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ORIGINAL ARTICLE

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An open, randomised, multi-centre study, comparing straight and tapered apex implants design, in partially and totally edentulous maxillae

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ABSTRACT

The design of the commercially available implant OsseoSpeed® (control) was changed to a tapered apex with a smaller apical diameter; OsseoSpeed® TX (test).

Objective: The present study evaluated the clinical outcome of marginal bone level as primary outcome, and cumulative implant survival rate, primary stability and condition of the peri-implant mucosa as secondary outcomes, one year after loading.

Material and methods: 92 subjects (150 implants, ten centres), with partially or totally edentate maxillae were randomized to receive either test or control implants. One to six implants were placed in each subject using a one-stage surgical procedure. Subjects received a permanent prosthesis 10–12 weeks after implant placement and were followed for one year

Results: 47 subjects in the test group received 82 implants and 45 subjects in the control group received 68 implants. Marginal bone level alterations from loading to 1-year follow-up was -0.02×0.41 mm (mean × SD) and -0.03×0.38 mm (mean × SD) for the test and the control group, respectively, indicating no difference between the groups. Non-inferiority was declared as confidence interval for the difference between control and test implants was no worse than 0.5 mm. The CSR was 98.8% in the test group and 100% in the control group, with no statistically significant difference between the groups.

Conclusions: Change of the apical design of a commercially available implant showed no significant effect on marginal bone level and CSR compared to the control implant. Missing data and many investigators may have influenced on the result.

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KEYWORDS
Dental implant design; survival rate; marginal bone level; randomised clinical trial

Introduction

Endosseous oral implants have today become a reliable treatment modality for patients with lost or compromised dentitions. Predictable long-term results have been reported for treatment of complete and partial edentulism, using various implant systems [1–3].

Astra Tech Implant System is a well-established implant system with reliable and reproducible results [4–11]. The system includes the OsseoSpeed implant (control), which is a screw-shaped and self-tapping implant made of commercially pure titanium with a moderately rough surface topography [12]. Studies of the control implant have shown good long-term results, e.g. maintenance of marginal bone levels and high survival rates [13–15]. However, there were some demanding clinical applications that required further development of the design. These challenging clinical situations were;

1. Facilitate installation in under-prepared osteotomies in low-density bone.
2. Simplify installation in extraction sockets.
3. Allow placement in positions where adjacent teeth apices are converging unfavourably, thus reducing mesial-distal distance.

In order to meet the above-mentioned challenges, the OsseoSpeed TX (test) were designed with a more tapered apex than the control implant.

Implant design is one of six factors that have been pointed out as important for the establishment of osseointegration of titanium implants [16]. A change of the implant design may influence the clinical outcome. It is therefore important to evaluate and verify the clinical outcome in controlled clinical studies before any final conclusions can be drawn regarding the clinical performance of the implant.

The aim of the present study was therefore, to evaluate the test implant compared to the control implant with regards to I) marginal bone level changes, one year after loading, as primary outcome II) cumulative implant survival rate, III) initial implant stability and IV) bleeding on probing and pocket depths as secondary outcomes. The hypothesis of this study was that the changed design of the implant

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apex would not influence the clinical outcome of the implant after one year in use.

Materials and methods

This study was designed as an open, randomised, multicentre study with a one-year follow-up period. The study was approved by the Regional Ethics Review Board (Dnr. 453-10). The investigation was conducted according to the principles of the World Medical Association Declaration of Helsinki – Ethical Principles for Medical Research involving Human Subjects and the CONSORT guidelines. The study was registered by the US National Institutes of Health Clinical Trial Registry under the number NCT01324778. Written Informed Consent was obtained from all subjects prior to any examination carried out for study purposes. Study data were securely stored at Astra Tech Company with restricted access.

Subjects

A total of 10 Swedish centres, both specialist and general practices, participated in the study. The ten centres were conveniently sampled. Between March 2011 and August 2013 consecutive subjects with partially or totally edentate maxillae seeking dental implant rehabilitation were asked to participate in the present investigation. Inclusion criteria were; provision of informed consent, female/male aged 18 years and over, history of edentulism in the study area of at least 3 months and a need for implant(s) replacing missing tooth/teeth in the maxilla. Furthermore, as judged by the investigators, the subject should be suitable for one stage surgery and have a 'functional' opposing dentition.

Exclusion criteria were; ongoing malignancy, history of radiation to the head and neck region and/or chemotherapy within 5 years prior to surgery, uncontrolled diabetes mellitus and/or present alcohol and/or drug abuse.

The study was powered to reach 90% power to detect a difference of 0.5 mm between the treatment groups which resulted in a need of 170 implants. A total of 92 (150 implants) subjects were recruited to the study. Due to difficulties in recruiting study patient enrolment was stopped after 150 included implants in order to not have an extended study period. For demographic characteristics and disposition of subjects see Table 1. Subject eligibility was established before treatment randomisation. A web-based randomisation tool was used to randomise subjects either to receive test or control implants. Subjects were randomised strictly sequentially in blocks and stratified by centre treatment group 'test implant' or control implant in a 1:1 fashion.

Implants

The control implants in the present study were screw-shaped and self-tapping with a micro thread on the coronal aspect of the implant. The test implants had the same features as control implants, but with the difference that the test implants had a tapered apex (Figure 1). The implant diameters available in this study were 3.5, 4.0 and 5.0. Provided in lengths, 6 mm (only available in diameter 4.0 mm) and 8, 9, 11, 13, 15, 17 mm (available in diameters 3.5, 4.0 and 5.0 mm).

Table 1. Subject population and disposition.

	Test	Control	Total
Population			
No. of patients randomised	47	45	92
No. of implants randomised	82	68	150
Demographic characteristics			
Sex (% of subjects)			
Male	17 (36)	21 (47)	38 (41)
Female	30 (64)	24 (53)	54 (59)
Age at inclusion (SD)			
Mean years	53 (±16.36)	50 (±18.08)	52 (±17.17)
Range	18 to 79	18 to 77	18 to 79

Figure 1. Test implant/control implant. Copyright Dentsply Sirona Implants.

Clinical PROCEDURE

Preoperative analgesics (1 g paracetamol) and antibiotics (2 g amoxycillin) were given. In case of allergy to penicillin (600 mg clindamycin) was given. One-stage (transmucosal) implant surgery was performed under local anaesthesia and sterile conditions. A mucoperiosteal flap was raised with or without releasing incisions. Bone quality and quantity was determined during surgery as described by *Lekoholm & Zarb*[17]. Depending on bone quality, specific drilling protocols as recommended by the manufacturer, were followed (Figure 2).

All subjects received at least one test or control implant. One to six implants were placed in the maxilla of each subject. Primary implant stability was assessed by ISQ (Osstell AB, Sweden). The measurements were made both bucco-palatally and mesio-distally for each implant and an average ISQ value for each implant was calculated based on these measurements. A healing abutment was mounted, and the flap was sutured. Postoperatively, 0.1% chlorhexidine rinse twice

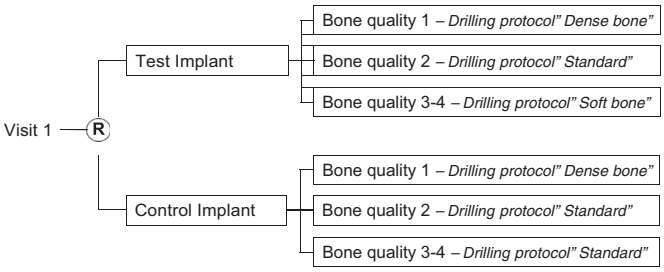

Figure 2. Study flowchart drilling protocol according to the manufacturer. R: Randomisation.

daily for 10 days and prescription free analgesics were recommended for pain control.

Screw or cemented retained restorations were delivered according to the manufacturer's instructions. All subjects received their permanent prostheses 10–12 weeks after implant placement and the implants were loaded.

Intraoral radiographs and clinical photos were taken at the time of surgery and at each follow-up visit, in addition any complications were recorded.

Implant stability was also manually examined after implant placements and at time of loading. The last follow-up visits in the study took place one year after functional loading. During this visit the status of the periimplant mucosa (Bleeding on Probing and Probing Pocket Depth) was evaluated.

Radiographic examination and evaluation of marginal bone level

Digital intraoral periapical radiographs were taken after implant placement, at prosthetic restoration delivery (i.e. radiographic baseline) and one year after prosthetic delivery. To ensure the reproducibility between the radiographic examinations, radiographs were taken with a paralleling technique using commercially available sensor holders. The threaded profile of the implant, both mesially and distally, had to be clearly visible. Marginal bone level alterations were determined from the radiographs and expressed as the difference from a reference point on the implant to the most coronal bone-to-implant contact on the mesial and distal aspect of the implant (Figure 3). A 7x magnifying device was used. For consistency in readings the same very experienced specialist in oral radiology performed all the measurements. Intra-rater reliability was not controlled in this report but has been evaluated previously by the same radiologist showing a difference of 0.04 mm (SD, 0.33) between two readings [18].

Probing pocket depth (PPD) and bleeding on probing (BOP)

Probing pocket depth was measured on four surfaces around the implant (mesial, distal, buccal and lingual) using a periodontal probe. Bleeding was registered as presence of bleeding on probing. A mean value was calculated for each implant.

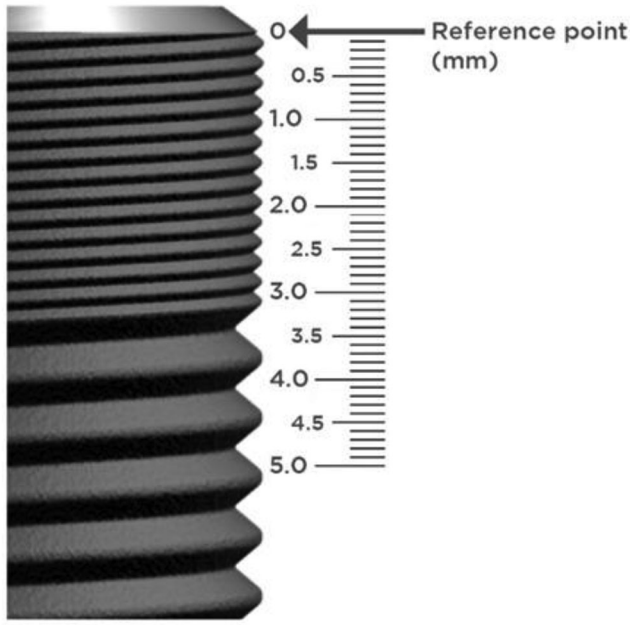

Figure 3. Reference point at the top of the implant. Copyright Dentsply Sirona Implants.

Statistical analyses

All registered parameters were stored in a database, in accordance with the ethical approval. Fisher's exact test was used for comparing the outcome of the binary variables Implant Survival and Bleeding on Probing (at each time point of interest) between the test group and the control group. Mann–Whitney U-test (Wilcoxon rank sum equivalent) was used for analysing differences between the two groups regarding the continous variables Marginal Bone Level alterations, ISQ and Probing Pocket Depth results. A two-sided *p*-value $<.05$ was considered statistically significant. For MBL, two-sample t-test was used to calculate the one-sided 97.5% confidence interval for the difference between the two implant designs. If the confidence interval shows that the test implant is no worse than 0.5 mm compared to control implant, non-inferiority will be declared.

Statistical tests were conducted with SPSS (IBM Corp., Armonk, NY) and Excel (Microsoft, Redmond, WA, USA) software. The statistical methods used were recommended, evaluated and reviewed by an independent statistician.

Results

Subjects and implants

Disposition of subjects and implants are presented in Table 2. Distribution of implant length and diameter is presented in Table 3.

I) MARGINAL BONE LEVEL (implant level)

On implant level, the mean marginal bone level at permanent restoration was 0.46 ± 0.69 mm (mean ± SD) for the test group and 0.25 ± 0.41 mm (mean ± SD) for the control group,

Table 2. Disposition of subjects and implants.

Centre	Number of Subjects	Number of Implants	Number of Subjects at 1 yr	Number of Implants at 1 yr
1	12	16	11	13
3	12	13	11	12
4	7	7	7	7
6	16	27	15	26
8	3	3	3	3
11	1	3	0	0
13	10	13	10	12
14	16	40	16	40
17	10	16	10	16
19	5	12	4	10
Total	**92**	**150**	**87**	**139**

Table 3. Distribution of implant lenghts and diameters.

TEST IMPLANT	IMPLANT LENGHT (mm)							
IMPLANT DIAMETER (mm)	6	8	9	11	13	15	17	TOTAL
3.5S			7	21	10	1		39
4.0S		1	9	14	15			39
5.0S			1	3				4
TOTAL		**1**	**17**	**38**	**25**	**1**		**82**

CONTROL IMPLANT	IMPLANT LENGHT (mm)							
IMPLANT DIAMETER (mm)	6	8	9	11	13	15	17	TOTAL
3.5S			7	13	11			31
4.0S		2	8	15	9	2		36
5.0S					1			1
TOTAL		**2**	**15**	**28**	**21**	**2**		**68**

showing no statistically significant difference between the two groups.

The mean marginal bone alterations from permanent restoration (baseline) to 1-year follow-up were −0.02 ± 0.41 mm (mean ± SD) and −0.03 ± 0.37 mm (mean ± SD) for the test and the control group respectively, with a parametric 95% confidence interval (−0.136, 0.137). No statistically significant difference between the two groups was evident (Figure 4). Data was missing from 10 implants in the test group and from 2 implants in the control group.

II) MARGINAL BONE LEVEL (subject level)

On subject level, the mean marginal bone level at permanent restoration was 0.34 ± 0.61 mm (mean ± SD) for the test group and 0.23 ± 0.32 mm (mean ± SD) for the control group, showing no statistically significant difference between the two groups.

The mean marginal bone alterations from permanent restoration (baseline) to 1-year follow-up was −0.06 ± 0.42 mm (mean ± SD) and −0.06 ± 0.36 mm (mean ± SD) for the test and the control group respectively, with a parametric 95% confidence interval (−0.176, 0.165). No statistically significant difference between the two groups was evident. Data was missing from 4 subjects in the test group and from 1 subject in the control group. As the confidence interval showed that the test implant was no worse than 0.5 mm compared to the control implant, on booth implant and subject level, non-inferiority was declared.

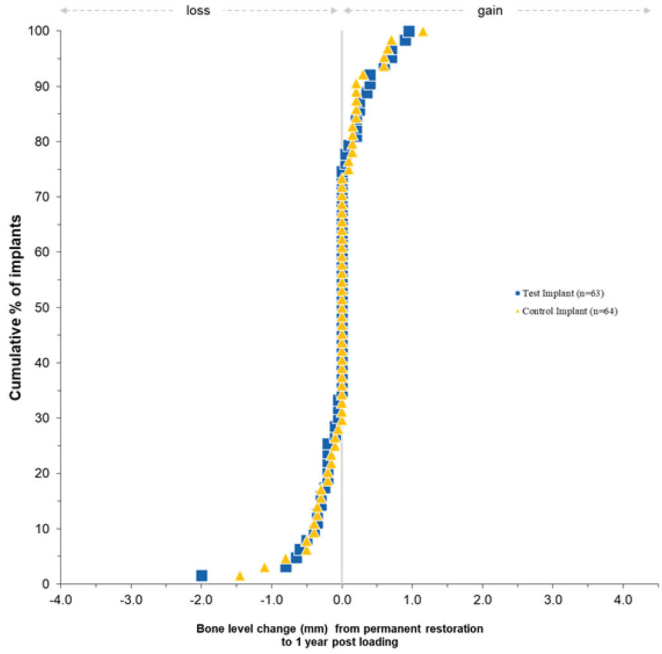

Figure 4. Mean marginal bone level changes from permanent restoration to 1-year post loading at implant level. Cumulative graph showing interproximal bone level changes between permanent restoration delivery and 1-year follow-up after loading. Each marker represents one implant. Negative value is bone loss. Positive value is bone gain. Test implant: Data is missing from 10 implants in the figure due to no MBL values being available from either loading or one - year follow-up. Control implant: Data is missing from 2 implants in the figure as no x-rays were available from loading.

III) cumulative implant survival rate

In the test group 47 subjects received 82 implants, and in the control group 45 subjects received 68 implants. In the test group one implant was lost 54 days after placement during the observation period due to lack of osseointegration. One subject needed total oral rehabilitation in the lower jaw and was discontinued from the study. In addition, two subjects were lost to follow-up (did not show up on their appointed visit) and one subject deceased, resulting in 43 subjects with 73 study implants in the test group. In the control group there was no failure during the entire study period. However, there was one subject lost to follow-up (did not show up on its appointed visit) after baseline, resulting in 44 subjects with 66 study implants in the control group. Subject/implant flow chart is presented in Figure 5.

The cumulative implant survival rate was 98.8% in the test group and 100% in the control group. There was no statistically significant difference in survival rate between the two groups.

IV) resonance frequency analysis

ISQ mean values, as measured by Osstell, at implant placement was 72.77 ± 8.42 (mean ± SD) in the test ($n = 79$) group and 73.09 ± 6.53 (mean ± SD) in the control ($n = 68$) group. The median value for the test group was 75.0 (range 47.0–87.5) and 75.0 (range 56.5–84.0) for the control group. There was no statistically significant difference between the two groups.

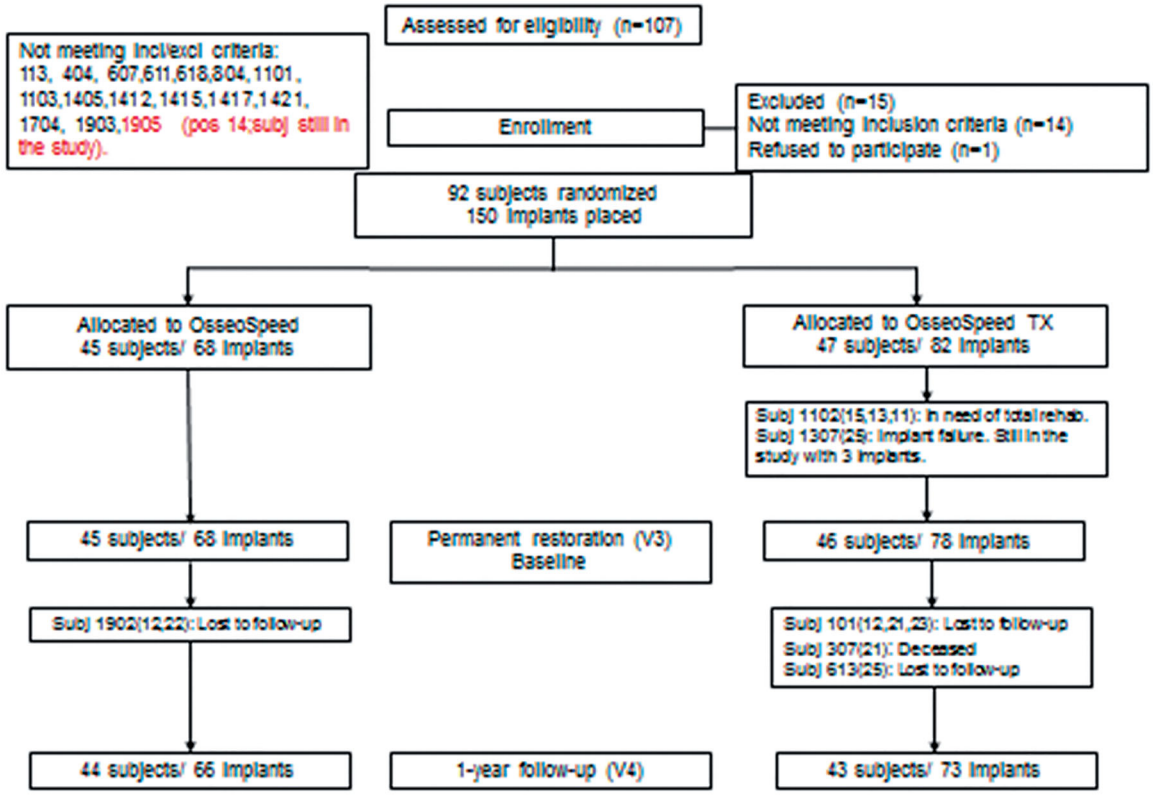

Figure 5. Subject/implant flow chart.

V) bleeding on probing and probing pocket depth

Bleeding on Probing (BOP) at implant level was detected in 38.5% in the test group ($n = 65$) and in 31.7% in the control group ($n = 60$). No statistically significant difference was found between the two groups.

After one year of loading the mean Probing Pocket Depth (PPD) at implant level was 2.57 ± 0.98 mm (mean ± SD) and 2.38 ± 0.84 mm (mean ± SD) in the test ($n = 64$) and control ($n = 60$) group respectively. There was no statistically significant difference between the two groups.

Additional results

During surgery, 73% of the implant sites in the test group and 69% of the implant sites in the control group were assessed to belong to bone quality group 3 and 4, as defined by *Lekholm & Zarb* (Table 4).

One abutment fracture occurred in the test group and two in the control group. In all cases with abutment fracture a new abutment and crown was manufactured.

There were two porcelain fractures of crowns in each group. Only one of those crowns had to be remade. The other porcelain fractures could all be repaired and/or polished.

Table 4. Bone quality and quantity at implant sites.

TEST IMPLANT	BONE QUALITY				
BONE QUANTITY	1	2	3	4	Total
A		6	10	1	17
B		11 (1)	38	1	50
C		4	6	1	11
D		1	2	1	4
E					
Total		**22**	**56**	**4**	**82**
CONTROL IMPLANT	BONE QUALITY				
BONE QUANTITY	1	2	3	4	Total
A		7	4	1	12
B		10	30	1	41
C		4	10		14
D			1		1
E					
Total		**21**	**45**	**2**	**68**

Implant failure in parenthesis.

Discussion

The present study evaluated the outcome of two commercially available implant designs after one year in function. The study was designed as a non-inferiority study, testing the hypothesis that there would be no clinically relevant differences between test and control one year after loading. The analysis showed no statistically significant differences between the two implants after one year in use, i.e. the hypothesis was not rejected, and non-inferiority was confirmed.

For both groups there were only minor marginal bone loss as measured from loading to one-year follow-up. The results are in line with previous studies [19–21]. There was no statistically significant difference between the test and control implants. A finding indicating that the tapered apical design did not exert any deleterious effect on the marginal

bone. The tapered apical design can facilitate implant placement between adjacent natural teeth with limited inter apical space or in areas where the insertion of a cylindrical implant would lead to perforation of the buccal bone plate. However, missing data were present in both groups on implant and subject level, four to five times higher in the test group. Missing data may not mean absence of disease. Hence, the results must be interpreted with caution. The stable marginal bone conditions may be due to the conical design of the abutment-implant connection. It has previously been shown that this type of connection exerts a favourable load transfer to the marginal bone and prevents leakage of bacteria in the abutment-implant zone [22,23].

The CSR was high for both groups and there was no statistically significant difference between the test and control implant. The CSR figures in the present study are similar to those reported in other studies [5,8,9,19,24]. The results in the present report indicates that a change in the macro design of the apex of the test implant seems not to have any major influence of implant survival after one year in use. At least in the present investigation. A conclusion that may not be valid in a larger population. However, the two patient groups were fairly equal regarding gender and age.

The implant sites for both groups had a similar distribution of bone quality type 3 and 4. The mean ISQ values showed good primary stability for both groups, well above the cut off values for implant failures [25], which maybe have contributed to the implant survival rates seen in the present study. A drawback of the RFA measurements is that the investigators were not inter nor intra calibrated regarding reliability. However, it is a method that has shown good reliability and validity [26,27]. Menicucci et al. showed in a clinical study that tapered implants generated improved primary implant stability compared to parallel walled implants [28]. The test implant in the present study was only tapered in the apical portion. The change was perhaps too small to have any influence on the primary stability as compared to the control implant.

There was a relatively high loss of data for BoP and PPD. Almost twice in the test group than the control group. A fact that reflects the difficulties to perform multicentre studies in routine clinical settings. A general drawback in the present report with many investigators is the possibility to get biased measurements, especially when the clinicians were not calibrated regarding inter and intra reliability. The purpose of the present study was however to perform it in a routine clinical practice establishing a mix of general practitioners and specialists and thereby mimic the clinical reality. Advantages of the present report is that the patients were randomised to control or test implant, the patients were blinded, and marginal implant design and surface properties were the same. The radiologic assessment was also performed by one experienced radiologist presenting good inter-rater reliability in another study. A fact that may give reliable readings in the present report.

BoP was in the same range reported in previous studies [29,30]. In the literatire review by Derks and Tomasi they reported a prevalence of peri implant mucositis ranging from 19–65% and estimated a weighted mean prevalence of peri implant mucositis to 43%. The BoP results are supported by the low mean PPD in both groups, which may reflect the stable marginal bone level. It has been shown that there is an association with BoP and increased pocket depth[31]. One plausible explanation for the similar results related to condition of marginal soft tissue for the two implant types is that no alteration was made to the coronal part of the test implant.

Conclusion

This one-year follow-up study showed that an alteration of the apical design, introducing a more tapered apex than the control implant, had no significant effect on MBL and CSR. Limitations of the present study were many investigator (clinicians) which may have given biased measurements. The effect of changed implant design on clinical success requires further randomised clinical trials with larger patient groups, control of inter and intra reliability and validity, and longer follow up time.

Acknowledgements

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Disclosure statement

The authors declare no conflict of interest in relation to this manuscript.

Author contributions

Concept/Design (C-JI), Data analysis/interpretation (C-JI, JL, SE, KJJ, PA), Drafting article (C-JI), Critical revision of article (C-JI, JL, SE, KJJ, PA), Approval of article (C-JI, JL, SE, KJJ, PA), Data collection (C-JI, JL, SE, KJJ, PA). All five authors meet the four CDI criteria for author credit.

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