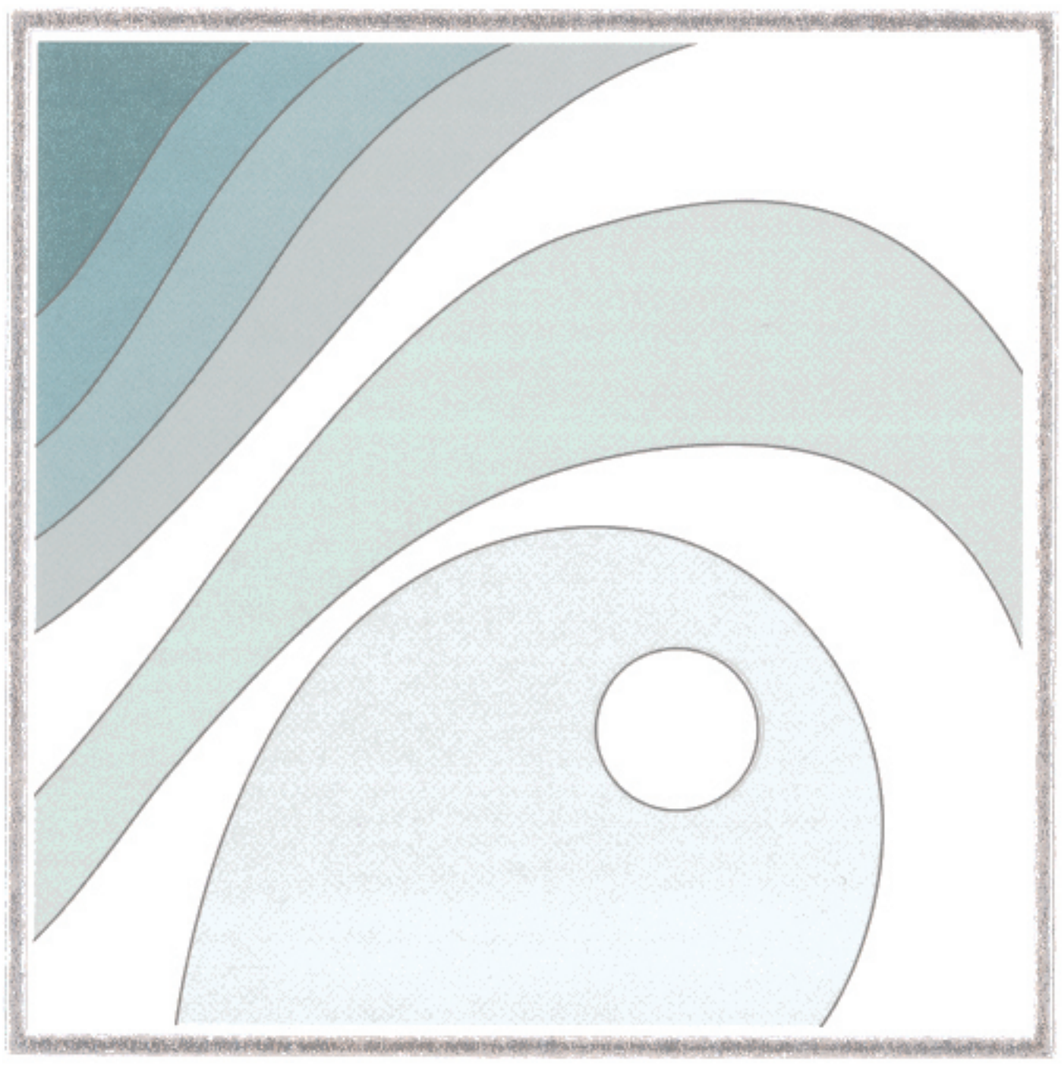
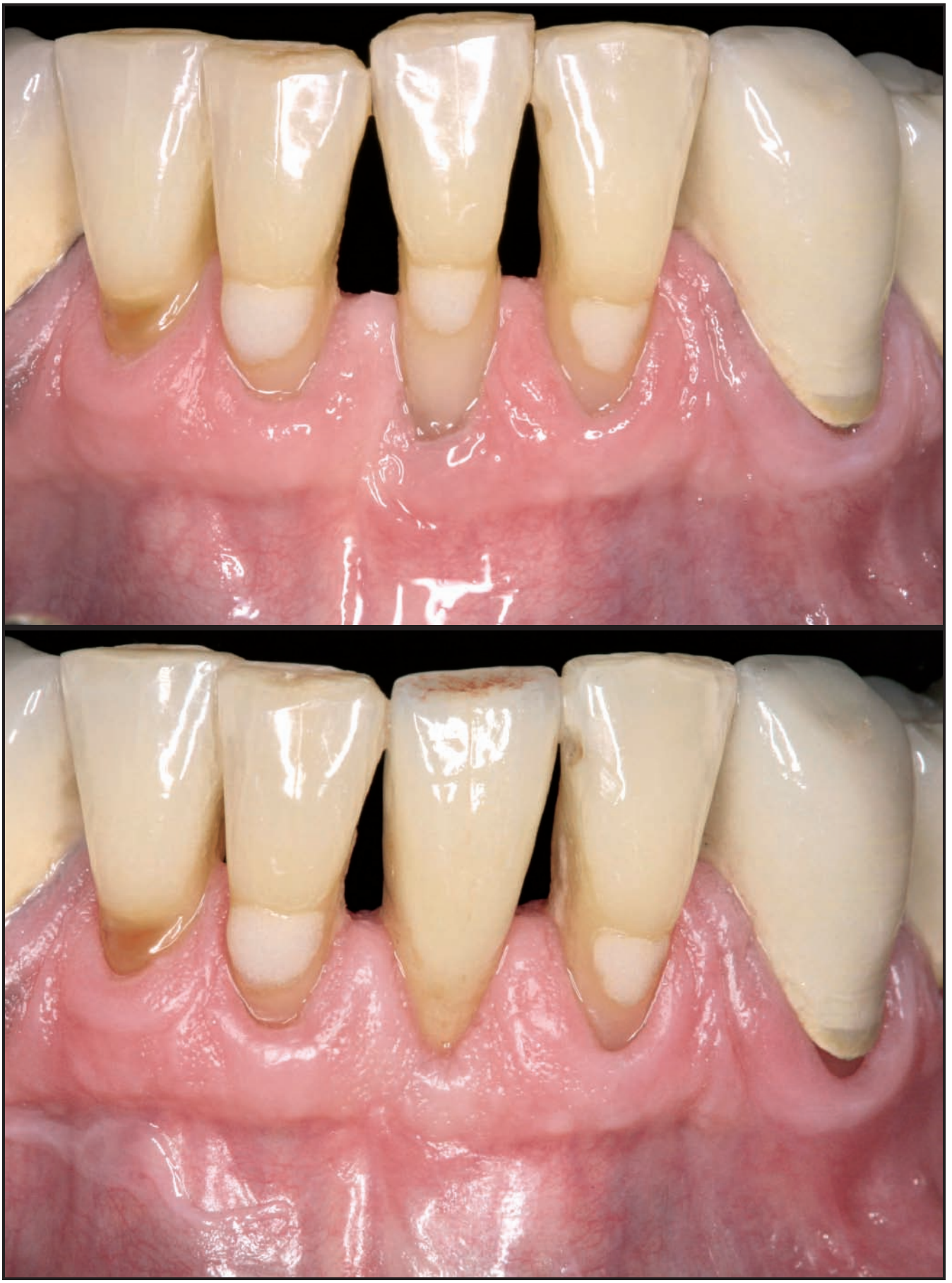
THE INTERNATIONAL JOURNAL
OF

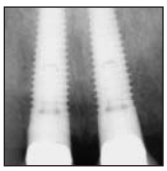
PERIODONTICS & RESTORATIVE DENTISTRY



Volume 27
Number 3
June 2007



Immediate Function with NobelPerfect Implants in the Anterior Dental Arch



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This study examined the clinical performance of the scalloped NobelPerfect implant in a one-stage procedure (immediate provisionalization in the esthetic zone). In 20 patients, immediate prosthetic restorations were placed on 31 NobelPerfect implants and followed for up to 27 months. Outcome variables were success rates, marginal bone levels, and Pink Esthetic Score (PES) assessed per implant. One implant failed (success rate: 96.8%). Marginal bone levels averaged 1.7 mm above the first thread and remained stable during the observation period. Mean PES ratings were 11.3 (range, 8 to 14). Survival rates, marginal bone levels, and esthetic results suggest proof of principle for the preservation of the interproximal bony lamella with a scalloped implant design. (Int J Periodontics Restorative Dent 2007;27:277–285.)

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The loss of a tooth in the esthetic zone is an event of far-reaching significance for a patient. Successful replacement of single teeth with implants has been documented in the literature for more than two decades.[1–6] However, traditional treatment concepts have advocated a 2- to 3-month consolidation period for the extraction socket and an additional 3 to 6 months of submerged—or at least unloaded—healing for osseointegration.[7,8] Although satisfactory rates of osseointegration have been reported, as cited above, there are major drawbacks with staged approaches in the esthetic zone. Apart from aspects essentially related to quality of life (long treatment period via provisional prosthesis), there are substantial biologic drawbacks to delayed implant placement (and function) in terms of involuntary loss of alveolar bone and gingiva and even substantial bone resorption during the unloaded healing time.[9] Both effects have been clearly shown to compromise long-term esthetic success.[10]

To overcome the disadvantages of staged implant surgery and treatment, immediate loading concepts[11] as well as flapless surgery approaches[12]

have been introduced in recent years. Specifically, promising results in terms of high success rates and remarkable esthetic outcomes have been reported for implants placed in extraction sockets and immediately loaded via provisional crowns and prostheses.[13–17] These techniques completely avoid a provisional removable denture and focus on preservation of the existing osseous and gingival structures through immediate function.

Although a better understanding of the maintenance of marginal bone levels has been achieved in recent years,[18] a fundamental problem of the marginal tissues has remained unsolved. The vast majority of the currently available implants have a flat prosthetic table. This configuration does not correspond to the natural topography of the healthy marginal bone contour, which features a vertical difference of 2.0 to 4.1 mm from the interproximal area to the facial aspect.[19] As a consequence, an implant must be placed inferior to the vertical minimum of the marginal contour to prevent titanium from being visible. Accordingly, remodeling of the marginal bone inevitably results in flattening of the interproximal marginal bone and loss of the bony support of the papillae. Especially between adjacent implants, this is not a trivial issue because severe esthetic problems may arise from inferior support of the papilla.

Although the scalloping of the natural marginal bone level is not the only determinant of marginal bone stability, this biologic consideration has encouraged the development of a scalloped implant design,[20] recently introduced as the NobelPerfect implant (Nobel Biocare). To date, the use of the NobelPerfect implant has been reported only in case reports and small case series.[21–25]

Thus, the purpose of this study was to systematically explore the clinical performance of the NobelPerfect implant after implant placement and immediate provisionalization in the esthetic zone. Specifically, the authors report success rates and the clinical, radio-graphic, and esthetic outcome within a follow-up period of up to 27 months.

Method and materials

Patients

Twenty patients (10 male, 10 female) with a mean age of 44.9 years (range, 29 to 69 years) were enrolled in this study. Inclusion criteria were as follows: tooth loss in the esthetic zone, good primary stability expected, and immediate provisional prosthetic restoration requested. Exclusion criteria were: previous radiation therapy, systemic bone diseases, or permanent immunosuppressive medication.

Between October 2003 and June 2005, 31 NobelPerfect implants with a 1.5-mm machined scalloped collar were placed. Twenty-four implants were placed in the anterior maxilla (premolars, canines, and incisors), and seven implants were placed in the mandibular incisor region. The reasons for removal were endodontic failure (n = 10), progressive periodontal disease (n = 8), longitudinal root fracture (n = 5), acute trauma (n = 4), and external root resorption (n = 3). One patient required an implant because of congenital aplasia of a canine.

Surgical technique

The hopeless teeth were extracted, and the alveolar socket walls and gingival architecture were maintained. The extraction site was cleaned of granulation tissue and, if necessary, of residual root canal filling materials with the assistance of a chairside microscope (ProDent, Zeiss) at 15× magnification.

Twenty-one implants were placed immediately after extraction, seven implants were placed after osseous consolidation of the extraction sockets, and three implants were placed secondary to extended alveolar ridge augmentation procedures. The facial bony lamella had defects or had been completely lost at six sites. Additional simultaneous bone-grafting procedures, all of which were done using autologous bone harvested from the mandibular ramus, were required at 18 implant sites (2 guided bone regeneration, 3 internal sinus floor elevation, and 13 buccal onlay grafts); another four sites required soft tissue augmentation with subepithelial connective tissue grafts. In 20 of 21 immediate cases, surgery was performed flapless, and in the remaining 11 cases full-thickness flaps were raised.

The implant sites were prepared according to the manufacturer's instructions. The implants were placed in the long axis of the root of the replaced tooth, in contact with the oral lamella of the socket. Placement depth was determined by the interproximal

and facial soft tissue and bone height. The TiUnite surface was placed in contact with interproximal bone, and the scalloped implant neck was placed about 2 mm apical to the circumferential soft tissue margin. Except for two implants (13 mm long), all other sites received implants that were 16 mm long. Fifteen implants were 3.5 mm in diameter, 12 implants were 4.3 mm in diameter, and 4 implants were 5 mm in diameter.

Immediate restoration

In situations requiring single-tooth replacement, acrylic resin denture teeth were adjusted to the implant site and cemented to titanium abutments. In situations requiring replacement of multiple teeth, the provisional restorations were fabricated by a lab technician. All provisional restorations were inserted on the day of implant placement and adjusted to clear all contacts in centric occlusion and during eccentric movements. For further stabilization against uncontrolled loading forces, 27 implants and their provisional restorations were splinted to neighboring teeth, and 17 adjacent implants were splinted to each other. Two implants remained unsplinted. To prevent infection, the patients received clindamycin 1 hour before surgery (single dose of 600 mg) and for 7 days after implant insertion (four doses of 300 mg each).

After a minimum of 3 months, the definitive crowns were fabricated from porcelain-fused-to-metal or Procera zirconia technology (Nobel Biocare). They were cemented with a long-lasting temporary cement (ImProv, Nobel Biocare) or glass-ionomer cement (Ketac-Cem, 3M Espe).

Follow-up and definition of outcome variables

Patients were examined clinically and radiographically at the time of implant placement and at least 6 months after implant placement. The primary outcome variables were as follows:

- Implant success. The implants were evaluated according to the criteria established by Smith and Zarb.[26] Specifically, these criteria considered loss or loosening of an implant, progressive marginal bone resorption, and inflammatory status of the gingiva.
- Marginal bone level. The marginal bone level was determined using digital sequential periapical radiographs (long-cone technique) with a commercial film holder (Dentsply/Rinn). Specifically, the vertical distance between the bone level (mesial and distal) and the prominence of the first thread of the implant was measured. Attachment levels crestal to the first thread were designated as positive values, and attachment levels apical to the first thread were designated as negative values.
- Pink Esthetic Score (PES) according to Fuerhauser et al.[27] This score consists of seven distinct items (configuration of the mesial/distal papilla, the vertical level of the gingiva, contour and symmetry of the soft tissue margin, and the texture and color of the soft tissue), each of which is given a score between 0 and 2 on a rating scale (Fig 1, Table 1).

All clinical esthetic evaluations were performed by one investigator (TM) who was not involved in the primary treatment of the patients and was blinded to the radiologic data and the initial esthetic status of the patients.

Statistical analysis

Survival probabilities were estimated by the Kaplan-Meier method. The endpoint of interest was implant failure according to the criteria established by Smith and Zarb.[26] Subpopulations within the study group (single-tooth versus multiple-tooth replacements) were compared using the nonparametric *U* test according to Wilcoxon, Mann, and Whitney. Analysis of the relationship between marginal bone levels and the PES used the Spearman rank-based correlations. The reported *P* values were two sided. To provide a graphic description of the results, scatter plots were created. All calculations were carried out using SPSS for Windows, Version 12 (SPSS Inc).

Results

Except for one dropout at 3 months, all patients complied with the scheduled treatment protocol and attended all follow-up appointments. Although the facial bony lamella had dehisced or was completely absent in six patients, all implants achieved sufficient primary stability (minimum final torque resistance of 35 Ncm) for immediate placement of a provisional restoration.

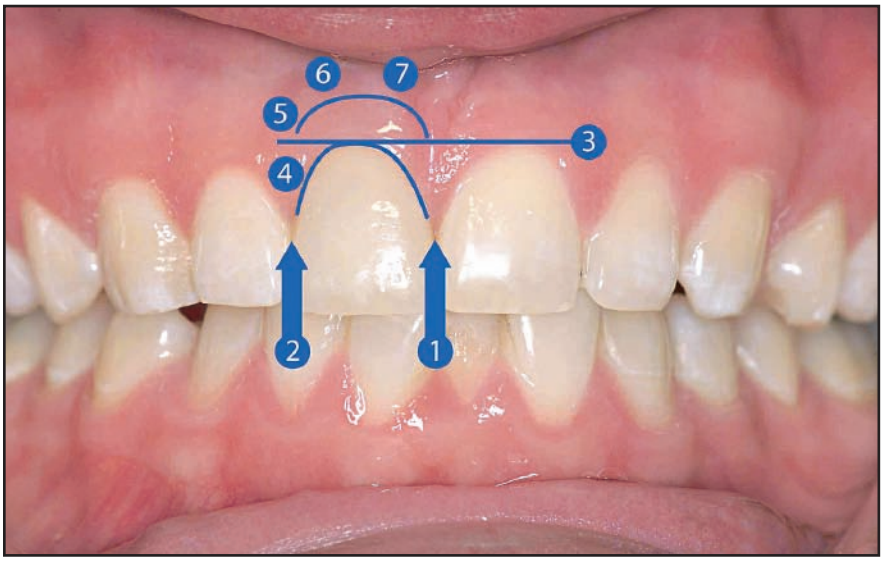

Fig 1 *Variables of the Pink Esthetic Score according to Fuerhauser et al.[27] The criteria were assessed per implant. (See Table 1 for explanation of numbers.)*

Table 1 Clinical variables of the Pink Esthetic Score according to Fuerhauser et al[27]

			Definition of scores		
No.	Variable	Description	0	1	2
1	Mesial papilla	Shape versus reference tooth	Absent	Incomplete	Complete
2	Distal papilla	Shape versus reference tooth	Absent	Incomplete	Complete
3	Level of soft tissue margin	Level versus reference tooth	Major discrepancy (> 2 mm)	Minor discrepancy (1–2 mm)	No discrepancy or < 1 mm
4	Soft tissue contour	Naturalness, matching reference tooth	Unnatural	Fairly natural	Natural
5	Alveolar process contour	Alveolar process deficiency	Obvious	Slight	None
6	Soft tissue color	Color versus reference tooth	Obvious difference	Moderate difference	No difference
7	Soft tissue texture	Texture versus reference tooth	Obvious difference	Moderate difference	No difference

Figures 2 and 3 illustrate the treatment concept in single-tooth replacements of maxillary and mandibular incisors. The cases represent the most favorable (Fig 2) and least favorable (Fig 3) results of single-tooth replacement situations, as defined by the marginal bone level and PES outcome variables. A multiple-tooth replacement procedure is illustrated in Fig 4.

Implant survival

During the follow-up period (1.4 to 26.6 months; median 12.9 months) one implant failed. The implant loss occurred in a nonsplinted single-tooth replacement case (lateral incisor) at 1.4 months after implant placement. There was no apparent cause for the implant failure, as the patient did not belong to the "high risk" subpopulation lacking the facial bone lamella. However, a noticeable tongue habit might have contributed to early loss of the implant. On the day of implant removal, a wider NobelPerfect implant was placed in a two-stage procedure. Thereafter, the secondary implant remained stable within a follow-up period of 25 months.

Survival estimates according to Kaplan-Meier were calculated for all implants and in addition on a per-patient basis using the esthetically most critical implant (nearest to the midline). Cumulative success rates according to the criteria specified by Smith and Zarb[26] were 96.8% for all implants and 95% when evaluating only the most critical implant per patient.

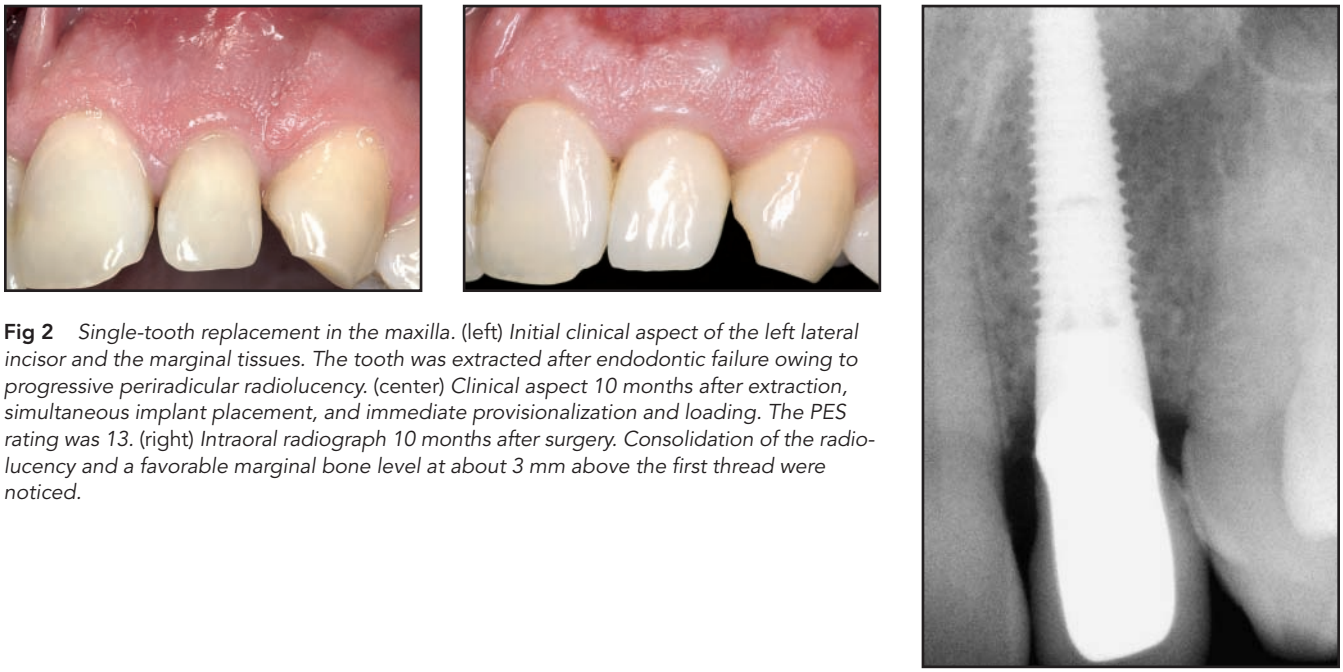

Fig 2 *Single-tooth replacement in the maxilla.* (left) *Initial clinical aspect of the left lateral incisor and the marginal tissues. The tooth was extracted after endodontic failure owing to progressive periradicular radiolucency.* (center) *Clinical aspect 10 months after extraction, simultaneous implant placement, and immediate provisionalization and loading. The PES rating was 13.* (right) *Intraoral radiograph 10 months after surgery. Consolidation of the radiolucency and a favorable marginal bone level at about 3 mm above the first thread were noticed.*

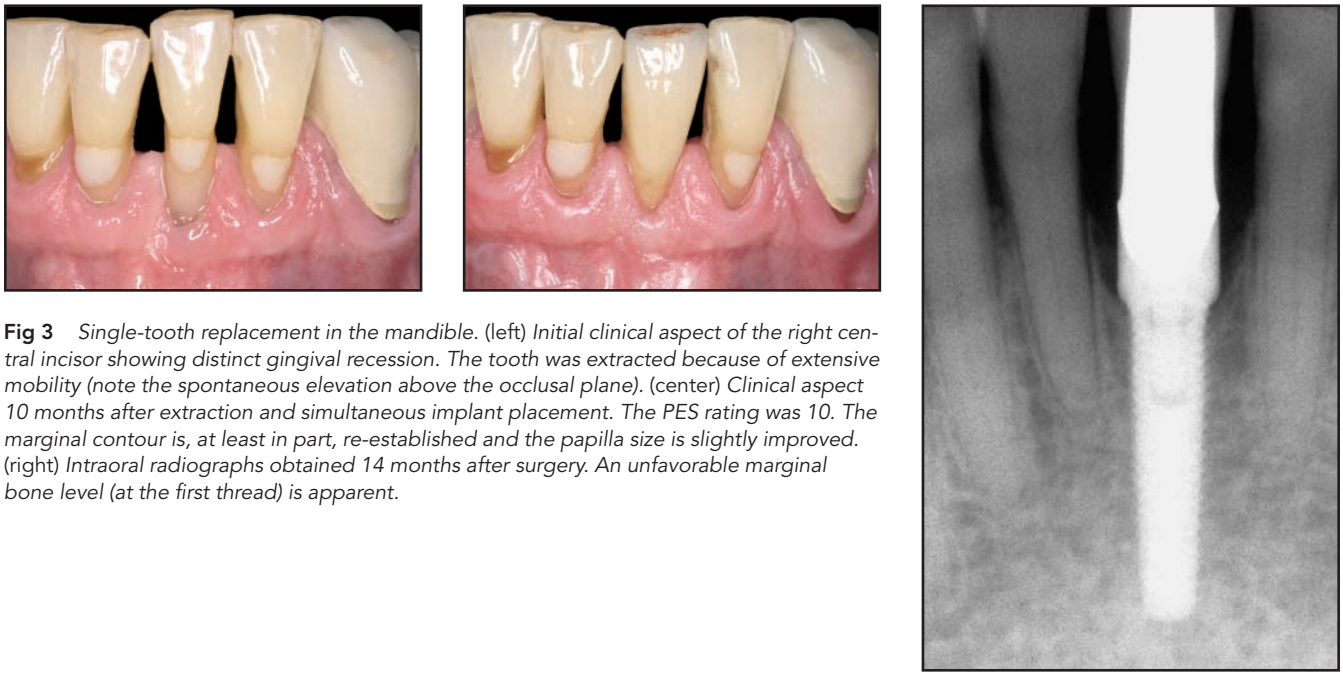

Fig 3 *Single-tooth replacement in the mandible.* (left) *Initial clinical aspect of the right central incisor showing distinct gingival recession. The tooth was extracted because of extensive mobility (note the spontaneous elevation above the occlusal plane).* (center) *Clinical aspect 10 months after extraction and simultaneous implant placement. The PES rating was 10. The marginal contour is, at least in part, re-established and the papilla size is slightly improved.* (right) *Intraoral radiographs obtained 14 months after surgery. An unfavorable marginal bone level (at the first thread) is apparent.*

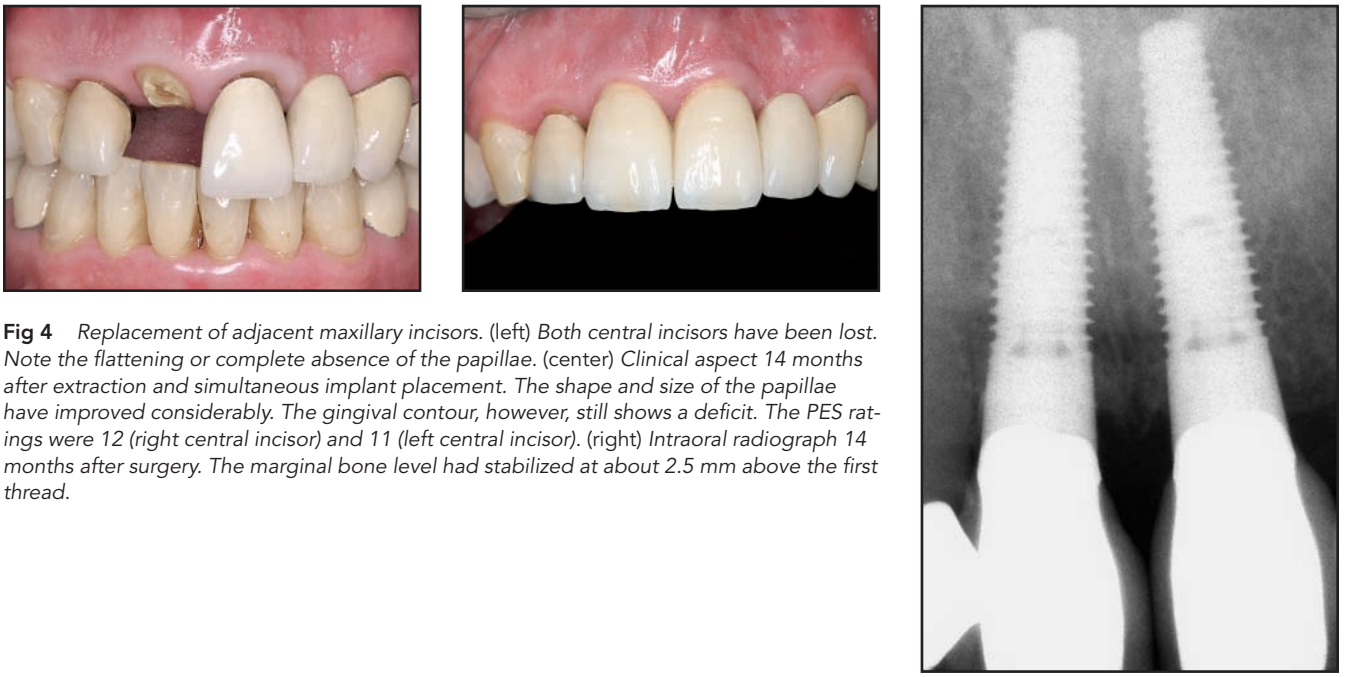

Fig 4 *Replacement of adjacent maxillary incisors.* (left) *Both central incisors have been lost. Note the flattening or complete absence of the papillae.* (center) *Clinical aspect 14 months after extraction and simultaneous implant placement. The shape and size of the papillae have improved considerably. The gingival contour, however, still shows a deficit. The PES ratings were 12 (right central incisor) and 11 (left central incisor).* (right) *Intraoral radiograph 14 months after surgery. The marginal bone level had stabilized at about 2.5 mm above the first thread.*

Marginal bone levels

Referring to the contour of the first thread, the average marginal bone level was 1.74 mm (range, 0.0 to 4.3 mm) at the mesial aspect and 1.68 mm (range, 0.0 to 4.1 mm) at the distal aspect of the implants. A slightly higher marginal bone level was noticed for implants replacing a single tooth (1.9 mm) than for multiple-tooth replacements (1.6 mm), but this difference did not reach statistical significance (P = .229; U test). However, the most favorable clinical outcome was noticed in a single-tooth replacement case, while the least favorable outcome occurred in a multiple-tooth replacement situation. When the marginal bone level was considered as a function of time, there was only a minimal inverse correlation between the marginal bone status and the length of the follow-up period, and this was far from statistically significant (r = –0.178, P = .347; Spearman rank correlation coefficient). Thus, by and large, bone levels remained stable during the observation period.

Pink Esthetic Score

In the study population the PES ranged from 8 to 14 (average, 11.3). Overall esthetic results were slightly better (P = .043; U test) in single-tooth replacements (mean PES, 12.2) than in multiple-tooth replacement cases (mean PES, 10.7). Moreover, when the height of the papillae was regarded as a single item, the difference between single-tooth and multiple-tooth replacements was highly significant (P = .003; U test). Substantially better esthetic outcomes (P = .00001; U test) were achieved in patients who had suffered trauma or endodontic failures (mean PES, 12.1) than in patients with progressive periodontal disease (mean PES, 9.1).

When looking at potential structural determinants of the PES, the interproximal marginal bone level showed a significant association with the esthetic result (r = 0.531, P = .0026; Spearman rank correlation coefficient) that was apparent in a scatter plot (Fig 5). In 18 patients, preoperative and postoperative scores were available. Improvement of the PES was noticed in five patients. In six patients, the esthetic status was unchanged, and seven patients sustained slight to moderate decreases on the esthetic rating scale (Fig 6).

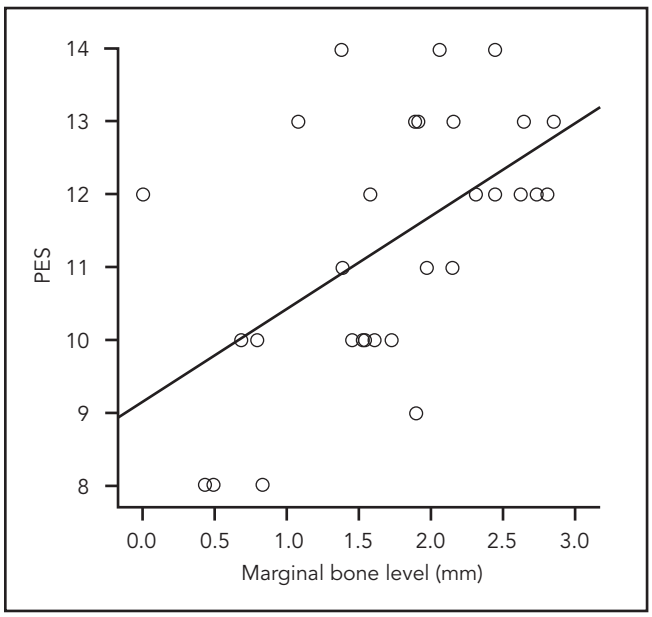

Fig 5 *Scatter plot of PES ratings of the marginal bone levels. The data suggest that, in the present cohort, the marginal bone level was a major determinant of the esthetic outcome.*

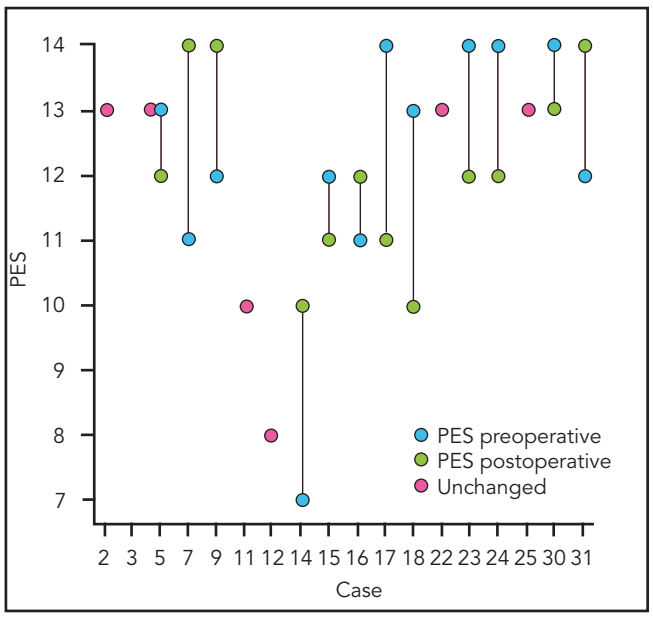

Fig 6 *Preoperative* (blue) *and postoperative* (green) *PES ratings. A nearly equal proportion of patients experienced an improvement, a slight decrease, and no change* (pink) *in esthetic status.*

Discussion

This study analyzed clinical performance of the NobelPerfect implant in highly demanding esthetic locations requiring immediate prosthetic restorations. The specific outcome parameters of this investigation were the clinical success rate, the interproximal marginal bone level, and the esthetic result as assessed by the PES according to Fuerhauser et al.[27] The results suggest a high clinical success rate and reasonable esthetic outcome, even following immediate provisionalization and loading. Although a substantial proportion (n = 6) of the patients treated in this series had extended defects of the facial alveolar bone lamella, the success rate is in line with the outcome reported for delayed-loading concepts[28] or for immediate loading in favorable bone conditions.[11,13,15,16,29–31] Because only one implant was lost, the authors were not able to identify predictive parameters of success/failure on a statistical basis. However, it is suspected that, in the failed case, parafunctional activity of the tongue and lack of stress protection via splinting caused the failure. Both conditions have been discussed separately as potentially harmful for immediately loaded implants.[12,32]

One key issue of this study was the interproximal marginal bone level, as the height of the interproximal bone has been reported to be highly predictive of the respective soft tissue contour.[33] It has been well documented that, because of biomechanical reasons, initial bone resorption and remodeling consistently result in a marginal bone level at or close to the first implant thread.[1,4,5,28,34] This provided the authors with a rationale to use the first thread of the implants as a reference point for the assessment of bone levels. In the 30 successful NobelPerfect implants, an average interproximal bone level of 1.7 mm above the first thread was verified. Only six patients showed a bone level that was less than 1 mm above the reference point, and no patients in this series showed bone loss below the first thread. At least during the observation period of up to 27 months, these data suggest proof of principle for the preservation of the interproximal bony lamella via a scalloped implant design. As seen in Fig 4c, this holds true even for the interproximal bone septa between adjacent implants.

In keeping with the favorable bony support, the overall esthetic results were quite reasonable. According to the evaluation criteria of the PES, replacement of multiple teeth and especially periodontal disease could be regarded as crucial indicators for an unfavorable outcome. Although Rocci and Gottlow[17] reported that papilla fill was not strictly related to the marginal bone support, the present results support a close association between preservation of interproximal bone and the esthetic outcome.

In spite of promising results with respect to bone preservation and reconstruction of the marginal soft tissue contour obtained in the present study, implant-supported tooth replacement in the esthetic zone remains a critical issue. Although, on average, comparable ratings for the PES were obtained at preoperative and postoperative evaluations, the data presented in Fig 6 indicate that a relevant proportion of the patients experienced some esthetic compromise compared to the preoperative situation. However, if the specified protocol is applied, in two thirds of the patients, preservation or improvement of the esthetic status was achieved.

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