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ORIGINAL ARTICLE

A prospective multicenter evaluation of immediately functionalized tapered conical connection implants for single restorations in maxillary anterior and premolar sites: 3-year results

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Abstract

Objectives This multicenter prospective clinical trial investigated immediately provisionalized, anodized, conical connection, tapered implants with platform shifting in maxillary anterior and premolar sites.

Materials and methods Patients requiring single-tooth implant-supported restorations in maxillary anterior and premolar sites were enrolled. Implants were immediately provisionalized and evaluated at insertion, 6 months, and annually thereafter. Outcome measures were marginal bone level change (ΔMBL), cumulative survival rate (CSR), and success rate, soft-tissue parameters, and oral health impact profile (OHIP). ΔMBL and Pink Esthetic Score were analyzed using Wilcoxon signed-rank tests. CSR was calculated using life table analysis. Other soft-tissue parameters were analyzed using sign tests.

Results Of 94 enrolled patients (99 implants), 84 (88 implants) attended the 3-year follow-up. After an initial bone loss between implant insertion and 6 months (− 0.92 ± 1.23 mm), bone levels stabilized from 6 months to 3 years (0.13 ± 0.94 mm) with no significant change. The 3-year CSR was 98.9%, and the cumulative success rate was 96.9%. Papilla index scores of 2 or 3 were observed at 88.6% of sites at the 3-year visit compared with 32.8% at implant insertion. Improvements were observed for all other outcomes, including bleeding on probing, esthetics, plaque, and OHIP.

Conclusions This restorative protocol was associated with high primary stability, patient satisfaction, stable bone levels, and an overall improvement of the soft tissue outcomes over a 3-year period.

Clinical relevance The presented treatment is a viable option for single-tooth restorations of maxillary anterior teeth and premolars with successful short- to mid-long-term clinical outcomes.

Keywords Conical connection · Platform shifting · Anterior maxilla · Immediate function · Insertion torque · Single implant

Introduction

To achieve long-term success of implant-supported restorations, peri-implant bone and soft-tissue levels should remain stable or recede minimally over time [1, 2]. When placing an implant in the maxillary anterior and premolar region, there is an even greater need for successful esthetic outcomes to ensure patient satisfaction [3–6]. Many factors can affect the clinical and radiological performance of implant-supported restorations, including biomechanical properties, biological responses, and implant features [2, 7–9]. Biomechanical factors, such as force distribution and strain, can affect micromotion and impair osseointegration [9]. Due to the interplay between hard and soft tissue response, biological factors, such as biologic width establishment and bone levels

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surrounding the implant, can have a profound impact on implant success [10–12]. Several implant features have been shown to improve hard and soft tissue outcomes. One example is the use of conical implant-abutment connections, which are intended to provide increased mechanical stability and tighter connections [13–18]. Platform shifting has also been shown to reduce marginal bone level change (ΔMBL) and improved soft-tissue outcomes [2, 7–9, 11, 16, 18–22]. In a clinical setting, a surgeon needs to devise a treatment plan that can balance these factors to achieve optimum success for their patient.This ongoing, 5-year, multicenter, prospective trial is investigating the clinical and radiological outcomes of immediately provisionalized, anodized, tapered implants with an internal hexagonal interlocking conical connection and built-in platform shifting (NobelReplace Conical Connection, Nobel Biocare, Gothenburg, Sweden) placed in maxillary anterior and premolar sites. Previous studies using this implant have shown that it can support immediate provisionalization in various indications [23–25]. The primary objective of this study is to evaluate ΔMBL. Additional secondary outcome measures include implant success and survival, soft-tissue health, esthetics, and oral health impact.

Materials and methods

A detailed description of the trial parameters and measures have been published previously [15]. In brief, patients were included if they were 18 years of age or older, were in good health physically and mentally, could commit to the study for the 5-year study period, had a full-mouth bleeding on probing (BOP) index and plaque index score no higher than 25%, had a tooth that was lost or extracted at least 2 months before implant placement, and was indicated for the procedure. The implant site had to be healthy, with favorable and stable occlusal relationships and adjacent natural roots. Patients were excluded if they had acute untreated periodontitis, a health condition preventing surgery, disorders in the implant area, infected tissue adjacent to the implant site or received oromaxillofacial radiation therapy. Additional exclusion criteria included use of interfering medications, history of drug or alcohol abuse, heavy smoking, uncontrolled diabetes, severe bruxism or other parafunctional habits, and pregnancy or lactation. A patient was considered as presenting bruxism based on self-report of clinching/grinding during sleep/wakefulness and additionally supported by clinical examination of tooth damage or other indicators. Bruxism was classified according to the following criteria: mild as occurring less than nightly with no damage to teeth or psychosocial impairment, moderate as occurring nightly with mild impairment of psychosocial functioning, and severe as occurring nightly with damage to the teeth, temporomandibular disorders, and other physical injuries or severe psychosocial impairment.

Patients with severe bruxism, as determined by self-reporting and clinical evaluation, were excluded from the study. Patients self-reporting minor or inconsistent grinding or clinching without obvious wear or damage at the occlusion were considered non-severe bruxers. During the 3-year follow-up analysis of the patient records, patients that were registered as bruxers were considered for a re-evaluation.

Patients could be excluded at surgery if there was insufficient bone volume to place a 3.5-mm diameter, 8-mm length implant, if the site needed substantial bone augmentation, or if the insertion torque was not within the trial-specified range of approximately 35–45 Ncm.

All implants were placed in healed sites and immediately functionalized with a cement- or screw-retained provisional crown on a titanium abutment. The definitive cement- or screw-retained crown was loaded within 6 months after implant placement on either a titanium or zirconia abutment based on the esthetic requirements. Outcome measures included ΔMBL, implant survival (implant remains in function), implant success as defined by van Steenberghe [26], BOP, plaque accumulation, papilla index, Pink Esthetic Score (PES), and oral health impact measured with the OHIP-14 questionnaire.

This study is reported in accordance with the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) statement [27].

Results

In total, 101 patients were initially enrolled in the study. Of those patients, source data verification revealed that five were in violation of the inclusion/exclusion criteria and were therefore removed from analysis. One additional patient was excluded at the time of surgery due to complications during implant insertion. A seventh patient had an implant placed and provisionalized. Data from this patient was included in the 1-year interim report; however, the patient has since been removed from analysis due to violating an exclusion criterion (described in detail below).

In total, 94 eligible patients had 99 implants placed, with 5 patients receiving 2 implants each (Table 1). The study population was 57.4% female and 42.6% male. The mean age of participants was 41.1 ± 14.3 years (range 18 to 79 years). Among participants, 85.1% were non-smokers, and 14.9% smoked previously or throughout the trial. Based on medical records, most patients were in good health, with only 4.2% presenting with a previous illness and 3.2% having ongoing serious illnesses. Two patients (2.1%) were previously classified as bruxers (not severe) and four (4.2%) had a history of periodontitis.

All implants were placed in maxillary anterior or premolar regions. Flaps were lifted in most cases, with 72 implant

Table 1 Main patient and implant characteristics

		Number (%)
Patient characteristics		
Age (years)	Mean	41.1
	Range	18–79
Gender	Female	54 (57.4)
	Male	40 (42.6)
Smoking habit	Non-smokers	80 (85.1)
	Smokers	14 (14.9)
Implant characteristics		
Platform diameter (mm)	3.5	57 (57.6)
	4.3	42 (42.4)
Implant length	8	2 (2.0)
	10	17 (17.2)
	11.5	16 (16.2)
	13	53 (53.5)
	16	11 (11.1)
Position	Central incisor	9 (9.1)
	Lateral incisor	17 (17.2)
	Canine	7 (7.1)
	First premolar	33 (33.3)
	Second premolar	33 (33.3)
Bone quality	1	8 (8.1)
	2	45 (45.5)
	3	45 (45.5)
	4	1 (1.0)
Bone quantity	A	33 (33.3)
	B	61 (61.6)
	C	4 (4.0)
	D	1 (1.0)
Tissue augmentation	Bone graft prior to surgery	5 (5.1)
	Bone graft during surgery	16 (16.2)
	Soft-tissue graft	13 (13.1)
Insertion torque (Ncm)	30	2 (2.0)
	35	48 (48.5)
	38	1 (1.0)
	40	14 (14.1)
	45	31 (31.3)
	50	3 (3.0)

placements (72.7%) not using a releasing incision and 23 (23.2%) using a releasing incision. Four implants (4.0%) were inserted with a flapless procedure. Soft-tissue grafting was performed in 13 implant sites (13.1%). Sixteen implants (16.2%) required bone grafting: eight with autologous bone and eight with xenograft material. In addition, five implant sites (5.1%) had undergone bone grafting prior to this study procedure. Implants were primarily placed in healed sites (89 implants, 89.9%) or sites with at least 8 weeks of healing (10 implants, 10.1%). With respect to torque, the protocol specified an insertion torque of 35–45 Ncm; however, torques between 30 and 50 Ncm were considered acceptable. Overall, 94 implants (95.0%) were placed with an insertion torque between 35 and 45 Ncm, 2 (2.0%) were inserted with a torque of 30 Ncm, and 3 (3.0%) were place with torque of 50 Ncm.

Following implant insertion, temporary abutments were placed in 86 implants, and final abutments were placed in 13 implants. All implants were immediately provisionalized; 56 immediate restorations were cemented while 43 were screw-retained. In total, 96 implants placed in 91 patients received a definitive prosthesis. Three patients with three implants missed their prosthesis delivery visit or were withdrawn from the study prior to delivery. Among definitive abutments, 56 (58.3%) received monolithic zirconia abutments and 40 (41.7%) received titanium abutments. These numbers differ from those provided in the 1-year report [15] because patients' medical histories were re-evaluated and those abutments defined as "other" were classified into their appropriate groups. Among definitive crowns, 89 implants (92.7%) received ceramic, 4 (4.2%) received acrylic, and 3 (3.1%) received porcelain veneers. A representative clinical case is provided in Fig. 1. Among patients who received definitive prostheses, 89 patients (92 implants) completed the 6-month follow-up visit. The 1-, 2-, and 3-year follow-up visits were attended by 88 patients (91 implants), 81 patients (84 implants), and 84 patients (88 implants), respectively.

X-rays were collected at the time of implant placement (baseline), and the mean marginal bone level was -0.38 ± 0.73 mm ($n = 95$). At 6 months, the mean marginal bone level was -1.33 ± 1.06 mm ($n = 91$); at 1 year, it was -1.28 ± 1.13 mm ($n = 91$); at 2 years, it was -1.00 ± 0.73 mm ($n = 80$); and at 3-years, it was -1.14 ± 1.02 mm ($n = 84$). As expected, there was moderate but statistically significant bone loss between insertion and the 6-month follow-up, with a mean ΔMBL of -0.92 ± 1.23 mm ($n = 89$, $p < .0001$). However, the bone level stabilized between 6 months and 1 year and remained stable between 1 and 2 years and 2 and 3 years (Table 2; Fig. 2).

Regarding implant survival, one implant failed 20 months after implant insertion. The implant displayed mobility, and the patient complained of pain. X-rays showed peri-implant bone loss; thus, the implant was removed and the patient was not included in any further analysis. There was an additional implant failure that occurred 1.5 months after implant insertion. The failure was published in the 1-year interim report of this trial [15]. The medical history and source data from the patient confirmed a history of severe bruxism that was believed to be under control at the time of enrollment. However, the occlusion of the provisional prosthesis with the patient's nightguard appears to have detrimentally influenced implant stability, leading to failure of the implant shortly after insertion. It was concluded that the patient was still a severe bruxer at the time of inclusion, which is an exclusion

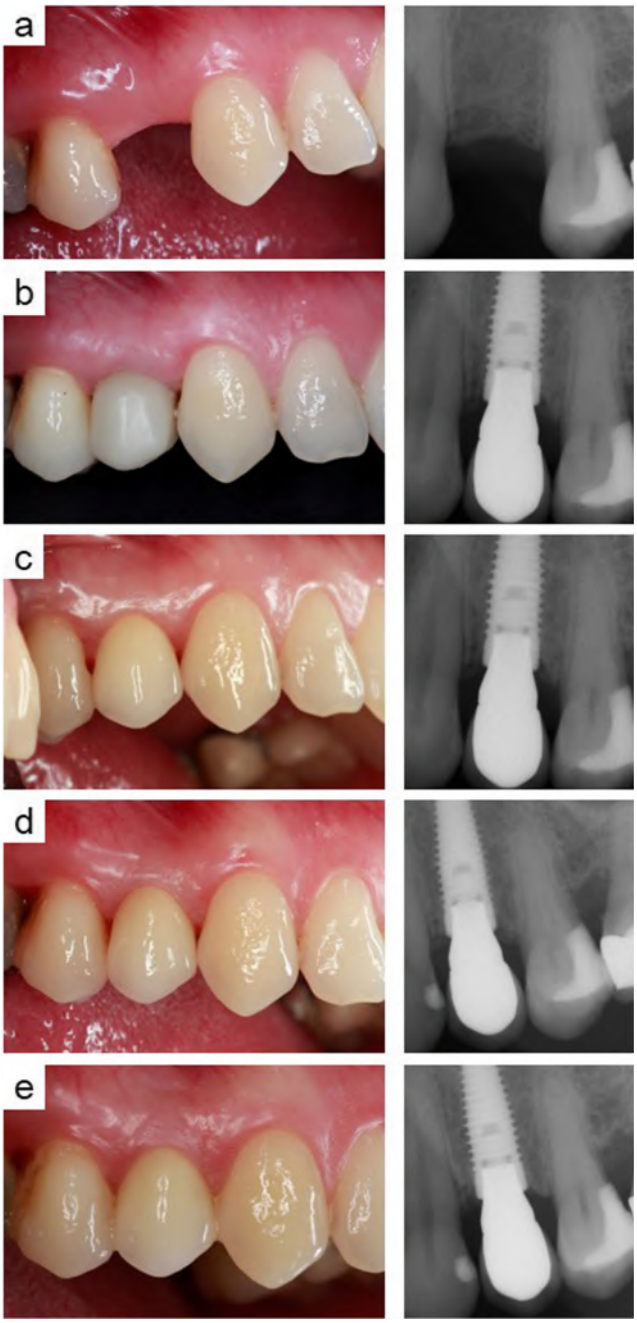

Fig. 1 Representative clinical case from a 41-year-old healthy female, treated in maxillary position 24 with an anodized tapered implant with conical connection. The implant was restored with a cemented monolithic zirconia abutment and NobelProcera crown. Clinical view and periapical radiograph prior to surgery (**a**), at 6-month follow-up (**b**), at 1-year follow-up (**c**), at 2-year follow-up (**d**), and at 3-year follow-up (**e**)

criterion of the study. Therefore, the patient was excluded from analysis. The resulting CSR at 3 years was 98.9%.

Two implants additionally showed signs of mobility in the early months after implant insertion. One patient presented with implant mobility of unknown etiology 6 months after placement. The crown was removed, and the implant was left in place to heal. A new crown was placed 6 months later. The implant was stable thereafter. The second patient presented with implant mobility 5 months after insertion. Definitive prosthesis placement was delayed to 8 months after implant insertion, and the implant was stable thereafter. Based on the van Steenberghe success criteria [26], the 1-, 2-, and 3-year cumulative success rates were 98.0% ($n = 93$), 96.9% ($n = 86$), and 96.9% ($n = 85$), respectively. No serious adverse events were reported during the 3-year study period. The only device-related adverse events reported were those of the survival and success failures described above.

Table 2 Marginal bone level change throughout the study period

	Implant insertion to 6 months	6 months to 1 year	1 year to 2 years	2 years to 3 years
Mean (mm)	− 0.92	0.05	0.22	− 0.08
SD (mm)	1.23	0.75	1.04	0.79
N	89	88	78	77
P value	< .0001	.14	.11	.48

Overall, the long-term soft-tissue response was favorable. At placement, 32.8% of implant sites had acceptable PI scores of 2 or 3. The scores improved then stabilized over time, with 87.5% of sites having acceptable PI scores at 6 months, 90.6% at 1 year, 92.8% at 2 years, and 88.6% at 3 years (all $p < .0001$ compared with placement and all $p > .25$ between follow-up visits). BOP also improved initially and stabilized thereafter, with no BOP observed at 88.0% of implant sites at 6 months, 84.6% at the 1-year visit, 94.1% at 2 years, and 80.7% at 3 years. There was a significant improvement between definitive prosthesis delivery and the 6-month, 1-year, and 3-year follow-up (all $p < .001$). PES scores followed a similar trend. The mean PES at definitive prosthesis placement was 8.48 ± 1.91. The score increased to 9.69 ± 2.04 at the 1-year follow-up, then stabilized to 10.04 ± 1.98 at the 2-year follow-up and 9.87 ± 2.19 at 3-year follow-up (all $p < .0001$ compared with definitive prosthesis placement; Fig. 3). No plaque was detected at 76.1%, 85.6%, 84.5%, and 65.9% of implant sites at the 6-month, 1-year, 2-year, and 3-year visits, respectively. There were significant differences between prosthesis delivery and all follow-up visits (all $p \leq .001$).

With respect to oral health impact, the median OHIP-14 score decreased from 11.45 ($n = 94$) at pretreatment to 3.94 ($n = 91$) at definitive prosthesis placement, 2.48 ($n = 89$) at 6 months, 1.62 ($n = 87$) at 1 year, 1.01 ($n = 81$) at 2 years, and 1.5 ($n = 84$) at 3 years. Analysis of OHIP-14 scores for only the patients who completed the survey for every time point ($n = 78$) shows a consistent decrease in median score over time (Fig. 4). Because lower OHIP scores indicate a lower frequency of perceived functional and psychological impacts, patient oral health-related quality of life (OHRQoL) improved significantly at the 6-month, 1-year, 2-year, and 3-year follow-up compared to implant insertion (all $p \leq .0005$).

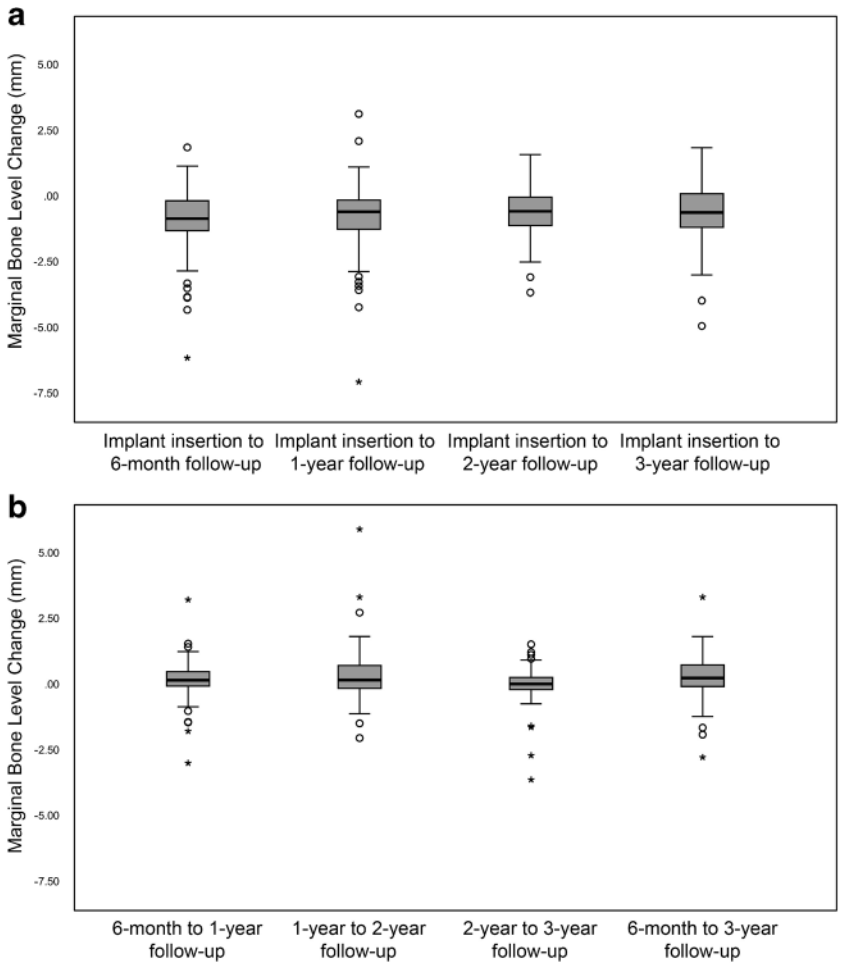

Fig. 2 Marginal bone level change between implant insertion and follow-up visits (**a**) and between follow-up visits after 6-months (**b**)

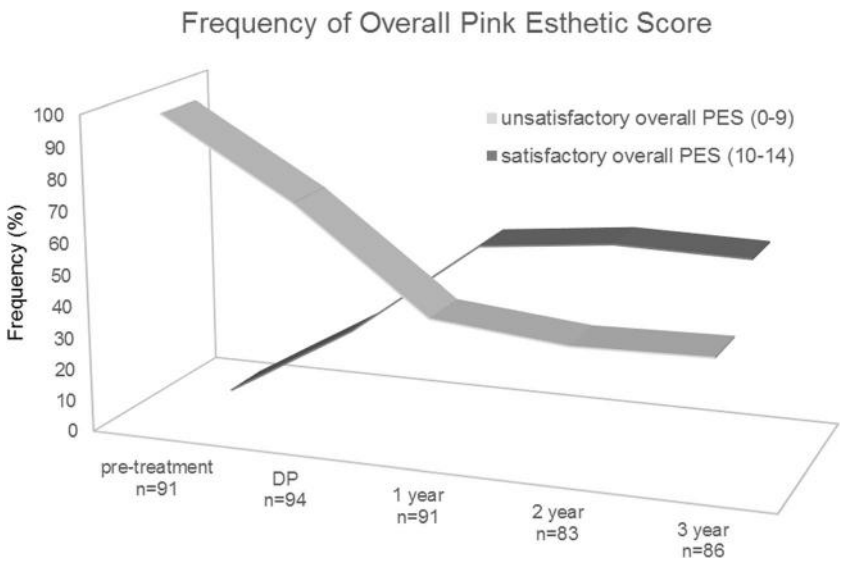

Fig. 3 Frequency of the overall satisfactory (10–14) and unsatisfactory (0–9) PES scores throughout the study

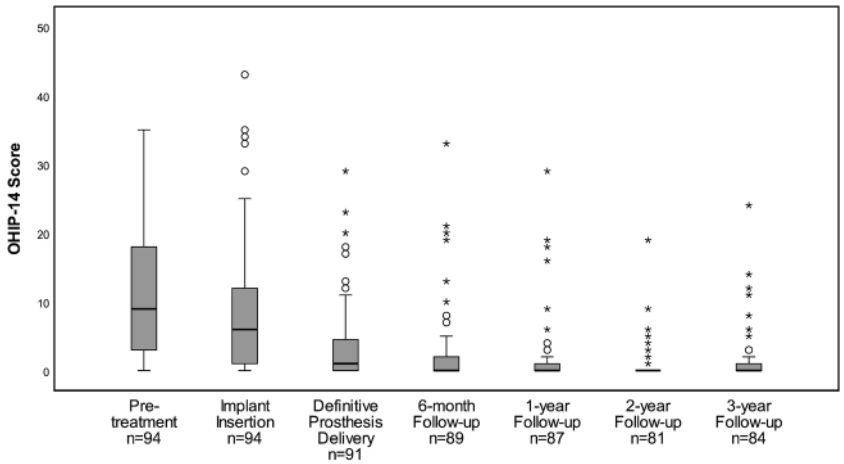

Fig. 4 Oral health impact profile over time. The sum of the OHIP-14 scores per patient were averaged for each time point. Bolded line represents the median value per time point and the boxes signify the first and third quartiles. Circles indicate outliers and stars indicate extreme cases

Discussion

In this 3-year interim report of a 5-year multicenter trial, marginal bone levels stabilized after an initial remodeling during the first 6 months and remained relatively steady through the 3-year time point. Similarly, this study had favorable 3-year survival and success rates of 98.8% and 96.9%, respectively. Only one case of probable peri-implantitis was observed, and it was secondary to an unstable implant. There were three device-related adverse events associated with implant mobility, two were resolved and the third implant failed as described above. In addition, similar to bone remodeling, soft-tissue levels, including BOP, plaque, and PES, recovered after 6 months and remained relatively stable through 2 years. There was a slight increase in BOP and plaque accumulation observed at the 3-year follow-up, but this is expected due to reduced compliance with oral hygiene protocols over the long term [28]. OHIP scores improved significantly between implant insertion and 6 months, and patients reported little negative impact up to the 3-year follow-up. Overall, the positive outcomes observed at 1 year were maintained throughout the 3-year follow-up [15], and comparisons made in the 1-year report between this trial and similar analyses [15, 16] remain valid.

There are several limitations to this study. Limitations outlined in the 1-year interim report, including variability between centers, variability in the cause of edentulism, treatment decisions that were left to the surgeon's discretion (i.e., abutment and prosthetic material and prosthetic retention method), and loss to follow-up, are still applicable [15]. There are also limitations related to our interpretations. Due to the number of centers involved in the trial, it is unlikely that every implant was perfectly placed at bone level, as evidenced by the range of marginal bone level values at implant insertion. Therefore, interpretation of these results should be handled conservatively, i.e., as an indicator of bone level stability. Another analytical limitation is the inability to definitively identify a single factor that contributes to good outcomes. Because of the study design, we cannot parse which factor or combination of factors produces the favorable result. Regardless, we can conclude that this protocol produces stable mid-term outcomes for single-tooth replacements in anterior and premolar sites of the maxilla.

As stated above, the favorable outcomes observed in this trial cannot be attributed definitively to a single factor. Rather, several biomechanical, biological, and methodological factors and implant features could potentially contribute to the mid- and ultimately long-term success of these implants. Among the factors and features that may impact implant success are soft-tissue maintenance, implant design features, and immediate loading.

The interplay between peri-implant soft tissue and hard tissue makes a substantial contribution to implant success. One factor that can help preserve soft tissue is adjacent natural teeth. Soft-tissue levels are affected by marginal bone levels of the neighboring teeth [10]. A clinical study of peri-implant mucosa surrounding single-tooth implants in the anterior maxilla showed that the facial dimension of peri-implant mucosa was slightly smaller, whereas those of adjacent tissue were similar to tissue that had not undergone surgery. Further, papilla level was shown to be dependent on the bone level of the adjacent tooth. Thus, adjacent natural teeth when combined with a thick mucosal biotype can provide sufficient support to preserve soft tissue levels [29]. In this study, implants were placed between natural teeth and soft tissue grafts were performed as needed. This combination could potentially help preserve papilla and encourage the formation and maintenance of the mucosal barrier.

There are several features of the implant itself that could contribute to our excellent outcomes. The first is the use of a

conical connection at the implant-abutment junction. Conical connections are designed to be more mechanically stable and form tighter connections than other types of attachments, leading to reduced micromotion and bacterial penetration [13]. A systematic review by Schmitt et al. [14] evaluated the microgap and mechanical properties of conical connection implants compared with non-conical ones. With respect to the microgap, conical connections have been shown to have significantly smaller microgaps compared to other connections. Currently, there are no implant-abutment interfaces that provide a perfect seal with no leakage. However, conical connection implants showed significantly lower levels of leakage and bacterial contamination compared with other connection systems. Regarding mechanical properties, they found that conical connections were able to maintain torque over time, had higher resistance to maximum bending and fatigue loading, had lower stress on the abutment screw, and had higher abutment stability than other types of connections. Generally, conical connection implants had less marginal bone loss with similar implant success and survival rates compared with implants without conical connections [14]. Overall, the current evidence seems to support the use of conical connection implants to reduce marginal bone loss.

The second implant feature that could contribute to our favorable outcomes is platform shifting. Numerous studies evaluating platform shifting have been conducted. Meta-analyses investigating the effects of platform shifting on marginal bone levels showed that platform shifting can reduce marginal bone loss, and one of those indicated that platform shifting does not sacrifice implant survival [19, 30–32]. A 3-year randomized controlled split-mouth trial compared platform-shifted internal conical connection implants with external hexagon, diameter-matched implants. In that study, vertical and horizontal marginal bone loss in the first 4 months after implant placement was significantly reduced in platform-shifted implants compared with that of diameter-matched implants. The authors hypothesized that the improvements in ΔMBL may be related to the re-establishment of biologic width [18]. Similar observations have been reported for several other studies [22, 33–37]. This outcome indicates that the effects of platform shifting manifest within the first 3–6 months and stabilize thereafter, which is consistent with our data. In addition to hard tissue outcomes, platform shifting could be beneficial for soft tissue as well. One study in canines investigated soft-tissue dimension and ΔMBL following the placement of one- or two-piece implants with varying surfaces. They compared different surgical techniques and strategies, including placement of the microgap at different levels in relation to crestal bone. This study found that there was less crestal bone loss and soft-tissue remodeling when the microgap was moved away from crestal bone [21]. Other studies have observed that the dimensions of the sulcular depth, junctional epithelium, and connective tissue contact are all affected by the location of the microgap [38, 39]. These observations support the concept of platform shifting, which moves the microgap away from the crestal bone without sacrificing the stability of placing implants at bone level. The mechanism underlying the improved outcome is still unclear. One biomechanically based theory hypothesizes that platform shifting reduces marginal bone loss by relocating mechanical stress away from the bone-implant interface and redirecting occlusal forces along the implant axis [40]. A more biologically based hypothesis is that platform shifting moves the microgap away from the bone crest which reduces the opportunity of bacteria and inflammatory cells to penetrate the peri-implant tissues, leading to marginal bone loss [19].

The final factor that could yield good outcomes is the immediate provisionalization of the prostheses. Traditional methods call for a healing period of several months between implant placement and prosthesis delivery to allow the implant to osseointegrate prior to adding occlusal forces. In theory, this strategy should reduce bone loss and soft tissue recession. However, extensive literature has shown that this healing period may not be necessary [41]. In addition, there is an increasing push by patients for an implant to yield esthetic results quickly and with fewer interventions [12]. The most recent Cochrane review on the topic of immediate loading showed that there was no difference in prosthesis or implant failure between immediate and delayed loading. They noted a statistically significant difference in marginal bone loss favoring immediately loaded implants; however, the magnitude of the difference was small and may not be clinically relevant [41]. Studies investigating soft-tissue outcomes between one- and two-stage protocols similarly show no statistical difference. A retrospective study comparing outcomes of single-tooth implants placed using different treatment strategies observed that marginal bone loss was not affected by the surgical protocol, time of prosthesis delivery, or length of the crown. All soft tissue outcomes were similar between the various treatment strategies. The one significant difference observed was higher patient satisfaction, based on a visual analog scale, for those that were immediately provisionalized compared with delayed loading [12]. Histological studies of ΔMBL in animals and humans observed similar levels of osseointegration around implants regardless of when they were loaded [42–45]. Histological studies of soft tissue remodeling around immediately provisionalized implants also show similar outcomes between one- and two-stage treatment protocols. A simian study comparing one- and two-stage protocols observed no difference in vertical dimension, biologic width, inflammatory cell infiltrate, or soft tissue anatomy between the two protocols [38]. This observation was supported by a prospective randomized clinical trial evaluating outcomes

of immediate loading. This study did not observe any differences in keratinized tissue between immediate and conventional implant loading. In the present study, the results of immediate provisionalization were at least as good as those that would be obtained using staged approach. Given the available information, we can conclude that the immediate loading protocol presented here yields favorable outcomes.

Conclusions

The mid-term results of this multicenter study showed a high primary stability of this conical connection implant placed in healed sites, favorable esthetics, high success and survival rates, and a high patient-reported OHRQoL following immediate provisionalization. This protocol is straightforward and produces good outcomes for single-tooth restorations.

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Compliance with ethical standards

Conflict of interest Dr. GH received grants and non-financial support from Nobel Biocare while the study was conducted. Dr. AF received grants from Nobel Biocare while the study was conducted. Dr. WZ received grants from Nobel Biocare while the study was conducted and personal fees from Nobel Biocare unrelated to this study; Dr. WZ also received non-financial support from Straumann; grants, personal fees, non-financial support, and other from Nobel Biocare; and personal fees from Zimmer Biomet that were unrelated to this study. Dr. CM received grants and non-financial support from Nobel Biocare while the study was conducted. Dr. RB received grants from Nobel Biocare while the study was conducted and personal fees from Nobel Biocare that were unrelated to this study. Dr. RN received grants from Nobel Biocare while the study was conducted and personal fees from Nobel Biocare that were unrelated to this study. Drs. AP, NB, AB, EG, and SC have no conflicts of interest to declare. All authors contributed equally to this work.

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

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. Ethical approval was granted by Comitato Etico Independiente, PTV, Rome, Italy (registration number 56/11); Ethical & Independent Review Services (E&I IRB), USA (registration number 11041-07); Ethik Kommission, Landesärztekammer Rheinland-Pfalz, Mainz, Germany (registration number 837.214.11(7756)); Ethik Kommission der Ärztekammer Hamburg, Germany (registration number PV3756); Freiburger ethik kommission, Germany (registration number 011/1203); Ethik Kommission der Medizinischen Universität Wien, Austria (registration number 356/2011); and Ethics Committee, Stomatology University, Belgrade, Serbia (registration number 36/12).

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