

# SCIENTIFIC FACT SHEET – STRAUMANN® BONE LEVEL IMPLANT

## Property Tests

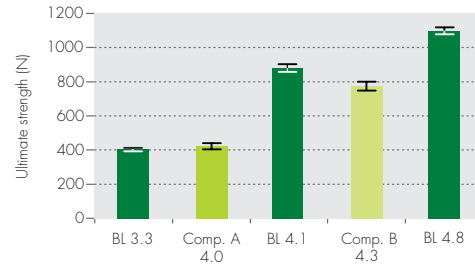
**Objective** Mechanical testing of ultimate strength

**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 the study.



Comparison of ultimate strength of the Bone Level implants and two competitor implants (n=3-5) Values are provided as mean ± SD.

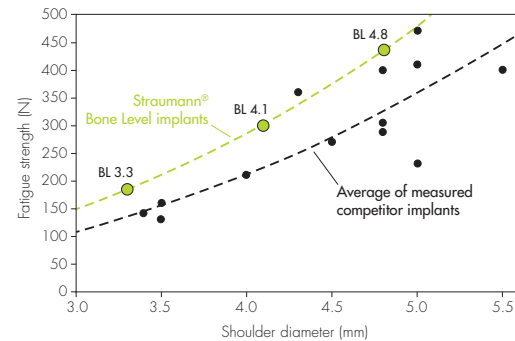
**Objective** Mechanical testing of fatigue strength

**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 fatigue 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.

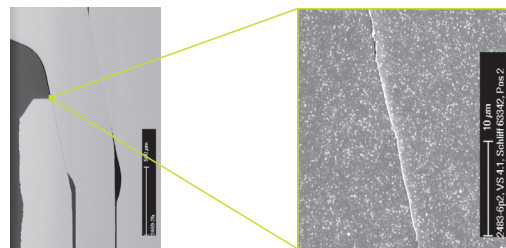
**Objective** Microgap measurements on polished micrograph sections

**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

## Preclinical Studies

Study	Principal Investigator(s)	Setup
Bone Level Implant Preclinical Study I	David L. Cochran, USA	60 Straumann® Bone Level Implants (SLActive™, Ø 4.1 mm) were placed bilaterally, submerged or non-submerged, at 3 different heights relative to the bone crest (1.0 mm above, 1.0 mm below, and at bone crest level) in the mandibles of 5 American foxhounds. After 3 months, abutments were inserted and the crowns were cemented; thereafter followed a 6-month loading period. Radiographs were obtained following implant placement, abutment insertion, and monthly for 6 months after loading. Histological evaluation was performed at endpoint.
Bone Level Implant Preclinical Study II	Nick Elian, Mitch Bloom, Giuseppe Cardaropoli, Dennis Tarnow, USA	72 Straumann® Bone Level Implants (SLActive™, Ø 4.1 mm) were placed in the mandibles of 12 mini pigs with an inter-implant distance of 3.0 mm and 4.0 mm, followed by immediate abutment placement to allow transmucosal healing. Radiographic bone level evaluations were performed on the day of placement and compared at 2 months post-insertion, along with histological and µCT assessment at the 2-month endpoint.

## Clinical Studies

Study	Principal Investigator(s)	Setup	End-point
Bone Level Implant Clinical Study I**	D. Buser, U. Belser, Switzerland	Open pilot study. Single tooth gaps in the anterior maxilla of 20 patients were treated and restored with Straumann® Bone Level Implants (SLActive™, Ø 4.1 mm). 2nd stage surgery and abutment connection after 6-7 weeks. Analysis of standardized radiographs after 3, 6, 12, 18, 24, and 36 months after abutment connection. Only in case of a bone defect of more than 3mm in any dimension, the healing time is 12 weeks.	Change of crestal bone level between abutment connection and 12 months later.
Bone Level Implant Clinical Study II**	C. Hämmerle, Switzerland 12 centers in Europe and USA	Randomized, controlled clinical study to compare submerged with non-submerged healing. Single Straumann® Bone Level Implants were placed in the anterior maxilla or mandible of 112 patients. Restoration after 12 weeks. Evaluation of crestal bone level by standardized periapical radiographs after 6 months and 12 months. Patients will be followed up for 5 years.	Change of crestal bone level between 1st stage surgery and 6 months after surgery.
Bone Level Implant Non-interventional Study** (NIS)	Over 120 active centers worldwide	Non-interventional, observational case-control study investigating the Straumann® Bone Level Implant mostly in a private practice setting. The data are collected via a web-based electronic data capture system. Descriptive statistical evaluation of results regarding different subgroups (surgical protocol, loading protocol, implant position, augmentation procedures, dental and/or systemic risk factors) will be performed.  Approximately 1,480 implants documented.	Implant survival and success rate (according to the criteria of Buser et al. 1991) 1, 2, and 3 years after abutment connection. Changes in crestal bone level.

\*\*On-going clinical studies: preliminary

## Key findings

- Very good and predictable bone preservation after loading (0.0 – 0.5 mm bone loss relative to the implant/abutment connection, see table).
- Simplified surgical procedure (one-stage) performs as well as two-stage procedure.
- Preliminary results of the histological analysis confirm crestal bone preservation seen in x-rays.
- Implants were well osseointegrated.

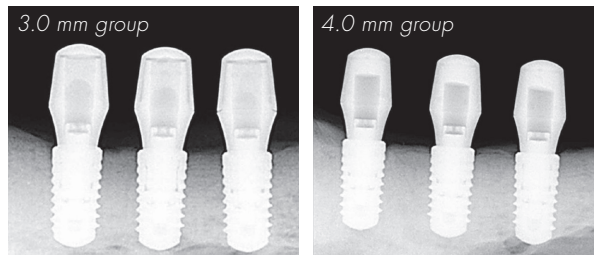


Placement	Bone loss submerged	Bone loss non-submerged
+1 mm	0.17 mm	-0.20 mm
-1 mm	-0.32 mm	-0.40 mm
0 mm	-0.15 mm	-0.47 mm



Left: exemplary x-ray. Table: bone loss relative to the implant/abutment connection. Right: exemplary mesiol-distal histological section. The x-ray and the histology were taken after 6 months of loading of implants placed at bone crest.

- Minimal changes in radiographic bone height for adjacent implants with 3.0 mm and 4.0 mm inter-implant distance.
- No statistically significant differences were found between the two groups. Interproximal bone height was maintained.



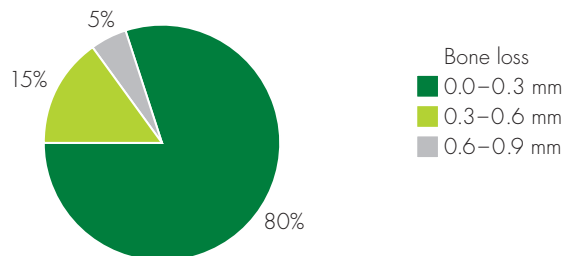
Radiographs of the 3.0 mm and 4.0 mm group 8 weeks after implantation.

## Key findings

No adverse events occurred at 6-month follow-up.

Bone loss after 6 months following abutment connection:

- 16 patients showed less than 0.3 mm of bone loss
- 3 patients show a slight bone loss of 0.3 to 0.6 mm
- 1 patient shows a bone loss of about 0.9 mm
- No patient showed 1.0 mm or more bone loss

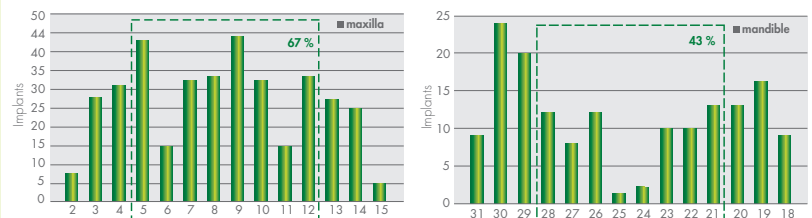


Excellent bone preservation was observed 6 months after abutment connection. The majority (80%) of the patients showed less than 0.3 mm bone loss.

- No implant failures or adverse events have been reported.
- Very positive feedback on application and handling products (e.g., primary stability, restorative options).

The interim results that are currently available strongly support that the Straumann Bone Level Implant can be successfully used following diverse surgical protocols and has displayed a high level of safety and reliability.

By the end of the recruitment phase (November 2007), approximately 1,480 implants were placed in more than 100 centers by investigators in 9 countries representing Europe, the USA, and Canada. By the end of December, more than 800 implants will have been implanted for 6 months or longer. The implants were placed in all tooth positions. More than half of the total implants placed were placed in positions outside the esthetic zone (outside of tooth positions 5 – 12).



Distribution of implants placed in different tooth positions in the maxilla and the mandible (German Data Set). 67% of all implants in the maxilla were placed in the esthetic zone (tooth positions 5-12). 43% of all implants in the mandible were placed in the anterior region (tooth positions 21 – 28).

# STUDY OVERVIEW ON STRAUMANN® BONE LEVEL IMPLANT

## Pre Clinical studies

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

## Clinical studies

	Topic	Content	Study Setup, Principal Investigators
Human	Basic clinical evidence	Performance and esthetic outcome in single tooth gaps in the anterior maxilla.	Single center, 20 patients D. Buser, Switzerland
	Esthetics	Submerged vs. non-submerged placement in the anterior maxilla or mandible.	12 centers in Europe and USA 134 patients, C. Hämmerle, Switzerland
	Daily practice	Implant success and survival rate in daily dental practice.	Over 100 active centers worldwide, approx. 1,480 implants
	Immediacy	Immediate provisional restorations on immediately placed implants (w/in 48 hours, test group) or delayed (12-14 weeks after implant placement; control group) after implant placement. Implant will be inserted into fully healed extraction sockets (8 weeks after tooth removal).	Single center, 24 patients N. Donos, UK
	Small diameter implants (3.3 mm)	Edentulous mandibles restored with a removable prosthesis on 2 small diameter Straumann® Bone Level Implants.	8 international centers, 88 patients B. Al-Nawas, Germany (8 weeks after tooth removal)

Clinical studies are initiated or ongoing.

## Additional scientific evidence

Topic	Content	Link to Straumann® Bone Level Implant
Straumann SLActive™	More than 15 published and 18 ongoing scientific studies substantiate this groundbreaking surface technology.	The Straumann® Bone Level Implant features the Straumann SLActive™ surface.
Thread geometry	Scientific studies prove the clinical performance of the Straumann® Tapered Effect thread geometry.	The Straumann® Bone Level Implant features the same thread geometry as the Straumann® Tapered Effect Implant.