CHAPTER — 8

SUMMARY
Osseointegration of implants has proven to be predictable. More recently, sustainable esthetics related to the implant crown, including its surrounding soft tissues have gained focus. The research in this PhD project predominantly addresses the effect of implant geometry on soft tissue development and maintenance. A randomized split mouth blinded prospective clinical trial was set up in which it was evaluated if an altered abutment design could result in better peri-implant soft tissue in terms of attachment strength, soft tissue stability, soft tissue development, maintenance of bone levels, effect on gingival biotype, esthetic perceptions of both dentists and patients, and patient satisfaction in general (Chapters 2-5). An exploratory study on gingival biotypes and crown dimensions comparing Caucasian and Indian subjects was undertaken in order to compare and objectively determine gingival biotypes in the Dutch and Indian population in order to eliminate the effect of possible racial differences (Chapter 6).

The specific aims were:

To evaluate, in a unicentric, left-right randomized split mouth clinical trial, the effect of two different abutment designs on soft tissue healing post 6 weeks of function in a delayed healing protocol (Chapter 2).

To quantitatively measure, in a unicentric, left-right randomized split mouth clinical trial, the peri-implant tissue thickness and to assess the change in biotype post 6 weeks of function in a delayed healing protocol (Chapter 2).

To assess, in a unicentric, left-right randomized split mouth clinical trial, the mucosal marginal stability and soft tissue resistance upon pulling pressure (deseating force) measured by a calibrated gauge, post 6 weeks of function in a delayed healing protocol (Chapter 2).

To assess, in a unicentric, left-right randomized split mouth clinical trial, the effect of two different abutment designs, over one year of loading, the soft tissue response through clinical Pink Esthetic Score (PES) parameters; namely: mesial and distal papilla, soft tissue level and contour, alveolar process deficiency, soft tissue color and texture (Chapter 3).

To assess, in a unicentric, left-right randomized split mouth clinical trial, the effect of two different abutment designs, over one year of loading, the marginal bone levels by clinical recording of marginal bone levels (Chapter 3).
To correlate, in a unicentric, left-right randomized split mouth clinical trial, the effect of two different abutment designs, over one year of loading, the interproximal papilla fill by means of Papilla Index Score (PIS) related to the radiological maximum bone level between the implant and adjacent root as well as the peri-implant marginal bone level (Chapter 4).

To compare, in the randomized clinical trial patients’ satisfaction and dentists’ observations, especially on muco-gingival esthetics, for divergent and curved titanium abutments for single implant crowns in the esthetic zone (Chapter 5).

To correlate gingival biotype and natural crown dimensions across Caucasian and Indian subjects (Chapter 6).

The effect of abutment geometry on muco-gingival esthetics

A split mouth study design was chosen because it effectively eliminates numerous clinical, biologic and technical variables. Patient selection criteria had strict exclusion criteria for smokers and compromised health conditions. Clinically, subjects had to be in need of replacement of at least two non-adjacent missing teeth in the esthetic zone (second bicuspid to second bicuspid) in the same jaw and adequate bone for 3-dimensional correct positioning of implant without the need for any hard or soft tissue augmentation. Bone volume to place implants of at least 3.5 mm in width and 10 mm in length was mandatory. A single surgeon performed all surgical procedures to eliminate inconsistency in operator skill. Left right randomization of experimental abutment (an abutment with an additional macro groove of about 0.5 mm in depth) and control abutment (conventional divergent abutment) during allocation was carried out for the two sites in the same mouth. Except for the difference in shape of the abutments, the metallurgical properties of the abutments were identical. Twenty-nine patients were included, involving 58 implants.
Overall study flow was as under

1st Stage (IP) - day of implant placement. Records taken-IOPA, photographs
   ↓ 17 -19 weeks later
2nd Stage-tissue punch used to remove cover screw, impressions made immediately after homeostasis. Randomized abutment allocation, abutment placed and adjusted in mouth, temp crowns given short of margins but in function
   ↓ 6 weeks later
Abutment deseated using dontrix guage. Impressions made immediately after. Same abutments repositioned with the temp crown
   ↓ 2 weeks later
Final crowns (PFM) cemented (T0) Records taken-IOPA, photographs, manual probing, plaque scores, gingival bleeding scores, VAS for patient satisfaction, PES by trained observer
   ↓ 1 year later
Recall appointment (T12) Records taken-IOPA, photographs, manual probing, plaque scores, gingival bleeding scores, VAS for patient satisfaction, PES by trained observer.

Chapter 2 evaluates the effect of the experimental abutment on the soft tissue healing and stability in comparison with the control abutment. A standardized impression technique was followed to record the punched areas during the second stage surgery appointment and plaster models were fabricated. After 6 weeks, the abutments were pulled with a calibrated dontrix gauge and the standardised impressions were made and models were fabricated.

Intraobserver repeatability of model measurements was determined by comparing scores of initial and repeated measurements for all locations on 20 randomly selected plaster models. The change in distance to the mucosal margin
as dependent variable and abutment type, diameter, height, and angle for all buccal and lingual measurements was analysed. Furthermore, the association between the ‘unseating force’ and the independent determinants abutment type, diameter, height, and angle was analysed. Split mouth differences (i.e. left/right dependency within a patient) was adjusted for by creating multilevel models.

The mean marginal recession between impressions at stage 2 and after 6 weeks was tabulated for various abutment characteristics. A statistically significant difference was never observed between control and experimental abutment types at any of the locations, nor for different abutment heights and diameters. In general, positive mean values for the difference between stage 2 and after 6 weeks were observed, indicating gain of marginal mucosa, but not to a statistically significant level, with one exception. Angled abutments elicit buccal recession at the mesial (-0.05 mm), labial (-0.43 mm) and distal (-0.06) measurement points, whereas a gain in soft tissue height was seen in straight abutments at corresponding sites (0.37, 0.14, and 0.28 mm, respectively). These differences were statistically significant. It could not be demonstrated that an abutment with a circumferential groove leads to a different response of the mucosal margin as compared with a conventional abutment.

Unseating forces varied between 0 and 16 ounce. However, the removal forces between different abutment types, heights, and angles never reached a statistically significant level.

As a clinical finding and from photographic evidence, it was noted that the dislodgement of the experiment abutment always caused more bleeding than the control abutment. No quantitative measurements were performed to determine the extent of bleeding.

Chapter 3 assessed the marginal bone loss and development of soft tissue at T0 and T12. 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 (T0) and after 1 year (T12) and compared between sites. Possible confounding variables (bone loss during surgical procedure, abutment angle, plaque presence, gingival bleeding, width of attached mucosa) were also
documented at both times. Marginal bone levels were recorded on periapical radiographs using standard procedures with customized bite blocks at IP, T0, and T12.

Standard photographs were obtained at IP, T0, and T12. PES values were analysed in a randomized manner, similar to radiographs.

No significant difference was observed in the mean marginal bone loss from T0 to T12 in experimental and control abutment sites. The difference in results regarding PES and mean probing depth at T0 and T12 for both abutments was statistically insignificant. Correlation and regression analysis showed no hints of predictive behaviour for bone loss during the surgical procedure, bone loss between implant placement and abutment placement, abutment angle, plaque presence, gingival bleeding or width of the attached mucosa. Clinical performance over a period of one year post cementation of a single implant in the aesthetic zone, for the different abutment designs did not show significant difference.

In chapter 4 the interproximal papilla fill was measured at T0 by means of the Papilla Index Score (PIS) and related to the maximum bone level between the implant and the adjacent tooth as well as the peri-implant marginal bone level at T12, both measured radiographically. The influence of the maximum bone level between the implant and the adjacent tooth as well as the peri-implant marginal bone level were analysed.

No significant differences were detected in papilla fill between the experimental and control group. A significant relationship between PIS and the maximum bone height between the implant and the adjacent tooth as well as the peri-implant marginal bone level was seen. A positive relationship between maximum bone height at natural tooth surface and papillary fill was observed. Whereas, a negative relationship between peri-implant marginal bone level at the implant surface was seen. Hence, it was concluded that the papilla fill is directly proportional to the height of the bone between the implant and the neighbouring tooth.

Chapter 5 compares patients’ satisfaction and dentists’ observations,
especially on muco-gingival esthetics of the experimental abutment and control abutment at two time points in the study - day of cementation (T0) and one year after (T12). Standard intraoral photographs were taken under standard light conditions at T0 and T12. Patients viewed these photos and looked at a mirror and marked their observations on a Visual Analogue Scale (VAS) in response to 3 questions formulated to gauge their satisfaction. The same photograph was then assessed by a dentist for the PES for all sites both at T0 and T12.

Overall patient satisfaction levels were high at both moments in time. No statistically significant differences were found at any time between the control and experimental abutments design, neither for the PES nor for the VAS scores. PES scores had slightly improved after one year, as had the VAS rating related to one of the questions. Patients’ and dentists’ appreciation determined generally showed a low, though statistically significant correlation. The experimental abutment performed no better than the control.

**A comparison of Caucasian and Indian biotypes**

With the intent of acquiring an objective criterion to measure gingival biotypes a concurrent study was conducted. The study described in Chapter 6 explored the reliability of the assessment of gingival morphotype with the aid of visual and crown dimension assessment. Seventy-three Dutch and Indian patients were included. Intraoral photographs were made and gingival biotype (thick or thin) was assessed by means of subjective assessment (two observers) and by identifying several landmarks to assess crown dimensions (objective, quantitative assessment).

From inter and intraobserver agreement assessment it was tentatively concluded that quantitative assessment of crown dimensions may be more reliable to predict gingival biotype outcome after implant restorative and surgical procedures. Cross cultural differences were also taken into account during the study. Of all parameters measured, only the mean crown width-length angle was smaller in Dutch as compared to Indian subjects in this sample ($P < 0.05$). Quantitative assessment could be a norm in the future to eliminate subjective visual assessment and individual interpretation to describe gingival biotype.
General conclusions

From the PhD research presented in this thesis it can be concluded that out of several factors which can contribute to the end esthetic result of a single tooth implant in the esthetic zone, the change of geometry of the abutment at the peri-implant gingival interface, as employed in this study, does not exhibit any difference in the soft tissue development around the implant. The mean crown width-length angle is smaller in Dutch as compared to Indian subjects. Gingival morphotype is best studied quantitatively.