Summary
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The use of dental implants supporting Fixed (FDP) or Removable Dental Prostheses (RDP) provides a solution for the replacement of missing teeth. One of the clinical criterions for success of dental implant treatment has been defined as crestal bone change around the implants. Dental implants are available in various surface characteristics, lengths, shapes and designs. All these factors could influence the crestal bone change during and after the osseointegration period. Furthermore site-specific characteristics as implant loading, bone density, soft tissue quality and thickness may influence these changes as well. The delicate balance between crestal bone change and crestal bone loss is possibly determined by the biological width. This zone of tissue has the ability to cope with the bacterial leakage from the microgap at the Implant-Abutment Interface (IAI). This microgap and IAI may be placed below, at the crestal bone level or above. The clinical consequences when changing the position of the IAI, has been studied in the past. However this has not been done using similar macro geometrical implants, loaded under the same circumstances in a randomized clinical trial. Therefore, as described in Chapter 1, the aim of the studies described in this thesis was to assess the crestal bone change, patient satisfaction, and performance of a bone and soft tissue level implant loaded in a randomized clinical trial loaded under the same circumstances in an early loading protocol. In Chapter 2 a systematic review and meta-analysis of the current literature was described. The PICO-question was; P: patients with functioning implants for a minimum of 1 year, I: Implant placed with prosthetic connection at bone level, C: Implant placed with prosthetic connection at soft tissue level and O: crestal bone level change between placement and a minimal one year of functioning. Is there any difference on crestal bone change around implants with the implant-abutment connection at crestal bone level or above? Significant more crestal bone change was seen (radiographically) in the soft tissue level group ($P < 0.00001$). The literature showed a mean crestal bone change over all implants of -0.62 mm in the group with bone and -0.85 mm in soft tissue level implants. Within the limitations of this systematic review, in general dental implants with the prosthetic connection at bone level showed significant less crestal bone changes after one year of loading when compared to implants with the prosthetic connection above the crestal bone level. However, none of these implants had the same macro geometrical shape, were loaded under the same conditions and all fixed dental prosthesis were cemented.

A prospective randomized clinical trial is described in Chapter 3. Patients were referred to ACTA for implant placement. Patients were subjected to inclusion and exclusion criteria and
received a minimum of 2 implants: an implant with the prosthetic abutment connection at the crestal bone level (MC, bone level) and one with the prosthetic abutment connection 2.5 mm supra crestal (LC, soft tissue level). The mesial or distal position of each implant type was blinded for the patient and randomized. The implants were loaded splinted after 3 weeks of healing. The primary outcome was bone level changes assessed after one year of loading. 33 Patients fulfilled the inclusion criteria. 39 Thommen SPI-ELEMENT LC implants and 39 MC were placed and each fixed dental prosthesis was supported by one LC and one MC implant. The intra-class correlation of measures performed by the first and second x-ray examiner was on the mesial side of the MC implant 0.990 (0.980-0.995; 95 % CI). 0.980 (0.962-0.990; 95 % CI) on the distal side of the MC implant. 0.979 (0.959-0.989; 95 % CI) and 0.988 (0.978-0.994; 95 % CI) mesial and distal of the LC implant respectively. The mean bone loss of the MC implant was 0.4 ± 0.4 mm. The mean bone loss of the LC implant was 0.2 ± 0.5 mm. The paired-samples test showed a statistical significant difference ($P < .05$) between the MC and LC implants.

The design of a dental implant has an influence on implant stability. Implant stability is critical to the long-term success of osseointegrated implants. Initially, the stability is provided by macro retention to the bony walls surrounding the implant. Resorption of bone due to morphological changes during healing takes place within a few days of implant insertion resulting in a loss of mechanical retention. Further, the loss of mechanical retention and the process of osseointegration do not occur simultaneously, thus causing a temporary decrease in implant stability. To measure implant stability, resonance frequency analysis (RFA) can be used and it is possible to assess changes in implant stability over time.

In Chapter 4 the study is described in which the RFA was measured using the Implants Stability Quotient (ISQ) at implant placement (T1), 2 weeks after surgery (T2), FDP mounting (T3) and after 12 weeks of loading (T12). 76 SPI-ELEMENT implants – 38 bone level (MC) and 38 soft tissue level (LC) implants – were placed in 32 patients. Early loaded soft tissue level implants showed a significant drop in ISQ values by 2.2 ± 3.6 ISQ ($P < 0.001$) by week 2. Changes in ISQ values were significant between weeks 3 and 12, and also between weeks 0 and 12, with mean differences of 4.2 ($P < 0.001$) and 2.8 ISQ ($P < 0.001$) respectively. Early-loaded bone level implants show a significant change in ISQ by 2.3 ± 3.7 ISQ at week 2 ($P < 0.01$) and at T12 when compared to T3 of 2.9 ± 4.9 ISQ ($P < 0.01$). Bone level implants achieved higher ISQ values compared to soft tissue level implants in weeks 0, 2, 3 and 12, with mean differences of 3.8 ± 5.5 ISQ ($P < 0.01$), 3.8 ± 6.1 ISQ ($P < 0.01$), 3.7 ± 6.7 ISQ ($P <
0.01), 2.3 ± 5.8 ISQ ($P < 0.05$) respectively. Thus a statistical significant dip in ISQ values was observed, with the lowest point at week 2. ISQ values remained higher in bone level implants throughout the process of healing and osseointegration. A site-specific characteristic is the soft tissue thickness, which contributes to the biological width and thus could influence the crestal bone change.

In **Chapter 5**, the crestal bone change is evaluated around bone and soft tissue level implants. Patients received in a prospective randomized clinical trial at least 2 implants: one with the prosthetic abutment connection at the crestal bone level (MC) and another with the prosthetic abutment connection at 2.5 mm supra crestal (LC). Flap thickness measurements were taken using a periodontal probe after raising the buccal flap. Patients were divided into 2 groups according to mucosal thickness – Group A (thickness, ≤ 2 mm) and Group B (thickness, > 2 mm). This study included 33 patients and 78 implants. Each patient received at least 1 implant of each type. The results of Group A (MC), 17 implants, showed a mean bone change of -0.6 ± 0.5 mm; Group B (MC), 20 implants showed a mean bone change of -0.2 ± 0.4 mm; Group A (LC), 15 implants showed a mean bone change of -0.1 ± 0.5 mm; and Group B (LC) and 22 implants showed a mean bone change of -0.2 ± 0.4 mm. A paired-samples t-test for Group A (MC) and B (MC) yielded a statistically significant difference ($P = .003$); there was no statistically significant difference for Groups A (LC) and B (LC) ($P = .518$): If the initial mucosal thickness surrounding bone level implants is more than 2 mm, there is significantly less crestal bone change compared to bone level implants placed in initial mucosal thicknesses of 2 mm or less. This difference was not statistically significant when soft tissue level implants are used and the implant-abutment connection is 2.5 mm above the crestal bone level.

The effect on the OHRQoL when the described dental implant treatment was performed was assessed in **Chapter 6**. There is a lack of evidence of the effect when implants are restored with fixed partial dentures on the OHRQoL in partially edentulous Kennedy class II (unilateral shortened dental arch) and III (unilateral diastema) patients. Kennedy class II and III patients received dental implants and an FDP. OHRQoL was measured by administration of the Oral Health Impact Profile-14 (OHIP-14NL) questionnaire at intake (T1), two weeks after surgery (T2), and after one year of loading (T3). The mean OHIP score at T1 was 6.5 +/- 1.2, 2.4 +/- 1.0 at T2, and 0.9 +/- 0.3 at T3. There was a statistically significant difference between T1 and T2 ($P = 0.002$) and T1 and T3 ($P < 0.001$) but not between T2 and T3 ($P = 0.407$). The OHIP score in Kennedy II patients decreased from 4.8 +/- 3.2 at T1 to 1.5 +/- 2.0
at T2 and 1.1 +/− 1.8 at T3, and that in Kennedy III patients decreased from 8.9 +/− 9.6 at T1 to 3.6 +/− 8.9 at T2 and 0.8 +/− 2.2 at T3. There were no statistically significant differences in the reductions in Kennedy II and III patients. OHRQoL changed positively in patients treated with implants and an FDP in both groups. There was no change in OHRQoL between the times of implant placement and FDP placement.

During my post-academic training in Implantology in the Academic Centre for Dentistry Amsterdam (ACTA), prior to every treatment, a surgical and prosthetic planning was being conducted. A part of this planning was the choice of dental implant system. Next to my own preference there is no protocol or guideline to help me as clinician, and thus the patient in the choice of dental implants. With the results of the studies mentioned above and the yielded conclusions several questions have now been addressed. Whether these findings are still present in, for example, 10 years remains unclear. Thus, a long-term follow-up of these patients is mandatory.

- Similar macro geometrical implants with the implant-abutment interface at the crestal bone level demonstrate statistically significant ($P < 0.05$) more initial bone loss than when the implant-abutment interface is 2.5 mm above the crestal bone level.

- The loading of 2-splinted implants in the (pre) molar area at week 3 is a predictable treatment option when torque values are above 10 Ncm.

- A drop in ISQ values by 2.2 in soft tissue level and 2.3 in bone level implants after 2 weeks of implant insertion indicates a significant dip in implant stability. After osseointegration, significantly higher implant stability is seen compared to the stability directly after placement.

- During healing, no differences in the development of ISQ values between bone and soft tissue level implants is observed, indicating no differences in the process of osseointegration between the two types of implant design.

- The high correlation between insertion torque and implant stability at placement suggests that implants with high insertion torque values generally have higher implant stability at placement. On the basis of the insertion torque values, 91% of the implants were loaded after 21 days of healing.

- If the initial mucosal thickness surrounding bone level implants is more than 2 mm, there is statistically significantly less crestal bone change when compared to bone
level implants placed in initial mucosal thicknesses of 2 mm or less. This difference is not statistically significant when tissue level implants are used or when the implant-abutment connection is 2.5 mm above the crestal bone level, indicating that when treating patients with initial mucosal thicknesses of 2 mm or less, choosing a tissue level implant with the implant-abutment connection 2.5 mm above the crestal bone level could prevent crestal bone loss.

- OHRQoL changes positively when partially edentulous patients are treated with implants and an FDP.
- There is no difference in improvement of OHRQoL between patients with a Kennedy II or III classification. There is, however, a difference in OHRQoL in patients with a Kennedy II or III classification at baseline.