Two-stage dental implants inserted in a one-stage procedure
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Chapter 7

Two-stage implants inserted in a one-stage or a two-stage procedure; a prospective comparative study.

This chapter is an edited version of the manuscript: Heydenrijk, K., Raghoebar, G.M., Meijer, H.J.A., van der Reijden, W.A., van Winkelhoff, A.J. & Stegenga, B. Two-part implants inserted in a one-stage or a two-stage procedure; a prospective comparative study. Journal of Clinical Periodontology. Accepted for publication.
INTRODUCTION

In oral implantology, different endosseous implant systems are currently used. Most implant systems consist of two parts, i.e. the implant which is submerged during a first surgical procedure, and the transmucosal part which is connected to the implant during a second surgical procedure. Therefore, these implant systems are collectively referred to as ‘two-stage’ systems. ‘One-stage’ systems consist of one part, which is inserted during a single surgical procedure. The transmucosal part of these implants is integrated to the implant. Well-documented long-term clinical studies have revealed that both implant types have good and predictable outcomes (Adell et al. 1990, Lindquist et al. 1996, Buser et al. 1999, Haas et al. 1996, Heydenrijk et al. 1998).

Inserting implants in one stage has several advantages (Buser et al. 1999). Only one surgical intervention is required which is convenient for the patient, especially for the medically compromised patient. In addition, there is a considerable cost-benefit advantage. The prosthetic phase can start earlier because there is no wound-healing period involved related to a second surgical procedure. Furthermore, the implants are accessible for clinical monitoring during the osseointegration period. On the other hand, one-stage implants are preferably not being inserted under the following circumstances (Røynesdal et al. 1999):

- in combination with an augmentation or guided bone regeneration procedure that requires the wound to be closed tightly to prevent infection and bone or membrane exposure;
- if the integrated abutment interferes with a functional or esthetical design of the suprastructure;
- to prevent undesirable loading of the implants during the osseointegration period when the temporary suprastructure can not be effectively adjusted.

Applying two-stage implants in a single surgical procedure has been reported to be promising in several recent studies (Bernard et al.1995, Ericsson et al.1994, 1996, 1997, Barber et al. 1996, Becker et al.1997, Abrahamsson et al.1999). The reported clinical and radiographic outcomes suggest that two-stage implants inserted in a one-stage procedure may be as predictable as when inserted in a two-stage procedure.

However, most of the studies consist of only small groups of participants and standardised radiographs for the evaluation of peri-implant bone changes were made in only a few studies. Furthermore, 12% of the implants inserted in a one-stage procedure failed to osseointegrate in one study (Røynesdal et al.1999), indicating that the prognosis might be less promising than suggested by the other studies.

One of the main reasons for implant insertion in the “traditional” two-stage procedure was to minimise the risk of infection, since the peri-implant tissue is allowed to heal separate from the oral microbial environment. It has been observed that bacteria colonise the inner region of two-stage implants following abutment connection and that this, in turn, may result in marginal bone loss (Ericsson et al.1995, Persson et al.1996).

Several studies, evaluating the microflora around dental implants have been published, some of which report the presence of suspected periodontal pathogens around failing or failed implants (review, Ellen 1998). It has been suggested that putative periodontal pathogens may be involved in peri-
implant bone loss. Possibly the micro-organisms or their products accommodating the microgap are responsible for the occurrence of this bone loss (Lindhe et al. 1992, Quirynen & van Steenbergh 1993, Ericsson et al. 1995, Persson et al. 1996). Putative periodontal pathogens have been implicated in the onset and progression of peri-implantitis, but it remains unclear whether these bacteria always constitute a risk factor for the maintenance of dental implants (Danser et al. 1997). The frequency of developing peri-implant infection in patients carrying these pathogens is, however, unknown. (van Winkelhoff et al. 2000, van Winkelhoff & Wolf 2000).

The aim of this prospective study was to explore the feasibility of inserting two-stage implants in a one-stage procedure. We compared peri-implant radiographic bone loss and clinical parameters of two-stage implants inserted by either a one-stage or a two-stage surgical procedure, and evaluated the impact of the colonisation of the peri-implant area by putative periodontal pathogens.

MATERIALS AND METHODS

Patient selection
Forty edentulous patients, 19 females and 21 males with a mean age of 58 years (SD=11 years), referred by their dentist to the Department of Oral and Maxillofacial Surgery and Maxillofacial Prosthetics of the University Hospital Groningen, were selected on the basis of the following inclusion criteria:

- the presence of a severely resorbed mandible (class V-VI according to the Cawood & Howell (1988) classification) resulting in 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 implantology.

The patients were informed about the two different treatment options. After obtaining written informed consent, the participants were randomly assigned to a group in which implants were inserted in the traditional two-stage procedure, or to a group in which implants were inserted in a one-stage procedure.

Treatment procedures
All patients received two IMZ implants (two-stage 4 mm IMZ cylinder implants with a TPS coating (Friedrichsfeld AG, Mannheim, Germany) in the canine region of the mandible. The implants were inserted under local anaesthesia, each about one centimetre from to the midline. All implants were inserted according to a strict surgical protocol by one experienced maxillofacial surgeon. The implants in the two-stage group were inserted as described by Kirsch (1983). The implants in the one-stage group also were inserted as described by Kirsch (1983) but with the modification for a one-stage implantation procedure using a labial flap and immediate connection of healing abutments as previously described (Heydenrijk et al. 2000). In none of the patients, palatal mucosa grafts were placed. Postoperatively, analgesics and chlorhexidin 0.2% mouth rinse were prescribed for two weeks. No systemic or local antibiotics were prescribed. Patients were not allowed to
wear the mandibular denture during the first two postoperative weeks.

Two weeks after the surgical procedure, 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, Illinois, U.S.A.). The patients of the one-stage group received oral hygiene instructions two, six and twelve weeks after the surgical procedure, and the manufacturing of a new maxillary denture and a mandibular overdenture was started three months after implant insertion. In the two-stage group, second stage surgery for connection of 5 millimetre high titanium prosthetic abutments was performed three months after implant insertion, and two weeks later the prosthetic procedure was started and oral hygiene instructions were given. For all patients a uniform prosthetic procedure (Batenburg et al. 1993) was performed by one experienced prosthodontist. In the one-stage group, the healing abutments were replaced by 5 millimetre high titanium prosthetic abutments. 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 were collected at three occasions during the first year, i.e. four weeks after insertion of the new prosthesis (T0), after six months (T6), and after 12 months (T12).

Clinical variables
The Mombelli index (score 0 – 3) was used to quantify the amount of plaque retained at four aspects of the surface of the supra-gingival part of the implant (Mombelli et al., 1987). The highest value per implant was used for data-analysis. The presence (score 1) or absence (score 0) of calculus per implant was also scored.

The degree of peri-implant inflammation was quantified by the ‘gingiva’ score (modified Løe and Silness index (Løe & Silness 1963), yielding a 0 – 3 score at each of four aspects of the implants. The highest score obtained per implant was used for data-analysis. In addition, the bleeding score according to Mühlemann (Mühlemann & Son 1971) modified by Mombelli (1987) was scored per implant (score 0-3).

The depth of the peri-implant ‘sulcus’ was measured mesially and distally of each implant to the nearest millimetre by using a periodontal probe (Merrit B, Hu Friedy, Chicago, Illinois, 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 (PPD). The deepest pocket per implant was used for data-analysis.

The Periotest® (Siemens, Bensheim, Germany) device was used to quantify implant mobility (Teerlinck et al. 1991). Mobile implants were regarded as being lost and were removed.

Radiographic evaluation
Standardised intra-oral radiographs were made using the long cone technique with an aiming device (Meijer et al. 1992). The distance from the implant/connector interface to the first bone-to-implant contact was measured with a digital calliper (Digitcal SI, Tesa SA, Renens, Switzerland) (Meijer et al. 1993).
Measurements were made at the two proximal implant sites. From a previous study addressing intra and inter-observer agreement of measurement of the level of bone, more consistent results were obtained when one experienced observer performs the measurement twice than when two observers perform the measurements once (Batenburg et al. 1998a). Therefore, in the present study the measurements were performed twice by the same observer with a two weeks time interval and averaged.

**Microbiological sampling**

Microbiological samples were obtained 12 months after functional loading of the implants (T12). Patients who had taken antibiotics (e.g. for medical reasons) during the previous three months were recalled for sampling 3 months later. Prior to the probing pocket depth measurements, supragingival plaque and calculus was carefully removed with sterile Teflon curettes (Hu-Friedy, Chicago, Illinois) and cotton pellets after which the sample site was isolated with cotton rolls and gentle air drying. Sterile paper points (Fine, UDM, West Palm Beach, Florida) were inserted in the peri-implant region and left in place for 10 seconds. Per implant the approximal sites were sampled twice. Per patient the paper points were collected in 4 separate vials containing 1.8 ml reduced transport fluid (RTF) (Syed & Loesche 1972). The presence and proportions of Actinobacillus actinomycetemcomitans, Porphyromonas gingivalis, Prevotella intermedia, Bacteroides forsythus, P. micros, Fusobacterium nucleatum and Campylobacter rectus were assessed. Samples were processed in the laboratory within six hours. Ten-fold serial dilutions of all samples were prepared in RTF. Aliquots of 0.1 ml were inoculated on 5% horse blood agar plates (Oxoid no. 2, Basingstoke, UK) with haemin (5 mg/l) and menadione (1 mg/l) for isolation and growth of obligatory anaerobic bacteria, and on TSBV plates for selective isolation and growth of A. actinomycetemcomitans (Slots 1982). Blood agar plates were incubated anaerobically in 80% N2, 10% H2 and 10% CO2 for up to 14 days. TSBV plates were incubated in air with 5% CO2 for 5 days (van Steenbergen et al. 1986). Blood agar plates were used for determination of the total number of colony forming units (CFU), the presence of dark-pigmented colonies, B. forsythus, F. nucleatum and P. micros. Representative dark-pigmented colonies were purified and identified using standard techniques (van Winkelhoff et al. 1985), including Gram-stain, fermentation of glucose, production of indole from tryptophan and production of specific enzymes (van Winkelhoff et al. 1986). B. forsythus was identified on the basis of the typical colony morphology, Gram-staining and production of trypsin-like enzyme (Braham & Moncla 1992). F. nucleatum and P. micros were identified on the basis of colony morphology, Gram-stain and production of specific enzymes (API 32A, Biomerieux, La Balme, Les Grottes, France).

**Data analysis**

Analyses were executed per implant. Qualitative data and quantitative data after categorisation were analysed using chi-square tests to assess between-group differences with regard to the distribution of clinical, radiographic and microbiological variables. Differences between quantitative variables were tested with the (paired) t-test when normally distributed and with Wilcoxon’s ranked sign test (paired data) or Mann-Whitney’s test (independent data) when the criteria for using parametric
tests were not fulfilled. The course of clinical and radiographic parameters within the groups during the evaluation period was evaluated with Friedman’s test for more than two related samples. For all univariate tests, a significance level of 0.05 was chosen. The strength of possible associations between clinical and radiographic parameters on one hand and the presence of target microorganisms on the other was assessed with Spearman’s rank correlation coefficient. A multiple stepwise regression analyses was performed to assess the joint contribution of the peri-implant mucosal condition (gingiva score, plaque score, probing pocket depth, bleeding score) and microbiological findings to the bone loss between T0 and T12.

RESULTS

Loss of implants
At T6 one implant of the one-stage group appeared to be mobile. This implant already showed a poor periodontal condition at T0. One implant of the two-stage group appeared to be mobile at T12. This implant did not show any clinical or radiographic signs of tissue breakdown at T6. Before removing the implant, microbiological samples were taken, revealing the presence of P. intermedia (7% of the anaerobic cultivable microbiota), P. micros (6%), F. nucleatum (13%), and B. forsythus (1%). Three weeks after removal of the mobile implants two new IMZ implants in both patients (one mesially and one distally of the former implant location) were successfully inserted.

Periodontal parameters
With regard to the plaque scores, the gingiva scores, the presence of calculus and the bleeding scores higher levels were found in the two-stage group compared to the one-stage group throughout the observation period (Figures 7.1-7.4). But only for the plaque score at T12 this difference was significant (p=0.001, Figure 7.1). In the one-stage group there was a significant reduction in the plaque score throughout the observation period (Friedman test, p=0.04, Figure 7.1). Figures 7.2 – 7.4 illustrate that the time course of the other periodontal parameters was comparable in both groups (Friedman test, p > 0.05). The mean probing pocket depth was comparable for both groups at T0 (one-stage group: mean 3.6 mm, median 3 mm, range 2-12 mm; two-stage group: mean 3.7 mm, median 4 mm, range 2-6 mm. At T12, the difference in probing pocket depth

Figure 7.1. Frequency distribution of the plaque scores at the baseline examination (T0) and 6 (T6) and 12 months (T12) after insertion of the overdenture. At T12 significant less implants of the one-stage group showed a plaque score ≥1 (P=0.001).
was not significant (one-stage group: mean 3.3 mm, median 3 mm, range 1-5 mm; two-stage group mean 3.7 mm, median 3 mm, range 2-8 mm). The mean periotest values were identical for both groups and ranged from -4.9 at T0 to -5.2 at T12.

**Radiographic parameters**
Radiographic observations could be made of 76 implants in 38 patients. In two patients (one from the one-stage group and one from the two-stage group) no standardised radiographs could be made of both implants, because the Dolderbar was placed labially to the implants to prevent interference with the floor of the mouth. In both groups, the mean loss of bone between T0 and T12 was 0.6 mm (SD=1.3 in the two-stage, and SD=0.9 in the one-stage group). Thirteen implants of the two-stage group and 11 of the one-stage group showed a stable...

**Figure 7.2.** Frequency distribution of the gingiva scores at the baseline examination (T0) and 6 (T6) and 12 months (T12) after insertion of the overdenture. Comparable scores were found for both groups during the evaluation period.

**Figure 7.3.** Frequency distribution of the calculus scores at the baseline examination (T0) and 6 (T6) and 12 months (T12) after insertion of the overdenture. Comparable scores for both groups were found during the evaluation period.

**Figure 7.4.** Frequency distribution of the bleeding scores at the baseline examination (T0) and 6 (T6) and 12 months (T12) after insertion of the overdenture. No significant differences were found between the two groups during the evaluation period.
bone level or bone gain. A multiple regression analysis did not yield a model relating clinical variables and target microorganisms with the amount of bone loss between T0 and T12.

**Microbiological parameters**

The mean number of colony forming units was $3.6 \times 10^5$ (SD=$6.9 \times 10^5$) in the one-stage group and $1.1 \times 10^5$ (SD=$2.2 \times 10^5$) in the two-stage group which was not significantly different. *A. actinomycetemcomitans* was not isolated. *P. gingivalis* was isolated at one implant site of the one-stage group. *B. forsythus* was isolated only at 3 implant sites of the two-stage group. Other putative periodontal pathogens were found in comparable frequencies in both groups (Table 7.1). An association was present between pockets $\geq 4$ mm and the presence of *P. micros* in the two-stage group (Spearman’s rho = 0.4, p= 0.007, Table 7.1). With regard to the plaque score, gingiva score and bleeding score, no associations were found with the presence of the microorganisms (Spearman’s rho, p>0.05, Table 7.1).

Bone loss was observed in 26 one-stage implants and 24 two-stage implants. These implants were divided into 2 subgroups, i.e. with sites showing £ 1mm bone loss and with sites showing > 1 mm bone loss. No association could be demonstrated between the amount of bone loss and the presence of any of the target microorganisms (Table 7.1).

**Table 7.1.** Results at T12. Number of implants with a gingiva score, plaque score or a bleeding score $\geq 1$ or a probing pocket depth $\geq 4$ mm or with different amounts of bone loss between T0 and T12, colonised with the target organisms. Comparable results were found between the two groups. The presence of *P. micros* is related to probing pocket depth $\geq 4$ mm in the two-stage group. Aa: *A. actinomycetemcomitans*, Pg: *P. gingivalis*, Pi: *P. intermedia*, Pm: *P. micros*, Bf: *B. forsythus*, Fn: *F. nucleatum*, Cr: *C. rectus*.

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<th>Aa 1-stage</th>
<th>Aa 2-stage</th>
<th>Pg 1-stage</th>
<th>Pg 2-stage</th>
<th>Pi 1-stage</th>
<th>Pi 2-stage</th>
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<th>Bf 1-stage</th>
<th>Bf 2-stage</th>
<th>Fn 1-stage</th>
<th>Fn 2-stage</th>
<th>Cr 1-stage</th>
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<td>28</td>
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<td>1</td>
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The site of the one-stage group harbouring *P. gingivalis* showed bone loss of 1.6 mm between T0 and T12.

**DISCUSSION**

The results of this prospective comparative study suggest that insertion of two-stage implants in a one-stage approach is at least as predictable as the conventional two-stage technique. The clinical results of the present study correspond with those of studies evaluating two-stage implants inserted in the common two-stage approach (Cox & Zarb 1987, Batenburg et al. 1998b, Heydenrijk et al. 1998) and in a one stage procedure (Ericsson et al. 1994, Bernard et al. 1995, Barber et al. 1996). There was a striking trend towards higher plaque, gingiva, calculus and bleeding scores with deeper probing pocket depth in the two-stage group, which might explain the occurrence in this group of *B. forsythus* and the higher frequency of *P. intermedia*.

To reveal the peri-implant marginal bone levels in clinical trials, standardised intra-oral radiographs are mandatory (Wennström & Palmer 1999). The intra-oral radiographs used in the present study are of sufficient quality to detect the first bone-to-implant contact to be used in a longitudinal trial (Batenburg 1998a). However, a major drawback of this technique is that the first radiograph can be obtained no sooner than after placement of the bar (i.e., five months after implant insertion, while the crestal bone loss around non-submerged implants has been shown to occur mainly within the first months after implant insertion (Pham et al. 1994, Hermann et al. 1997). The mean bone loss of 0.6 mm between T0 and T12 found in the present study is comparable with the results of other studies in which one-stage or two-stage implants were evaluated (Lindquist et al. 1988, Ericsson et al. 1994, Åstrand et al. 1996, Brägger et al. 1998, Batenburg et al. 1998b). On the other hand, implant sites with bone loss exceeding 1.0 mm between T0 and T12 were also observed in both groups. Because this is substantially more than the average in our study, these implants are possibly at risk for failure and are, therefore, of special interest for long-term evaluation.

In our study, inclusion was restricted to edentulous patients because they provide a unique situation to study the colonisation of dental implants. Before implantation, these patients are devoid of tooth surfaces serving as sources for *A. actinomycetemcomitans* and *P. gingivalis* to colonise (Aspe et al. 1989, Koka et al. 1993, Mombelli et al. 1995, Quirynen et al. 1990, 1996, Lee et al. 1999, van Winkelhoff et al. 2000). Therefore, edentulous patients are only rarely colonised by *A. actinomycetemcomitans* or *P. gingivalis* (Danser et al. 1997). Danser et al. (1997) studied 20 edentulous patients treated with either IMZ or Brånemark implants. Neither *A. actinomycetemcomitans* nor *P. gingivalis* were detected. The peri-implant microflora they found was comparable with the present study. In our study, *A. actinomycetemcomitans* was also not detected, while a low incidence of *P. intermedia* and a high incidence of *F. nucleatum* was observed. There was a striking difference with the study of Augthun et al. (1997), in which a high incidence of *A. actinomycetemcomitans* and *P. intermedia* and a low incidence of *F. nucleatum* were found. The main reason for the different results probably is the inclusion of only failing implants in the study of Augthun et al. (1997). In a third recently
published study, in which the subgingival flora around IMZ implants was evaluated, partially edentulous patients with a history of moderate to advanced periodontitis were included and only bacterial morphotypes were enumerated (Pontoriero et al. 1994). Therefore, their results were difficult to compare with the present study.

Except for an association between pockets ≥ 4 mm and the presence of P. micros in the two-stage group, we did not find any associations between other clinical parameters or peri-implant bone loss and any of the target organisms. While several recent studies showed associations between clinical parameters and the peri-implant microflora (Mombelli & Mericske-Stern 1990, Sanz et al. 1990, Rams et al. 1991, Papaioannou et al. 1995, Danser et al. 1997, Keller et al. 1998), in several other studies no correlation was established between the frequency of any group of microorganism and the clinical parameters (Lekholm et al. 1986b, Adell et al. 1986, Aspe et al. 1989, Mombelli et al. 1995, Sbordone et al. 1999). Although suspected periodontal pathogens were identified at implant sites in these latter studies, the clinical parameters were not indicative for deteriorating support, suggesting that the presence of potential periodontal pathogens around implants may not always be associated with future attachment loss or implant failure. However, like in the dentate situation, it is possible that elevated numbers of these bacteria ought to be present for extended periods of time in order to have an adverse impact on the tissues (Mombelli et al. 1995).

In the literature there are indications that implant failure probably should be regarded primarily at a patient level and secondarily at implant level from a clinical or microbial perspective (Salcetti et al. 1997, Kronström et al. 2000). The one-stage implant that was lost at T6 showed a poor periodontal condition at T0. It is likely that only partial osseointegration had occurred after implantation, which was too incomplete to withstand the forces of the overdenture during function. In all known human clinical studies evaluating two-stage implants inserted in a one-stage procedure, some implants were lost during the osseointegration period (Ericsson et al. 1994, Becker et al. 1997, Collaert & De Bruin 1998). Fixtures installed according to the traditional two-step procedure are indirectly loaded (i.e., via the mucosa) by the adjusted denture, while fixtures installed according to the one-stage procedure most likely are loaded directly, at least to some extent. This loading might inhibit osseointegration, although two-stage implants inserted in the conventional submerged way sometimes fail to osseointegrate as well. Thus, the true reason for the failure to osseointegrate largely remains obscure. The lost two-stage implant, harbouring high percentages of P. intermedia, P. micros and F. nucleatum, probably failed due to infection. This is supported by a study comparing two clinically distinct types of failures (infection versus trauma), in which high percentages of P. micros and Fusobacterium species were related to implant failure due to infection (Rosenberg et al. 1991).

In one patient of the one-stage group, P. gingivalis was cultured at one implant site. This implant showed bone loss of 1.6 mm between T0 and T12, suggesting a possible contribution of P. gingivalis to this bone loss. Colonisation of implants in edentulous patients with P. gingivalis, which is considered the most periodontopathic species in adults, can occur by transmission from another subject (Danser et al. 1998).
CONCLUSIONS

The results of this study suggest that dental implants designed for a submerged implantation procedure can be used in a one-stage procedure and may be as predictable as the conventional two-stage approach. The peri-implant sulcus can and does harbour potential periodontal pathogens without significant signs of tissue breakdown.

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