Received: 23 June 2021 | Revised: 9 March 2022 | Accepted: 4 May 2022

DOI: 10.1111/clr.13949

ORIGINAL ARTICLE

CLINICAL ORAL IMPLANTS RESEARCH WILEY

Evaluation of implant placement following ridge preservation in periodontally compromised molar extraction sockets: Three-year results of a prospective cohort study

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Funding information
This study was supported in part by the Capital foundation for Clinical Characteristics, Application Research, Grant #Z161100000516042, and the Capital Medical Development and Research Fund, PRC (2011-4025-04) and Peking University Clinical Scientist Program (BMU2019LCKXJ010)

Abstract

Objective: To investigate the 3-year implant-related outcomes following alveolar ridge preservation in periodontally compromised molar sockets.

Material and methods: Thirty implants were placed in 26 patients following either ridge preservation (test, $n = 16$) or natural healing (control, $n = 14$) at deficient molar extraction sites after a 6-month healing period. The need for additional augmentation procedures at implant placement was recorded. Patients were assessed for 3 years following a definitive restoration. Patient information being collected included modified plaque index, the modified sulcus bleeding index, the peri-implant probing depth clinically, and alterations of marginal bone level (MBL) radiographically.

Results: There was a 100% survival rate of implants in both groups after 3-year follow-up. During implant placement operation, 35.7% in the control group and 6.3% in the test group required additional augmentation procedures. No statistically significant differences were determined for peri-implant parameters and marginal bone levels between the two groups. The overall mean difference of MBL was 0.072 mm (95% CI [−0.279, 0.423]) during the 3 years of follow-up. The success rate was 81.2% in the test and 78.6% in the control group.

Conclusions: Implants placed into periodontally compromised molar-extracted sites after ridge augmentation resulted in comparable outcomes to implant placement at naturally healed sites after 3-year functional loading. (Chinese Clinical Trial Registry ChiCTR-ONN-16009433).

KEYWORDS
dental implants, implant survival, marginal bone loss, socket augmentation

1 | INTRODUCTION

The most important prerequisite for achieving optimal and functional implant-supported rehabilitations is the presence of sufficient qualitative and quantitative alveolar bone. Irregular and severe alveolar bone loss before tooth extraction may be present mostly due to periodontal disease, trauma, or periapical pathology (Horvath et al., 2013; Van der Weijden et al., 2009). After tooth extraction, the alveolar ridge changes due to the remodeling process, resulting in noticeable regressions of ridge bone volume and contour (Tan et al., 2012). In order to attenuate the physiological dimensional changes after tooth extraction, alveolar ridge preservation (ARP) has been proposed (Darby et al., 2009). Previous studies reported potential benefits of ridge preservation, including implant placement with less additional augmentation procedures, the reduction of sinus pneumatization, and the decrease in demand for sinus augmentation in the posterior maxilla (Barone et al., 2013; Cardaropoli et al., 2012; Levi et al., 2017; Park et al., 2020; Rasperini et al., 2010). A plethora of clinical studies demonstrated the beneficial outcomes of ridge preservation in comparison to naturally healed sites (Barone et al., 2017; Jung et al., 2018; Walker et al., 2017). However, the majority of studies regarding ridge preservation sampled intact or small bone deficiencies and non-inflammatory extraction sites, which fail to consider deficient alveolus due to advanced periodontal disease. In general, molar teeth are frequently extracted (Brugger et al., 2015), and compromised teeth are often affected by periodontal disease (69.20%), endodontic failure (25.67%), and trauma (6.20%) (López-Martínez et al., 2015). Few studies demonstrated that ridge augmentation in periodontitis-diseased anterior and/or posterior teeth was effective in reducing the amount of ridge resorption to later facilitate the implant placement (Aimetti et al., 2018; Ben Amara et al., 2021; Kim et al., 2017; Lee et al., 2018; Zhao et al., 2018).

Although numerous investigations have been done to reiterate the positive results of ridge preservation, data regarding the long-term prognosis of implants placed in ridge-preserved and naturally healed extraction sockets of periodontally compromised molars were still scarce. At the 1-year observation phase, the stability of implants placed in augmented sockets ranged between 93% to 100% when applying different success criteria; the success rates of implants placed in ridge-preserved sites and naturally healed sockets were equivalent (Apostolopoulos & Darby, 2017; Cardaopoli et al., 2015; Patel et al., 2013). However, the evidence regarding the clinical outcomes of implants inserted following ridge preservation in damaged molar sockets due to periodontal disease is absent. Therefore, the purpose of this prospective controlled study was to compare implant-related outcomes for periodontally compromised molar sockets between preserved and spontaneously healed ridges.

2 | MATERIAL AND METHODS

2.1 | Subject population and selection

The present study was designed as a prospective cohort study and administered in compliance with the ethical principles founded in the Helsinki Declaration of 1975, as revised in 2013. The study protocol was approved by the relevant independent committee on the Institutional Review Boards of the Peking University School and Hospital of Stomatology (Protocol number: PKUSSIRB-201310068a). The trial was registered in the Chinese Clinical Trial Registry (ChiCTR-ONN-16009433) and reported following the STROBE guidelines (Supplementary Material). Patients who were scheduled for molar extractions due to severe periodontal disease and the subsequent placement of implant-retained prostheses were enrolled (Zhao et al., 2018). The inclusion criteria were elaborately studied throughout the 6-month healing period and prior to implant placement. Patient who was chosen to receive tooth extraction due to severe periodontitis was included in the present trial, complying with the presentation of periodontitis stage III/IV, grade C. Radiographic evidence of bone loss where the height of the defect is >50% of the corresponding root length and had at least two socket walls with 3 mm of alveolar bone height as measured prior to extraction (Zhao et al., 2018). Exclusion criteria were teeth extracted due to caries, endodontic failures or fracture; smoking more than 10 cigarettes per day; suffering from bone disease or using medication that interferes with bone healing or metabolism; history of head and neck radiotherapy. The baseline periodontal condition and the characteristics of alveolar sockets have been reported in previous study in detail (Zhao et al., 2018). In the test group, ridge preservation was performed with Bio-Oss in combination with Bio-Gide coverage while in the control group no grafting was performed. All patients received verbal and written informed consent. The study timeline and flowchart of subject data collection are illustrated in Figure 1.

The null hypothesis tested was that no significant differences would exist in clinical and radiographic outcomes between implants placed in ridge-preserved and naturally healed sockets of periodontally diseased molar after 3 years of functional loading.

2.2 | Ridge preservation and augmentation

The preliminary report described the surgical protocol in detail (Zhao et al., 2018). To summarize, following minimally traumatic extraction of the unsalvageable tooth, ridge preservation was performed using Bio-Oss (0.25–1 mm; Geistlich Pharma AG) and covered by an absorbable collagen membrane (Bio-Gide; Geistlich, Pharma, AG). In the test group, the buccal flaps were coronally repositioned,

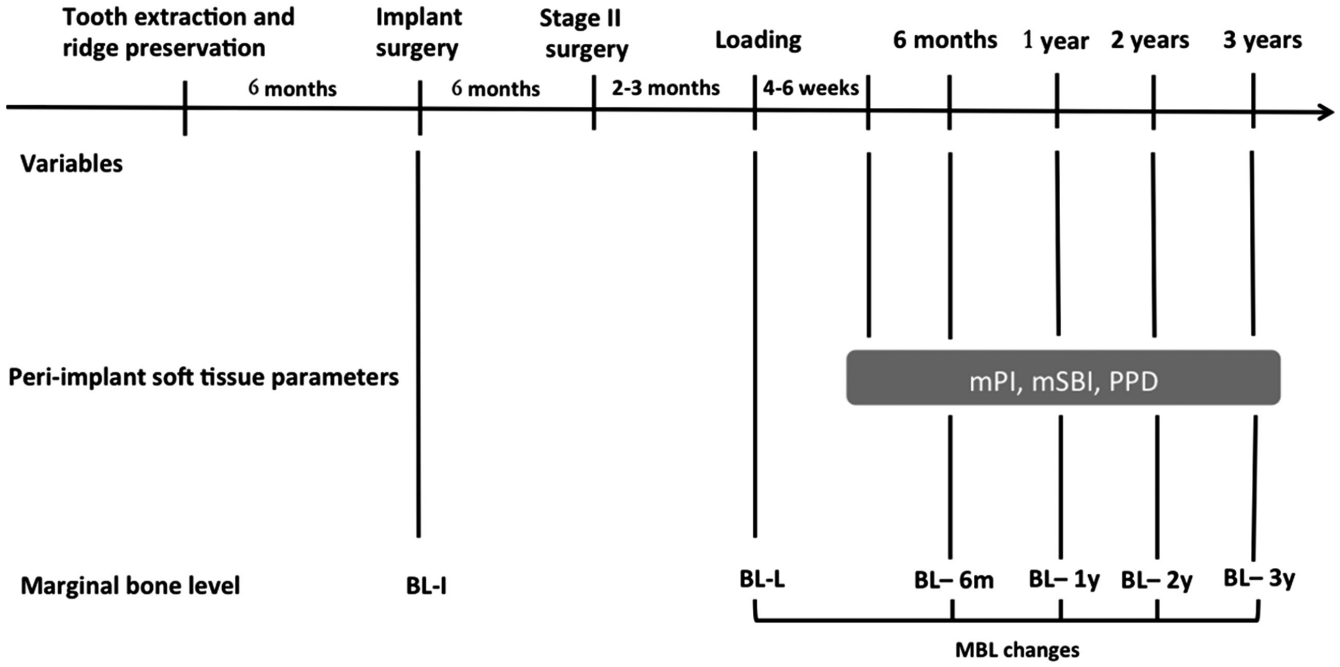

FIGURE 1 Flow chart of study data collection. mPI, modified plaque index, PPD, peri-implant probing depth, mSBI, modified sulcus bleeding index, BL-I, marginal bone level immediately after implant placement, BL-L, marginal bone level at loading, BL-6m, marginal bone level at 6 months of follow-up, BL-1y, marginal bone level at a 1-year follow-up, BL-2y, marginal bone level at a 2-year follow-up, BL-3y, marginal bone level at a 3-year follow-up

allowing maximum primary soft tissue coverage to attempt primary flap closure. In the control group, only a cross suture was performed after debridement. For 3–4 weeks, it was recommended and prescribed that the subjects use a local disinfection by rinsing with a 0.12% chlorhexidine solution twice a day until the soft tissue healed and suture removal.

2.3 | Implant placement and loading

Implant placement was performed 6 months' post-extraction and post-ARP. A full-thickness flap was reflected at the implant placement sites. Implants (Straumann AG; Bicon, Integra-CP, USA) were inserted by a research investigator (WH) following the manufacturer's recommendation. Ancillary bone augmentation procedure was completed using the same biomaterial if the implant surface was exposed after implant placement (where buccal dehiscence was encountered). A tension-free flap was implemented to obtain primary soft tissue closure. The post-operative protocol was the same as prescribed previously after the ridge preservation surgery, and suture removal was scheduled after 7–14 days. Because of the submerged healing protocol, the reopening procedure took place 6 months after the implant placement, followed by the restorative phase executed by a prosthodontist (YL) according to standard protocol. Occlusion was checked and adjusted to eliminate any premature or heavy contacts at the maximum intercuspal position using occlusal foil (Hanel, 12 microns) and in lateral excursions at the time of the prosthesis delivery.

2.4 | Clinical and radiographic examination

Following the implant placement procedure, all participants were instructed to follow a personalized peri-implant maintenance regimen. The regimen consisted of oral hygiene instructions and professional plaque control 6 weeks, 1 year, 2 years, and 3 years after the delivery of the implant-supported crown. All mechanical and biological complications were recorded.

A manual periodontal probe (UNC-15 periodontal probe; Hu-Friedy, Chicago, IL) was used to evaluate the modified plaque index (mPI), the modified sulcus bleeding index (mSBI) (Mombelli et al., 1987), and the peri-implant probing depth (PPD). The final results of PPD, mPI, and mSBI were determined by calculating the average scores; all measurements of PPD were rounded up to the nearest millimeter and checked at six locations per implant and the mPI and mSBI were assessed at buccal and lingual/palatal sites for each implant. All examinations were conducted by the same clinician (WH).

In order to evaluate the peri-implant marginal bone level (MBL) immediately after implant prosthesis insertion, 1-year, 2 years, and 3 years after functional loading, a parallel cone technique was used to obtain digital intra-oral periapical radiographs (70 kVp, 12–20 mA). A paralleling device and individualized silicone bite records were used to standardize all periapical radiographs (Figure 2). The marginal bone level was defined as the distance between the shoulder (abutment connection) of the implant and the most coronal alveolar bone in direct contact with the mesial and distal aspects of each implant. Reference lines and landmarks were determined and drawn including line (a), the long axis of the

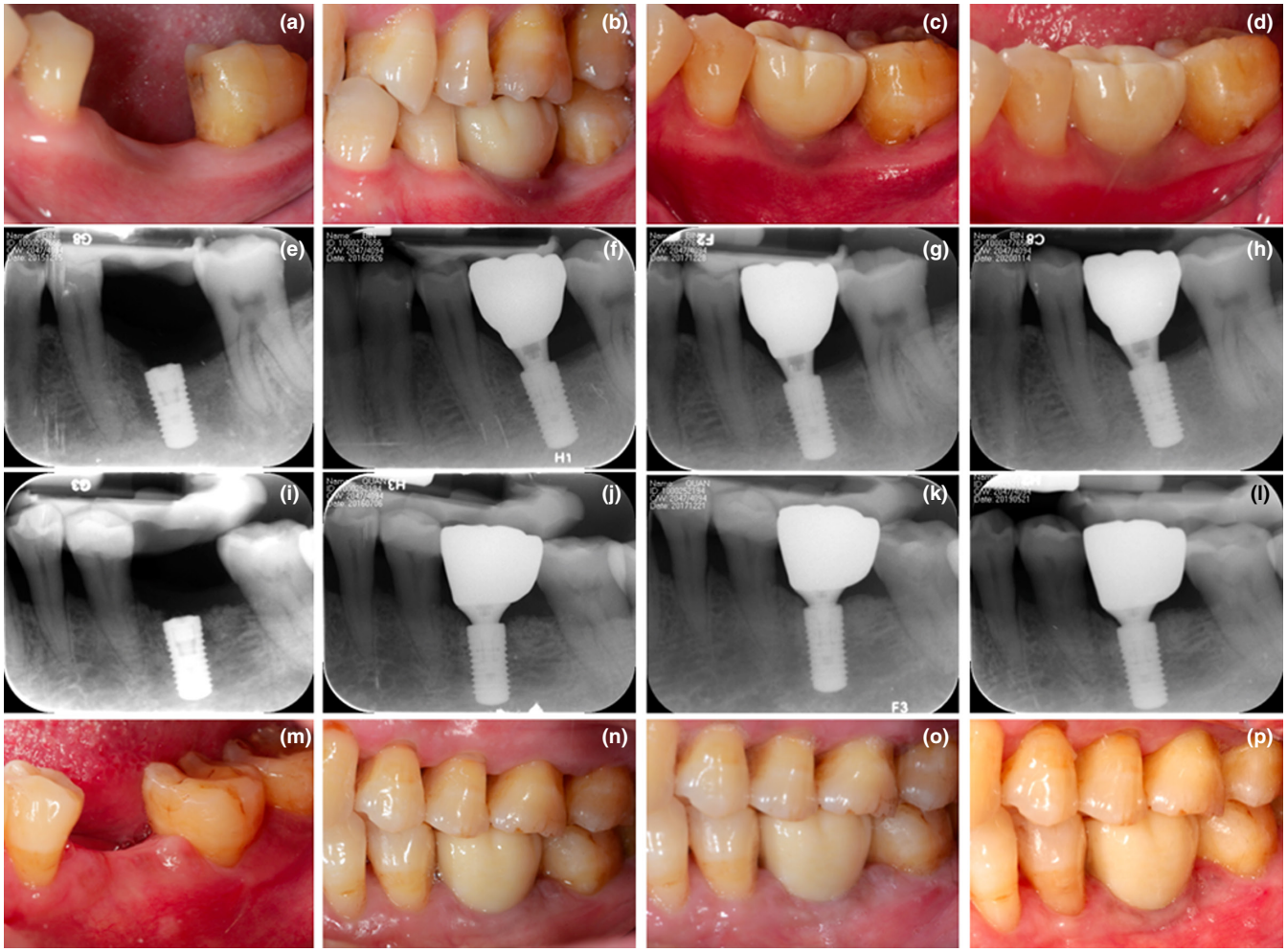

FIGURE 2 Clinical images and periapical radiographs obtained at four stages of an implant in the control (a–h) and test group (i–p): (a), (e), (l), and (m) represent immediately after the implant placement; (b), (f), (g), and (n) demonstrate seating of the prosthesis; (c), (g), (k), and (o) at 1-year post-loading follow-up; (d), (h), (l), and (p) at 3-years post-loading follow-up

implant, line (b), the line of the implant platform perpendicular to the long axis of line a at the most coronal level of the implant, line (c), the most coronal bone-to-implant contact on the mesial aspect of the implant parallel to line (a), and line (d), the most coronal bone-to-implant contact on the distal aspect of the implant parallel to line (a) (Figure 3; Lai et al., 2013).

Measurements were recorded by using the distance between three implant threads as the basis for calibration and determination of the exact MBL. For implants with threads not obviously detected on the radiographs, the known fixture diameter and length were used. Depending on the placement of the shoulder of the implant at the bone level, either a positive value (coronal placement) or a negative value (apical placement) was assigned. The mean MBL of mesial and distal radiographic measurements was calculated for each implant. One single calibrated examiner (LZ) performed all radiographic calculations to the nearest 0.01 mm using digital computer software (The Geometer's Sketchpad, Key Curriculum Press, USA). To test the reputability of the examiner, duplicated measurements were taken within one week in 10 randomly selected radiographs. Marginal bone loss (ΔMBL) was defined as the difference in bone levels of the prosthetic restoration between the time of delivery and the 1 year, 2-year, and 3-year follow-up visit.

2.5 | Criteria for implant survival and success

Implant survival was defined as the presence of a dental implant in the jaw during re-evaluation appointments. According to the following criteria, a successful implant was defined as: (1) absence of mobility; (2) absence of persistent pain, foreign body sensation, and/or dysesthesia; (3) no PPD >5 mm; (4) no PPD of 5 mm and bleeding on probing (BOP); and (5) absence of continuous radiolucency around the implant (Karoussis et al., 2004).

2.6 | Data analysis

Sample size calculation was based on data reported in a previous study for peri-implant marginal bone level changes in implants after molar extraction and ridge preservation at 1-year post-loading

(Tallarico et al., 2017). Seven patients were needed per group to reject the null hypothesis, setting a two-sided alpha at 0.05 and a power of 90%.

The primary outcome measure was the changes in peri-implant marginal bone level, and the secondary outcomes included mPI, PPD, mSBI, and implant survival and success rates, Descriptive analyses with mean values, standard deviation (SD), and frequency distribution (%) were calculated. The implant was the unit of analysis. The difference in primary outcome between treatment groups was analyzed using the linear mixed model with repeated measurements, adjusting for baseline value, time of follow-up visits (Year 1, Year 2, and Year 3) and its interaction with the treatment, and other baseline characteristics, including age, gender, implant position, and need for further augmentation, with the R package lme4 (R Foundation, version 4.12). Statistical significance was set at $\alpha = 0.05$.

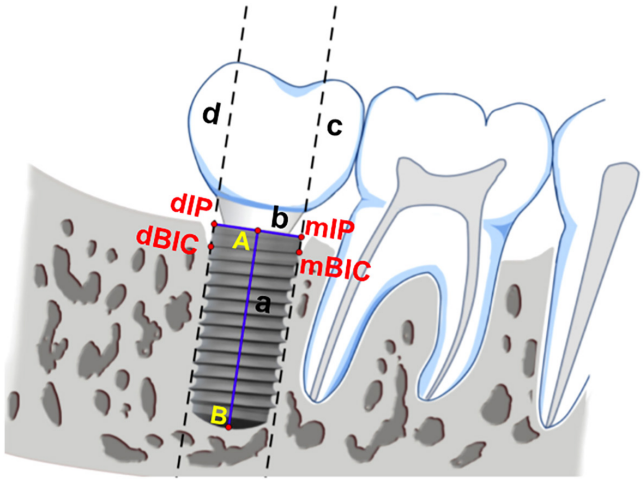

FIGURE 3 Schematic drawing of marginal bone level measurements from the periapical radiographic film. a, the line of the long axis of the implant. b, the line of the implant platform perpendicular to line at the most coronal level of the implant. c, the line of the most coronal bone-to-implant contact on the mesial aspect of the implant parallel to line a. d, the line of the most coronal bone-to-implant contact on the distal aspect of the implant parallel to line a. A midpoint of line b. B apical area of the implant. mIP mesial aspect of the implant platform. dIP distal aspect of the implant platform. mBIC most coronal bone to implant contact on the mesial aspect of the implant surface. dBIC most coronal bone to implant contact on the distal aspect of the implant surface

3 | RESULTS

Of the 32 patients initially enrolled, 26 patients (19 males and 7 females), receiving 30 implants were available for 3 years of follow-up (Table 1). Despite several contact attempts, six patients withdrew 6 months after the tooth extraction due to either relocation or economics. Of the remaining patients, 23 contributed one implant, two patients contributed two non-adjacent implants and one patient contributed three non-adjacent implants. The age distribution of participants was 51.7 years (SD 7.4) and 49.9 years (SD 7.5) in the control and test groups, respectively. No patients reported having any systematic diseases or a history of smoking. During the implant placement, 5/14 (35.7%) implants in the control group and 1/16 (6.3%) implants in the test group required a supplementary bone augmentation procedure ($p = .072$). No biological or mechanical complications were observed.

Throughout the observation timeframe, there were no statistically significant between-group differences for mean changes from baseline observed in terms of mPI, PPD, and mSBI between the control and test groups, as shown in Table 2.

The marginal bone level ranging from the implant crown delivery to the 3-year follow-up period is shown in Figure 4 and Table 3. Limited changes in bone levels were observed between the initial crown seat and 3 years thereafter in both the test and control groups. The MBL at crown delivery was −0.77 mm (SD 0.59) for the control and −0.44 mm (SD 0.75) for the test group. The mixed model revealed that the interaction between the group and year of measurement was not significant, and the overall mean difference between treatment groups during 3 years of follow-up was 0.072 mm (95% CI [−0.279, 0.423]).

All 30 of the implants studied were functioning at the 3-year follow-up assessment, revealing a survival rate of 100% for both groups. During the 3-year follow-up, one of the implants from control group exhibited a PPD >5 mm; one site with a PPD of 5 mm and BOP was observed in two implants in the control and test groups, the total implant success rate was 78.6% in the control group and 81.2% in the test group.

TABLE 1 Demographic characteristic and implant positions

	Control Group	Test Group	*p* value
Age (years)			
Mean (SD)	51.7 (7.1)	49.9 (7.5)	.540
Gender (M: F)	7: 5	13: 3	.231
Total number of implants	14	16	
Implant position, *n* (%)			
Maxillae	6 (42.9)	2 (12.5)	.101
Mandible	8 (57.1)	14 (87.5)	
Need for further augmentation, *n* (%)	5 (35.7)	1 (6.3)	.072

Abbreviations: SD, standard deviation.

TABLE 2 Peri-implant probing, modified plaque index and bleeding index after crown insertion, 1 year, 2 years, and 3 years in function

Variable	Control Group Mean (SD)	Test Group Mean (SD)	
Modified plaque index (mPI)			
Baseline	0.39 (0.45)	0.53 (0.56)	
1 year	0.50 (0.44)	0.53 (0.53)	*p* for Year: 0.075
2-year	0.46 (0.46)	0.50 (0.55)	*p* for (Group x Year) interaction: 0.847
3-year	0.71 (0.51)	0.72 (0.26)	
Overall mean differences (95% CI)	−0.082 (−0.497, 0.333)		
Peri-implant probing depth (PPD)			
Baseline	2.66 (0.57)	2.48 (0.42)	
1 year	2.87 (0.51)	2.74 (0.62)	*p* for Year: 0.657
2-year	2.69 (0.52)	2.88 (0.62)	*p* for (Group x Year) interaction: 0.784
3-year	2.83 (0.57)	2.74 (0.68)	
Overall mean differences (95% CI)	−0.091 (−0.756, 0.574)		
Modified sulcus bleeding index (mSBI)			
Baseline	1.21 (0.80)	0.69 (0.81)	
1 year	1.43 (1.16)	0.88 (1.06)	*p* for Year: 0.413
2-year	1.54 (0.95)	1.19 (1.12)	*p* for (Group x Year) interaction: 0.722
3-year	1.21 (0.58)	0.75 (0.98)	
Overall mean differences (95% CI)	−0.462 (−1.551, 0.627)		

Note: Overall mean differences were fitted by the linear mixed-effect model in which fixed effects are Group, Year and the interaction, with adjustment for baseline value, age, gender, implant position, need for further augmentation.

Abbreviations: CI, confidence interval; mPI, modified plaque index; mSBI, modified sulcus bleeding index; PPD, peri-implant probing depth; SD, standard deviation.

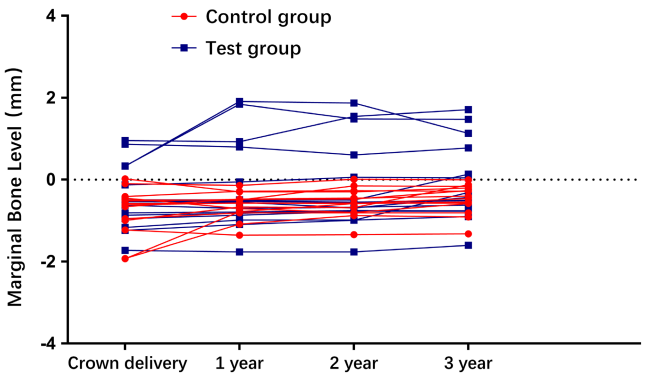

FIGURE 4 Spaghetti plot showing changes in marginal bone level in control and test group throughout the follow-up period

4 | DISCUSSION

Whether ridge preservation in periodontally compromised molar extraction sockets should be considered clinically significant in the long-term outcome of dental implants was an important and unsettled issue. The aim of the current prospective controlled study was to investigate post-loading outcomes following ridge preservation in deficient molar sockets due to advanced periodontitis. Within the limitations of the study, the null hypothesis was accepted because there were no statistically significant differences with respect to success rate, clinical or radiographic outcomes of implants placed in grafted sites versus those placed in naturally healed sites.

The results of the current study show that at the 3-year follow-up assessment, there were no significant differences in the survival rates between implants placed in periodontally compromised molar sites that were previously augmented and implants placed in naturally healed sites. The results of this study agreed with findings reported in previous studies investigating the ridge preservation procedure (Apostolopoulos & Darby, 2017; Norton & Wilson, 2002; Patel et al., 2013). The study criteria determined the implant success rates; previous studies reported implant success based on the success criteria defined by Albrektsson (Albrektsson et al., 1986). Marconcini and colleagues examined success rates of implants in premolar and molar sites placed 3 months after ridge preservation using cortical porcine bone, collagenated corticocancellous porcine bone or no graft material insertion; cumulative success rates for all implants were 100% at a 4-year evaluation (Marconcini et al., 2018). Norton and Wilson reported success rates of dental implants

TABLE 3 Peri-implant marginal bone level of test and control group after crown delivery, 1 year, 2 years, and 3 years of follow-up (mm)

Variable	Control Group Mean (SD)	Test Group Mean (SD)	
Marginal bone level (MBL)			
Baseline	−0.77 (0.59)	−0.44 (0.75)	
1-year	−0.62 (0.32)	−0.23 (1.05)	*p* for Year: 0.049
2-year	−0.56 (0.34)	−0.21 (1.04)	*p* for (Group x Year) interaction: 0.560
3-year	−0.47 (0.36)	−0.12 (0.93)	
Overall mean differences (95% CI)	0.072 (−0.279, 0.423)		

Note: Overall mean differences were fitted by the linear mixed-effect model in which fixed effects are Group, Year and the interaction, with adjustment for baseline value, age, gender, implant position, need for further augmentation.

Abbreviations: CI, confidence interval; mPI, modified plaque index; mSBI, modified sulcus bleeding index; PPD, peri-implant probing depth; SD, standard deviation.

placed after ridge preservation with bioactive glass at the 1-year follow-up, the cumulative success rate was 90% (Norton & Wilson, 2002). Patel and colleagues reported success rates of implants in alloplastic and xenograft groups of 84.6% and 83.3%, respectively (Patel et al., 2013). Apostolopoulos and Darby demonstrated similar implant success rates of 51% and 58% for implants placed in either grafted or naturally healed sockets using the success criteria defined by Karoussis et al (Apostolopoulos & Darby, 2017; Karoussis et al., 2004). In the current study, we adopted the criteria defined by Karoussis et al to evaluate the results of implants placed in periodontally compromised molar sites; we revealed that the success rates of implants placed in augmented sites were similar to implants placed in naturally healed sites.

No statistically significant differences were determined in the clinical or radiographic parameters between the control and test groups. Peri-implant parameter analysis in Table 2 revealed no significant differences at any observation time between either group. One possible reason for this outcome could be that the subjects complied with a personalized supportive periodontal therapy to maintain peri-implant soft tissue health. The plaque & bleeding indexes and peri-implant probing depth remained low, stable, and comparable from the time of loading throughout the 3-year period. According to a systematic review presented by Zangrando, patients with periodontally compromised teeth may exhibit significantly higher incidences of peri-implantitis when compared with periodontally healthy subjects (Zangrando et al., 2015). Costa reported that the maintenance program could keep the likelihood of pre-existing peri-implant mucositis progressing to peri-implantitis at a low level (Costa et al., 2012).

A systematic review confirmed that the application of ridge preservation could significantly decrease the need for additional bone augmentation procedure at implant placement in comparison with spontaneous healing (Mardas et al., 2015). A retrospective study found that additional augmentation procedures were performed more significant at naturally healed sites (69.4% vs. 79.7%) (Park et al., 2020). One clinical study reported that 58% in healed sites required additional bone augmentation procedure, compared to 7% in ridge preservation sites (Cardaopoli et al., 2015). In the present study, 36% of implants placed within non-grafted sockets required bone augmentation, whereas 6% of the sites in the test group reported the need for further bone augmentation.

There are limitations when using two-dimensional radiography to review three-dimensional bony structure; yet periapical radiography allows a simple, non-invasive, and reproducible method to evaluate marginal bone level, and remains the most common clinical method to monitor long-term implant success. The results of the present study, in terms of marginal bone level between the test and control groups, are in accordance with the results presented by previous studies (Barone et al., 2012; Patel et al., 2013). Wennstrom suggested reporting the differences in marginal bone loss relative to the baseline radiographs rather than only reporting the marginal bone levels during the prosthesis delivery (Wennstrom et al., 2005). Therefore, marginal bone level alterations between the initial crown delivery and the 3-year follow-up period were evaluated in the current study. After loading for 3 years, the overall mean difference was 0.072 mm (95% CI [−0.279, 0.423]). These results demonstrate that crestal bone levels of implants placed in ridge-preserved and augmented periodontally compromised molar sites remain stable over time compared with grafted unaltered peri-implant bone. The investigations of marginal bone changes following ridge preservation are scant and outcomes were not consistent. Meta-analysis reported implants inserted into the previously grafted sockets showed lower marginal bone loss than the implants inserted into the non-grafted sites (Ramanauskaite et al., 2019). A recent retrospective study found the mean MBL was lower at ridge-preserved sites after 2 and 3 years in function, but was greater beyond 4 years in function than the naturally healed sites. While other studies found no statistically significant differences in the marginal bone level were detected between grafted and non-grafted extraction

sockets, which is consistent with the present study (Barone et al., 2012; Park et al., 2020; Wu et al., 2019). Barone et al., (2012) observed the MBL was 1.00 mm (SD 0.2) at the ridge-preserved sites and 1.02 mm (SD 0.3) at naturally healed sites at a 3-year follow-up study. Wu et al. (2019) observed the mean MBL changes were 0.09 mm (SD 0.34) and 0.06 mm (SD 0.51) in the ridge preservation and naturally healed sites in a retrospective study. The results may be attributed to the baseline MBL at the time of implant placement, not at the time of implant prosthesis insertion. To our knowledge, this is the first prospective controlled study to evaluate marginal bone levels associated with implants placed in native bone and in sites following ridge preservation limited to infected and deficient molar extraction sockets due to periodontal disease in humans.

Important limitations to note in this study are lack of randomization, lack of a control (healthy group/non-periodontal), and relatively short follow-up periods. In addition, another limitation of the present investigation is that two different implant systems were simultaneously combined in the control group. Considering the limited sample size, the correlations between the implant systems and clinical and radiographic parameters were not compared.

5 | CONCLUSIONS

Within the limits of the present study, implants placed at ridge-preserved and naturally healed sockets of periodontally compromised molar demonstrated comparable outcomes with regard to survival and success rates, peri-implant parameters, and marginal bone levels at a 3-year post-loading evaluation. A longer-term assessment should be conducted to support these preliminary findings.

AUTHOR CONTRIBUTIONS

Liping Zhao contributed to conception and design of the study, data collection, statistic data analysis and interpretation, manuscript preparation, and approval of the submitted and final versions Wenjie Hu contributed to conception and design of the study, conduction clinical procedures, manuscript review, and approval of the submitted and final versions. Yunsong Liu carried out conception and design of the study, conduction restorative procedures, manuscript review, and approval of the submitted and final versions. Kwok-Hung Chung carried out conception and design of the study, restoration consultation, analyzing the data, editing, and approval of the submitted manuscript.

ACKNOWLEDGMENTS

We thank Dr. Joelle Moussi for editorial assistance with the manuscript, Yiping Wei for suggestions on revision of the manuscript and Professor Yangfeng Wu for advices on analytical methods.

CONFLICT OF INTEREST

The authors declare no conflicts of interest related to this study.

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available from the corresponding author upon reasonable request.

PATIENT CONSENT STATEMENT

All patients received verbal and written informed consent.

CLINICAL TRIAL REGISTRATION

This study was registered in the Chinese Clinical Trial Registry (ChiCTR-ONN-16009433).

ETHICAL APPROVAL

This study was administered in compliance with the ethical principles founded in the Helsinki Declaration of 1975, as revised in 2013, and approved by the relevant independent committee on the Institutional Review Boards of the Peking University School and Hospital of Stomatology (Protocol number: PKUSSIRB-201310068a).

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SUPPORTING INFORMATION

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How to cite this article: Zhao, L., Hu, W., Liu, Y., & Chung, K.-H. (2022). Evaluation of implant placement following ridge preservation in periodontally compromised molar extraction sockets: Three-year results of a prospective cohort study. *Clinical Oral Implants Research*, *33*, 735–744. https://doi.org/10.1111/clr.13949