



Quantitative clinical adjustment analysis of posterior single implant crown in a chairside digital workflow: A randomized controlled trial

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Abstract

Objectives: To compare the three-dimensional changes in quantity and morphology following clinical adjustment of a posterior single implant crown between chairside digital workflow (test) and hybrid digital workflow (control).

Materials and Methods: A total of 33 participants were included for single-tooth replacement with screw-retained crowns in posterior sites of either the maxillary or mandible. A total of 17 participants were carried to a chairside digital workflow, receiving monolithic lithium disilicate (LS2)-crowns (test), while the remaining 16 participants were fitted with CAD/CAM-fabricated zirconia superstructures and hand-layered ceramic veneering crowns (control). As each crown underwent intraoral scanning (3Shape TRIOS Color, 3Shape), 3D digital models were rendered. These scans were taken both before and after try-in. Clinical adjustment dimensional changes were measured by superimposing the optical scans of models within a reverse software (Geomagic Control 2014). Adjustment counts and amounts (from vertical dimension) between two workflows were assessed and compared. Time consumption was recorded for efficiency analysis.

Results: All patients were successfully treated in both groups. The median maximum vertical adjustment (taking both occlusal and interproximal surfaces into consideration) was $237 \mu\text{m} \pm 112$ in the test group and $485 \mu\text{m} \pm 195$ in the control group ($p < .0001$), respectively. The median adjustment count was 2.00 ± 1.09 in test group and 3.00 ± 1.05 in control group ($p = .001$), respectively. The total active working time/ total time for two workflows was 92.3/113.7 min for the test group and 146.3/676.3 min for the control group, respectively.

Conclusion: The test group showed fewer adjustments and apparent precision on the occlusal surface compared with the control group with only a fifth of the consumption of a hybrid workflow.

KEYWORDS

accuracy, CAD/CAM, dental implants, modeling, occlusal adjustment

1 | INTRODUCTION

In recent years, CAD/CAM technology has increasingly become a research hotspot in the field of dental implantation. Continuous improvements in digital systems and materials have allowed clinicians to design and machine dental ceramic restorations in posterior single implant crowns (SIC) (Joda & Bragger, 2014; Wismeijer, Bragger, et al., 2014; Zaruba & Mehl, 2017). At present, the fabrication of implant-supported reconstruction utilizing digital technologies can be divided into two workflows dependent on the amount of involvement in a conventional laboratory process: a completely digital workflow/ a hybrid digital workflow (Muhlemann, Kraus, Hammerle, & Thoma, 2018).

Current literature (Jung, Zembic, Pjetursson, Zwahlen, & Thoma, 2012; Kapos & Evans, 2014; Mangano et al., 2010) shows highly survival rates consistent with those of the hybrid digital workflows for SIC. Although, an entity model for technicians to complete the entire prosthesis is needed. By contrast, chairside digital workflow, as represented as a complete pathway (Kapos & Evans, 2014), saves time, and manufacturing steps during one visiting time. This enhanced workflow is not only convenient for dentists, technicians, and patients, but also it allows providers to treat higher volumes of patients and increase potential clinic income. However, research into posterior SIC focusing on chairside digital workflow is rare as few chairside systems are available and practices with the proper equipment are few and far between (Di Fiore, Vigolo, Graiff, & Stellini, 2018; Kurbad, 2016).

Additionally, despite the previous clinical findings regarding the time-efficiency, cost-effectiveness, subjective patient outcomes, and functional evaluation between digital and conventional workflow (Joda & Bragger, 2015b, 2016a, 2016b; Joda, Ferrari, & Bragger, 2017b; Joda, Ferrari, Bragger, & Zitzmann, 2018; Joda, Katsoulis, & Bragger, 2016; C. Y. Lee, Wong, Ganz, Mursic, & Suzuki, 2015;

F. Mangano & Veronesi, 2018; Schepke, Meijer, Kerdijk, & Cune, 2015; Spies, Pieralli, Vach, & Kohal, 2017), evidence such as accuracy, precision, and efficiency within the clinical setting of the completely chairside digital workflow is strongly needed. For many years, the ability to accurately assess clinical adjustment has yet to be fully elucidated. Given that the proliferation of accurate intra-oral scanning machines has been driving up 3D measurement and analysis (Deferm et al., 2017; Gan, Xiong, & Jiao, 2016; Guth, Keul, Stimmelmayer, Beuer, & Edelhoff, 2013; Lee, Betensky, Gianneschi, & Gallucci, 2015), improvements in three-dimensional evaluation techniques have increased both the quality and morphology after clinical adjustment could be realized.

This randomized controlled trial (RCT) sought to compare and contrast the three-dimensional changes in quality and morphology following clinical adjustment on a posterior SIC between chairside digital workflow (test) and hybrid digital workflow (control) via three-dimensional optical measurement and analysis. Meanwhile, the whole process time included in this study. The null hypothesis contended both clinical adjustment amount and whole protocol time was less in chairside group compared with hybrid group.

2 | MATERIAL AND METHODS

2.1 | Patient enrollment protocol

This study was organized as a randomized controlled trial comparing chairside digital workflow (test group) to a hybrid workflow (control group). It was conducted from November 2017 to September 2018 at Peking University School and Hospital of Stomatology, Department of Oral Implantology.

Enrollment in the study consisted of 33 patients (12 females and 21 males) with a mean age of 46.8 years (range of 25–69 years). No changes were made to study methods following to commencement

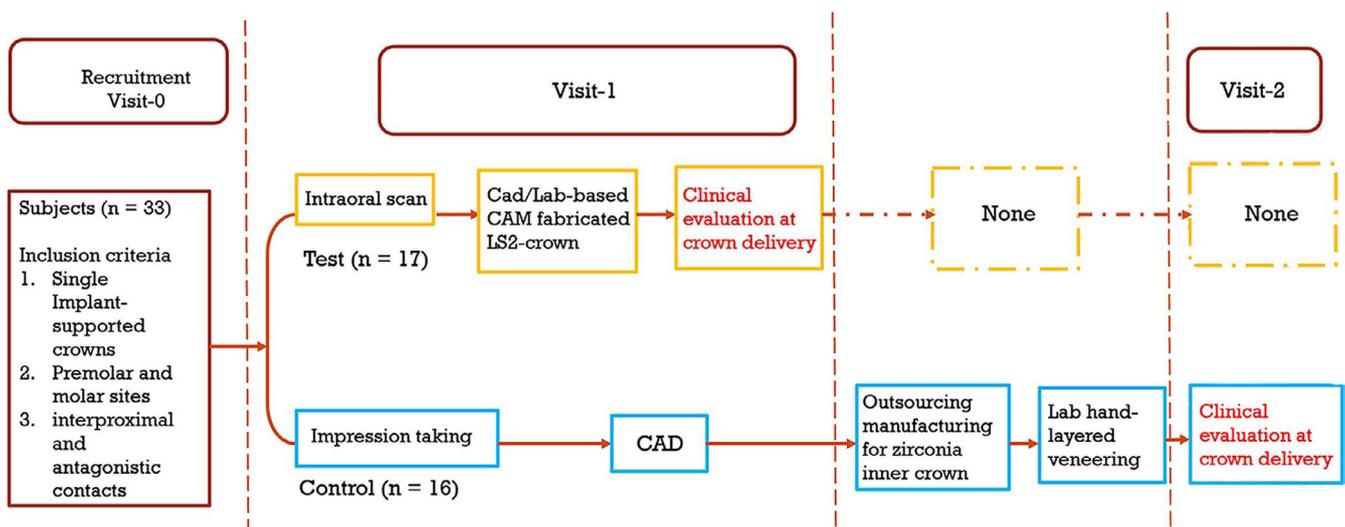


FIGURE 1 Flowchart displaying treatment sequences: recruitment (visit-0); after group determination, test group received an intraoral scan which was subsequently restored with a Ti-base abutment plus LS2 crown during in single visit (visit-1); the control group has impressions taken during visit-1; extra outsourcing manufacturing for zirconia inner crown and laboratory hand-layered ceramic veneering time were needed before try-in. Finally, a visit-2 was required to make clinical evaluation at crown delivery

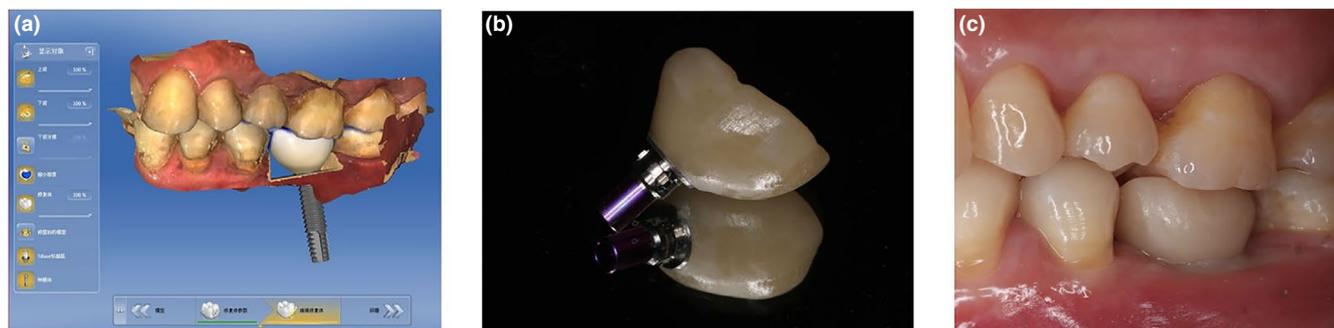


FIGURE 2 (a) Chairside system for CAD (CEREC Omnicam, Sirona Dentsply); (b) prefabricated Ti-base abutments plus monolithic lithium disilicate (LS2)-crowns; (c) seated final restoration in situ during visit-1

of the trial (Figure 1). Inclusion criteria consisted of individuals requiring single-tooth replacement with screw-retained implant crowns on the particular implant system (CAMLOG[®] SCREW-LINE, Camlog Biotechnologies AG) in posterior sites with interproximal and antagonistic contacts, subjects 18–70 years in good medical health with no contraindications for implant treatment, no history of poor oral habits such as smoking or bruxism, and proper treatment compliance. The baseline consisted of prosthetic rehabilitation. It was assumed a significant difference between test, and control groups could be elucidated given the similar try-in time for both the test group (7.4 min \pm 0.2) and control group (10.5 min \pm 1.7) according to a preliminary assessment (Joda & Bragger, 2016b). Under conditions of $\alpha = .05$, $\beta = .10$, it was calculated that 3 individuals should be included per group. In case of a higher SD level and non-normal distribution, 12–13 individuals were needed to enlarge the number. Treatment for the two groups was randomly distributed applying the envelope technique. A non-subject-related researcher performed the random allocation sequence, and the principal investigator enrolled and assigned all study participants to intervention. All participants were informed about the study protocol. Written informed consent was obtained from all participants. A fully blind study was not applicable due to the trial design trial design.

This RCT followed the CONSORT 2010 statements (<https://www.consort-statement.org/consort-2010>) and was officially approved by the local ethical committee (Institutional Review Board of Peking University School and Hospital of Stomatology, Approval Number: PKUSSIRB-201736075) and registered on Chinese Clinical Trial Registry (Registration number: ChiCTR1800015285; <http://www.chictr.org.cn/listbycreator.aspx>). The work was supported by Capital Health Development Research Project (2018-2-4102).

2.2 | Intervention

Included patients received trans-occlusal screw-retained implant crowns produced from a chairside digital workflow or a hybrid digital workflow (Figure 1). All prosthetic work steps were performed by a single-experienced team of the same dentist (P.D.)/dental assistance and a dental technician who had several years of experience in fabricating restorations with the CAD-CAM systems.

The test restorations ($n = 17$) were manufactured in the chairside digital workflow. The 3D implant position and the antagonistic dentition, as well as the bite registration, were captured using a quadrant-like IOS (CEREC Omnicom, Sirona Dentsply). After completing the designing process, the virtual design file was sent to the milling unit (CEREC MC XL Premium, Sirona Dentsply) for the milling of a monolithic LS2-crown (IPS e.max CAD, Ivoclar Vivadent). Through staining and crystallization (Programmat 700, Ivoclar Vivadent), the ceramic structure was bonded to the prefabricated Ti-base abutment (Multilink Implant, Ivoclar) and the excess cement was thoroughly cleaned with the cementation joint cautiously polished. All fabrication was conducted with a model-free process (Figure 2).

The control restorations ($n = 16$) were manufactured in a hybrid digital workflow. Meanwhile, the conventional silicone impressions (Silagum, DMG) were made using the closed-tray technique to transfer the position of the implant to the master cast. A stone model was made, scanned, and converting into a file for CAD/CAM (Trios lab, 3 Shape). The zirconia inner crown was milled and sintered by outsourcing manufacturing. Afterward, it was individually finalized with veneering ceramics then bonded to the prefabricated Ti-base abutment (Multilink Implant, Ivoclar) in laboratory (Figure 3).

2.3 | Clinical fitting and adjustment

Prior to clinical fitting, restoration was set to a standard platform and scanned by one well-experienced operator with the same intraoral scanning (3Shape TRIOS Color, 3Shape) to get a standard tessellation language (STL) file (PRE).

For clinical evaluation, the healing abutments were removed, and the bonded crowns were tried in. Firstly, the interproximal fit was assessed with dental floss for mesial and distal aspects. If applicable, clinical adjustments were made with diamond burs and silicone polishers to create adequate interproximal contacts. Where gaps to appear, there would be a space in which floss could pass by with less resistance. In these cases, more porcelain would be required for the missing contact point. Also, a new Ti-base was requested to get bonded with the crown again, as a result firing for adding porcelain may deform the old Ti-base slightly. Secondly, the occlusion was carefully checked with articulating papers statically and dynamically. We standardized the adjustment to achieve light occlusal contacts by using a 40 μ m articulating paper



FIGURE 3 (a) Laboratory system for CAD (Trios lab, 3 Shape); (b) Ti-base abutments plus CAD/CAM-fabricated zirconia superstructure and hand-layered ceramic veneering; (c) seated final restoration in situ in the second clinic

(Arti-Fol shimstock foil, Dr. Jean Bausch GmbH & Co.) during forceful occlusion, and no contact was evaluated by using a 12 μm articulating film (Arti-Fol shimstock foil, Dr. Jean Bausch GmbH & Co.), which could be pulled out with no resistance during light occlusion. If applicable, adjustments were warranted and required installation in the same way as described for interproximal corrections.

After finishing clinical adjustment, the restorations were removed and set to the same standard platform to get another scan by the same operator, generating a new STL file (POST). Both STL files (PRE and POST) were exported to the Geomagic Control 2014 (Geomagic) and were trimmed, such that only the crown and transfer remained. Set the trimmed pre-fitting file (PRE) as a reference and the post-fitting file (POST) as the test, the superimposition of which was performed employing a “best fit alignment” (Al-Bakri, Hussey, & Al-Omari, 2007). After 3D compare for deviation, a color-coded 3D deviation map of each superimposition was displayed for visual analysis (Figure 4). Among the datasets provided by 3D map, focus was especially placed on the maximum adjustment (the deepest color) amount in vertical and the counts of adjustment.

Finally, the restorations were mounted with a manual torque control ratchet (35 N-cm) onto the implants, and the screw access was sealed with Teflon and composite.

2.4 | Time consumption

Time consumption for each technical and clinical step of both workflows was recorded respectively in minutes (Figure 5, Table 4).

The fabrication of the crowns included impression time, design, milling, heat pressing, and technician processing (adding porcelain, staining, and glazing). The waiting time during heat-pressing was recorded.

The total treatment time referred to the placement of the final crown and chairside adjustments, which included removal of the healing cap, insertion of the final crown, adjustment and screw retention, and closure. Results of the time for restoration scans were excluded.

2.5 | Statistical analysis

Statistical analysis was performed using SPSS software (SPSS version 22.0; SPSS) at a significance level of $p = .05$.

Descriptive statistics were performed first to obtain an overview of the data. The non-parametric Mann-Whitney U test was applied to evaluate the differences in time consumption and adjustment conditions between test and control. A two-way analyses of variance (ANOVA) were performed to determine the significant differences on clinical adjustment counts and the maximum amounts in μm (both from occlusal and contact) between test and control.

3 | RESULT

Table 1 includes baseline demographic patient data. A total of 33 posterior CAD-CAM implant restorations (17 in chairside workflow, 16 in the hybrid workflow) were fabricated and tried in. Among them, two crowns in test group required no adjustment, while all members of the control group required corrections to their crowns. With regard to requiring additional porcelain, it occurred in both group with one of seventeen (1/17) for test group and five of sixteen (5/16) for control group.

The maximum adjustment amount was $237 \mu\text{m} \pm 112$ in the test group and $485 \mu\text{m} \pm 195$ in the control group ($p < .0001$). The median adjustment count was 2.00 ± 1.09 in test and 3.00 ± 1.05 in control ($p = .001$). Overall, the test group demonstrated fewer adjustments and showed better fabricating accuracy compared with the control group (Table 2).

Additionally, this study attempted to elucidate both occlusal and contact on adjustment counts as well as the maximum amount comparing test to control. It suggested that there were no significant differences between contact adjustment counts ($p = .292$) and max. Amount ($p = .121$); nevertheless, the test group showed fewer corrections and obvious precision on the occlusal surface compared with the control group (Figure 4). Detailed data were shown in Table 4.

The total time for both workflows was 113.7 min (test group) and 676.3 min (control group). Given that milling and outsourcing sintering time do not bind working time for dentists and dental technician, the active working time for both workflows was 92.3 min (test group) and 146.3 min (control group), as shown in Table 4. Detailed mean time in minutes for laboratory and clinical steps are present in Figure 5.

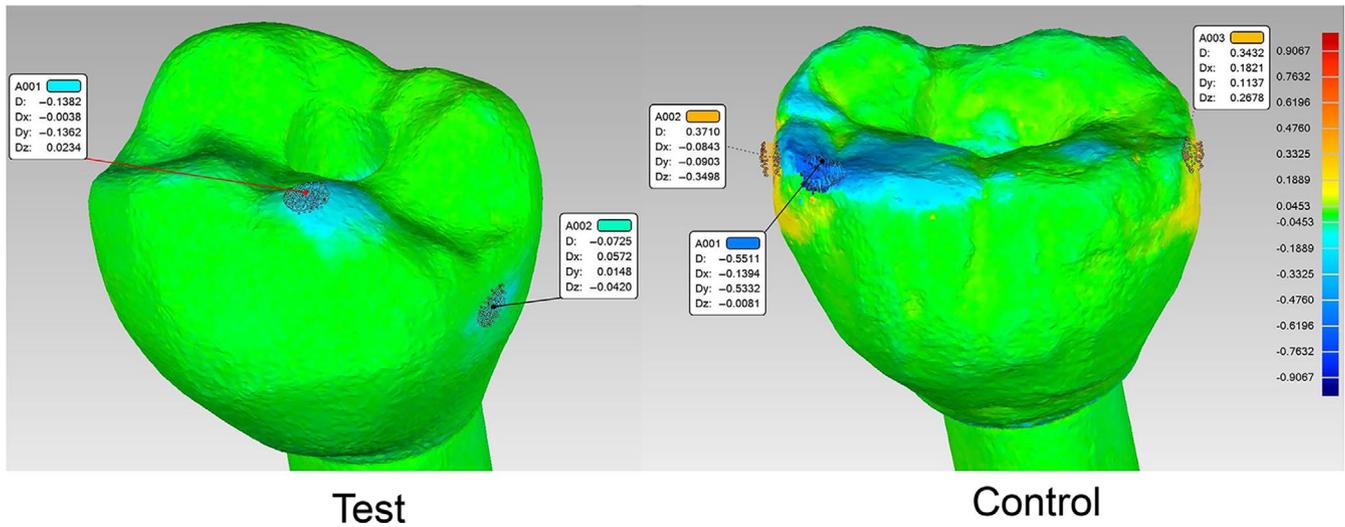


FIGURE 4 Clinical adjustment in two groups with 3D establishment. The blue areas represent reduced area of adjustments while the yellow represents an additional area. Modification amount could be shown as specific values (mm)

TABLE 1 Baseline demographic characteristics in the test and control group

Demographic data	Total	Test	Control
Study participants	n = 33	n = 17	n = 16
Mean age	46.8 years	44.4 years	49.4 years
Gender ratio	36%females	24%females	50%females
Implant sites			
Molar	n = 25	n = 12	n = 13
Premolar	n = 8	n = 5	n = 3

TABLE 2 Clinical adjustment quantification in two groups

	Test	Control
Maximum ± SD adjustment amount*	237 μm ± 0.112	485 μm ± 0.195
Median ± SD adjustment count**	2.00 ± 1.09	3.00 ± 1.05
Need adding	1/17	5/16
No adjustment	2/17	0/16

*p < .0001,
**p = .001.

4 | DISCUSSION

This study attempted to establish three-dimensional data for before and after restoration adjustment in order to quantify the modification in a color spectrum. As a result, the chairside test workflow took advantage in clinical precision and efficiency compared with hybrid digital workflow, especially for the occlusal surface fabrication.

For the first time, the present randomized controlled study revealed the advantages of chairside digital workflow in manufacturing precision of single implant crowns. Without waiting time for taking impression and complicated fabrication, SIC in chairside

digital workflow could be completed during one visit with satisfactory clinical effects. Additionally, we presented a new effective method to compare the three-dimensional changes in quantity and morphology following clinical adjustment of a posterior single implant crown.(Joda & Bragger, 2015a, 2015b; Joda et al., 2016).This novel concept provides quantitative figures to evaluate the clinical adjustment change, avoiding errors resulted from other subjective factors.

Digital scanning and dedicated software for superimposition of the resultant STL datasets represent an efficient technique to measure and compare accuracy (Ender, Attin, & Mehl, 2016; Ender & Mehl, 2013, 2014; Ender, Zimmermann, Attin, & Mehl, 2016; Guth et al., 2013; Mehl, Ender, Mormann, & Attin, 2009; Mehl, Koch, Zaruba, & Ender, 2013; Windisch et al., 2007),both from the aspects of trueness and precision. In Guth et al studies, the same analysis was used to compare the accuracy of three-dimensional construction datasets and the result of direct IOS was 17 μm /- 13 μm,SD ± 19 μm (Guth et al., 2013). Based on the previous researches, our study aimed to analyze the three-dimensional changes before and after clinical adjustment, the results of which were considered to be caused by adjustment, while the systematic error resulted from IOS could be neglected. For more profound application, the method of 3D quantification on adjustment may have important implications for occlusal and wear analysis.

TABLE 3 Maximum adjustment amount and count on occlusal in two groups

Adjustment on occlusal	Test	Control
Max ± SD adjustment amount*	162 μm ± 0.131	485 μm ± 0.194
Median ± SD Adjustment count**	1.00 ± 0.86	3.00 ± 1.01

* $p = .0001$,** $p = .002$.

The results demonstrate significantly less adjustment amount, counts, and time required for the occlusal surface, while on the contact surface, the difference was not obvious between two groups. Considering that both occlusal and contact surfaces of crown in control group were hand-layered by the same technician who had been engaged in implant laboratory for 20 years, the increased adjustment values on occlusal was mainly attributed to the manufacturing process itself, such as impression taken and transformed, especially on the difference in determining the occlusal relationship. For the test group, we performed quadrant-like IOS, which contained the upper, lower arches, and buccal information. The patient needed to clench teeth in the normal position and keep it until occlusal registration finished. Hence, we got the real-time occlusal relationship in oral without errors in impression making or jaws relationship transferring. As a contrast, we transformed the dentitions and implants information by impressions and plaster cast in the control group. Some details on the occlusal surfaces might lose. What's more, the occlusion relationship aligned by technician might not be the real one within oral. However, in the contact area, both groups showed a similar adjustment amount ($p = .121$) and counts ($p = .292$). During the scanning period, we found that some situation where the approximal surfaces of adjacent teeth were hardly captured by oral scanning. The contact area may be estimated according to the built-in algorithm. Overall, both adjustments amount and counts of contact area between two groups had no remarkable differences.

The finding in this study also revealed the superiority of chairside digital workflow in respect to total time consumption compared with hybrid digital workflow. Most commonly however, the

most predominant reduction of time lied in the technical fabrication time.

According to a recent systematic review (Muhlemann et al., 2018), clinical studies on time and efficiency should include an exact description of every work step involved. In the present study, records of everything from preparation of impression taking and clinical adjustments were diligently carried out. Moreover, time for reconstruction design was taken into account, which was eliminated in the previous literature. Besides, owing to the control group needed outsourcing CAD/CAM processes, waiting time including the zirconia milling and fritting was also recorded.

Our result was in accordance with the finding of previous studies' results reported by Joda and his colleagues. Their results demonstrated fabrication time for model-free monolithic CAD/CAM crowns bonded with prefabricated abutment ranged between 46.8 min and 54.5 min (Joda & Bragger, 2014, 2016b). Veneering resulted in 74.4 min out of 132.5 min overall time in a hybrid workflow (customized zirconia abutment) (Joda & Bragger, 2016b). Our study chose veneered crowns to bond to prefabricated Ti-bases to serve as abutment as control, for the sake of confounding factors. Therefore, the time for the centralized processing of zirconia inner crowns is arguably the most time-consuming step.

With regard to clinical time, 14.8 min for IOS and 8.3 min for impression taking were consistent with previous studies (Joda & Bragger, 2015b, 2016b; Schepke et al., 2015; Wismeijer, Mans, van Genuchten, & Reijers, 2014). As for fitting and adjustment time, the chairside crowns (15/17) needed to be adjusted before they were positioned completely. For comparison, no model-free monolithic CAD/CAM crowns required adjustment in any of three studies (Joda & Bragger, 2014, 2016a; Joda, Ferrari, & Bragger, 2017a). Like due to specific digital and technical differences. What's more, we pointed out the operator's skill and the subsequent learning curve was needed for every phase involved in the novel chairside digital workflow (van der Zande, Gorter, & Wismeijer, 2013; Zaruba & Mehl, 2017), which should be considered when interpreting the result of this study.

Overall, our research provides the objective and quantitative basis for comparison of manufacturing precision and time consumption between chairside and hybrid digital workflow. The new

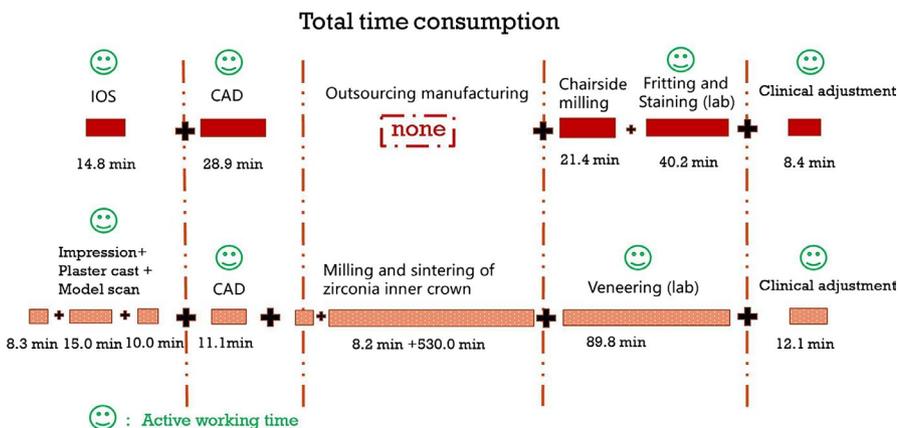
**FIGURE 5** A total time consumption of two workflows

TABLE 4 Time consumption of the Chairside workflow (Test) and Hybrid workflow (Control)

	Mean ± SD time for test (min)	Mean ± SD time for control (min)
IOS/ Model obtained	14.8 ± 2.2	Impression: 8.3 ± 0.5 Plaster cast: 15.0 Model scan: 10.0
CAD	28.9 ± 8.4	11.1 ± 2.0
Chairside milling/ Outsourcing milling	21.4	8.2
Outsourcing sintering	none	530.0
Laboratory fabrication*	40.2 ± 8.7	89.9 ± 12.2
Clinical adjustment**	8.4 ± 3.5	12.3 ± 3.7
Total active working time	92.3	146.3
Total time	113.7	684.5

* $p < .0001$,** $p = .0071$.

method of 3D model establishment does not only give a portrait of adjustment morphology, but also provide specific numerical values for quantitative analysis. Furthermore, this method can be applied to occlusal and wear analysis, which may have important implications and more extensive application in the field of dentistry.

The limitations of present study include small-scale sample enrolled, no follow-up result. It should be reminded that our results may not be transferable to other digital protocol because of the specific digital system and workflow (Wisemeijer, Bragger, et al., 2014) as well. There remain many uncertain conclusions in digital field to be proved, such as esthetic results and long-term complications. Therefore, further long-term trials with large-scale are needed to confirm the reliability and superiority of digital workflow.

5 | CONCLUSION

Based on the results of the RCT, the chairside test workflow took advantage in clinical precision and efficiency compared with hybrid digital workflow, especially for the occlusal surface fabrication. Benefit from visual CAD and monolithic CAM design, complicated fabrication and time could be saved, as well as better clinical effects could be realized. With limitations of the present study (such as small-scale sample enrolled and no follow-up result), further long-time clinical studies with large-scale are necessary to confirm the reliability and superiority of digital workflow.

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CONFLICT OF INTEREST

The authors declare no potential conflict of interests with respect to the authorship and/or publication of this article.

AUTHOR CONTRIBUTIONS

Yifan Zhang: Study design; data collection and analysis; drafting article. Jiehua Tian: Conceived the ideas; critical revision of article. Donghao Wei: Conceived the ideas; technique support; critical revision of article. Ping Di: Concept; funding secured by; critical revision of article. Ye Lin: Concept; critical revision of article.

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