Original Article

Baseline selection for evaluation of peri-implant soft tissue changes: a clinical trial

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Background: To select the optimal baseline for evaluation of peri-implant soft tissue changes among 1, 2, and 3 weeks after definitive crown insertion.

Methods: A total of 22 individuals who required implant restoration were recruited to this study. Each participant received a screw-retained conventional implant restoration. Peri-implant soft tissue was captured by an intraoral scanner and analyzed by 3D analysis software. Soft tissue changes [mucosal margin (MM) and soft tissue thickness (STT)] on the buccal side of implant sites were evaluated at 1, 2, and 3 weeks after definitive crown insertion. One-way analysis of variance (ANOVA) for repeated measurement and Tukey's test were used to analyze significant differences between the 3 time points (α=0.05).

Results: An increased volume of peri-implant soft tissue was observed shortly after definitive crown insertion. Based on the findings of peri-implant soft tissue changes, significant differences were observed between weeks 1 and 2 ($P<0.01$), and weeks 1 and 3 ($P<0.01$), while there was no significant difference between weeks 2 and 3 ($P>0.05$).

Conclusions: Minimal peri-implant soft tissue changes occurred in this study. The time point of 2 weeks after definitive crown insertion was preliminarily selected as the baseline. The small sample size and few time points must be taken into consideration when interpreting these findings.

Trial Registration: This study was retrospectively registered in the Chinese Clinical Trial Registry (Registration number: ChiCTR2000037954; Date of registration: 6 September 2020).

Keywords: Baseline selection; definitive crown insertion; peri-implant soft tissue changes; evaluation

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Introduction

Recently, with the wide use of implant restoration, many researchers have closely observed the pattern of peri-implant soft tissue changes after definitive crown insertion (1-4). Several studies have investigated the patterns of change (3-5); however, the baselines among them have been inconsistent.

In 2011, Schneider *et al.* performed autogenous subepithelial connective tissue graft (SCTG) 6 months after

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guided bone regeneration (GBR) with simultaneous implant placement and evaluated peri-implant soft tissue changes within 1 year, applying a baseline of 1 week after definitive crown insertion (6). In 2017, Bienz *et al.* performed implant placement simultaneously with or without SCTG after GBR and evaluated peri-implant soft tissue changes within 5 years with the baseline of 1 week after definitive crown insertion (5). In 2018, Huber *et al.* compared the effect of 2 soft tissue augmentations, xenogenous three-dimensionally (3D) stable collagen matrix (VCMX) and SCTG, with a follow-up period of 1 year and baseline of 2 weeks after definitive crown insertion (4). In 2020, Thoma *et al.* compared the above 2 soft tissue augmentations of VCMX and SCTG with 3 years follow-up duration and baseline of 2 weeks after definitive crown insertion (3). These previous studies obtained the intraoral digital information by model scanner and did not explain the reason why they select these time points as baseline (1 or 2 weeks).

The results of soft tissue thickness (STT) changes were different between Schneider *et al.* (–0.02 mm) (6) and Huber *et al.* (–0.20 mm) (4), which may have been due to the different baselines (1 or 2 weeks). To date, studies investigating baseline selection have been scarce.

The objective of this study was to determine the optimum baseline for evaluation of peri-implant soft tissue changes among 1, 2, and 3 weeks after definitive crown insertion.

We present the following article in accordance with the Transparent Reporting of Evaluations with Nonrandomized Designs (TREND) reporting checklist (available at https://dx.doi.org/10.21037/atm-21-3335).

Methods

Study design and setting

Baseline selection for evaluation of peri-implant soft tissue changes was the goal of this clinical trial. Peri-implant soft tissue changes were evaluated using digital method at 1, 2, and 3 weeks after definitive crown insertion. The study protocol was carried out in accordance with the Declaration of Helsinki (as revised in 2013) and was approved by the Biomedical Ethics Committee of Peking University School and Hospital of Stomatology, Beijing, China (ethical batch number: PKUSSIRB-201946083). The dentist who enrolled the participants and the investigator who evaluated peri-implant soft tissue changes were blinded to the study protocol and purpose.

The sample size was calculated in PASS (Power Analytics and Sample Size Software, NCSS, LLC, Kaysville, UT, USA) software (α=0.05, 80% power) according to the ΔAMM data (the first 3 patients recruited) of this study. After calculating, a study population of at least 20 participants was necessary. Considering a dropout rate of 10%, a total of 24 patients were recruited.

Participants

The study was carried out in the Department of Periodontology and Prosthodontics, Peking University School and Hospital of Stomatology, from October 2018 to February 2020. All patients signed consent forms prior to participation. Continuous patients who required implant restoration were recruited according to the following inclusion criteria: (I) age ≥20 years old (7); (II) no systemic disease or active periodontitis; (III) plaque index and bleeding index <25% (8); (IV) posterior tooth loss with a medium to thick gingival biotype (periodontal probe not visible when inserted into the buccal gingival margin) (9); and (V) fully autonomous behavior and expression ability, with good compliance. Exclusion criteria were as follows: (I) poor oral hygiene; (II) adjacent teeth with acute and chronic tooth disease at the implant site; (III) uncontrolled diabetes or other systemic disease; and (IV) heavy smoker (≥10 cigarettes/day). In addition, implants were excluded if they manifested complications during the period of this study that required additional treatments. The dentist responsible for participant recruitment was blinded to the study protocol and purpose.

Surgical procedures

Systematic supportive periodontal therapy before surgery was executed for all participants, and the clinical treatment plans were discussed and agreed upon prior to implantation. A timeline of the clinical treatment process is shown in *Figure 1*. The two-stage implant was placed according to the manufacturer's instructions (Bone Level, Straumann®, Basel, Switzerland) under local anesthesia. A healing abutment was inserted 6 months later followed by a definitive all-ceramic zirconia crown (titanium abutment) 3 months after the second-stage procedure.

Clinical examination

All participants received oral prophylaxis. An evaluator

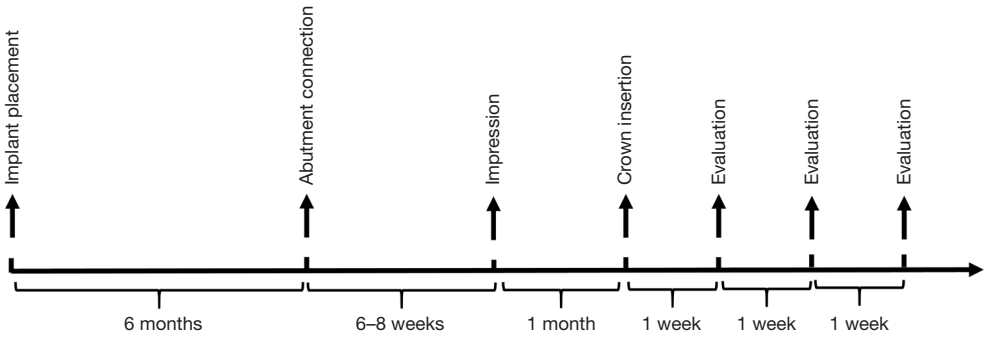

Figure 1 Timeline of the clinical treatment process.

recorded the following indicators 3 times, which were then averaged. Values were recorded at mesial, midfacial, distal, and palatal sites and then averaged. The gingival index (GI) (10) and bleeding on probing (BOP, positive or negative; %) (11) were recorded after probing (Williams, Hu-Friedy, Chicago, IL, USA). The GI and BOP are commonly used to determine whether there is inflammation surrounding an implant (12).

Peri-implant soft tissue evaluations

All measurements were carried out by 1 evaluator. The following indicators were recorded 3 times and then averaged. The investigator who evaluated peri-implant soft tissue changes was blinded to the study protocol and purpose.

Intraoral scanning

First, 3D oral information was captured by an intraoral scanner (TRIOS Color Pod; software version: 1.18.1.3, 3Shape, Copenhagen, Denmark) at each time point. All scanning data were saved in DCM (a software-dedicated file format) format. Then, the digital files were imported into orthodontic software (Ortho Analyzer™, software version: 1.18.1.2, 3Shape, Denmark) and saved as a virtual reality modeling language (VRML) file. After the file format transform process, a color digital model (colored by VRML procedure) was obtained and imported into 3D analysis software (Geomagic Control 2014, 3D Systems, Rock Hill, SC, USA) to evaluate the peri-implant soft tissue changes.

Digital model alignment

In the Geomagic Control software, the scanning data obtained immediately after crown insertion was set as the reference model and the follow-up scanning data as the test model, then "best fit alignment" (iterative closet point algorithm) was conducted (*Figure 2A*). According to the accuracy of the intraoral scanner, maximum and minimum nominal values were set at 150 and –150 μm, respectively (2). The area of interest on the buccal side was then selected, with the coronal border represented by the mucosal margin (MM), the apical border by the vestibular groove, and the mesial and distal border by the axis angle. Directions of X-axis, Y-axis, and Z-axis are shown in *Figure 2B*,*2C*. Root mean square (RMS) was recorded after alignment. The RMS of the test model compared to the reference model was used to estimate the congruency of two superimposed records (13,14) by the formula (15):

$$RMS = \sqrt{\frac{\Sigma_{i=1}^{n} X_{1,i}^2 - X_{2,i}^2}{n}} \quad [1]$$

where $X_{1,i}$ is measuring point i on test model, $X_{2,i}$ is measuring point i on reference model, and n is the total number of measuring points per model.

Analysis of changes in mucosal margin (ΔAMM)

First, the "insertion point" function was used to select gingival zenith at mesial, midfacial, and distal sites of the buccal side. Then, the 3D coordinates at the 3 sites were recorded (*Figure 2D*). The difference between the Z-axis coordinates in the reference and test models was represented as the changes in the MM. Changes at the 3 sites were then averaged (ΔAMM). Negative values represented the mucosal recession.

Analysis of changes in STT

The changes in STT at 1, 3, and 5 mm below the MM were analyzed (16). First, "2D comparison" function was used to generate 2D cross sections at mesial, midfacial, and distal

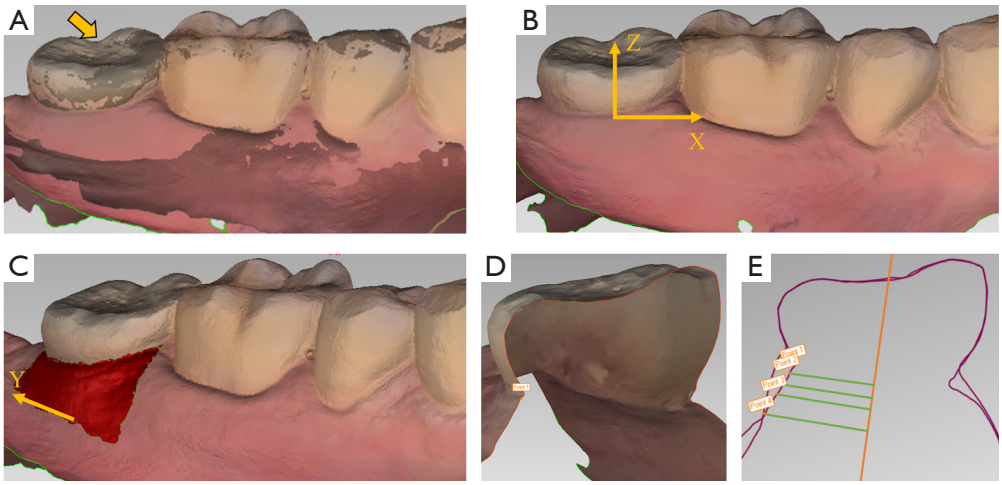

Figure 2 Digital analysis. (A) Best fit alignment; (B) direction of X-axis and Z-axis; (C) direction of Y-axis; (D) analysis of changes in mucosal margin; (E) analysis of changes in soft tissue thickness. The arrow in (A) indicates implant restoration. The arrows in (B) indicate directions of X and Z axis respectively. The arrow in (C) indicates direction of Y axis.

sites of the buccal side respectively (*Figure 2E*). To evaluate STT at each level, longitudinal lines were drawn parallel to the long axis of the implant in each 2D section. Distances at each level between the reference model and test model were then used to represent the changes in STT. Changes at the 3 sites were then averaged (ΔASTT). Negative values represented soft tissue collapse.

Statistical analysis

The participant was treated as the unit of statistical analysis (every participant with a single implant). Descriptive statistics [mean ± standard deviation (SD)], normality (Kolmogorov-Smirnov test), and homogeneity of variance (Levene test) were performed for all variables (repeated measurement data) using SPSS software (IBM®, SPSS®, Statistics 20, Chicago, IL, USA). The one-way analysis of variance (ANOVA) was used to analyze ΔAMM and ΔASTT among the 3 time points. If proven to be statistically significant, Tukey's test was used to perform multiple comparison. The Friedman test was used to compare GI and BOP among the 3 time points. A P value <0.05 was considered statistically significant.

Results

Participant and implant characteristics

A flow diagram of the recruitment process is shown in *Figure 3*. Of the 24 patients (24 posterior implants) enrolled, 2 did not complete the follow-up due to study abroad or having no discomfort A total of 22 participants (22 implants) were therefore included in this study, 11 females (11 implants, 3 in maxilla and 8 in mandible) and 11 males (11 implants, 9 in maxilla and 2 in mandible), with an average age of 53.0±8.8 years (34–73 years). *Table 1* shows the detailed participant characteristics.

Clinical outcomes

Table 2 shows the clinical outcomes. The mean GI values were 0.89±0.28, 0.79±0.30, and 0.88±0.33 at 1, 2, and 3 weeks, respectively. The mean BOP values were 11.36±12.74, 12.50±14.94, and 10.23±14.76 at 1, 2, and 3 weeks, respectively. There was no significant difference among the 3 time points (GI: P=0.234; BOP: P=0.695). After initial therapy, peri-implant soft tissue was in healthy status.

Peri-implant soft tissue evaluations

The mean RMS values were 27.24±11.61, 28.78±11.69, and 25.75±11.41 μm at 1, 2, and 3 weeks, respectively (*Table 2*).

The ΔAMM and ΔASTT values at 1, 2, and 3 weeks after baseline are shown in *Table 3*. *Table 4* shows the one-way ANOVA results. Based on the findings of peri-implant soft tissue changes, significant differences were observed between weeks 1 and 2 (P<0.001), and weeks 1 and 3 (P<0.01), while there was no significant difference between

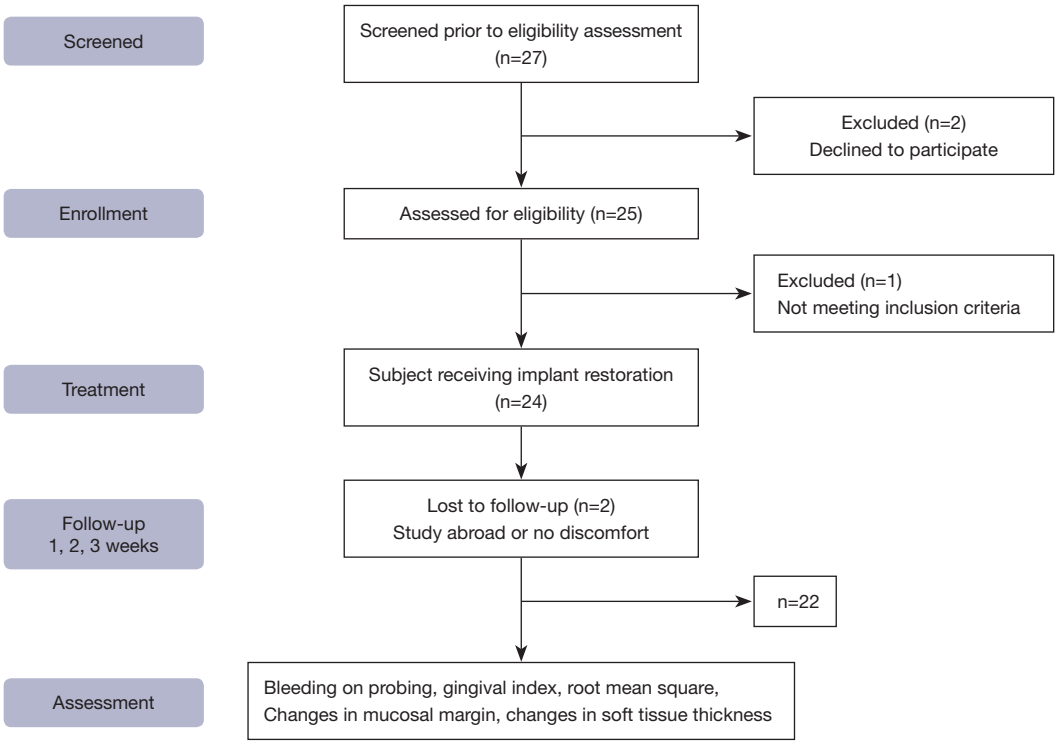

Figure 3 Flow diagram of the recruitment process.

Table 1 Participant characteristics

Parameters	Characteristics
Mean age	53.0
Female	11 (11 implants)
Implant sites	3 in maxilla and 8 in mandible
Male	11 (11 implants)
Implant sites	9 in maxilla and 2 in mandible

Table 2 Results of GI, BOP, and RMS

Parameters	1 w	2 w	3 w	P[a]
GI, mean ± SD	0.89±0.28	0.79±0.30	0.88±0.33	0.234
BOP (%), mean ± SD	11.36±12.74	12.50±14.94	10.23±14.76	0.695
RMS (μm), mean ± SD	27.24±11.61	28.78±11.69	25.75±11.41	–

1 w, 2 w, and 3 w: 1 week, 2 weeks, and 3 weeks after definitive crown insertion respectively. [a], results of Friedman test. GI, gingival index; BOP, bleeding on probing; RMS, root mean square; SD, standard deviation.

Table 3 Descriptive statistics (mean ± SD, mm) of changes in peri-implant soft tissue

Parameters	1 w	2 w	3 w
ΔAMM	0.13±0.07	0.03±0.09	0.02±0.10
$\Delta ASTT_{-1\ mm}$	0.20±0.04	0.04±0.05	0.03±0.06
$\Delta ASTT_{-3\ mm}$	0.14±0.08	0.03±0.08	0.03±0.07
$\Delta ASTT_{-5\ mm}$	0.13±0.05	0.02±0.06	0.02±0.07

1 w, 2 w, and 3 w: 1 week, 2 weeks, and 3 weeks after definitive crown insertion respectively; SD, standard deviation; ΔAMM, changes in mucosal margin; ΔASTT, changes in soft tissue thickness.

weeks 2 and 3 (P>0.05). The soft tissue changes became relatively stable 2 weeks after definitive crown insertion (*Figure 4*). The time point of 2 weeks after definitive crown insertion was therefore preliminarily selected as the baseline.

Discussion

In this study, peri-implant soft tissue contour was captured

Table 4 One-way ANOVA results

Parameters	Source	Sum of squares	df	Mean square	F value	P[a]
ΔAMM	Time	0.1742	2	0.0871	12.97	<0.001 (1 *vs.* 2 w)
	Individual	0.1956	21	0.0093	1.39	0.003 (1 *vs.* 3 w)
	Total	0.6518	65	–	–	0.930 (2 *vs.* 3 w)
$\Delta ASTT_{-1\ mm}$	Time	0.4156	2	0.2078	99.84	<0.001 (1 *vs.* 2 w)
	Individual	0.0689	21	0.0033	1.58	<0.001 (1 *vs.* 3 w)
	Total	0.5719	65	–	–	0.578 (2 *vs.* 3 w)
$\Delta ASTT_{-3\ mm}$	Time	0.1791	2	0.0895	24.18	<0.001 (1 *vs.* 2 w)
	Individual	0.2000	21	0.0095	2.57	<0.001 (1 *vs.* 3 w)
	Total	0.5346	65	–	–	0.860 (2 *vs.* 3 w)
$\Delta ASTT_{-5\ mm}$	Time	0.1789	2	0.0895	25.87	<0.001 (1 *vs.* 2 w)
	Individual	0.0639	21	0.0030	0.88	<0.001 (1 *vs.* 3 w)
	Total	0.3881	65	–	–	0.998 (2 *vs.* 3 w)

[a], results of Tukey test. df, degrees of freedom; ANOVA, analysis of variance; ΔAMM, changes in mucosal margin; ΔASTT, changes in soft tissue thickness.

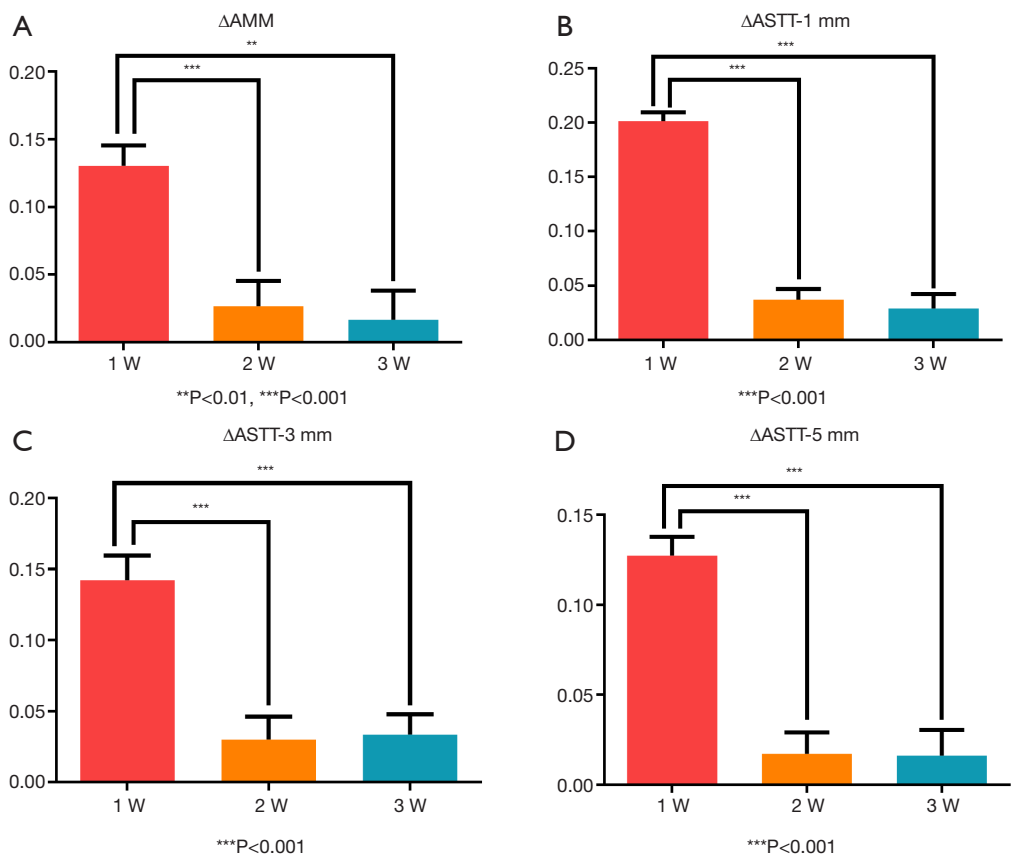

Figure 4 Analysis for baseline selection. (A) Result of ΔAMM among the 3 time points; (B-D) result of ΔASTT among the three time points. 1 w, 2 w, and 3 w, 1 week, 2 weeks, and 3 weeks after definitive crown insertion respectively; ΔAMM, changes in mucosal margin; ΔASTT, changes in soft tissue thickness.

by a 3Shape intraoral scanner which is reportedly noninvasive (17) and superior in terms of precision (18,19), and changes of soft tissue (MM and STT) were evaluated using digital method. In 2019, Fageeh *et al.* compared the precision for evaluating gingival recession among 4 methods [periodontal probe, digital vernier calipers, and digital methods (soft tissue was obtained by 3Shape intraoral scanner or 3Shape model scanner)] (20). The results showed that digital methods (soft tissue was obtained by 3Shape intraoral scanner) were superior in terms of precision (20). The results of this study showed that the soft tissue changes become relatively stable 2 weeks after definitive crown insertion.

It has been reported that RMS <50 μm represents good congruency of two superimposed records (21). In this study, the RMS was lower than 50 μm which met the requirements of congruency.

Interestingly, the increased volume of peri-implant soft tissue was observed within the short-term following definitive crown insertion in this study. According to the results of GI and BOP, the peri-implant soft tissue was in a healthy state. The possible reason for this is that the peri-implant mucosa is affected by definitive crown insertion, causing a coronal shift in the peri-implant MM; however, this has not been fully supported by research. A previous study suggested that the abutment connection was a factor impacting peri-implant soft tissue changes (8,22). There is therefore a need for further studies to be designed to verify these viewpoints. Moreover, based on our findings, significant differences were observed between weeks 1 and 2, and weeks 1 and 3, while there was no significant difference between weeks 2 and 3, suggesting that mucosal changes resulting from crown insertion recovers within 2 weeks.

Among literatures evaluating peri-implant soft tissue changes after definitive crown insertion, Schneider *et al.* (6) and Bienz *et al.* (5) selected 1 week after crown insertion as baseline and performed soft tissue and bone augmentations in the implant process while Huber *et al.* (4) and Thoma *et al.* (3) selected 2 weeks after crown insertion as baseline and performed soft tissue augmentation in the implant process. In this study, 2 weeks after definitive crown insertion was selected as the baseline and soft tissue or bone augmentations were not involved. The result of baseline selection in this study is different from Schneider *et al.* (6) and Bienz *et al.* (5), while similar to Huber *et al.* (4) and Thoma *et al.* (3). These studies might have selected baseline based on clinical experience. The various baselines might affect peri-implant soft tissue change patterns after definitive crown insertion. From comparison between the four previous literatures and the current study, soft tissue and bone augmentations in the implant process might affect the baseline selection for evaluation of peri-implant soft tissue changes.

However, there were some limitations in this study. First, the sample size was small, and the follow-up was short. Second, only 3 time points and 1 implant system were involved in this study. Although these limitations exist, this study may still provide a reference for future clinicians.

Conclusions

Minimal peri-implant soft tissue changes occurred in this study. The time point of 2 weeks after definitive crown insertion was preliminarily selected as the baseline. Small sample size and few time points must be taken into consideration when interpreting our findings.

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Footnote

Reporting Checklist: The authors have completed the TREND reporting checklist. Available at https://dx.doi.org/10.21037/atm-21-3335

Data Sharing Statement: Available at https://dx.doi.org/10.21037/atm-21-3335

Conflicts of Interest: All authors have completed the ICMJE uniform disclosure form (available at https://dx.doi.org/10.21037/atm-21-3335). The authors have no conflicts of interest to declare.

Ethical Statement: The authors are accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are

appropriately investigated and resolved. The study was conducted in accordance with the Declaration of Helsinki (as revised in 2013). The study was approved by the Biomedical Ethics Committee of Peking University School and Hospital of Stomatology, Beijing, China (ethical batch number: PKUSSIRB-201946083). Written informed consent was provided by all individuals included in the study.

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