A Prospective Clinical Study Evaluating the Safety and Effectiveness of Narrow-Diameter Threaded Implants in the Anterior Region of the Maxilla

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The aim of the present study of single-tooth implants was to compare the success rate and marginal bone resorption of a narrow-diameter self-tapping implant placed in less available bone volume with the standard-diameter self-tapping implant placed in a well-dimensioned alveolar process. A new abutment technique and a different permanent abutment design were also evaluated. Fifty-five patients were included in the study; 27 patients received 28 standard-diameter (3.75-mm) implants, and 28 patients received 32 narrow-diameter (3.25-mm) implants replacing either a central or a lateral incisor in the maxilla. In an attempt to create an ideal emergence profile and to regenerate papillae, individual acrylic resin tooth-shaped temporary abutments were fabricated, based on impressions made immediately following implant placement, and connected to the implant after 6 months. A minimum of 2 months were then allowed before definitive restorative procedures were performed. Impressions were always made at the implant level. Follow-up examinations were performed at 6 months after loading and 1, 2, and 3 years after loading. Two narrow-diameter implants were lost after 6 months, but no other failures were subsequently observed in any of the groups after that. In both groups, marginal bone loss followed the same pattern and was recorded radiographically to be a mean of 0.4 mm from the first to the last examination. (Int J Oral Maxillofac Implants 2001;16:217–224)

Key words: *bone resorption, dental abutments, dental implants, dental papilla, implant diameter*

A number of clinical studies have documented the predictability of oral implants ad modum Brånemark in edentulous[1,2] as well as in partially edentulous arches.[3,4] In the last decade, prospective longitudinal studies on single-tooth implant restorations have been published, with promising results.[5–9] Previous studies focused on implant survival rates and implant and component-related complications. A more recent focus has been on the esthetic aspect of implant restorations. The single-tooth restoration is compared with the adjacent teeth and periodontium. Thus, the position of the implant, transition contour, soft tissue configuration, and the shape and color of the crown have become more important issues.

New and refined techniques have been introduced. Implants with narrow and wide diameters have been developed, and methods for augmenting the alveolar process have increased the application of the Brånemark method, making more desirable implant positioning possible. New clinical procedures and components facilitate restoration. However, documentation of available new components and techniques is often missing. The aim of this study was to compare narrow-diameter self-tapping implants placed in areas with less bone volume (less than 6 mm between adjacent teeth and/or an alveolar process less than 5 mm wide) with standard-diameter self-tapping implants placed in a well-dimensioned alveolar process. In addition, a new abutment technique and a different permanent abutment design were also evaluated.

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Fig 1 The 3.75-mm standard-diameter and the 3.25-mm narrow-diameter self-tapping titanium implants.

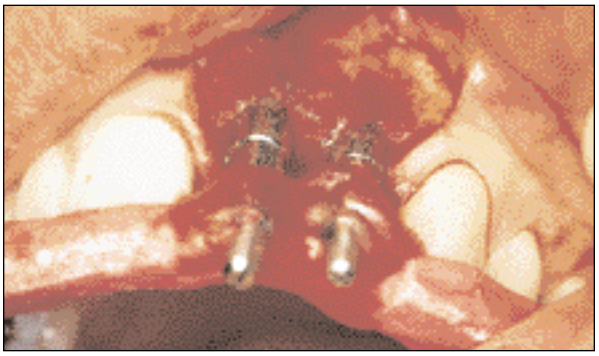


Fig 2 Implants in position at the stage 1 procedure are connected to the impression caps, which are fused to an acrylic resin splint.

MATERIALS AND METHODS

Fifty-five patients, referred to the Department of Oral Surgery and Oral Medicine, Dental Faculty, University of Oslo, for single-tooth restorations in the anterior region of the maxilla, were included in this study. Twenty-seven patients (14 females and 13 males) received 28 standard-diameter self-tapping titanium implants (group 1) and 28 patients (15 females and 13 males) received 32 smaller-diameter (3.25-mm) self-tapping titanium implants (group 2) to replace either a central or a lateral incisor in the maxilla (Implant Innovations Inc, West Palm Beach, FL) (Fig 1). Both groups of patients were included in the study based on strict inclusion criteria with respect to medical and anatomic considerations. The patients had to be physically and psychologically able to tolerate conventional surgical and restorative procedures. The adjacent teeth had to be intact or only conservatively restored and free of active periodontal disease. Patient age at implant placement ranged from 17 to 41 years (mean 23.0) in group 1 and ranged from 17 to 54 years (mean 23.2) in group 2; no patients received any implants before skeletal tissue maturation had occurred. The dimensions of the alveolar process were measured with a caliper to enable selection of the optimal implant diameter. At least 1 mm bone at the labial and palatal aspects of the implant was required, but small labial dehiscences were allowed. Space between the adjacent teeth and the implant had to be at least 1.5 mm, and the alveolar ridge volume had to permit placement of an implant almost totally embedded in bone. All participants in the study gave their written informed consent at the consulting appointment, having been informed about the implant treatment procedure and prognosis as well as alternative options.

The surgical protocol recommended by the manufacturer was followed in a standard 2-stage procedure.[10] Pretreatment clinical and radiographic examination, treatment planning, and surgical procedures were performed by the same surgeon. Incisions at implant placement were made without involving the papillae of the adjacent teeth. In situations involving labial bony dehiscences, small bone chips were harvested from the nasal spine. Implants were either 13 or 15 mm long. Implant positioning was directed by a surgical template. After implant placement, an impression was made of the implant top using an acrylic resin splint made preoperatively on a cast.[11,12] Figure 2 shows the impression procedure in a patient who received both a standard-diameter and a narrow-diameter implant to replace the left central incisor and left lateral incisor, respectively. The purpose of this procedure was to custom-fabricate an acrylic resin tooth-shaped abutment to create an ideal emergence profile and facilitate regeneration of papillae (Fig 3).

The abutment procedure was performed after 6 months, and at the same time, the crestal bone level was documented photographically and determined radiographically. All acrylic resin restorations were autoclaved before connection to the implant. At this stage, the implant was placed under loading forces. Eight implants (1 in group 1 and 7 in group 2) received a standard healing abutment at stage 2 surgery and therefore were not loaded until a definitive restoration was fabricated about 1 month later. The temporary acrylic resin tooth in these instances was either not found to be precisely fabricated, or

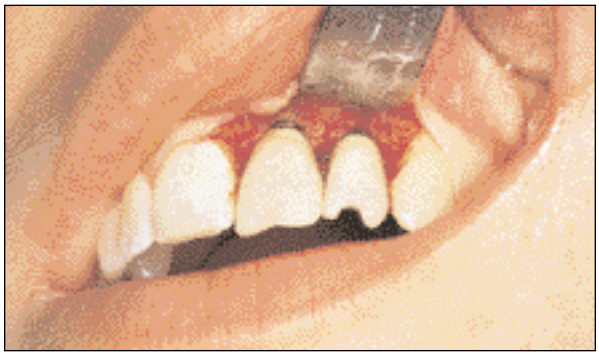


Fig 3 Custom-fabricated acrylic resin tooth-shaped abutments in place on the implants in the left central incisor (standard-diameter implant) and the left lateral incisor (narrow-diameter implant) regions.

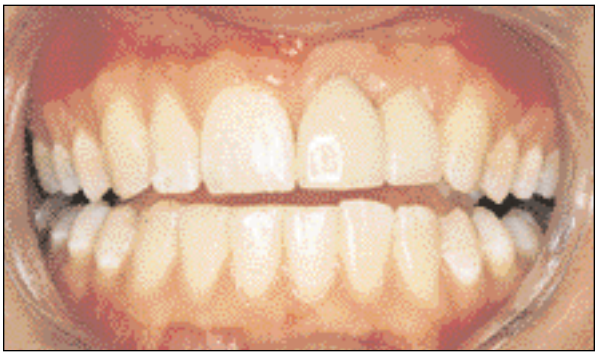


Fig 4 The definitive restorations in place. Notice the papillae.

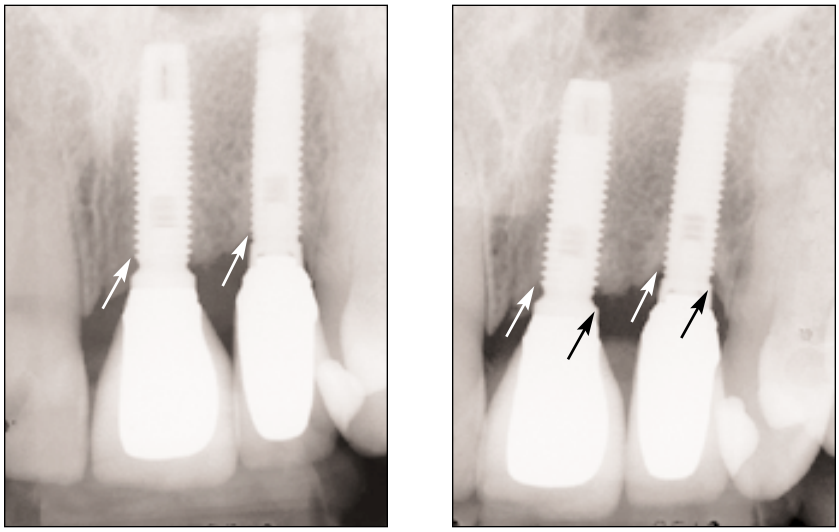
anatomic considerations favored the selection of healing abutments.

The definitive restorations were placed 2 months after stage 2 surgery at the earliest and were fabricated by the same prosthodontist. Following impressions at the implant level, all definitive abutments were individually designed and cast to match the implant position and gingival contour created by the temporary abutment. Forty-four implants had custom-fabricated, porcelain-covered UCLA abutments secured by an abutment screw for retention of cemented ceramic crowns (Fig 4). Individually cast gold abutments were used for 3 patients in group 1 and for 6 patients in group 2 because of unfavorable implant angulation related to the anatomy of the alveolar process. Because of lack of horizontal space, 3 implants in group 1 and 4 implants in group 2 received crowns screwed directly to their hexagonal tops. The gold abutments and crowns served as control for the porcelain-covered abutments with respect to soft tissue response and marginal bone resorption. All abutment or implant screws were tightened manually by hand.

The follow up-procedure was accomplished in a standard manner 6 months and 1, 2, and 3 years following loading. All restorations were evaluated clinically and radiographically using standardized identical periapical radiographs. Patient's opinions of the esthetics and function of their restorations were recorded at each visit, as well as soft tissue conditions. Marginal bone loss was determined radiographically both at the mesial and distal aspects by an independent radiologist. With an electronic caliper (Clas Ohlson AB, Insjön, Sweden), the bone level was measured radiographically from a defined point on the implant. The radiographs were obtained, using an identical technique at each examination, with an Eggen filmholder (Lillehammer, Norway) and a polyether rubber impression material (Impregum, ESPE, Seefeld, Germany). Only radiographs with quality according to the criteria defined by Strid[13] were used in the investigation. The defined reference point was constituted by the edge of the neck of the abutment (Figs 5a and 5b). All measurements were performed at the 0.01 mm level, and the standard error of the caliper was estimated to approximately 5%. The bone level was defined using an X-wiever (an optical magnifier; 2.5×) (Dental X-ray APS, Hellerup, Denmark). The papillae were measured clinically and documented photographically at each examination. Routinely, patients were additionally asked about comfort, fit, speech, appearance, chewing ability, and general satisfaction at each follow-up examination. Success rates were determined according to Albrektsson and coworkers' criteria.[14]

RESULTS

Life table analyses showed that the cumulative implant success rates after 6 months in groups 1 and 2 were 100% and 93.8%, respectively (Table 1). Two implants were lost in group 2. One implant was diagnosed as not integrated at stage 2 surgery, and the other was diagnosed as mobile at the 6-month follow-up visit. None of the remaining implants in either groups were lost after 6 months in function during the 3-year follow-up period. Therefore, the cumulative success rates remained at the same levels in both groups. After 3 years, 5 patients (2 patients from group 1 and 3 patients



Figs 5a and 5b Radiographs taken after the definitive restoration was completed *(left)* and at the 3-year follow-up appointment *(right).* Notice the arrows indicating the marginal bone level *(white)* and the neck of the implant *(black).*

Table 1 Implant Success Rates

Time period	No. of implants		Failed		Withdrawn		Success rate during interval		Cumulative success rate	
	SD	ND	SD	ND	SD	ND	SD	ND	SD	ND
Placement	28	32	0	0	0	0	100%	100%	100%	100%
Loading –1 year	28	30	0	2	0	0	100%	93.8%	100%	93.8%
1–2 years	28	29	0	0	0	1	100%	100%	100%	93.8%
2–3 years	27	28	0	0	1	1	100%	100%	100%	93.8%
3 years	26	27	0	0	1	1	100%	100%	100%	93.8%

SD = standard-diameter implants; ND = narrow-diameter implants.

from group 2, with 1 implant each) had withdrawn from the study (9.1%). Three patients had moved, and 2 patients never responded to recalls.

Mean calculated values of marginal bone height are provided in Table 2 and Fig 6. Mean values of the marginal bone loss measurements on the radiographs showed increasing values for both groups from the time of abutment connection to the time of the 3-year examination. Changes in marginal bone height were comparable and followed the same pattern, with similar changes over the years for the 2 groups. There were no differences in mean marginal bone loss between patients with gold abutments/crowns and those with porcelain abutments in either group.

Twenty-five restorations each in group 1 (89%) and in group 2 (78%), respectively, demonstrated preserved adjacent papillae against natural teeth. Seven patients (88%) who received standard temporary abutments rather than acrylic resin temporary abutments demonstrated preserved papillae. Gingival bleeding was recorded with scores according to the Löe and Silness Gingival Index system.[15] Fourteen percent and 7% of the implants in group 1, and 19% and 6% of the implants in group 2 were recorded as score 1 and 2, respectively, after 6 months in function. In the consecutive follow-up examinations, the figures decreased to 7% of implants with score 1 and no implants with score 2, following hygiene instructions that were given to both groups. The width of buccal keratinized gingiva increased from a mean of 4.0 mm to 4.5 mm in group 1, and from a mean of 4.2 mm to 5.0 mm in group 2 from the time of the first to the last follow-up visit. There were no differences for the patients with different abutment material with respect to the dimension of keratinized gingiva.

During the 3-year observation period, 4 implant-retained crowns in each group showed abutment screw loosening. In 2 patients, a new porcelain

Table 2 Marginal Bone Levels in mm (Mean ± Standard Deviations)

Time period	Group 1	Group 2
Abutment connection	1.10 ± 0.40	0.89 ± 0.55
1 year	1.36 ± 0.45	1.03 ± 0.41
2 years	1.63 ± 0.47	1.09 ± 0.48
3 years	1.50 ± 0.56	1.41 ± 0.54
Total change (year 3 – baseline)	0.40 ± 0.16	0.52 ± –0.01

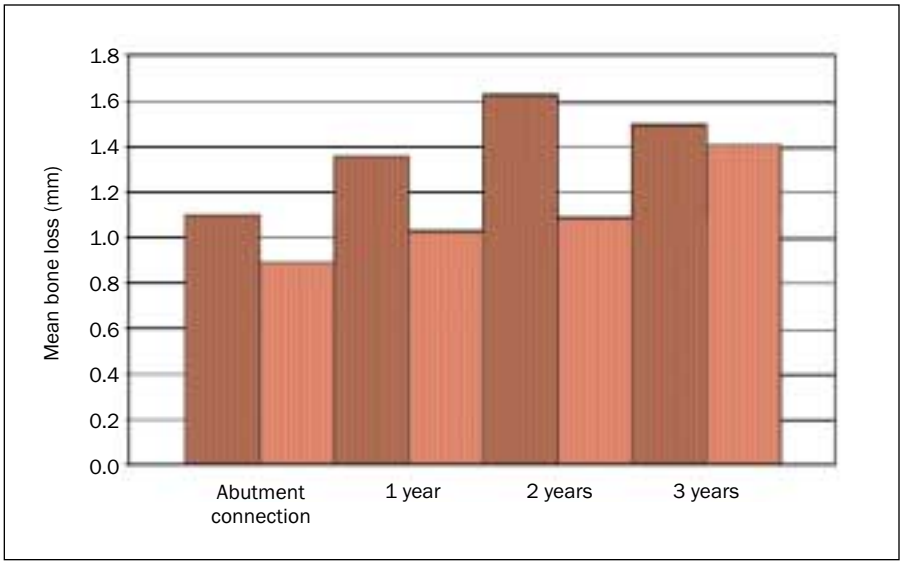


Fig 6 Graph indicating mean bone loss (in mm) for group 1 *(dark red)* and group 2 *(light red)*.

crown was fabricated. Six fistulae occurred in group 1 during the first 2 years of function, and 1 was accompanied by a loose abutment screw. One fistula was found in conjunction with an implant with a gold abutment. The same number of fistulae was recorded in group 2 (3 were in patients with gold abutments), and in 2 of these a loose implant crown was seen. Loosened abutment screws were always retightened manually, and the fistulae were treated with a chlorhexidine gel (Corsodyl Dental Gel 1%, SmithKline Beecham, Brentford, United Kingdom) applied directly in the fistula orifices. In 5 patients, the procedure had to be repeated after 2 months before the infection terminated. After 2 years in function, 1 patient in group 2 had a peri-implant marginal abscess, which was treated surgically with removal of granulation tissue. There was no sign of infection after completion of treatment. In another patient in group 2, an asymptomatic circular radiolucency was found apical to the implant 2 years after placement. This radiolucent-appearing process was believed to be an aseptic necrosis, and no treatment was considered necessary. The process healed spontaneously and could not be detected radiographically 2 years later.

Patient satisfaction was high, and no complaints were recorded with respect to comfort and function.

DISCUSSION

The cumulative success rates in the 2 groups were equal, despite the fact that 2 implants were lost in group 2. Both of the failed implants in group 2 were diagnosed as not integrated, either at the abutment connection procedure or soon after loading. Because the remaining implants in both groups continued to function during the rest of the follow-up period, the cumulative success rate after 6 months was 100%. The reason for the 2 failures in

group 2 could have been the result of compromised local bone quality, rather than differences in implant diameter. In both situations where an implant was lost, the patient had a standard-diameter implant successfully placed in conjunction with a bone transplant and a barrier membrane 3 months after explantation.

The mean bone loss from the abutment procedure to the final follow-up examination was the same for the 2 groups. Both groups showed a measurable tendency toward increased mean bone loss at each examination. In group 1 the mean value 2 years after the abutment operation was higher than for the 3-year value, but this may have been the result of the standard error of the measurement system.

Scheller and coworkers[8] showed that a steady-state situation was accomplished by approximately 18 months after implant loading in single-tooth restorations, and that major changes are not to be expected. Malavez and colleagues[16] observed that marginal bone loss in single-tooth restorations remained stable at an average marginal bone loss level of 0.65 mm for a period of 36 months, with a mean bone loss of 0.5 mm during the first year in function for standard Brånemark System implants. This is comparable to the results in the present study, where the restorations were followed for 3 years. The 3-year follow-up period was considered sufficient, because a steady-state situation was expected to be achieved during this time. Eighteen months would probably have been enough, but a longer period was needed to evaluate the treatment result of the complications. Marginal bone resorption tends to terminate at the level of the first thread for implants with a smooth neck,[17] and the structural differences above the first thread between the 2 implant systems probably do not affect the bone level once a steady-state situation is reached.

Ivanoff and coworkers[18] demonstrated in an experimental study that removal torque increases for wider implant diameters. Mean removal torques (± SD) for the 3.0-mm and 3.75-mm Brånemark System implants in rabbit tibiae were 13.7 ± 6.2 N and 24.8 ± 15.1 N, respectively. Despite the reduced dimension and less resistance to withstand loading forces for the narrow implant, there was no difference between the 2 groups with respect to implant survival. The 3.25-mm implant may even have a better prognosis than the standard implant in areas where bone volume is compromised. In narrow alveolar ridges, primary stability of a standard implant may be jeopardized because of reduced cortical bone support. Polizzi and colleagues[19] presented retrospective material on thirty 3.0-mm Brånemark System implants for single-tooth restorations in the maxillae and mandibles of 21 patients, and only 1 implant was lost because of fracture after 5 years in function. Marginal bone loss followed the same pattern as in the present study.

The anatomy of the papillae seemed to remain intact in a relatively high number of patients compared to the report by Jemt,[20] where only 58% of the papillae were completely regenerated after 1 to 3 years. The favorable observations in this study may be the result of the flap design and the idea of using an anatomically shaped temporary abutment and the custom-fabricated definitive abutment. No percentage difference in the number of preserved papillae between patients with fabricated and standard abutments was seen in this study. Creation of new papillae between adjacent implant-retained crowns, however, is often a challenge. As shown in Fig 4, the papilla between the 2 implant-retained crowns is less prominent than the papillae adjacent to the natural teeth. The width of the keratinized gingiva seemed to remain stable, with a slight increase after the restorations had been in function for approximately 1 year. Gingival inflammation tended to decrease after patients received hygiene instruction, reflecting the situations around the adjacent teeth. The bleeding index was comparable to previous observations, but in contrast to the findings of Andersson and coworkers.[6]

In 5 of 6 of the group 1 patients with fistulae, the abutments had porcelain coverage. In group 2, the 6 fistulae were equally divided between porcelain-covered abutments and gold abutments. Apparently there was no connection between poor hygiene and fistula formation, since the fistulae were found evenly spread among patients with a gingival index score of 1 or 2, as well as in those with a healthy periodontium. Quirynen and colleagues[21] found that surface roughness had an impact on the microbiology around the abutments. On the other hand, Bollen and coworkers[22] concluded that a rough abutment provides opportunity for a better soft tissue seal. Abrahamsson and associates[23] found that the abutment material influenced the location and quality of the attachment of peri-implant mucosa. In their histologic study, they showed that there was a mucosal attachment consisting of both epithelium and fibrous tissue at the titanium and ceramic (highly sintered aluminum oxide) abutment surfaces. However, no attachment was found at the surface of abutments made of gold or dental porcelain. This is in accordance with observations of the present study, where no differences between the 2 abutment types with respect to soft tissue and bone response were seen.

The relatively high percentage of fistulae seen in this study might be explained by the poor soft tissue seal around the abutments, which led to bacterial colonization. This implant concept, however, leaves a microgap between the abutment and the implant where microorganisms are likely to grow.[24,25] The custom-made abutments are believed to be even less accurate and may contribute to the occurrence of fistulae. Another factor may be bacterial contamination of the sulcus area from the acrylic resin provisional restoration, resulting either from the surface structure or the less accurate implant connection. The infections, however, always subsided upon application of bactericide gel in the fistulae openings.

The number of loose abutment screws was unfavorably high in this study, and could probably have been lower if the abutment screws had been machine-tightened by a torque controller rather than tightened by hand. The ductile advantage of the gold abutment screw demonstrated by Jörnéus and associates[26] is not fully exploited using manual tightening forces.

According to the questionnaire, patient satisfaction was very good. Because the abutments were individually designed, no metal was visible, even after slight gingival recession in a few patients. No patient complained about either comfort or functional problems. In the 5 patients with compromised esthetic situations, the smile line was low and conditions were acceptable both from the patients' and the prosthodontists' perspectives.

CONCLUSION

This study indicated that narrow-diameter implants used in the anterior region of the maxilla as support for single-tooth replacements show results that are comparable to standard-diameter implants placed in the same region. After 3 years in function, the narrow-diameter threaded implant system appears to fulfill accepted criteria for implant success. In addition, the treatment concept using a temporary acrylic resin tooth-shaped abutment and individually fabricated definitive abutments seemed to be advantageous with respect to preserving papillae. Complications were reported, especially numerous fistulae and screw loosening, but all were treatable without causing implant failure.

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