



PERIIMPLANT TISSUE RESPONSE FOLLOWING IMMEDIATE PROVISIONAL RESTORATION OF SCALLOPED IMPLANTS IN THE ESTHETIC ZONE: A ONE-YEAR PILOT PROSPECTIVE MULTICENTER STUDY

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Statement of problem. Flat platform implants may present a limitation when irregular or scalloped bone topography is encountered, resulting in compromised periimplant bone and soft tissue contours.

Purpose. This 1-year pilot prospective multicenter study assessed the success rates and periimplant tissue response of scalloped implants undergoing immediate provisional restoration in the maxillary esthetic zone.

Material and methods. Twenty-nine patients, 15 men and 14 women, mean age of 45.1 (range: 18-70) years, were included in this study. Thirty-eight scalloped implants with a 1.5-mm machined surface collar and a titanium oxide surface (TiUnite) were placed both in healed sites (15) and extracted sites (23), and provisional restorations were placed immediately. The definitive restorations were placed an average of 12.6 months later. The patients were evaluated clinically with respect to gingival papilla appearance, presence or absence of plaque and gingivitis, and radiographically for bone level measurements at 0, 3, 6, and 12 months after implant placement. Descriptive statistics were used to analyze the data.

Results. At 12 months, all implants remained in function. The mean (SD) marginal bone change from the time of implant placement to 12 months was 0.1 (3.3) mm. For implants placed in extracted sites the mean (SD) marginal bone change was 1.0 (3.6) mm, compared to those in healed sites, which was -1.6 (1.9) mm. The marginal bone level in 9 of the initial 22 sites (41%) was retained in the scalloped area of the implants at 12 months. In the follow-up, after 3 months of function, no significant changes with respect to mean papilla index score were observed. The patients maintained acceptable hygiene throughout the follow-up period.

Conclusions. Although favorable implant success rates and periimplant tissue response can be achieved with immediate provisional restoration of scalloped implants in the esthetic zone, bone was not regularly maintained at the original levels around the scalloped area of the implants. (J Prosthet Dent 2007; 97: S109-S118.)

CLINICAL IMPLICATIONS

The concept of a scalloped implant platform appears to be sound based on the preliminary findings of this study, even though the current implant design could be enhanced. With better understanding of bone physiology as it relates to implant geometry and surface, it is hoped that the implant design can be further developed to maintain the periimplant tissues.

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The viability and success of osseointegrated implants for maxillary anterior tooth replacement have been substantiated by several studies.¹⁻³ The classic prerequisites for osseointegration required healing periods of 3-6 months, during which functional load should be avoided.^{4,5} However, long healing periods can present challenges esthetically, functionally, psychologically, as well as socially, to some patients. In 1998, Wöhrle advocated immediate provisional restoration of single implants in the esthetic zone, reporting no failures up to 36 months.⁶ Since then, studies have substantiated the viability of such treatment for both healed and extracted sites.^{7,8}

Essentially, all commercially available dental implant designs have the implant/abutment interface machined perpendicular to the long axis of the implant. This design presents a limitation in that, when irregular or scalloped bone topography is encountered, especially in the anterior maxilla, the bone and soft tissue contours can be compromised. If the implant is placed within 1 mm of the facial bony crest of the tooth to allow for optimal facial gingival esthetics, the implant/abutment interface will be inevitably positioned below the interproximal bone, resulting in proximal bone loss. However, if the implant/abutment interface is placed above the bone on the proximal area to avoid or minimize the resorptive process, the risk of exposing the implant collar at the facial area increases, thereby compromising esthetics. In view of natural, scalloped (nonlinear), osseous and gingival tissue topography, and to improve the biologic and esthetic outcome, it has been suggested that the current implant design featuring a flat, rotation-symmetric shoulder be reexamined.⁹⁻¹²

The scalloped platform implant (NobelPerfect; Nobel Biocare, Yorba Linda, Calif) was designed to mimic the scalloped bony and soft tissue topography around maxillary anterior teeth.¹³ This design intends for the

shoulder of the implant to be placed above the bone on the proximal area to minimize bone loss. At the same time, it is lower in the middle (facial/lingual aspect), so there is minimal esthetic compromise due to titanium shoulder exposure in situations where differential gingival height is present between the facial and proximal aspect of the implant site. The purpose of this 1-year pilot prospective multicenter study was to assess the success rates, changes in marginal bone level, and the papilla index of scalloped implants undergoing immediate provisional restoration in both healed and extracted sites in the maxillary esthetic zone (first premolar to first premolar). Surgical and prosthodontic complications were also evaluated.

MATERIAL AND METHODS

This study was conducted at the Center for Prosthodontics and Implant Dentistry, Loma Linda University School of Dentistry in California, and a private practice in Perth, Australia. The ethics review board of each center approved the study. To ensure that both centers used similar techniques for clinical registrations, a detailed study protocol was followed. The patients were selected according to specific inclusion and exclusion criteria and included in the study only after providing informed consent. The inclusion criteria were: missing or failing teeth in the maxilla (from premolar to premolar) and sufficient bone to allow for placement of an implant with the minimum dimensions of 3.5 x 10.0 mm. The exclusion criteria were: failing teeth with active infection; aspects of the medical history that might complicate the outcome of the study, such as alcohol, drug dependency, poor health, or any other medical, physical, or psychological reason that might affect the surgical procedure or the subsequent prosthodontic treatment and required follow-ups; a history of head and neck radiation treatment; a history of parafunctional habit; and insufficient

bone quantity that required bone augmentation before implant placement. However, bone augmentation to fill the gap between the implant and the extraction socket and/or to cover exposed implant threads was included as part of the study.

Thirty-one consecutive patients with a mean age of 45.1 years (range of 18 to 70 years) underwent immediate implant placement and provisional restoration in the maxillary esthetic zone. Two patients withdrew from the study after the implants were placed. Thirty-eight titanium oxide surface (TiUnite) scalloped implants (NobelPerfect; Nobel Biocare) from 29 patients were evaluated. The sample included 19 central incisors, 12 lateral incisors, 1 canine, and 6 first premolars. Fifteen implants were placed in healed sites in 12 patients, and 23 implants were placed in extracted sites in 19 patients (2 patients had implants placed in both healed and extracted sites). The implant distribution according to diameter and length is shown in Table I. Seven patients received multiple implants (16), 4 of which had multiple adjacent implants (10). Bone quality,¹⁴ clinically evaluated at time of implant placement, was categorized as either type II (10 implants; 26%) or type III (28 implants; 74%). Twenty-five implants were placed at the Center for Prosthodontics and Implant Dentistry, Loma Linda University School of Dentistry, Loma Linda, California, and 13 implants were placed at the private practice in Perth, Australia.

All patients received diagnostic procedures and treatment planning information and consented to the treatment. The implants used in this study were tapered with a titanium oxide (TiUnite; Nobel Biocare) surface and had a 1.5-mm machined surface collar (NobelPerfect; Nobel Biocare). The clinical technique used in this study has been previously published.^{13,15} An acrylic resin (Jet; Lang Dental, Wheeling, Ill) provisional shell of the missing or failing tooth was fabricated prior to implant surgery. For

TABLE I. Implant distribution according to length and diameter

Implant Length (mm)	Implant Diameter (mm)			Total
	3.5	4.3	5.0	
10	0	0	0	0
13	2	7	4	13
16	3	11	11	25
Total	5	18	15	38

the dentate site, the surgical phase involved minimally traumatic tooth extraction and immediate implant placement (NobelPerfect; Nobel Biocare) after ascertaining the integrity of the labial bony plate. The clinical scenario of 1 patient, a 29-year-old man with oblique subosseous root fractures caused by a traumatic injury (Fig. 1, A), is presented. Two adjacent implants were immediately placed in extraction sockets (Fig. 1, B) with screw-retained provisional crowns (Fig. 1, C). For the healed site, the osseous architecture was recontoured as deemed appropriate prior to implant placement. Autogenous bone graft (collected during osteotomy) and xenograft (Bio-Oss; Osteohealth, Shirley, NY) were used to cover minor thread exposure and/or to fill the gaps presented between the implant body and the tooth extraction socket following immediate implant placement. Primary implant stability was confirmed prior to the immediate provisional restoration procedure.

The provisional crowns were either cemented or screw-retained (Fig. 1, C). The appropriate abutment (Straight or 10-degree, NobelPerfect; Nobel Biocare) was hand tightened into the implant, and the prefabricated provisional shell was relined, using light-polymerizing composite resin (PermaFlo; Ultradent Products Inc, South Jordan, Utah). The relined provisional crown was provisionally cemented (Temp-Bond; Kerr Corp, Orange, Calif) and was adjusted so there were no centric or eccentric oc-

clusal contacts. The screw-retained crowns were fabricated from laboratory processed heat-polymerized acrylic resin (Ivocron; Ivoclar Vivadent, Schaan, Liechtenstein) and inserted within several hours of implant placement.

Appropriate antibiotic (amoxicillin, 500 mg or equivalent, taken orally 3 times daily for 1 week) and analgesic (ibuprofen, 800 mg or equivalent, taken orally every 4-6 hours as needed for pain) regimes were prescribed. The patients were instructed not to brush the surgical site, but rinse with and lightly swab the surgical area with a cotton-tipped applicator soaked in 0.12% chlorhexidine gluconate (Peridex; Procter & Gamble, Cincinnati, Ohio), and to consume a liquid diet for 2 weeks. A soft diet was recommended for the remaining duration of the implant healing phase. The patient was advised against functioning in the surgical site.

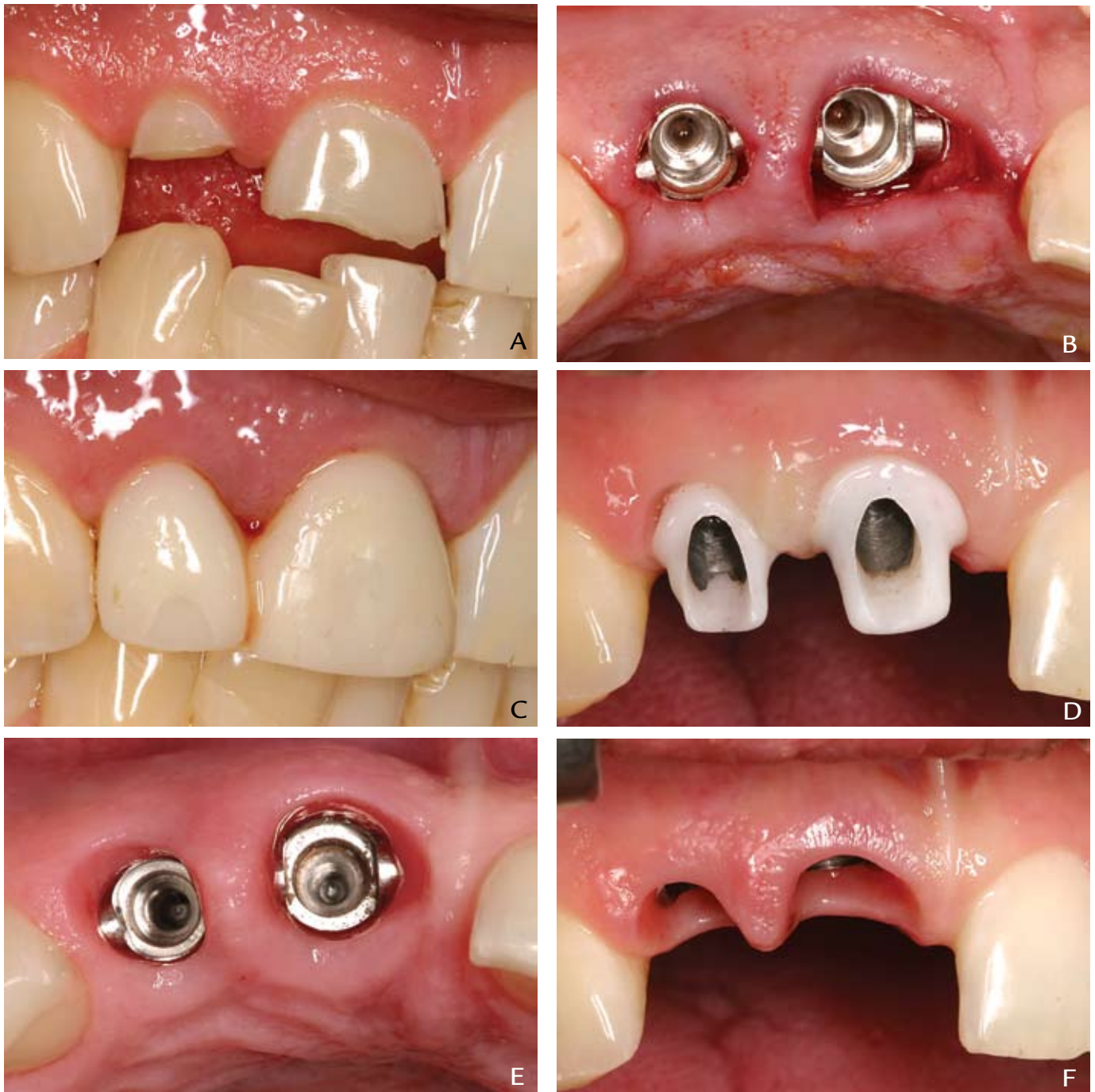
The definitive implant impression was made after 5 months using high viscosity vinyl polysiloxane (Aquasil; Dentsply Caulk, Milford, Del) for fabrication of either a cement-retained or screw-retained definitive restoration. For the cement-retained restorations, in addition to the prefabricated metal abutments (Straight or 10-degree; NobelPerfect; Nobel Biocare), customized ceramic abutments were also used. The abutments and definitive screw-retained restorations were torqued to 35 Ncm, according to the manufacturer's recommendation (Nobel Biocare) and shown in Figure

1, D. The definitive cement-retained restorations were cemented (RelyX Luting Cement; 3M ESPE, St. Paul, Minn).

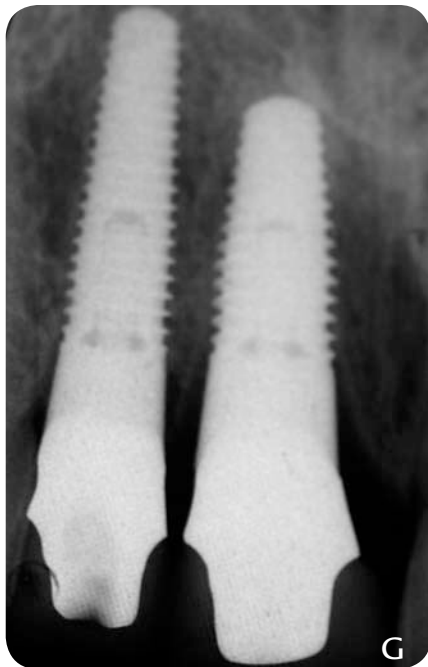
All examinations and data collections were performed by 1 examiner at each center. Evaluations were made at 0, 3, 6, and 12 months (unless otherwise noted) after implant placement and provisional restoration. Postoperative photos at 6 months (Figs. 1, E and F) and a postoperative radiograph 12 months following implant insertion (Fig. 1, G), accompanied by a labial view of the definitive restorations (Fig. 1, H) of a representative patient, are provided.

The following variables were recorded and compared with the available data in the literature: implant success/failure,¹⁶⁻²³ marginal bone changes,²⁴⁻²⁸ papilla index,²⁹ oral hygiene status,³⁰⁻³⁴ and any related complications. Oral hygiene status was recorded as presence or absence of plaque and gingivitis around the implant restoration during each recall appointment. Complications were also recorded and included soft tissue complications, periimplant radiolucency, and prosthodontic complications. The implants were evaluated according to the success criteria proposed by van Steenberghe.¹⁶ Implants were considered failures if 1 or more of the following conditions were observed: periimplant radiolucency, mobility, infection, allergic/toxic reaction, implant fracture, or bending.

Marginal bone level was measured using sequential periapical radio-



1 Clinical scenario of 29-year-old man with traumatic injury and immediate extraction sites. A, Clinical pretreatment situation of oblique subosseous root fractures. B, Immediate implant placement. C, Immediate splinted screw-retained provisional crowns. D, Zirconia-titanium abutments E, Postoperative follow-up; incisal view at 6 months. F, Postoperative follow-up; labial view at 6 months.



1 continued G, Postoperative radiograph of definitive prosthesis at 12 months. H, Postoperative labial view at 12 months.

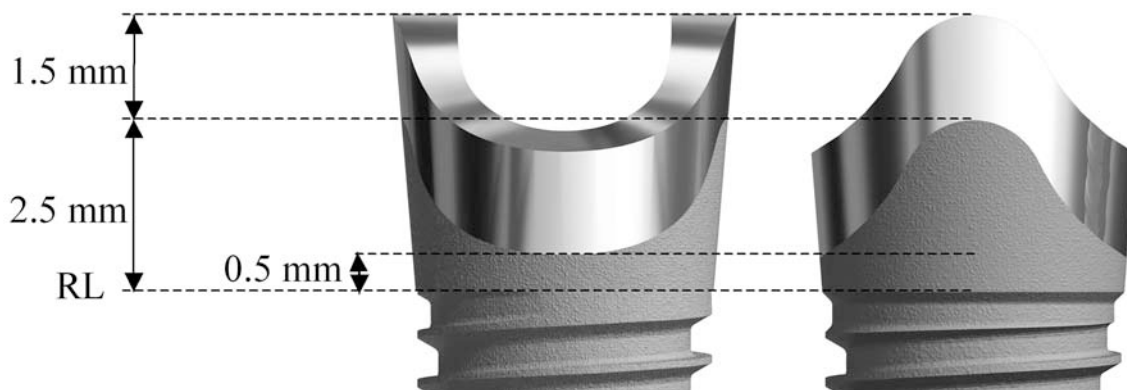
graphs made with the long cone paralleling technique with radiographic film holders (Rinn XCP post bite blocks 54-0862; Dentsply Rinn, Elgin, Ill). A vinyl polysiloxane (Exabite; GC America Inc, Alsip, Ill) occlusal jig was used to standardize the angulation and position of the film relative to the x-ray beam. Marginal bone levels on the mesial and distal aspects of the implants at each time interval were measured by an independent radiologist at x7 magnification to the nearest 0.1 mm using the apical corner of the implant collar as the reference line (Fig. 2). A positive value indicated a level coronal to the reference line,

and a negative value indicated a level apical to the reference line.

The interproximal soft tissue contours were evaluated using the papilla index score introduced by Jemt.²⁹ The papilla index score values were defined as: 0 = no papilla; 1 = less than half the height of the papilla; 2 = at least half of the height of the papilla was present, but not all the way to the contact point; 3 = papilla filled the entire proximal space; and 4 = hyperplastic papilla. The mean papilla index score in the extracted sites was measured at pretreatment, and 3, 6, and 12 months following implant surgery. Since the papilla index score

could not be categorized when the tooth was missing, the mean papilla index score in the healed sites was measured only at 3, 6, and 12 months following the implant surgery.

A power of 80% was set for the sample size calculation where a marginal bone change of 0.7 mm was set to be clinically relevant, and standard deviation was set as 0.9 mm. Means and standard deviations were calculated for each clinical parameter at each time interval where applicable. Descriptive statistics were used to analyze the data.



2 Measurement of marginal bone level. Apical corners of implant collar were used as reference line (RL). Scalloped portion of implant starts at 0.5 mm coronal to RL. Polished collar is 1.5 mm wide and starts at 2.5 mm coronal to RL.

RESULTS

After 1 year of function, all implants (38/38) were stable and none had lost osseointegration. This corresponds to an overall implant success rate of 100%. One patient became pregnant during the study and, thus, only a clinical evaluation was performed throughout the study period without radiographic examination. Two patients declined radiographic examination at 3 months, 1 at 6 months, and 1 at both the 3- and 6-month follow-up appointments. Two patients did not attend the 6-month follow-up appointment. A 3-month radiograph of 1 patient was not suitable for evaluation. The number of sites evaluated clinically and radiographically at each appointment is presented in Tables II-V.

The mean (SD) overall marginal bone levels at 0, 3, 6, and 12 months following the implant surgery were 0.1 (3.3) mm, -0.6 (2.2) mm, -0.4 (1.6) mm, and -0.1 (1.1) mm, respectively. While the mean (SD) overall marginal bone changes from 0 to 12 months were minimal (-0.1 (3.3) mm) (Table II), there was a wide variation,

ranging from -5.1 to 9.2 mm.

The mean (SD) marginal bone change from 0 to 12 months was 1.0 (3.6) mm for implants placed in extracted sites, compared to -1.6 (1.9) mm for implants placed in healed sites. The mean (SD) marginal bone levels in extracted sites at 0, 3, 6, and 12 months following the implant surgery were -1.1 (3.7) mm, -1.2 (1.8) mm, -0.9 (1.8) mm, and -0.2 (1.2) mm, respectively. The corresponding mean (SD) marginal bone levels for healed sites were 1.8 (1.7) mm, 0.3 (2.4) mm, 0.3 (1.0) mm, and 0.1 (1.0) mm, respectively (Table II).

The frequency distribution of marginal bone levels at 0 and 12 months after the surgery is shown in Table III. At 12 months, the marginal bone levels in 5/22 (23%) of extracted sites and 4/15 (27%) of healed sites were at the scalloped area of the implant (between 0.5 to >2.5 mm from the reference line, whereas at baseline, the distributions were 11/23 (48%) and 11/15 (73%), respectively.

The mean (SD) papilla index score in extracted sites at pretreatment, and 3, 6, and 12 months following the implant surgery were 2.4 (0.8),

2.6 (0.7), 2.6 (0.7), and 2.7 (0.5), respectively (Table IV). The mean (SD) papilla index score in the healed sites at 3, 6, and 12 months following the implant surgery were 2.3 (0.7), 2.4 (0.6), and 2.4 (0.6), respectively (Table V). The low percentage of gingivitis (13, 3, and 0%) and plaque (13, 0, and 8%) scores present at 3, 6, and 12 months, respectively, indicated that acceptable hygiene had been maintained in most sites throughout the follow-up period.

Three patients experienced unseating of provisional restorations, 2 of which had multiple recurrences. All incidences involving unseating of provisional restorations were resolved by using stronger cement (IRM; Dentsply Intl, York, Pa) in place of the initially used provisional cement (Temp-Bond; Kerr Corp). One patient fractured a provisional crown. One patient experienced gingival graying at the 1-year follow-up and resolution required placement of a connective tissue graft. No other complications (soft tissue or prosthodontic) or periimplant radiolucencies were observed.

TABLE II. Marginal bone level at baseline, 3, 6, and 12 months after surgery, and bone level changes from baseline to 12 months

	Mean ± SD (mm)		
	Overall (N)	Extracted Site (N)	Healed Site (N)
Baseline	0.1* ± 3.3 (38)	-1.1 ± 3.7 (23)	1.8 ± 1.7 (15)
3 months	-0.6 ± 2.2 (33)	-1.2 ± 1.8 (19)	0.3 ± 2.4 (14)
6 months	-0.4 ± 1.6 (33)	-0.9 ± 1.8 (21)	0.3 ± 1.0 (12)
12 months	-0.1 ± 1.1 (37)	-0.2 ± 1.2 (22)	0.1 ± 1.0 (15)
Bone level change, baseline to 12 months	-0.1 ± 3.3 (37) Range: -5.1 to 9.2	1.0 ± 3.6 (22) Range: -5.1 to 9.2	-1.6 ± 1.9 (15) Range: -4.2 to 1.7

*Calculated from mean marginal bone level per position (mean of mesial and distal values)

TABLE III. Overall frequency distribution of mean marginal bone level calculated per position (mean of mesial and distal values) at baseline and 12 months after surgery

MBL (mm)	Number of Sites (%)					
	Overall		Extracted Sites		Healed Sites	
	Baseline	12 Months	Baseline	12 Months	Baseline	12 Months
>2.5	6 (16)	0 (0)	1 (4)	0 (0)	5 (33)	0 (0)
0.5 to 2.5	16 (42)	9 (24)	10 (44)	5 (23)	6 (40)	4 (27)
0.1 to 0.4	1 (3)	7 (19)	0 (0)	3 (14)	1 (7)	4 (27)
0	1 (3)	2 (5)	1 (4)	2 (9)	0 (0)	0 (0)
-0.1 to -1.0	5 (13)	15 (41)	2 (9)	9 (41)	3 (20)	6 (40)
-1.1 to -2.0	3 (8)	3 (8)	3 (13)	2 (9)	0 (0)	1 (7)
<-2.0	6 (16)	1 (3)	6 (26)	1 (5)	0 (0)	0 (0)
Total	38*	37	23	22	15	15

*Individual percentages were rounded to whole numbers, total percentage may not equal 100%

TABLE IV. Papilla index score in extracted sites at pretreatment as well as 3, 6, and 12 months after surgery

	Papilla Index Score					N	Mean (SD)
	0	1	2	3	4		
Pretreatment	2	2	16	24	0	44	2.4 (0.8)
3 months	1	1	12	30	0	44	2.6 (0.7)
6 months	1	2	9	32	0	44	2.6 (0.7)
12 months	0	1	11	32	0	44	2.7 (0.5)

TABLE V. Papilla index score in healed sites at 3, 6, and 12 months after surgery

	Papilla Index Score					N	Mean (SD)
	0	1	2	3	4		
3 months	0	3	12	11	0	26	2.3 (0.7)
6 months	0	1	12	9	0	22	2.4 (0.6)
12 months	0	2	12	12	0	26	2.4 (0.6)

DISCUSSION

The implant success rate for the immediate provisional restoration of the scalloped, threaded, tapered titanium oxide (TiUnite) surface implants in both healed and extracted sites reported in this pilot study was 100% (38/38) following 1 year of function. Comparably high success rates have been reported when implants were immediately, provisionally restored in the esthetic zone either in an extracted site (98%)^{7,17,18} or healed site (100%).^{18,19} In addition, similar implant success rates (100%) have been reported with implants with a titanium oxide surface (TiUnite)²⁰⁻²² and scalloped platform design (100%).²³

In this study, only minor overall mean (SD) marginal bone change (-0.1 (3.3) mm) around the scalloped implants was noted 1 year after immediate provisional restoration (Table II). This was well below the mean marginal bone loss observed in delayed loaded implants with a flat platform²⁴ and in a previous clinical report on immediately loaded scalloped implants after the first year of function.²³ The relatively low mean marginal bone loss observed in this study may be attributed to the fact that the majority of the implants (23/38 = 60.5%) were immediately placed into extraction sockets. In fact, the implants in the extracted sites in this study experienced a mean (SD) bone gain of 1.0 (3.6) mm after 1 year of function. Similar bone gains have been previously reported and attributed to spontaneous bone filling in the gap between the implant and the extraction socket following immediate implant placement.⁷ In addition, placement of bone graft materials into the gap in this study may have enhanced bone fill. However, the mean (SD) marginal bone change in healed sites in this study of -1.6 (1.9) mm after 1 year of function may be related in part to the relative position of the interproximal bone to the machined portion of the scalloped implant. Numerous authors have shown that

crestal bone will remodel around the machined junction of an implant.²⁵⁻²⁷ Therefore, subcrestal placement of machined surfaced implant collars will result in additional bone loss.²⁵⁻²⁷ In the healed sites in this study, the initial bone level in 33% (5/15) were in contact with or above the machined collar of the scalloped implant (>2.5 mm), but none remained in contact with the machined collar after the 12-month follow-up (Table III). These results indicate the inability of the bone to maintain contact with the machined collar, and that appears to have been a factor in the marginal bone loss that occurred in the healed sites.

While the periimplant marginal bone change is one of the most common parameters evaluated in osseointegrated implant studies,^{1,7,19,20,28} the eventual location of the marginal bone level is seldom discussed. The bone level change identifies the dynamic aspect of periimplant marginal bone in a quantifiable manner, and it represents the bone reaction to the implant surface. However, the dynamic bone level change can be affected by implant site (healed versus extracted) and/or initial bone-implant contact level (on machined collar versus treated implant surface). However, the eventual location of the marginal bone level, which is the stable bone position after remodeling, describes the static aspect of the marginal bone. Studies have shown that periimplant marginal bone levels were stable after 1 year of function, and subsequent changes were negligible.^{1,20,28} For scalloped implants in the present study, the trend for static bone level is consistent despite variability in the initial bone-implant contact level and does not seem to be affected by the implant site (healed versus extracted). By understanding the static bone level, clinicians and researchers can predictably anticipate the dynamic bone level change, as well as recognize the effect of the implant design and propose improvements. With the scalloped implants

used in this study, the bone level in 5 of 11 extracted sites (45%) and 4 of 11 healed sites (36%) remained in the scalloped area of the implants (0.5 to >2.5 mm from reference line) at 12 months (Table III). In an attempt to further improve bone retention, microthreads have been added to the scalloped area of the implants, and the machined collar has been replaced with a titanium oxide surface in the new version of scalloped implants (NobelPerfect Groovy; Nobel Biocare). Additional studies are now needed to evaluate the periimplant tissue response around this newer scalloped design since it was not used in this study.

The papilla index score²⁹ is used to quantify the amount of interproximal dark spaces present between teeth. However, it may not accurately identify the magnitude of papilla height change because the contact area of the implant restoration can be cervically positioned so there is no dark space even though the papilla height has decreased. This may explain in part the improvements in the mean papilla index score for extracted sites that were found after 1 year of function (Table IV). Regardless, the minor improvements of the mean (SD) papilla index score for extracted sites from pretreatment to 12 months (2.4 (0.8) to 2.7 (0.5)) were clinically inconsequential. This result suggests that the papilla index score can be maintained using this treatment protocol. Glauser et al²⁸ reported a mean papilla index score of approximately 2 for immediately loaded implants placed in healed and extracted sites 1 year following implant insertion, whereas, in the current study, using scalloped implants (NobelPerfect; Nobel Biocare), the mean (SD) papilla index scores were 2.7 (0.5) and 2.4 (0.6) for extracted sites and healed sites, respectively.

Although the influence of oral hygiene on implant success has been controversial,³⁰⁻³⁴ it is generally agreed that plaque accumulation could induce a negative mucosal response.

The low percentage of gingivitis (13, 3, and 0%) and plaque (13, 0, and 8%) scores present at 3, 6, and 12 months, respectively, implies that acceptable hygiene had been maintained in most sites throughout the study. Since brushing the surgical site was not recommended during the first month of implant surgery to minimize soft tissue disturbance, oral hygiene appears to have been adequately maintained through light swabbing of the area with a cotton-tipped applicator soaked in 0.12% chlorhexidine gluconate (Peridex; Procter & Gamble).⁷

Graying of the periimplant mucosa following immediate implant placement and provisional restoration can occur, especially in patients with a thin periodontal biotype. The single graying episode observed in this study was resolved by placing a connective tissue graft, but more treatments of this nature are necessary to determine the effectiveness of such grafting in eliminating soft tissue darkness.³⁵ Additionally, the long-term stability of the improved coloration needs to be assessed.

One of the original 3 centers withdrew from the study, thus reducing the sample size. While useful information could be deduced from this pilot study, the limitations of the study should be acknowledged. A larger sample size and long-term follow-up will provide more insightful evidence on the periimplant tissue response of scalloped implants. The concept of a scalloped implant platform appears to be sound, even though the current implant design could be enhanced. Fortunately, with better understanding of bone physiology as it relates to implant geometry and surface, the implant design can be further developed, and hopefully, in the near future, the point where the concept and reality meet will be reached.

CONCLUSIONS

Within the limitations of this pilot study, the following conclusions were drawn:

1. The 1-year results indicate that the implant success rate (100%) and the periimplant tissue response following placement of immediate provisional restorations for scalloped implants were considered to be favorable. There was no evidence of periimplant radiolucencies.

2. Bone was not regularly maintained (9/22 sites, 41%) around the scalloped area of the implants.

3. After 12 months, the mean marginal bone change was 1.0 mm (range = -5.1 to 9.2 mm) in the extracted sites and -1.6 mm (range = -4.2 to 1.7 mm) in the healed sites, with the mean overall marginal bone change of -0.1 mm.

4. After 3 months of function no significant changes with respect to mean papilla index score were observed.

5. Prosthodontic and soft tissue complications encountered were generally minor and could be readily resolved.

REFERENCES

- Astrand P, Engquist B, Anzen B, Bergendal T, Hallman M, Karlsson U, et al. A three-year follow-up report of a comparative study of ITI Dental Implants and Branemark System implants in the treatment of the partially edentulous maxilla. *Clin Implant Dent Relat Res* 2004;6:130-41.
- Naert I, Koutsikakis G, Duyck J, Quirynen M, Jacobs R, van Steenberghe D. Biologic outcome of single-implant restorations as tooth replacements: a long-term follow-up study. *Clin Implant Dent Relat Res* 2000;2:209-18.
- Cooper L, Felton DA, Kugelberg CF, Ellner S, Chaffee N, Molina AL, et al. A multicenter 12-month evaluation of single-tooth implants restored 3 weeks after 1-stage surgery. *Int J Oral Maxillofac Implants* 2001;16:182-92.
- Albrektsson T, Branemark PI, Hansson HA, Lindstrom J. Osseointegrated titanium implants. Requirements for ensuring a long-lasting, direct bone-to-implant anchorage in man. *Acta Orthop Scand* 1981;52:155-70.
- Branemark PI. Osseointegration and its experimental background. *J Prosthet Dent* 1983;50:399-410.
- Wohrle PS. Single-tooth replacement in the aesthetic zone with immediate provisionalization: fourteen consecutive case reports. *Pract Periodontics Aesthet Dent* 1998;10:1107-14.
- Kan JY, Rungcharassaeng K, Lozada J. Immediate placement and provisionalization of maxillary anterior single implants: 1-year prospective study. *Int J Oral Maxillofac Implants* 2003;18:31-9.
- Malo P, Friberg B, Polizzi G, Gualini F, Vighagen T, Rangert B. Immediate and early function of Branemark System implants placed in the esthetic zone: a 1-year prospective clinical multicenter study. *Clin Implant Dent Relat Res* 2003;5 Suppl 1:37-46.
- Gadhia MH, Holt RL. A new implant design for optimal esthetics and retention of interproximal papillae. *Implant Dent* 2003;12:164-9.
- Gallucci GO, Belser UC, Bernard JP, Magne P. Modeling and characterization of the CEJ for optimization of esthetic implant design. *Int J Periodontics Restorative Dent* 2004;24:19-29.
- Grunder U, Gracis S, Capelli M. Influence of the 3-D bone-to-implant relationship on esthetics. *Int J Periodontics Restorative Dent* 2005;25:113-9.
- Holt RL, Rosenberg MM, Zinser PJ, Ganelles J. A concept for a biologically derived, parabolic implant design. *Int J Periodontics Restorative Dent* 2002;22:473-81.
- Wohrle PS. NobelPerfect esthetic scalloped implant: rationale for a new design. *Clin Implant Dent Relat Res* 2003;5 Suppl 1:64-73.
- Lekholm U, Zarb GA. Patient selection and preparation. In: *Tissue-integrated prostheses*. Branemark PI, Zarb GA, Albrektsson T, editors. Chicago: Quintessence; 1985. p. 199-209.
- Wohrle PS, Jovanovic SA. NobelPerfect-A biologic approach to predictable natural esthetics. *Appl Osseointegration Res* 2004;4:49-54.
- van Steenberghe D. Outcomes and their measurement in clinical trials of endosseous oral implants. *Ann Periodontol* 1997;2:291-8.
- Cornellini R, Cangini F, Covani U, Wilson TG Jr. Immediate restoration of implants placed into fresh extraction sockets for single-tooth replacement: a prospective clinical study. *Int J Periodontics Restorative Dent* 2005;25:439-47.
- Norton MR. A short-term clinical evaluation of immediately restored maxillary TiOblast single-tooth implants. *Int J Oral Maxillofac Implants* 2004;19:274-81.
- Proussaefs P, Kan J, Lozada J, Kleinman A, Farnos A. Effects of immediate loading with threaded hydroxyapatite-coated root-form implants on single premolar replacements: a preliminary report. *Int J Oral Maxillofac Implants* 2002;17:567-72.
- Glauser R, Lundgren AK, Gottlow J, Sennerby L, Portmann M, Ruhstaller P, et al. Immediate occlusal loading of Branemark TiUnite implants placed predominantly in soft bone: 1-year results of a prospective clinical study. *Clin Implant Dent Relat Res* 2003;5 Suppl 1:47-56.
- Vanden Bogaerde L, Rangert B, Wendelhag I. Immediate/early function of Branemark system TiUnite implants in fresh extraction sockets in maxillae and posterior mandibles: an 18-month prospective clinical study. *Clin Implant Dent Relat Res* 2005;7 Suppl 1:121-30.

22. Aalam AA, Nowzari H. Clinical evaluation of dental implants with surfaces roughened by anodic oxidation, dual acid-etched implants, and machined implants. *Int J Oral Maxillofac Implants* 2005;20:793-8.
23. Nowzari H, Chee W, Yi K, Pak M, Chung WH, Rich S. Scalloped dental implants: a retrospective analysis of radiographic and clinical outcomes of 17 NobelPerfect implants in 6 patients. *Clin Implant Dent Relat Res* 2006;8:1-10.
24. Goodacre CJ, Bernal G, Rungcharassaeng K, Kan JY. Clinical complications with implants and implant prostheses. *J Prosthet Dent* 2003;90:121-32.
25. Cochran DL, Hermann JS, Schenk RK, Higginbottom FL, Buser D. Biologic width around titanium implants. A histometric analysis of the implanto-gingival junction around unloaded and loaded nonsubmerged implants in the canine mandible. *J Periodontol* 1997;68:186-98.
26. Herrman JS, Schoolfield JD, Schenk RK, Buser D, Cochran DL. Influence of the size of the microgap on crestal bone changes around titanium implants. A histometric evaluation of unloaded non-submerged implants in the canine mandible. *J Periodontol* 2001;72:1372-83.
27. Hammerle CH, Bragger U, Burgin W, Lang NP. The effect of subcrestal placement of the polished surface of ITI implants on marginal soft and hard tissues. *Clin Oral Implants Res* 1996;7:111-9.
28. Glauser R, Ruhstaller P, Windisch S, Zembic A, Lundgren A, Gottlow J, et al. Immediate occlusal loading of Branemark System TiUnite implants placed predominantly in soft bone: 4-year results of a prospective clinical study. *Clin Implant Dent Relat Res* 2005;7 Suppl 1:52-9.
29. Jemt T. Regeneration of gingival papillae after single-implant treatment. *Int J Periodontics Restorative Dent* 1997;17:326-33.
30. Smith DE, Zarb GA. Criteria for success of osseointegrated endosseous implants. *J Prosthet Dent* 1989;62:567-72.
31. Adell R, Lekholm U, Rockler B, Branemark PI, Lindhe J, Eriksson B, et al. Marginal tissue reactions at osseointegrated titanium fixtures (I). A 3-year longitudinal prospective study. *Int J Oral Maxillofac Surg* 1986;15:39-52.
32. Berglundh T, Lindhe J, Marinello C, Ericsson I, Liljenberg B. Soft tissue reactions to de novo plaque formation on implants and teeth. An experimental study in the dog. *Clin Oral Implants Res* 1992;3:1-8.
33. Apse P, Zarb GA, Schmitt A, Lewis DW. The longitudinal effectiveness of osseointegrated dental implants. The Toronto Study: peri-implant mucosal response. *Int J Periodontics Restorative Dent* 1991;11:94-111.
34. Henry PJ, Tolman DE, Bolender C. The applicability of osseointegrated implants in the treatment of partially edentulous patients: three-year results of a prospective multi-center study. *Quintessence Int* 1993;24:123-9.
35. Kan JY, Rungcharassaeng K, Lozada JL. Bilaminar subepithelial connective tissue grafts for immediate implant placement and provisionalization in the esthetic zone. *J Calif Dent Assoc* 2005;33:865-71.

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