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Soft tissue changes and crestal bone loss around platform-switched implants placed at crestal and subcrestal levels: 36-month results from a prospective split-mouth clinical trial

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Abstract

Objective: The aim of the present 36-month prospective split-mouth clinical trial was to investigate the peri-implant soft tissue changes and crestal bone loss (CBL) around delayed loaded platform-switched implants placed at crestal and subcrestal levels.

Material and methods: Twenty-three individuals with bilaterally missing either mandibular first or second molars were included. The test and control sites were defined as follows: (i) test sites: implants placed 2 mm below the alveolar crest (subcrestal); (ii) control sites: implants placed at bone level (crestal). Forty-six implants (23 implants in test sites and 23 in control sites) were placed in the center of the healed alveolar ridge in the posterior mandible. Peri-implant bleeding on probing (BOP), probing depth (PD \geq 4 mm), and CBL was compared at 6, 18, and 36 months of follow-up. $P < 0.05$ was considered statistically significant.

Results: Sixteen males and seven females with a mean age of 43.5 years (29–50) were included. In the control group ($n = 23$), the highest mean percentage of sites that showed BOP and PD \geq 4 mm were at 6 months (7.4% and 1.4%, respectively). In the test group ($n = 23$), the highest mean percentage of sites that showed BOP and PD \geq 4 mm were at 6 months (2.4% and 1.2%, respectively). The total amount of CBL around crestal and subcrestal implants after 36 months of loading was 0.45 ± 0.2 and 0.3 ± 0.2 mm, respectively. At all follow-up intervals, all intragroup and intergroup comparisons showed no significant differences in BOP, PD \geq 4 mm, and CBL around implants placed at crestal and subcrestal levels.

Conclusion: Up to 36 months of follow-up, soft tissue parameters and crestal bone levels can remain equally stable around dental implants placed at crestal and subcrestal levels. The need for long-term follow-up clinical trials is also emphasized.

Maintenance of crestal bone height plays an essential role in the long-term success and survival of dental implants (Etoz et al. 2014); and stability of peri-implant crestal bone is an essential prerequisite for the integrity of overlying soft tissues (Aimetti et al. 2015). One of the major reasons for CBL around implants in the long-term is peri-implant tissue inflammation, which commonly occurs as a result of poor oral hygiene maintenance (Kozlovsky et al. 2007; Elemek & Almas 2014). Platform switching (PS) is an implant platform-reducing (switching) design where the diameter of the abutment is smaller than the implant neck (Aimetti et al. 2015). Such implant design has been associated with decreased means of CBL compared with platform-matched implants.

This could be due to the internally repositioned implant-abutment junction (IAJ), which limits bone resorption by bringing out the bacteria and the inflammatory cell infiltrate away from the adjacent crestal bone and by shifting the stress concentration inward (Maeda et al. 2007; Canullo et al. 2010). However, according to some authors, peri-implant mucosal thickness is a more important factor (than PS) that influences CBL around dental implants (Vervaeke et al. 2014; Linkevicius et al. 2015).

In addition to PS, the depth of placement and location of the IAJ in relation to the crest of the bone could affect the amount of peri-implant CBL (Schwarz et al. 2015). A recent clinical study (Aimetti et al. 2015)

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investigated the soft tissue changes around subcrestally placed platform-switched dental implants. In this study, 58 dental implants were placed and were loaded within 8 months of placement (Aimetti et al. 2015). The results showed that subcrestal placement of platform-switched implants helps in preserving crestal bone and esthetics around dental implants. Moreover, it has been reported that dental implants placed approximately 2 mm below the alveolar crest (subcrestal placement) are associated with significantly less CBL as compared to implants placed at bone level (crestal placement) (Calvo-Guirado et al. 2014, 2015; Romanos & Javed 2014; Kutan et al. 2015). Calvo-Guirado et al. (Calvo-Guirado et al. 2014) compared the CBL placed immediately in a crestal or subcrestal position in postextraction sockets in a canine model. The results suggested that implant positioning 2 mm apically is associated with less resorption of the lingual and buccal crest of alveolar bone (Calvo-Guirado et al. 2014). An explanation in this regard is that subcrestal placement of the implant–abutment interface helps in maintaining the texture and tonality of the soft tissues and also favors the reestablishment of favorable marginal tissue architecture than crestally placed implants (Novaes et al. 2009). However, contradictory results have also been reported (Pellicer-Chover et al. 2016). In a recent experimental study on dogs with ligature-induced peri-implant inflammation, Huang et al. (Huang et al. 2015) investigated the effect of placement depth on peri-implant CBL. The results showed that CBL was significantly higher with subcrestal as compared to crestal placement during the plaque accumulation period (Huang et al. 2015). Moreover, results from a prospective randomized controlled clinical trial (Palaska et al. 2016) and a recent systematic review (Al Amri 2016) showed no statistically significant difference in CBL around crestally and subcrestally placed dental implants. Similar results were reported by Koh et al. (Koh et al. 2011) and Romanos et al. (Romanos et al. 2015).

In the present split-mouth clinical trial, it was hypothesized that dental implants placed 2 mm subcrestally exhibit a stable soft tissue profile and undergo significantly less CBL compared with implants placed at bone level. Based on this hypothesis, the aim of the present 36-month follow-up prospective split-mouth clinical trial was to investigate the peri-implant soft tissue changes and CBL around delayed loaded platform-switched implants placed bilaterally in the posterior

mandibular area at the bone level and 2 mm below the bone crest.

Materials and methods

Ethical guidelines

This single-center prospective clinical study was conducted in accordance with the revised World Medical Association Declaration of Helsinki and was approved by the research ethics committee of the college of Applied Medical Sciences, King Saud University (Saudi Arabia). An information sheet describing the objectives and methods of this study was presented to all participants. Consenting individuals were informed about possible risks and benefits and were requested to sign a consent form. Participation was completely voluntary.

Eligibility criteria

The inclusion criteria were as follows: (i) patients who signed the consent form and volunteered to participate in this study; (ii) adult patients with bilaterally missing mandibular first or second molars and systemically healthy individuals; and (iii) non-smoking individuals. Third molars need for bone augmentation techniques, tobacco smokers, pregnant and/or lactating females, individuals with bruxism or systemic diseases such as diabetes mellitus, osteoporosis, and patients on medications such as bisphosphonates were excluded.

Participants grouping and randomization

Adult patients aged 21 years or older requiring fixed implant-supported prosthetic rehabilitations of bilaterally missing mandibular molars were recruited. Initially, 29 individuals were invited to participate in this study. The information that explained the purpose and methodology used was provided to all individuals. All individuals were invited to ask any questions they had about the present investigation. Six individuals refused to participate in the investigation without providing any reason (Fig. 1). In total, 23 individuals volunteered to participate in this study. Depending upon the depth of implant placement, the test and control sites were defined as follows: (i) test sites: implants placed 2 mm below the alveolar crest (subcrestal); (ii) control sites: implants placed at bone level (crestal). Randomization was performed by tossing a coin.

Preoperative management

All participants ($n = 23$) underwent a full mouth scaling using ultrasonic scalers (VV DENTA, Guangxi, China) and curettes. All

patients were premedicated with 2 g of Amoxicillin 1 h prior to implant surgery. In case of allergy to penicillin, 600 mg clindamycin was prescribed.

Surgical protocol

All surgical procedures were performed by one trained clinician. After local anesthesia, a crestal incision was made using a no. 15 surgical blade and full-thickness mucoperiosteal flaps were raised to expose the bone in the mandible. Regular crossfit connection implants (Straumann® Dental Implant System, Institut Straumann, AG Peter Merian-Weg 12 CH-4002 Basel, Switzerland) were placed in the center of the healed alveolar ridge in the posterior mandible. In the test and control sites, the implants were placed approximately 2 mm below the level of the alveolar crest and at the level of the alveolar crest, respectively, using an insertion torque of 35 Ncm. Healing abutments were connected to the implants using hand torque. The flaps were sutured around the healing abutment using resorbable sutures (4/0 Vicryl), and digital intraoral postoperative radiographs were taken.

Postoperative management and follow-up

Postoperative antibiotics (amoxicillin 500 mg or clindamycin 300 mg) and analgesics (ibuprofen 600 mg) were prescribed and written, and verbal oral hygiene instructions were given to the patients. All participants also received biannual full mouth mechanical plaque and calculus debridement during the 36-month follow-up.

Clinical and radiographic evaluations

Postoperative clinical and radiographic examinations were performed by a trained and calibrated examiner who was blinded to the study groups. To calculate the kappa score, peri-implant probing depths (PD) of 10 study participants were measured by one examiner using a graded manual probe (Hu-Friedy Co., Chicago, IL, USA). Probing was performed randomly and repeated twice on the same day to monitor intraexaminer agreement. The examiner had to have a substantial correlation as measured by Cohen's kappa ($\text{kappa} \geq 0.6$) before conducting the actual investigation (Andrade et al. 2012). In addition to the Kappa agreement, the measurements had to show a 90% agreement for ± 1 mm, as well as an exact agreement in 75% of the PD repeated measurements. The kappa score for intraexaminer reliability for PD was 0.86. Peri-implant bleeding on probing (BOP) and PD was measured in the test and control sites at six sites per implant

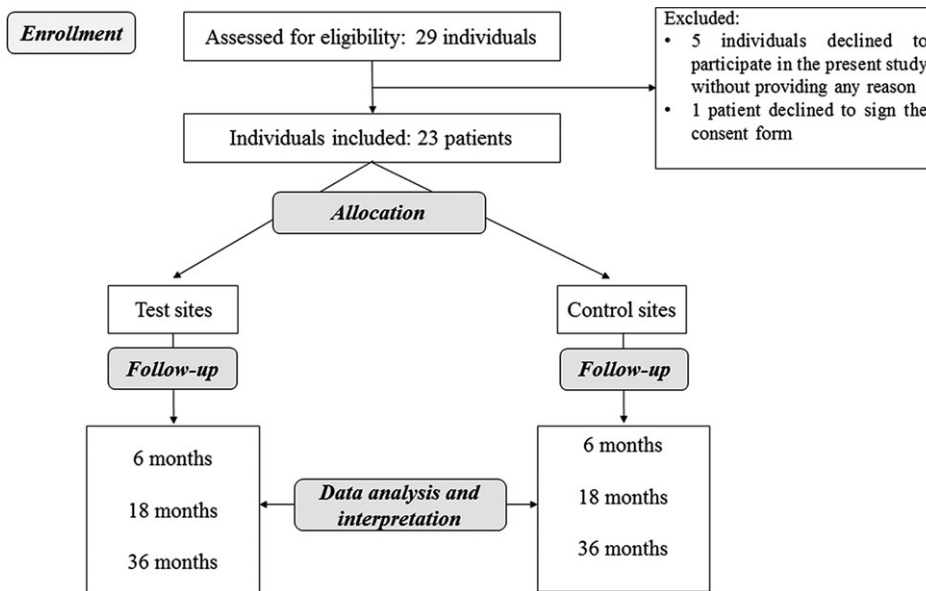


Fig. 1. Consort flow diagram of enrollment, allocation, and follow-up of participants.

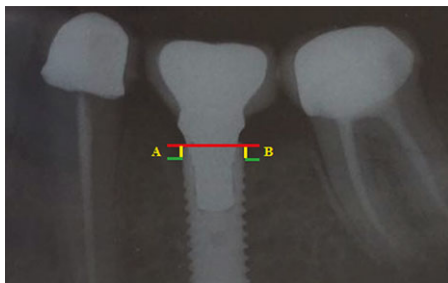


Fig. 2. Measurement protocol for the mesial (A) and distal (B) crestal bone loss around implants. The yellow line represents the linear distance (in millimeters) from the implant platform (red line) to the alveolar crest (green line).

(mesiobuccal, midbuccal, distobuccal, mesiolingual, midlingual, and distolingual). The presence of suppuration was noted as well.

Likewise, peri-implant CBL (mesial and distal) was blindly measured on digital radiographs of 10 patients once a week over two consecutive weeks by one investigator (MDA). It was mandatory for the measurements to show a 90% agreement for ± 0.2 mm of CBL and an exact agreement in 75% of the CBL repeated measurements. The *Kappa* score for intraexaminer reliability for CBL measurement was 0.90. Digital radiographs were taken using the long-cone paralleling technique (Adriaens & De Boever 1982). The patients were seated upright with the Frankfort plan parallel to the floor. A film holder (Dentsply Rinn, York, PA, USA) was used as a guiding device for X-ray beams to standardize the angulation of the X-ray beam to the implant. The central X-ray beam was directed perpendicular to the electronic sensor and long axis

of the implant. In the test and control sites, both mesial and distal peri-implant CBL were analyzed at $\times 20$ magnification at 6, 18, and 36 months of follow-up using CORELDRAW 11.0 software (Corel Corp and Coral Ltd, Ottawa, ON, Canada). Then, the total CBL was calculated by averaging the mesial and distal scores. For the assessment of CBL at 6, 18, and 36 months of follow-up, the linear vertical distance from the implant platform to the most coronal portion of the alveolar bone on the mesial and distal surfaces of the implant was digitally measured according to a previously published technique (Pellicer-Chover et al. 2016). At each timepoint, CBL measurements were compared to the baseline measurement (after implant placement). The difference between the value recorded at the time of placement (baseline) and at 6, 18, and 36 months of follow-up was used to calculate bone loss mesial and distal to the implant. In the subcrestal group, if the implant platform remained embedded in surrounding alveolar bone, CBL was gauged as positive value indicating a subcrestal position of the implant platform. In both groups, negative CBL values indicated a supracrestal location of the implant platform (Fig. 2). CBL values of zero indicated that there was no difference in bone level between the baseline and the timepoint in question.

Statistical analyses

Statistical analysis was performed using software program SPSS version 18 (SPSS Inc., Chicago, IL, USA). In the test and control sites, BOP, PD, and CBL scores were

compared at 6, 18, and 36 months of follow-up using the paired *t*-test. *P*-values less than 0.05 were considered statistically significant.

Results

Sixteen males and seven females seeking bilateral replacement of missing mandibular molars volunteered to participate in this study. In total, 46 PS implants (23 implants in test sites and 23 in control sites) were placed bilaterally to restore missing mandibular first ($n = 32$) or second ($n = 14$) molars. The mean age of the participants included was 43.5 years (range 29–50 years). The implants used had a regular crossfit connection with diameter of 4.1 mm and ranging in length from 10–14 mm. After a mean duration of 3.7 months (range 3–4 months), implant loading was performed using screw-retained crowns. The survival/success rate was 100% in both groups without any signs or symptoms (Table 1).

Clinical peri-implant parameters (BOP and $PD \geq 4$ mm)

In control group ($n = 23$), the mean percentage of sites that showed BOP at 6 and 18 months of follow-up were 7.4% and 2.5%, respectively. The mean percentage of sites that had $PD \geq 4$ mm at 6 and 18 months of follow-up were 1.4% and 1.1%, respectively. At 36 months of follow-up, the percentage of BOP and $PD \geq 4$ mm decreased to 2.1% and 1.2%, respectively. There was no significant difference in BOP and $PD \geq 4$ mm at 6, 18, and 36 months of follow-up.

In the test group ($n = 23$), the mean percentage of sites that showed BOP at 6 and 18 months of follow-up were 2.4% and 1.4%, respectively. The mean percentage of sites that had $PD \geq 4$ mm at 6 and 18 months of follow-up were 1.2% and 1.1%, respectively. At 36 months of follow-up, the percentage of BOP and $PD \geq 4$ mm decreased to 1.0% and 0.7%, respectively. There was no significant difference in BOP and $PD \geq 4$ mm at 6, 18, and 36 months of follow-up. Likewise, inter-group comparisons showed no significant differences in BOP and $PD \geq 4$ mm around subcrestal and crestal implants at all follow-up intervals (Table 2). There was no clinical evidence of suppuration around implants placed at crestal and subcrestal levels throughout the study period (Table 1).

Radiographic peri-implant parameters (CBL)

At 6 and 18 months of follow-up, the average amount of CBL around crestal implants was 0.03 ± 0.1 and 0.25 ± 0.1 mm, respectively.

Table 1. Descriptive data of participants and implants included

| | (Control Group) Crestal implants (n = 23) | (Test Group) Subcrestal implants (n = 23) |
|-------------------------------|------------------------------------------------------------|------------------------------------------------------------|
| Gender | Male = 16 Female = 7 | Male = 16 Female = 7 |
| Mean age (range) | 43.5 years (range 29–50) | 43.5 years (range 29–50) |
| Tooth replaced | Mandibular first molar = 14 Mandibular second molar = 9 | Mandibular first molar = 18 Mandibular second molar = 5 |
| Implant length/diameter (mm) | 10/4.1 = 16 12/4.1 = 6 14/4.1 = 1 | 10/4.1 = 18 12/4.1 = 5 |
| Mean healing time (months) | 3.5 (3–3.8) | 3.8 (3–4) |
| Design of connection | Regular crossfit (RC) | Regular crossfit (RC) |
| Type of retention | Screw retained = 23 | Screw retained = 23 |
| Evidence of suppuration (%) | 0 | 0 |
| 36-month survival/Success (%) | 100 | 100 |

At 6 and 18 months of follow-up, the average amount of CBL around subcrestal implants was zero and 0.20 ± 0.1 mm, respectively. The total amount of CBL around crestal and subcrestal implants after 36 months of loading was 0.45 ± 0.2 and 0.3 ± 0.2 mm, respectively. Due to subcrestal placement, all implant platforms in the test group remained embedded in the surrounding alveolar bone despite the 0.3-mm CBL. The bone level was 0.45 mm apical to the implant platform in the control group (crestally placed implants). Within both groups, there was no significant difference in CBL at 6, 18, and 36 months of follow-up. Likewise, intergroup comparisons showed no significant differences in CBL around crestal and subcrestal implants at all follow-up intervals (Table 2).

Discussion

The present study was based on the hypothesis that dental implants placed 2 mm subcrestally exhibit a stable soft tissue profile and undergo significantly less CBL compared with implants placed at bone level. An explanation in this regard is that subcrestal placement of the implant–abutment interface helps in maintaining the texture and tonality of the soft tissues and also favors the reestablishment of favorable marginal tissue architecture than implants placed at the bone

crest (Novaes et al. 2009). The present results are in contradiction to this hypothesis as there was no significant difference in soft tissue profiles and crestal bone levels around subcrestal as well as crestal implants up to 3 years of follow-up. It therefore seems that both crestal and subcrestal placements of implants show comparable clinical and radiographical outcomes. This current finding is in agreement with previous studies (Koh et al. 2011; Romanos et al. 2015; Palaska et al. 2016). In a recent systematic review (Al Amri 2016), human- and animal-based studies showed no significant difference in CBL around crestally and subcrestally placed dental implants, although some studies found significant differences (Calvo-Guirado et al. 2014, 2015; Aimetti et al. 2015; Kutan et al. 2015; Schwarz et al. 2015). These discrepancies among studies have been attributed to differences in the surgical technique, implant-abutment connection, interimplant distance, platform surface texture, repeated disconnection/reconnection of the healing abutment, and the initial mucosal thickness (Aimetti et al. 2015).

However, it is pertinent to mention that there are a variety of factors that may have influenced the outcomes of the present study. Firstly, all implants placed had a platform-switched design, that is, implants had IAJ placed closer to the center of the implant.

Studies (Prosper et al. 2009; Trammell et al. 2009; Fernandez-Formoso et al. 2012; Telleman et al. 2012; Vandeweghe & De Bruyn 2012) have shown that platform-switched dental implants undergo minimal peri-implant CBL compared with non-platform-switched implants (implants with matching abutment and implant-body diameters). Such design helps bringing out the bacteria and the inflammatory cell infiltrate away from the adjacent crestal bone and shifting the stress concentration inward (Maeda et al. 2007; Canullo et al. 2010). However, it has also been documented that three-dimensional implant positioning, width of the alveolar ridge, and control of micromotion at the IAJ are the more essential factors, which can influence CBL besides platform switching (Romanos & Javed 2014). Another factor that could have played a role in maintaining the soft tissue status and crestal bone levels around implants in both groups is the dental hygiene prophylaxis which the patients received biannually. According to Degidi et al. (Degidi et al. 2012), long-term bone levels around dental implants are maintained when levels of oral hygiene are kept adequate. Moreover, Lin et al. (Lin et al. 2011) also demonstrated that under optimal oral hygiene maintenance, a 100% survival rate of implants can be achieved. The outcomes of the present split-mouth clinical trial support these results by Degidi et al. (Degidi et al. 2012) and Lin et al. (Lin et al. 2011).

In the present study, CBL was measured on digital radiographs according to the technique presented in a recent study (Pellicer-Chover et al. 2016). In the subcrestal group, the level of alveolar bone stayed at a coronal position in relation to the IAJ at 36 months of follow-up. Therefore, even though crestal bone remodeling may have occurred in these implants, the IAJ remained embedded in bone throughout the study period. It is so pertinent to mention that other factors such as use of platform-switched implants and dental prophylaxis may also have contributed in minimizing CBL. There is a possibility

Table 2. Mean scores and standard deviations of bleeding on probing, probing depth (≥ 4 mm), and crestal bone loss around crestal and subcrestal implants at 6, 18, and 36 months of follow-up

| | Crestal implants (n = 23) | | | Subcrestal implants (n = 23) | | |
|--------------------|---------------------------|-----------------|-----------------|------------------------------|----------------|----------------|
| | 6 months | 18 months | 36 months | 6 months | 18 months | 36 months |
| Mean (\pm SD) | | | | | | |
| BOP (%) | 7.4 ± 0.4 | 2.5 ± 0.2 | 2.1 ± 0.2 | 2.4 ± 0.2 | 1.4 ± 0.2 | 1.0 ± 0.08 |
| PD ≥ 4 mm (%) | 1.4 ± 0.1 | 1.1 ± 0.08 | 1.2 ± 0.1 | 1.2 ± 0.1 | 1.1 ± 0.2 | 0.7 ± 0.06 |
| Total CBL | -0.03 ± 0.1 | -0.25 ± 0.1 | -0.45 ± 0.2 | 0 | 0.2 ± 0.1 | 0.3 ± 0.2 |
| Mesial CBL | 0 | -0.2 ± 0.02 | -0.4 ± 0.01 | 0 | 0.1 ± 0.01 | 0.2 ± 0.02 |
| Distal CBL | -0.05 ± 0.02 | -0.3 ± 0.04 | -0.5 ± 0.04 | 0 | 0.3 ± 0.04 | 0.4 ± 0.05 |

SD, Standard deviation.

that if the implants included in the present study had been followed for longer duration, the present outcomes might have been different. Further long-term studies are needed in this regard.

In an effort to standardize intragroup and intergroup comparisons, the implant healing period and the design and occlusion of the restorations among both groups were sustained comparable. In addition to excluding patients with parafunctional habits, the occlusal table size was maintained to minimum with light centric contacts and complete disocclusion in eccentric movements. Furthermore, all implants were restored with screw-retained crowns to preclude the detrimental effect of excess cement on peri-implant tissues. The implementation of these measures, in addition to the strict patient selection criteria and biannual oral hygiene maintenance program, played a role in the favorable clinical and radiographic outcomes and the 100% survival rate (Misch et al. 2006; Lin et al. 2011; Degidi et al. 2012; Aimetti et al. 2015; Al Amri 2016).

It is pertinent to mention that this clinical study presents a number of limitations. The first limitation is that strict patient selection criteria were imposed. An important parameter that has been reported to influence CBL is soft tissue thickness around dental implants (Vervaeke et al. 2014; Linkevicius et al. 2015). It has been suggested that a minimum of 3 mm of peri-implant soft tissue thickness is essential to minimize the possibility of CBL around dental implants (Cochran et al. 1997). Although the biological width remained uninvestigated in the present

study, it seems to be within the proposed limits (3–4 mm) as CBL was minimal around implants throughout the study period. Moreover, it is also known that systemic conditions such as poorly controlled diabetes and habits such as tobacco smoking are associated with CBL (Javed et al. 2007, 2015, 2016; Javed & Romanos 2009). It is possible that in case tobacco smokers and patients with systemic disorders were included, there could have been a difference on CBL between the test and control sites. It is hypothesized that CBL is higher around implants placed at bone level as compared to those placed subcrestally in smokers and in patients with systemic diseases. Another limitation is that the participants in this study were relatively young (mean age was 43.5 years) with uneven distribution of males and females, which may have been a source of bias. There is a possibility that hormonal changes in females (particularly in the postmenopausal phase) may influence the clinical and radiographic parameters of peri-implant inflammation. Moreover, in the present study, implants were placed in the mandible. As the bone density varies between the maxilla and mandible (Fuster-Torres et al. 2011), it is hypothesized that jaw location may have influenced CBL around implants.

Furthermore, digital radiographs were taken using the traditional long-cone paralleling technique (Adriaens & De Boever 1982), and parallelism was established solely using a film holder with no modifications, such as use of silicone spacers, used to ensure parallelism. It is therefore hypothesized that this limitation in the radiographic technique may have

influenced the crestal bone levels reported in the present investigation. Lastly, it is pertinent to observe that molars in the present investigation have been replaced with RC implants of 4.1 mm platform. Therefore, it was expected that the emergence profile of a molar to pose significant challenges in probing around these implants. However, this challenge was meticulously managed in probing around all crowns except in two situations where the crowns had to be removed. Further long-term randomized clinical trials are needed to test the aforementioned hypotheses.

Conclusion

Within the limits of the present clinical trial, it is concluded that soft tissue parameters and crestal bone levels can remain equally stable around crestally and subcrestally placed implants in the posterior mandible up to 36 months of follow-up. The need for long-term follow-up clinical trials is also emphasized.

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Conflict of interest statement

None declared.

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Supporting Information

Additional Supporting Information may be found in the online version of this article:

Appendix S1. CONSORT 2010 checklist of information to include when reporting a randomised trial.