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Crown Accuracy and Time Efficiency of Cement-Retained Implant-Supported Restorations in a Complete Digital Workflow: A Randomized Control Trial

Shuxin Ren, DMD, Xi Jiang, DMD, Ye Lin, DMD,PhD, & Ping Di, DMD,PhD

Department of Oral Implantology, Peking University School and Hospital of Stomatology, Beijing, China

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Cement-retained crown; split-file technique; digital impression; crown accuracy.

Correspondence
Dr. Ping Di, Department of Oral Implantology, Peking University School and Hospital of Stomatology, 22 Zhongguancun South Avenue, Haidian District, Beijing 10081, PR China. E-mail: diping@bjmu.edu.cn

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Abstract

Purpose: This is a clinical study to compare complete digital workflows generated using intraoral scanning and the split-file technique with a conventional workflow for cement-retained implant-supported restorations.
Materials and methods: Forty patients requiring posterior single-unit implant restorations were included. Twenty patients were randomly assigned to the complete digital workflow group, involving intraoral scanning and manufacture of cement-retained crowns using the split-file technique (test group). The remaining 20 patients were assigned to the hybrid workflow group (control group), involving conventional impressions and CAD-CAM fabricated crowns based on stone casts. Scanning of the crowns was performed before and after clinical adjustment using an intraoral scanner (TRIOS Color; 3Shape). Two 3D digital models were trimmed and superimposed to evaluate changes in dimensions using Geomagic Control 2014 software. Chair-side and laboratory times for the entire workflow were recorded. Independent-sample t tests were used for the statistical analysis.
Results: All crowns were inserted without refabrication. The average maximum occlusal adjustment of the crowns, measured as maximum deviation of occlusal area in superimposed pre and post scans, was -212.7 ± 150.5 and -330.7 ± 192.5 μm in the test and control groups, respectively ($p = 0.037$). The average area of occlusal adjustment, measured as area of deviation larger than 100 μm, was 8.4 ± 8.1 and 17.1 ± 12.3 mm^2 in the test and control groups, respectively ($p = 0.012$). The mesial and distal contact adjustment amounts, maximum deviations of proximal area, were -33.0 ± 96.2 and -48.6 ± 70.5 μm in the test group, and -3.7 ± 66.7 μm and -11.4 ± 106.7 μm in the control group, respectively. The mean chair-side time was 20.20 ± 3.00 and 26.65 ± 4.53 minutes in the test and control groups, respectively ($p < 0.001$). The mean laboratory time was 43.70 ± 5.56 and 84.55 ± 5.81 minutes in the test and control groups, respectively ($p < 0.001$).
Conclusions: Single-unit cement-retained crowns with complete digital workflows required fewer crown adjustments and had shorter clinical and laboratory times compared to conventional impressions and hybrid workflows. Digital impressions and the split-file technique provided customized abutments and cement-retained crowns, thus broadening the indications for digital workflows for implants.

Clinical trials have demonstrated that a model-free digital workflow for single implant-supported crowns is accurate, efficient, and reliable.[1–4] Model-free digital workflows produce computer-aided design and computer-aided manufacturing (CAD-CAM) milled crowns, mainly screw-retained, zirconia crowns with prefabricated titanium abutments. However, digital workflows also have some limitations.

First, as the prefabricated titanium base has a standard diameter, and standard gingival and abutment heights, it can only be used in specific clinical situations.[5] Prefabricated abutments with standard heights offer limited retention and resistance to large, cemented crowns in cases of increased interocclusal space, and increase the risk of crown dislodgement.[5] In the premolar area, the standard gingival height of titanium abutments may not match the emergence profile, which leads to unesthetic soft tissue discoloration.[6] In patients with limited mouth opening, mesial tilt of the posterior implants is sometimes inevitable, which compromises the position of the prosthesis.[6] In such cases, passive fit of a screw-retained restoration cannot be achieved because of adjacent teeth. In these clinical situations, customized abutments are preferable to prefabricated abutments.[7,8]

In addition, mechanical risks of posterior hybrid-abutment-crowns with prefabricated titanium abutments have been demonstrated by laboratory and clinical studies. Nouh et al[9] reported that 18.8% of all-ceramic hybrid-abutment-crowns fractured during thermo-mechanical fatigue loading, indicating that restorations with short (3 mm) titanium bases in the posterior region should be avoided. A clinical study conducted by Korsch et al[5] showed that 7.7% of crowns with prefabricated abutments loosened, compared to 0% of crowns with custom abutments, suggesting a lower decementation risk with customized abutments.

Therefore, although screw-retained crowns with prefabricated abutments are considered the first choice in digital workflows and should be recommended in most clinical situations, they are not feasible in complicated situations.[10] Cement-retained crowns and customized abutments, if available, could supplement the digital workflow. However, model-free digital workflows for customized abutments and cement-retained crowns have not been reported so far in clinical studies.

A segmented approach is commonly used to fabricate customized abutments and crowns, i.e., milling customized abutments first and then designing crowns based on stone casts.[11,12] However, the introduction of the split-file technique might change the paradigm. The split-file technique allows the design of customized abutments and crowns that fit together intimately, and saves laboratory time and resources because they are manufactured simultaneously. Previous laboratory studies[13,14] have demonstrated that the split-file protocol provides marginal gap sizes meeting clinical standards following adjustments. However, no clinical studies have evaluated the accuracy of occlusion and interproximal contact of crowns fabricated using the split-file protocol.

The aim of this randomized controlled trial (RCT) was to evaluate the crown accuracy and time efficiency provided by a complete digital workflow for cement-retained implant-supported restorations, using digital impressions and the split-file technique, compared to a workflow using conventional impressions and the segmented approach. The null hypothesis was that complete digital and conventional workflows have similar crown accuracy, and clinical and laboratory times.

Materials and methods

The study was a single-center, unblinded, randomized controlled trial of two parallel groups. Participants were assigned to either the complete digital workflow or conventional segmental workflow (allocation ratio 1:1). The study was independently reviewed and approved by the Institutional Review Board (Ethical approval No.: PKUSSIRB-201840188) and registered in a Clinical Trial Registry (ChiCTR No.: ChiCTR2000033306). The Consolidated Standards of Reporting Trials (CONSORT) guidelines were used as a framework for this study.

All participants were informed about the study protocol and written consent was obtained. The inclusion criteria consisted of individuals (age $\geq$18 years) requiring single premolar or first molar implant (Camlog Screw Line; Camlog Biotechnologies GmbH, Basel, Switzerland) with sufficient prosthetic space (vertical height $\geq$5 mm, mesiodistal distance $\geq$ 6 mm). The exclusion criteria included individuals with local or systemic contraindications for implant therapy, adjacent or antagonistic teeth with Class I to III mobility.

Forty patients with single-unit implants, placed 4 months previously and ready for impressions, were included in this study. Twenty patients were randomized to the test group (intraoral scanning [IOS], split-file technique, and crown delivery), while the remaining twenty patients were allocated to the control group (conventional impressions, segmented approach, and crown delivery) (Fig 1).

Randomization was performed using computer software. A researcher not involved in the study placed a computer-generated group number into sequentially numbered, opaque, sealed envelopes. The envelopes were sequentially opened by the principal investigator as participants meeting the inclusion criteria signed the consent form. Complete blinding was not possible due to the study design. No changes were made to the study methods following commencement of the trial.

In the test group, digital impressions that included the edentulous area, implant, two adjacent teeth, the opposing arch, and bite registration were recorded using an intraoral scanner (TRIOS Color; 3Shape, Copenhagen, Denmark). Digital impressions were transferred to CAD software (Dental Designer; 3Shape). Virtual crowns were designed from the implant up and split into customized abutments and crowns (Figs 2,3 to 4). The abutment margins were set 0.5 mm subgingival buccally and 0.5 mm supragingival lingually. The restoration settings were established in a pilot study, as follows: cement gap: 40 μm; extra cement gap: 30 μm; distance to margin line: 0.8 mm; occlusion contact: 0.3 mm; and interproximal contact: −10 μm. The virtual abutment standard tesselation file (STL) was transferred to the milling center and the titanium abutment was manufactured using a 5-axis milling machine (Organical Multi 5X; Organical CAD/CAM GmbH, Berlin, Germany). A separate crown file (STL) was transferred and the crown was manufactured using another 5-axis milling machine (Organical Multi & Changer 20; Organical CAD/CAM GmbH) from proprietary zirconia (Organic Zircon; Organical CAD/CAM GmbH). After milling and sintering, an experienced technician polished and refined the milled abutments and crowns to improve the marginal fit.

In the control group, conventional silicone impressions recorded with the closed-tray technique were used to transfer the implant position to the master cast, which was then digitalized by the laboratory scanner (TRIOS; 3shape). Customized titanium abutments were designed using the Dental Designer software and milled using a 5-axis milling machine (Organical Multi 5X). Following adjustments and refinement of the milled abutments by the same technician, master casts were again digitalized, and crowns were designed on the abutment using the same software. Zirconia crowns (Organic Zircon) were fabricated using a 5-axis milling machine (Organical Multi & Changer 20) and refined by the technician to improve the marginal fit.

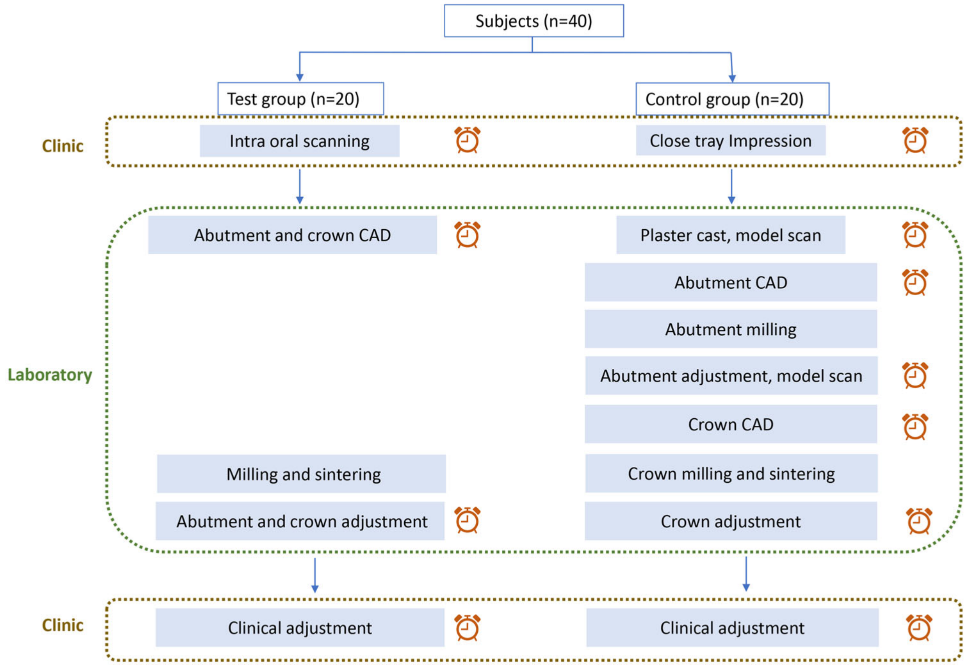

Figure 1 Flowchart of treatment sequences and time record in the test and control groups.

Figure 2 Intraoral scanning.

Figure 3 Customized abutment.

All crowns were scanned chair-side using the same intraoral scanner (TRIOS Color; 3Shape) prior to any clinical adjustments. STL files were generated and marked as "PRE files."

The customized abutment was screwed into the implant with a torque of 35 Ncm, under local anesthesia if required. Interproximal fit and occlusal contact were assessed after a zirconia crown was inserted on the customized abutment. Dental floss passing with moderate resistance indicated favorable interproximal contact; light occlusal contact without lateral occlusal interference checked using 40-μm articulating paper (Arti-Fol Shimstock foil; Dr. Jean Bausch GmbH & Co., Köln, Germany), indicated favorable occlusal contact. Diamond burs and silicone polishers were used to remove premature contact points, and porcelain was added in the laboratory in case of missing contact points. Before cementation, post-adjustment crowns were scanned using the same scanner to generate new STL files, marked as "POST files." The crowns were cemented to the abutments using glass ionomer cement (Hy-Bond GlasIonomer CX; Shufu Global, Kyoto, Japan) (Figs 5 and 6).

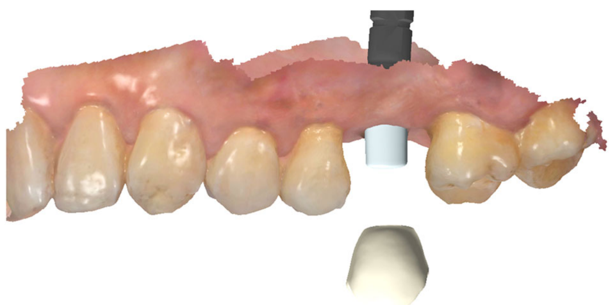

Figure 4 Customized abutment and crown with split-file technique in CAD.

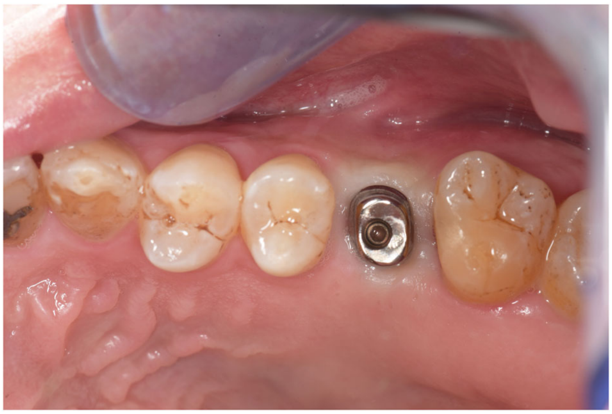

Figure 5 Delivery of customized abutment.

Figure 6 Delivery of crown.

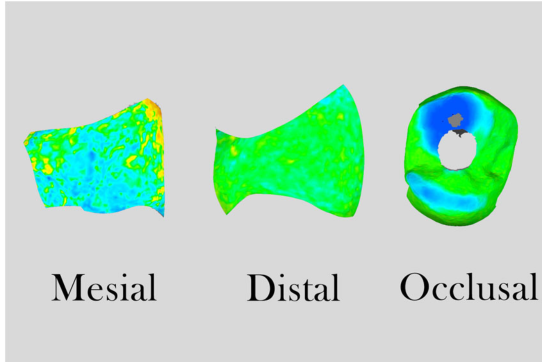

Figure 7 Before-and-after adjustment of mesial, distal and occlusal surface of crown.

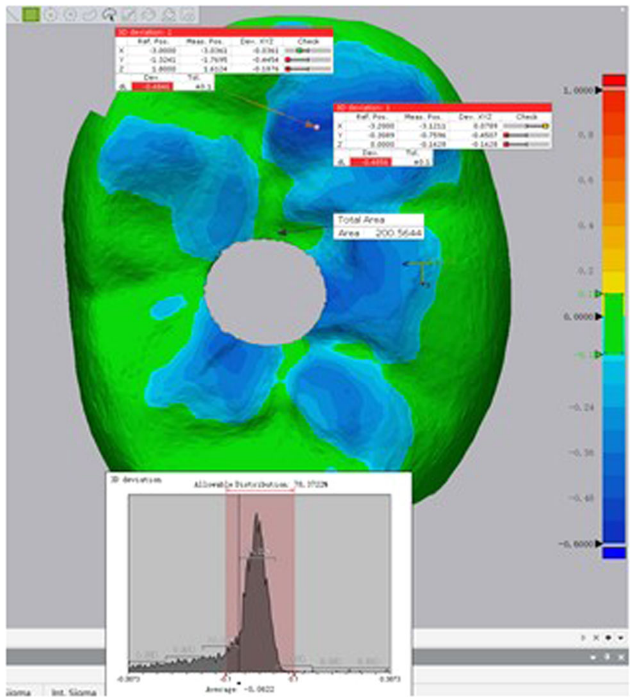

Figure 8 Maximum occlusal adjustment, total size and allowable distribution of deviation between –0.1 mm to 0.1 mm.

PRE and POST files were exported to the analysis software (Geomagic Control 2014; Geomagic, NC) for crown adjustment evaluation. After trimming, POST files were superimposed on the PRE files using an algorithm for best-fit alignment. Mesial and distal interproximal surfaces were trimmed off and classified as "INTERPROXIMAL" for both PRE and POST files. The remaining files were classified as "OCCLUSION". Three-dimensional deviation analysis between PRE and POST files was performed for both the INTERPROXIMAL and OCCLUSION files (Fig 7). After comparison of deviation, a color-coded 3D deviation map of each superimposition was generated for visual analysis. The maximum vertical adjustment, indicated by the deepest color, was extracted from 3D maps for the INTERPROXIMAL and OCCLUSION files (Fig 8). Areas of vertical adjustments less than 100 μm appeared green on the color-coded OCCLUSION map. The size of the other areas was calculated to determine the extent of occlusal adjustment.

Clinical and laboratory times were recorded for both workflows (in minutes) by an independent investigator. In the clinical phase, impression and crown delivery times (occlusal and interproximal contact adjustments) were recorded. In the laboratory phase, fabrication, intraoral scanning, restoration design, and processing (manual adjustments and polishing) times were recorded. Waiting time, which included the milling and sintering times, was excluded from the analysis. The steps are shown in Figure 1.

The primary outcome measure of this study was crown adjustments evaluated based on the depth and size of the crown modifications. Sample size was calculated based on a previous study using a two-sample *t* test, with standard deviations of 237 μm in the test group and 485 μm in the control group (mean difference = 248 μm)[4]. With a confidence level of 95%, a significant difference could be elucidated with eight participants per group. To achieve a higher confidence level, 20 participants were included in each group. An independent-sample t test was used to compare crown adjustments between the test and control groups.

The secondary outcomes were the clinical and laboratory time durations. An independent-sample t test was used to com-

Table 1 Demographic characteristics of the test and control groups

Demographic data	Total	Test	Control
Participants (n)	40	20	20
Mean age (years)	44.1	44.6	43.7
Sex ratio (% female)	50	60	40
Implant sites (premolar:molar)	7:33	3:17	4:16

pare the time taken for the clinical and laboratory phases between the test and control groups. SPSS statistics software (version 22.0; IBM Corp., Armonk, NY) was used for statistical analyses. A 5% significance level was used for all tests.

Results

In total, 40 patients (20 females and 20 males) with a mean age of 44.1 years (range: 20-74 years) were included in the study. The demographic characteristics of the test and control groups are listed in Table 1. There were no losses or exclusions after randomization.

The clinical crown adjustments in the two groups are presented in Table 2. The maximum deviation on occlusion was -212.7 ± 150.5 and -330.7 ± 192.5 µm in the test and control groups, respectively ($p = 0.037$). The sizes of the adjustment areas were 8.4 ± 8.1 and 17.1 ± 12.3 mm^2 in the test and control groups, respectively ($p = 0.012$). The depth and size of the occlusal adjustment indicated greater accuracy of the occlusal surface using the digital workflow. The maximum mesial deviation was -33.0 ± 96.2 and -3.7 ± 66.7 µm in the test and control groups, respectively ($p = 0.270$). The maximum distal deviation was -48.6 ± 70.5 and -11.4 ± 106.7 μm in the test and control groups, respectively ($p = 0.202$). Interproximal modifications in the test group were slightly greater compared to the control group, but the difference was not statistically significant.

The chair-side times were similar between the groups (Table 3). The time taken for clinical crown adjustment was 6.45 ± 2.21 and 13.15 ± 3.84 minutes in the test and control groups, respectively ($p < 0.001$), where fewer crown adjustments were required in the test group. However, the impressions recorded using IOS (13.75 ± 2.45 minutes) were not more time-efficient compared to conventional impressions (13.50 ± 2.62 minutes).

In the dental laboratory, the manufacturing steps and working times for technicians were significantly reduced by the digital workflow. Although the split-file technique required longer manual adjustments (18.90 ± 3.80 minutes) on crowns and abutments compared to the control group (6.60 ± 2.93 minutes), the total time in the test group (43.70 ± 5.56 minutes) was nearly half that in the control group (84.55 ± 5.81 minutes) ($p < 0.001$). The details of the data are shown in Table 4.

Discussion

This is the first clinical study to evaluate the accuracy of the occlusal and interproximal contact of cement-retained crowns in a complete digital workflow. The study demonstrated that posterior single-unit cement-retained implant-supported restorations produced using split-file digital workflows had better crown accuracy and time efficiency in the clinical and laboratory phases than conventional workflows.

The split-file technique was first used by commercial agents; laboratory studies[13,14] then confirmed that crown margin adaptation met clinical standards after adjustments, such that the technique could be used clinically. One study quantitatively analyzed adjustments of screw-retained crowns and showed that the maximum vertical adjustment was smaller for digital (237 ± 112 µm) compared to conventional workflows (485 ± 195 μm).[4] In this study, cement-retained restorations showed similar crown accuracy (maximum vertical adjustment = 212.7 ± 150.5 µm) to screw-retained restorations. This study segmented the crown morphology file into occlusal surface, and mesial and distal interproximal surfaces, to analyze these surfaces independently. The results showed that the complete digital workflow had better precision, particularly on the occlusal surface. The reliability of virtual interocclusal records obtained with intraoral scanning[15] could explain the improved accuracy of the occlusal surfaces. However, this is only applicable when there is one tooth missing, and cannot be expected with multiple implants. Other studies[1,16] demonstrated superior crown accuracy, reflected in shorter chair-side adjustment times. This study demonstrated that the clinical time required for crown adjustment was reduced from 13.2 minutes with the conventional workflow to 6.5 minutes for the digital workflow. These results accorded with previous studies, but the data could not be compared due to time-recording differences.

The benefits of the digital workflow for laboratory procedures were also obvious; IOS obviates the need for plaster casting and model scanning, while the split-file technique circumvents the need for a second digital model. Several manual fabrication steps could be skipped, so the laboratory time was dramatically reduced from 84.6 minutes in the control group to 43.7 minutes in the test group. However, manual adjustments of the crowns and abutments took longer in the test compared to control group, because the crowns and abutments were milled simultaneously and required more modifications.

Several studies[17,18] have emphasized the importance of manual correction of the crown-abutment fit, and the experience of the technicians was proven to be critical to obtain good marginal accuracy. Sheridan et al[13] showed that the mean marginal gap was reduced from 215 to 69 μm via manual adjustments by an experienced technician. Zeller et al[14] showed that the mean marginal gap after adjustment for the split-file group was 38 µm. Although the marginal gap in split-file group was slightly larger than in the segmented digital group (26 μm), it was still clinically acceptable. To obtain favorable marginal gaps, multiple calibrations and adjustments must be made to the milling machines and crown design, because different material properties and milling programs influence the marginal fit. Our pilot study achieved marginal gap sizes similar to previous reports by setting a cement gap of 40 µm, extra cement gap of 30 µm, and distance to the margin line of 0.8 mm. However, settings and parameters might be significantly altered if the material or manufacturing technology changes. Further investigations are required to establish standardized

Table 2 Crown adjustments in the test and control groups

	Test	Control	p-value
Maximum occlusion adjustment (μm)	−212.7 ± 150.5	−330.7 ± 192.5	0.037
Area of occlusion adjustment (mm^2)	8.4 ± 8.1	17.1 ± 12.3	0.012
Maximum mesial adjustment (μm)	−33.0 ± 96.2	−3.7 ± 66.7	0.270
Maximum distal adjustment (μm)	−48.6 ± 70.5	−11.4 ± 106.7	0.202

Table 3 Clinical chair-side times (minutes) in the test and control groups

	Test	Control	p-Value
Impression taking	13.75 ± 2.45	13.50 ± 2.62	0.757
Crown adjustment	6.45 ± 2.21	13.15 ± 3.84	0.000
Total	20.20 ± 3.00	26.65 ± 4.53	0.000

Table 4 Laboratory times (minutes) in the test and control groups

	Test	Control	p-Value
Plaster cast and model scan	0	16.20 ± 2.31	0.000
CAD	24.80 ± 3.04	28.35 ± 2.46	0.000
Manual adjustment	18.90 ± 3.80	6.60 ± 2.93	0.000
Total	43.70 ± 5.56	84.55 ± 5.81	0.000

CAD = computer-aided design.

CAD-CAM parameters for various manufacturing machines and materials.

The split-file technique allows for implant-supported cemented crowns to be produced via a complete digital workflow. The clinical conditions in which prefabricated abutments cannot be used represent the indications for a digital workflow. When the implant is inclined or the vertical restorative space is either too big or too small, the split-file technique is recommended for customized abutments and crowns. Further clinical studies are required to compare these two digital workflows in terms of restoration precision, clinical and laboratory efficiency, and long-term stability.

Conclusion

A digital workflow for single-unit cement-retained implant-supported restorations using digital impressions and the split-file technique required fewer crown adjustments, and less clinical and laboratory time, compared to conventional impressions and a hybrid workflow.

Conflict of interest

The authors have no conflicts of interest to declare.

References

1. Joda T, Bragger U. Time-efficiency analysis of the treatment with monolithic implant crowns in a digital workflow: a randomized controlled trial. Clin Oral Implants Res 2016;27: 1401-1406
2. Joda T, Bragger U. Time-efficiency analysis comparing digital and conventional workflows for implant crowns: a prospective clinical crossover trial. Int J Oral Maxillofac Implants 2015;30: 1047-1053
3. Joda T, Bragger U. Complete digital workflow for the production of implant-supported single-unit monolithic crowns. Clin Oral Implants Res 2014;25:1304-1306
4. Zhang Y, Tian J, Wei D, et al. Quantitative clinical adjustment analysis of posterior single implant crown in a chairside digital workflow: a randomized controlled trial. Clin Oral Implants Res 2019:1059-1066
5. Korsch M, Walther W. Prefabricated versus customized abutments: a retrospective analysis of loosening of cement-retained fixed implant-supported reconstructions. Int J Prosthodont 2015;28:522-526
6. Wittneben JG, Joda T, Weber HP, et al. Screw retained vs. cement retained implant-supported fixed dental prosthesis. Periodontol 2000 2017;73:141-151
7. Zarauz C, Pitta J, Pradies G, et al. Clinical recommendations for implant abutment selection for single-implant reconstructions: customized vs standardized ceramic and metallic solutions. Int J Periodont Restorat Dent 2020;40:31-37
8. Sailer I, Muhlemann S, Zwahlen M, et al. Cemented and screw-retained implant reconstructions: a systematic review of the survival and complication rates. Clin Oral Implants Res 2012;23(Suppl 6):163-201
9. Nouh I, Kern M, Sabet AE, et al. Mechanical behavior of posterior all-ceramic hybrid-abutment-crowns versus hybrid-abutments with separate crowns-a laboratory study. Clin Oral Implants Res 2019;30:90-98
10. Joda T, Ferrari M, Gallucci GO, et al. Digital technology in fixed implant prosthodontics. Periodontol 2000 2017;73:178-192
11. Lee H, Son K, Lee WS, et al. Displacement of customized abutments designed on a working cast and in the oral cavity: a comparative in vivo study. J Prosthodont 2020;29:12-18
12. Taha D, Nour M, Zohdy M, et al. The effect of different wax pattern fabrication techniques on the marginal fit of customized lithium disilicate implant abutments. J Prosthodont 2019;28: 1018-1023
13. Sheridan RR, Verrett R, Haney S, et al. Effect of split-file digital workflow on crown margin adaptation. J Prosthodont 2017;26: 571-580
14. Zeller S, Guichet D, Kontogiorgos E, et al. Accuracy of three digital workflows for implant abutment and crown fabrication using a digital measuring technique. J Prosthet Dent 2019;121: 276-284
15. Ren S, Morton D, Lin WS. Accuracy of virtual interocclusal records for partially edentulous patients. J Prosthe Dent 2020;123: 860-865
16. Zhang R, Ding Q, Sun Y, et al. Assessment of cad-cam zirconia crowns designed with 2 different methods: a self-controlled clinical trial. J Prosthet Dent 2018;120:686-692

17. Buchi DL, Ebler S, Hammerle CH, et al. Marginal and internal fit of curved anterior cad/cam-milled zirconia fixed dental prostheses: an in-vitro study. Quintessence Int 2014;45: 837-846
18. Witkowski S, Komine F, Gerds T. Marginal accuracy of titanium copings fabricated by casting and CAD/CAM techniques. J Prosthet Dent 2006;96:47-52