Clinical and Radiologic Evaluation of 2-Stage IMZ Implants Placed in a Single-Stage Procedure: 2-year Results of a Prospective Comparative Study

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Purpose: *The aim of this study was to evaluate the feasibility of using a 2-stage implant system in a single-stage procedure and to study the impact of the microgap between the implant and the abutment.* ***Materials and Methods:*** *Sixty edentulous patients (Cawood class V or VI) participated in this study. After randomization, 20 patients received 2 IMZ implants placed in a single-stage procedure, 20 patients received 2 IMZ implants placed in the traditional 2-stage procedure, and 20 patients were treated with 2 ITI implants (single-stage procedure). The implants were placed in the canine area of the mandible. After 3 months, mandibular overdentures were fabricated, supported by a bar-and-clip attachment. A standardized clinical and radiographic evaluation was performed immediately after prosthesis placement and after 12 and 24 months.* ***Results:*** *One IMZ implant of the 1-stage group and 1 IMZ implant of the 2-stage group were lost after 6 and 12 months, respectively. Apart from several significant but clinically irrelevant differences, the 3 groups did not appear to differ markedly with regard to clinical parameters during the evaluation period. The mean bone loss within the first 2 years of functioning (1.1 mm IMZ 1-stage, 0.8 mm IMZ 2-stage, 1.2 mm ITI) was comparable for the 3 groups.* ***Discussion and Conclusions:*** *The results of this study suggest that dental implants designed for a submerged implantation procedure can also be used in a single-stage procedure and may be as predictable as when the same implants used in a 2-stage procedure or as 1-stage implants. Placement of the microgap at the crestal level in 2-stage implants did not appear to have an adverse effect on the amount of peri-implant bone loss at 2 years in this study population.* (Int J Oral Maxillofac Implants 2003;18:424–432)

Key words: *dental abutment, endosseous dental implantation, endosseous dental implants*

Many different endosseous implant systems are currently available for use in implant dentistry. A distinction can be made between implants placed in a 1-stage approach and implants placed in a 2-stage approach. In a 2-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 the cover screw is removed, a transmucosal abutment is connected. The microgap at the junction between implant and abutment is generally situated at the bone crestal level. By contrast, in a 1-stage implant system the transmucosal part is usually integrated into the implant. After the implant is placed, the transmucosal part is left exposed in the oral cavity. The microgap with this implant type is situated a few millimeters above the bone crest. It has been proposed that peri-implant marginal bone loss is more extensive around 2-stage implants than around 1-stage implants as a result of the location of the microgap.[1,2]

Despite the differences in design, both 1-stage and 2-stage implant systems have been demonstrated

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to have highly predictable, favorable clinical outcomes.[2–7] The placement of implants in a 1-stage procedure has several advantages[2]:

- Only 1 surgical intervention is required, which is much more convenient for the patient.
- Costs are lower.
- Time is saved, 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 may be more favorable to place implants in a 2-stage procedure[8]:

- 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 the crestal level, giving the possibility for a more flexible emergence profile of the transmucosal part
- To provide the possibility to remove supramucosal and transmucosal components when the patient is not able to perform sufficient oral hygiene and when possible infections endanger the general health
- When implants are placed in patients who will receive radiotherapy in the implant region in the foreseeable future

Application of 2-stage dental implants in a single surgical procedure has been reported with promising results.[8–16] Thus, the advantages of both system types may be combined. Moreover, there are 2 additional advantages. First, the surgeon needs to maintain an inventory only of a 2-phase implant system for executing both submerged and nonsubmerged procedures. Second, there is the possibility to switch from a nonsubmerged procedure to a submerged procedure if this appears to be preferable perioperatively or during the osseointegration period.

Many studies have reported the long-term results of implants placed for mandibular overdenture treatment. Most studies describe a single implant system. Long-term studies comparing a 1-stage and a 2-stage implant system are sparse. No studies have been published comparing a 1-stage implant system and a 2-stage implant system placed in a 1-stage procedure. The aim of the present study was to explore the feasibility of placing a 2-stage implant system in a 1-stage approach by comparing the clinical outcome and peri-implant bone radiographically. Furthermore, the aim was to evaluate the impact of the microgap between implant and abutment.

MATERIALS AND METHODS

Patient Selection

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

- Presence of a severely resorbed mandible (class V or VI according to Cawood and Howell[17]) with reduced stability and insufficient retention of the mandibular denture
- An edentulous period of at least 2 years
- No history of radiotherapy to the head and neck region
- No history of preprosthetic surgery or previous oral implants

Eligible patients were informed about the 3 different treatment options, and written informed consent was obtained from all participants. They were randomly assigned to 1 of 3 groups:

- One group received IMZ implants (2-stage, 4-mm-diameter cylindric implants with a TPS coating; Interpore International, Irvine, CA) placed in the traditional submerged procedure.
- A second group received the same 2-stage IMZ implants placed in a nonsubmerged, single-stage procedure.
- The third group received ITI implants (1-stage, 4.1-mm-diameter, solid-screw implants with a TPS coating; Straumann AG, Waldenburg, Switzerland).

The randomization process was as follows: a series of 60 integers were randomized and subsequently assigned to the consecutive patients. The first 20 randomized integers were assigned to IMZ 1-stage, the second 20 integers to IMZ 2-stage, and the remaining integers to ITI. A note with the assigned treatment modality was put in an envelope for each patient. In this way, the consecutive patients received a randomly assigned treatment modality.

Treatment Procedures

All patients received 2 implants placed bilaterally in the canine region of the mandible. The implants were placed under local anesthesia, each about 1 cm from the midline. An experienced maxillofacial surgeon placed all implants according to a strict surgical protocol. The IMZ implants in the 2-stage group were placed as described by Kirsch.[18] The IMZ implants in the single-stage group also were placed as described by Kirsch,[18] but with modifications for a single-stage implantation procedure, ie, use of a labial mucosa flap and immediate connection of healing abutments as previously described.[19] The surgical procedure used for placement of the ITI implants has been previously described.[20] In none of the patients were grafts of any kind placed. Postoperatively, analgesics and chlorhexidine 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 2 weeks postoperatively.

Two, 6, and 12 weeks after the surgical procedure, the patients were recalled. At the first recall visit, sutures were removed and the existing mandibular denture was adjusted by selective grinding at the implant location and relining with Coe-Soft (Coe Laboratories, Chicago, IL). At all recall visits, patients received oral hygiene instructions.

Three months after implant placement, second-stage surgery for the connection of 5-mm-high titanium prosthetic abutments was performed in the 2-stage IMZ group. Two weeks later, fabrication of a new maxillary denture and a mandibular overdenture was initiated. In the 1-stage IMZ group and the ITI group, the prosthetic procedure was started 3 months after implant placement. A uniform prosthetic treatment procedure was performed for all patients by 1 experienced prosthodontist.[21] In the IMZ group, the healing abutments were replaced by 5-mm titanium connectors. A Dolder bar with subsequent clip attachment supported the overdentures. A balanced occlusion and monoplane articulation concept with porcelain teeth were used for the prosthesis fabrication.

Outcome Measures

Data collection was performed at the baseline assessment (4 weeks after placement of the new prosthesis [T0]) and again 6 months (T6), 12 months (T12), and 24 months (T24) later. Data collection was started approximately 4 months after implant placement because it was not possible to make standardized radiographs immediately after implant placement since an aiming device, connected to the bar, was needed. It would be too risky to connect an aiming device to a non-osseointegrated implant.

Clinical Outcome Measures. The following clinical parameters were assessed.

- *Gingiva score:* The modified Löe and Silness index (score 0 to 3) was used to quantify the degree of peri-implant inflammation.[22] The gingiva score was measured at 4 aspects of the implants, with the highest score per implant being used for data analysis.
- *Plaque score:* The Mombelli index (score 0 to 3) was used to quantify the amount of plaque retained on the surface of the supragingival part of the implant.[23] The plaque score was measured at 4 aspects of the implants, with the highest value per implant being used for data analysis.
- *Calculus:* The presence (score 1) or absence (score 0) of calculus per implant was recorded.
- *Bleeding score:* The Mühlemann index (0 to 3) modified by Mombelli and coworkers[23] was scored at 4 aspects of the implants, with the highest value per implant being used for data analysis.[24]
- *Probing pocket depth:* The depth of the peri-implant "sulcus" was measured, to the nearest millimeter, mesially and distally of each implant by using a periodontal probe (Merrit B, Hu Friedy, Chicago, IL) after removal of the bar.[24] 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.[25] Mobile implants were considered as being lost and were removed.

Radiographic Outcome Measures. Standardized intraoral radiographs were obtained using the long-cone technique with an aiming device.[26] The distance from a fixed reference point on the implants to the first bone-to-implant contact was measured with a digital caliper (Digital SI, Tesa SA, Renens, Switzerland).[27] The measurements were made at the 2 proximal implant sites. The site showing the most bone loss was used for data analysis. In the ITI group, the neck of the implant was used as the reference point, 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 1 experienced observer performs the measurements twice rather than 2 observers

performing the measurements once.[6] Therefore, the measurements were performed twice by the same observer with a 2-week time interval and averaged.

Data Analysis

Qualitative and quantitative data after categorization were analyzed using the Kruskal-Wallis analysis of variance (ANOVA) among the 3 groups. Possible associations between variables were analyzed 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 1-way ANOVA was performed. When the criteria for using parametric tests were not fulfilled, the Kruskal-Wallis test (independent data) or the Friedman test (dependent data) was applied. In all analyses, a significance level of .05 was chosen. As in earlier implant literature, it has been assumed that 2 implants placed in the same patient are statistically independent. Thus, the statistical methods used may not be valid.

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. One IMZ implant of the 1-stage group had to be removed at 6 months because of mobility. Three weeks after removal, 2 new implants (1 mesial and 1 distal to the former implant location) were placed successfully. At 12 months, 1 IMZ implant of the 2-stage group appeared to be mobile and was removed after the standardized radiographs were taken and after the clinical data were collected. Therefore, the data for this implant were included in the T12 results. New implants were placed mesial and distal to the former implant location, but they had 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 1-stage group, the 2-year evaluation (T24) comprised 117 implants in 59 patients.

Periodontal Parameters

Frequency distributions of the clinical parameters are depicted in Figs 1 to 5. At T0, significant differences between the 3 groups with regard to the bleeding scores and to the number of probing pocket depths > 3 mm were found (Kruskal-Wallis tests). At T12, a significant difference between the groups was found with regard to the plaque score and the number of probing pocket depths > 3 mm (Kruskal-Wallis test). Significant differences between the 3 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 3 groups throughout the observation period.

In the ITI group there was a significant increase in the bleeding score throughout the observation period (Friedman test, $P = .02$; Fig 4). In the IMZ 2-stage group, a significant reduction in the number of probing pocket depths > 3 mm was found (Friedman test, $P = .01$; Fig 5). The time course of the other periodontal parameters was comparable within the 3 groups (Friedman test, $P > .05$).

The plaque score was associated with the gingiva score at T24 in the IMZ 2-stage group (chi-square test, $P = .005$). No other significant associations between the clinical parameters were found (chi-square test, $P > .05$).

Radiographic Parameters

In 3 patients (1 in each group) the Dolder bar was placed labial to the implants to prevent interference with the floor of the mouth. As a result, no standardized 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 3 groups during the observation period (1-way ANOVA, $P > .05$; Table 1). Comparable numbers of implants in each group were found demonstrating bone loss exceeding 1 mm in the first year of functioning and exceeding 0.2 mm in the second year (Kruskal-Wallis test, $P > .05$; Figs 6 and 7). No associations between the amount of bone loss and clinical parameters were found (chi-square test, $P > .05$).

DISCUSSION

This prospective randomized study is the first in which 2-year clinical and radiographic results of 2-stage nonsubmerged implants are compared with those of 2-stage submerged implants and 1-stage implants. This study showed no major differences between the 3 groups, suggesting that a 2-stage implant system can be used for implant placement in a nonsubmerged procedure.

After 2 years of loading, 97.5% of the IMZ implants and all ITI implants were functioning

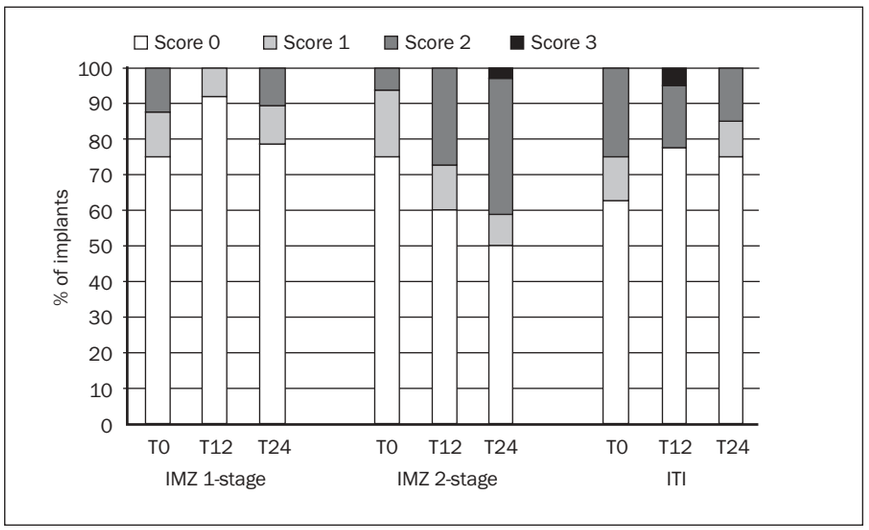

Fig 1 Frequency distribution of the plaque scores at the baseline examination (T0) and at 12 (T12) and 24 months (T24) after placement of the overdenture. Score 0 = no plaque; score 1 = plaque detected by running a probe across the implant; score 2 = plaque can be seen by the naked eye; score 3 = abundance of plaque.

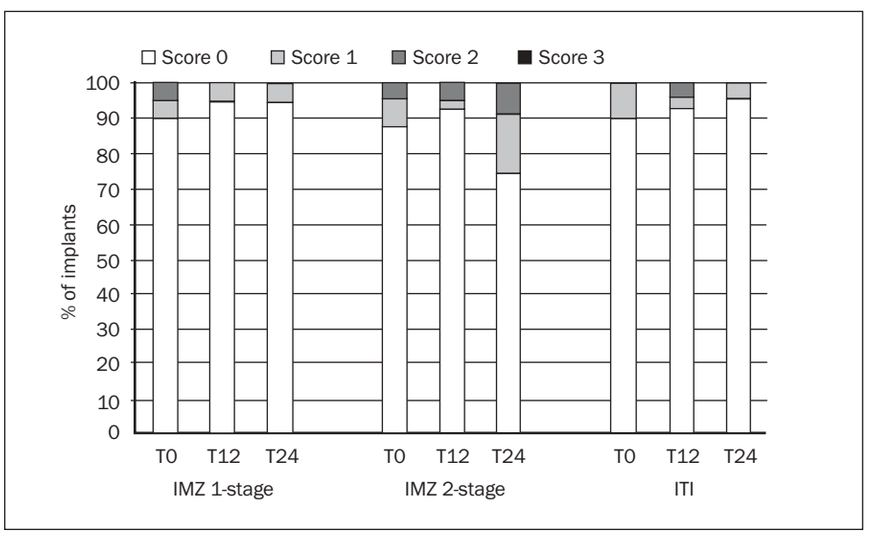

Fig 2 Frequency distribution of the gingival scores at the baseline examination (T0) and at 12 (T12) and 24 months (T24) after placement of the overdenture. Score 0 = normal peri-implant mucosa; score 1 = mild inflammation; score 2 = moderate inflammation; score 3 = severe inflammation.

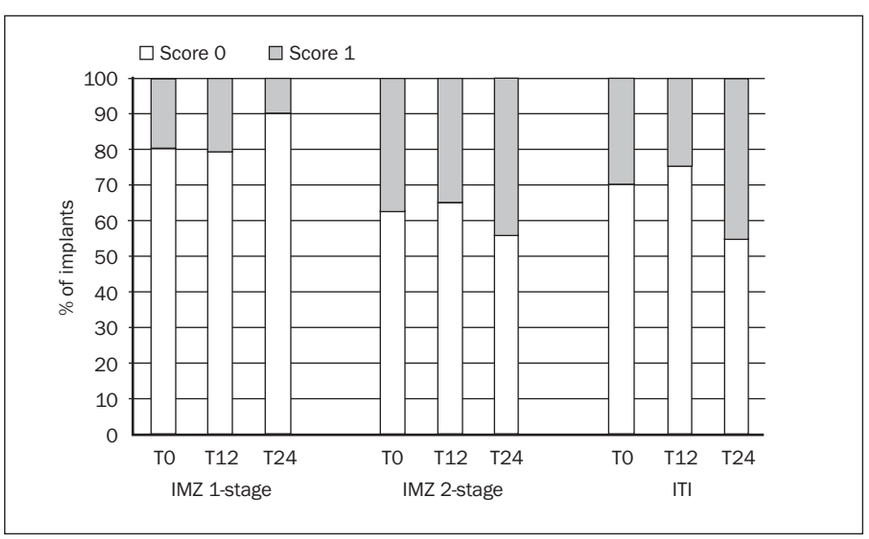

Fig 3 Frequency distribution of the calculus scores at the baseline examination (T0) and at 12 (T12) and 24 months (T24) after placement of the overdenture. Score 0 = no calculus; score 1 = presence of calculus.

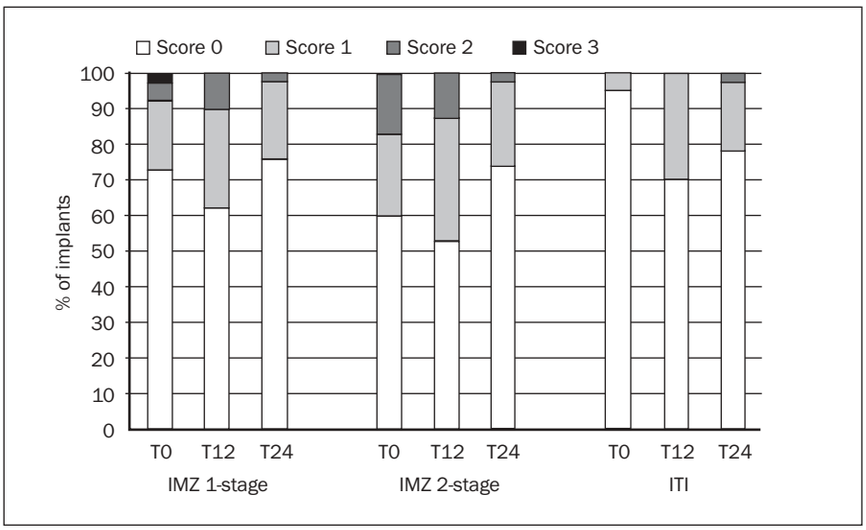

Fig 4 Frequency distribution of the bleeding scores at the baseline examination (T0) and at 12 (T12) and 24 months (T24) after placement of the overdenture. Score 0 = no bleeding after probing; score 1 = isolated bleeding spots; score 2 = confluent line of blood; score 3 = heavy or profuse bleeding.

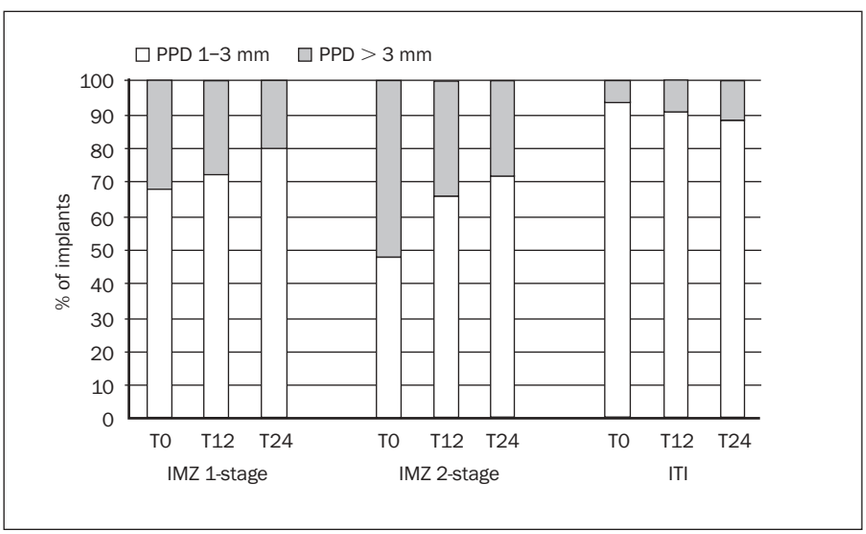

Fig 5 Frequency distribution of the probing pocket depths at the baseline examination (T0) and at 12 (T12) and 24 months (T24) after placement of the overdenture.

Table 1 Mean Bone Loss Between Baseline (T0) and 1 Year After Functioning (T12) and Between Baseline and 2 Years After Functioning (T24)

	Bone loss T0–T12 (mm)			Bone loss T0–T24 (mm)		
Group	n	Mean	SD	n	Mean	SD
IMZ 1-stage	37	0.6	0.9	37	1.1	1.0
IMZ 2-stage	38	0.6	1.3	36	0.8	1.1
ITI	38	0.6	0.8	38	1.2	1.1

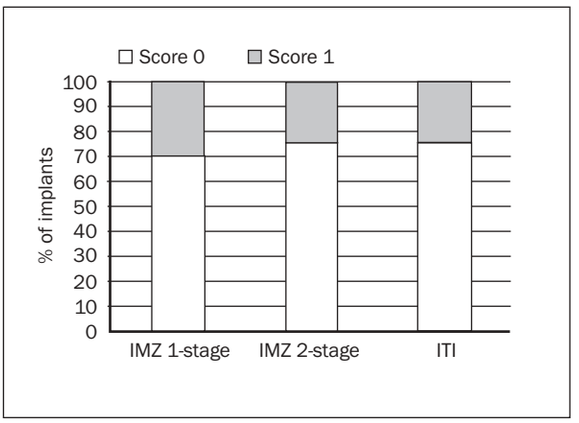

Fig 6 Frequency distribution of the amount of bone loss between the baseline examination (T0) and 1 year later (T12). Score 0 = bone loss ≤ 1 mm; score 1 = bone loss > 1 mm.

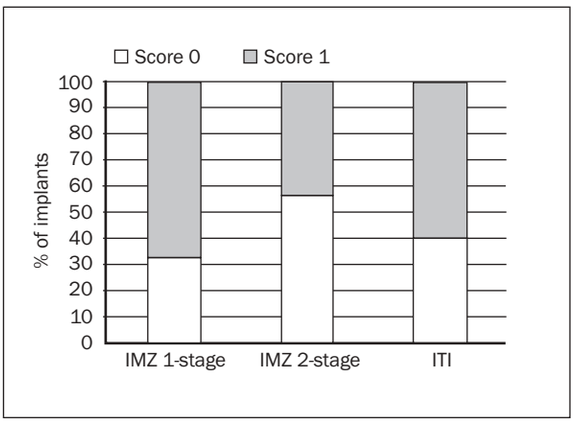

Fig 7 Frequency distribution of the amount of bone loss between T12 (1 year after functioning) and T24 (2 years after functioning). Score 0 = bone loss ≤ 0.2 mm; score 1 = bone loss > 0.2 mm.

uneventfully. The implants that had to be removed were lost during the first year of function. Placement of new implants mesial and distal to the previous implant sites resulted in surviving implants at the time of this report.

The clinical results are comparable with the results of studies in which 1-stage or 2-stage implant systems were evaluated.[28–31] 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.[32] At T24, higher plaque and gingiva scores were found in the IMZ 2-stage group compared to the other groups, and the IMZ 2-stage group showed a higher calculus score than the IMZ 1-stage group. Differences in scores of periodontal parameters between 2 different implant types can be explained by different implant characteristics, but differences in scores of periodontal parameters between the 2 IMZ groups are harder to explain. It is presumed to be a coincidence that the IMZ 2-stage group included 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.[25,29,31,33] Reproducible radiographs of sufficient quality are necessary in a longitudinal trial to accurately detect the first bone-to-implant contact. The intraoral radiographs used in the present study have been shown to satisfy this criterion.[6] The landmarks necessary for the evaluation were easy to identify. A major drawback of this technique is that the first radiograph could be obtained no sooner than after placement of the bar, which was at least 4 months after implant placement. 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 the 3 groups is below the limit of 0.9 to 1.6 mm that was reported by Brägger and coworkers[34] 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 placement and adaptation of bone to withstand functional forces.[35,36] An annual bone loss of 0.2 mm after this period has been recognized as acceptable.[37] Several studies described the peri-implant bone changes in the second year of functioning, reporting a mean bone loss of approximately 0.1 mm.[4,25,33,38–41] In the 3 groups of the present study, the peri-implant bone loss between T12 and T24 was more extensive (Table 1). However, when assessing the amount of bone loss between T0 and T24, the values were within the limit of 0.9 to 1.6 mm considered to be acceptable for the first year of function.[34] It does not seem to be coincidental 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 3 groups. Probably the high quality of the standardized radiographs used in the present study is responsible for the different outcomes. Long-term follow-up evaluations will be needed to show whether bone loss continues in subsequent years.

It has been proposed that marginal bone loss is more extensive around 2-stage implants as compared with 1-stage implants.[2] The microgap between the implant and the abutment at the crestal level in 2-stage implants has been suggested to play a prominent role in the development of bone loss.[1] Because of the different location of the microgap between the implant and the abutment, it was expected that the implants in both IMZ groups would show more bone loss compared to the ITI group. ITI implants lack a microgap between implant and abutment at the crestal level, and therefore, less bone loss was expected to develop in the ITI group.[1] However, in the present study, a comparable amount of bone loss was found in all 3 groups. This is a striking finding, because it suggests that a microgap at the crestal level may not influence the amount of peri-implant bone loss.

There are several reasons why comparable outcomes were not found in the study of Hermann and associates,[1] in which, for example, the location of the microgap did appear to have a significant effect on the amount of crestal bone loss. First, the first radiographs were obtained no sooner than after completion of the prosthetic procedure, which was at least 4 months after implant placement. It was possible that a considerable amount of bone loss could have occurred in these 4 months in the IMZ groups and not in the ITI group. However, after this period a comparable amount of bone loss did occur among the 3 groups. Thus, bone loss also may occur around ITI implants. Second, the study of Hermann and associates was a group animal study in which the implants were not functionally loaded. Therefore, only limited conclusions can be drawn from this study. More and long-term studies with standardized radiographs are needed to further evaluate the peri-implant bone level changes of 1-stage and 2-stage implants.

CONCLUSIONS

The results of this study population indicated that:

1. Dental implants designed for a submerged implantation procedure could be used in a single-stage procedure and may be as predictable as when used in a 2-stage procedure or 1-stage implants.
2. Location of the microgap at the crestal level in 2-stage implants did not appear to have an adverse effect on the amount of peri-implant bone loss in the 2-year evaluation period.

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