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ORIGINAL ARTICLE

Immediate provisionalization in the esthetic zone: 1-year interim results from a prospective single-cohort multicenter study evaluating 3.0-mm-diameter tapered implants

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Abstract

Objectives The aim of this interim analysis of a 5-year prospective multicenter study is to evaluate clinical and radiological performance of immediately provisionalized 3.0-mm-diameter tapered implants.

Materials and methods Patients needing implant rehabilitation of maxillary lateral incisors or mandibular lateral and central incisors were treated with 3.0-mm-diameter implants placed in extraction or healed sites and immediately provisionalized. Clinical and radiographic examinations were performed at implant insertion, 6 months thereafter, and are ongoing. Marginal bone levels and changes, complications, the papilla, plaque, and bleeding indices, and the pink esthetic score (PES) were evaluated at each follow-up visit.

Results Of 112 enrolled patients, 77 patients (91 implants) met the inclusion criteria. Seventy-one patients with 82 implants completed the 1-year follow-up. Three implants failed yielding a CSR of 96.7%. All failures occurred within the first 3 months after implant insertion. Marginal bone level changes from insertion to 6 months was − 0.57 ± 1.30 mm ($n = 75$) and from insertion to 12 months − 0.25 ± 1.38 mm ($n = 72$). Fifteen non-serious complications were recorded. Papilla index score and PES improved at the 1-year follow-up. Plaque formation and bleeding-on-probing showed no statistically significant differences between the 6-month and the 1-year visit.

Conclusions This 1-year analysis demonstrated high survival, stable bone levels, and healthy soft tissue with 3.0-mm-diameter implants.

Clinical implications Narrow diameter implants are a safe and predictable treatment option in patients with limited bone volume and/or limited interdental space and eligible for immediate loading protocols.

Keywords Narrow diameter implants · Immediate loading · Esthetic zone · Single tooth

Introduction

Missing a tooth in the esthetic area can have a strong negative impact on a person's quality of life related to both speech and appearance. For these reasons, patients want their implant-supported restorations in the esthetic zone to be both immediate and visually pleasing [1–3]. However, implant sites in this region might lack the bone quantity needed to stably place an

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implant. In addition, implant placement in the esthetic zone requires thorough esthetic considerations in order to provide a natural-looking emergence profile, healthy soft tissue, and support for an esthetically pleasing prosthesis [2, 4, 5].

Restoring lateral maxillary incisors and lateral and central mandibular incisors presents an additional challenge due to the limited space available for implant placement, frequently further complicated by apically converging roots of the adjacent teeth. Narrow-diameter tapered implants offer an important option for addressing these challenges [6, 7]. They can fit between adjacent natural tooth roots and prevent the crestal bone loss observed when implants are placed too close to the adjacent teeth [2]. Additionally, they are well-suited for an optimized emergence profile of the final restoration in these esthetic locations. Previous studies of narrow-diameter implants demonstrated survival rates similar to those of regular-diameter implants (reviewed in [8]), indicating that narrow implants can provide a functional solution to the challenges associated with implant-supported restorations in the esthetic zone.

Because an implant should be placed at least 1.5 mm from adjacent dentition, single-tooth implants in lateral maxillary incisor and lateral and central mandibular incisor positions may require a small diameter while still providing sufficient primary stability to successfully support a provisional crown [5]. However, few two-piece implants have a diameter of 3 mm or lower, and those that are 3.0 mm are rarely indicated for immediate provisionalization [8]. To date, there are only a few studies investigating two-piece implants with a true diameter of 3.0 mm for immediately provisionalized applications.

The purpose of this open, prospective, single-cohort, multicenter study is to evaluate the efficacy and safety of variable-thread tapered 3.0 mm implants placed in immediate function in private clinic and hospital-based settings with a focus on bone level changes and esthetic outcomes over a 5-year follow-up period. Patients included had to meet strict criteria for immediate loading, such as being a non-smoker with good oral health and sufficient bone quality and quantity. This 1-year interim report describes cumulative survival rate (CSR), bone level changes, adverse events, and soft tissue response data.

Materials and methods

Study design and setting

This open, prospective, single-cohort, multicenter study enrolled patients in need of immediately provisionalized single-tooth restorations in maxillary lateral incisor or mandibular central or lateral incisor sites. The study originally included 11 study sites in Austria, Canada, Germany, Italy, Sweden, and the USA. All implants were placed between March 10, 2011, and March 18, 2015. The study was conducted in accordance with ISO 14155:2011 and the Declaration of Helsinki (2004 revision) and is registered at ClinicalTrials.gov as NCT02184845. Ethics Committee approval was obtained for each center participating in the trial. This interim analysis includes data collected until March 18, 2016. This observational study is reported according to the STROBE guidelines for cohort studies (http://www.strobe-statement.org).

Study participants

Inclusion criteria were as follows. Patients (1) provided informed consent; (2) were ≥ 18 years of age and ceased growth; (3) needed one or more single-tooth implant-supported restorations in the maxillary lateral incisor or mandibular central or lateral incisor site; (4) had natural tooth roots on both sides adjacent to the implant site; (5) were physically and mentally capable of completing the study through the 5-year follow-up period; (6) had sufficient bone volume at the implant site to place a 3.0-mm tapered implant that was ≥ 10 mm in length; (7) met the criteria for immediate provisionalization within 24 h, i.e., having a final implant insertion torque ≥ 35 Ncm; (8) had an implant site free of tooth remnants; (9) had an extraction socket with at least three intact walls in cases of immediately placed implants (a dehiscence defect up to 3 mm was permitted on the fourth wall); (10) had a properly and thoroughly debrided extraction socket in cases of immediately placed implants; (11) were healthy and compliant with good oral hygiene; and (12) had an overall favorable and stable occlusal relationship.

Patients were excluded if he or she (1) could not provide informed consent; (2) had health conditions that did not permit surgical treatment; (3) could have been negatively affected by treatment, e.g., having a history of psychiatric problems; (4) had a disorder in the planned implant area, such as previous tumors, chronic bone disease, or previous irradiation; (5) had teeth adjacent to the implant site with ongoing infections, endodontic problems, or periodontal problems; (6) had a record or history of alcohol or drug abuse; (7) was a heavy smoker (> 10 cigarettes/day); (8) had uncontrolled diabetes, i.e., a subject with diagnosed diabetes that has a history of neglecting doctor's recommendations regarding treatment or food and alcohol intake; (9) had any other disease or medication that could influence involved tissues, such as bisphosphonate or heparin treatment, osteogenesis imperfecta, or osteoporosis; (10) had a tight bite, severe bruxism or other destructive habits; or (11) had a final implant insertion torque < 35 Ncm or if the implant could not be immediately provisionalized, as judged by the clinician.

Implants were placed in both healed and extraction sites. Surgical procedures were performed in accordance with each clinic's standard protocol. Decisions about the surgery,

including medications, anesthetics, flap or flapless approach, and bone or soft tissue grafting, were made on a case-by-case basis at the clinician's discretion. All implants had a 3.0 mm diameter, a variable-thread tapered geometry (NobelActive, Nobel Biocare AB, Göteborg, Sweden), a moderately rough anodized surface (TiUnite, Nobel Biocare AB) and were placed according to the manufacturer's recommendations. Implants were placed with a final insertion torque of 35–45 Ncm; however, due to the imprecision of the measurement, 30 and 50 Ncm were considered acceptable. In cases where bone grafting was deemed necessary, clinicians used autogenous bone, anorganic bovine bone matrix (Bio-Oss, Geistlich, Wolhusen, Switzerland), or allograft particulate (Symbios, Dentsply, Waltham, USA). If soft tissue grafting was required, clinicians used autologous tissue, buccal and lingual flaps, or roll flaps. For immediate provisionalization, a range of abutments were used as appropriate at the clinician's discretion. Temporal crowns, of acrylic, ceramic, or other materials, were inserted with cement or screws. Temporal crowns were adjusted to have no occlusal contacts in both static and dynamic movements, resulting in a non-functional occlusion. All had proximal contacts, though no bonding or splinting to adjacent teeth or crowns. For definitive prostheses, abutment selection as well as time of placement was determined by the treating clinician. All final abutments were titanium, either straight or angled 15°. Crowns of acrylic, ceramic or metal-ceramic were screw- or cement-retained. Following surgery, no protective occlusal wafers were prescribed, though patients were advised to restrict biting/function in the area of treatment for approximately 8–10 weeks and/or maintain a soft diet for 6 weeks.

Following implant placement, patient inclusion was reviewed internally and with an external advisor to ensure participants met the study guidelines. If a patient did not meet the inclusion criteria, e.g., had poor oral hygiene, defined as having radiologically detectible calculus and plaque visible on clinical photographs, he/she was excluded from analyses.

Data collection and analysis

The purpose of this open, prospective, single-cohort, multicenter study is to evaluate the efficacy and safety of variable-thread tapered 3.0 mm implants placed in immediate function in private clinic and hospital-based settings with a focus on bone level changes and esthetic outcomes over a 5-year follow-up period. The primary outcome measure of this study was to evaluate immediately provisionalized 3.0-mm-diameter implants by assessing the peri-implant marginal bone level and bone level changes over time. The secondary outcome measures were to evaluate implant success rate, CSR, complications, including implant device-related adverse events and non-device-related adverse events, and soft tissue parameters, including the papilla index score, plaque accumulation, bleeding on probing, and pink esthetic score (PES).

The study was powered to detect a mean bone level change of 0.5 mm with an assumed standard deviation (SD) of 1.0 mm, which resulted in a sample size of 65 patients. After accounting for a 20% subject withdrawal and to ensure an equal number of patients were included per clinic, 84 subjects were enrolled in the study.

Marginal bone levels were evaluated using periapical radiographs. Radiographic examination was performed using a standardized long-cone parallel technique with a custom-made bite block. Only images including the implant platform and clearly visible threads were used for analysis. Bone height was measured using Adobe Illustrator by an independent radiologist (University of Gothenburg, Gothenburg, Sweden) as the distance between the most apical bone level to the implant-abutment junction. Distance was calibrated to the implant diameter, and measurements were accurate to 0.1 mm. Marginal bone levels are presented as averages, (mesial + distal)/2. Negative numbers indicate bone levels below the reference point, and positive numbers indicate bone levels above the reference point. Bone level change was calculated for each side of the implant (mesial and distal) separately, and the average was calculated for each implant site. The radiograph collected immediately following surgery was designated as the baseline. Negative numbers indicate bone loss.

A surviving implant was defined as an implant that remains in the jaw, is stable, and is functionally successful even if all individual success criteria are not fulfilled. Implant failure was defined as an implant that has been removed, fractured beyond repair, or cannot be classified as a successful or surviving implant. The success criteria used were a modified version of the success criteria suggested by van Steenberghe [9]. A successful implant was defined as one that does not cause allergic, toxic, or gross infectious reactions either locally or systemically; offers anchorage to a functional prosthesis; does not show any signs of fracture or bending; does not show any mobility when individually tested by tapping or rocking with a hand instrument; and does not show any signs of radiolucency on an intraoral radiograph using a paralleling technique perpendicular to the implant-bone interface.

Complications were monitored throughout the study period. The nature of all adverse events were recorded, including mechanical and prosthesis complications, categorized by whether the adverse event was implant device related, or non-device related.

Assessment of soft tissue contour adjacent to the implant was performed using the papilla index described by Jemt [10]. The papilla index was assessed at each visit. For each implant, the mesial and distal papilla was scored and the worse value of the two was recorded.

The plaque accumulation was assessed using the modified plaque index, and the bleeding tendency was assessed using a modified sulcus bleeding index, both described in Mombelli et al. [11]. The bleeding tendency of peri-implant mucosa was

assigned an ordinal variable based on the most severe bleeding for each implant. Plaque accumulation was analyzed in the same manner.

The pink esthetic score (PES) was calculated by an independent expert (Medical University in Vienna, Vienna, Austria) based on the parameters defined by Fürhauser et al. [12]. Seven variables were assessed, including the mesial papilla, distal papilla, soft tissue level, soft tissue contour, alveolar process deficiency, soft tissue color, and soft tissue texture. The mesial and distal papillae were evaluated for completeness, incompleteness, or absence. All other variables were assessed by comparison with a reference tooth, i.e., the corresponding tooth (anterior region) or a neighboring tooth (premolar region). The variables were ranked from 0 to 2 with 2 being the best. For the overall PES score, the individual scores are summed, meaning the highest possible score is 14. The overall PES score statistics were performed at the patient level.

Statistical evaluation

All data collected from the surgery and through the 1-year follow-up were used for statistical analysis. Missing data were not imputed nor included in the statistical evaluation. Wilcoxon sign rank tests, frequencies, and decrease/increase over time were used for statistical analysis of bone level changes and soft tissue remodeling. Implant success rate and CSR were evaluated using life-table analyses. The distribution of continuous variables (bone level, bone level changes, and PES) was presented as mean ± SD, and of ordinal variables (papilla, modified plaque, and sulcus bleeding indices as well as soft tissue level, a PES variable) as frequency and percentage. Aggregation of values to patient level was done using the worst outcome for ordinal (i.e., a patient was scored as a failure with the first failed implant for the CSR) and the mean for continuous variables (PES). Calculations were performed using the SAS System (version 9, SAS Institute, Cary, NC, USA) and SPSS software version 21.0 (SPSS Inc., Chicago, IL, USA).

Results

Patients and implants

Out of the 11 originally included study sites, one withdrew prior to patient inclusion. The initial enrolment included 112 patients (127 implants). Following the additional review, 35 patients (36 implants) were excluded from the study. Patients and one study site were excluded for lack of protocol adherence, lack of favorable and stable occlusal relationships, infections, endodontic problems, or periodontal problems in teeth adjacent to the implant site; severe bruxism or other destructive habits, or poor oral hygiene defined as radiologically detectible calculus and plaque visible on clinical photographs. After the review, 77 patients enrolled at nine centers were included in the study. Baseline characteristics of the included patients are provided in Table 1, and the numbers of individuals at each stage of the study are provided in Fig. 1.

In total, 91 implants were included in the study. Implant parameters are provided in Table 2, and, to illustrate the dimensions of the narrow diameter implants, a cross-sectional image is presented in Fig. 2. Most implants were placed in bone quality 3 (59%) and bone quantity A (46%) and B (45%), defined using the Lekholm and Zarb classification [13]. The final mean insertion torque was 38.9 ± 4.6 (n = 91). Definitive prostheses were placed in 69 patients (80 prostheses) at time points ranging from 1 day to 1 year after implant placement (average 6 months). Five patients with six implants had not received their definitive prostheses at 1 year after implant placement. Prostheses were cement-retained in 68 cases (85%) and screw-retained in 12 cases (15%), on straight (78%) or 15°-angled (22%) titanium abutments. Of the crowns placed, 10 (13%) were acrylic, 69 (86%) were ceramic, and 1 (1%) was metal-ceramic.

The 6-month follow-up visit (6.54 ± 1.27 months) was attended by 70 (out of 77) patients with 82 implants. The 1-year follow-up visit (12.93 ± 2.13 months) was attended by 71 (out of 77) patients with 82 implants.

Implant survival and success

Within the first 3 months of implant placement, three implants failed in three patients. One implant was removed due to pain and two were found mobile following surgery. Two patients, with two implants, were withdrawn due to trauma resulting in severe overload before osseointegration (within 1 month of surgery). Specifically, one implant in one patient became loose after the patient had accidentally bitten on a spoon, and one implant in another patient was mobile after the patient was under strong alcohol influence to the point of memory loss. Therefore, the implant-level CSR at 1 year was 96.7%. Because there were no adverse events that affected implant success the success rate was also 96.7% at 1 year. The patient-level CSR and success rate were both 96.1% at 1 year.

Bone levels and bone level changes

In three cases of implants placed in extraction sites, the X-rays collected at implant insertion showed bone levels of − 6 mm. These implants were excluded from analysis to prevent skewing of the data, which would result in a false positive bone gain. After implant placement, the mean marginal bone level was − 0.47 ± 1.11 mm (n = 85; 6 images were not readable). At 6 months, the mean marginal bone level decreased to − 1.02 ± 0.96 mm (n = 80; 1 image was not readable, 5 images

Table 1 Baseline patient characteristics

Patients, *n*	77
Male/female, *n*	28/49
Age, mean ± SD (years)	41 ± 19
Smokers, *n* (%)	9 (12)
Ongoing serious illness, *n* (%)	
Diabetes	2 (3)
Other	6 (8)
History of periodontitis, *n* (%)	7 (9)

Table 2 Implant parameters

Implants, *n*	91
Implant sites, *n* (%)	
Healed	67 (74)
Extraction	24 (26)
Chronic infection at implant site, *n* (%)	5 (5)
Implant location, *n* (%)	
Maxilla	59 (65)
Mandible	32 (35)
Implant length, *n* (%)	
10.0 mm	4 (4)
11.5 mm	16 (18)
13.0 mm	34 (37)
15.0 mm	37 (41)
Surgical approach, *n* (%)	
Flap with releasing incisions	56 (62)
Flap without releasing incisions	15 (16)
Flapless	20 (22)
Bone grafting, *n* (%)	
Prior to surgery	7 (8)
At implant placement	20 (22)
Soft tissue grafting, *n* (%)	15 (16)

were not taken during the visit or because the patient missed the appointment, 5 implants were lost), and at 12 months, it increased to −0.81 ± 0.82 mm ($n = 77$; 1 image was not readable, 8 images were not taken during the visit or because the patient missed the appointment, 5 implants were lost). From implant insertion to 6 months, the mean bone level change was − 0.57 ± 1.30 mm ($n = 75$), and from insertion to 1 year was − 0.25 ± 1.38 mm ($n = 72$). The mean bone gain between the 6-month and 1-year follow-ups was + 0.22 ± 1.00 mm ($n = 71$). The distribution of bone level change values is provided in Table 3.

Adverse events

No serious adverse events and 15 non-serious complications were recorded during 1-year follow-up. The seven non-device-related complications included postoperative pain and swelling with radiolucency around the apical part of the implant (two complications in one patient), fracture of temporary crown (two patients), trauma resulting in severe overload within 1 month of surgery before osseointegration (two patients), and crown replacement on request (one patient). The remaining eight adverse events were device-related and included two implant failures, three abutment screw fractures, two suprastructure complications, and one sulcular exudation. All adverse events were resolved by the end of the study period.

Soft tissue

Papilla regeneration was robust. At implant insertion, only 20% of papilla had optimal contour (index score 3) and 43% had most of the papilla present (index score 2). At 6 months, 48% of the papilla had a score of 3 and 37% had a score of 2, while at 1 year over half of the papilla (53%) had a score of 3 and 34% had a score of 2. The papilla improvement from

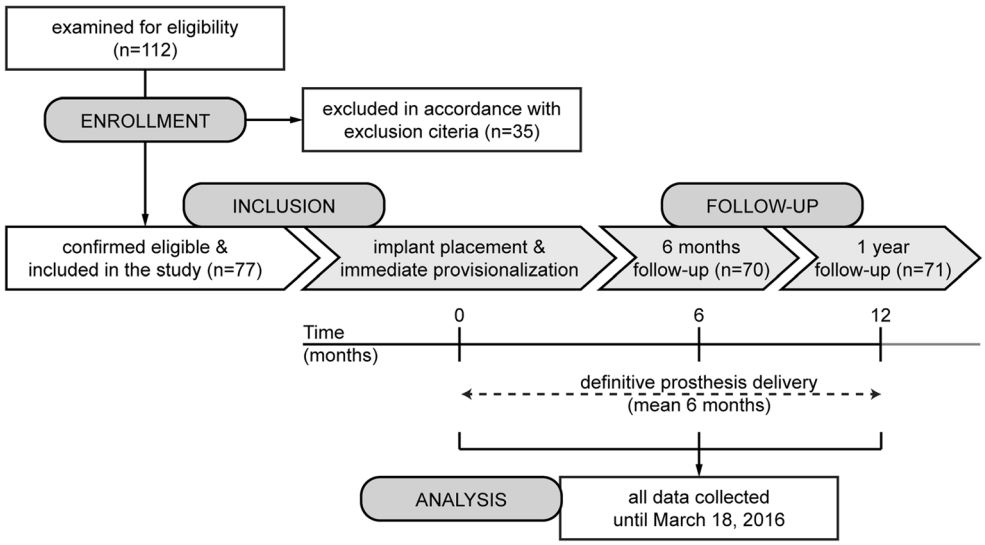

Fig. 1 Flowchart of included patients at each stage of the study, with protocol timeline. Included patients underwent implant placement (baseline/0 months) and immediate provisionalization within 24 h. Patients underwent follow-up visits at 6 months (6.54 ± 1.27 months) and 1 year (12.93 ± 2.13 months) after implant insertion, receiving definitive prostheses from 1 day to 1 year after baseline (mean 6 months)

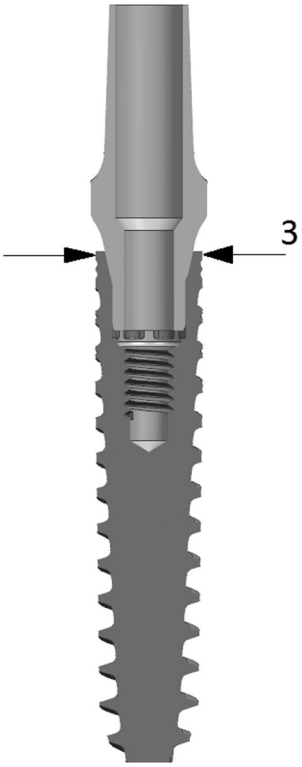

Fig. 2 Cross-sectional image of the narrow diameter tapered implant used in the study. The presented image shows the 3-mm-diameter implant at the most frequently used length in the study, 15 mm, with the most frequently used definitive abutment, an esthetic titanium abutment 1.5 mm

implant insertion to both 6-month and 1-year visit was statistically significant ($p = 0.0044$ and $p = 0.0026$, respectively). No plaque was observed at 66% of implants at 6 months and 74% of implants at 1 year. No bleeding on probing was observed at 76% of implants at 6 months and 83% at 1 year. The differences observed for plaque or bleeding on probing were not statistically significant.

Soft tissue level, a PES variable, continued to improve throughout the study period. At insertion, most sites (75%) showed a moderate discrepancy (1–2 mm) when compared with the reference tooth, while for 10% of sites the discrepancy was over 2 mm, and for 14% of sites, the discrepancy was low or absent (less than 1 mm). At permanent prosthesis placement, 7.4% of sites showed discrepancy over 2 mm, 45.7% had moderate discrepancy, and at 46.9% of sites the discrepancy was low or absent. One year after surgery, most of the sites (65.7%) showed little or no discrepancy, 28.8% showed moderate discrepancy, and only 5.5% of sites has a discrepancy of over 2 mm. The overall mean patient-level PES improved significantly over the study period, from 6.45 ± 2.9 ($n = 67$) at pretreatment to 8.45 ± 2.14 ($n = 66$) at definitive prosthesis placement, and 10.72 ± 2.6 ($n = 63$) at the 1-year follow-up. The improvements in PES between pretreatment and definitive prosthesis, definitive prosthesis and 1-year follow-up, and pretreatment and 1-year follow-up were all statistically significant (all $p < 0.0001$). The PES implant-level results listed by variable are provided in Table 4. A sample clinical case from the study is shown in Fig. 3.

Discussion

The purpose of this open, prospective, single cohort, multicenter study is to evaluate the efficacy and safety of variable thread tapered 3.0 mm implants placed in immediate function in private clinic and hospital-based settings with a focus on bone level changes and esthetic outcomes over a 5-year follow-up period. The primary outcome measure analysis, i.e.,

Table 3 Marginal bone level change on implant level

	Implant insertion to 6 months		Implant insertion to 1 year		6 months to 1 year	
Mean (mm)	− 0.57		− 0.25		0.22	
SD	1.30		1.38		1.00	
N	75		72		71	
p value	0.0003		0.0601		0.0225	
Bone level change (mm)	*n*	%	*n*	%	*n*	%
> 2.1	5	6.7	4	5.6	2	2.8
1.1–2.0	3	4.0	5	6.9	7	9.9
0.1–1.0	7	9.3	11	15.3	24	33.8
0	7	9.3	6	8.3	16	22.5
− 1.0 to − 0.1	24	32.0	22	30.6	17	23.9
− 2.0 to − 1.1	20	26.7	19	26.4	3	4.2
− 3.0 to − 2.1	7	9.3	5	6.9	1	1.4
− 4.0 to − 3.1	2	2.7	0	0.0	1	1.4
< − 4	0	0.0	0	0.0	0	0.0
Total	75	100.0	72	100.0	71	100.0

Table 4 Pink esthetic scores (PES) itemized by scoring variables

Time point	Pretreatment ($n = 78$)	Definitive prosthesis ($n = 77$)	1 year ($n = 74$)
Papilla mesial	0.5 ± 0.6	1.0 ± 0.6	1.3 ± 0.5
Papilla distal	0.7 ± 0.6	1.1 ± 0.6	1.5 ± 0.5
Soft tissue level	1.0 ± 0.8	1.4 ± 0.6	1.6 ± 0.6
Soft tissue contour	1.0 ± 0.5	1.0 ± 0.4	1.3 ± 0.6
Alveolar process	1.4 ± 0.6	1.6 ± 0.5	1.7 ± 0.5
Soft tissue color	1.1 ± 0.6	1.1 ± 0.5	1.5 ± 0.6
Soft tissue texture	1.1 ± 0.4	1.3 ± 0.4	1.6 ± 0.5
Overall PES	6.3 ± 0.4	8.5 ± 2.1	10.5 ± 2.5
Overall PES p value	Baseline	< 0.0001	< 0.0001

assessment of bone level and bone level change at 1 year since implant insertion, indicates that the study implant supports excellent hard tissue health similar to the results seen with the same implant of a diameter > 3 mm. [14, 15]

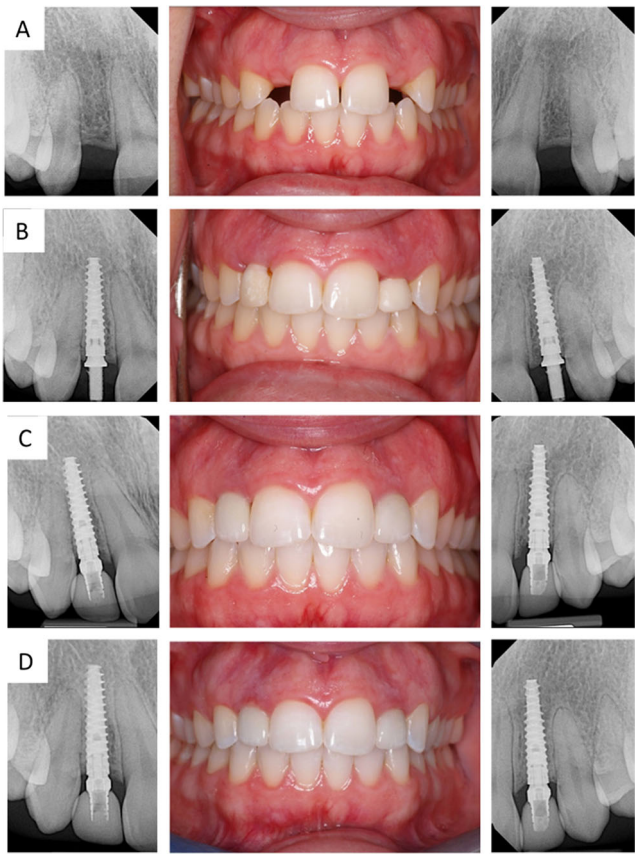

Fig. 3 A representative clinical case. Clinical view and periapical radiographs prior to surgery (**a**), at implant placement with immediately loaded provisional prosthesis (**b**), at 6 month follow-up (6.98 months) with definitive prosthesis (**c**), and 1 year after implant placement (**d**). A 25-year-old female with congenitally missing lateral incisors was treated with two 3.0-mm-diameter and 15-mm-long implants (insertion torque 40 Ncm). The implants were immediately restored with temporary titanium abutments and acrylic crowns. A definitive ceramic crown was cemented on an esthetic titanium abutment 1.5 mm after 6.98 months

One critical aspect of implant performance is osseointegration after implant placement. In the present study, the mean marginal bone level change at 1 year was − 0.25 ± 1.38 mm, which is consistent with the results reported in a retrospective analysis on the same implant, where the mean marginal bone level change was − 0.36 ± 0.85 mm after 1 year [6]. These values, combined with bone gain between the 6-month and the 1-year follow-up shown in the current study, indicate a healthy bone response around the 3.0-mm tapered implant when used for immediate provisionalization or loading applications. These results are similar to those seen with its larger diameter counterpart. In those studies, the bone level change ranged from − 0.10 to − 0.33 mm at the 1-year follow-up [14, 15].

How does the bone level change result in this study compare to the outcomes with other narrow-diameter implants? A systematic review of clinical studies with implants with a diameter of ≥ 3.0 and ≤ 3.5 mm identified nine studies that measured changes in peri-implant bone height 1 year after implant loading [16]. Out of these nine studies, two reported a minimal bone loss under 0.08 mm, while in the remaining seven studies, the bone loss was higher than in the present study and had a wide range of 0.3 to 1.6 mm. In addition, the mean marginal bone level change in this study was comparable to the − 0.41 mm observed at 1 year in a group treated with titanium-zirconium 3.3 mm implants within a randomized control trial [17].

The CSR and success rate in our study were both 96.7% at 1 year, which is comparable to the results of the other study using the same implant. In that retrospective multicenter case series, which included 42 patients treated with 58 implants using both immediate ($n = 23$) and delayed loading ($n = 35$), the CSR at the 1-year follow-up was 95.3% [6]. The CSR in the present study is also consistent with the rates reported by studies of the same implant but with larger diameters. In those studies, the follow-up was 4 months to 1 year, and the CSRs ranged from 92 to 100% [14, 15, 18, 19]. The CSR in the present study is also similar to those of other narrow-diameter implants. Klein et al. recently published a systematic

review of narrow-diameter implants that included eight papers evaluating two-piece 3.0-mm diameter implants ($n = 643$) over 1–5 years of follow-up. They reported CSRs ranging from 95.9 to 100% [8]. A review by Sohrabi et al. of narrow-diameter implants included seven studies reporting on 3.0-mm diameter implants ($n = 1467$) with follow-ups spanning from 1 to 3 years. The CSRs reported in that review ranged from 96.7 to 100% [20]. Sierra-Sánchez et al. also reviewed narrow-diameter implants. Their review included six studies on 3.0-mm diameter implants ($n = 394$ implants) with 1–4 years of follow-up. They reported CSRs ranging from 95.7 to 100% [16].

While patient factors such as smoking, hygiene, parafunction (e.g., bruxism), and overloading are important across different loading protocols, the authors consider these factors particularly crucial for immediate loading of narrow implants. Therefore, some initially enrolled patients were subsequently excluded from this study. Moreover, two patients withdrew as a result of trauma leading to severe implant overload, indicating that immediate loading protocols require high patient compliance. Thus, a careful patient selection combined with thorough patient education to ensure sufficient compliance appear key prerequisites for successful treatment outcomes with immediate loading.

While functional outcomes, such as bone level change and survival, are important components of implant success, good soft tissue outcomes are needed to produce an esthetically pleasing prosthesis, which is critical for achieving patient satisfaction. Soft tissue outcomes in the present study were excellent. At 1 year, 87% of the implant sites had papilla index scores of 2 or 3, little bleeding was observed, and the average PES score was 10.72 ± 2.6. Similar soft tissue outcomes were reported in the other study using the 3.0-mm tapered implant. In that study, 93.6% of implant sites had papilla index scores of 2 or 3 and no bleeding or plaque was observed at the 1-year follow-up [6]. Among the other studies using larger diameter tapered implants, papilla index scores increased over the course of the studies with the greatest improvement during the first year [19]. Plaque levels did not change significantly throughout the study period. Bleeding on probing showed no significant difference or increased following implant placement [14, 15]. These values, when compared with those of the 3.0-mm tapered implant, demonstrate that the soft tissue outcomes are equivalent or better than that of larger diameter implants.

With respect to other narrow-diameter implants, soft tissue outcome reporting is sporadic and its results are varied. In a 3-year RCT comparing immediate versus one-stage restoration of maxillary lateral incisors using a different 3.0-mm diameter implant, there were no significant differences in bleeding or plaque over the course of the study [21]. In a 1-year prospective single-arm study of early provisionalized 3.0-mm-diameter implants placed in the anterior region, bleeding increased slightly at 6 months but had returned to baseline levels by the 1-year follow-up [22]. Another 1-year prospective study investigated the outcomes of immediately provisionalized 3.0-mm-diameter implants replacing maxillary and mandibular incisors. In that study, papilla index scores increased significantly and plaque and bleeding were stable at the 1-year follow-up [23]. Based on the available data, the 3.0-mm tapered implant has similar soft tissue outcomes to other narrow-diameter implants.

In the present study, the 3.0-mm tapered implant was selected for several reasons. First, the implant had a high success rate in the authors' hands prior to beginning this investigation. Second, the high primary stability makes the implant amenable to immediate loading. Third, the two-piece system provides flexibility, in that the implant can be buried if the final torque at placement is not high enough to support immediate loading. Fourth, the implant taper allows the implant to be placed in cases when the adjacent teeth have converging roots at the apical end. Fifth, this specific implant has a true 3.0-mm diameter, i.e., its diameter measures 3.0 mm at its widest point, which is critical for sites with limited interdental space.

One concern with the use of narrow diameter implants is decreased fatigue resistance [24], arising from reducing the width of the implant. One-piece implants are an alternative in indications with limited space, given their increased fatigue resistance compared with two-piece implants [25]. However, studies have demonstrated that combining the implants used in this study with titanium abutments provides the two-piece system with sufficient fatigue resistance (Nobel Biocare data on file, TER 85632). Indeed, in this study, we observed no serious adverse events including implant or abutment fractures. Together with the reduced prosthetic versatility of one-piece implants and poor clinical outcomes compared with two-piece systems [26], one-piece implants, despite some strengths, are not a superior option for restorations in limited space indications.

There are a number of limitations to this study. First, this is a cohort study, which introduces the potential for bias based on the inclusion criteria and bias related to loss to follow-up. Second, this is a single-cohort study; thus, direct comparisons between groups could not be made. Overall, this study demonstrated that the 3.0-mm tapered implants had high survival, stable bone levels, and healthy soft tissue at 1 year, indicating an overall favorable tissue response. Taken together, these implants provide a safe and predictable treatment option for immediately provisionalized restorations in the esthetic zone when patients have limited bone volume or interdental space. Further studies and longer follow-up are needed to fully assess

long term outcomes of this implant for immediately provisionalized applications in the esthetic zone.

Conclusion

This 1-year follow-up analysis demonstrated that 3.0-mm-diameter implants are a safe and predictable treatment option for patients suitable for immediate loading and with limited bone volume and/or limited inter-dental space. High survival, stable bone levels, and healthy soft tissue at 1 year indicate a favorable tissue response at these implants.

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Compliance with ethical standards

Conflict of interest Drs. MK and WZ received grants from Nobel Biocare while the study was conducted. Dr. WZ received non-financial support from Straumann as well as financial support from Nobel Biocare and ZimmerBiomet unrelated to this study. Drs. PH, SL, BF, GB, DT, WW, MM, AP, JW, EB, CV, and PW have no conflicts of interest to declare.

Ethical approval All procedures were conducted in accordance with the ethical standards of the institutional and/or national research committees and with the 1964 Helsinki declaration and its later amendments.

Informed consent All patients provided written informed consent prior to inclusion in the study.

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