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Hard and soft tissue alterations during the healing stage of immediate implant placement and provisionalization with or without connective tissue graft: A randomized clinical trial

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Abstract

Aims: To evaluate the hard and soft tissue alterations of immediately placed and provisionalized implants with or without connective tissue graft (CTG).

Materials and Methods: Single unsalvageable maxillary incisors were replaced with immediately placed and provisionalized implants in 42 participants. The patients were randomly assigned to receive simultaneous CTG (test group) and not receive CTG (control group). Digital impression and cone-beam computed tomography images were obtained before extraction and after 6 months. Mid-facial gingival margin migrations, soft tissue contour changes and hard tissue remodelling were analysed and compared between the two groups using three-dimensional superimposition method.

Results: Forty participants completed the study. The test group showed significantly less buccal tissue collapse in the area 2–5 mm apical to the gingival margin. In both groups, the mid-facial gingival margin migrated in an apico-palatal direction and the socket void, except for a triangular space in the bucco-coronal region, demonstrated radiographic new bone formation without statistically significant differences.

Conclusions: The CTG used with immediate implant placement and provisionalization could compensate for the facial tissue collapse, but it did not benefit maintenance of the mid-facial gingival margin position during the 6-month follow-up. New bone formation observed radiographically can be expected in most areas of the socket void, regardless of CTG use (ChiCTR-1900028494).

KEYWORDS

aesthetics, connective tissue graft, extraction socket remodelling, immediate implant, immediate provisionalization

1 | INTRODUCTION

Immediate implant placement and provisionalization (IIPP) in the extraction socket is an attractive treatment modality that facilitates immediate tooth replacement and reduces treatment time, cost and surgical trauma as compared to delayed approaches (Kan, Rungcharassaeng, & Lozada, 2003; Noelken, Neffe, Kunkel, & Wagner, 2014). However, this treatment concept has been controversial in terms of implant survival (Slagter et al., 2014; Tonetti et al., 2019) and aesthetic outcomes in particular, when anterior

maxilla is involved. Clinical studies have demonstrated high aesthetic risk of mid-facial gingival recession in mid- to long-term follow-ups (Evans & Chen, 2008; Kan, Rungcharassaeng, Lozada, & Zimmerman, 2011). Systematic reviews have also revealed that immediate implants may result in advanced (>1 mm) gingival recession, which could lead to aesthetic failure of the implant restoration (Chen & Buser, 2014; Cosyn, Hooghe, & De Bruyn, 2012). In contrast, IIPP was also reported to achieve favourable aesthetic outcomes in recent clinical studies, but on the conditions that the implant was placed in the correct three-dimensional position (Chen, Darby, & Reynolds, 2007; Evans & Chen, 2008), bone substitute was applied (Cardaropoli, Tamagnone, Roffredo, & Gaveglio, 2015; Sanz, Lindhe, Alcaraz, Sanz-Sanchez, & Cecchinato, 2017), provisionalization was immediately connected (Amato, Polara, & Spedicato, 2018; De Rouck, Collys, & Cosyn, 2008), soft tissue grafting was implemented (Migliorati, Amorfini, Signori, Biavati, & Benedicenti, 2015; Yoshino, Kan, Rungcharassaeng, Roe, & Lozada, 2014), and the case was carefully selected to have a thick buccal plate and thick gingival biotype (Buser, Chappuis, Belser, & Chen, 2017).

The use of connective tissue graft (CTG) has been proposed with immediate implants in order to stabilize the mid-facial gingival level and to compensate for the buccal tissue volume loss by thickening the buccal soft tissue. Although few clinical studies have focused on this issue, the evaluation methods were inconsistent (Migliorati et al., 2015; van Nimwegen et al., 2018; Noelken, Moergel, Pausch, Kunkel, & Wagner, 2018; Yoshino et al., 2014). Further research is needed to verify how and to what extent CTG can benefit IIPP, using parameters that are more objective.

The alveolar ridge undergoes tremendous reduction after tooth loss (Chappuis et al., 2013; Jiang, Zhang, Chen, & Lin, 2017; Schropp, Wenzel, Kostopoulos, & Karring, 2003), which is independent of immediate implant placement (Araujo, Sukekava, Wennstrom, & Lindhe, 2005; Botticelli, Berglundh, & Lindhe, 2004). Grafting the gap between the implant and the socket wall has been proven to limit the loss of ridge volume (Araujo, Linder, & Lindhe, 2011; Sanz et al., 2017), which could benefit the stability of the labial gingival level after immediate implant placement. However, the characteristics, quantitative alterations and potential factors affecting alveolar ridge remodelling after IIPP with bone grafting have still not been studied extensively.

The aim of this randomized controlled clinical study was to analyse hard and soft tissue alterations during the healing stage of 6 months after IIPP with or without CTG. The methodologies were based on three-dimensional superimposition of Standard Tessellation Language (STL) files from intra-oral scanning data and the Digital Imaging and Communications in Medicine (DICOM) data from cone-beam computed tomography (CBCT). The hypothesis is that IIPP with CTG can maintain the mid-facial gingival level and compensate for the loss of facial contour. Grafting the gap between the buccal bone plate and the implant can preserve the hard tissue volume. The primary objective is the alterations of mid-facial gingival position, and secondary outcomes include changes of the facial tissue contour and bone volume.

Clinical Relevance

Scientific rationale for study: Connective tissue graft (CTG) is often used in immediate implant placement and provisionalization (IIPP) in the aesthetic zone; however, the role of CTG in tissue stability is still unclear. This study quantitatively analysed the hard and soft tissue alterations using digital methods in participants undergoing IIPP with or without CTG

Principal findings: CTG compensated for the collapsed facial tissue but did not improve the maintenance of the mid-facial gingival positions after 6 months of healing. Moreover, CTG did not interfere with bone remodelling.

Practical implications: CTG could benefit the soft tissue contour after IIPP in the aesthetic zone.

2 | MATERIALS AND METHODS

2.1 | Patient enrolment criteria

This study was approved by the local ethical committee (Institutional Review Board of Peking University School and Hospital of Stomatology (Approval Number: PKUSSIRB-201523074) and registered at chictr.org.cn (Registration number ChiCTR1900028494). The trial was carried out from October 2016 to November 2018 in the Department of Oral Implantology at Peking University School and Hospital of Stomatology. The inclusion and exclusion criteria were as follows:

Inclusion criteria:

1. Aged 20–65 years
2. Single unsalvageable maxillary incisor (12–22) due to root fracture, trauma, non-restorable residual tooth and root resorption
3. Healthy periodontal conditions of neighbouring teeth
4. Intact buccal bone after extraction and at least 35 N-cm of final insertion torque
5. Willingness to participate in this clinical study.

Exclusion criteria:

1. History of periodontal disease with loss of attachment of the extracted or neighbouring teeth
2. Buccal plate deficiency after extraction
3. Poor bone quantity or quality that cannot fulfil implant placement with insertion torque of at least 35 N-cm
4. Pregnancy
5. Heavy smoker (>10 cigarettes per day)
6. Other local or general health conditions that contraindicate implant surgery.

Once included in the study, the patients were randomly assigned to two groups. The random sequence was generated by computer software (SPSS version 18.0, SPSS Inc.), and an independent researcher performed the allocation by using sealed envelopes, which were opened during the surgery, with an equal number of participants for the test group, IIPP with simultaneous CTG, and control group, IIPP without soft tissue grafting.

2.2 | Clinical procedures

Prior to extraction, CBCT images (Planmeca ProMax 3D, Planmeca Oy) were obtained to record the hard tissue profile. The technique parameters were as follows: field of view (FOV) diameter, 13 cm; FOV height, 10 cm; acceleration voltage, 90 kV; beam currency, 8.0 mA; and voxel size, 0.2 mm. Intra-oral scanning was performed to record the soft tissue contour as the baseline condition (3Shape Trios, 3Shape; software version: 2014-1).

Pre-operative prophylactic antibiotics (cefuroxime 0.25 g) were administered 1 hr before surgery. The patients were asked to rinse with a 0.2% chlorhexidine solution for 1 min. The surgical area was anaesthetized using primacaine adrenaline (Produits Dentaires Pierre Rolland, Acteon Pharma Division) by local infiltration. A flapless immediate implant protocol was followed. The extraction procedure followed for the unsalvageable tooth was as minimally invasive as possible to protect the periodontal hard and soft tissues. The integrity of the buccal bone was checked after extraction. Sequential osteotomy was performed against the palatal wall of the socket and directly into the basal bone of the maxilla. The implant (NobelActive, Nobel Biocare AB) was placed around 4 mm apical to the gingival margin with a gap of at least 2 mm between the buccal bone wall and implant platform. Primary stability was achieved by a final insertion torque >35 N-cm; if not, the participant was excluded from the study. Deproteinized bovine bone mineral (DBBM) (Bio-Oss, Geistlich) was used to graft the gap between the implant and the socket wall from the apical to the gingival margin beyond the bony wall. In the test group, a CTG, approximately 15 mm (long) × 5 mm (width) × 1.5 mm (thickness), was harvested from the posterior palatal region and inserted beneath the labial gingival by the tunnelling technique, whereas no further interventions were performed in the control group. An implant-level impression was taken immediately after surgery. In both groups, a screw-retained provisional restoration without occlusal and eccentric contacts was delivered within 24 hr (Figure 1).

All patients with the provisional restoration were routinely revisited to monitor the healing process after 1 week, 1 month and 6 months. CBCT scan and intra-oral scan were performed 6 months postoperatively before the final restoration process. All surgical and prosthetic procedures were performed by an experienced practitioner (Dr. X. J.).

2.3 | Measurement of hard tissue remodelling

The two sets of DICOM data from CBCT, baseline conditions before extraction and 6 months postoperatively, were transferred to a volumetric imaging software (Mimics 15.0, Materialise), in which virtual models of the upper jaw were three-dimensionally reconstructed and superimposed. To illustrate the bone remodelling features accurately, the residual tooth was virtually removed from the pre-surgical model in the software.

After superimposition, an image of a cross-sectional plane that bisected the extraction socket mesiodistally and along the long axis of the tooth was exported and used to evaluate the hard tissue remodelling. To standardize the measurement, a two-dimensional coordinate system was constructed. The bucco-coronal point of the buccal plate was set as the origin. The Frankfort plane was set as the x-axis. The Frankfort plane was generated by 15° rotation of the occlusal plane, which can be virtually constructed using three points from the CBCT image (the incisor edge of the maxillary central incisor and the mesiobuccal cusps of the left and right first molars) in the Mimics software. The axis perpendicular to the x-axis was defined as the y-axis.

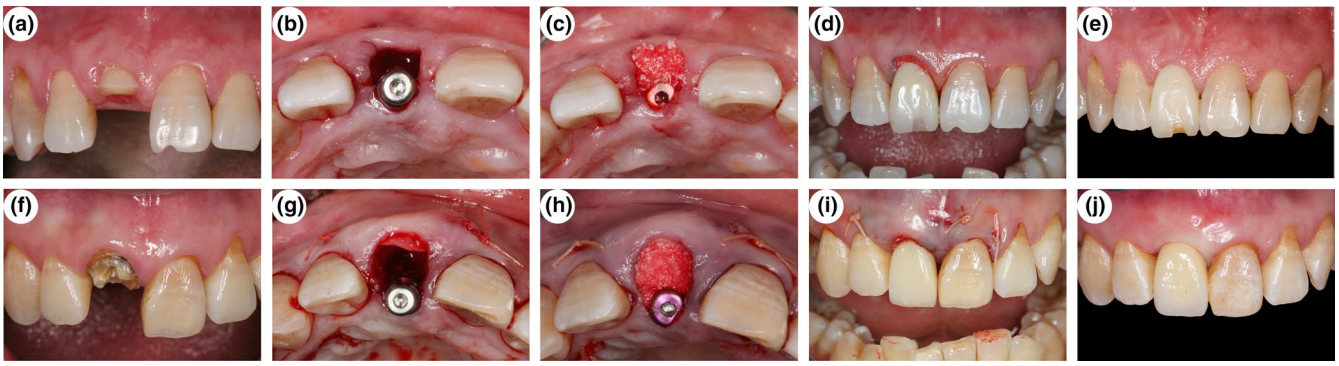

FIGURE 1 Clinical procedure of the control (a–e) and test groups (f–j). (a) Residual tooth to be extracted; (b) immediate implant placement; (c) bone grafting into the gap; (d) immediate provisionalization; (e) six months after healing; (f) residual tooth to be extracted; (g) immediate implant placement with simultaneous connective tissue graft beneath the buccal gingiva; (h) bone grafting into the gap; (i) immediate provisionalization; (j) six months after healing

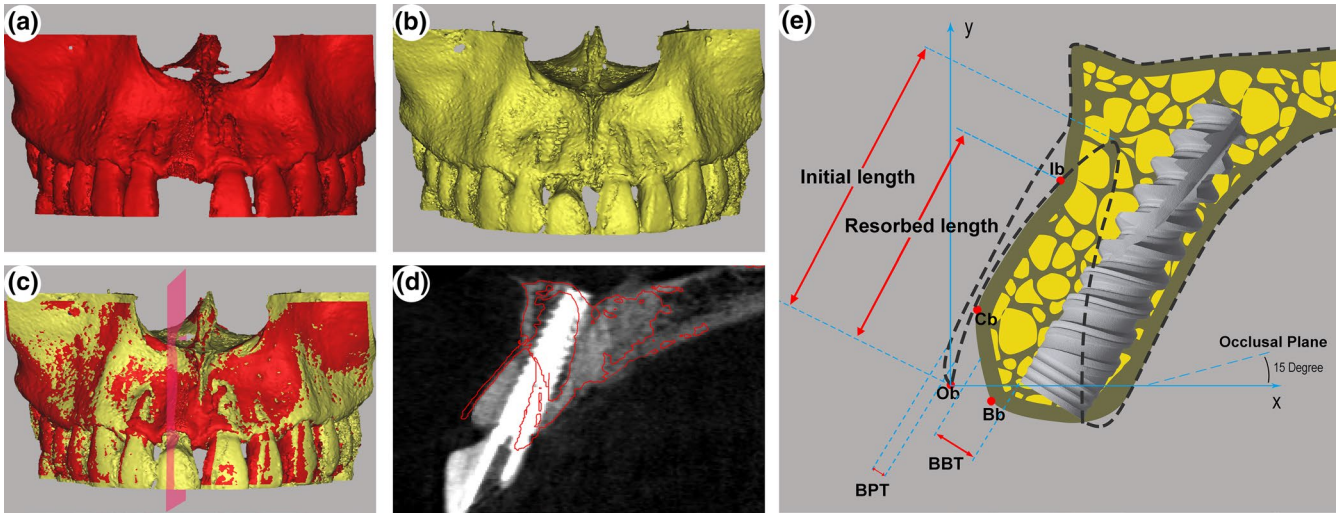

FIGURE 2 Hard tissue remodelling analysis using CBCT data superimposition. (a) Virtual model of the maxilla before surgery, the residual tooth of 11 is virtually removed; (b) virtual model of the maxilla 6 months after immediate implant placement and provisionalization; (c) three-dimensional superimposition before and 6 months after surgery (a cross-sectional plane [pink] was used to evaluate hard tissue remodelling); (d) cross-sectional image of an actual participant (red line shows the bony outline before extraction; CBCT image 6 months after surgery); (e) schematic drawing of the cross-sectional plane for analysis (black dotted outline indicates the bony boundary of the extraction socket, and yellow outline indicates the alveolar ridge 6 months after surgery). CBCT, cone-beam computed tomography

The following landmarks were identified in the cross-sectional plane for the measurements: point O_b (origin), the bucco-coronal point of the buccal plate of the extraction socket; point B_b, the bucco-coronal point of the healed alveolar ridge; point C_b, the "contact" point of the outline of the healed ridge with the buccal plate of the extraction socket; and point I_b, the intersectional point of the outlines of the healed ridge with the bony profile before extraction (Figure 2).

The following values were recorded to describe hard tissue remodelling:

- Coordinate values of point B_b and point C_b, which confined the buccal and coronal outline of the healed ridge
- BPR: buccal plate resorption ratio, the percentage of buccal plate resorption length (measured from point I_b to point O_b) compared to the initial buccal plate length of the extraction socket (measured from the apex to the point O_b)
- BPT: initial buccal plate thickness, 1 mm apical to the coronal point.
- BBT: buccal bone thickness of the implant after 6 months of healing. Linear distance of implant platform to the outline of the healed ridge
- BPP: bucco-palatal position of the placed implant, the distance from the central point of implant platform to the outer surface of the buccal plate (w) compared with the initial width (w′) of the extraction sockets (illustrated in Figure S1).

Image analysis of this cross-sectional plane, including coordinate system construction, landmark identification and measurements, was performed using image procession software (Adobe ® Photoshop ® CS6, Adobe Systems Incorporated).

2.4 | Measurement of soft tissue contour alterations

The two sets of STL files from the intra-oral scanner, baseline before extraction and 6 months after surgery, were exported to image analysis software (Geomagic Qualify 12; 3D Systems). Two STL files were superimposed using best-fit alignment algorithm by manually selecting the area of the neighbouring teeth surfaces of both virtual models.

Images of a cross-sectional plane that passed through the mid-facial gingival margin of the residual tooth and perpendicular to the maxillary panoramic curve and occlusal plane were used to evaluate soft tissue contour alterations. To standardize the measurement, a two-dimensional coordinate system was constructed. The facial gingival margin point of the tooth to be extracted was set as the origin. The Frankfort plane was set as the x-axis. The Frankfort plane was generated by a 15° rotation of the occlusal plane, which can be virtually constructed by three points from the intra-oral scanning files (the incisor edge of the maxillary central incisor and the mesiobuccal cusps of the left and right first molars). The axis perpendicular to the x-axis was defined as the y-axis.

The following landmarks were identified in the cross-sectional plane for the measurements: point O_g (origin), the mid-facial gingival margin of the tooth extracted at the baseline; and point P_g, the gingival margin point of the provisional restoration 6 months after healing. Five horizontal lines were drawn 1–5 mm apical to the origin and intersected with the soft tissue profiles at baseline and 6 months after healing.

The following values were recorded to describe the soft tissue profile alterations (Figure 3):

- Coordinate values of point P_g, representing the gingival margin-level alterations after 6 months of healing

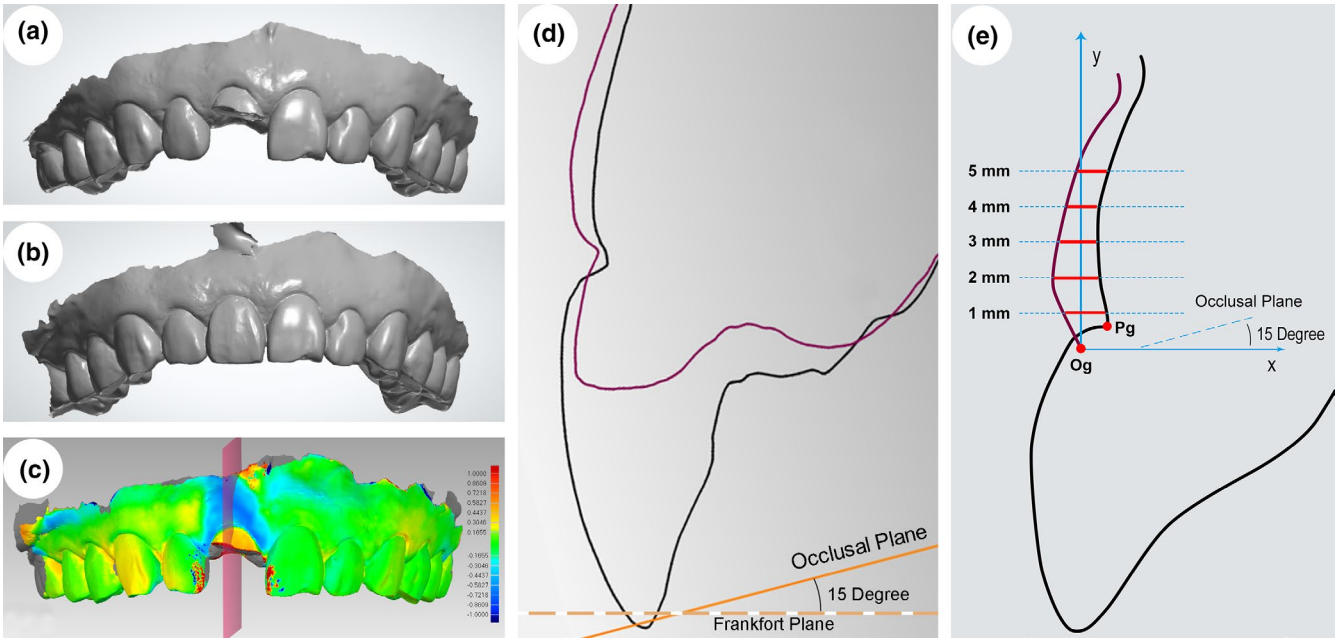

FIGURE 3 Tissue contour analysis using Standard Tessellation Language (STL) file superimposition. (a) STL file from an intra-oral scan before extraction; (b) STL file from intra-oral scan 6 months after surgery; (c) three-dimensional superimposition of the STL file before and 6 months after surgery (a cross-sectional plane [pink] was used to evaluate the soft tissue contour changes); (d) cross-sectional image of an actual participant (purple outline indicates the tissue profile before extraction, black outline represents the tissue profile 6 months after surgery, orange line indicates the occlusal plane, and dotted orange line indicates the Frankfort plane); (e) schematic drawing of the cross-sectional plane for analysis (purple outline indicates the tissue profile before extraction but the outline of the residual tooth is not shown, and black outline represents the tissue profile 6 months after surgery)

- Length of the five horizontal line sections, qualitatively describing the facial profile collapse during the 6-month healing stage.

Image analysis of this cross-sectional plane, including coordinate system construction, landmark identification and measurements, was performed using image procession software (Adobe ® Photoshop ® CS6, Adobe Systems Incorporated).

2.5 | Statistical analysis

According to a previous study on IIPP with or without CTG in the aesthetic zone (Yoshino et al., 2014), a mean difference of 0.45 mm in the mid-facial gingival position alterations and a standard deviation of 0.40 mm were estimated to acquire power of 90% and 5% type-1 error in power calculation. The sample size was determined to be 19 patients in each group. Considering an approximate 10% dropout rate, 42 participants were needed.

Parameters of demography, and hard and soft tissue alterations were described as mean values and standard deviations. All the data were recorded in Excel 2013 spreadsheet (Microsoft Corporation) and transferred to the software package (Statistical Package for the Social Sciences version 18.0, SPSS Inc.) for statistical analysis. All parameters were compared between the test and control groups. If normally distributed data with approximately equal variances were present, parametric methods (Student's *t* test, multi-factor analysis of variance and Tukey's test for *pos hoc* comparison) were used.

TABLE 1 Demographics, teeth positions and implant types in the two groups

	Test group	Control group
Age (Mean ± *SD*) (range)	34.3 ± 7.0 (25–51)	37.7 ± 13.3 (20–66)
Sex male/female	8/12	11/9
Tooth position CI/LI	16/4	18/2
Implant (diameter × length) (mm)		
3.5 × 18	5	10
3.5 × 15	14	9
3.5 × 13	1	1

Abbreviations: CI, central incisor; LI, lateral incisor.

Otherwise, non-parametric tests (Mann–Whitney *U* test) were used. For all tests, a *p*-value < .05 was considered significant.

3 | RESULTS

3.1 | Demographics

This study initially enrolled 42 participants. Two patients, one in each group, were lost due to inability to establish contact, while 40 patients completed the 6-month follow-up. Information regarding demographics, tooth positions and implant types is summarized in Table 1.

3.2 | Baseline data of the socket

In the test and control groups, the buccal plate thickness (BPT) of the socket was 0.54 ± 0.20 mm and 0.69 ± 0.30 mm. The initial socket width (w′) was 7.10 ± 0.73 mm and 7.43 ± 0.85 mm. The central point of implant platform to the outer surface of the buccal plate (w) was 4.79 ± 0.61 mm and 4.98 ± 0.57 mm. The BPP values, which reflect the BPP of placed implant in relation to the socket, were 67.58 ± 5.24% and 67.20 ± 4.56%. No statistically significant differences were found between two groups of all these baseline parameters (Table S1).

3.3 | Complications and implant survival

The implant survival rates were 100% in both groups. One participant in the test group and two in the control group experienced loosening of the provisional restoration around 3–6 weeks post-surgery. The provisional crowns were re-tightened, and the healing process was uneventful. At the 1-week revisit, the soft tissues completely healed in the control group. In the test group, signs of tissue swelling and reddish gingival margin were observed. At the 1-month revisit, both groups showed thorough soft tissue healing with pink and scallop attached gingival margins.

3.4 | Buccal plate resorption of the socket

In both groups, tremendous buccal bone resorption was detected. The buccal plate resorption ratio (BPR) was 92.8 ± 27.8% and 77.5 ± 44.5% in the test and control groups, respectively, without statistically significant differences ($p = .23$). In several cases, surface bone resorption occurred at the basal bone of the maxilla beyond the root apex, resulting in BPR values >100%. In both groups, participants with thick buccal bone plate (BPT >1 mm) showed very limited resorption (Figure 4).

3.5 | Hard tissue remodelling

From the cross-sectional image of the superimposed DICOM data obtained from CBCT scans, in the apical and palatal regions of points B_b and C_b, completely new bone formation within the socket void could be detected in all participants. The points B_b, C_b and the buccal plate of the extraction socket outlined the labial bone profile over the implant after 6 months of remodelling. Compared to the original ridge profile before extraction, a triangular shape (O_b-B_b-C_b) of the ridge contour diminished on the bucco-coronal side.

The coordinate values of the bucco-coronal point (B_b) were (1.27 ± 0.52 mm, −0.84 ± 1.05 mm) in the test group and (1.01 ± 0.49 mm, −1.16 ± 0.92 mm) in the control group. The coordinate values of the contact point (C_b) were (0.97 ± 0.52 mm, 1.39 ± 0.79 mm) in the test group and (0.78 ± 0.62 mm, 0.91 ± 1.03 mm) in the control group. The BBTs over the implant shoulder were 2.56 ± 0.50 mm and 2.72 ± 0.73 mm in the test and control groups, respectively. All the coordinate values and linear measurements showed no statistical differences between the groups (Table S2).

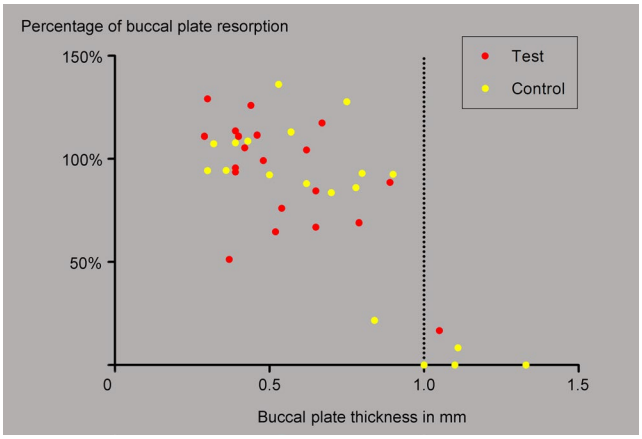

FIGURE 4 Buccal plate thickness (BPT) in relation to buccal plate resorption rate. Thick buccal plate (BPT > 1 mm) shows very limited or no resorption

In both groups, the y-axis values of B_b were less than zero with statistically significant differences ($p < .01$), which indicated that the alveolar ridge had a slight vertical bone gain in this pre-defined coordinate system.

3.6 | Soft tissue alterations

From the cross-sectional image of the superimposed STL files obtained from intra-oral scanning, the coordinates of the gingival margin point (P_g) with provisional restoration after 6 months of healing were (0.63 ± 0.53 mm, 0.16 ± 0.60 mm) in the test group and (0.63 ± 0.55 mm, 0.26 ± 0.54 mm) in the control group. No statistically significant differences were found between the groups ($p = .65$ and $p = .72$, respectively) (Table S3). The distributions of point P_g in all the participants in the coordinate system are shown in Figure 5.

Labial tissue profile collapse was measured at vertical levels 1–5 mm apical to the gingival margin. The test group showed significantly less tissue profile alteration at 2–5 mm vertical levels as compared to the control group, but no statistically significant differences were found in the 1-mm area between the two groups (Table S4). Regarding the impact of different vertical levels, the control group showed no significant differences at varying levels from 1 to 5 mm ($p = .97$), while there were statistically significant differences in tissue collapse magnitude at different vertical levels in the test group ($p = .00$) (Figure 6).

4 | DISCUSSION

Recently, the potential benefits of CTG in immediate implant placement in the aesthetic zone have been widely discussed, but there are limited data regarding how exactly hard and soft tissues

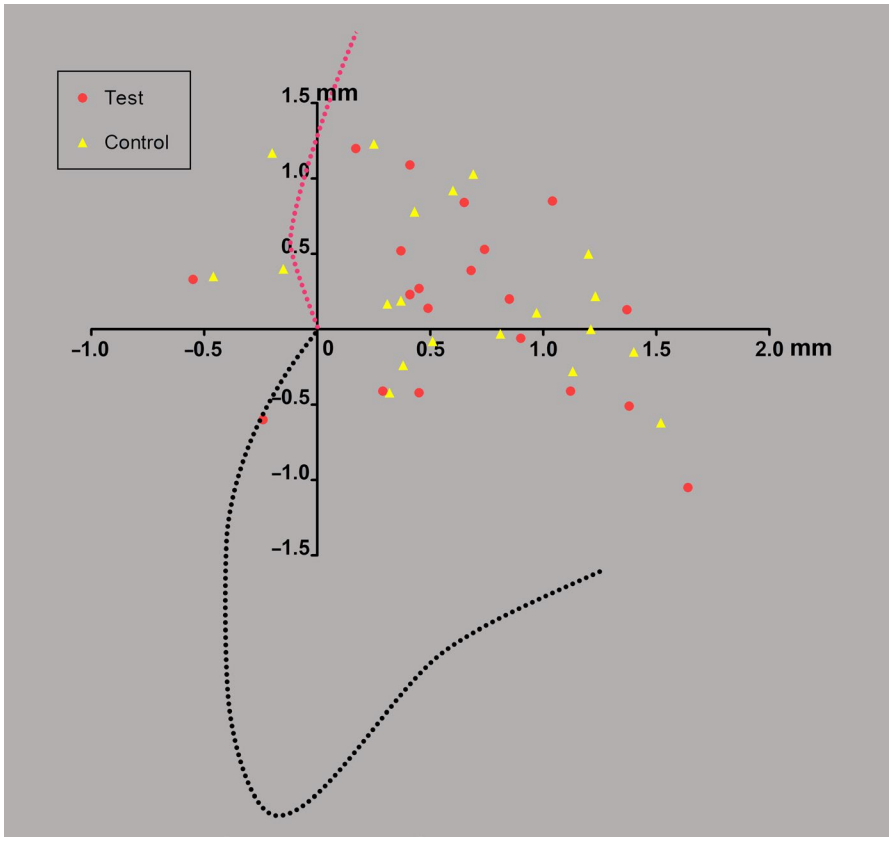

FIGURE 5 Distribution of the gingival margin points (P_g) 6 months after surgery in both groups in the coordinate system (the dotted outline indicates the profile of the original crown of the natural tooth (black) and gingiva (pink) on a reduced scale

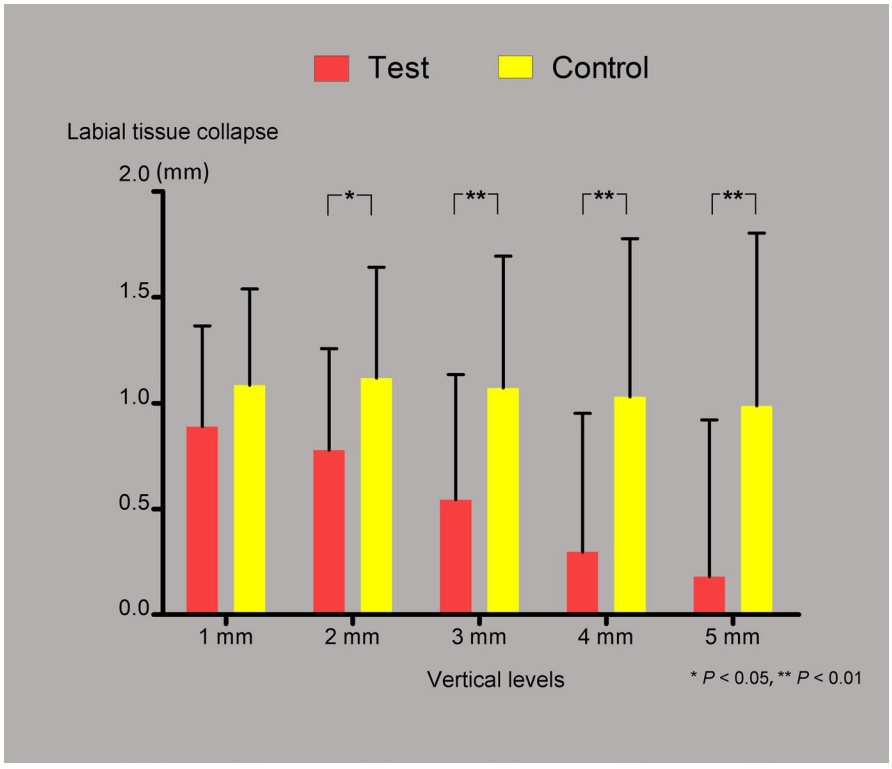

FIGURE 6 Linear values of buccal tissue contour collapse in the area 1–5 mm apical to the original gingival margin in both groups

change with CTG, that this study aimed to provide. The results demonstrated that CTG might compensate for the buccal tissue profile loss but did not help in the maintenance of the midfacial gingival margin. Radiographic new bone formation could be expected in the socket void, independent of CTG. The hypothesis was partially accepted.

The resorption of buccal plate has not been quantitatively described in IIPP, but in some studies focusing on the remodelling

of the extraction socket. Using the same evaluation methods of three-dimensional superimposition, Chappuis reported a median buccal plate loss of 7.5 mm after 2 months with spontaneous socket healing in thin-wall phenotypes (<1 mm) (Chappuis et al., 2013). Jiang also demonstrated an average vertical facial bone wall resorption of 7.85 mm after 4 months of extraction (Jiang et al., 2017). These results are in accordance with those of the present study, with an average BPR of 92.8% and 77.5% in the test and control groups, respectively. These findings imply that a thin buccal plate, completely composed of bundle bone, would undergo resorption irrespective of the treatment strategies. None of bone grafting, IIPP or CTG would interfere with the biological resorption process.

Interestingly, we noticed that the basal bone of the maxilla near the apex of the extraction sockets showed some surface bone resorption after 6 months in several cases. This phenomenon has not been reported before and could be explained as the resorption process of the buccal plate almost involving the adjacent maxillary basal bone.

The BBT over the implant platform after 6 months of healing was 2.56 ± 0.50 mm and 2.72 ± 0.73 mm in the test and control groups, respectively, without statistically significant differences. A slight vertical and horizontal hard tissue volume loss of approximately 1 mm was expected in the bucco-coronal region of the ridge, according to the coordinate values of points B_b and C_b, and this was in accordance with previous studies (Chan et al.., 2019; Lee, Gonzalez-Martin, & Fiorellini, 2014; Morimoto, Tsukiyama, Morimoto, & Koyano, 2015; Roe et al., 2012; Sanz-Martín, Encalada, Sanz-Sánchez, Aracil, & Sanz, 2019). Thickness of buccal plate of the extraction socket is not a decisive factor for the existence or absence of the future regeneration of the buccal bone over the implant. On the other hand, the bone-forming ability in the gap is extremely important for the regeneration of future buccal bone. The mean BPP values were 67.58% and 67.20% in the test and control groups, which meant the implants were placed at around the 2/3 position bucco-palatally; besides, narrow implants with diameter of 3.5 mm were used, which guarantee enough dimension for bone regeneration in the gap. However, the long-term stability of the buccal bone cannot be extrapolated from this study.

Slight vertical bone gain was noticed in both groups, which has not been reported in the literature of IIPP to the best of the authors' knowledge. This might be explained in several possibilities. First, the new radiographically observed bone formed above the original bony margin might not be real bone histologically, and the long-term stability is certainly unknown. Second, the vertical direction was defined as perpendicular to the Frankfort plane rather than the long axis of the socket. Lastly, the compacted grafting material above the bony margin and further stabilization by the provisional crown might contribute to a more stable bone-forming environment.

Soft tissue stability has been the main concern after immediate implant placement in the anterior maxilla. CTG was introduced to facilitate the maintenance of mid-facial gingival level and compensate for tissue contour loss (Migliorati et al., 2015; Yoshino et al., 2014). In the present study, the mid-facial margin tended to show minor recession (0.16 ± 0.60 mm in the test group and 0.26 ± 0.54 mm in the control group) without statistically significant differences between the two groups. This result is different from that of previous clinical studies, in which the CTG groups maintained the mid-facial gingival at a significantly more coronal level as compared to the group without soft tissue graft at 1-year (van Nimwegen et al., 2018; Yoshino et al., 2014) and 2-year (Migliorati et al., 2015) follow-ups. The discrepancies might mainly be caused by the very short follow-up time of only 6 months in the present study as compared to the 1- or 2-year follow-ups recorded in previous studies. More obvious mid-gingival margin migration occurred in the palatal direction (0.63 ± 0.53 mm in the test group and 0.63 ± 0.55 mm in the control group), which has not been described in other studies.

For the buccal tissue contour alterations, the test group demonstrated significantly less tissue collapse in the area 2–5 mm apical to the gingival margin, which is certainly beneficial for aesthetic results. However, a recent study by Nimwegen et al. revealed that CTG did not result in less mucosal volume loss after 12 months when compared to IIPP performed without CTG (van Nimwegen et al., 2018). This could be attributed to different evaluation methods. In Nimwegen's study, the mean dimensional change per area was used to evaluate the contour change. In the present study, linear distances of tissue outline were measured in a cross-sectional plane, where the most obvious contour change occurred. Other potential factors were the different inclusion criteria (incisor, canine and first bicuspid versus incisors only) and different follow-up periods (1 year vs. 6 months). Both studies agreed that CTG could not fully compensate for tissue volume loss after extraction. No differences were found in the region 1 mm apical to the gingival margin between the two groups, indicating that the CTG could not stably locate and heal at the gingival marginal area. This could be due to the pressure of the provisional crown pushing the graft to the apical position or the limitation of the surgical technique itself.

Coordinate systems were constructed to evaluate the hard and soft tissue changes in a more objective way. The coordinate systems were based on the Frankfort plane, which is more consistent and reproducible among different participants than the axis of the placed implant or the tooth structures used as reference markers during evaluation. A cross-sectional plane with the most prominent changes in the tissue profile was chosen to make a two-dimensional evaluation rather than a three-dimensional volumetric analysis in the present study. As the most pronounced changes were most clinically relevant, the mesial and distal tissue alterations alongside the cross-sectional plane gradually decreased (Farmer & Darby, 2014; Tian et al., 2019). The volumetric data can certainly provide the information regarding the change in volume, but it is less explicit for clinicians to visualize.

The limitations of this study include: (a) short follow-up time of 6 months. The long-term stability of hard and soft tissue is now the most controversial issue in immediate implants. The present study provided very limited evidence for the reliability and predictability of IIPP in the aesthetic zone. Long-term follow-up (≥5 years) with clinical and radiographic parameters is certainly needed. Delivery of the final restoration will certainly result in tissue contour changes

that could be set as the starting point for future studies. This is also the main reason that we chose 6-month follow-up before final restoration as the endpoint of this trial. (b) Inability to match the DICOM data with STL files. To inspect the hard and soft tissue alterations, the DICOM data and STL files were superimposed using different software. If all the data could be matched together, the interactions between the hard and soft tissue could be analysed in detail, such as the soft tissue thickness. (c) Lack of objective aesthetic evaluation. At the endpoint of the study, patients were still wearing the provisional restoration, and the final aesthetic outcomes were not evaluated. This should be included in the future trials conducted with long-term follow-up.

5 | CONCLUSIONS

1. The CTG in IIPP might compensate for the facial tissue collapse in the area 2–5 mm apical to the gingival margin during the 6-month follow-up time. However, CTG can neither maintain the tissue profile in the marginal area nor the position of the mid-facial gingival margin. The mid-facial gingival margin migrated in an apico-palatal direction independent of the CTG graft.
2. Tremendous buccal plate resorption was observed in thin-wall phenotypes (<1 mm) of IIPP with or without CTG. New bone formation was detected radiographically in most spaces of the socket void, except for a triangular area in the bucco-coronal region. CTG did not have any effect on hard tissue remodelling.

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CONFLICT OF INTEREST

All authors report no conflicts of interest related to this study. This study was funded by the Capital's Funds for Health Improvement and Research (Grant/Award Number: 2018-2-4102) and National Key Research and Development Project (Grant/Award Number: 2016YFC1102705).

AUTHOR CONTRIBUTIONS

Xi Jiang conceived the study, participated in clinical investigation and drafted the article. Ping Di conceived the study and acquired funding. Shuxin Ren contributed to statistics, data connection and analysis. Yu Zhang critically revised the manuscript and recruited the participants. Ye Lin critically revised the manuscript and acquired funding.

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SUPPORTING INFORMATION

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

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