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Comparison of 6-mm and 11-mm dental implants in the posterior region supporting fixed dental prostheses: 5-year results of an open multicenter randomized controlled trial

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Abstract

Objective: The aim of this multicenter, randomized controlled trial was to compare the clinical and radiographic outcomes of 6-mm or 11-mm implants, placed in the posterior maxilla and mandible, during a 5-year follow-up period.

Materials and methods: Ninety-five patients with adequate bone height for 11-mm implants, were randomly allocated to a 6-mm group (test group with short implants) or an 11-mm group (control group with standard-length implants). Two or three implants of the same length were placed in each patient and after 6 weeks loaded with a splinted provisional restoration. This was followed by definitive splinted restoration 6 months after implant placement. Clinical and radiographic parameters, including the occurrence of complications were recorded.

Results: A total of 49 patients were enrolled to receive 6-mm implants (n = 108) and 46 patients to receive 11-mm implants (n = 101). Three implants (two of 6 mm and one of 11 mm in length) were lost before loading and one 6-mm implant after 15 months of function, and one 11-mm implant was lost during the first year of function. The 5-year survival rates were 96.0% and 98.9% in the 6-mm and 11-mm group, respectively. The mean marginal bone level changes 5 years post-loading were 0.01 ± 0.45 mm (bone gain) in the 6-mm group and −0.12 ± 0.93 mm (bone loss) in the 11-mm group (p = .7670). Clinical parameters, including plaque, bleeding on probing and pocket probing depth were not significantly different between the groups, and also technical complications were low.

Conclusion: The clinical and radiographic outcomes of 6-mm short and 11-mm standard-length implants were not different during a 5-year evaluation period.

KEYWORDS

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

1 | INTRODUCTION

Implant dentistry has been accepted as a treatment option with favorable long-term survival and success rates (Hjalmarsson et al., 2016; Moy et al., 2016). Dental Implants with reduced length and diameter have been utilized in sites with limited alveolar bone height and width. More favorable surface structures and alloys used in fabricating dental implants have resulted in dental implants with reduced dimensions, in both diameter and length (Altuna et al., 2016; Thoma et al., 2017). The use of short implants expands treatment options and reduces the need for significant bone augmentation procedures in cases with diminished bone height in edentulous areas, resulting in shorter treatment time, reduced costs and less morbidity. Recent clinical studies with 5-year results on performance of short 6-mm implants suggest similar survival rates to longer implants (Felice et al., 2019; Guljé et al., 2019; Naenni et al., 2018; Rossi et al., 2016; Thoma et al., 2018). It must be noted, however, that in all these studies both groups were affected by or suffered from peri-implant bone loss or biological complications. The question remains if bone loss and complications in the groups with a combination of an augmentation procedure and longer implants must be attributed to the fact that resorbed posterior sites are augmented. Especially in the mandibular posterior region, multiple complications are mentioned with vertical augmentation procedures, irrespective of the surgical technique (Camps-Font et al., 2016). To test in a randomized controlled trial whether short implants perform equally to longer implants, the bone dimensions must be similar and large enough to accommodate short implants as well as longer implants. Although it may not be clinically relevant to test short implants in a large bone height, this eliminates the risk of having to perform bone augmentation procedures, with possible complications, in the control group with longer implants. One could hypothesize, with short implants it is more challenging to obtain initial stability than with longer implants, possibly resulting in early implant loss (de Oliveira et al., 2016; González-Serrano et al., 2018). However, to the authors' knowledge, there are no randomized controlled clinical trials in which short implants are compared with longer implants without the combination of an augmentation procedure in the posterior region of maxilla and mandible. Therefore, the aim of the present randomized controlled trial was to compare clinical performance of implants with a length of 6 mm with implants of standard length (11 mm), inserted in minimally resorbed edentulous spaces in the posterior maxilla and mandible, during a 5-year follow-up period.

2 | MATERIAL AND METHODS

2.1 | Study design

The study outline has been described before in the 1-year report of Guljé et al. (2013) and the 3-year report of Zadeh et al. (2018). Inclusion/exclusion criteria, treatment and evaluation procedures are described in detail in these publications. 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 summary of the procedures utilized in the present 5-year evaluation is described below.

The design was an international multicenter randomized clinical trial. The study groups were:

- 6-mm group: patients to receive two or three 6-mm implants (to replace two or three missing premolars/molars) and a fixed denture prosthesis (Figure 1);
- 11-mm group: patients to receive two or three 11-mm implants (to replace two or three missing premolars/molars) and a fixed denture prosthesis (Figure 2).

Titanium implants (either 6 mm in length or 11 mm in length) with a diameter of 4 mm were used (OsseoSpeed implants, Dentsply Sirona Implants).

The study protocol was registered with clinicaltrials.gov (registration number NCT00545818) prior to its commencement. The study took place at six centers in six countries worldwide. All six study centers obtained approval of their institutional review boards

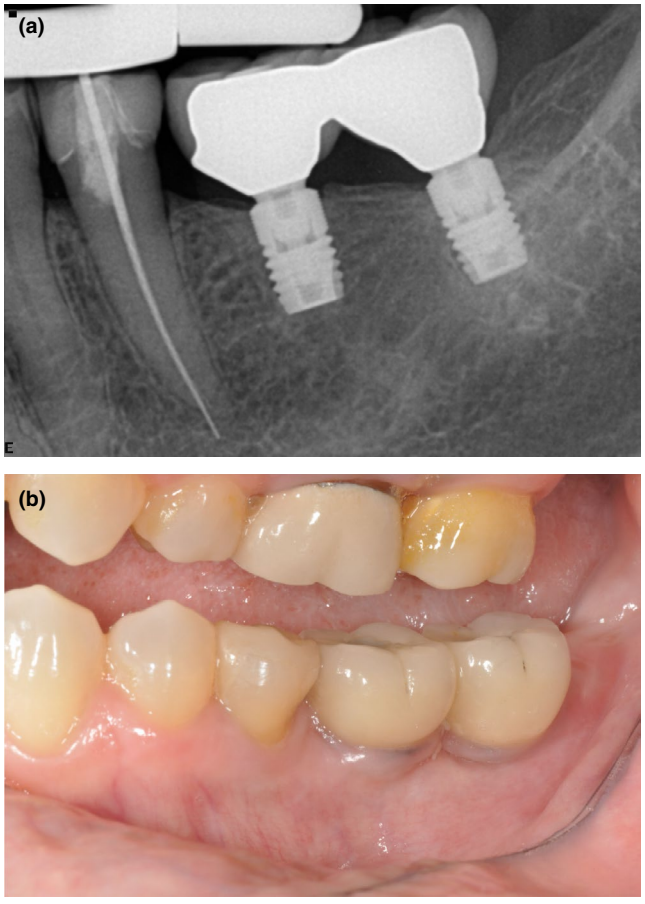

FIGURE 1 Five-year follow-up radiograph (a) and clinical photograph (b) of patient with two 6-mm implants (case images; courtesy of Dr. Homayon Zadeh)

or medical ethics committees prior to the initiation of the study. The enrollment of participants started November 2007 and the last patient was included in June 2010.

2.2 | Surgical and prosthetic procedures

To be included in the study, participants had to have an edentulous space during at least 4 months, spanning 2–3 teeth in the posterior maxilla or mandible and presence of natural teeth, partial prosthesis and/or implants in the opposite jaw in contact with the planned bridge. Patients also had to be able to receive an 11 mm long and 4 mm wide dental implant. Furthermore, each patient had to sign an informed consent. Randomization was done at the time of surgery by opening a sealed envelope containing information if 6-mm implants or 11-mm implants would be used.

Implant surgery was performed under local anesthesia by a single surgeon at each center. Pre-operatively patients were given 2 g of amoxicillin or 600 mg of clindamycin. Post-operatively, the patients were instructed to rinse with chlorhexidine solution twice a day for 10 days. The implants were used with corresponding components and were installed according to the manufacturer's recommendations. Implant placement was performed following a one-stage surgical procedure. Corresponding healing abutments were placed and torqued to 15 Ncm. Six weeks after surgery an acrylic screw-retained provisional restoration was placed in occlusion. A definitive screw-retained fixed partial prosthesis (porcelain fused to metal) was installed on abutments (Uni-Abutment or Angled Abutment) 6 months following the installation of the provisional restoration and was torqued to 15 Ncm.

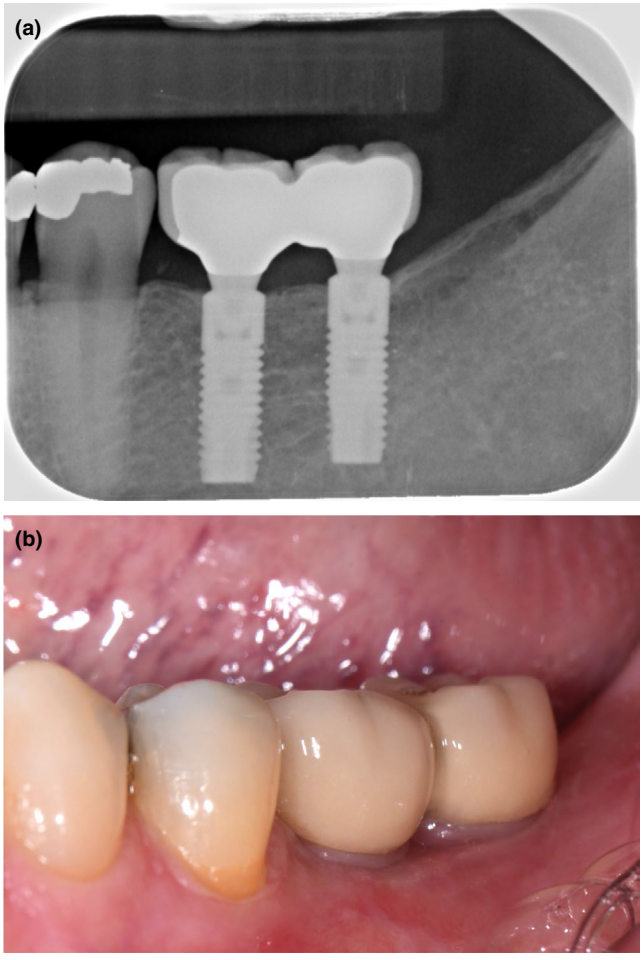

FIGURE 2 Five-year follow-up radiograph (a) and clinical photograph (b) of patient with two 11-mm implants (case images; courtesy of Dr. Stephen Chen)

2.3 | Outcome

Evaluated parameters were:

- Implant failure (noted at any time throughout the 5-year follow-up period);
- Presence of plaque, probing depth (PPD) and bleeding on probing (BoP) was measured on four sites (mesial, distal, buccal, and lingual) around the implant (measured at time of provisional restoration, at time of definitive restoration and at annual follow-up visits);
- Radiographic peri-implant bone level changes (mean of mesial and distal aspects of each implant) with the intraoral radiograph taken at time of provisional restoration, as baseline and compared with the radiograph at 5-year evaluation. An independent, external radiologist evaluated all radiographs. The interproximal threaded profile of the implants, both mesially and distally, had to be clearly visible and the distance was recorded to the nearest 0.1 mm using a 7× magnifying device.
- Prevalence of peri-implant mucositis and peri-implantitis (implant level). The prevalence of mucositis and peri-implantitis at the 5-year evaluation was determined, based on the criteria outlined in the consensus document by Berglundh et al. (2018). The criteria include: (a) bleeding/suppuration on gentle probing, (b) any increased probing depth compared to previous examination (c) interproximal radiographic bone loss greater than 0.5 mm after initial remodeling (loading). Peri-implant mucositis was diagnosed in sites exhibiting bleeding on gentle probing that did not have the radiographic bone loss.
- Presence of technical or biological complications (noted any time throughout the follow-up period).

2.4 | Statistical analysis

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 with a power of 80%. Primary outcome was mean peri-implant bone level change, measured per implant, and a mean difference of 0.5 mm (standard deviation 0.8 mm) was chosen as a meaningful level of difference to be detected. Compensating for a withdrawal rate of 20% resulted in a sample size of 100 patients. Each study center could enroll patients up to a maximum of 33 participants.

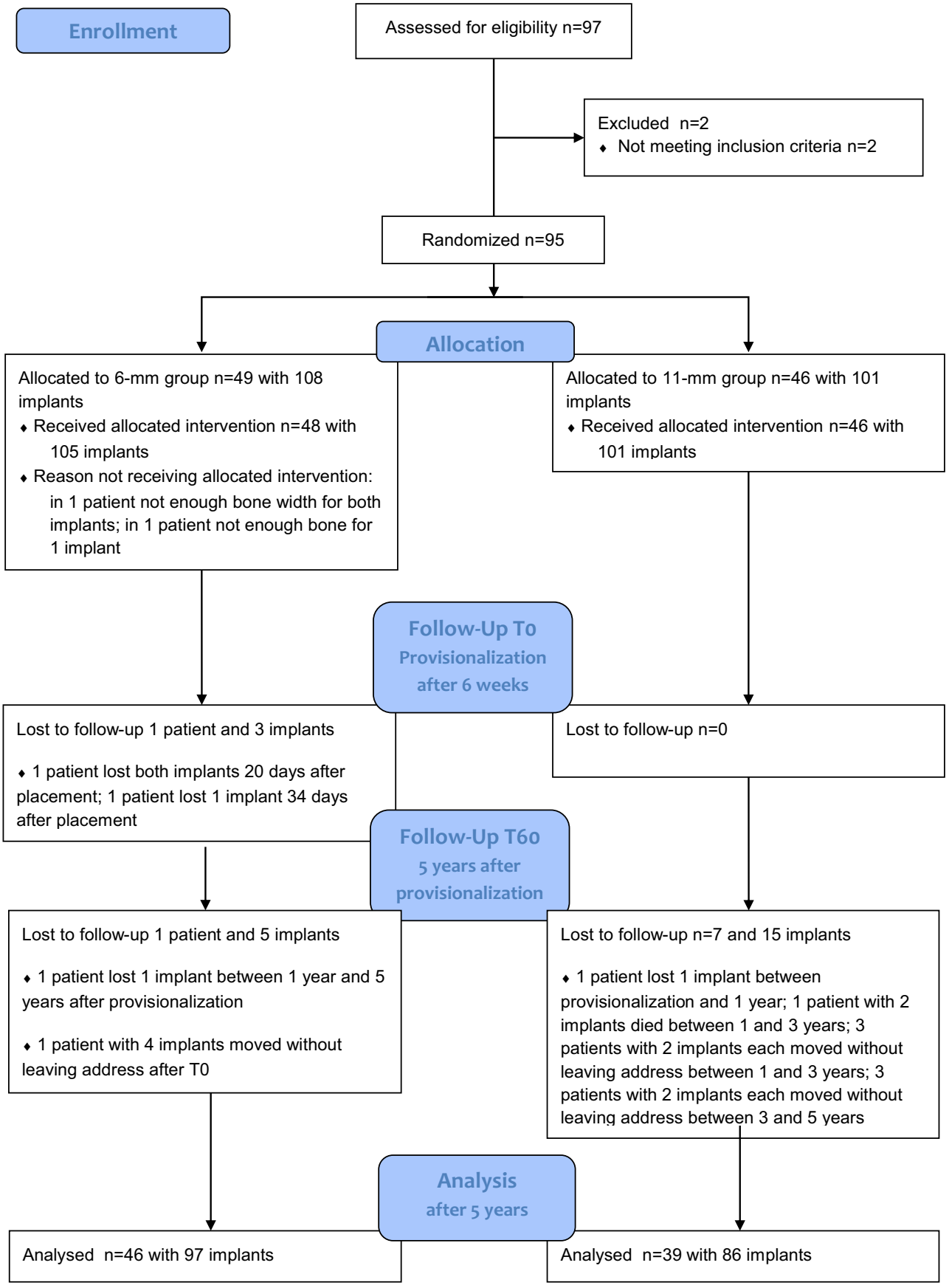

FIGURE 3 Flow diagram of randomized controlled trial on 6-mm implants versus 11-mm implants during 5 years of follow-up with number of patients and number of implants

The study protocol pre-determined the statistical tests.

When testing changes over time a non-parametric statistical approach was applied because of the nature of the data that may not be normally distributed. Wilcoxon signed rank test (exact) was used for continuous data to test if the changes over time within treatment group, for example, marginal bone levels and probing pocket depth, were equal to zero. McNemar's test was used for categorical data, for example, bleeding on probing and plaque. Fisher's exact test was used for categorical data, for example, BOP and implant survival, testing the hypothesis that the percent of BOP and the survival rate are equal in the two treatment groups.

TABLE 1 Baseline characteristics of the 6-mm group (49 participants with 108 implants) and the 11-mm group (46 participants with 101 implants)

	Group 6-mm	Group 11-mm
Mean age in years	55 ± 9, range 26–69	54 ± 10, range 34–70
Gender (number male/female)	21/28	27/19
Received a 2-implant restoration	39	37
Received a 3-implant restoration	10	9

TABLE 2 Mean value (in mm), standard deviation (*SD*), and frequency distribution in (number and percentages) of marginal bone change between loading and 5 years in function

	6-mm group ($n = 94$)	11-mm group ($n = 80$)
mean bone change (*SD*)	+0.01 (0.45)	−0.12 (0.93)
bone loss>−2.0 down	1 (1.1%)	6 (7.5%)
bone loss>−2.0 up to and including −1.5	1 (1.1%)	1 (1.2%)
bone loss >−1.5 up to and including −1.0	1 (1.1%)	0 (0%)
bone loss >−1.0 up to and including −0.5	8 (8.5%)	3 (3.8%)
bone loss >−0.5 up to and including 0.0	47 (50.0%)	33 (41.2%)
bone gain >0.0 up to and including 0.5	27 (28.6%)	28 (35.0%)
bone gain > 0.5 up to and including 1.0	5 (5.3%)	6 (7.5%)
bone gain > 1.0 up to and including 1.5	3 (3.2%)	3 (3.8%)
bone gain > 1.5 up to and including 2.0	1 (1.1%)	0 (0%)
bone gain > 2.0 up	0 (0%)	0 (0%)

3 | RESULTS

Forty-nine patients were randomized to receive 6-mm implants (test group) and 46 patients to receive 11-mm implants (control group). The baseline characteristic of the patients is depicted in Table 1. A flow-diagram from enrollment to 5-year follow-up can be found in Figure 3. A total of 209 implants were inserted: 108 implants in the 6-mm group and 101 implants in the 11-mm group. During the 5-year follow-up, three patients (with 8 implants) were lost to follow-up in the 6-mm group (one patient had not enough bone to place implants, one patient lost both implants, and one patient moved without leaving address).

In the 11-mm group, seven patients (with 14 implants) were lost to follow-up (one patient died, six patients moved without leaving address). Remaining patients could all be evaluated at the 5-year evaluation visit. In the 6-mm group, three subjects lost a total of four implants (three prior to loading and one after 15 months in function). In the 11-mm group, one implant was lost (after 2 months in function). This led to a 5-year implant survival rate of 96.0% and 98.9% for the 6-mm and 11-mm group respectively, with a p-value = .376 indicating no difference between the groups.

From loading to the 5-year follow-up, a mean marginal bone level change of 0.01 ± 0.45 mm (bone gain) in the 6-mm group and −0.12 ± 0.93 mm (bone loss) in the 11-mm group was found (Table 2), without a significant difference between the groups ($p = .767$). At the 5-year evaluation, the radiographs of three implants in the 6-mm group and six implants in the 11-mm group were not of sufficient diagnostic quality to perform a secure analysis. It was decided not to include these implants in the statistical analysis. p-values indicated no differences between the groups concerning presence of plaque, bleeding on probing and pocket probing depth (Table 3). However, the 6-mm group tended to have higher proportion of bleeding than the 11-mm group.

Prevalence of peri-implant mucositis at time of the 5-year follow-up was 44% of the implants in the 6-mm group and 33% of the implants in the 11-mm group ($p = .131$). Prevalence of peri-implantitis

TABLE 3 Clinical measures of implants with plaque (in percentages), implants with bleeding on probing (in percentages) and mean (±*SD*) probing depth at implant level (in mm) at T0 (placement and loading of provisional restoration) and at T60 (5-year follow-up after loading of provisional restoration), and p-value of differences between the groups at both evaluation periods

	Baseline (6 weeks after implant installation)			5-year follow-up		
	6-mm group ($n = 102$)	11-mm group ($n = 101$)	p-value	6-mm group ($n = 98$)	11-mm group ($n = 86$)	p-value
Implants with plaque	12.6%	20.4%	.177	16.3%	7.0%	.068
Implants with bleeding	15.8%	25.5%	.111	43.9%	32.6%	.131
Mean probing depth ± *SD* in mm	2.0 ± 0.8	1.9 ± 0.8	.281	2.0 ± 0.8	2.6 ± 0.7	.298

TABLE 4 Number of technical complications at implant level and patient level (between brackets) during 5 years of follow-up

	6-mm group $n_{implants = 97}$ ($n_{patients = 46}$)	11-mm group $n_{implants = 86}$ ($n_{patients = 39}$)
Fracture of provisional restoration	3 (3)	3 (3)
Fracture of definitive restoration	0 (0)	0 (0)
Fracture of veneering	0 (0)	1 (1)
Fracture of abutment	4 (1)	3 (3)
Fracture of bridge screw	0 (0)	1 (1)
Loosening of abutment	0 (0)	0 (0)
Loosening of bridge screw	5 (3)	10 (5)

at time of the 5-year follow-up was 6% in the 6-mm group and 7% in the 11-mm group ($p = 1.000$).

The reported technical complications were equally divided between the groups, only loosening of bridge screws occurred twice as often in the 11-mm group and was also the most common complication both groups (Table 4).

4 | DISCUSSION

Both 6-mm short implants and 11-mm conventional length implants performed well to support a fixed denture prosthesis in the posterior region of maxilla and mandible. A high implant survival rate, limited peri-implant bone change, healthy peri-implant soft tissues and limited biological and technical complications were noticed during the 5-year functional period.

There was a 5-years implant survival rate of 96.0% and 98.9%, respectively, for the 6-mm and 11-mm group, without any significant differences. Recent clinical studies with 5-year results on performance of short 6-mm implants, compared to longer implants (Felice et al., 2019; Guljé et al., 2019; Naenni et al., 2018; Rossi et al., 2016; Thoma et al., 2018) also showed no significant difference between the short implants and longer implants. Implant survival rates in the short-implant groups varied from 86.7% to 98.5% and from 96.7% to 100% in the longer-implant groups. Although not significantly different, implant survival rate in the short-implant groups was always lower than in the longer-implant groups. This was already seen in the systematic review of Telleman et al. (2011), stating that there was a tendency toward an increasing survival rate per implant length. Analysis of the time point when the implants were lost showed that in the present study three short implants were lost during the osseointegration period, possibly suggesting that the surgical procedure is more critical reaching stability. However, comparison with the aforementioned studies could not confirm this idea, as in these studies short implants were lost throughout the entire evaluation period.

From loading to the 5-year follow-up, a mean marginal bone level change of 0.01 ± 0.45 mm (bone gain) in the 6-mm group and −0.12 ± 0.93 mm (bone loss) in the 11-mm group was found (Table 2), without a significant difference between the groups ($p = .7670$). Bone loss in the present study can best be compared with the 5-year follow-up study of Thoma et al. (2018) and Guljé et al. (2019), because the same implant system and endpoints were evaluated. Thoma et al. (2018) reported a mean marginal bone level change of −0.12 ± 0.54 in the 6-mm group and −0.18 ± 0.96 in the group with longer implants, without a significant difference between the groups. Guljé et al. (2019) reported a mean marginal bone level change of −0.12 ± 0.36 mm and −0.14 ± 0.63 mm in the 6-mm group and the 11-mm group, respectively, without a significant difference between the groups. These bone level changes throughout 5 years of functioning were very limited. These results corroborate with the outcomes of the present study. Conical-connection implants with platform-switching between implant and abutment, together with an optimum surface roughness at the neck of the implant, appear to provide optimal conditions by which to maintain a stable peri-implant marginal bone level (Cooper et al., 2019). Notwithstanding the much less bone-to-implant contact area of short implants, they are still able to withstand functional forces equally well as longer implants.

The presence of plaque is limited, but bleeding on probing is more commonly found at the 5-year evaluation (Table 3). It must be said that there was no distinction in grades of bleeding; and that any isolated bleeding spot was counted as bleeding. Taking into account the low values of mean pocket probing depth in both groups, one could conclude that peri-implant soft tissues are relatively healthy, probably due to the yearly oral hygiene regime patients were subjected to within the scope of this study. Prevalence of peri-implantitis at time of the 5-year follow-up was 6% in the 6-mm group and 7% in the 11-mm group. In the publication of Thoma et al. (2018), it was mentioned that there was 2% peri-implantitis in the 6-mm group and 0% in the longer-implant group. Guljé et al. (2019) observed no peri-implantitis in either groups. These numbers are low and very much alike the present study, although it should be noted that these studies used a slightly different definition of peri-implantitis. In both groups, technical complications occurred during the 5-year follow-up period (Table 4). The most common complication in both groups was loosening of bridge screws connecting the prosthesis to the abutments. In the 11-mm group the loosening occurred twice as often. No explanation could be found for this finding since there is no difference in absolute crown height and length of screws between the groups. Replacement of fractured abutments and the handling of complications related to the definitive restorations could all be easily managed chair side.

Ten patients (three in the 6-mm group and seven in the 11-mm group) of the initial 95 patients were lost to follow-up at the 5-year evaluation. At the 1-year evaluation marginal bone level change was −0.06 mm and −0.02 mm for respectively the 6-mm group and the 11-mm group, without a significant difference ($p = .48$). At the 5-year evaluation marginal bone level change was + 0.01 mm and −0.12 mm for respectively the 6-mm group and the 11-mm group, without a significant difference ($p = .77$). With such minimum bone changes

between 1 and 5 years (in both groups) there is no reason to believe that "lost to follow-up patients" could have influenced mean marginal bone level change in a clinically relevant matter.

No analysis was performed if there was a possible difference in outcomes between the different centers. One reason is that the number of patients was not equally divided between the centers, making exploration for significant differences hardly reasonable. Next to this, randomization was performed using a block randomization sequence to provide equal distribution of subjects treated with 6 mm or 11 mm implants at each center. Also at each center not only the same protocol for surgery and prosthetics was prescribed, but also for aftercare. Therefore, the authors think that a priori there is no reason to suspect that there will be any qualitative differences between the centers regarding any of the efficacy variables nor regarding the safety variables.

Implant survival is also a relevant variable in comparison of clinical performance of dental implants and could also have been used as primary outcome. The authors have chosen to use peri-implant bone level changes as primary outcome, because it is a predictor for possible implant loss in the future. In this way, in an earlier stadium significant differences can be calculated and conclusions drawn.

The aim of the study was to compare short 6-mm implants with conventional 11-mm implants. However, the results from this study cannot be directly compared with most of the other studies on short implants, since most studies have been focusing on short implants restored with single crowns aiming at evaluating the more challenging clinical situations. Thus, we cannot, based on our study results, determine if short implants will perform equally, as standard-length implants for single tooth restorations. Previously, it was recommended to splint restorations to distribute forces, especially with shorter implants (Guichet et al., 2002). However, in a more recent study, comparing splinted and non-splinted restorations, no significant differences were found (Vigolo & Zaccaria, 2010). In the studies of Thoma et al. (2018) and Guljé et al. (2019) non-splinted single tooth restorations were made, showing the same promising results, as in the present study. One proposed advantage of non-splinted restorations is to provide a better approach to oral hygiene. Another limitation of the study design is that the 6-mm implants were inserted in minimally resorbed edentulous spaces in the posterior maxilla and mandible, meaning that the results cannot be extrapolated to extremely resorbed posterior edentulous spaces. The present data did not find any correlations between crown-to-implant ratio and implant survival or marginal bone level changes (data not shown). However, it is important to note that since the implants were placed in minimally resorbed alveolar bone, the implants were restored with prostheses with relatively short clinical crown height spaces.

A strength of the present study is its design. Being a prospective, randomized multicenter study, the results are regarded to be relatively high clinical evidence, supporting the validity of the measured outcomes. Another strength is the large number of patients taking part in the study, generating data with high statistical power.

5 | CONCLUSIONS

The present study found no significant difference between the clinical performance, including peri-implant bone level changes and implant survival, of implants with 6 mm and 11 mm lengths, inserted in minimally resorbed edentulous spaces in the posterior maxilla and mandible, during a 5-year follow-up period.

AUTHOR CONTRIBUTIONS

Felix L. Guljé: Conceptualization (equal); Data curation (lead); Formal analysis (equal); Investigation (equal); Methodology (equal); Project administration (equal); Validation (equal); Visualization (equal); Writing-original draft (lead). **Henny J. A. Meijer:** Conceptualization (equal); Data curation (equal); Formal analysis (equal); Methodology (equal); Project administration (equal); Validation (equal); Visualization (equal); Writing-original draft (equal). **Stephen Chen:** Conceptualization (equal); Data curation (equal); Formal analysis (equal); Investigation (equal); Methodology (supporting); Project administration (equal); Validation (equal); Visualization (equal). **Homayoun H Zadeh:** Conceptualization (equal); Data curation (equal); Formal analysis (equal); Investigation (equal); Methodology (supporting); Project administration (equal); Validation (equal); Visualization (equal); Writing-review & editing (equal). **Paul J. Palmer:** Data curation (supporting); Investigation (equal); Project administration (equal); Validation (supporting); Writing-review & editing (supporting). **Ingemar Abrahamsson:** Data curation (supporting); Investigation (equal); Project administration (equal); Validation (supporting); Writing-review & editing (equal). **Christopher A. Barwacz:** Data curation (supporting); Formal analysis (supporting); Investigation (supporting); Project administration (equal); Validation (equal); and Writing-review & editing (equal). **Clark M. Stanford:** Conceptualization (equal); Data curation (equal); Formal analysis (equal); Investigation (equal); Project administration (equal); Validation (equal); Writing-review & editing (equal).

DATA AVAILABILITY STATEMENT

N/A.

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SUPPORTING INFORMATION

Additional supporting information may be found online in the Supporting Information section.

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