B, Dahlgren S, Gröndahl K, Engquist E, Feldmann H. Astra Tech and Brånemark system implants: a 5-year prospective study of marginal bone reactions. Clin Oral Implants Res 2004;15:413–420.

[6] Cooper L, Felton DA, Kugelberg CF, Ellner S, Chaffee N, Molina AL, Moriarty JD, Paquette D, Palmqvist U. A multicenter 12-month evaluation of single-tooth implants restored 3 weeks after 1-stage surgery. Int J Oral Maxillofac Implants 2001;16:182–192.

[7] De Bruyn H, Van de Velde T, Collaert B. Immediate functional loading of TiOblast dental implants in full-arch edentulous mandibles: 1 3-year prospective study. Clin Oral Implants Res 2008;19:717–723.

# 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).

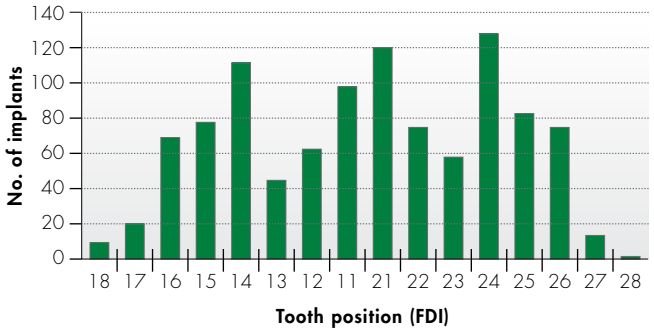


**Fig. 1:** Implant distribution in the maxilla

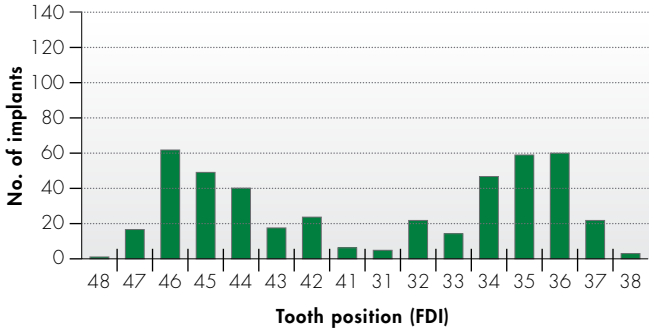


**Fig. 2:** Implant distribution in the mandible

Most implants (56.4 %) were placed using the submerged technique; 34.7 % were placed transmucosally, and 8.5 % were placed semi-submerged. Augmentations were performed at just over half (55 %) of the implant sites. Conventional loading was used in the majority (61.6 %) of cases. Of the 578 final restorations documented, 348 (60.2 %) were single crowns, 165 (28.6 %) were bridges, 44 (7.6 %) were full prostheses, and 11 (1.9 %) were partial prostheses. As of July 2008, only 12 implants have been reported as failures.

## 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

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