

ORIGINAL RESEARCH

Marginal bone level and survival of short and standard-length implants after 3 years: An Open Multi-Center Randomized Controlled Clinical Trial

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Abstract

Objectives: The present multi-center randomized controlled clinical trial sought to compare the marginal bone level (MBL) changes and survival of 6- and 11-mm implants.

Material and Methods: Ninety-five patients receiving a total of 209 dental implants were enrolled. Subjects were randomly allocated to two cohorts: test (4.0 × 6 mm; N = 108) or control (4.0 × 11 mm; N = 101) implant groups. To be randomized, all edentulous sites were anatomically qualified to receive 11 mm implant. Two to three implants were placed in maxillary or mandibular posterior regions and loaded with splinted provisional restoration after 6 weeks and definitive restoration 6 months thereafter. Test and control implants were followed by clinical and radiographic examinations on an annual basis up to 3 years.

Results: Radiographic assessment of MBL 3 years after loading revealed the bone to be located at 0.27 mm (±0.40) and 0.44 mm (±0.74) apical to the implant platform in the test and control groups, respectively. During the 3 years of follow-up since loading, 0.04 mm (±0.43) MBL gain and 0.02 mm (±0.76) of MBL loss were observed in the 6-mm (test) and 11-mm (control) groups, respectively. The MBL's for test and control were significantly different ($p = 0.000$) in favor of short implants. The cumulative survival rates from placement after 3 years were 96% and 99% for the 6- and 11-mm implants, respectively, with no statistical significance.

Conclusions: Reconstruction of partially edentulous posterior maxilla or mandible with 6- or 11-mm implants led to stable marginal bone level and high implant survival rate after 3 years.

KEYWORDS

dental implants, marginal bone loss, randomized controlled clinical trial, short, survival

1 | INTRODUCTION

Vertical deficiency of the alveolar ridge in posterior regions of the maxilla and mandible is a very common presentation. Proximity of the maxillary sinus or mandibular canal often limits the volume of available

bone for oral implant therapy. Traditionally, implants of 10 mm or longer have been considered to represent standard length for implant therapy (Atieh, Zadeh, Stanford, & Cooper, 2012). Such prerequisite requires vertical augmentation of the alveolar bone prior to implant placement. Vertical augmentation of the posterior maxilla has

commonly been achieved by maxillary sinus augmentation. Similarly, vertical augmentation of the posterior mandible has been achieved by vertical ridge augmentation, distraction osteogenesis, or nerve lateralization. The main drawbacks of these augmentation procedures include morbidities such as post-operative infection, mucosal tissue breakdown, pain, bleeding, and neurosensory deficit. The alternative approach for the treatment of sites with vertical ridge deficiency has included short implants, defined as implants ≤ 10 mm (Feldman, Boitel, Weng, Kohles, & Stach, 2004; Weng et al., 2003), 8.5 mm or shorter (Atieh, et al., 2012), 8 mm (Renouard & Nisand, 2005), 7 mm (Pommer, et al., 2011). Implants that are 6 mm or shorter have been referred to as extra-short (Monje, et al., 2013) or ultra-short (Deporter, Ogiso, Sohn, Ruljancich, & Pharoah, 2008). This mode of therapy has been documented through extensive clinical studies (Atieh et al., 2012). Most of the clinical studies have used implant survival as the primary outcome measure (Atieh, et al., 2012; Telleman, et al., 2011). Systematic reviews of the available evidence have demonstrated that the survival rates of short and standard-length implants are not different. However, it is important to document the long-term clinical performance of dental implants through more rigorous outcome measures, such as marginal bone stability. Randomized controlled trials documenting marginal bone outcome of short implants are scant (Esposito et al., 2015; Felice, Cannizzaro, Barausse, Pistilli, & Esposito, 2014; Felice, et al., 2015; Guljé et al., 2012; Pohl et al., 2017). The primary objective of the present randomized controlled clinical trial was to test the hypothesis that the alteration in marginal bone level is equal (i.e. a two-sided hypothesis) in patients randomized to 6 mm and patients randomized to 11 mm implant groups.

2 | MATERIAL AND METHODS

This study was designed as an international multi-center clinical trial and was fully supported by Dentsply Sirona Implants (Mölnådal, Sweden). The present report has been prepared in accordance with guidelines outlined in the CONSORT statement for reporting of randomized controlled trials (Moher et al., 2010). A copy of the checklist has been included (Supporting Information Appendix S1). The study protocol was registered with clinicaltrials.gov (registration number NCT00545818) prior to its commencement.

2.1 | Study sites

The study took place at six centers, which included: (a) The University of Southern California, Ostrow School of Dentistry, Los Angeles, USA, (b) The University of Iowa, College of Dentistry, Iowa City, Iowa, USA, (c) Private practice "de Mondhoek", Apeldoorn, The Netherlands, (d) King's College Dental Institute, London, London, UK; (e) The Sahlgrenska academy at University of Gothenburg, Department of Periodontology, Gothenburg, Sweden, (f) The University of Melbourne, Dental School, Melbourne, Australia. Block randomization was used, and blocks were distributed to the centers. The randomization was carried

out according to a computer-generated randomization list provided by Trial Form Support. The randomization code was not disclosed to the investigators until the study was completed. For the randomization procedure, randomization envelopes were used. There was one set of randomization envelopes for the maxilla, and one set for the mandible. Half of the envelopes consists of instructions for treatment with 6-mm implants and the other half consists of instructions for treatment with 11 mm implants. The patients were assigned a randomization envelope after confirmation by the investigator that all inclusion criteria, but no exclusion criteria were fulfilled.

2.2 | Study participants

The study design was an open prospective randomized controlled multicenter clinical trial. Six centers participated in the study. Each study center obtained approval from their respective institutional review board or medical ethics committee prior to the initiation of the study. The ethics committee approvals for each of the centers are:

Site-1 UK

Ethics committee: Guy's & St Thomas' NHS Foundation Trust
Approval: (R&D number) RJ1 08/0188

Site-2 SE

Ethics committee: Regionala Etikprövningsnämnden i Göteborg
Approval: (Diarienummer) Dnr: 384-07

Site-3 (NL)

Ethics committee: Independent Review Board Nijmegen
Approval: (Reference number) IRBN2007010 F-Hdj/Hdj

Site-4 (AU)

Ethics committee: Human Research Ethics Committee, The University of Melbourne
Approval: (Ethics ID) 0718459

Site-5 (US)

The University of Southern California Institutional Review Board
Approval: (Protocol #) HS-07-00414

Site-6 (US)

Ethics committee: Western Institutional Review Boards (WIRB)
Approval: (WIRB Work order number) 1-855902-1, (WIRB Protocol number) 20090681

The number of participants was determined by power calculation, as previously described (Guljé et al., 2012). Each study center enrolled patients, based on predetermined uniform inclusion and exclusion criteria, up to a maximum of 33 participants per center. At the end of enrolment period, 95 participants requiring 209 implants were enrolled into the study.

To be considered for inclusion in the study, participants had to have an edentulous space spanning 2–3 teeth in the posterior maxilla or mandible anatomically qualified to receive an 11-mm oral implant. They would receive one fixed partial denture (FPD) supported by 2–3 implants. The proposed FPD should have an even distribution of opposing contacts.

Once participants satisfied the pre-screening criteria, they were further evaluated for fulfilling all the inclusion and none of the exclusion criteria. The clinical characteristics of study participants are listed in Table 1. Screening procedure included complete review of medical history, clinical photographs, complete oral examination, periodontal and restorative evaluation, radiographic evaluation, and CBCT/CT imaging as required. A removable radiographic guide was used in obtaining CBCT/CT imaging. Participants meeting all the criteria were then informed orally and in writing about the study. Once informed consent was obtained, study participants were enrolled in the study.

2.3 | Study overview and interventions

The flow diagram in Figure 1 details all of the visits from recruitment to the 3-year follow-up visit of the study as well as the data

and intervals for collection of the data. In order to have equal distribution of participants in the test and control group at each center a block randomization sequence was used. The randomization was performed at the time of surgery after the flaps were raised by opening a sealed envelope containing information about the length of the implants to be placed, that is, 6 or 11 mm. An individual subject received either 6- or 11-mm implants for all devices placed.

Implant surgery was performed by a single surgeon at each center under local anesthesia according to the sponsor's "Surgical procedures" manual, modified to a one-stage procedure. The final drill diameter was determined by the bone quality. When the bone density, perceived by the surgeon, had low cutting torque during initial osteotomy steps, the protocol permitted the surgeon to select a smaller diameter final drill. The diameter of the final drill was recorded. In the event of small dehiscence, autogenous grafting was allowed by harvesting bone in areas close to the surgical site. The

TABLE 1 Subject characteristics of the study population

| | Investigational product OsseoSpeed™ 6 mm | Comparator OsseoSpeed™ 11 mm | Total |
|--|---|---------------------------------|---------|
| Population | | | |
| N ^S randomized | 49 | 46 | 95 |
| N ^I randomized | 108 | 101 | 209 |
| Demographic characteristics | | | |
| N ^S Sex (% of subjects) | | | |
| Male | 21 (43) | 27 (59) | 48 (51) |
| Female | 28 (57) | 19 (41) | 47 (49) |
| Age (SD) | | | |
| Mean years | 54.8 (9.3) | 54.1 (10.0) | |
| Range | 26–69 | 34–70 | |
| N ^S Smoking (% of subjects) | | | |
| Non-smoker | 29 (59) | 33 (72) | 62 (65) |
| Ex-smoker | 17 (35) | 8 (17) | 25 (26) |
| Occasional smoker | 1 (2) | 2 (4) | 3 (3) |
| Habitual smoker | 2 (4) | 3 (7) | 5 (5) |
| Baseline characteristics | | | |
| N ^S Oral examination | | | |
| Abnormal jaw | 5 | 8 | 13 |
| Hyperkeratosis | 0 | 0 | 0 |
| Hyperplasia | 0 | 0 | 0 |
| Leukoplakia | 0 | 0 | 0 |
| Periodontitis | 12 | 7 | 19 |
| Bruxism | 3 | 3 | 6 |
| Other oral conditions | 3 ^a | 1 ^b | 4 |

Notes. N^S: Number of subjects; N^I: Number of implants.

^aAmalgam tattoos, horizontal and sagittal overbite > 10 mm, occlusal erosive tooth wear.

^bDentigerous cyst.

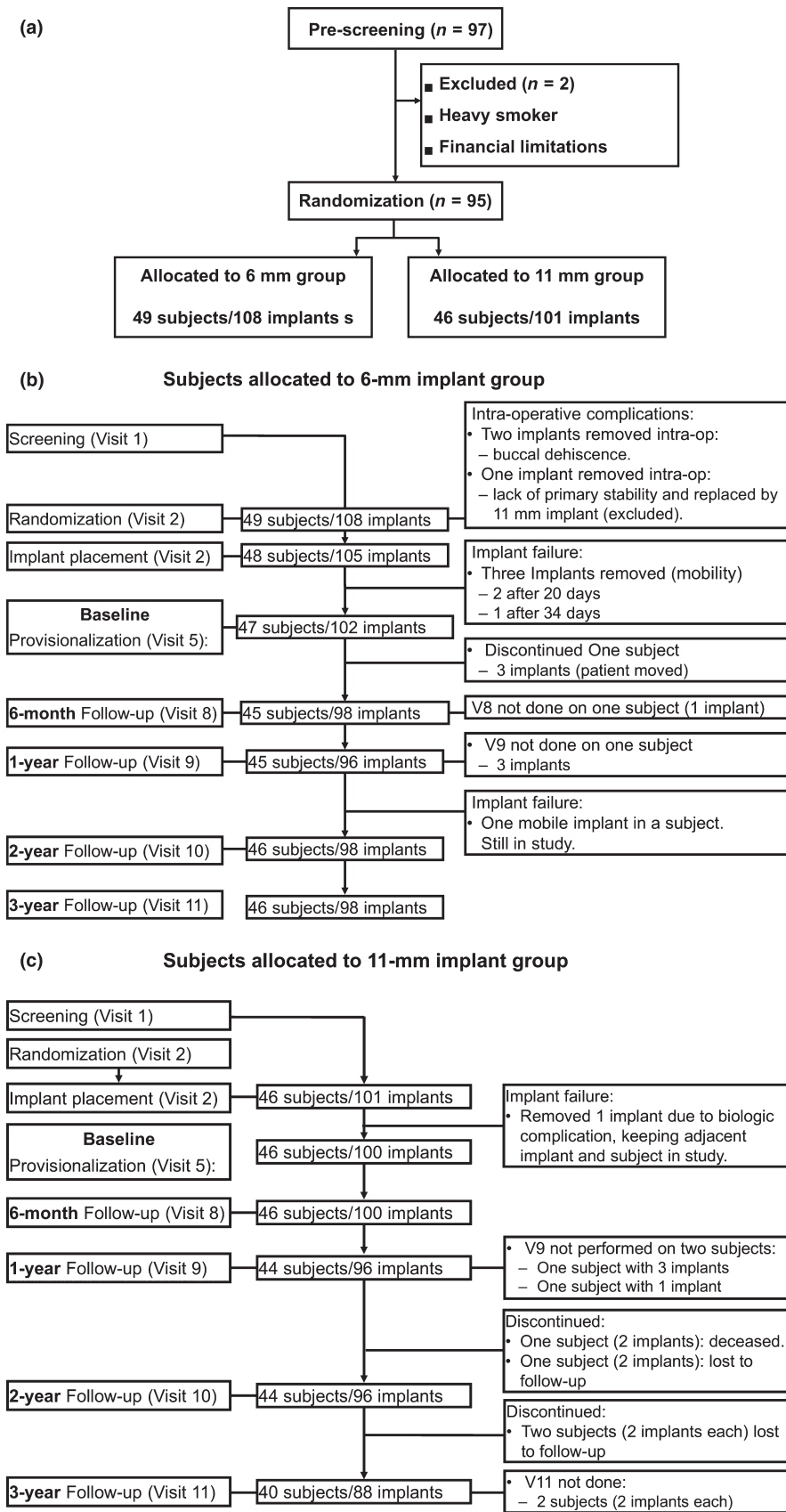


FIGURE 1 Flow diagram, outlining the number of subjects, and implants at each visit. Randomization and allocation of study participants (a). Allocation of subjects randomized to the test (b) and control (c) groups

protocol did not allow application of any other form of graft material. Six implants (two test and four control) required autogenous bone chips to repair minor dehiscence defects. In case of lack of primary

stability, a two-stage protocol with extended healing time was instituted. One subject in each group, with two implants were treated with a two-stage surgery and extended healing.

TABLE 2 Implant survival is presented as probability of implant survival and cumulative survival rate analyzed according to Kaplan-Meier method

| Interval | Number of implants at risk | | Failures | | Censored ^a | | Interval survival probability | | Cumulative survival proportion | |
|---|----------------------------|-------|----------|-------|-----------------------|-------|-------------------------------|--------|--------------------------------|--------|
| | 6 mm | 11 mm | 6 mm | 11 mm | 6 mm | 11 mm | 6 mm | 11 mm | 6 mm | 11 mm |
| Implant installation | 108 | 101 | 0 | 0 | 3 ^b | 0 | 1.000 | 1.000 | 1.000 | 1.000 |
| Implant installation to loading (6 weeks) | 105 | 101 | 3 | 0 | 0 | 0 | 0.9714 | 1.000 | 0.9714 | 1.000 |
| Implant loading to 6 months follow-up | 102 | 101 | 0 | 1 | 3 | 0 | 1.000 | 0.9901 | 0.9714 | 0.9901 |
| 6 months to 1 year post-loading | 99 | 100 | 0 | 0 | 0 | 4 | 1.000 | 1.000 | 0.9714 | 0.9901 |
| 1–2 year post-loading | 99 | 96 | 1 | 0 | 0 | 4 | 0.9899 | 1.000 | 0.9616 | 0.9901 |
| 2–3 year post-loading | 98 | 92 | 0 | 0 | 0 | 4 | 1.000 | 1.000 | 0.9616 | 0.9901 |
| 3 year post-loading | 98 | 88 | 0 | 0 | 0 | 0 | 1.000 | 1.000 | 0.9616 | 0.9901 |

^aLost to follow-up.^bThree implants were removed immediately after installation based on surgical consideration.**TABLE 3** Implant survival values, percentages, and statistical analysis

| | 6 mm, N (%) | 11 mm, N (%) | Total, N (%) |
|----------------------|-------------|--------------|--------------|
| Failure N (%) | 4 (4.1) | 1 (1.1) | 5 (2.7) |
| Success N (%) | 94 (96) | 87 (98.9) | 181 (97.3) |
| Total | 98 (95.9) | 88 (100) | 186 (100) |
| p-value ^a | 0.37187 | | |

^ap-Value Fisher's exact test, two-sided.

The option of antibiotics administration was at the discretion of the treating dentist. Patients were given 2 g of amoxicillin or 600 mg of clindamycin (in case of allergy to penicillin), pre-operatively. Post-operatively, patients were instructed to use a chlorhexidine rinse twice a day for 10 days. No other form of antimicrobial therapy was recommended as part of the study protocol.

The oral implants were all of one brand (OsseoSpeed, Astra Tech Implant System, Dentsply-Sirona Implants, Mölndal, Sweden) and were installed in accordance to the recommended protocol in the Astra Tech manual "Surgical Procedures". Primary stability was assessed by subjective assessment of the surgeon at the time of installation. Screw retained Abutments (Dentsply-Sirona Implants) included 20-degree Uni Abutments (86/105 test and 74/101 control implants), 45-degree Uni Abutments (5/105 test and 15/101 control implants), angled abutments (1/106 test and 2/101 control implants), or unknown abutments (13/106 test and 10/101 control implants) were used. Abutments were delivered at the time of surgery and torqued at 15 Ncm and protected with healing caps during the six-week healing period. Flaps were sutured and radiographs, and clinical photographs were obtained. One week to 10 days after the surgery, the sutures were removed and clinical photographs were taken.

Five weeks after the surgery, implant stability was assessed by percussion test to determine whether the implants have

achieved adequate integration to be loaded. Abutment level impressions were made, using an open tray technique, for fabrication of acrylic screw-retained provisional restorations. One week later, that is, 6 weeks after implant placement, provisional restorations were delivered. Provisionals were seated in place and the bridge screws torqued at 15 Ncm, as recommended by the manufacturer. Implant stability was again assessed in preparation for the definitive restoration, which was 6 months following provisional restoration.

Definitive restorations were fabricated either on the casts used for fabrication of provisional restorations or in some cases from newly obtained impressions. Decision to use old cast or make new impression was based on the clinical judgment of the treating restorative dentist.

The peri-implant mucosal conditions, including probing pocket depths (PD) and bleeding on probing (BOP), were measured and recorded on the four surfaces at the time of provisional restoration, 4 weeks later (post-operative visit), 6 months later (at time of definitive restoration), as well as at each of the annual follow-up visits (12, 24 and 36 months following provisional restoration).

Radiographs and clinical photographs were also obtained at pre-operative visit, implant installation, at provisional restoration visit (6 weeks post-implant installation), at definitive restoration visit, and at each of the annual visits (12 and 36 months following provisional restoration).

Adverse events, serious adverse events, and adverse device effects were recorded at each visit. Failed implants and the failure date were recorded.

Comparison of marginal bone level (MBL) changes of the 6-mm experimental and 11-mm control groups was predetermined as the primary outcome measure for this study. Determination of implant survival of the experimental and control groups was set as the secondary outcome measure of this clinical trial.

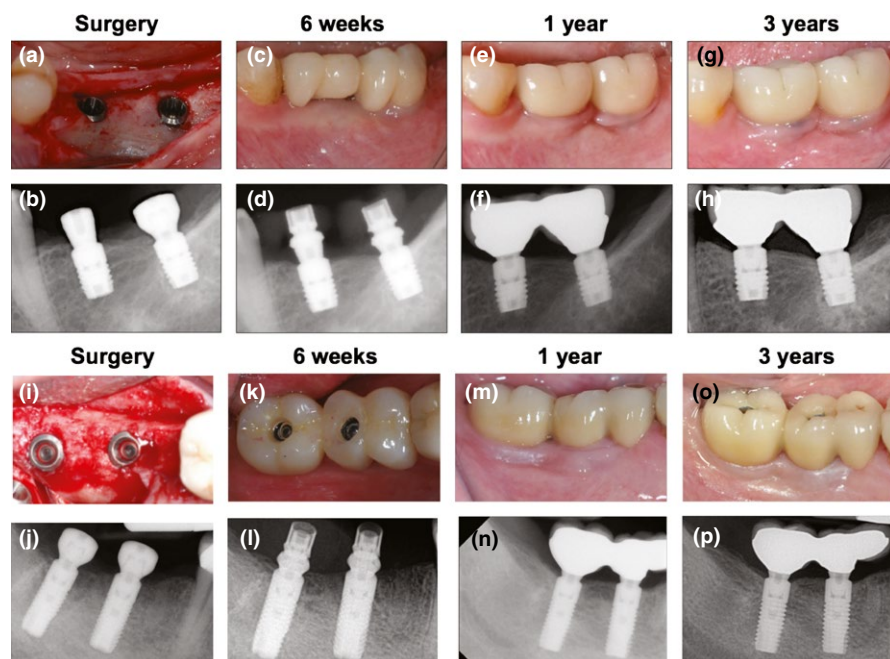


FIGURE 2 Representative clinical photo and radiographs of a test (6 mm) and control (11 mm) participant. The photos and radiographs of a representative test patient at implant installation visit (a, b), provisionalization visit after 6 weeks (c, d), 1-year post-provisional restoration follow-up (e, f) and 3-year post-provisional restoration follow-up (g, h) are shown. The photographs and radiographs of a representative control patient at implant installation visit (i, j), provisionalization visit after 6 weeks (k, l), 1-year post-provisional restoration follow-up (m, n) and 3-year post-provisional restoration follow-up (o, p) are illustrated

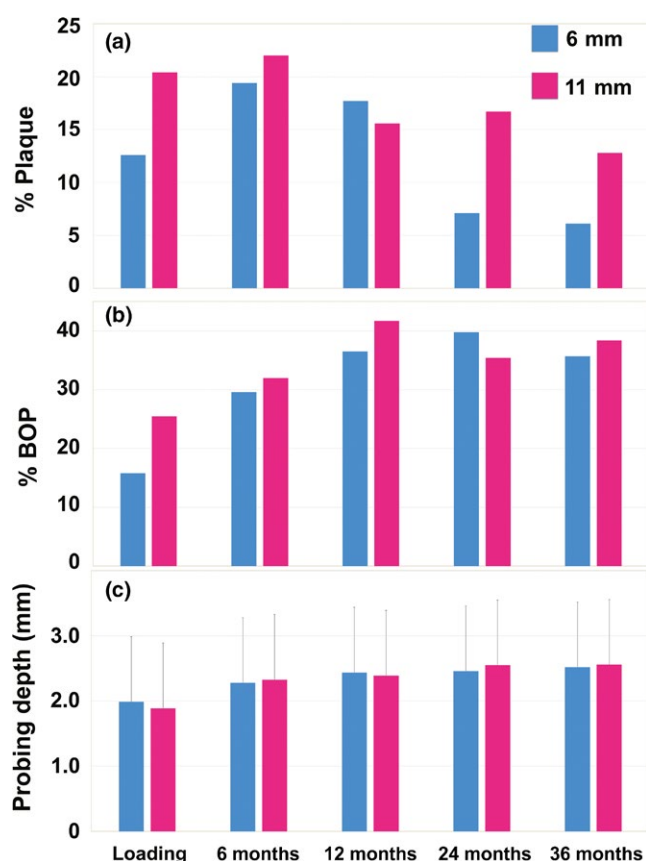


FIGURE 3 Clinical measures of test and control implants. Percentage of implants with plaque (a) or bleeding on probing (b) present on any of the four surfaces (mesial, distal, buccal, lingual/palatal). Mean of the probing depths recorded on all four aspects of restored implants (c)

2.4 | Radiographic analysis of marginal bone level changes

All radiographs were taken with a paralleling technique utilizing film holders. Best efforts were used to obtain images with the threads of the implants in sharp focus.

There were two radiographic measurements, marginal bone levels, and anatomical crown height. All measurements were performed by an experienced radiologist from the Department of Radiology at the University of Gothenburg. The radiologist was independent of the investigators and the sponsor.

The images were displayed in appropriate software (Illustrator® CS; Adobe Systems Inc., San Jose, CA, USA) on a 24-inch LCD screen (iMac Apple Inc., Cupertino, CA, USA). The screen resolution was 1,920 × 1,200 pixels. Brightness, contrast, and zoom were adjusted for optimum viewing. Marginal bone levels were determined by measuring the distance from the implant reference point (junction between the machined bevel and the micro threads) and first bone to implant contact on both the mesial and distal surfaces for each implant. The mean of these measurements was used to represent marginal bone level for each implant at baseline (i.e., delivery of provisional restoration) and at 12 and 36-month follow-up time intervals. If the implant reference point was subcrestal, the value was considered to be zero. Changes in marginal bone levels were determined by comparing these mean values over time.

For anatomic C/I ratio, the length of the crown was defined as the distance between the implant platform and crown top peak, and the implant length was considered the distance between the most apical point of the implant and the implant platform (Huynh-Ba, 2015).

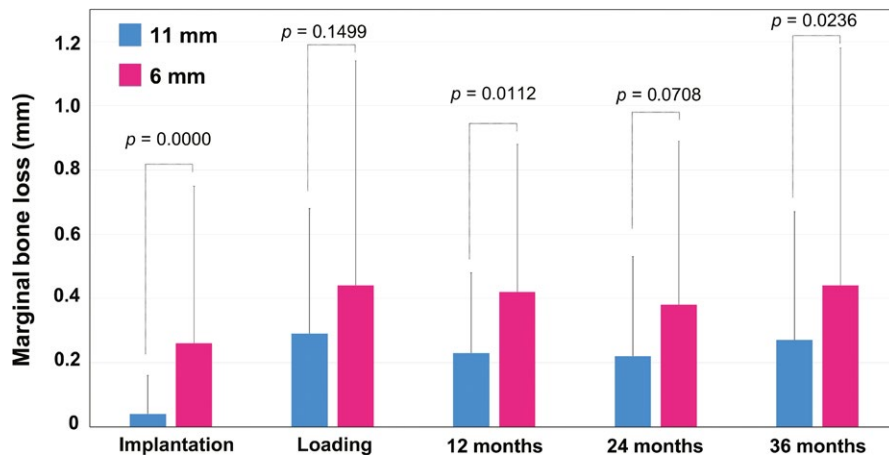


FIGURE 4 Mean (columns) and standard deviation (error bars) of marginal bone level (mm) for test (6 mm) and control (11 mm) implants at each visit

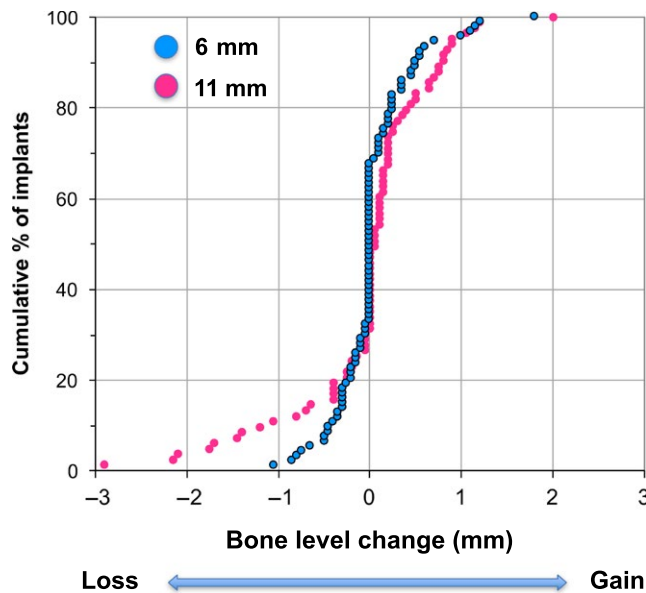


FIGURE 5 The cumulative percentage of implants exhibiting marginal bone level changes (mm) from baseline to 3-year follow-up. Each dot represents the marginal bone level change for a single test (6 mm) or control (11 mm) implant from baseline to 3-year follow-up

2.5 | Statistical analysis methodology

Statistical tests were conducted with SPSS (IBM Corp., Armonk, NY, USA) and Excel (Microsoft, Redmond, WA, USA) software. The statistical tests to be used were pre-determined by the study protocol. Descriptive statistics were used to analyze participant and implant characteristics, i.e., mean, median, Standard Deviation (SD), minimum (min), maximum (max) and frequency tables. A non-parametric statistical approach was applied because of the nature of the data. Wilcoxon rank-sum test (Exact) was used for continuous data, for example, marginal bone levels to test for differences in marginal bone level changes between the groups as well as differences in crown to implant ratio. Cumulative implant survival rates were calculated using the Kaplan–Meier estimate. Implant was used as the

computational unit. Nominal *p*-values are presented but not called statistically significant. No formal adjustment for multiplicity has been applied. Fisher's exact test was used for categorical data, for example, BOP and implant survival.

The primary outcome measure (the mean marginal bone level alteration per patient) was used to estimate the number of patients needed to be randomized. The difference worth detecting between the groups in the alteration (from loading to the last visit) of the marginal bone level was set as 0.5 mm. The standard deviation was assumed to be 0.8 mm, based on prior study which had many of the same parameters as the present study (Wennström, et al., 2004). The number of patients required per group was calculated after assuming a two-sided hypothesis to be rejected if the *p*-value was below 5% and the power was 80%. Compensating for a withdrawal rate of 20% resulted in 100 patients as the sample size.

3 | RESULTS

3.1 | Subject allocation, randomization, and follow-up

The characteristics of study participants enrolled in this study, including demographics, smoking habits, and baseline characteristics, are listed in Table 1. These data demonstrated that the characteristics of the participants allocated to the control and test groups were not different. Subject allocation and randomization is summarized in a flow diagram (Figure 1a). Two patients were excluded during the pre-screening because they did not meet inclusion and exclusion criteria. Forty-nine subjects (108 implants) were allocated to the 6-mm implant and 46 subjects (101 implants) allocated to the 11-mm implant cohorts. The first patient was enrolled in November 2007 and the last patient in June 2010, thereby taking nearly 3 years to recruit 95 individuals, who consented to participate in the study. Based on clinicians' and patients' preferences, 39 of 48 participants in the test group and 34 of 46 in the control group received pre-operative antibiotics.

In the test group (Figure 1b), buccal dehiscence was present after osteotomy in two sites in one patient. Because bone augmentation

TABLE 4 Marginal bone level changes at implant level and subject level at each visit relative to surgical installation (Gain +/Loss −)

| Parameter | Surgery to provisionalization (surgical installation + 6 weeks) | | | | | | Surgery to definitive restoration (provisionalization + 6 months) | | | | | |
|----------------------|--|-------|-------|---------------|-------|-------|--|-------|-------|---------------|-------|-------|
| | Implant-level | | | Subject level | | | Implant-level | | | Subject level | | |
| | 6-mm | 11-mm | Total | 6-mm | 11-mm | Total | 6-mm | 11-mm | Total | 6-mm | 11-mm | Total |
| N | 105 | 101 | 206 | 48 | 46 | 94 | 105 | 101 | 206 | 48 | 46 | 94 |
| Missing | 11 | 6 | 17 | 4 | 3 | 7 | 12 | 3 | 15 | 5 | 1 | 6 |
| Valid N | 94 | 95 | 189 | 44 | 43 | 87 | 93 | 98 | 191 | 43 | 45 | 88 |
| Mean | −0.23 | −0.17 | −0.20 | −0.17 | −0.21 | −0.18 | −0.19 | −0.19 | −0.19 | −0.19 | −0.17 | −0.18 |
| SD | 0.37 | 0.73 | 0.58 | 0.29 | 0.66 | 0.51 | 0.28 | 0.54 | 0.43 | 0.21 | 0.57 | 0.43 |
| Min | −1.85 | −4.15 | −4.15 | −1.05 | −2.68 | −2.68 | −1 | −2 | −2 | −0.72 | −1.75 | −1.75 |
| Median | 0 | 0 | 0 | −0.15 | −0.05 | −0.1 | −0.1 | −0.1 | −0.1 | −0.15 | −0.12 | −0.13 |
| Max | 0.6 | 2.8 | 2.8 | 0.1 | 2.1 | 2.1 | 0.6 | 1.45 | 1.45 | 0.2 | 2.03 | 2.03 |
| p-Value ^a | 0.1077 | | | 0.0661 | | | 0.5133 | | | 0.5364 | | |

^ap-Value is a two-sided p-value from Wilcoxon rank-sum test (Mann–Whitney *U* equivalent) comparing 6- to 11-mm implant groups.

TABLE 5 Crown-to-implant ratio

| Parameter/Group | Crown height (mm) | | Crown-to-Implant ratio | |
|----------------------|-------------------|-------|------------------------|-------|
| | 6 mm | 11 mm | 6 mm | 11 mm |
| Mean | 10.67 | 10.19 | 1.78 | 0.93 |
| SD | 2.12 | 1.86 | 0.35 | 0.17 |
| Min | 6.8 | 6.5 | 1.13 | 0.59 |
| Median | 10.5 | 9.9 | 1.75 | 0.9 |
| Max | 16.8 | 15.3 | 2.8 | 1.39 |
| p-Value ^a | 0.1359 | | 0.000 | |

^ap-Value is a two-sided p-value from Wilcoxon rank-sum test (Mann–Whitney *U* equivalent).

was not permitted under this study protocol, the patient was exited from the study, so that the sites could be managed by augmentation for delayed implant placement. These implants were excluded from analysis. In another site, following osteotomy, adequate primary stability was not achieved; therefore, the site was exited from the study so that a longer implant could be placed.

Of the 49 subjects with 108 implants randomly allocated to the test group receiving 6-mm implants, 46 subjects with 98 implants completed the 3-year follow-up (Figure 1b). One subject had failure of two test implants at 20 days postoperatively, and the subject was exited from study. Another participant had failure of one implant after 34 days and the site was excluded. One of the participants moved and was unavailable for follow-up visits.

Among 46 subjects and 101 implants randomly allocated to the control group (Figure 1c) receiving 11-mm implants, 40 subjects with 88 implants completed the 3-year follow-up (Figure 1c). One implant was removed due to post-operative infection, leading to peri-implant bone loss. The site was grafted, and new implant was placed that was not part of the study. The adjacent implant was

kept in study. Three subjects with two control implants in each were lost to follow-up. One subject with two control implants deceased. Two subjects with two control implants in each were not available for 3-year follow-up evaluation, although they remained in the study.

3.2 | Implant survival

Figure 1b, c illustrate the implant failures, their timing and reason for their failures. 105 test implants (6 mm) and 101 control implants (11 mm) were initially placed. Three test implants failed to integrate and exhibiting mobility, and they were removed prior to loading and one was lost before the 2-year evaluation. In the control group, one 11-mm implant was lost 3 months after implant placement because of poor oral hygiene and abundant biofilm deposit on the implant, which exhibited acute bone loss. Despite its stability, the decision was made to remove the implant. This lead to a cumulative survival rate of 96.2% for the 6-mm implants and 99% for the 11-mm implants (Table 2).

Two adjacent test implants in maxillary right first and second molar positions with quality four bone lost stability and were removed 20 days after placement. One test implant in maxillary left second premolar position with quality three bone lost stability and was removed 34 days after installation. Another test implant in mandibular right second molar position with quality two bone failed approximately 6 months after definitive restoration.

One of the two implants (mandibular right second premolar) in a control patient with poor oral hygiene during the healing period exhibited excessive bone loss and was removed approximately 2-month post-installation before loading.

The cumulative implant survival of control and test implants was compared using two-sided Fisher's exact test (Table 3), which showed no statistically significant difference between the two groups.

| Surgery to 1-year follow-up (Provisionalization + 12 months) | | | | | | Surgery to 3-year follow-up (Provisionalization + 36 months) | | | | | |
|---|-------|-------|---------------|-------|-------|---|-------|-------|---------------|-------|-------|
| Implant-level | | | Subject level | | | Implant-level | | | Subject level | | |
| 6-mm | 11-mm | Total | 6-mm | 11-mm | Total | 6-mm | 11-mm | Total | 6-mm | 11-mm | Total |
| 105 | 101 | 206 | 48 | 46 | 94 | 105 | 101 | 206 | 48 | 46 | 94 |
| 16 | 7 | 23 | 6 | 3 | 9 | 11 | 16 | 27 | 3 | 7 | 10 |
| 89 | 94 | 183 | 42 | 43 | 85 | 94 | 85 | 179 | 45 | 39 | 84 |
| -0.19 | -0.15 | -0.17 | -0.20 | -0.16 | -0.18 | -0.23 | -0.15 | -0.19 | -0.25 | -0.16 | -0.21 |
| 0.34 | 0.69 | 0.54 | 0.27 | 0.66 | 0.50 | 0.41 | 0.90 | 0.69 | 0.36 | 0.79 | 0.60 |
| -1.4 | -2.3 | -2.3 | -0.88 | -1.85 | -1.85 | -1.7 | -3.75 | -3.75 | -1.57 | -2.1 | -2.1 |
| 0 | 0 | 0 | -0.18 | -0.05 | -0.1 | 0 | 0 | 0 | -0.13 | 0 | -0.09 |
| 0.6 | 3 | 3 | 0.22 | 2.43 | 2.43 | 0.6 | 3 | 3 | 0.22 | 2.38 | 2.38 |
| 0.3599 | | | 0.2897 | | | 0.0160 | | | 0.1104 | | |

3.3 | Clinical characteristics of subjects

Figure 2 shows a representative clinical case for each of the 6-mm test and 11-mm control groups. The photographs and radiographs illustrate the steps at implant installation visit (a, b, i, j), provisionalization visit after 6 weeks (c, d, k, l), 1-year post-provisional restoration follow-up (e, f, m, n), and 3-year post-provisional restoration follow-up (g, h, o, p).

The quantitative clinical characteristics of study subjects, namely plaque, BOP, and probing depths, are illustrated in Figure 3. These data demonstrate that the site characteristics of study subjects in control and test groups were not significantly different.

Approximately 6%–22% of the restored implants had detectable plaque, during follow-up visits (Figure 3a). Figure 3b reveals that the percentage of implant sites exhibited bleeding on probing started at 16%–25% at the time of provisional restoration delivery. Following restoration, BOP percentages were generally higher and ranged from 32% to 43%. Differences between the percentage of BOP-positive control and test implants, using two-sided Fisher's exact test were not statistically significant. Examination of peri-implant mucosa demonstrated that the mean probing depths of test and control

sites were between 2 and 3 mm at all observation periods with no differences between the two groups (Figure 3c).

In order to discern the prevalence of peri-implant mucositis, the sites with positive BOP, probing depth > 4 mm and bone loss < 0.2 mm per year after loading were considered (Coli, Christiaens, Sennerby, & Bruyn, 2000). Accordingly, one (among 93) test implants in one (among 45) test subjects and four (among 82) implants in three (among 39) subjects in the control group were classified as mucositis. Therefore, the percentages of mucositis after 3 years of post-loading observation in this study were 1.1% of test implants, 2.2% of test subjects, 4.9% of control implants, and 7.7% of control subjects.

3.4 | Marginal bone levels (MBL)

The mean MBLs reported at implant-level, as well as at subject-level of analysis in the control and test groups are shown in Figure 4. During the observation period of this study from implant installation to 36-months post-loading, the bone levels in both intervention groups were stable. At time of installation, the test and control implants were positioned at 0.04 and 0.26 mm relative to the bone

TABLE 6 Adverse device events. Technical complications related to the study devices are listed

| Adverse event | Incidence 6-mm implants | Incidence 11-mm implants |
|---|----------------------------|-----------------------------|
| Study implant failure (mobility, excessive bone loss, pain) | 4 | 1 |
| Bridge screw loosening | 3 | 7 |
| Bridge screw fracture | 3 | 0 |
| Displaced of healing cap | 1 | 1 |
| Abutment fracture | 5 | 2 |
| Provisional prosthesis fracture | 1 | 2 |
| Definitive prosthesis porcelain fracture | 0 | 1 |

crest, respectively. These positions were statistically significantly different ($p = 0.000$) as a group. The mean marginal bone level changes from surgical installation to 3-year follow-up remained below 0.25 mm (Table 4). Interestingly, at 36-month follow-up, the mean MBL change observed in the 6-mm implant group was statistically less than that of the 11-mm group ($p < 0.05$).

To gain additional insights about MBL changes of all implants examined, the MBL changes, up to 36 months post-loading of individual implants, were plotted against their cumulative percentage. The data in Figure 5 illustrate that approximately 85% of 11-mm implants and 92% of 6-mm implants exhibited marginal bone level changes less than 0.5 mm during the 3-year post-loading period. Approximately 19% of 11-mm and 12% of 6-mm implants exhibited bone gain ranging from 0.5 to 2.0 mm during the 3-year follow-up. Approximately 7% of the 6-mm implants lost between 0.5 and 1 mm of marginal bone. None of the 6-mm implants exhibited more than 1 mm of bone loss. Approximately 10% of 11-mm implants lost more than 1 mm of marginal bone. Three 11-mm implants lost between 2 and 3 mm of bone.

In order to calculate the prevalence of peri-implantitis, the sites with positive BOP, probing depth > 5 mm and bone loss > 2 mm post-loading were considered (Coli et al., 2000). Accordingly, only one (among 82) implants in one (among 39) control subjects can be classified as peri-implantitis. None of the test implants were found to exhibit peri-implantitis. Therefore, the percentages of peri-implantitis after 3 years of post-loading observation in this study were 0% of test implants/subjects, 1.2% of control implants, and 2.6% of control subjects.

3.5 | Crown to implant heights

The mean clinical crown heights for 6- and 11-mm implants were 10.67 and 10.19 mm, respectively (Table 5). Because of differences in implant length, the crown-to-implant ratios were 1.78 and 0.93 for the 6- and 11-mm implants, respectively.

3.6 | Adverse device events/complications

The adverse device events (ADE) are listed in Table 6. Four 6-mm implants and one 11-mm implant failed during this study. Prosthesis and/or screw loosening was noted among three of the test and seven of the control patients. Abutment fracture was observed in five test and two control implants.

4 | DISCUSSION

Treatment options for patients with vertical atrophy of the alveolar ridge have included alveolar ridge vertical augmentation (Khojasteh, Motamedian, Sharifzadeh, & Zadeh, 2016), sinus augmentation (Wallace et al., 2012), as well as short implants (Atieh et al., 2012). Systematic reviews on the efficacy of alveolar ridge vertical augmentation have demonstrated limitations on the magnitude of

vertical gain that can be achieved. Maxillary sinus augmentation is a predictable procedure with the possibility to gain adequate vertical augmentation to allow placement of longer implants (Del Fabbro, Wallace, & Testori, 2013). However, both alveolar ridge vertical augmentation and maxillary sinus augmentation have the disadvantage of significant morbidity. Therefore, short implants have been considered an attractive alternative therapeutic strategy for reconstructing patients with an atrophic ridge in the posterior region of the mouth. Multiple systematic reviews have demonstrated that the survival of short implants is equivalent to those of standard length implants (Atieh, et al., 2012; Lee, Lee, Fu, Elmisaleti, & Chuang, 2014; Lemos, Ferro-Alves, Okamoto, Mendonça, & Pellizzer, 2016; Nisand, Picard, & Rocchietta, 2015; Thoma, et al., 2015). A limited number of randomized controlled clinical studies have compared the outcomes of short implants to those of alveolar ridge vertical augmentation (Esposito et al., 2015; Felice, et al., 2014; Pistilli, Felice, Cannizzaro, et al., 2013; Pistilli, Felice, Piattelli, et al., 2013), as well as to the maxillary sinus augmentation (Esposito et al., 2015; Pistilli, Felice, Cannizzaro, et al., 2013; Thoma, et al., 2015). These studies have demonstrated that the survival, as well as the marginal bone levels of short implants are comparable to those of longer implants placed in sites in conjunction with maxillary sinus augmentation or alveolar ridge vertical augmentation. The only significant differences identified in those studies have been increased surgical complications observed in the augmentation cohorts. Therefore, short implants have emerged as a viable alternative with less morbidity and surgical complication rate.

The literature on short implants has some deficiencies, including paucity of (a) randomized control clinical trials, (b) long-term data beyond one year, and (c) outcomes other than survival including marginal bone level changes. The present prospective randomized control clinical trial is an interim report of a 5-year multi-center trial. The 1-year data have been previously reported and found a survival rate of 97% for the 6-mm implants and 99% for the 11-mm implants (Guljé et al., 2012), as well as stable marginal bone levels for control and test implants.

In examining marginal bone level differences between test and control implants, it is notable that the 6- and 11-mm implants were installed at mean positions of 0.04 and 0.26 mm supra-crestal. This difference, although very small, was statistically significant. This may be due to the fact that for longer implants there is higher likelihood of proximity to critical anatomic structures such as the inferior alveolar nerve or maxillary sinus. It is possible that surgeons were more cautious to avoid impinging on these anatomic structures with longer implants, and as a result these implants were positioned slightly more supra-crestal. The present report also found very stable marginal bone levels for both control and test implants, as the mean MBL changes of both groups during the 36-month period post-loading remained at or below 0.2 mm.

An interesting observation among the 6-mm implants was the maximum degree of bone loss at 3 years was 1 mm. On the other hand, among the 11-mm implants, approximately 7% of the implants exhibited 1–2 mm of bone loss and three implants showed between

2 and 3 mm of bone loss at 3 years. The observation of increased bone loss among a small percentage of 11 mm, but not 6-mm implants, is noteworthy. One may only speculate as to reasons why longer implants may manifest more bone loss, including the possibilities of (a) increased generation of heat during surgery with deeper osteotomy preparation, (b) stress shielding, which is likely to increase with longer implants, or (c) a manifestation of the more crestal position of the head of the 11 mm implants. Although there are no data on stress shielding mediated by dental implants, this phenomenon has been investigated in orthopedics (Bilhan et al., 2010).

Some of the previous studies reporting marginal bone levels of short implants have demonstrated that the mean marginal bone loss of short and standard length implants to be roughly 1.5 mm (Romeo, Ghisolfi, Rozza, Chiapasco, & Lops, 2006; Rossi, Ricci, Marchetti, Lang, & Botticelli, 2010). Although this may not be problematic for standard length implants relative to their total length, 1.5 mm could represent 25% of the length of a short implant. A recent systematic review comparing the outcome of various short implants reported a significantly higher marginal bone loss around external connection than internal connection implants (Monje, et al., 2014). The implants investigated in the present study have an internal conical connection. In addition, these implants have a horizontal offset between implant and abutment, also referred to as "platform switching." Previous studies have demonstrated less marginal bone level changes around implants with this configuration (Chrcanovic, Albrektsson, & Wennerberg, 2015). The implants used in the present study also had microthreads. Limited data have suggested less marginal bone loss around implants with microthreads (Abrahamsson & Berglundh, 2006). It should be emphasized that marginal bone stability is more critical around short implants because of their limited length. The observation of marginal bone stability, particularly around the 6-mm implant, is indeed reassuring.

The adverse events observed with regard to bridge screw loosening or fracture, as well as abutment fracture were concerning. These may be due to the fact the abutments and bridge screw used in this study were torqued at 15 Ncm. Since then, there have been changes made to this abutment system, which have increased the screw diameter and require torqueing the abutment and the bridge screw at 25 Ncm.

As with any study, it is important to discuss the limitations of the study. The present study examined implants placed in a relatively intact alveolar ridge, as it was necessary to randomize the patients, who had to qualify for either 6- or 11-mm implants. For that reason, the mean crown-to-implant ratios of the reconstructions used in this study were below 2 (1.78 and 0.93 for 6- and 11-mm implants, respectively). Previous studies have failed to demonstrate any significant effects of crown-to-implant ratios on implant survival or marginal bone loss (Blanes, 2009). The protocol in this study specified to place multiple implants with two or three implants that were restored with splinted restorations after only 6 weeks of healing. However, previous studies on short implants failed to demonstrate any significant effects of splinting on implant survival or marginal bone loss (Maló, Araújo, & Rangert, 2007; Nedir et al., 2004; Tawil,

Aboujaoude, & Younan, 2006; Weber & Sukotjo, 2007). Another limitation maybe the fact that the recruitment was over a prolonged period and the surgeons may have potentially had evolving experience. In view of the fact that participants were required to possess adequate vertical height of bone in the posterior mandible or maxilla to allow random placement of either 6- or 11 mm implants, availability of qualified subjects was scarce. The present study is ongoing, and the 5-year outcomes will be reported when data on all subjects under observation have been collected.

5 | CONCLUSIONS

The present multi-center prospective randomized controlled clinical trial has demonstrated that treatment of patients with implants of 4.0 mm in diameter with 6- or 11-mm in length led to a high degree of implant survival and stable marginal bone level after 3 years of observation.

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SUPPORTING INFORMATION

Additional supporting information may be found online in the Supporting Information section at the end of the article.

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