

Randomized, controlled clinical study comparing change in peri-implant bone level between submerged and transmucosal placement of bone level implants in the anterior maxilla and mandible: 24-month results

Cordaro L et al. 'Submerged vs non-submerged healing of implants for single tooth replacement in the esthetic zone. Two year results from a multicenter RCT' Oral presentation at the 19th Annual Scientific Meeting of the European Association of Osseointegration, 7.–9. October 2010, Glasgow (UK).

Introduction

Both the surgical procedure and implant design 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.³

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 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 various steps. Secondary parameters included soft tissue parameters, implant success and survival rate as well as success rate of prosthetic restorations.

- Indication: Single-tooth replacement in the anterior region
- Implant: Bone Level Ø 4.1 mm SLActive®
- Control: Submucosal healing (SMH)
- Test: Transmucosal healing (TMH)

The patients were recalled for several follow-up visits at various points in time. During these visits, various parameters were assessed such as:

- Probing Pocket Depth (PPD)
- Clinical attachment level (CAL)
- Crestal bone change
- Patient satisfaction

Results

The Intent-to-Treat (ITT) population for the 2-year results included 120 patients (58 patients TMH group, 62 patients SMH group). One implant was lost at placement of the final prosthesis (6 months after surgery). Thus, the survival rate results in 99.2%.

Radiographic evaluation/Crestal bone change

Periapical radiographs were taken at surgery (baseline), 6, 12 and 24 months post-surgery to evaluate crestal bone change. Mean crestal bone change showed remodeling patterns at 6 and 12 months with mean values of -0.31 mm and -0.46 mm for the entire ITT population. From 12 to 24 months there was a minor bone change of -0.01 mm, indicating a stable bone. Comparing the crestal bone change of the two groups, no statistically significant difference was found and the bone change pattern was similar for both groups (Figure 1).⁴



Figure 1: There was no statistically significant difference between test and control group. Both showed a bone remodeling effect the first 12 months and then a stable crestal bone situation

Frequency analysis of crestal bone change from 12 to 24 months did not show any statistically significant difference between the two groups (Figure 2).

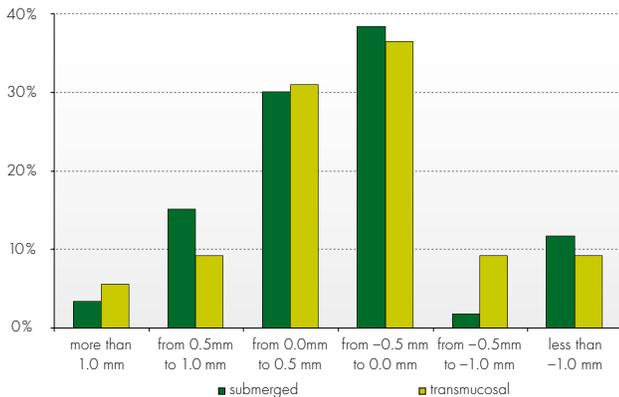


Figure 2: In both groups a positive bone change or a negative up to -0.5 mm was observed in more than 80% of the cases

Soft tissue parameters

The mean CAL and PPD values remained stable between screening and 2-year follow-up for both groups (SMH and TMH) as displayed in table 1.

	Group	Screening	2-year FU
CAL	SMH	2.6 ± 0.9	2.6 ± 1.0
	TMH	2.5 ± 0.9	2.6 ± 1.1
PPD	SMH	2.3 ± 0.5	2.4 ± 0.6
	TMH	2.1 ± 0.5	2.4 ± 0.6

Table 1: Soft tissue parameters (mean and standard deviation) at screening and 2-years follow-up visit in mm.⁴

When evaluating the soft tissue parameters at the 2-year visit, no statistically significant difference between test and control group was found.⁴

Patient feedback

Patients were asked about general treatment satisfaction with their final prosthesis. In 77% of the cases the patients rated their solution as excellent.

Conclusions

- High survival rate (99.2%)
- There was no statistically significant difference between the control and test group (submucosal and transmucosal group) supporting BL for both healing types
- Minimal crestal bone change was observed 24 months after implant placement
- Stable crestal bone between 12 and 24 months was observed (-0.01 mm)⁴
- Soft tissue parameters did not reveal any substantial changes between screening and 24-month follow-up
- High patient satisfaction

References

- 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) Data on file

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