Immediate Nonfunctional Loading of NobelPerfect Implants in the Anterior Dental Arch in Private Practice – 5-Year Data

Robert Noelken, Dr Med Dent;* Martin Kunkel, ProfDr MedDr Med Dent;†
Britta A Jung, Priv Doz Dr Med Dent;‡ Wilfried Wagner, Prof Dr Med Dr Med Dent§

ABSTRACT

Background: The concept of scalloped implants to maintain the natural contour of the alveolar ridge has been a source of controversy for many years.

Purpose: This study examined the long-term clinical performance of the scalloped NobelPerfect implant in a one-stage procedure (immediate loading in the esthetic zone).

Materials and Methods: In 20 patients, immediate prosthetic restorations were placed on 31 NobelPerfect implants in a private practice and followed for up to 78 months. 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. All implants were provisionalized on the day of implant placement and adjusted to clear all contacts in centric occlusion and during eccentric movements. Outcome variables were success rates, marginal bone levels, and pink esthetic score (PES) assessed per implant.

Results: One implant failed after 1.4 months. Five patients with six implants in total were scored in the 5-year follow-up as dropouts. Mean follow-up period of remaining 24 implants was 65 months (range, 55–78 months). Cumulative success rates according to the criteria specified by Smith and Zarb were 96.8%. Marginal bone levels averaged 1.1 mm above the first thread. Mean PES ratings were 10.5 (range, 3–13).

Conclusions: 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 in long-term data.

KEY WORDS: flapless implant placement, immediate implant placement, immediate implant provisionalization, long-term results, scalloped implant

INTRODUCTION

The concept of scalloped implants to maintain the natural contour of the alveolar ridge has been a source of controversy for many years. Only a short period of time after the introduction of the NobelPerfect implant,[1] inconsistent data were reported ranging from impressive bone preservation and overwhelming esthetic results[2–9] to severe interproximal bone loss and subsequent collapse of the alveolar soft tissues.[10]

The reasons for these striking differences have never been fully elucidated, rendering scalloped implants to appear somewhat of a matter of belief in implantology. On principle, the scalloped shape of the implant table corresponds to the natural topography of the healthy marginal bone contour, suggesting better support of the interproximal papillae. However, it remained an open issue whether this theoretical advantage could be translated into long-term biological stability of the peri-implant bone and tissue.

Thus, early in 2003, we set out to systematically explore the clinical performance of the NobelPerfect implant and initiated a retrospective study, which

*Private practice for Oral Surgery, Lindau/Lake Constance, Germany and research fellow, Department of Oral and Maxillofacial Surgery, University of Mainz, Germany; †professor and head of clinic, Department of Oral and Maxillofacial Surgery, University Hospital of Bochum, Germany; ‡consultant, Department of Orthodontics, University Hospital of Mainz, Germany; §professor and head of clinic, Department of Oral and Maxillofacial Surgery, University Hospital of Mainz, Germany

Reprint requests: Dr. Robert Noelken, Private Practice for Oral Surgery, Paradiesplatz 7-13, D-88131 Lindau/Lake Constance, Germany; e-mail: rnoelken@me.com

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included patients requiring implants in the esthetic zone immediately loaded via provisional crowns and bridgework. Initial (1 year)[8] and midterm (3 years)[11] results of this cohort have been reported so far. Meanwhile, the first set of patients, whose initial results have been published in 2007, have been followed for another 4 years, allowing for a reevaluation of functional and esthetic results 5 to 7 years after treatment.

Thus, it was the aim of this communication to present long-term results of the NobelPerfect implant in order to either challenge or support the principle of a scalloped implant table to maintain the natural marginal contour. Specifically, we report success rates and the clinical, radiographic, and esthetic outcome of this cohort within a follow-up period of up to 78 months.

MATERIALS AND METHODS

Patients

The demographic parameters of the cohort have been described in a previous report.[8] Briefly, 20 patients (10 male, 10 female; 5 smokers, 15 nonsmokers) were enrolled in this study. Inclusion criteria were as follows: tooth loss in the esthetic zone, good primary implant stability expected, and immediate provisional prosthetic restoration requested. Exclusion criteria were as follows: previous radiation therapy, uncontrolled diabetes, systemic bone disease, or permanent immunosuppressive medication.

These patients received 31 NobelPerfect implants with a 1.5-mm machined scalloped collar. Between October 2003 and June 2005, 24 implants were placed in the anterior maxilla, and seven implants were placed in the mandibular incisor region. 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 (two guided bone regeneration, three 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. Fourteen patients received single-tooth implants with natural neighboring teeth, and six patients received two to four implants for a multiunit reconstruction.

The reasons for removal of the teeth are given in Table 1.

The study type is a solely retrospective analysis of data obtained in a cohort of patients treated with a Conformité Européenne-certified implant in a private practice. As the product is already approved in accordance with the German Medical Devices Act, additional ethics approval was not required for treatment. Informed consent was obtained from the patient prior to any examination, which was carried out for study purposes.

Surgical Technique and Immediate Restoration

The surgical protocol has been described in detail.[8] The cornerstones of the procedure are as follows:

- Preservation of all alveolar socket walls via longitudinal extraction after periotomy avoiding orovestibular luxation;
- Meticulous cleaning of the extraction site under microscope magnification (ProDent, Zeiss, Germany);
- Placement of rather long implants that allow for a high level of primary stability;
- If required, simultaneous reconstruction of the facial bony lamella via autologous bone chips harvested at the mandibular ramus, completely bridging the incongruence between the alveolar socket and the implant;
- Immediate restoration by provisional crown and bridgework either by individual chair side contouring and adjustment of acrylic resin denture teeth or by lab-fabricated restorations (in case of multiple teeth); all provisional restorations were inserted on the day of implant placement and adjusted to clear all contacts in centric occlusion and during eccentric movements. Thus, the concept of treatment has to be classified as nonfunctional loading;
- Final crowns inserted after 3 months (porcelain-fused-to-metal or Procera® Zirconia Technology, Nobel Biocare AB, Göteborg, Sweden).

Follow-Up and Definition of Outcome Variables

Patients were examined clinically and radiographically at the time of implant placement and at least 55.4

TABLE 1 Clinical Parameters and Results of Patients Included in This Study

Patient	Age	Gender	Reason for Tooth Loss	Implant Site	Time Point of Insertion	PES Preop	PES Final	MBL at Final Examination
T.B.	50	Female	Endodontic failure	7	Immediate	13	7	0.97
T.B.	52	Male	Periodontitis	22	Delayed	n/a	8	0.97
				23	Delayed	n/a	3	–0.39
				25	Delayed	n/a	7	0.27
				27	Delayed	n/a	9	0.50
F.B.	51	Male	Endodontic failure	8	Immediate	11	11	1.87
			Endodontic failure	9	Immediate	12	12	1.99
S.F.	31	Male	Trauma	7	Immediate	13	13	1.96
H.H.	62	Male	Periodontitis	24	Immediate	7	11	1.52
R.P.	53	Male	Endodontic failure	9	Secondary to ridge augmentation	n/a	12	1.89
C.R.	37	Female	Root fracture	7	Immediate	13	13	1.82
			Endodontic failure	8	Immediate	14	11	1.65
			Endodontic failure	9	Immediate	14	12	0.94
			Endodontic failure	10	Immediate	13	12	1.42
M.S.	69	Female	Root fracture	8	Immediate	n/a	12	1.59
J.S.	32	Male	Root fracture	8	Immediate	11	12	1.35
I.S.	41	Female	Root fracture	25	Immediate	14	12	0.27
I.S.	47	Female	Root fracture	7	Immediate	10	Failure	Failure
K.S.	38	Female	Trauma	6	Immediate	13	13	0.59
			Trauma	7	Immediate	13	12	1.30
H.S.	62	Female	Periodontitis	4	Delayed	n/a	7	1.43
			Periodontitis	7	Immediate	8	8	0.96
			Periodontitis	8	Immediate	10	9	1.80
E.H.	39	Female	Root fracture	8	Immediate	12	13	1.76
E.Z.	45	Female	Endodontic failure	25	Immediate	n/a	12	–1.73

MBL = marginal bone level; n/a = not applicable; PES = pink esthetic score.

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.[12] Traditionally, these criteria considered loss or loosening of an implant, progressive marginal bone resorption, and inflammatory status of the gingiva. In addition, a marginal bone level below the first thread was considered as failure in our study.
- *Marginal bone level.* The marginal bone level was determined using digital sequential periapical radiographs. To ensure reproducibility between the examinations, radiographs were taken with paralleling technique using commercially available film holders (Dentsply/Rinn, Elgin, IL, USA). Specifically, the vertical distance between the bone level (mesial and distal) and the prominence of the first thread of the implant was measured. The distance was recorded to the nearest 0.1 mm using ×7 magnification. 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. For details, see Figure 1, which illustrates the concept of measurements.
- *Pink esthetic score* (PES) according to Fuerhauser and colleagues.[13] This score evaluates the configuration of the mesial/distal papilla, the vertical level of the gingiva, the contour and symmetry of the soft tissue margin, and the texture and color of the soft tissue. Each item is classified on a rating scale of 0 to 2. The PES is calculated as the sum of seven distinct items.

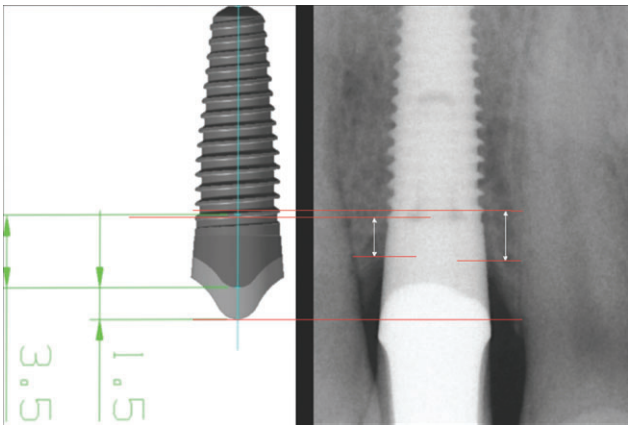

Figure 1 Measurement of marginal bone level in relation to the prominence of the first thread as reference line.

The final clinical esthetic evaluations were performed by one investigator (B.A.J.) who was not involved in the primary treatment of the patients and was blinded to the radiographic data and the initial esthetic status of the patients.

Statistical Analysis

Survival probabilities were estimated by the Kaplan-Meier method.[14] The end point of interest was implant failure according to the criteria defined above (modified according to Smith and Zarb[12]). Subpopulations within the study group (single-tooth vs multiple-tooth replacements) were compared using the nonparametric *U* test according to Wilcoxon, Mann, and Whitney.[15] For the analysis of the relationship between marginal bone levels and the PES, the Spearman's rank-based correlations were used. 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 Mac, Version 18 (SPSS Inc., Chicago, IL, USA).

RESULTS

Five patients (with six implants) did not fully attend the follow-up. Two of these patients discontinued the study for relocation, and another three were dropouts (see Table 2 for details). The dropouts had a final mean PES rating of 12.3 (range: 12–13). Mean marginal bone level of dropouts was 2.42 mm (range: 2.15–2.65 mm) coronal to the first thread at final clinical examinations (mean: 12.1 months; range: 3.2–16.6 months). None of the dropout patients showed bone levels below the first thread at the final radiographic examination.

The remaining patients (see Table 1) complied with the treatment protocol and attended all follow-up visits until the 5-year follow-up (mean: 65.2 months; range: 55.4–77.6 months). All implants achieved sufficient primary stability (minimum final torque resistance of 35 Ncm) for immediate placement of a provisional restoration.

Figures 2 and 3 illustrate the treatment concept in single-tooth replacements of maxillary and mandibular incisors. The cases represent an unfavorable (see Figure 2) and a favorable (see Figure 3) pretreatment situation for single-tooth replacements, as defined by the marginal bone level and PES variables. A multiple-tooth replacement procedure is illustrated in Figure 4.

Implant Survival and Success

During the follow-up period, one implant failed after 1.4 months, which was replaced by an implant of a wider diameter using a delayed loading protocol. The early results after a follow-up period of 1 year (median: 12.9 months; range; 1.4–26.6 months) were published previously.[8] In the following years, the implants were evaluated at 6-month intervals. Five patients with six implants did not fully attend the follow-up as described previously.

The remaining 24 implants in 14 patients were evaluated 55.4 to 77.6 months (mean: 65.2 months) following implant installation.

Survival estimates according to Kaplan-Meier were calculated for all implants and in addition on a per

TABLE 2 Clinical Parameters and Reason for Incomplete Follow-Up of Five Patients with Six Implants

Patient	Age	Implant Site	PES Preop	PES Final	Reason
H.F.	34	5–6	n/a	6–8	Moved away after 10.5 months and did not leave the new address
K.F.	43	10	n/a	12	Did not attend follow-up appointment at 3.2 months
L.M.	45	7	n/a	12	Did not attend follow-up appointment at 16.6 months
M.T.	42	10	14	12	Moved away after 8 months and did not leave the new address
S.J.	29	11	12	13	Did not attend follow-up appointment at 16.5 months

n/a = not applicable; PES = pink esthetic score.

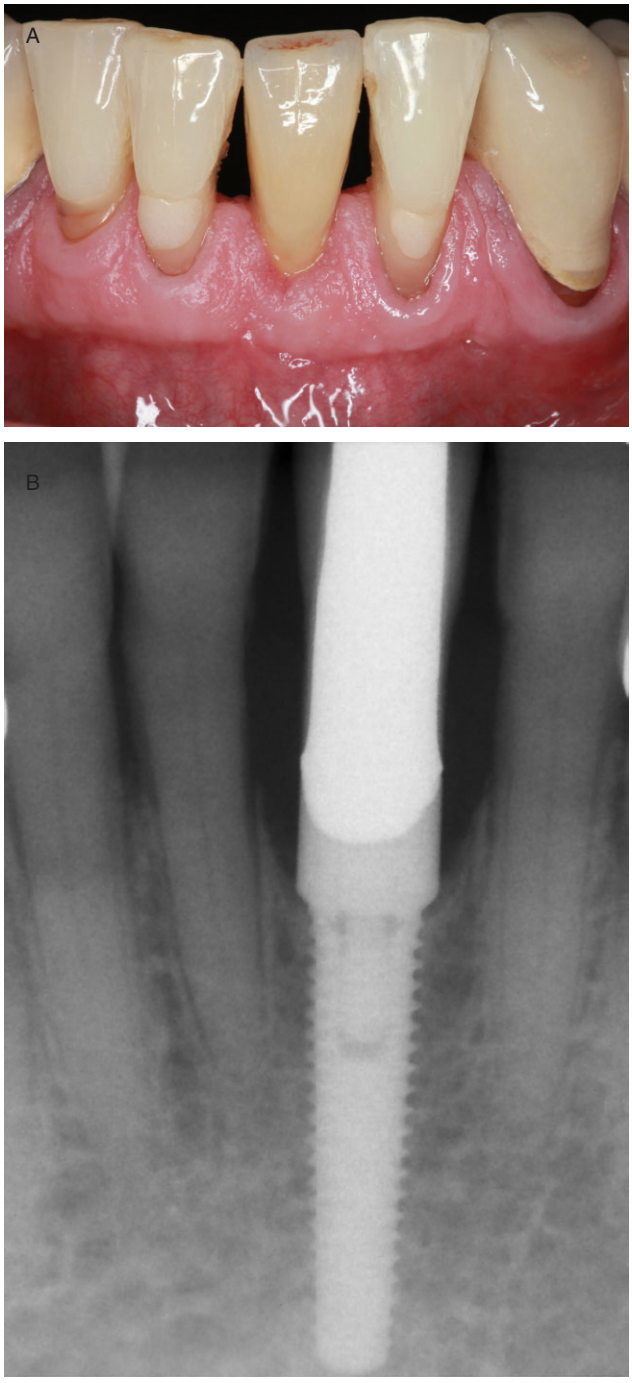

Figure 2 Single-tooth replacement in the mandible. (A) Clinical aspect 68 months after extraction and simultaneous implant placement. The PES rating is 11. The marginal contour is reestablished. Width and thickness of attached mucosa are improved. (B) Intraoral radiograph obtained 68 months after surgery. A marginal bone level slightly coronal to the first thread is apparent. (PES = pink esthetic score.)

patient basis using the esthetically most critical implant (nearest to the midline). Cumulative success rates according to the criteria specified by Smith and Zarb[12] were 96.8% for all implants and 95% when evaluating only the most critical implant per patient. Thus, the success rate of the implants remained stable when compared with our initial report.

Cumulative survival rate according to the modified criteria specified by Smith and Zarb[12] including a marginal bone level at or above the first thread was 86.5% for all implants (Figure 5). Thus, the vast majority of the implants did not only succeed in terms of implant survival but also maintained a largely stable marginal bone level.

Marginal Bone Levels

Referring to the contour of the first thread, the average marginal bone level of the remaining 24 implants averaged 1.1 mm (range, −1.7 to 2 mm; SD 0.9 mm), 1.1 mm at the mesial aspect and 1.2 mm at the distal aspect of the implants. Thus, compared with our initial report, we witnessed an average cumulative marginal bone loss of 0.6 mm within the next 4 years of follow-up (Table 3). No relevant difference of marginal bone level was noticed for implants replacing a single tooth (1.2 mm) and for multiple-tooth replacements (1.1 mm). However, the most unfavorable outcome occurred in a multiple-tooth replacement situation. When the marginal bone level was considered as a function of time, there was no strict correlation between the marginal bone status and the length of the follow-up period ($r = 0.089$, $p = .156$; Spearman's rank correlation coefficient), suggesting that bone levels remained, by and large, stable during the observation period (Figure 6).

PES

In the long-term study population, the PES ranged from 3 to 13 (average, 10.5). Overall esthetic results were slightly better in single-tooth replacements (mean PES, 11.6) than in multiple-tooth replacement cases (mean PES, 9.8), but the difference did not reach a statistical significance ($p = .117$; Mann-Whitney U test). The difference between single- and multiple-tooth replacements was more pronounced when the height of the papillae was regarded as a single item. For this specific esthetic feature, the difference between single- and multiple-tooth replacements was significant ($p = .036$; Mann-Whitney U test).

Like in the early follow-up, the most important determinant of the PES was the periodontal condition of the replaced teeth ($p = .00001$; U test). Again, the

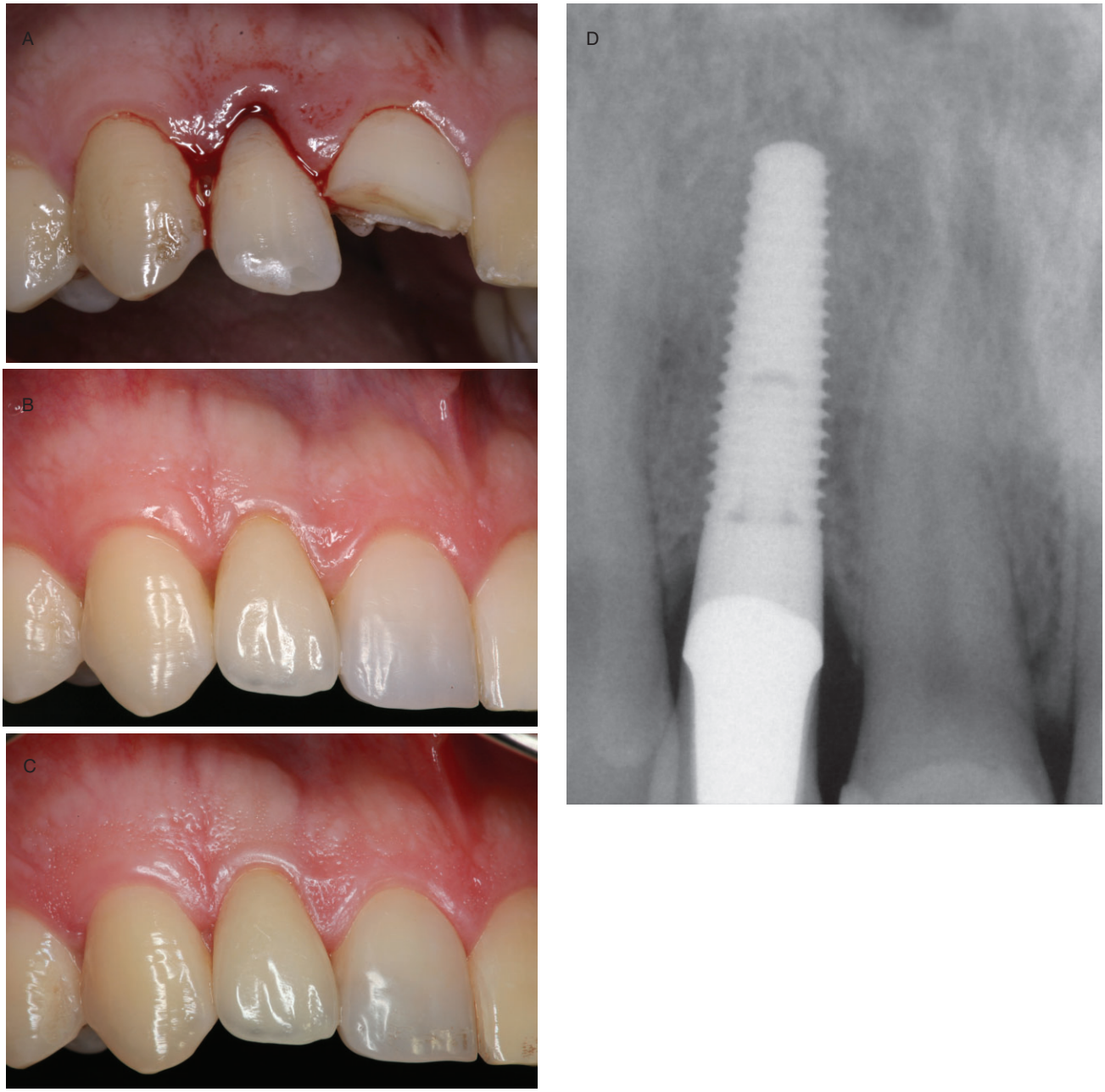

Figure 3 Single-tooth replacement in the maxilla. (A) Initial clinical aspect of the right lateral incisor and the marginal tissues after trauma of the incisors. The lateral incisor was fractured horizontally and was extracted. (B) Clinical aspect 24 months after extraction, simultaneous implant placement, and immediate provisionalization and loading. The PES rating was 12. (C) Clinical aspect 77 months after implant placement reveals improvement of the height of the marginal contour and the distal papilla. The PES rating is 13. (D) Intraoral radiograph 77 months after surgery. Consolidation of the radiolucency and a favorable marginal bone level at about 2 mm above the first thread are noticed. (PES = pink esthetic score.)

patients who initially suffered from progressive periodontal disease had markedly inferior esthetic outcome (mean PES, 7.7) compared with those patients who lost their teeth due to trauma or endodontic failures (mean PES, 11.8) (Figure 7).

Unlike in the early phase of the study, the interproximal marginal bone level showed no relevant association with the esthetic result ($r = 0.079$, $p = .183$; Spearman's rank correlation coefficient) as determined by the PES. That was visualized in a scatter plot (Figure 8).

In 16 patients, preoperative and postoperative scores were available. Improvement of the PES was noticed in three patients (18.75%). In six patients, the

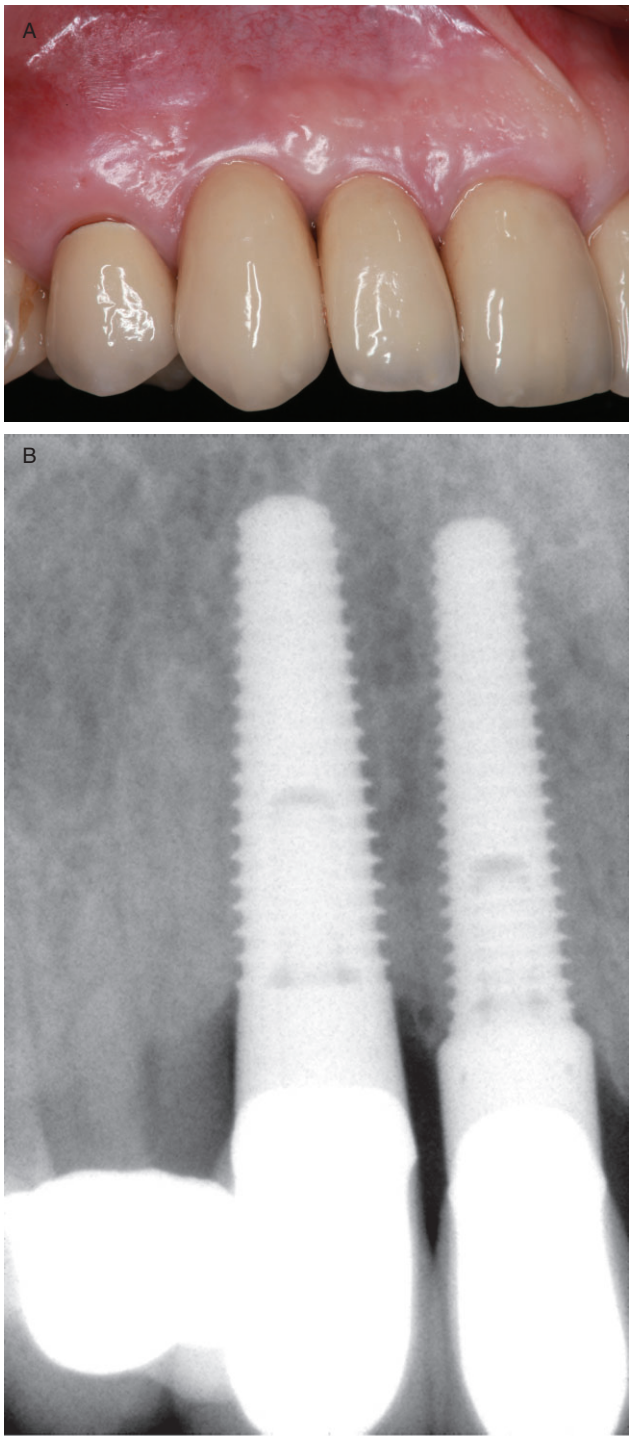

Figure 4 Replacement of adjacent teeth in the right maxilla. (A) Clinical aspect 78 months after immediate implant placement. Height of the mesial papilla of the lateral incisor decreased slightly. The interproximal papilla height is stable although the interimplant distance is just 1.5 mm. The PES ratings are 13 (right cuspid) and 12 (right lateral incisor). (B) Intraoral radiograph 78 months after surgery. The marginal bone levels have stabilized slightly coronal to the first thread. (PES = pink esthetic score.)

esthetic status was unchanged (37.5%), and seven patients sustained slight to moderate decreases on the esthetic rating scale (43.75%) (Figure 9).

DISCUSSION

This study scrutinizes the 5-year clinical performance of the NobelPerfect implant in highly demanding esthetic locations requiring immediate prosthetic restorations and allows for a comparative analysis of early (1 year following implant placement) and late results. We used the same outcome parameters in both investigations, namely, the clinical success rate, the interproximal marginal bone level, and the esthetic result as assessed by the PES according to Fuerhauser and colleagues.[13]

While overall implant survival remained stable within this period, we witnessed an average interproximal bone level decrease from 1.71 to 1.15 mm above the first thread, which corresponds to an annually decrease of 0.14 mm from year two to five. Compared with the measurements immediately following implant insertion (thus including the first year), the average bone loss even amounts to 1.6 mm within a mean follow-up of 65.2 months. In spite of this fundamentally alarming phenomenon, there was only a slight reduction in the PES score from the 1-year to the 5-year follow-up visit, specifically the mean PES decreased from 11.3 to 10.5 from the first to the fifth year, which appears largely negligible.

When going into further details of Figures 6 and 7, it becomes apparent that both figures display one specific case with a markedly unfavorable outcome. It is noteworthy that these are two different implants, which again underline that there was no strict correlation between marginal bone level and PES. However, these cases show similarities. Both implants were inserted for replacement of mandibular incisors and both patients had marked periodontal disease with even increased plaque scores over time.

Taken together, these data support that except for severe and continuous periodontal disease, the initial (first year) marginal bone resorption slowed down and continued on a low basal level.

Laurell and Lundgren[16] recently analyzed marginal bone level changes (MBLCs) at Astra Tech, Brånemark, and Straumann dental implants after 5 years of function. In their meta-analysis, they included implant types with at least two independent studies, reporting MBLC after 5 years of follow-up. The pooled mean MBLCs

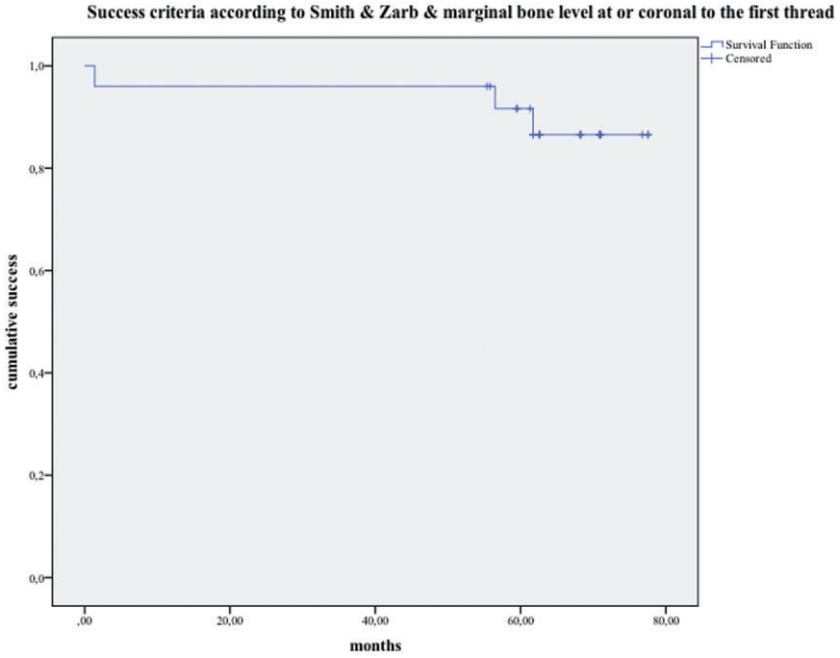

Figure 5 Cumulative success rate according to the modified criteria specified by Smith and Zarb[12] was 86.5% for all implants. In addition, a marginal bone level below the first thread was considered as failure in this estimation by Kaplan-Meier.

amounted to −0.24 mm (Astra Tech) (range, 0.12 to −0.48 mm), −0.48 mm (Straumann) (range, −0.15 to −1.0 mm), and −0.75 mm (Brånemark) (range, −0.11 to −1.8 mm) for the time of prosthetic loading to the 5-year follow-up.

Long-term results for immediate provisionalization of dental implants are rare. In a prospective 5-year follow-up study on 550 dental implants (Maestro, BioHorizons, Birmingham, AL, USA), Degidi and colleagues[17] compared immediate functional in edentulous and nonfunctional loading in partial-edentulous situations to traditional one- or two-stage surgical approach with a healing period of 6 months. The marginal bone loss in the immediate loaded implant group amounted 0.3 mm in the first year and further 0.6 mm in the following years, while the control group lost 0.3 mm in the first and further 0.5 mm up to the fifth year. No differences were found in survival and bone resorption rates for the immediately functionally loaded and the nonfunctionally loaded implants. Mijiritsky and colleagues[18] reported on 16 patients with 24 implants (XiVe, Frialit 2, Dentsply, Konstanz, Germany; Seven, MIS, Shlomi, Israel) in fresh extraction sites with immediate infraocclusal provisional restorations and nonfunctional immediate loading with a mean follow-up time of 40.7 months. The overall implant survival rate was 95.8% (one failure) with a mean marginal bone loss of 0.9 ± 1.1 mm at the conclusion of the study.

Thus, the results in our cohort are, by and large, in line with the data available for immediate implant placement and immediate provisionalization. Compared with staged surgical approaches, overall marginal bone resorption thus amounts to a moderately higher level. Though limited to a follow-up of approximately 5 years,

TABLE 3 Marginal Bone Level Changes in Relation to the Contour of the First Thread

	Implant Placement	First Publication	Current Follow-Up
Observation time		12.9 months (1.4–26.6 months)	65.2 months (55–78 months)
Mesial	2.75 mm (1.2–4.26 mm)	1.74 mm (0.0–4.3 mm)	1.08 mm (−2.07–2.34 mm)
Distal	2.67 mm (1.25–4.34 mm)	1.68 mm (0.0–4.1 mm)	1.21 mm (−1.74–1.99 mm)
Mean	2.71 mm	1.71 mm	1.15 mm

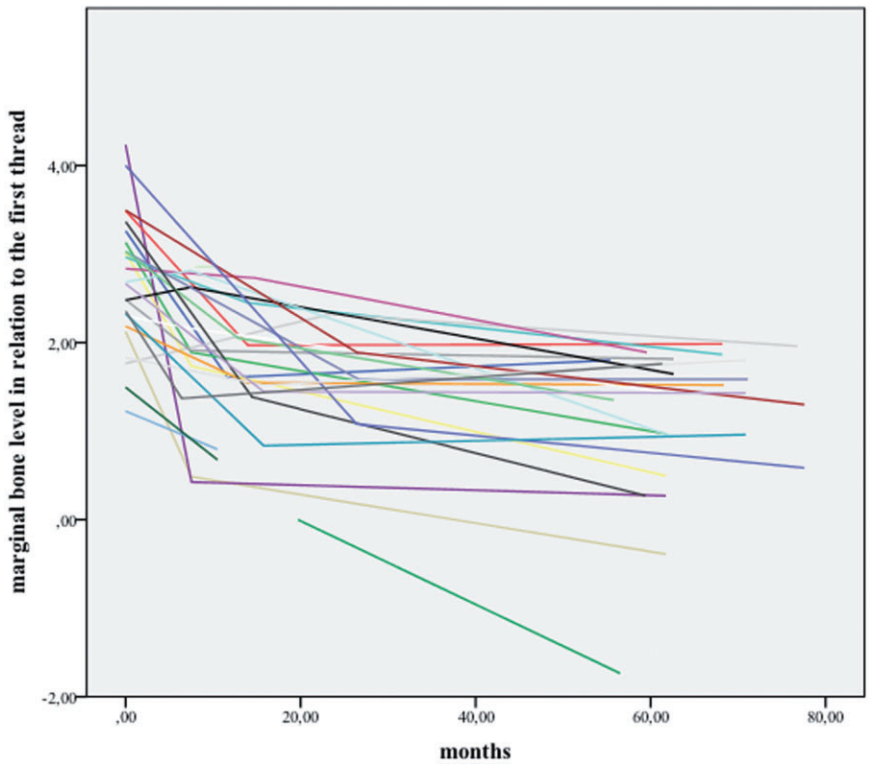

Figure 6 When the marginal bone level was considered as a function of time, the marginal bone levels remained, by and large, stable during the observation period.

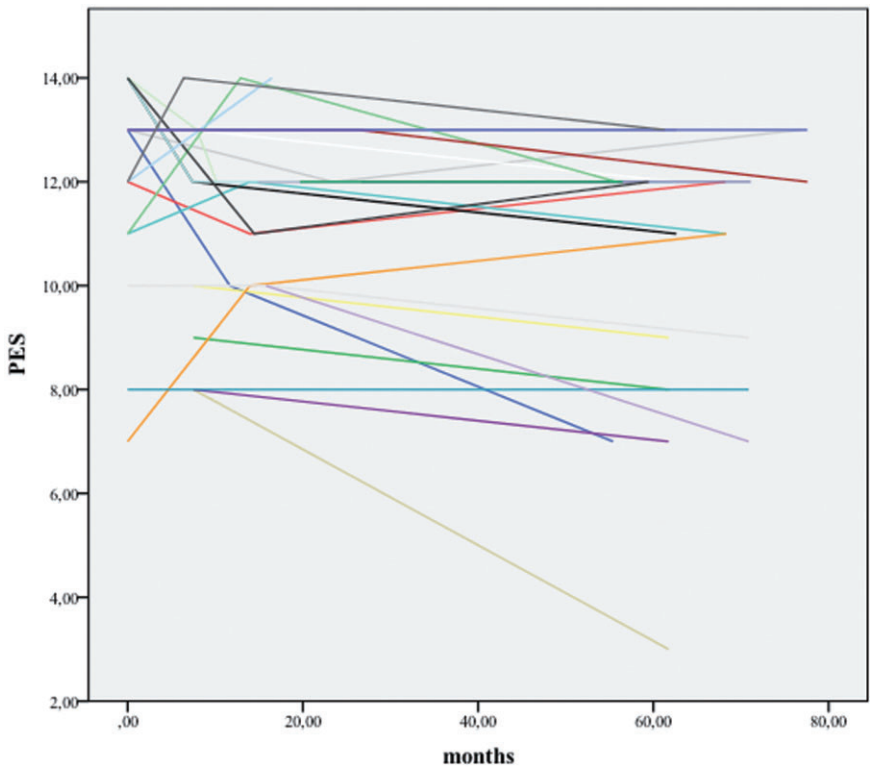

Figure 7 The patients who initially suffered from progressive periodontal disease had markedly inferior esthetic outcome compared with those patients who lost their teeth due to trauma or endodontic failures. (PES = pink esthetic score.)

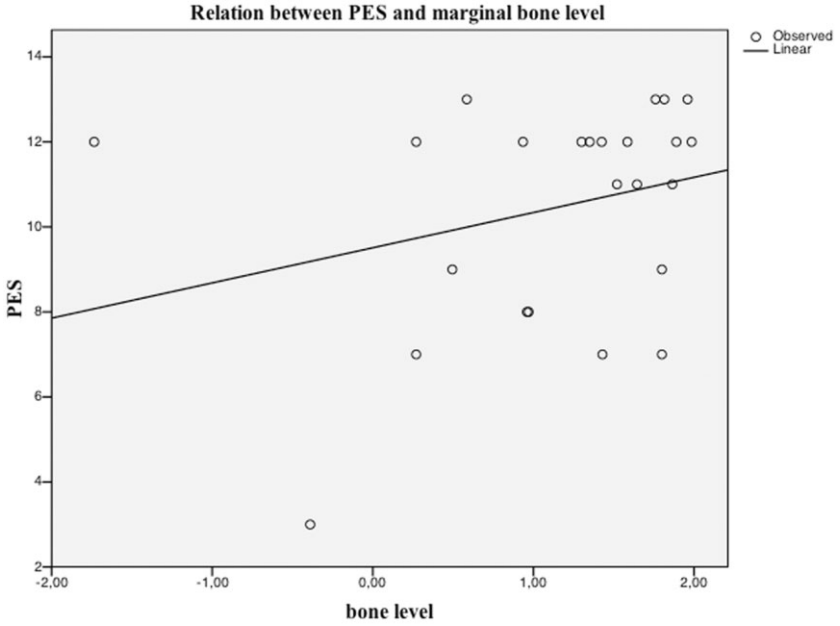

Figure 8 Scatter plot of PES ratings according to the marginal bone level. The data do not support the suggestion that the marginal bone level is a determinant of the esthetic outcome. (PES = pink esthetic score.)

our results are unique as, for the first time, individual longitudinal data are presented, which not only describe implant survival and marginal bone level but also include the time-related development of detailed esthetic parameters by a well-established scoring system. To the best of our knowledge, this type of longitudinal data representing the "evolution" of esthetic results in relation to the marginal bone situation has not been reported so far. Although numerous studies and case series[2–7,9] address the issue of marginal bone level and

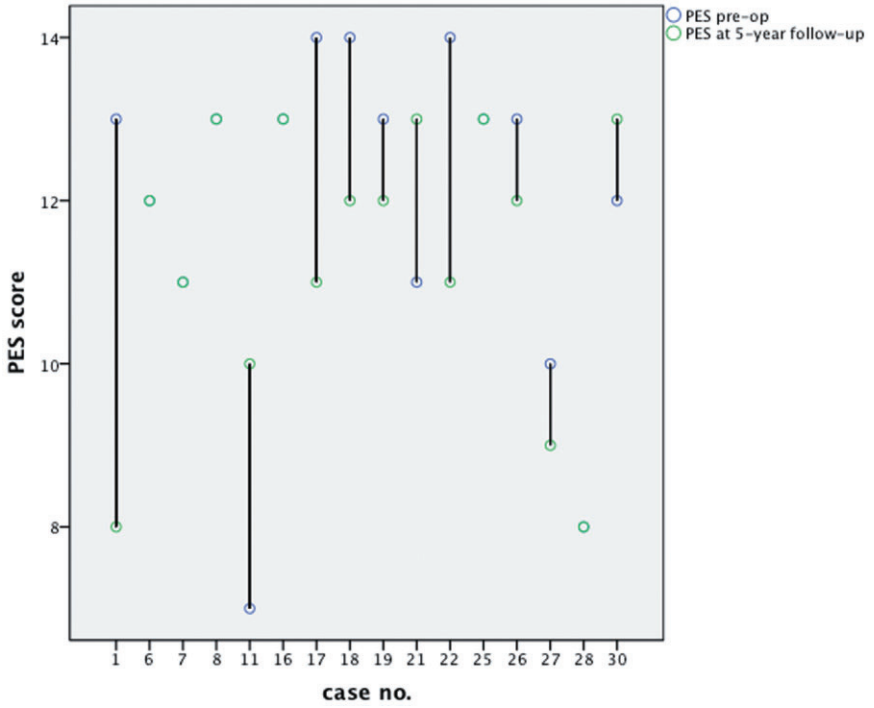

Figure 9 Preoperative (blue) and postoperative (green) PES ratings at 5-year follow-up. The data suggest that, in the present cohort, a nearly equal proportion of patients experienced an unchanged (green) or improved and decreased esthetic outcome. (PES = pink esthetic score.)

esthetics, they did not describe the profile of the individual esthetic development with time (see Figures 6 and 7).

Still, 5 years after implant insertion, more than 50% of patient's esthetic appearance improved or remained the same when compared with the preoperative ratings obtained by initial evaluation of the natural teeth. Therefore, our findings support the data of McAllister[7] and Kan and colleagues[9] who reported high success rates although the interproximal bone contour was not regularly preserved by scalloped designed implants.

By contrast, Nowzari and colleagues[10] reported combined interproximal bone and soft tissue loss in six patients treated with scalloped implants, with an average marginal bone loss of 4.0 mm at 18 months. However, regarding our genuine longitudinal data, we do not expect such a dramatic change in marginal soft and hard tissue architecture after 5 years of stability in these patients. Anyway, we will continue with a close follow-up of this cohort for another 5 years to further explore the potentially implant specific relation between marginal bone and soft tissue contour.

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