The effect of different implant neck configurations on soft and hard tissue healing: a randomized-controlled clinical trial

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Key words: clinical outcomes, dental implants, marginal bone levels, randomized-controlled clinical trial, Standard Plus "S" implants

Abstract

Objective: To compare the soft and hard tissue healing and remodeling around tissue-level implants with different neck configurations after at least 1 year of functional loading.

Material and methods: Eighteen patients with multiple missing teeth in the posterior area received two implants inserted in the same sextant. One test (T) implant with a 1.8 mm turned neck and one control (C) implant with a 2.8 mm turned neck were randomly assigned. All implants were placed transmucosally to the same sink depth of approximately 1.8 mm. Peri-apical radiographs were obtained using the paralleling technique and digitized. Two investigators blinded to the implant type-evaluated soft and hard tissue conditions at baseline, 6 months and 1 year after loading.

Results: The mean crestal bone levels and soft tissue parameters were not significantly different between T and C implants at all time points. However, T implants displayed significantly less crestal bone loss than C implants after 1 year. Moreover, a frequency analysis revealed a higher percentage (50%) of T implants with crestal bone levels 1–2 mm below the implant shoulder compared with C implants (5.6%) 1 year after loading.

Conclusion: Implants with a reduced height turned neck of 1.8 mm may, indeed, lower the crestal bone resorption and hence, may maintain higher crestal bone levels than do implants with a 2.8 mm turned neck, when sunk to the same depth. Moreover, several factors other than the vertical positioning of the moderately rough SLA surface may influence crestal bone levels after 1 year of function.

In recent years, increasing esthetic demands require a subgingival placement of restoration margins also in implant dentistry. This has resulted in more apical placements of transmucosal, tissue-level implants in the zone of esthetic priority. Therefore, the placement of the rough/smooth implant border of non-submerged implants was recommended to be slightly below the crestal bone level [Hess et al. 1998]. However, such a deliberate more apical positioning of the rough/smooth interface has been associated with an increased crestal resorption of the alveolar bone [Hämmerle et al. 1996].

Implant design and surface configuration have been demonstrated to affect crestal bone levels (for a review see Lang & Jepsen 2009).

In order to cope with the increased crestal bone resorption observed following deliberate sinking of one-stage implants, industry has provided new implant designs based on the hypothesis that moderately rough implant surfaces may give rise to more coronal osseointegration levels.
Consequently, the Standard Plus® Straumann dental implant was developed with a sprayed-up moderately rough surface to a level of only 1.8 mm apical to the implant shoulder in comparison to the 2.8 mm turned surface of the Standard® Straumann implant. The 1.8 mm turned neck of the Standard Plus® implant was supposed to allow a more apical (by 1 mm) positioning of the implant in order to eliminate a visible crown margin through an appropriate emergence profile of the prosthetic crown. The roughened surface of the Standard Plus® implant hereby was supposed to maintain crestal bone levels that would otherwise be affected by increasing sink depth (Hämmnerle et al. 1996). However, such a hypothesis has never been tested clinically.

It remains questionable whether the introduction of this shorter turned implant collar will result in less crestal bone loss to accommodate the biological width of the soft tissues. Similar to natural teeth, a biological width is established around implants. The biological width around teeth based on human autopsy specimens was a mean of 2.04 mm, with an average measurement of 0.97 mm for the epithelial attachment and 1.07 mm for the connective tissue attachment (Gargiulo et al. 1961). When comparing implants with teeth, the biological width around implants was reported to be greater than that of teeth in experimental animals (Berglundh et al. 1991). In that dog study, it was found that the length of the connective tissue attachment around implants was 1.66 mm compared with 1.12 mm around teeth. The epithelial attachment compartment was similar for both implants and teeth. The overall height of the supracrestal soft tissue at the implant sites was 3.8 mm, and at the tooth sites 3.17 mm including the histologic sulcus. The biological width does not appear to differ between implant systems (Abrahamsson et al. 1996). Similar dimensions and composition of the mucosal barrier between the Astra Tech® Implant System, the Nobel Biocare® Implant System and the Straumann® Dental Implant System were identified, and it was concluded that a minimum width of peri-implant mucosa is required to establish a proper epithelial–connective tissue attachment (Abrahamsson et al. 1996). If this dimension is not satisfied, crestal bone resorption will occur to ensure the establishment of the biological width (Berglundh & Lindhe 1996).

Since the introduction of the Standard Plus® Straumann dental implants with a 1.8 mm turned neck configuration, only a few studies have reported on the crestal bone level changes over time. Such a pilot study on 21 implants with the implant shoulder placed 0.5–1 mm supracrestally, revealed a mean distance from the implant shoulder to the first bone-to-implant contact (BIC) of 2.19 mm after 32 months (Gerber et al. 2003). This distance was substantially lower than that reported in previous studies of implants with a 2.8 mm turned neck configuration. In earlier studies, the distance between the implant shoulder and the first visible implant contact was at a mean of 3.79 mm 1 year after implant insertion (Buser et al. 1990). Moreover, 0.78 mm bone loss after 1 year, with the distance between the implant shoulder to the bone level amounting to about 2.99 mm in 57 hollow screw implants [ITI® Dental Implant System] was reported [Brägger et al. 1998].

To date, there is still no randomized controlled clinical trial (RCT) examining the benefits of using tissue-level implants with a reduced height turned neck as compared with that with a regular turned neck configuration.

The aim of this RCT was thus to compare the clinical and radiographic outcomes of tissue-level implants with different neck configurations, inserted to the same sink depth, at least 1 year after loading accounting for the bone remodeling process after implant installation.

### Material and methods

This RCT was conducted in the Department of Periodontology and Fixed Prosthodontics at the University of Berne, Switzerland.

Eighteen adults in good systemic health were recruited for the study. They were patients who were consecutively seen at the department for implant therapy and agreed to participate in the study giving informed consent. The subjects had missing chewing units in the same posterior sextant to be restored with fixed reconstructions [single crowns or a fixed dental prosthesis] on two implant abutments.

Both implants were placed in a single surgical visit after the edentulous region had healed for at least 4 months following tooth extraction (Type 4 placement). No bone augmentation procedures were performed.

The subjects went through comprehensive dental treatment planning, case presentation and successfully completed active periodontal therapy, if indicated, before implant therapy.

The procedure for the placement of the implants was according to the manufacturer’s recommendation for a one-stage transmucosal tissue level oral implant. In brief, after raising a mucoperiosteal flap, the tip of the alveolar crest was flattened by a round bur to establish a flat platform before implant placement. The two implants (center points) were placed at a minimum distance of 4 mm from the neighboring tooth/teeth surfaces and with a minimum distance of 7 mm between the centers of the two implants.

Before implant placement, the position of the test implant, with a 1.8 mm turned neck [Standard Plus® implant, Straumann AG, Basel, Switzerland] within the sextant was randomly chosen by the toss of a coin. An implant with a turned neck of 2.8 mm [Standard® implant, Straumann AG] was placed in the second position and served as a control. The Standard Plus® implant (Test) was sunk to the originally recommended depth of 1.8 mm, with the borders between the moderately rough (SLA) and turned surfaces being at the level of the alveolar crest. The Standard® implant (Control) within the same sextant was then sunk to the same depth of 1.8 mm, resulting in the fact that the border between the moderately rough (SLA) and turned surfaces was positioned approximately 1 mm subcrestally. Following this, the flap was sutured with Dafilon® 5.0 (B. Braun Melsungen AG, Melsungen, Germany) sutures and carefully adapted against the healing cap of the implants. Postoperative care was according to the protocol described by Heitz et al. (2004).

Intraoperatively, the baseline evaluation of the sites was assessed by the surgeon placing the implants. These parameters included:

- Intra-operative measurement of the distance from the implant shoulder to the alveolar crest (six sites per implant).
Thicknss of the alveolar bone, buccally and orally to the implant was assessed using a periodontal probe [Hu-Friedy, Chicago, IL, USA; UNC # 15].

Mean flap thickness.

Standardized peri-apical radiographs were taken at suture removal, 1 week postimplant installation, 6 months and 1 year after loading using the paralleling technique [Brägger et al. 1991]. The radiographs were digitized for analysis. The process included capturing the radiographs using a black and white video camera [Canon, Still Video Products Group, Tokyo, Japan] and transferring the images to a computer and digitizing with a frame grabber hardware [Matrox Electronic Systems MVP/AT, Dorval, QC, Canada]. Using a image-processing software, digitized images were stored with a resolution of 512 × 512 × 8 bits pixels [256 shades of gray]. Stored images were then displayed on a monitor and linear measurements were performed independently by two calibrated and blinded examiners with the help of a cursor [Brägger et al. 1996]. The measurement assessed included the mean crestal bone levels [the distance from the implant shoulder to bone–implant contact [S-BIC]].

Soft tissue parameters were examined after 1 year of loading by a specialist in Periodontology [B. E. P.] calibrated for reproducibility and accuracy. These parameters included probing pocket depth (PPD) at six sites per implant, with a periodontal probe [Hu-Friedy, UNC # 15], probing attachment level [PAL] for the implants [six sites per implant] and presence [+] or absence [−] of bleeding on probing [BOP] at approximately 0.25 N.

Statistical analysis

Paired t-tests were used to compare between test and control implant results in the same patient. The baseline parameters were analyzed, and the mean crestal bone levels [S-BIC] measured on standardized digitized radiographs 1 week after implant installation, after 6 months and after at least 1 year in function.

Wilcoxon’s matched pairs signed-rank tests were additionally used to compare the crestal bone levels between test and control implants after at least 1 year in function and to compare the changes in crestal bone level from baseline to 12 months between test and control implants. The matched-pairs Wilcoxon’s signed-rank tests were also used to compare the mean PPDs and PALs between the test and control implants.

The comparison of the percentage of BOP and percentage of implants with peri-implantitis between test and control implants was performed using the Pearson $\chi^2$ test.

The level of significance for all statistical tests was set at $\alpha = 0.05$.

All analyses were conducted using Stata® version 10.1 (StataCorp, College Station, TX, USA).

Results

Nine male and nine female patients were recruited for the present study. In these 18 patients, 10 pairs of implants placed in the maxilla and eight pairs placed in the mandible were available for the comparison of test and control implants, respectively.

Baseline measurements

At the time of implant insertion, baseline parameters were measured as presented in Table 1.

Table 1. The mean insertion depth of the test implants was 1.57 mm (SD 0.37) compared with an insertion depth of 1.65 mm (SD 0.48) for the control implants. The difference between the values was not statistically significant. Furthermore, the differences in the thickness of the mucosal flaps [2.77 vs. 2.94 mm] and the amount of bone buccally and orally to the implants were not significant either (Table 1).

Crestal (marginal) bone levels

Mean crestal bone levels [implant shoulder to the first BIC] were measured on standardized digitized radiographs 1 week after implant installation, after 6 months and after at least 1 year in function [Table 2].

The mean crestal bone levels, evaluated on radiographs at 1 week after implant insertion, were 1.74 mm [SD 0.66] for test and 1.54 mm [SD 0.56] for the control implants, respectively [$P = 0.082$]. At the 6 months evaluation, the respective figures were 2.28 mm [SD 0.72] for the test and 2.66 mm [SD 0.95] for the control implants [$P = 0.071$]. After at least 1 year of functional loading, the mean crestal bone levels evaluated on digitized peri-apical radiographs were 2.61 mm [SD 1.03] for the test implants and 2.85 mm [SD 0.64] for the control implants, respectively. This difference did not reach statistical significance [$P = 0.37$].

Performing a frequency analysis of the crestal bone levels after at least 1 year in function, 50% of the test implants displayed crestal bone levels between 1 mm and 2 mm below the implant shoulder that would be expected from an implant with a 1.8 mm turned neck compared with only 5.6% of the control implants. Test implants yielded crestal bone levels between 2 and 3 mm in 27.8%, while 72.2% were in this category for the control implants. For both

Table 1. Flap thickness, thickness of the bone buccally and orally to the implants and position of the implant shoulder measured at six sites per implant intra-operatively

<table>
<thead>
<tr>
<th>Position of the implant shoulder (mean height in mm)</th>
<th>Test implants</th>
<th>Control implants</th>
<th>t-test*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean flap thickness (mm)</td>
<td>2.77</td>
<td>2.94</td>
<td>0.201</td>
</tr>
<tr>
<td>Mean thickness of the buccal bone (mm)</td>
<td>1.52</td>
<td>1.44</td>
<td>0.776</td>
</tr>
<tr>
<td>Mean thickness of the oral bone (mm)</td>
<td>1.66</td>
<td>1.72</td>
<td>0.736</td>
</tr>
<tr>
<td>Position of the implant shoulder (mean height in mm)</td>
<td>1.57</td>
<td>1.65</td>
<td>0.438</td>
</tr>
</tbody>
</table>

*Derived from paired t-tests.
Test: Straumann Standard Plus® implants (1.8 mm turned neck portion).
Control: Straumann Standard® implants (2.8 mm turned neck portion).
and after at least 1 year in function around test and control implants with peri-implantitis as defined by either PPDs ≥ 6 mm with positive BOP, or PPDs ≥ 6 mm with positive BOP for the present study, showed no significant difference between test and control implants (Table 5).

Discussion

This RCT tested the hypothesis of no difference in clinical outcomes between Standard Plus® and Standard® Straumann tissue-level dental implants installed to a sink depth of approximately 1.8 mm measured from the transmucosal implant shoulder. The test implants had a turned neck of 1.8 mm identical to the sink depth, while the control implants yielded a turned neck of 2.8 mm resulting in the location of the interface of the moderately rough (SLA) with the turned surface approximately 1 mm apical to the alveolar crest after implant installation. Hence, it was assumed that the moderately rough implant surface of the test implants would prevent crestal bone resorption in comparison to the control implants.

Based on the results of the present study, the null hypothesis cannot be refuted, although differences in the postsurgical bone loss have been observed between the test and the control implants. While the former had lost a total of 0.87 mm over the period of 1 year in function, the corresponding value for the controls was 1.31 mm. This difference reached a borderline statistical significance ($p = 0.028$). However, due to the small number of patients the present study has reduced power to detect small differences. Hence, the results of the present study may be used to calculate an adequate sample size for a future RCT to be able to refute the null hypothesis.

The randomization of the patients in the present study resulted in clinical and radiographic parameters that did not statistically differ between the test and control sites. Hence, the baseline for the RCT provided optimal conditions for the test of postoperative bone loss.

Compared with previous studies of the same implant system, the bone loss encountered in the Standard® Straumann implants of the present study was comparable to that encountered in earlier studies [Buser et al. 1990; Weber et al. 1992]. Moreover, the clinical experimental study performed to test the effect of an increased sink depth [Hämmérle et al. 1996] revealed similar amounts of radiographic bone loss compared with the similar situation (control) in the present study.

In a retrospective radiographic analysis, crestal bone level changes were compared of implants with a 1.8 mm turned neck portion and a 2.8 mm turned neck portion [Hänggi et al. 2003]. Crestal bone levels remodeled to about the level of the moder-

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**Table 2.** Mean crestal bone levels (S-BIC) measured on standardized digitized radiographs 1 week after implant installation, after 6 months and after at least 1 year in function.

<table>
<thead>
<tr>
<th></th>
<th>Test implants</th>
<th></th>
<th>Control implants</th>
<th></th>
<th>t-test*</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Mean</td>
<td>SD</td>
<td>Range</td>
<td>Mean</td>
<td>SD</td>
</tr>
<tr>
<td>Mean crestal bone level after 1 week (mm)</td>
<td>1.74</td>
<td>0.66</td>
<td>0.2–2.7</td>
<td>1.54</td>
<td>0.56</td>
</tr>
<tr>
<td>Mean crestal bone level after 6 months in function (mm)</td>
<td>2.28</td>
<td>0.72</td>
<td>1.4–3.3</td>
<td>2.66</td>
<td>0.95</td>
</tr>
<tr>
<td>Mean crestal bone level after at least 1 year in function (mm)</td>
<td>2.61</td>
<td>1.03</td>
<td>0.8–5</td>
<td>2.85</td>
<td>0.64</td>
</tr>
</tbody>
</table>

*Derived from paired t-tests.

**Table 3.** Frequency analysis of the crestal bone levels around test and control implants after at least 1 year in function.

<table>
<thead>
<tr>
<th>Crestal bone levels (mm)</th>
<th>Test</th>
<th>Frequency</th>
<th>%</th>
<th>Cumulative (%)</th>
<th>Control</th>
<th>Frequency</th>
<th>%</th>
<th>Cumulative (%)</th>
<th>P-value*</th>
</tr>
</thead>
<tbody>
<tr>
<td>1–2</td>
<td>9</td>
<td>50</td>
<td>50</td>
<td></td>
<td>1</td>
<td>5.6</td>
<td>5.6</td>
<td></td>
<td>0.122</td>
</tr>
<tr>
<td>2–3</td>
<td>5</td>
<td>27.8</td>
<td>77.8</td>
<td></td>
<td>13</td>
<td>72.2</td>
<td>77.8</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3–4</td>
<td>3</td>
<td>16.7</td>
<td>94.4</td>
<td></td>
<td>4</td>
<td>22.2</td>
<td>100</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4–5</td>
<td>1</td>
<td>5.5</td>
<td>100</td>
<td></td>
<td>0</td>
<td>0</td>
<td>100</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*Derived from a Wilcoxon signed-rank test.

**Table 4.** Change in crestal bone level between baseline (1 week after implant installation) and after at least 1 year in function around test and control implants.

<table>
<thead>
<tr>
<th></th>
<th>Test implants</th>
<th>Control implants</th>
<th>P-value*</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Mean</td>
<td>SD</td>
<td>Mean</td>
</tr>
<tr>
<td>Change in crestal bone level between baseline and after 1 year in function (mm)</td>
<td>0.87</td>
<td>0.8</td>
<td>1.31</td>
</tr>
</tbody>
</table>

*Derived from a Wilcoxon signed-rank test.
Table 5. Mean probing pocket depths, probing attachment levels, incidence of bleeding on probing (BOP) and peri-implantitis

<table>
<thead>
<tr>
<th></th>
<th>Test implants</th>
<th>Standard implants</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean probing pocket depth (mm)</td>
<td>3.35 ± 0.76</td>
<td>3.22 ± 0.51</td>
<td>0.634*</td>
</tr>
<tr>
<td>Mean probing attachment levels (mm)</td>
<td>2.17 ± 0.54</td>
<td>2.37 ± 0.53</td>
<td>0.101*</td>
</tr>
<tr>
<td>Bleeding on probing (%)</td>
<td>52.9%</td>
<td>47.1%</td>
<td>0.493**</td>
</tr>
<tr>
<td>Peri-implantitis (%) defined as PPD ≥ 5 mm and BOP+</td>
<td>29.4%</td>
<td>41.2%</td>
<td>0.473**</td>
</tr>
<tr>
<td>Peri-implantitis (%) defined as PPD ≥ 6 mm and BOP+</td>
<td>17.7%</td>
<td>5.9%</td>
<td>0.287**</td>
</tr>
</tbody>
</table>

*Derived from Wilcoxon’s signed-rank tests
**Derived from a Pearson χ².

PPD, probing pocket depth.

By modifying the surface roughness of the neck of the Straumann implants and – at the same time – reducing the dimensions of the turned neck postsurgical, crestal bone resorption was expected to diminish. Indeed, the tendency for such a phenomenon was demonstrated in the present study. This was substantiated by the frequency analysis of crestal bone levels of test and control implants. It showed a higher percentage of test implants with crestal bone levels from the implant shoulders in the expected magnitude of up to 2 mm when compared with control implants. This, in turn, means that the test implants were superior to maintain the crestal bone levels at the time of implant installation. Only at one (5.6%) control implant, the bone level was maintained after 1 year of function, while at 9 (50%) of the test implants the crestal preoperative bone levels were maintained. In this respect, the results of the present study corroborate those of a retrospective study [Hanggi et al. 2005], where crestal bone levels were maintained after the installation of Standard Plus® Straumann implants without compromising on the biological width of the implants.

Frequency analysis of bone level changes appears to be more relevant outcomes than the reporting of the mean bone levels [Wennström et al. 2005]. In the present study such a suggestion was verified. The frequency analysis gave a more accurate image of the changes in bone levels than did the mean scores. It is evident that small sample sizes would reflect high proportions within a category of crestal bone levels and hence, the actual number of subjects affected should not be forgotten. Outliers in a data set will also be revealed by a frequency analysis.

Soft tissue analysis after 1 year in function showed no significant differences in soft tissue parameters between the test and control implants indicating the establishment of a biological width irrespective of the configuration of a transmucosal implant at its neck portion.

In the present study a relatively high proportion of peri-implantitis was identified. Depending on the definition, the prevalence varied between 6% and 41%. No statistically significant differences were found between test and control implants, although impressive values of 17.7% (n = 3) for test and 5.9% (n = 1) for control implants were noticed. Again, the small number of patients did not allow a proper statistical analysis. It must, however, be assumed that peri-implantitis may develop at implant sites irrespective of the configuration or the design of the implant [Abrahamsson et al. 1998].

In conclusion, the present study has indicated that implants with a reduced height turned neck of 1.8 mm may, indeed, reduce the crestal bone resorption, and hence may maintain higher crestal bone levels than do implants with a 2.8 mm turned neck, when sunk to the same depth. Thus, in cases of esthetic priority, where visible metal margins of reconstructions ought to be avoided, the installation of implants with 1.8 mm turned neck should be favored. Moreover, several factors other than the vertical positioning of the moderately rough SLA surface may influence crestal bone levels after 1 year. Further research with adequately powered patient samples is warranted.

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Tan et al - Vertical depth of implant placement