Two-stage dental implants inserted in a one-stage procedure
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Chapter 8
Clinical and radiological evaluation on one-stage and two-stage implant placement; two-years’ results of a prospective comparative study

This chapter is an edited version of the manuscript: Heydenrijk K, Meijer H.J.A., Raghoebar G.M. & Stegenga B. Clinical and radiological evaluation on one-stage and two-stage implant placement; two-years’ results of a prospective comparative study. International Journal of Oral and Maxillofacial Implants. Submitted for publication.
INTRODUCTION

Many different endosseous implant systems are currently applied in oral implantology. Roughly, a distinction can be made between implants inserted in a one-stage approach and implants inserted in a two-stage approach. In a two-stage approach, the implant is submerged during the first surgical procedure. During the second surgical procedure the soft tissue covering the implant is reflected and, after removing the covering screw, a transmucosal abutment is connected. The microgap at the junction between implant and abutment is situated at crestal level. By contrast, in a one-stage implant system the transmucosal part is usually integrated into the implant. After inserting the implant the transmucosal part is exposed in the oral cavity. The microgap in this implant type is situated a few millimetres above crestal level. It has been proposed that peri-implant marginal bone loss is more extended around two-stage implants than around one-stage implants as a result of the location of the microgap (Hermann et al. 1997, Buser et al. 1999).

Despite the differences in implant design, one-stage and two-stage implant systems have been demonstrated to have highly predictable favourable clinical outcomes (Adell et al. 1990, Lindquist et al. 1996, Haas et al. 1996, Batenburg et al. 1998a, Buser et al. 1999, Noack et al 2000). Insertion of implants in a one-stage procedure has several advantages (Buser 1999):

- only one surgical intervention is required, which is much more convenient for the patient;
- there is a cost-benefit advantage;
- there is a time-benefit since the prosthetic phase can start earlier because there is no wound healing period involved related to a second surgical procedure;
- during the osseointegration period, the implants are accessible for clinical monitoring.

However, there are situations in which it is more favourable to insert implants in a two-stage procedure (Røynesdal et al. 1999), i.e.,

- in combination with a bone augmentation procedure and guided bone regeneration when the wound has to be closed tightly to prevent bone or membrane exposure;
- to prevent undesirable loading of the implants during the osseointegration period when the temporary suprastructure cannot be adjusted effectively;
- when the coronal part of the implant is located at crestal level, giving the possibility for a more flexible emergence profile of the transmucosal part;
- to provide the possibility to remove supramucosal and transmucosal parts when the patient is not able to perform a sufficient oral hygiene and when possible infections endanger the general health;
- when implants are inserted in patients who will receive radiotherapy in the implant region in the foreseeable future.

Applying two-stage dental implants in a single surgical procedure has been reported to be promising (Bernard et al. 1995, Ericsson et al. 1994, 1996, 1997, Becker et al. 1997, Collaert & De Bruin 1998, Abrahamsson et al. 1999, Røynesdal et al. 1999, Fiorellini et al. 1999). In this way the advantages of both system types are combined. Moreover, there are two additional advantages. First, the surgeon only needs to have a two-phase
implant system in stock for executing both submerged and non-submerged procedures. Second, there is a possibility to switch from a non-submerged procedure to a submerged procedure if this appears to be preferable per-operatively or during the osseointegration period. Many studies have reported the long-term results of implants inserted for mandibular overdenture treatment. Most studies describe a single implant system. Long-term studies comparing a one-stage and a two-stage implant system are sparse. No studies have been published comparing a one-stage implant system and a two-stage implant system inserted in a one-stage procedure. The aim of the present study was to explore the feasibility of inserting a two-stage implant system in a one-stage approach by comparing the clinical outcome and peri-implant radiographic bone. Furthermore, the aim was to evaluate the impact of the microgap between implant and abutment.

**MATERIALS AND METHODS**

**Patients selection**

From the patients referred to the Department of Oral and Maxillofacial Surgery and Maxillofacial Prosthetics of the University Hospital Groningen, 60 consecutive edentulous patients were selected on the basis of the following inclusion criteria:

- the presence of a severely resorbed mandible (class V-VI, Cawood & Howell 1988) with a reduced stability and insufficient retention of the lower denture;
- an edentulous period of at least two years;
- no history of radiotherapy in the head and neck region;
- no history of pre-prosthetic surgery or previous oral implants.

Eligible patients were informed about the three different treatment options and written informed consent was obtained from all participants. They were randomly assigned to one of three groups:

- a group receiving IMZ implants (two-stage 4 mm IMZ cylinder implants with a TPS coating (Friedrichsfeld AG, Mannheim, Germany)) inserted in the traditionally submerged procedure
- a group receiving the same two-stage IMZ implants inserted in a non-submerged single-stage procedure
- a group receiving ITI implants (one-stage 4.1 mm solid screw ITI dental implants with a TPS coating (Straumann AG, Waldenburg, Switzerland).

**Treatment procedures**

All patients received two implants in the canine region of the mandible. The implants were inserted under local anaesthesia, each about one centimetre from to the midline. An experienced maxillofacial surgeon, according to a strict surgical protocol, inserted all implants. The IMZ implants in the two-stage group were inserted as described by Kirsch (1983). The IMZ implants in the single-stage group also were inserted as described by Kirsch (1983) but with the modification for a single-stage implantation procedure using a labial mucosa flap and immediate connection of healing abutments as previously described (Heydenrijk et al. 2000). The surgical procedure used for the ITI-
implants has been previously described (Sutter et al. 1988). In none of the patients, palatal mucosa grafts were placed. Post-operatively, analgesics and chlorhexidin 0.2% mouth rinse were prescribed for 14 days. Systemic or local antibiotics were not prescribed. Patients were not allowed to wear the mandibular denture during the first two weeks post-operatively.
Two, six and twelve weeks after the surgical procedure, the patients were recalled. At the first recall visit, sutures were removed and the lower denture was adjusted by selective grinding at the implant location and relining with Coe-soft (Coe laboratories, Inc. Chicago, U.S.A.). At all recall visits, patients received oral hygiene instructions.

Three months after implant insertion, second stage surgery for connection of 5 millimetre high titanium prosthetic abutments was performed in the two-stage IMZ group. Two weeks later manufacturing of a new maxillary denture and a mandibular overdenture was initiated. In the one-stage IMZ group and the ITI group the prosthetic procedure was started three months after implant insertion. A uniform prosthetic procedure (Batenburg et al.1993) was performed for all patients by one experienced prosthodontist. In the IMZ group, the healing abutments were replaced by 5 mm high titanium connectors. A Dolder bar with subsequent clip attachment supported the overdentures. A balanced occlusion and monoplane articulation concept with porcelain teeth was used.

OUTCOME MEASURES

Data collection was performed at baseline assessment (four weeks after insertion of the new prosthesis (T0), and 6 months (T6), 12 months (T12) and 24 months (T24) later.

Clinical outcome measures
The following clinical parameters were assessed:

- Gingiva-score: the modified Löe and Silness index (score 0 - 3) was used to quantify the degree of peri-implant inflammation (Löe & Silness 1963). The gingiva score was measured at four aspects of the implants, the highest score per implant being used for data-analysis;

- Plaque-score: the Mombelli index (score 0 - 3) was used to quantify the amount of plaque retained on the surface of the supra-gingival part of the implant (Mombelli et al. 1987). The plaque score was measured at four aspects of the implants, the highest value per implant being used for data-analysis;

- Calculus: the presence (score 1) or absence (score 0) of calculus per implant was scored;

- Bleeding-score: the Mühlemann index (0-3) modified by Mombelli et al. (1987) was scored at four aspects of the implants, the highest value per implant being used for data-analysis (Mühlemann & Son 1971);

- Probing pocket depth: the depth of the peri-implant ‘sulcus’ was measured, to the nearest millimetre, mesially and distally of each implant by using a periodontal probe (Merrit B, Hu Friedy, Chicago, U.S.A.) after removal of the bar (Quirynen et al. 1991). The distance between the marginal border of the gingiva and the tip of the pocket probe was scored as the ‘probing pocket depth’. The deepest pocket per implant was used for data-analysis;
• Mobility: the Periotest® (Siemens, Bensheim, Germany) device was used to evaluate the mobility of the implants (Teerlinck et al. 1991); mobile implants were considered as being lost and were removed.

Radiographic outcome
Standardised intra-oral radiographs were made using the long cone technique with an aiming device (Meijer et al. 1992). The distance from a fixed reference point of the implants to the first bone-to-implant contact was measured with a digital calliper (Digitcal SI, Tesa SA, Renens, Switzerland) (Meijer et al. 1993). The measurements were made at the two approximal implant sites. The site showing most bone loss was used for data-analysis. In the ITI group the neck of the implant and in the IMZ groups the implant/connector interface was used as the reference point. From a previous study, addressing intra and inter-observer agreement of measurement of the level of bone, it was concluded that the reproducibility is more consistent if one experienced observer performs the measurements twice rather than two observers performing the measurements once (Batenburg et al. 1998a). Therefore, the measurements were performed twice by the same observer with a two weeks time interval and averaged.

Data analysis
Qualitative data and quantitative data after categorisation were analysed using the Kruskal-Wallis analysis of variance between the three groups. Possible associations between variables were analysed with chi-square tests. The Friedman test was used to assess the course of clinical and radiographic parameters during the evaluation period within the groups. To evaluate possible differences between the groups with regard to normally distributed quantitative variables, a one-way analysis of variance was performed. When the criteria for using parametric tests were not fulfilled, Kruskal-Wallis test (independent data) or Friedman’s test (dependent data) was applied. In all analyses, a significance level of 0.05 was chosen.

RESULTS

Patients
Thirty-four women and 26 men (mean age of 58 ± 11 years) participated in this study. Twenty patients were included in each group. An IMZ implant of the one-stage group had to be removed at T6 because of mobility. Three weeks after removal, two new implants (one mesially and one distally of the former implant location) were successfully inserted. At T12, an IMZ implant of the two-stage group appeared to be mobile and was removed after the standardised radiographs were taken and after collecting the clinical data. Therefore, the data of this implant were included in the T12 results. New implants were inserted mesially and distally of the former implant location, but they have not been in function because the patient died a few months later. Because of the death of this patient and the loss of the implant in the IMZ one-stage group, the 2-years evaluation (T24) comprised 117 implants in 59 patients.
Periodontal parameters

Frequency distributions of the clinical parameters are depicted in Figures 8.1-8.5. At T0, significant differences between the three groups with regard to the bleeding scores and to the amount of probing pocket depths > 3 mm, were found (Kruskal-Wallis tests). At T12, a significant differences between the groups were found with regard to the plaque score and the amount of probing pocket depths >3 mm (Kruskal-Wallis test). Significant differences between the three groups at T24 were found for the plaque score, gingiva score and calculus score (Kruskal-Wallis test). The periotest values (mean -5, ±1.3) were comparable for all three groups throughout the observation period.

In the ITI group there was a significant increase in the bleeding score throughout the observation period (Friedman test, p=0.02, Figure 8.4). In the IMZ two-stage group, a significant reduction of the number of probing pocket depths > 3 mm was found (Friedman test, p=0.01, Figure 8.5). The time course of the other periodontal parameters was comparable for the three groups (Friedman test, p>0.05).

The plaque score was associated with the gingiva score at T24 in the IMZ two-stage group (chi-square p=0.005). No other significant associations between the clinical parameters were found (chi-square test, p>0.05).

Radiographic parameters

In three patients (one of each group) the Dolderbar was placed labially to the implants to prevent interference with the floor of the mouth. As a result, no standardised radiographs could be made of these implants. Therefore, including the lost implants,
Radiographic observations were made of 113 implants in 57 patients at T12, and of 111 implants in 56 patients at T24. A small radiolucent line was visible along the implants that appeared to be mobile.

The mean amount of bone loss was comparable for the three groups during the observation period (one-way analysis of variance, p>0.05, Table 8.1). Comparable number of implants in each implant group were found showing bone loss exceeding 1 millimetre in the first year of functioning and exceeding 0.2 millimetre in the second year (Kruskal-Wallis test, p>0.05, Figures 8.6 and 8.7). No associations between the amount of bone loss and clinical parameters were found (chi-square test, p>0.05).

Figure 8.3. Frequency distribution of the calculus scores at the baseline examination (T0) and 12 (T12) and 24 months (T24) after insertion of the overdenture. Score 0: no calculus, score 1: presence of calculus.

Figure 8.4. Frequency distribution of the bleeding scores at the baseline examination (T0) and 12 (T12) and 24 months (T24) after insertion of the overdenture. Score 0: no bleeding after probing, score 1: isolated bleeding spots, score 2: confluent line of blood, score 3: heavy or profuse bleeding.

Figure 8.5. Frequency distribution of the pocket probing depths at the baseline examination (T0) and 12 (T12) and 24 months (T24) after insertion of the overdenture.
DISCUSSION

This prospective randomised study is the first in which the two-year clinical and radiographic results of two-stage non-submerged implants are compared with two-stage submerged implants and with one-stage implants. This study showed no major differences between the three groups, suggesting that a two-stage implant system can be used for implant insertion in a non-submerged procedure.

After two years of loading, 97.5% of the IMZ implants and all ITI implants were functioning uneventful. The implants that had to be removed were lost during the first year of functioning. Insertion of new implants at mesial and distal locations of the previous implant site resulted in successful re-implants.

The clinical results are comparable with the results in studies in which one-stage or two-stage implant systems were evalu
ated (Quirynen et al. 1991, Mericske-Stern et al. 1994, Åstrand et al. 1996, Batenburg et al. 1998b). At T0 and T12, more IMZ implants than ITI implants had pockets > 3 mm. This might be attributed to the cup shaped transmucosal part of the ITI implants, which may hamper easy insertion of the probe into the pocket (Spiekermann et al. 1995). At T24 a higher plaque and gingiva score were found in the IMZ two-stage group compared to the other groups and the IMZ two-stage group showed a higher calculus score compared to the IMZ one-stage group. Differences in scores of periodontal parameters between different implant types can be explained by different implant characteristics, but differences in scores of periodontal parameters between the two IMZ groups are harder to explain. We presume that it is by coincidence that the IMZ two-stage group contains more patients with poorer oral hygiene maintenance, illustrated by higher plaque, calculus and gingiva scores.

No significant associations between the peri-implant mucosal aspects and the amount of bone loss between T0 and T12 or between T12 and T24 were found, which has been reported earlier (Quirynen et al. 1991, Mericske-Stern et al. 1994, Batenburg et al. 1998b, Weber et al. 2000). Reproducible radiographs of sufficient quality are necessary in a longitudinal trial to accurately detect the first bone to implant contact. The intra-oral radiographs used in the present study have been shown to satisfy this criterion (Batenburg et al. 1998a). The landmarks necessary for the evaluation were easy to identify. A major drawback of this technique is that the first radiograph can be obtained no sooner than after placement of the bar, which was at least 4 months after implant insertion. Therefore, no information was available considering the initial peri-implant bone level changes. The mean bone loss of 0.6 mm between T0 and T12 in our three groups is below the limits of 0.9 to 1.6 mm as reported by Brägger et al. (1998) to be acceptable as a radiographic criterion for implant success. Bone loss during the first year of functioning has been described previously, and is related to maturation of bone after implant insertion and adaptation of bone to withstand functional forces (Adell et al. 1981, van Steenberghe et al. 1999). An annual bone loss of 0.2 mm after this period has been recognised as acceptable (Albrektsson et al. 1986). Several studies described the peri-implant bone changes in the second year of functioning reporting a mean bone loss of approximately 0.1 mm (Adell et al. 1986, Cox & Zarb 1987, Bower et al. 1989, Quirynen et al. 1991, Versteegh et al. 1995, Lindquist et al. 1996, Weber et al. 2000). In our three groups the peri-implant bone loss between T12 and T24 was more extended (Table 8.1). However, when looking at the amount of bone loss between T0 and T24, the values are within the limits of 0.9 to 1.6 mm considered to be acceptable for the first year functioning (Brägger et al. 1998). It does not seem to be a coincidence to find relatively low amounts of bone loss in the first year and high amounts of bone loss in the second year of functioning in the present study compared to the findings from the literature, since comparable amounts of bone loss were found in all of the three groups. Probably, the high quality of the standardised radiographs used in the present study is responsible for the different outcomes. Long-term follow-up evaluations have to show whether bone loss continues in the subsequent years.

It has been proposed that marginal bone loss is more extended around two-stage implants as compared with one-stage
implants (Buser et al. 1999). Therefore, it could have been expected that the implants in both IMZ groups would show more bone loss compared with the ITI group. ITI implants lack a microgap between implant and abutment at the crestal level. The microgap between the implant and the abutment at the crestal level has been suggested to play a prominent role in the development of bone loss (Hermann et al. 1997). In the present study, a comparable amount of bone loss was found between the three groups suggesting that the microgap at crestal level does not influence the amount of peri-implant bone loss.

**CONCLUSIONS**

The results of this study indicate that:

1. Dental implants designed for a submerged implantation procedure can be used in a single-stage procedure and may be as predictable as used in a two-stage procedure or one-stage implants.

2. The microgap at crestal level in two-stage implants does not appear to have an adverse effect on the amount of peri-implant bone loss.
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