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# Early loading of splinted implants in posterior mandible: Three-year results of a prospective multicenter study

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## Abstract

**Objective:** To evaluate the clinical outcomes of an early loading protocol of splinted implants with a fluoride-modified nanostructure surface and a tapered apex design for the therapy of posterior partial edentulism of mandible.

**Materials and Methods:** One hundred and seven implants were placed in the mandible of 45 subjects at three centres in China. A minimum of two and a maximum of three implants were placed in an edentulous region using a one-stage protocol. Each subject received a screw-retained, splinted and fixed permanent prosthesis 6–8 weeks after surgery. Marginal bone level (MBL) change, implant survival and soft tissue health were assessed at 6, 12, 24 and 36 months after loading. A total of 92 implants from 40 subjects were recalled and investigated in this clinical trial.

**Results:** After three-year loading, the survival rate of implant was 100%. On a subject level, there was a mean (±*SD*) marginal bone gain of 0.23 ± 0.48 mm at 36-month recall and the change in MBL was statistically significant ($p = .00061$) compared with time of loading. On an implant level, the change in MBL was statistically significant ($p = .03914$, $p = .01494$, $p = .00000$) at 12, 24 and 36 months of loading compared with time of loading.

**Conclusion:** Three-year data indicate that early loading protocol of splinted implants with a fluoride-modified nanostructure surface and a tapered apex design is feasible and safe for the therapy of partial edentulism in posterior mandible, which may contribute to bone gain when the suitable occlusal load and oral hygiene maintenance are kept.

KEYWORDS

dental implants, early loading, marginal bone level, one-stage surgery, splinted restorations

Jianzhang Liu, Qingfeng Huang and Xiaodong Wang are contributed equally.

## 1 | INTRODUCTION

Early loading of dental implants is defined as the loading of dental implants between 1 week and 2 months of post-placement of implants (Gallucci et al., 2014; Weber et al., 2009). Early loading of implants reduces the load-free healing period, which may be beneficial for patients. Pre-mature loading may be easier to lead to fibrous tissue encapsulation around implants instead of direct osseointegration (Branemark, 1983; Branemark et al., 1983, 1969, 1977). Although the protocols of immediate loading or early loading for implants can provide ideal survival rates and clinical outcomes in certain specific situations in some studies (Blanco et al., 2013; Fuh et al., 2010; Galindo-Moreno et al., 2017; Haverstock et al., 2012; Jokstad & Alkumru, 2014), using an early loading protocol for an indication where it is not a viable treatment option may cause implant failure. Faced with different clinical realities, relevant factors should be considered when choosing an early loading protocol, for example maintenance of implant stability and controlled loading (Glauser, Lundgren, et al., 2010), achievement of primary stability (Eliyas & Al-Khayatt, 2008; Esposito, Grusovin, Willings, Coulthard, & Worthington, 2007; Glauser, Rée, et al., 2010), selection of implant system (Albrektsson, Branemark, Hansson, & Lindstrom, 1981; Geckili, Bilhan, & Bilgin, 2009; Simunek et al., 2012, 2010), types of restoration, bone quality (Simunek et al., 2012, 2010) and implant sites (Glauser, Rée, et al., 2010). This is particularly the case for restorations of partial edentulism in the posterior jaws, where high occlusal forces exist as compared with those in the anterior jaws.

One-year results from this clinical trial have previously been described showing the achievement of a MBL gain (Zhou et al., 2016). Increased MBL or peri-implant bone gain has also been reported by other studies (Blanes, Bernard, Blanes, & Belser, 2007; Bruschi et al., 2014; Cecchinato et al., 2008; Donati et al., 2015). The crestal bone changes around implants are influenced by many factors, for example the implant properties (Blanes et al., 2007; Donati et al., 2008; Hartman & Cochran, 2004), occlusal forces (Quirynen, Naert, & van Steenberghe, 1992), initial gingival tissue thickness (Linkevicius, Apse, Grybauskas, & Puisys, 2009), bleeding on probing (BoP), and presence of plaque (Donati et al., 2015), stimulating effects of the loadings on the remodelling of the peri-implant bone (Brunski, 1999), surgical trauma, microleakage, implant anatomy on the crestal area and peri-implantitis (Macedo et al., 2016; Oh, Yoon, Misch, & Wang, 2002). We hypothesize that subjecting splinted implants (containing a fluoride-modified surface, and platform switching, conical seal, MicroThread and tapered apex designs) to an early loading protocol provide beneficial clinical outcomes by preserving the marginal bone, which may lead to stable or even increased MBL. Therefore, this open, prospective, multicentre study was initiated to assess early loading in the posterior mandible. Primary outcome variable of this report was to assess marginal bone level (MBL) alterations over time. Secondary outcome variables include implant survival rate and clinical assessment of soft tissue status by measuring the probing pocket depth (PPD), bleeding on probing (BoP) and presence of plaque. The MBL gain seen at the 12-month follow-up in the previous study (Zhou et al., 2016) indicated that the splinted implants were suitable for the chosen location and early loading. If acceptable occlusal loads on the implant and prosthetic structure as well as the prevention of microbial infections can be maintained, it is possible that there might be further bone gain to be seen. The present article reports study outcomes after a completed observation period of 3 years.

## 2 | MATERIALS AND METHODS

### 2.1 | Study design and clinical procedures

In total, 45 subjects aged 20–75 years with partial edentulism in posterior regions of the mandible were recruited in three centres (15 subjects from each centre): Department of Prosthodontics, Hospital of Stomatology, Peking University, Beijing, China; Department of Prosthodontics, Hospital of Stomatology, Sun Yat-sen University, Guangzhou, China; and Department of Prosthodontics, Ninth People's Hospital affiliated to Shanghai Jiaotong University, Shanghai, China. The study protocols were approved by the Committees of Medical Ethics at the 3 involved hospitals (IRB00001052-11004 for Beijing; [2011] 10 for Shanghai; ORAL [2010] Ethic Approval [11] for Guangzhou).

The subjects were provided verbal and written information concerning the trial. All the subjects and the study prosthodontists signed the informed consent forms at the beginning of the study.

The registration number on clinicaltrials.gov for this clinical trial is NCT01346683. The eligibility criteria and clinical parameters were same for all three centres. The inclusion and exclusion criteria and subject characteristics have all been described in the previous publication (Zhou et al., 2016). The development of this clinical study has followed the CONSORT guideline. One hundred and seven OsseoSpeed TX implants (Astra Tech Implant System, Dentsply Sirona Implants) with length between 8 and 13 mm and diameter between 3.5 and 5.0 mm were placed in 45 subjects. The therapy contained one-stage implantation and abutment installation, implant loading after healing of 6–8 weeks, and scheduled recall visits at 6, 12, 24 and 36 months of post-loading. Two or three splinted implants were delivered in the posterior mandible for each subject. The surgery was performed following the implant operation manual for a one-stage procedure provided by the manufacturer. The implants were vertically positioned at the marginal bone level or slightly below. Excess bone above the implant was flattened. Open tray impressions were then taken at the abutment level approximately six weeks after implant placement using polyether impression material (Impregum, 3M). The permanent prostheses (splinted porcelain-fused-to-metal crowns) were installed about one week after the impression taking, and loading was then applied. All the prostheses were screw-retained using Uni abutments (Astra Tech Implant System, Dentsply Sirona Implants) with narrow occlusal platforms and flat cusps.

The occlusion was adjusted in order to achieve only light centric contacts, avoiding any contacts protrusively or laterally. Pressure sensitive indicator paper was used to confirm that there were less evident

signs of contact on the implant-supported restorations than on that of the neighbouring teeth. That is to say, articulating film (Bausch Arti-Fol®, ultra-thin 8 microns, Dr. Jean Bausch KG) could be pulled out in light biting when implant-supported restorations bited.

## 2.2 | Measurement of study parameters

Marginal bone levels (MBLs), bleeding on probing (BoP) and probing pocket depth (PPD) were examined at six time points: immediately after surgery, at loading and at 6-, 12-, 24- and 36-month recall visits post-loading. At each visit, implant stability was manually assessed, and in addition, any clinical complications or adverse device effect (ADE) was recorded.

MBL was measured from intraoral radiographs and recorded as the distance from the junction of the machined bevel and the start point of the microthread surface to the most coronal bone–implant contact point on the mesial and distal side of the implant (Figure 1a–f). To ensure the reproducibility across different visits, radiographs with a paralleling technique were taken using commercially available film holders. To reduce the risk of radiographic error, threaded profile of the implant at both mesial and distal sides had to be clearly distinguishable in the X-ray films. All the radiographs taken in this report were assessed by an external radiological expert from the University of Gothenburg (Sweden), independent of the study group.

BoP and PPD were examined on four surfaces (buccal, lingual, mesial and distal). The proportion of surfaces that revealed BoP and presence of plaque were presented at implant level. Mean PPD was provided for each implant. Methods and additional information were previously described in the earlier publication (Zhou et al., 2016).

## 2.3 | Statistical analyses

Results were provided using descriptive statistics, for example number of subjects (*N*), mean, median, standard deviation (*SD*), range (minimum, maximum) and frequency tables. No covariates were evaluated to influence outcomes of the primary or secondary variables. SPSS (version 22.0, for Windows, IBM) and Microsoft Excel (2010) were applied to statistic calculation. PP analysis for change over time (within group) in MBL was performed using a Wilcoxon signed-rank test. All the statistical tests were performed with a statistically significance level of $p < .05$. Only complete blocks were applied to the statistical analyses.

In cases where only one side of the implant was distinguishable on X-ray films, MBL was recorded as a value at either mesial or distal side, whichever was readable. Only on four occasions was it possible

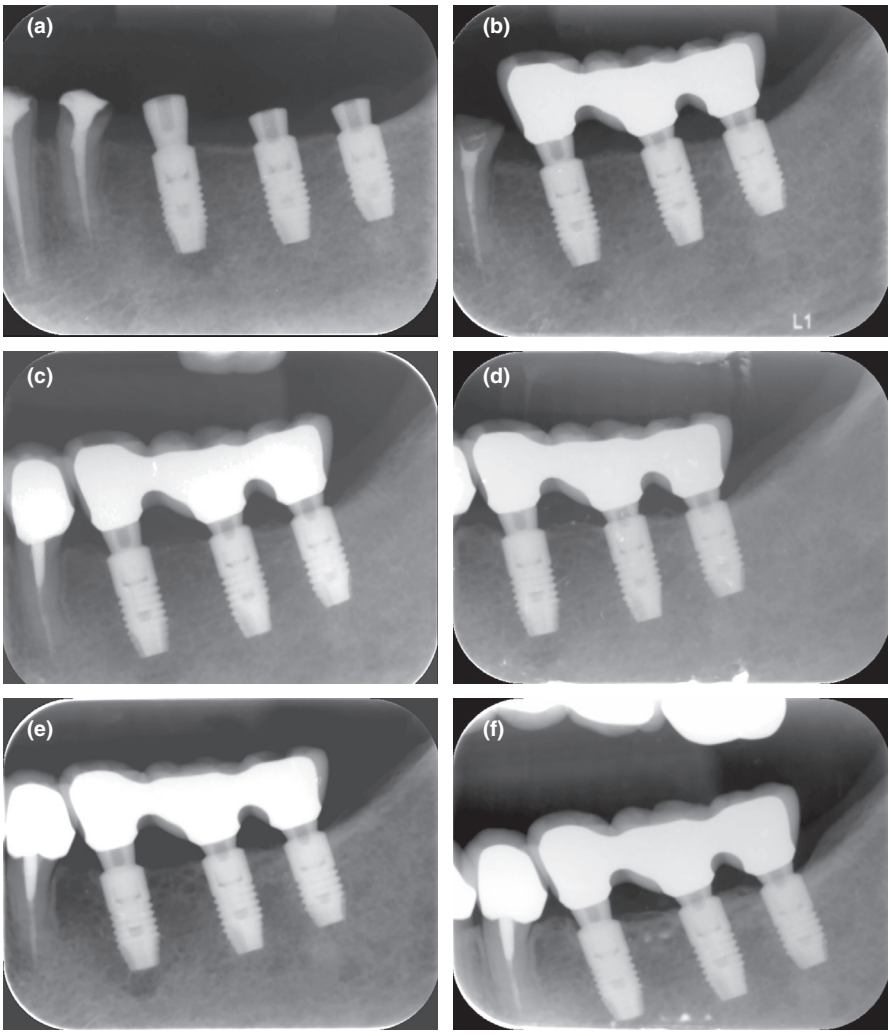


**FIGURE 1** Radiographic documentation of (a) OsseoSpeed implant, UniAbutment and healing cap after implant placement; (b) at definitive prosthesis delivering (loading baseline); (c) at the 6-month follow-up; (d) at the 12-month follow-up; (e) at the 24-month follow-up; (f) at the 36-month follow-up

**TABLE 1** MBL absolute values for each subject (each implant) at loading point and follow-up

| MBL average (mm) | Implant placement | Loading | Loading + 6 months | Loading + 12 months | Loading + 24months | Loading + 36 months |
|---|---|---|---|---|---|---|
| $N_{subjects}$ | 40 | 40 | 38 | 36 | 40 | 38 |
| Mean ± *SD* | 0.32 ± 0.38 | 0.47 ± 0.36 | 0.44 ± 0.32 | 0.36 ± 0.34 | 0.36 ± 0.37 | 0.25 ± 0.45 |
| Min/Max | 0/1.38 | 0/1.28 | 0/1.23 | 0/1.18 | 0/1.40 | 0/2.30 |
| Median | 0.17 | 0.38 | 0.41 | 0.30 | 0.28 | 0.11 |
| $N_{implants}$ | 92 | 92 | 87 | 82 | 91 | 88 |
| Mean ± *SD* | 0.30 ± 0.51 | 0.45 ± 0.46 | 0.44 ± 0.44 | 0.35 ± 0.39 | 0.33 ± 0.40 | 0.22 ± 0.41 |
| Min/Max | 0/2.20 | 0/1.95 | 0/2.50 | 0/1.50 | 0/1.90 | 0/2.30 |
| Median | 0.00 | 0.30 | 0.35 | 0.20 | 0.20 | 0.00 |

**TABLE 2** Marginal bone level (MBL) change (in mm) from implant installation, subject level (implant level)

| MBL average (mm) | Loading | Loading + 6 months | Loading + 12 months | Loading + 24 months | Loading + 36 months |
|---|---|---|---|---|---|
| $N_{subjects}$ | 40 | 38 | 36 | 40 | 38 |
| Mean ± *SD* | −0.15 ± 0.42 | −0.12 ± 0.46 | −0.02 ± 0.46 | −0.04 ± 0.49 | 0.08 ± 0.58 |
| Min/Max | −1.28/1.30 | −0.80/1.35 | −1.18/1.35 | −1.15/1.35 | −2.10/1.35 |
| Median | −0.16 | −0.18 | −0.02 | 0.00 | 0.06 |
| $N_{implants}$ | 92 | 87 | 82 | 91 | 88 |
| Mean ± *SD* | −0.15 ± 0.55 | −0.13 ± 0.55 | −0.02 ± 0.55 | −0.02 ± 0.55 | 0.10 ± 0.61 |
| Min/Max | −1.95/2.10 | −1.55/1.95 | −1.40/1.55 | −1.45/2.10 | −2.10/2.10 |
| Median | −0.05 | −0.20 | 0.00 | 0.00 | 0.00 |

to read only one of the two sides. Due to a small percentage of this situation, it was estimated to have ignored impact on the overall study result.

The data were analysed on subject and implant level. This report was not designed to analyse inter-centre differences, and therefore, the data from the three centres were pooled for further analyses.

## 3 | RESULTS

Forty-five subjects were enrolled in the study but 15 implants in five enrolled subjects were excluded from analyses owing to lack of primary implant stability, 2-stage surgery and/or delayed loading. A total of 92 implants in 40 subjects were consequently followed up and investigated in this study. Nine subjects suffered a history of periodontitis, but the condition was under control at the time of implant surgery. One subject suffered from bruxism. One subject with three splinted implants was lost to follow-up at the 12-month visit because the subject transferred to another city, but we were informed through a telephone contact that the splinted restorations on the three implants were still in function. Nevertheless, this subject was recorded as lost to recall. All other implants were investigated and analysed.

The survival rate of implant at 36 months after loading was 100%. Table 1 presents MBL values at the time of implant placement and at the scheduled follow-up examinations. Between implant surgery and loading, there was a slight decrease of 0.15 ± 0.42 mm in MBL (marginal bone loss) on a subject level and 0.15 ± 0.55 mm (marginal bone loss) in MBL on an implant level (Table 2). At 6, 12, 24 and 36 months after loading, the MBL increased (marginal bone gain) by 0.01 ± 0.33 mm, 0.11 ± 0.34 mm, 0.11 ± 0.37 mm and 0.23 ± 0.48 mm, respectively, on a subject level and −0.01 ± 0.49 mm, 0.11 ± 0.42 mm, 0.12 ± 0.46 mm and 0.24 ± 0.51 mm, respectively, when calculated on implant level (Table 3). The cumulative percentage of subjects and implants that indicated marginal bone gain or loss is presented in Figures 2 and 3.

The respective comparison of MBL at 6, 12, 24 and 36 months after loading with MBL at time of loading was presented in Table 4. At subject level, there was no statistical difference ($p > .05$) at 6, 12 and 24 months after loading compared with MBL at time of loading. However, a significant difference (marginal bone gain, $p = .00061$) was observed at 36 months after loading compared with MBL at time of loading. At implant level, there was no significant difference ($p > .05$) for 6 months after loading compared with MBL at time of loading. There were statistical differences for 12, 24 and 36 months after loading compared with MBL at time of loading (marginal bone gain, $p = .03914$, $p = .01494$, $p = .00000$, respectively).

In terms of clinical examination, plaque existed in 29.3% of implants at loading, in 16.3% of implants at the 6-month follow-up, in 16.7% of implants at the 12-month follow-up, in 19.6% of implants at the 24-month follow-up and in 20.7% of implants at the 36-month follow-up (Table 5). The mean increase in PPD for all subjects from loading to 36 months was 0.8 ± 0.9 mm (Tables 6 and 7).

**TABLE 3** Marginal bone level (MBL) change (in mm) from loading point (baseline), subject level and implant level

| MBL Average (mm) | Loading + 6 months | Loading + 12 months | Loading + 24 months | Loading + 36 months |
|---|---|---|---|---|
| $N_{subjects}$ | 38 | 36 | 40 | 38 |
| Mean ± *SD* | 0.01 ± 0.33 | 0.11 ± 0.34 | 0.11 ± 0.37 | 0.23 ± 0.48 |
| Min/Max | −0.60/0.90 | −0.65/0.93 | −1.10/0.90 | −1.55/1.28 |
| Median | 0.00 | 0.06 | 0.05 | 0.24 |
| $N_{implants}$ | 87 | 82 | 91 | 88 |
| Mean ± *SD* | −0.01 ± 0.49 | 0.11 ± 0.42 | 0.12 ± 0.46 | 0.24 ± 0.51 |
| Min/Max | −2.50/1.05 | −1.00/1.25 | −1.60/1.40 | −1.55/1.95 |
| Median | 0.00 | 0.00 | 0.00 | 0.15 |

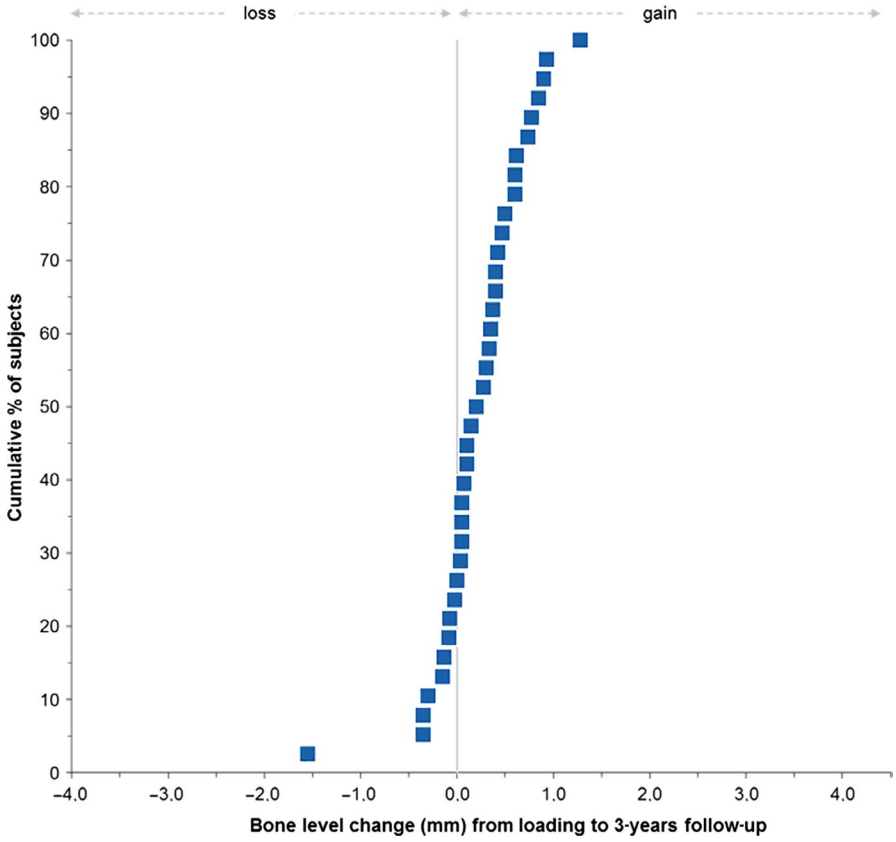


**FIGURE 2** Bone level change (mm) from loading point to 3-year follow-up (subject level)

BoP occurred in 17.4% of implants at loading, in 22.8% of implants at the 6-month follow-up, in 24.4% of implants at the 12-month follow-up, in 15.2% of implants at the 24-month follow-up and in 32.6% of implants at the 36-month follow-up (Table 8). During the 36-month study period, one subject experienced loose bridge screws, one subject experienced loose bridge screws and splint crown loosening, one subject experienced porcelain chipping, and one subject experienced bone resorption around implants. The loose screws were re-fixed according to the manufacturer's instructions for use. The porcelain-chipped crown was removed and re-installed after repair. For the case that experienced bone resorption around implants, the crown was removed. After cleansing around the implant and alternately flushing with 0.12% chlorhexidine and 2% hydrogen peroxide, minocycline hydrochloride ointment (Sunstar INC) was applied and the crown was re-fixated. Subsequently, the bone levels remained stable. No other technical or biological complications associated with the dental implants were reported.

## 4 | DISCUSSION

For success of early loading, controlling the micro-movement (Szmukler-Moncler, Salama, Reingewirtz, & Dubruille, 1998; Tarnow, Emtiaz, & Classi, 1997) and promoting the process of osseointegration is very important. In this study, several factors promoted these objectives. First, the OsseoSpeed TX implant used in this study contains a fluoride-modified nano-surface, with low amounts of fluorion

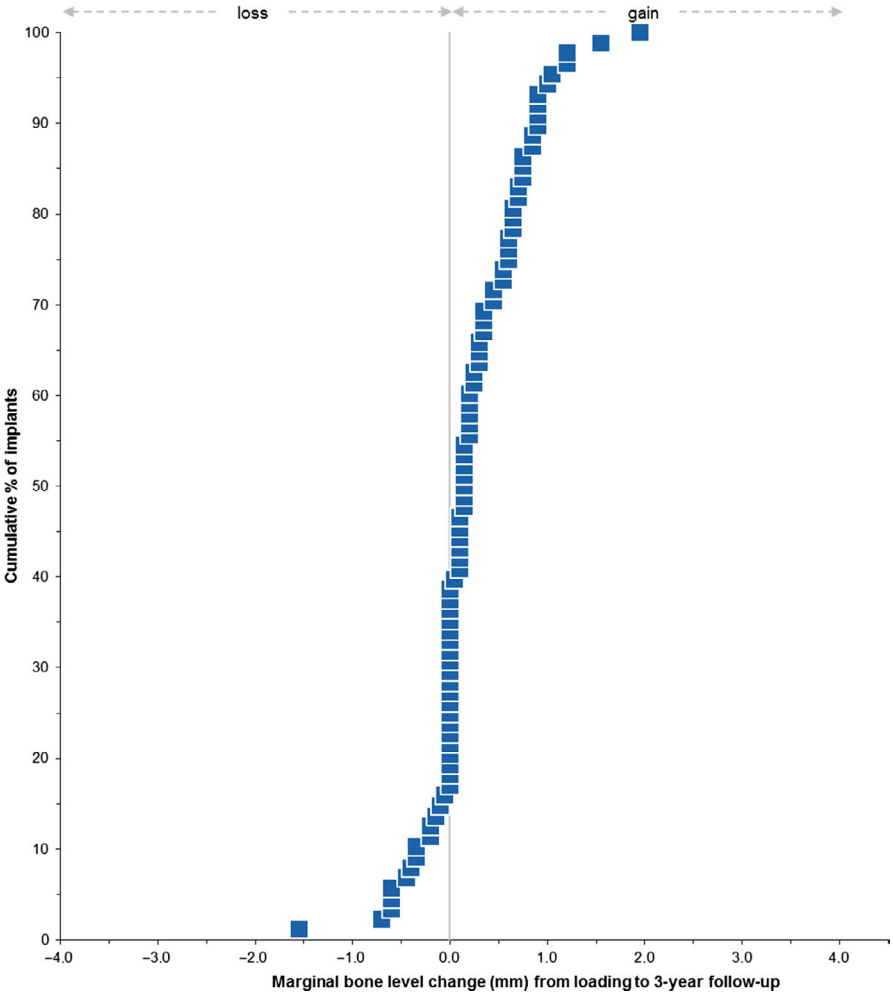


**FIGURE 3** Bone level change (mm) from loading point to 3-year follow-up (implant level)

| | Subject level (Baseline = Loading point) | Implant level (Baseline = Loading point) |
|---|---|---|
| Loading + 6 months | 0.89382 | 0.85339 |
| Loading + 12 months | 0.05568 | 0.03914 |
| Loading + 24 months | 0.05924 | 0.01494 |
| Loading + 36 months | 0.00061 | 0.00000 |

**TABLE 4** *p*-values for marginal bone level (MBL) change over time, subject level and implant level [PP analysis]

**TABLE 5** Plaque for each implant at loading point and follow-up

| Data | Loading | Loading + 6 months | Loading + 12 months | Loading + 24months | Loading + 36 months |
|---|---|---|---|---|---|
| Number of subjects | 40 | 40 | 39 | 40 | 40 |
| Number of implants | 92 | 92 | 90 | 92 | 92 |
| Number (Proportion) of implants with plaque | 27 (29.3%) | 15 (16.3%) | 15 (16.7%) | 18 (19.6%) | 19 (20.7%) |
| Number of surfaces | 368 | 368 | 360 | 368 | 368 |
| Number (Proportion) of surfaces with plaque | 56 (15%) | 32 (9%) | 35 (10%) | 21 (6%) | 34 (9%) |

ions bound to the $TiO_2$ layer, which has been found to improve bone formation and bone–implant contact, with a quicker healing time as a result (Abrahamsson, Albouy, & Berglundh, 2008; Cooper et al., 2006; Monjo, Lamolle, Lyngstadaas, Rönöld, & Ellingsen, 2008). The implant has a design of tapered apex, which is conducive to placing the implant into the drilled site. This allows a minimal site preparation and increases primary stability. Secondly, the posterior mandible normally has more cortical bone for which mechanical engagement

**TABLE 6** Probing pocket depth (PPD) for each implant at loading point and follow-up

| PPD (Absolute values in mm) | Loading | Loading + 6 months | Loading + 12 months | Loading + 24months | Loading + 36 months |
|---|---|---|---|---|---|
| $N_{implants}$ | 92 | 92 | 90 | 92 | 92 |
| Mean ± *SD* | 1.3 ± 0.5 | 1.6 ± 0.6 | 1.7 ± 0.7 | 1.7 ± 0.7 | 2.1 ± 0.9 |
| Min/Max | 0.0/2.8 | 0.8/4.0 | 0.8/4.3 | 1.0/4.8 | 1.0/5.5 |
| Median | 1.1 | 1.4 | 1.5 | 1.5 | 1.8 |

**TABLE 7** Probing pocket depth (PPD) for each implant change (in mm) from loading point (baseline)

| PPD (Change from Loading) | Loading | Loading + 6 months | Loading + 12 months | Loading + 24 months | Loading + 36 months |
|---|---|---|---|---|---|
| $N_{implants}$ | 92 | 92 | 90 | 92 | 92 |
| Mean ± *SD* | 0.0 ± 0.0 | 0.3 ± 0.7 | 0.4 ± 0.8 | 0.4 ± 0.7 | 0.8 ± 0.9 |
| Min/Max | 0.0/0.0 | 2.3/−1.5 | 3.0/−1.5 | 2.8/−1.5 | 4.5/−0.5 |
| Median | 0.0 | 0.0 | 0.3 | 0.4 | 0.8 |

**TABLE 8** Bleeding on probing for each implant at loading point and follow-up

| Data | Loading | Loading + 6 months | Loading + 12 months | Loading + 24months | Loading + 36 months |
|---|---|---|---|---|---|
| Number of subjects | 40 | 40 | 39 | 40 | 40 |
| Number of implants | 92 | 92 | 90 | 92 | 92 |
| Number (Proportion) of bleeding implants | 16 (17.4%) | 21 (22.8%) | 22 (24.4%) | 14 (15.2%) | 30 (32.6%) |
| Number of surfaces | 368 | 368 | 360 | 368 | 368 |
| Number (Proportion) of bleeding surfaces | 29 (7.9%) | 38 (10.3%) | 38 (10.6%) | 24 (6.5%) | 59 (16%) |

is more easily acquired for implants. In this study, D1 type of bone quality (Misch, 1990) of the posterior mandible accounted for 4.7%, D2 for 58.9%, D3 for 36.4% and D4 for 0%, which was suitable for early loading. Thirdly, to achieve adequate stability for the implants of early loading, 2 or 3 implants were splinted together in each edentulous area. It has been demonstrated that the implant splinting can decrease the initial tissue strains at bone–implant interface compared with the non-splinted ones (Akca, Akkocaoglu, Comert, Tekdemir, & Cehreli, 2007) and that splinted restorations have significantly less displacement of abutment than the non-splinted restorations (Yilmaz, Seidt, & Clelland, 2014). Guichet, Yoshinobu, & Caputo (2002) recommended splinting of the restorations to evenly distribute stresses among implants and to provide a predictable long-term survival of prosthesis. Fourthly, we used Uni abutments, which were tightened using a force of 15 Ncm immediately after the implant had been placed. When the splinted crowns were inserted, the tightening torque was only 15 Ncm as well, to avoid overloaded stress during tightening. Moreover, splinted crowns can decrease the probability of micro-movement during tightening and the initial loading phase. Further, only implants with adequate primary stability (>15 Ncm) were included in the present study which also yielded contribution to the success of this protocol. With all those contributing factors, the survival rate of implants at 36 months after early loading was 100%. In conclusion, early loading for the splinted implants with a fluoride-modified nano-surface and a design of tapered apex in the healed posterior edentulism of the mandible, with adequate primary implant stability, provides a predictable, effective and safe treatment strategy.

In this study, from the implant placement to the loading time point, there were significant levels of bone absorption, and these findings were corroborated by reports from previous studies (Astrand et al., 1999; Cochran, Nummikoski, Schoolfield, Jones, & Oates, 2009; Donati et al., 2015; Schliephake et al., 2012). The main reasons for bone absorption maybe were surgical damage, interruption of the blood supply to the bone tissues during the implant site preparation and acute inflammatory reactions causing peri-implant bone loss (Cochran et al., 2009). A previous study showed that most of the bone loss took place during the first three months after implant installation (Donati et al., 2015). We think that early loading definitively reduces the duration of rapid bone absorption which correspondingly helps to decrease the bone resorption.

In our study, the MBLs started to increase after loading. On implant level, statistically significant levels of bone gain can be seen, at 12, 24 and 36 months after loading. On the subject level, statistically significant levels of bone gain can be seen at 36 months after loading. Bone gain was observed for the majority of the implants (>70% both on implant and subject level). For subjects and implants with bone level reduction, the bone losses were <1 mm, except for one subject with a bone loss of 1.6 mm at 3 years after loading.

In this study, good oral hygiene maintenance reduced the chance of simultaneous microbial infection, the splinting of restorations and the occlusal features ensured suitable mechanical stimulation applied to the peri-implant structure, both of which may result in bone gain around dental implants (Berglundh, Abrahamsson, & Lindhe, 2005; Bruschi et al., 2014; Donati et al., 2015; Gotfredsen Berglundh, & Lindhe, 2001b,2001c, 2001a; Schenk & Buser, 1998; Tawil, 2008). The implant design concepts of OsseoSpeed TX, including fluoride-modified nano-surfaces, and platform switching, MicroThread and conical seal designs are more conducive to reducing microbial leakage and facilitating bite force conduction, which partially attribute to the gain in MBL (Zhou et al., 2016).

In a recent report, the application of splinted 6-mm-short implants of the same brand was evaluated in posterior regions. Bone loss less than 1.0 mm was shown in 12.7% implants, and bone gain as much as 1.9 mm was shown in 22.5% implants. No change in bone level was shown in 62.0% implants (Han, Tang, Zhang, & Meng, 2018). In the current study, the proportion of implants showing bone gain was 61.4%, which was even higher than that reported by Han et al.

There are several possible reasons for why we have a high proportion of bone gain. Firstly, in the current study the final Uni abutments were connected at implant placement, impressions were recorded approximately 6 weeks at the abutment level, and we did not need to connect the abutment during impression which reduced the risks of causing bone loss. Any operation around the tissue at the coronal portion of the implant would affect the bone tissue and gingival tissues around the implant. Gingival flap elevation can result in a bone loss around implants (Moghaddas & Stahl, 1980; Smith, Ammons, & Van Belle, 1980; Wood, Hoag, Donnenfeld, & Rosenfeld, 1972). All these prosthodontic procedures, such as removal of the healing abutments or cover screws, final abutment placement, impression material application, placement of a provisional restoration and placement of the final restoration, may interfere in the remodelling of the bone and gingival tissues around the implant, contributing obvious inflammation, likely in response to microbial contamination (Callan, Cobb, & Williams, 2005; Cochran et al., 2009). Secondly, we used permanent, screw-retained, splinted, porcelain-fused-to-metal crowns that were loaded in full functional occlusion 6 weeks following implant placement. No temporary crowns were used, which possibly reduced the adverse stress on the tissues surrounding the implant. Thirdly, the present study was accomplished under ideal clinical situations by applying strict subject selection, excluding subjects with known risk factors such as uncontrolled diabetes or existed pathologic processes in the oral cavity and heavy smokers. All the surgical procedures were carried out by experienced teams. We used implants that ranged 8–13 mm in length, and each subject was treated with two or three splinted implants in the posterior mandible. This may have allowed for a better distribution of the stress forces around the implant–bone interface, compared with Han J et al.'s study, in which 6-mm implants with a diameter of 4 mm were placed in posterior maxilla and mandible.

The present study has certain limitations since it was not randomized and with no control group. Further investigations with longer follow-ups and with a randomized controlled design are still needed to draw a definitive conclusion.

## 5 | CONCLUSION

Marginal bone level and soft tissue health around dental implants remained stable during the study, and most of the implants even showed a slight increase in MBL after the first three years in function. Within the limitations of this prospective multicentre study, the conclusion can be drawn that the early loading protocol of splinted implants with a fluoride-modified nanostructure surface and a tapered apex design is effective, feasible and safe for therapy of posterior partial edentulism in mandible. This study also shows that under optimal conditions, some peri-implant bone gain may be achieved during the first three years after loading.

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## CONFLICT OF INTEREST

The authors declare that they have no conflicts of interests.

## AUTHOR CONTRIBUTIONS

This study is an industry-sponsored multicentre study, conducted in three centres in China. The results of our three centres are shared, and the three principal investigators contributed equally to the study. Yongsheng Zhou, Xinquan Jiang and Ke Zhao conceived and designed the experiments; Jianzhang Liu, Qingfeng Huang and Xiaodong Wang performed the data analyses and wrote the manuscript; Yan Li, Jianfeng Zhou and Deliang Zeng helped perform the analysis with constructive discussions.

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