CHAPTER — 3

This chapter is an edited version of the manuscript:

Patil, R.C., den Hartog, L., van Heereveld, C., Jagdale, A., Dilbaghi, A. & Cune, M.S.

Comparison of two different abutment designs on marginal bone loss and soft tissue development.

Aim
To assess the response of soft tissues around two different abutment designs in healed sites in the esthetic zone.

Material and methods
Twenty-six subjects received two endosseous implants in healed, bilateral implant sites in the esthetic zone in the maxilla or the mandible. After 17 to 19 weeks and left/ right randomization, the implants were restored with either a conventional (control) or curved (experimental) titanium abutment and a provisional crown. Eight weeks after abutment placement, definitive crowns were cemented (T0). Soft tissue development was assessed based on peri-implant bone loss, Pink Esthetic Score (PES), and probing depths immediately after placement of the definitive crown and after 1 year (T12) and compared between sites. Possible confounding variables (abutment angle, plaque presence, gingival bleeding, width of attached mucosa) were also documented at T0 and T12.

Results
The mean peri-implant marginal bone loss from T0 to T12 was 0.00 ± 0.37 mm in the experimental group and 0.12 ± 0.27 mm in the control group. Differences were not statistically significant ($P = 0.25$). At T12, the curved abutment scored a mean PES of 10 ± 2.3 and the divergent abutment scored 9.7 ± 2.3. The difference was not significant ($P = 0.46$). Probing depths were also not significantly different between the two groups ($P = 0.85$). Correlation and regression analysis showed no hints of predictive behavior for the possible confounding variables.

Conclusion
A titanium abutment with a circumferential curved design is of no additional benefit to soft tissue development and preservation of marginal bone compared to a conventional divergent abutment design for the restoration of single-tooth implants in the esthetic zone.
Comparison of two different abutment designs on marginal bone loss and soft tissue development

Introduction

In addition to the shape, size, form, and color of an implant crown, harmonious, stable and healthy soft tissues are key indicators of implant success or failure in the esthetic zone. Hence, development of the soft tissue contour and the extent to which embrasure spaces lateral to implant-supported crowns are filled are challenging aspects of implant treatment; this is true when replacing single teeth and even more so when multiple teeth are being replaced. The levels of supporting bone and surrounding soft tissue dimensions around single implants are essentially governed by the surgical and prosthetic parameters and their variables. Iatrogenic factors such as implant positioning in a correct three-dimensional orientation are imperative to an esthetic outcome, regardless of the implant system used. The relationship of the position of the implant and its proposed restoration should be based on the implant shoulder, as this is presumed to influence the final hard and soft tissue response (Belser et al, 2004). Other factors, such as the presence of attached mucosa, keratinized mucosa, and gingival biotype, are also presumed to play significant roles in the final position of the soft tissues around implants (Alberktsson et al, 1986; Kan et al, 2003; Linkevicius & Apsei, 2008; Zigdon & Machtei, 2008).

Recession of the marginal soft tissue up to 1.5 mm after 1 year of function, most of which occurs during the first 3 months, has been reported (Small & Tarnow, 2000; Grunder, 2000; Cardaropoli et al, 2006). This increases concern regarding the long-term adhesion of the connective tissue, which supports the epithelium and resists apical migration of the implant-abutment interface. Hence, multiple factors have been identified that may affect the peri-implant tissue topography and have led to several innovations over the years aimed at preservation and esthetic enhancement (Rompen et al, 2003; Myshin & Wiens, 2005; Rompen et al, 2006; Teughels et al, 2006).

Variations in abutment geometry, especially those with an inwardly concave
part plus macrogroove, have been hypothesized to increase the interface between
the abutment and the soft tissue, creating an "O-ring connective tissue" (Rompen et al, 2007). This approach could encourage collagen fibers, both circumferential and
horizontal, to invade the grooved space, resulting in intimate contact of junctional
epithelial cells and functional orientation of collagen fibers with the enlarged
abutment collar surface. The thickness of the soft tissue around the abutment can
be enhanced further through the use of less flared and concave abutments, allowing
for a more stable biologic space and a tight mucosal ring around the abutment.
To date, studies of the benefits of this concept have produced conflicting results

The objective of the current study was to compare experimental curved
and conventional divergent implant abutments in vivo. They were compared with
respect to soft tissue behavior, bone level changes and the Pink Esthetic Score (PES)
(Fürhauser et al, 2005) around single-tooth implant crowns over an observation
period of 1 year post loading. It was hypothesized that the experimental abutment
would lead to superior clinical performance versus the conventional abutment.
Material and methods

The study was set up as a single-center clinical trial with a split-mouth randomization design. Two non-adjacent missing teeth in the esthetic zone (right second premolar to left second premolar) in the same arch were required for inclusion in the study, and patients needed to be in good general health. Bone volume needed to be sufficient for placement of implants at least 3.5 mm wide and 10 mm long without additional augmentation procedures (Fig. 1). Twenty-six subjects aged 17 to 56 years (mean, 37.7 years) were included (Table 1). Necessary ethical approval and written informed consent were obtained for the study.

Surgical and prosthetic procedures

Fifty-two tapered implants (Replace Select™, Nobel Biocare) were placed with conventional drilling osteotomy procedures (IP). The facial side of the implant shoulder was placed at the crest of the osteotomy. Implant diameter was 3.5, 4.3, or 5.0 mm. The implant site was closed with nonresorbable sutures (Mersilk

| Table 1. Baseline characteristics and treatment specifications of included patients |
|-----------------------------------------------|------------|-------|
| Variable                                      | Curved abutment (n = 26) | Divergent abutment (n = 26) |
| Tooth gap location                            |            |       |
| Central incisor                              | 1          | 1     |
| Lateral incisor                              | 6          | 3     |
| Canine                                        | 2          | 4     |
| First premolar                               | 8          | 12    |
| Second premolar                              | 9          | 6     |
| Jaw distribution                              |            |       |
| Maxilla                                       | 20 (77%)   | 20 (77%) |
| Mandible                                      | 6 (23%)    | 6 (23%) |
| Use of angled (15°) abutments                 | 14 (54%)   | 13 (50%) |
| Implant diameter                              |            |       |
| 3.5 mm                                        | 14 (54%)   | 14 (50%) |
| 4.3 mm                                        | 8 (31%)    | 11 (46%) |
| 5.0 mm                                        | 4 (15%)    | 1 (4%) |
| Implant length                                |            |       |
| 10 mm                                         | 15 (58%)   | 7 (27%) |
| 13 mm                                         | 9 (35%)    | 17 (65%) |
| 16 mm                                         | 2 (8%)     | 2 (8%) |
Ethicon 3-0 Johnson and Johnson) in a submerged healing procedure. Two-piece implants were chosen since the procedures were in the esthetic zone.

Stage-two surgery was performed 17 to 19 weeks after implant placement. The cover screws were removed with a small punch and a scalpel, with standardization maintained at each step. The two different abutment designs used were a conventional divergent titanium abutment (Esthetic™, Nobel Biocare; Fig. 2) as the control, and a curved and grooved titanium abutment (Curvy™, Nobel Biocare; Fig. 2) as the experimental abutment. The experimental abutment had an additional macrogroove about 0.5 mm in depth, with a total concave profile height of 1.25 mm. Either straight or 15-degree angled abutments with gingival heights varying from 1 to 3 mm were used. Abutments were prepared directly in the mouth under a standardized protocol. Individual impression trays with polyether impression material were used (Impregum Soft, 3M ESPE, St. Paul, MN, USA). The subjects received porcelain-fused-to-metal crowns as the definitive restorations 8 weeks after abutment insertion (T0). No special modifications with respect to contact areas were made to support the papillae during the provisional or the definitive prosthetic phase. The relative shape and size of the definitive restoration were maintained as per the proportions of the existing teeth, and care was taken to avoid over contouring of the restorations to compensate for the deficiencies of the soft tissues.

Analysis was done at two time points: T0 and T12 (1 year post-definite crown placement). Standardized periapical radiographs were obtained to measure marginal bone loss, photographs were taken to assign PES, and probing depths were measured manually to the nearest 1 mm using a Williams probe. The seven attributes of peri-implant soft tissue evaluated in the PES were mesial and distal papillae, soft tissue level and contour, alveolar process deficiency, and soft tissue color and texture.

Additional variables documented and analyzed were the bone level at IP, bone loss between IP and T0 and between T0 and T12, abutment angle, undisclosed plaque (Loe and Silness Plaque Index), gingival bleeding (Ainamo and Bay Gingival Index) and width of attached mucosa (Cox and Zarb Quality Index) (Loe, 1967; Ainamo & Bay, 1975; Cox & Zarb, 1987).
Radiographic assessment
Marginal bone levels were recorded on periapical radiographs using standard procedures with customized bite blocks at IP, T0, and T12. Measurement of changes in the bone levels between experimental and conventional abutments at T12 was done using the method of analysis described by den Hartog et al (2011). Radiographs were calibrated using the available data on implant dimensions. A reference line was drawn along the top of the implant. Reference points at the bone-implant interface (A) and the bone-adjacent teeth (B) were used to determine the marginal bone levels on the radiographs (Fig. 3). Bone level was defined as the average of mesial and distal bone loss. Images were modified so that the type of abutment and measurement time could not be determined from the radiographs. Therefore, the examiner was blinded with regard to abutment type and time point.

Photographic assessment
All photographs were taken with a Canon Rebel XT equipped with a 100-mm macro lens with ring flash under similar light conditions. Photographs were made perpendicular to the facial aspect of the teeth. Each photograph included the implant-supported crown along with adjacent teeth in a 1:1.5 ratio (Fig. 4). Photographs
were obtained at IP, T0, and T12. PES values were analyzed in a randomized manner, similar to radiographs. Analysis was done using the measurement tools available in Adobe Photoshop CS6 Extended.

Reliability of radiographic and photographic assessments
Intraclass correlation coefficients (ICCs) were calculated to evaluate intraobserver variability with the use of eight random samples (four from both groups) per radiograph and photograph, respectively. ICCs of 0.84 for radiographs and 0.96 for photographs were obtained, signifying high levels of intraobserver agreement for a random sample size.

Data analysis
Sample size was calculated using Power & Sample Size Calculator (Statistical Solutions). A difference of mean marginal bone loss of 0.5 mm between T0 and T12 was considered superior performance for the curved abutment. With an expected standard deviation of 0.6 mm, as derived from the literature, (den Hartog, 2008) sample size analysis with a two-sided significance level of 0.05 and a power of 90% showed that a minimum of 16 subjects was required. For statistical analysis, values of P < 0.05 were considered significant. The data were collected in a Microsoft Excel worksheet. This was later converted to a master sheet in IBM SPSS Statistics (version 20, SPSS) for statistical analysis.
Variables were analyzed as follows.

- Peri-implant marginal bone loss: The radiographs provide continuous data. The difference in bone loss between T0 and T12 was analyzed with a paired test. Kolmogorov-Smirnov with Lillefors significance correction showed that the dataset was normally distributed. Therefore, a paired t-test was performed.

- PES: The PES variable consists of a nominal scale. To compare the performance of the grooved versus the conventional abutment, a paired comparison (Wilcoxon signed rank test) was used for both the differences in PES between T0 and T12 and the differences in PES between groups at T12.

- Probing depths: Kolmogorov-Smirnov with Lillefors significance correction showed that the data were not normally distributed. Therefore, the Wilcoxon signed rank test was performed.

To explore possible confounding variables, Pearson correlation analysis was performed for the amount of peri-implant bone loss between IP and T0, abutment angle, plaque presence, and gingival bleeding. For the non-continuous variables, point-biserial correlation analysis was used. The point-biserial correlation is mathematically equivalent to the Pearson correlation, in case of a continuously measured variable ‘x’ and a dichotomous variable ‘y’. Also, logistic regression analysis was performed to assess predictors for the mean peri-implant marginal bone loss.

Results

The mean peri-implant marginal bone loss from T0 to T12 was 0.00 ± 0.37 mm in the experimental group and 0.12 ± 0.27 mm in the control group. This difference was not significant ($P = 0.25$). Most of the bone loss occurred within the first months after implant placement (Table 2, Fig. 5). In both study groups, bone levels were located beneath the implant shoulder at T0, the time of definitive crown placement (Table 2, Fig. 5). At T0, the implant provided with the curved abutment exhibited a mean loss of 0.54 ± 0.87 mm, while the divergent abutment showed 0.81 ± 0.70 mm bone loss.
<table>
<thead>
<tr>
<th></th>
<th>IP</th>
<th></th>
<th>T0</th>
<th></th>
<th>T12</th>
<th></th>
<th>T0 to T12</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Peri-implant marginal bone loss (mm)</td>
<td>0.71 ± 0.55</td>
<td>0.61 ± 0.51</td>
<td>1.25 ± 0.64</td>
<td>1.39 ± 0.66</td>
<td>1.26 ± 0.60</td>
<td>1.48 ± 0.66</td>
<td>0.00 ± 0.37</td>
<td>0.12 ± 0.27</td>
</tr>
<tr>
<td>PES</td>
<td>8.8 ± 2.1</td>
<td>9.1 ± 2.0</td>
<td>10 ± 2.3</td>
<td>9.7 ± 2.3</td>
<td>1.2 ± 2.0</td>
<td>0.6 ± 2.0</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Attached mucosa (mm)</td>
<td>2.77 ± 0.43</td>
<td>2.85 ± 0.46</td>
<td>2.85 ± 0.37</td>
<td>2.85 ± 0.46</td>
<td>0.32 ± 0.37</td>
<td>0.29 ± 0.40</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Probing depth (mm)</td>
<td>3.09 ± 0.35</td>
<td>3.08 ± 0.30</td>
<td>3.41 ± 0.30</td>
<td>3.37 ± 0.36</td>
<td>-0.08 ± 0.39</td>
<td>0.00 ± 0.28</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
At T0, the curved abutment sites scored an average PES of 8.8 ± 2.1 and the divergent abutment sites scored 9.1 ± 2.0. At the 1-year follow-up (T12), the curved abutment sites scored an average PES of 10 ± 2.3 and the divergent abutment sites scored 9.7 ± 2.3. The difference in mean PES from T0 to T12 was 1.2 ± 2.0 in the experimental group and 0.6 ± 2.0 in the control group. These differences were not significant ($P = 0.41$). Distribution of the PES is depicted in Figure 6.

The mean probing depth at T0 was 3.09 ± 0.35 mm for the experimental curved abutment and 3.08 ± 0.30 mm for the control divergent abutment. At T12 the experimental abutment showed mean probing depths of 3.41 ± 0.30 mm and the divergent abutment showed mean probing depths of 3.37 ± 0.36 mm. The differences between mean probing depths from T0 to T12 were -0.08 ± 0.39 mm in the experimental group and 0.00 ± 0.28 mm in the control group. Differences were not significant ($P = 0.85$).
Confounding variables
Correlation analysis was performed to determine the influence of peri-implant marginal bone loss between IP and definitive crown cementation (T0). Bone loss at IP was used and loss between IP and T0 was used. There was no significant correlation between bone loss at IP in the control group \( (P = 0.80) \) or in the experimental group \( (P = 0.30) \). For bone loss between IP and T0 in the control group, there was no significant correlation \( (P = 0.55) \). There was a significant correlation in the experimental group \( (P = 0.01) \) \( \text{(Pearson correlation of -0.5 mm)} \). However, because the mean bone loss after abutment placement was close to zero, this result is of little clinical relevance.

Abutment angle was converted to a dichotomous variable to differentiate between no angle (0 degrees) and 15 degrees. Pearson correlation showed no significant relationship for the use of an angled abutment and relative bone loss in the control group \( (P = 0.94) \) or in the experimental group \( (P = 0.13) \). Plaque was converted into a dichotomous variable to differentiate between the presence and absence of plaque. Pearson correlation showed no significant relationship between plaque presence and relative bone loss in the control group \( (P = 0.21) \) or in the experimental group \( (P = 0.44) \). Gingival bleeding at T12 was used. Pearson correlation showed no significant relationship between bleeding and relative bone loss in the control group \( (P = 0.34) \) or in the experimental group \( (P = 0.33) \). Pearson correlation showed no significant relationship between the width of the attached mucosa and relative bone loss in the control group \( (P = 0.61) \) or in the experimental group \( (P = 0.27) \). Because the correlation analysis showed no significant relationships, logistic regression was used for further analysis. Relative bone loss was converted to a dichotomous variable with a cutoff point of 0.5 mm based on the median value of mean peri-implant marginal bone loss in both groups. None of the earlier analyzed variables presented statistically significant results in a logistic regression model.
Discussion

This split-mouth clinical trial aimed to elucidate the potential superiority of a curved and grooved titanium implant abutment over a divergent abutment with respect to early soft tissue response, tissue stability, and marginal bone loss. In a different study, morse taper connection with platform switch (test group) compared with an internal connection and matching-diameter abutment (control group) showed slightly increased marginal bone loss in the control group; however, the peri-implant soft tissues were stable in both groups (Pieri et al, 2011). In the current study, matching-diameter implant abutments were used in experimental and control groups, with identical connections in both, eliminating any variation in the implant-abutment microgap. More early marginal bone loss than is generally encountered in implants with a non-platform-switched design was seen, (Cardaropoli et al, 2003) with little additional bone loss thereafter and no difference between experimental and control abutment designs. The former is in accordance with observations by others (Weinlander et al, 2009). For the analysis of bone levels, it may have been better to obtain radiographs directly after abutment connection, rather than at cementation. In general, the majority of bone loss is expected after abutment connection, although some amount of bone loss is expected after implant placement.

Mean PES values in this study at the 1-year follow-up were 10 ± 2.3 for the curved abutment and 9.7 ± 2.3 for the divergent abutment (not significant; P = 0.46). PES in another study revealed statistically significant differences in favor of the divergent abutment. In that study, however, posterior sites were assessed and an immediate provisionalization protocol was followed (Weinlander et al, 2011).

In contrast to the findings of Rompen et al (2007) mechanical attachment of the peri-implant connective tissue to the grooved surface of the abutment or within the excessive space made available for the soft tissue attachment in the concave-shaped abutment was not successfully demonstrated. Hence, the hypothesis that a curved and grooved abutment may demonstrate better soft tissue development compared to a conventional divergent abutment in a 1-year delayed crown protocol must be rejected. A difference may possibly be seen in the longer term, for example after 5 years. Computer aided design/computer aided manufacturing (CAD/CAM)
based custom abutment solutions can produce multiple degrees of curvatures to support transgingival morphology. The customization assists in precise fabrication of abutment shape, length, and margins to enhance esthetics and retention of the definitive crowns. Further studies comparing customized CAD/CAM abutments and standard stock abutments may be useful. However, since the current study did not demonstrate differences between divergent and curved abutments, this specific design feature may be of limited significance. Strategies developed around other attachment possibilities such as micromechanical, chemical, or biologic modification of the shape and design; controlling cell behavior by altering the surface topography; and/or modifying surface coatings using nanotechnology or growth factors—have been discussed in the quest to improve the durability and function of implants and soft tissues. The pursuit of the optimal biologically and functionally stable attachment seal of peri-implant mucosa continues.

Conclusion

Both conventional (divergent) and experimental (curved and grooved) abutment designs provided stable soft tissues after a 1-year observation period, with no noticeable statistically significant differences between the two. Possible confounding factors assessed for their effect on bone loss showed no predictive behavior.
References


