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A double-blind randomized within-subject study to evaluate clinical applicability of four digital workflows for the fabrication of posterior single implant crown

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Abstract

Objective: To compare efficiency and clinical efficacy of posterior single implant crowns (PSIC) fabricated using four digital workflows.

Materials and Methods: Twenty-two patients with one missing first molar were included. Each patient received four screw-retained implant crowns fabricated through four different workflows including a fully digital workflow with immediate digital impression (Group i-IOS), a fully digital workflow with digital impression after implant osseointegration (Group d-IOS), a model-based hybrid workflow using immediate analogue impression (Group i-AI), and a model-based hybrid workflow with conventional analogue impression after implant osseointegration (Group d-AI). The crown delivery sequence was randomized and blinded. The efficiency for each workflow and clinical outcome of each crown were recorded.

Results: The average clinical working time in fully digital workflows (i-IOS 46.90 min, d-IOS 45.66 min) was significantly lower than that in the hybrid workflows (i-AI 54.59 min, d-AI 55.96 min; $p < .001$). Significantly more laboratory time was spent in hybrid workflows (i-AI 839.60 min, d-AI 811.73 min) as compared to fully digital workflows (i-IOS 606.25 min, d-IOS 607.83 min, $p < .01$). No significant differences in the chairside time at delivery were found. More crowns in Group i-AI (15%) needed additional laboratory interventions than in the other groups ($p = .029$).

Conclusion: Digital impression and model-free fully digital workflow improved prosthetic efficiency in the fabrication of PSIC. With the limitation that the results were only applicable to the implant system used and the digital technologies applied, findings suggested that workflows integrating immediate impression with implant surgery procedure was clinically applicable for restoration of PSIC.

KEYWORDS
CAD/CAM, digital workflow, immediate impression, implant, single implant crown

1 | INTRODUCTION

The fabrication of single implant-supported crowns (SIC) by means of digital technologies has received significant attention due to its improved efficiency and high precision (Hammerle et al., 2015; Sailer et al., 2018). Applications of intraoral scans (IOS) simplify the impression procedure, shorten clinical time, and improve comfort of treatment (Joda, Ferrari, Gallucci, et al., 2017; Mangano et al., 2017; Muhlemann et al., 2022; Richert et al., 2017). Computer aided design/computer-aided manufacturing (CAD/CAM) technologies and five-axis computer numerical control (CNC) milling help effectively reducing the accumulated manual operation errors (Joda et al., 2016), ensuring data integrity, decreasing material consumption and increasing time efficiency during restoration manufacturing process (Joda & Bragger, 2015; Koch et al., 2016; Muhlemann et al., 2021).

Advances in equipment, software and materials offer constant evolutions in digital workflows for single implant crowns (Joda et al., 2016; Joda & Bragger, 2015; Kapos & Evans, 2014; Ting-Shu & Jian, 2015). Hybrid workflows in which conventional impressions, models as well as wax-ups were digitized by laboratory scanning have been compared to the fully digital workflow which combined model-free fabrication, the use of prefabricated abutments, and monolithic design of the reconstructions (Muhlemann et al., 2018). It has been proven that the later could improve clinical efficiency and production quality (Joda & Bragger, 2014; Joda, Ferrari, & Bragger, 2017).

Is it possible to further improve clinical efficiency for the fabrication of SIC? A few studies suggested that the digital impression could be taken immediately after implant placement by updating implant position to an existing digital impression. Thereby, the SIC could be fabricated by means of a model-free fully digital workflow and delivered with the same clinical outcome as those made from conventional hybrid workflow (Guo et al., 2019; Pan et al., 2019). The immediate IOS was proven to be reliable reference for the delivery of a posterior SIC 3 months after implant placement (Pan et al., 2019).

Apart from IOS, a prefabricated titanium base (Cooper et al., 2010), a digital guide (Oh et al., 2019), and an resin-positioning impression post (Lindeboom et al., 2006; Schincaglia et al., 2008; Testori et al., 2007) have also been reported as implant position recording device to record implant position in analog stone model. Commonly, a resin positioning impression post consists of an implant transfer post and self-cured acrylic resin. By fixing the resin positioning impression post into the stone model, the implant position in relation to the adjacent teeth was determined.

Evidence for clinical and laboratory time efficiency and clinical outcome measures of posterior SICs made from immediate impression and digital workflows is still lacking. Furthermore, the feasibility of immediate digital and analogue impressions for the fabrication of single posterior implant crowns needs to be evaluated.

The aim of this double-blind randomized controlled study was to evaluate efficiency and prosthetic efficacy of a fully digital workflow using immediate digital impressions, compared to three other digital workflows including a model-based hybrid workflow using immediate analogue impression, a fully digital workflow using digital impression 3 months after implant placement, and a model-based hybrid workflow using conventional analogue impression 3 months after implant placement. The null hypothesis was that there would be no difference in the efficiency and no difference in the clinical evaluation of crowns when comparing the four different digital workflows.

2 | MATERIALS AND METHODS

2.1 | Participants

This study was conducted in the Department of Prosthodontics, Peking University School and Hospital of Stomatology, and was monitored by the Clinic of Fixed and Removable Prosthodontics and Dental Material Science, University of Zurich.

The study was reviewed and approved by the Institutional Review Board of Peking University School and Hospital of Stomatology (Ethical approval No: PKUSSIRB-201943027). The study had been registered in Chinese Clinical Trial Registry (ChiCTR) (ChiCTR1900022421).

This study was undertaken with the understanding and written consent of each subject and according to the World Medical Association Declaration of Helsinki (version 2013).

The inclusion criteria were:

a. Age ≥ 18 years.
b. Missing single first molar for at least 3 months.
c. Mesial and distal teeth/restorations present and intact.
d. Sufficient bone height and width at implant site (vertical bone height ≥ 10 mm, buccal-lingual bone width ≥7 mm).
e. Sufficient prosthetic space (Vertical height ≥5 mm, mesial-distal distance ≥6 mm).
f. Willing to receive implant treatment.

The exclusion criteria were:

a. Local or systemic contraindication for implant therapy (i.e., uncontrolled diabetes, hemophilia, metabolic bone disorder, history of renal failure, radiation treatment to the head or neck region, and current chemotherapy etc.).
b. Smoking ≥10 cigarettes per day.
c. Major guided bone regeneration (GBR) indicated.
d. Implant need submerged healing.
e. Pregnancy.

In this study, 132 patients were screened, and 110 were excluded. Twenty-two patients who fulfilled the inclusion/exclusion criteria and satisfied the following periodontal requirement after the hygienic phase were included:

a. Plaque index ≤20%.
b. Bleeding on probing ≤20%.
c. Probing depth at all teeth ≤4 mm.

2.2 | Treatment planning and implant surgery

Study flowchart was shown in Figure 1.

For each participant, the clinical examination and cone beam computed tomography (CBCT, NewTom VGi, NewTom) were carried out for implant planning. An IOS (3Shape Trios® 3Basic, 3ShapeA/S) of the maxillary and mandibular arches including the bite registration was acquired. Stone models of patient's upper and lower dentitions were made from conventional impressions (Impregum Penta, 3M ESPE GmbH).

During surgery, full-thickness flap was raised under local anesthesia (Primacaine adrenaline 1:100,000, Dentaires Pierre Rolland). Each patient received a bone level tapered implant (Straumann Bone level Tapered; 4.1 × 10 mm or 4.8 × 10 mm; Roxolid®, SLActive®, Institut Straumann AG) placed in the ideal 3-dimensional prosthetic position enabling fabrication and delivery of a screw-retained crown. A transmucosal healing abutment (Straumann RC Healing Abutment, Institut Straumann AG) was connected and flap was sutured.

2.3 | Prosthetic procedure with four digital workflows for SICs

For each patient, four screw-retained monolithic zirconia crowns (Zenostar® T sc, Wieland Dental) on the prefabricated titanium base (Straumann RC Variobase, Institut Straumann AG) were fabricated following the digital workflows listed below, and Figure 2 summarized the clinical and laboratory process.

a. Immediate IOS group (Group i-IOS): Immediately after implant placement, a scan body (Straumann® RC CARES® Mono Scanbody Institut Straumann AG) was connected to the implant. The IOS digital impression taken in the first appointment was retrieved in the scanner, and the tooth missing area was "cut out" in IOS impression. This tooth-missing area with installed implant/scan body was then re-scanned and integrated into the existing digital impression. Then crown A was fabricated through a model-free fully digital workflow.
b. Immediate Analogue Impression group (Group i-AI): After immediate IOS, an implant transfer post (Straumann RC, Institut Straumann AG) was connected to the implant. Self-curing acrylic resin (Protemp™ 4, 3 M ESPE GmbH) was applied around the transfer post and extended onto the occlusal surface of adjacent teeth to generate a resin positioning transfer post (Figure 3), which contributed to reduce the chairside time and the risk of infection caused by direct contact of the surgical area and impression material. The transfer post was then taken off together with the cured resin. In the dental laboratory, the corresponding implant analogue was connected. On the stone model made previously, a hole was prepared in the surgical area to accommodate the transfer post and analogue. The resin positioning transfer post was then "seated" in the stone model using the cured resin

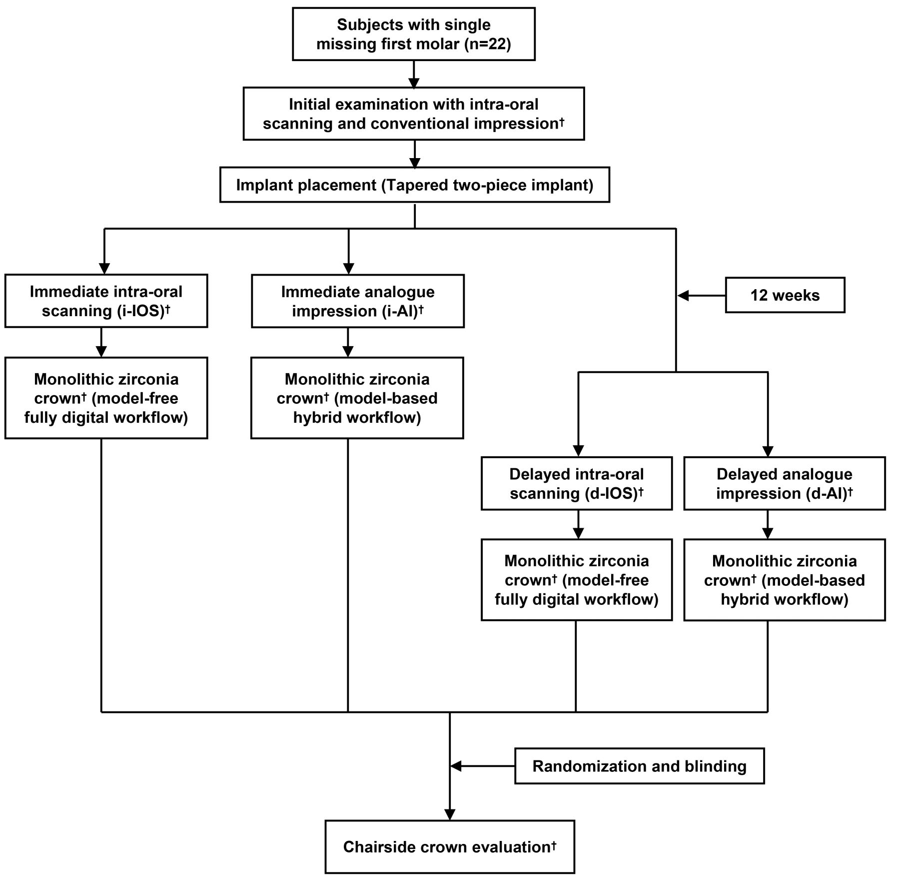

FIGURE 1 Study flowchart. †Time efficiency evaluation.

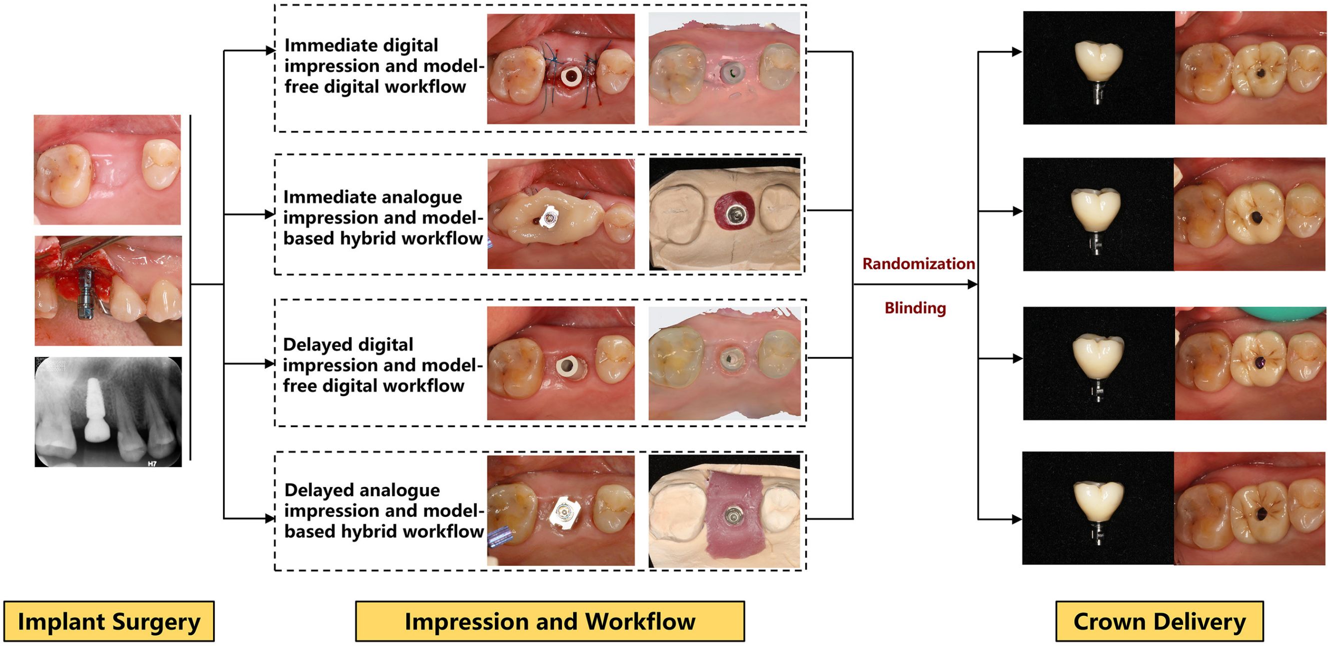

FIGURE 2 Process of the four digital workflows.

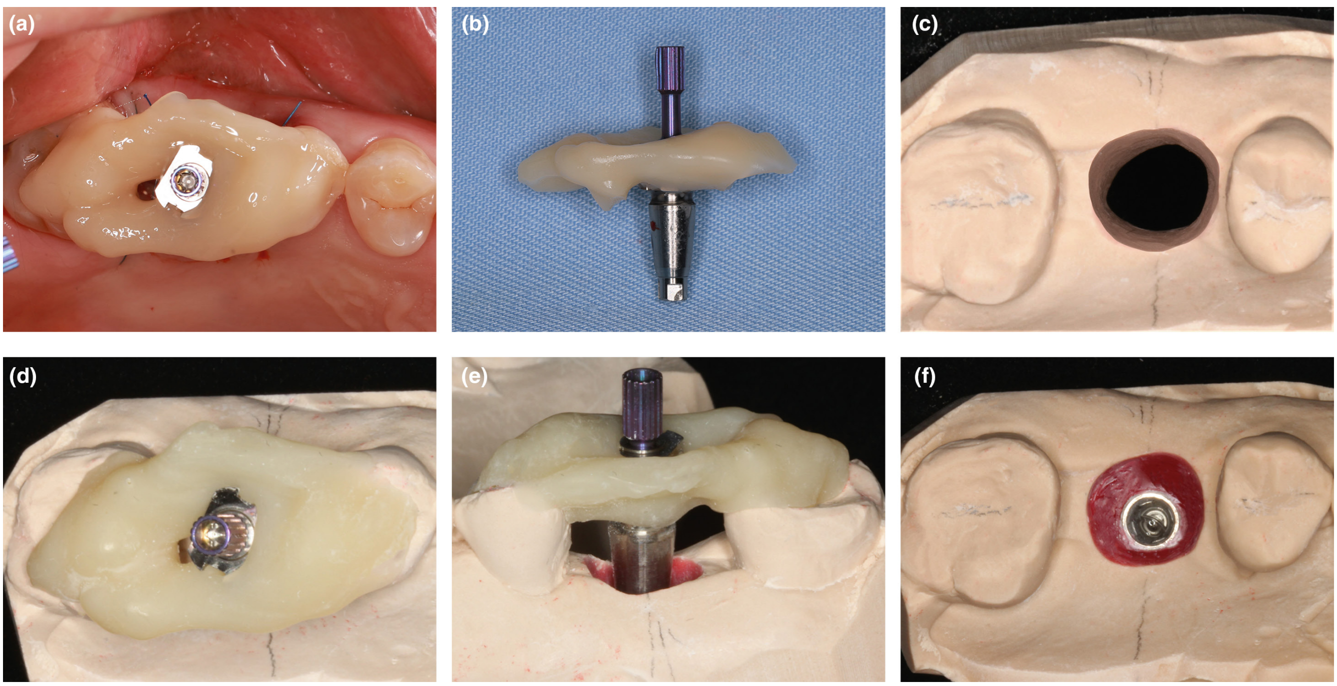

FIGURE 3 Procedures of immediate analogue implant impression: (a) Recording implant position immediately after surgery using acrylic resin; (b) Resin positioning transfer post; (c) Model preparation; (d) Positioning transfer post on the model; (e, f) Fixation of implant analogue.

"wings" as positioning indicator and fixed using pattern resin (GC PATTERN RESIN, GC Corporation). Then crown B was fabricated through a model-based hybrid digital workflow.

c. Delayed IOS group (Group d-IOS): 3 months after implant surgery, a second digital impression was taken with the scan body fixed on the implant. A complete IOS of the maxillary and mandibular arches including the bite registration were taken. Then crown C was fabricated through a model-free fully digital workflow.

d. Delayed Analogue Impression group (Group d-AI): In the same appointment and after d-IOS, a conventional open-tray analogue impression was taken using an implant transfer post and polyether material. Before the impression, the plastic tray (PRESIDENT Impression Tray System, Coltène/Whaledent AG) was prepared by grinding a "window" at the implant area and then sealing the "window" with a thin layer of wax. A conventional impression was taken for the opposing arch with alginate

(Alginoplast, Kulzer GmbH). Bite registration was taken. Then crown D was fabricated through a model-based hybrid workflow.

For Group i-AI and Group d-AI, the stone models were digitalized using a laboratory scanner (3Shape D2000, 3ShapeA/S). Digital scanning data from the four groups were then imported into the same CAD software (Dental Designer, 3Shape). The same settings in the CAD software were used for the design of the interproximal contact point (−20 μm, meaning 20 μm thicker) and the occlusal contact point (+120 μm, meaning 120 μm thinner) for each group. The SICs were fabricated by means of laboratory-based CAM system (Zenotec CAM V3, Zenotec Select S2, Thermo-Star M2/P1, Wieland Dental). In both model-based hybrid workflow groups (Group i-AI and Group d-AI), the final crowns were adjusted on stone models by the same technician. Then four crowns were finished and adhesively fixed (Panavia 21, Kuraray Noritake Dental Inc.) onto the titanium base. The four SICs of each patient were then put into four separate sealed envelopes.

2.4 | Randomization and blinding

Computer-generated randomized try-in sequences of the four SICs for the 22 patients were obtained using reduced Latin square matrix (Jacobson & Matthews, 1996). The randomized scheme and sequence were generated by an independent investigator (Y.Z.) and sent to the dental technician to ensure a randomized CAD sequence. The four SICs for each patient were designed independently including the gingival emergence profile and crown contour.

At crown delivery, for each patient, an independent investigator (Y.Z.) sealed the four crowns in four envelopes marked with 1, 2, 3, or 4 according to the randomization scheme and sequence previously defined. Only this independent investigator was aware of the corresponding relation between the number and the randomization sequence. Both clinicians and patients were blinded regarding the manufacturing process of the four monolithic zirconia crowns. At the completion of the study, the independent investigator (Y.Z.) conducted unblinding to announce the actual treatment assignment.

2.5 | Crown delivery and clinical performance

At the delivery appointment three and a half months following implant surgery, the sequence of chairside delivery of the four SICs will be from No.1 to No.4 which was marked on the envelopes. A 10-min washout period between every two crowns was applied. During this period, the healing abutment was reinserted in the implant. Fitting accuracy and quality of each crown were evaluated by two prosthodontists (D.G. & S.P.) using modified USPHS criteria (Sailer et al., 2009; Spies et al., 2017). The occlusal contacts were checked with Shimstock foil (Arti-Fol shimstock foil, Dr. Jean Bausch GmbH & Co.) for light occlusal contacts without lateral occlusal disturbance (Delize et al., 2019). Interproximal contacts were checked with dental floss (Colgate Total Tartar Control, Colgate) passing through with moderate resistance (Delize et al., 2019). Finally, one SIC was chosen by the prosthodontist (D.G.) as the final restoration. The number of crowns in need of chairside adjustments in each group was recorded.

2.6 | Time record

The total working time including impression taking, surgery, laboratory duration, and crown delivery were recorded respectively in minutes by a trained dental assistant using a stopwatch (Table 1). At crown delivery, the chairside working time only included clinical time for chairside adjustment, excluding the laboratory intervention.

2.7 | Statistical analysis

The primary parameter for sample size calculation was the chairside time needed for immediate IOS scans and crown delivery compared with chairside time needed for delayed IOS scans and crown delivery (minutes [min]). Sample size calculation was conducted with reported data from previous research (Pan et al., 2019) using the statistical software G*Power (Version 3.1.9.2). Results indicated that to obtain 80% power with a significance level of 5% and effect size of 0.7 in a repeated-measures analysis, a minimum of 20 patients was required to show the difference in chairside time between the conventional (25.7 min) and digital (23.2 min) workflow. Accounting for dropouts, the sample size was set at 22.

The data were analyzed using SPSS 22.0 software (IBM SPSS Statistics v22; IBM Corp). Categorized data were analyzed for general descriptive statistics and sorted into row list data. The accuracy of four crowns was compared using Cochran's Q test, and pairwise comparison was analyzed by McNemar test. After Shapiro–Wilk test, some of the data conforming to non-normal distribution, the time consumption among four groups was compared using non-parametric Friedman test. Pairwise comparison within the group was analyzed by Bonferroni method. The time between two groups was compared using Wilcoxon signed-rank test. The level of statistical significance was set at $p < .05$.

3 | RESULTS

Thirteen females and nine males with a mean age of 40.7 years were recruited in this study. Twenty-two bone level tapered implants (Straumann Bone level Tapered; 4.1 × 10 mm, $n = 5$; 4.8 × 10 mm, $n = 17$) were placed to replace 8 maxillary first molars and 14 mandibular first molars. The number of implants in each first molar location is shown in Table 2. There were no post-surgical complications such as sinus pathologies, inferior alveolar nerve damage, hemorrhages, or inflammation observed. All implants achieved successful osseointegration without adverse events.

TABLE 1 Procedures with time recorded in the four digital workflows (minutes).

	Implant surgery	Impression taking	Laboratory duration[a]	Crown delivery
i-IOS	Anesthesia Implant placement Suture	*Before surgery*: Full-arch IOS before surgery Bite registration Shade selection *After implant placement*: Connection of scan body Updating implant position Healing abutment connection	Data transfer into CAD CAD CAM (including sintering) Finalization of crown	Interproximal adjustments Occlusal adjustments
i-AI	Anesthesia Implant placement Suture	*Before surgery*: Impression tray preparation Impressions of both jaws Bite registration Shade selection *After implant placement*: Connection of transfer post and record its position with resin Healing abutment connection	Impression disinfection Fabrication of models (including stone setting) Fixation of analogue in stone model Model scanning Data transfer into CAD CAD CAM (including sintering) Adjustments on stone models Finalization of crown	Interproximal adjustments Occlusal adjustments
d-IOS	Anesthesia Implant placement Suture	Healing abutment removal Connection of scan body Full-arch IOS Healing abutment connection Bite registration Shade selection	Data transfer into CAD CAD CAM (including sintering) Finalization of crown	Interproximal adjustments Occlusal adjustments
d-AI	Anesthesia Implant placement Suture	Impression tray preparation Healing abutment removal Connection of transfer post Impressions of both jaws Healing abutment connection Bite registration Shade selection	Impression disinfection Fabrication of models (including stone setting) Model scanning Data transfer into CAD CAD CAM (including sintering) Adjustments on stone models Finalization of crown	Interproximal adjustments Occlusal adjustments

[a]Laboratory duration includes manual operation and waiting time.

TABLE 2 The number of implants in each first molar location.

First molar location	16	26	36	46
Number of implants	3	5	9	5

Table 3 shows the total working time and total chairside treatment time of the four groups, including the time for impression taking, implant surgery, laboratory procedures and crown delivery. The total chairside time in each fully digital workflow group (Group i-IOS, 46.90, 41.81/53.39 min; Group d-IOS, 45.66, 40.30/50.49 min) was significantly less than that of both hybrid workflows (Group i-AI, 54.59, 49.27/57.53 min; Group d-AI, 55.96, 53.33/63.32 min) ($p<.001$). The immediate IOS impression took less time than the immediate analogue impression did (Table 4). The clinical chairside impression time in workflows using IOS (Group i-IOS, 8.23, 7.61/9.00 min; Group d-IOS, 6.95, 6.41/7.37 min) was significantly less than that in workflows using analogue impression (Group i-AI, 14.30, 13.38/15.55 min; Group d-AI, 18.47, 17.90/19.71 min). (Table 3).

The laboratory duration of the two model-free fully digital workflows (Group i-IOS, 606.25, 604.93/610.83 min; Group d-IOS, 607.83, 605.34/613.12 min) was significantly less than that of the two model-based hybrid workflows (Group i-AI, 839.60, 834.47/845.17 min; Group d-AI, 811.73, 807.73/815.50 min). In the hybrid workflow using immediate analogue impression (Group i-AI), significantly more model fabrication time was needed than that in the conventional hybrid workflow (Group d-AI; Table 5).

No significant difference was found in the mean chairside time at crown delivery among the four digital workflows (Table 3). For the crowns fabricated using two immediate impressions (Group i-IOS, 0.00, 0.00/2.53 min; Group i-AI, 0.00, 0.00/0.33 min), the time of shape and transmucosal contour adjustment was significantly longer than that spent for crowns using delayed impressions (Group d-IOS, 0.00, 0.00/0.00 min; Group d-AI, 0.00, 0.00/0.00 min) (Table 6).

Out of the 88 crowns, 80 needed occlusal adjustments, especially in the lateral excursion. The number of crowns that needed interproximal adjustment (12 mesial and 11 distal) in Group i-AI were significantly larger than those in the other three groups (Table 7).

There were significantly more events in Group i-AI (10/66) that needed laboratory intervention than in the other three groups ($p=.029$). According to the results of McNemar test, more laboratory interventions were required for the Group i-AI compared to the Group d-IOS ($p=.039$) and the Group d-AI ($p=.039$). The other paired comparison results did not show statistical differences

TABLE 3 Mean full working time and chairside treatment time of the four digital workflows (median, Q25/Q75, minutes) ($n=22$).

	Group i-IOS	Group i-AI	Group d-IOS	Group d-AI	$p(\chi^2$, df)
Impression taking	8.23 (7.61, 9.00)	14.30 (13.38, 15.55)	6.95 (6.41, 7.37)	18.47 (17.90, 19.71)	<.001* (62.564, 3)
Implant surgery	31.50 (28.00, 36.00)	31.50 (28.00, 36.00)	31.50 (28.00, 36.00)	31.50 (28.00, 36.00)	/
Laboratory procedures	606.25 (604.93, 610.83)	839.60 (834.47, 845.17)	607.83 (605.34, 613.12)	811.73 (807.73, 815.50)	<.001* (59.891, 3)
Crown delivery	6.49 (3.95, 8.20)	6.89 (4.43, 10.01)	6.81 (3.00, 8.84)	5.69 (1.83, 9.91)	.288 (3.764, 3)
Total chairside time	46.90 (41.81, 53.39)	54.59 (49.27, 57.53)	45.66 (40.30, 50.49)	55.96 (53.33, 63.32)	<.001* (35.450, 3)
Full time	653.12 (649.50, 664.15)	895.10 (886.55, 899.43)	654.53 (647.50, 662.02)	869.05 (861.01, 878.69)	<.001* (59.400, 3)

*$p<.05$.

TABLE 4 Mean time for immediate IOS & immediate analogue impressions (Median, Q25/Q75, minutes) ($n=22$).

Immediate impression	Before surgery	After implant placement	Total
IOS	3.75 (3.39, 4.20)	4.55 (3.83, 4.83)	8.23 (7.61, 9.00)
Analogue	8.15 (7.60, 8.70)	6.30 (5.68, 7.18)	14.30 (13.38, 15.55)
$p(Z)$	<.001* (−4.109)	.001* (−3.117)	<.001* (−4.075)

*$p<.05$.

TABLE 5 Laboratory working time of four digital workflows (Median, Q25/Q75, minutes) ($n=22$).

Laboratory procedures	Group i-IOS	Group i-AI	Group d-IOS	Group d-AI	$p(\chi^2$, df)
Model fabrication[a]	NA	217.18 (213.08, 220.72)	NA	189.09 (188.64, 189.40)	<.001*
Model scanning[a]	NA	4.46 (4.33, 4.54)	NA	4.34 (4.28, 4.51)	.121
Data transfer	1.0 (0.9, 1.1)	1.0 (0.9, 1.1)	1.0 (0.9, 1.1)	1.0 (0.9, 1.1)	/
CAD	8.55 (7.98, 9.73)	8.63 (8.00, 9.30)	8.60 (8.24, 9.42)	8.39 (7.85, 8.87)	.139 (2.067, 3)
Milling and sintering	553.38 (552.66, 553.78)	553.38 (552.66, 553.78)	553.38 (552.66, 553.78)	553.38 (552.66, 553.78)	/
Try-in on model[a]	NA	9.5 (7.01, 12.25)	NA	9.0 (7.35, 11.00)	.161
Finalization	44 (43, 46)	45 (42.75, 46)	45 (42, 49.25)	45.01 (44.45, 47.25)	.316 (3.535, 3)
Total	606.25 (604.93, 610.83)	839.60 (834.47, 845.17)	607.83 (605.34, 613.12)	811.73 (807.73, 815.50)	.001* (59.891, 3)

[a]The time between groups was compared using Wilcoxon signed-rank test and the result was reported with p value.
*$p<.05$.

TABLE 6 Clinical fitting and adjusting time of four digital workflows (Median, Q25/Q75, minutes) ($n=22$).

Adjustment time	Group i-IOS	Group i-AI	Group d-IOS	Group d-AI	$p(\chi^2$, df)
Interproximal	0.00 (0.00, 3.28)	0.69 (0.00, 3.57)	0.00 (0.00, 2.49)	0.00 (0.00, 2.30)	.151 (5.306, 3)
Occlusal	3.59 (1.36, 5.40)	4.16 (3.20, 5.45)	3.60 (0, 7.01)	4.40 (1.83, 6.90)	.269 (3.932, 3)
Contour	0.00 (0.00, 2.53)	0.00 (0.00, 0.33)	0.00 (0.00, 0.00)	0.00 (0.00, 0.00)	.044* (8.104, 3)

*$p<.05$.

TABLE 7 The number of crowns that received clinical adjustment at delivery.

Group	Interproximal adjustment: Mesial	Interproximal adjustment: Distal	Occlusal adjustment	Contour adjustment
i-IOS ($n=22$)	6	8	20	5
i-AI ($n=22$)	12	11	21	5
d-IOS ($n=22$)	5	5	20	2
d-AI ($n=22$)	4	5	19	2
Total ($n=88$)	27	29	80	14

(Table 8). Four crowns for one patient showed severe color mismatch with the natural teeth. Other crowns showed good results in margin integrity, contour and esthetics.

3.1 | USPHS criteria

Except for the four crowns with mismatched color from one patient, all other 84 crowns met the "A" score of modified USPHS criteria in the aspect of color, surface roughness, contour, and marginal integrity.

TABLE 8 Comparison of events that needed laboratory intervention during delivery among the four groups.

Group	Missing interproximal contact		No occlusal contact ($n=22$)	Total ($n=66$)
	Mesial ($n=22$)	Distal ($n=22$)		
i-IOS	3 (14%)	2 (9%)	0 (0%)	5 (8%)
i-AI	4 (18%)	2 (10%)	4 (18%)	10 (15%)
d-IOS	1 (5%)	1 (5%)	0 (0%)	2 (3%)
d-AI	1 (5%)	0 (0%)	1 (5%)	2 (3%)
$p(\chi^2)$	.392 (3.000)	.766 (2.200)	.062 (8.600)	.029* (9.000)

*$p<.05$.

Finally, eight crowns in Group i-IOS, three crowns in Group i-AI, five crowns in Group d-IOS and six crowns in Group d-AI were chosen and delivered to patients.

4 | DISCUSSION

This randomized double-blind clinical trial using within-subject evaluation indicated that clinical efficiency can be significantly improved by adoption of a fully digital workflow for posterior single implant crowns. The IOS impression in both fully digital workflows in the present study took significantly less chairside time than conventional analog impressions. This result echoed previous findings comparing digital and analog impressions (Guo et al., 2019; Lee et al., 2022; Mangano & Veronesi, 2018; Muhlemann et al., 2022; Pan et al., 2019). Meanwhile, our study showed that the crowns adjustment time in fully digital workflows (Median for i-IOS: 6.49 min, for d-IOS: 6.81 min) was not significantly increased, this is also in consistence with previous research findings (Joda et al., 2016; Joda & Bragger, 2015, 2016; Lee et al., 2022; Ren et al., 2021).

Compared with the hybrid workflow, less laboratory time was needed in the fully digital workflows due to optical intraoral scanning, fast and intact data transfer, and a model-free manufacturing process. In this study, the fabrication time of monolithic SICs using a model-free digital workflow was approximate 200 min less than that for the hybrid workflows, indicating the advantage of fully digital workflows in improving the efficiency of laboratory process (Joda & Bragger, 2016; Muhlemann et al., 2021, 2022; Ren et al., 2021; Zhang et al., 2019). Even though the finalization step on stone model was eliminated, the clinical chairside adjustment time in the model-free workflow was not significantly increased. This demonstrated that the accuracy of restorations made from digital impression and CAD/CAM was similar to those made from the conventional workflow. The model-free fully digital workflow eliminated the process of analogue model production and this helped avoiding the possible error introduced by material deformation and manual operation (Basaki et al., 2017).

It was demonstrated in previous studies (Guo et al., 2021; Pan et al., 2019) that definitive SIC made from immediate impression during implant surgery was a viable restorative solution for posterior single implants. Two different immediate impressions were investigated in this study. More chairside time was needed for the analogue impression than it did for the IOS impression. More crowns in the immediate analogue impression (i-AI) group required interproximal adjustments than those in the immediate IOS (i-IOS) group, indicating accumulated errors related to multiple manual operations of the i-AI method. There were some disadvantages about the immediate analogue impression technique used in this study. It was technique sensitive and needed significantly more manual work for both the clinician and technician. The risk of contamination was increased with resin in contact with the surgical area. It might be difficult to take out and fit the resin positioning transfer post onto the stone model when the resin flowed into undercuts of the neighboring teeth. Despite the above-mentioned limitations, results from this study still suggested that this immediate resin positioning analogue impression was viable to locate implant position immediately after implant placement when an intraoral scanner is unavailable. Alternative workflows have also been suggested, a study reported that the immediate IOS and resin positioning analog impression were also suitable for submerged healing protocol. Both digital and hybrid workflows with immediate impression allowed successful crown delivery at the second stage surgery (Edinger et al., 2023).

The design sequence of the four SICs adopted a random scheme to reduce the subjective bias. In the conventional model-based hybrid workflow, it took 189.09 min to complete the model fabrication. The model fabrication using resin positioning analogue impression technique needed additional 28 min to prepare. The model-free digital workflow significantly improved the laboratory efficiency and reduced approximately 3.5 h working time (Mangano & Veronesi, 2018; Sailer et al., 2017).

Most of the crowns in this study could be successfully delivered. With suitable compensation of design parameters (−20 μm at interproximal contact, and +120 μm in occlusion), the clinical adjustment time for crowns fabricated from the two model-free fully digital workflows was equal to that of the model-based workflows. However, most of the crowns needed minor interproximal and occlusal adjustments. The slight discrepancy between the Ti-base and the milled zirconia crown may result in slight crown rotation during cementation, thus contribute to changes in the occlusion and interproximal contact in the cemented crown. Our experience showed that in fully digital workflow, the crown should be cemented in the initial inserted position on the Ti-base without rotational force applied. In hybrid workflow (i-AI &d-AI), the crown can be cemented with the Ti-base on stone model. The interproximal surface of the neighboring teeth can guide the insertion path of the crown.

More adjustments on shape and transmucosal contour were needed for crowns fabricated based on immediate impressions (Table 6, $p=.044$). Two factors may contribute to this result. First, there were differences in the transmucosal contour between the surgery stage and the healed stage. Second, adjacent teeth position may slightly change during the 3-month healing period after implant placement (Guo et al., 2021). Even though the crowns were polished after adjustments, the smoothness of the transmucosal portion of the crown might be reduced, and the health of peri-implant soft tissue still needs further investigation in long-term follow-up. In this study, types of healing abutments were sent to the technician as reference of crown design. Results from our previous study on migration of neighboring and antagonist teeth (Guo et al., 2021) were considered in designing compensation parameters in the lab to improve the accuracy of the crowns. Every crown was designed separately, so there were differences in crown emergence profile among the four crowns for the same patient. Impressions of both d-IOS and d-AI workflows recorded emergency profile in healed mucosa, resulting in a better transmucosal contour in the final crown.

The emergency profile designed correctly can maintain peri-implant health and stability (Hamilton et al., 2023). Previous study proposed that the individualized healing abutment could be designed based on natural tooth to achieve ideal emergency profile (El-Danasory et al., 2023). Edinger and colleagues has reported better values in evaluation of papilla in the immediate analog impression group than in the immediate IOS group. It was suggested that it took a learning curve to shape the emergence profile on screen (Edinger et al., 2023). A satisfactory emergence profile can be achieved by scanning the temporary crown, data registration can better replicate the gingival emergency profile into the final crown (Dhingra et al., 2020; Zimmermann et al., 2022).

Most SICs in this study needed clinical adjustment. Eighty-five percent of the crowns received minor occlusal grinding. This clearly showed that the error accumulation during crown production could not be completely eliminated (Miyazaki & Hotta, 2011). More than 90% of crowns fabricated using both model-based hybrid workflows still needed clinical adjustments at delivery.

There was no significant difference in clinical outcome among crowns fabricated from four different digital workflows. The "final" delivered crowns distributed equally among the four groups. The fully digital workflow using digital impression improved the efficiency and efficacy of posterior SIC fabrication. Immediate digital impression could further reduce the number of clinical visits and simplify the treatment procedures.

Some key points need further investigation in the application of a fully digital workflow for SICs. First, individualized healing abutment may provide a stable and reliable mucosal contour that can facilitate crown delivery. Second, the standard operating procedure using the immediate digital impression and model-free digital workflow need to be established.

The limitation of this study is that results are only applicable to the implant system used and the digital technologies applied. The application of chairside manufacturing system and the long-term evaluation of crowns fabricated by different workflows still need further investigation. In this study, the three-dimensional volume change of each crown before and after clinical adjustment was not recorded by scanning, future studies are needed to quantify this volume change.

5 | CONCLUSION

Digital impression and a model-free fully digital workflow improved prosthetic efficiency in the fabrication of posterior single implant crowns. The study is limited by the fact that the results were only applicable to the implant system used and the digital technologies applied. In spite of its limitations, the study suggested that workflows integrating immediate impression with the implant surgery procedure was clinically applicable for restoration of posterior single missing tooth. The clinical outcome of the crown and the health of peri-implant soft tissue still need further investigation in long-term follow-up.

AUTHOR CONTRIBUTIONS

Sven Mühlemann, Shaoxia Pan, Ronald E. Jung conceived the ideas; Shaoxia Pan and Danni Guo collected the data; Shaoxia Pan, Danni Guo, Yongsheng Zhou analyzed the data; and Danni Guo, Shaoxia Pan, Sven Mühlemann, Ronald E. Jung led the writing.

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CONFLICT OF INTEREST STATEMENT

The authors declare no conflict of interest.

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available from the corresponding author upon reasonable request.

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REFERENCES

Basaki, K., Alkumru, H., De Souza, G., & Finer, Y. (2017). Accuracy of digital vs conventional implant impression approach: A three-dimensional comparative In vitro analysis. *The International Journal of Oral & Maxillofacial Implants*, *32*(4), 792–799. https://doi.org/10.11607/jomi.5431

Cooper, L. F., Raes, F., Reside, G. J., Garriga, J. S., Tarrida, L. G., Wiltfang, J., Kern, M., & de Bruyn, H. (2010). Comparison of radiographic and clinical outcomes following immediate provisionalization of single-tooth dental implants placed in healed alveolar ridges and extraction sockets. *The International Journal of Oral & Maxillofacial Implants*, *25*(6), 1222–1232.

Delize, V., Bouhy, A., Lambert, F., & Lamy, M. (2019). Intrasubject comparison of digital vs. conventional workflow for screw-retained single-implant crowns: Prosthodontic and patient-centered outcomes. *Clinical Oral Implants Research*, *30*(9), 892–902. https://doi.org/10.1111/clr.13494

Dhingra, A., Taylor, T., & Flinton, R. (2020). Digital custom impression technique to record emergence profile and fabrication of an esthetic implant supported restoration. *Journal of Prosthodontics*, *29*(7), 636–639. https://doi.org/10.1111/jopr.13200

Edinger, D., Henningsen, A., Bibiza, E., Smeets, R., & Joda, T. (2023). Comparison of functional and esthetic outcomes in digital versus analog rehabilitation of one-piece screw-retained implant crowns placed at second stage surgery. *Journal of Prosthodontics*. Online ahead of print. https://doi.org/10.1111/jopr.13699

El-Danasory, M. B., Khamis, M. M., Abdel Hakim, A. A., & Fahmy, R. A. (2023). Outcomes of bio-esthetic single implant-supported restorations after peri-implant soft tissue conditioning with two prosthetic techniques: A 1-year randomized clinical trial. *The Journal of Prosthetic Dentistry*. https://doi.org/10.1016/j.prosdent.2023.02.012

Guo, D., Liu, Y., Pan, S., Wang, P., Wang, B., Liu, J., Gao, W. H., & Zhou, Y. (2019). Clinical efficiency and patient preference of immediate digital impression after implant placement for single implant-supported crown. *The Chinese Journal of Dental Research*, *22*(1), 21–28. https://doi.org/10.3290/j.cjdr.a41771

Guo, D., Pan, S., Muhlemann, S., Zhou, Y., & Jung, R. (2021). The migration of neighboring and antagonist teeth three months after implant placement in healed single tooth-missing sites. *Clinical Oral Implants Research*, *32*(2), 233–241. https://doi.org/10.1111/clr.13694

Hamilton, A., Putra, A., Nakapaksin, P., Kamolroongwarakul, P., & Gallucci, G. O. (2023). Implant prosthodontic design as a predisposing or precipitating factor for peri-implant disease: A review. *Clinical Implant Dentistry and Related Research*, *25*, 710–722. https://doi.org/10.1111/cid.13183

Hammerle, C. H., Klinge, B., & Quirynen, M. (2015). The 4th EAO consensus conference 11–14 February 2015, Pfaffikon, Schwyz, Switzerland. *Clinical Oral Implants Research*, *26*(11), iii–iv. https://doi.org/10.1111/clr.12668

Jacobson, M. T., & Matthews, P. (1996). Generating uniformly distributed random latin squares. *Journal of Combinatorial Designs*, *4*(6), 405–437. https://doi.org/10.1002/(sici)1520-6610(1996)4:6<405::aid-jcd3>3.0.co;2-j

Joda, T., & Bragger, U. (2014). Complete digital workflow for the production of implant-supported single-unit monolithic crowns. *Clinical Oral Implants Research*, *25*(11), 1304–1306. https://doi.org/10.1111/clr.12270

Joda, T., & Bragger, U. (2015). Time-efficiency analysis comparing digital and conventional workflows for implant crowns: A prospective clinical crossover trial. *The International Journal of Oral & Maxillofacial Implants*, *30*(5), 1047–1053.

Joda, T., & Bragger, U. (2016). Time-efficiency analysis of the treatment with monolithic implant crowns in a digital workflow: A randomized controlled trial. *Clinical Oral Implants Research*, *27*(11), 1401–1406. https://doi.org/10.1111/clr.12753

Joda, T., Ferrari, M., & Bragger, U. (2017). Monolithic implant-supported lithium disilicate (LS2) crowns in a complete digital workflow: A prospective clinical trial with a 2-year follow-up. *Clinical Implant Dentistry and Related Research*, *19*(3), 505–511. https://doi.org/10.1111/cid.12472

Joda, T., Ferrari, M., Gallucci, G. O., Wittneben, J. G., & Bragger, U. (2017). Digital technology in fixed implant prosthodontics. *Periodontology 2000*, *73*(1), 178–192. https://doi.org/10.1111/prd.12164

Joda, T., Katsoulis, J., & Bragger, U. (2016). Clinical fitting and adjustment time for implant-supported crowns comparing digital and conventional workflows. *Clinical Implant Dentistry and Related Research*, *18*(5), 946–954. https://doi.org/10.1111/cid.12377

Kapos, T., & Evans, C. (2014). CAD/CAM technology for implant abutments, crowns, and superstructures. *The International Journal of Oral & Maxillofacial Implants*, *29*, 117–136. https://doi.org/10.11607/jomi.2014suppl.g2.3

Koch, G. K., Gallucci, G. O., & Lee, S. J. (2016). Accuracy in the digital workflow: From data acquisition to the digitally milled cast. *Journal of Prosthetic Dentistry*, *115*(6), 749–754. https://doi.org/10.1016/j.prosdent.2015.12.004

Lee, S. J., Jamjoom, F. Z., Le, T., Radics, A., & Gallucci, G. O. (2022). A clinical study comparing digital scanning and conventional impression making for implant-supported prostheses: A crossover clinical trial. *The Journal of Prosthetic Dentistry*, *128*(1), 42–48. https://doi.org/10.1016/j.prosdent.2020.12.043

Lindeboom, J. A., Frenken, J. W., Dubois, L., Frank, M., Abbink, I., & Kroon, F. H. (2006). Immediate loading versus immediate provisionalization of maxillary single-tooth replacements: A prospective randomized study with BioComp implants. *Journal of Oral and Maxillofacial Surgery*, *64*(6), 936–942. https://doi.org/10.1016/j.joms.2006.02.015

Mangano, F., Gandolfi, A., Luongo, G., & Logozzo, S. (2017). Intraoral scanners in dentistry: A review of the current literature. *BMC Oral Health*, *17*(1), 149–160. https://doi.org/10.1186/s12903-017-0442-x

Mangano, F., & Veronesi, G. (2018). Digital versus analog procedures for the prosthetic restoration of single implants: A randomized controlled trial with 1 year of follow-up. *BioMed Research International*, *2018*, 5325032. https://doi.org/10.1155/2018/5325032

Miyazaki, T., & Hotta, Y. (2011). CAD/CAM systems available for the fabrication of crown and bridge restorations. *Australian Dental Journal*, *56*(1), 97–106. https://doi.org/10.1111/j.1834-7819.2010.01300.x

Muhlemann, S., Hjerppe, J., Hammerle, C. H. F., & Thoma, D. S. (2021). Production time, effectiveness and costs of additive and subtractive computer-aided manufacturing (CAM) of implant prostheses: A systematic review. *Clinical Oral Implants Research*, *3*(Suppl 21), 289–302. https://doi.org/10.1111/clr.13801

Muhlemann, S., Kraus, R. D., Hammerle, C. H. F., & Thoma, D. S. (2018). Is the use of digital technologies for the fabrication of implant-supported reconstructions more efficient and/or more effective than conventional techniques: A systematic review. *Clinical Oral Implants Research*, *29*(18), 184–195. https://doi.org/10.1111/clr.13300

Muhlemann, S., Lamperti, S. T., Stucki, L., Hammerle, C. H. F., & Thoma, D. S. (2022). Time efficiency and efficacy of a centralized computer-aided-design/computer-aided-manufacturing workflow for implant crown fabrication: A prospective controlled clinical study. *Journal of Dentistry*, *127*, 104332. https://doi.org/10.1016/j.jdent.2022.104332

Oh, K. C., Jeon, C., Park, J. M., & Shim, J. S. (2019). Digital workflow to provide an immediate interim restoration after single-implant placement by using a surgical guide and a matrix-positioning device. *Journal of Prosthetic Dentistry*, *121*(1), 17–21. https://doi.org/10.1016/j.prosdent.2018.03.029

Pan, S., Guo, D., Zhou, Y., Jung, R. E., Hammerle, C. H. F., & Muhlemann, S. (2019). Time efficiency and quality of outcomes in a model-free

digital workflow using digital impression immediately after implant placement: A double-blind self-controlled clinical trial. *Clinical Oral Implants Research*, *30*(7), 617–626. https://doi.org/10.1111/clr.13447
Ren, S., Jiang, X., Lin, Y., & Di, P. (2021). Crown accuracy and time efficiency of cement-retained implant-supported restorations in a complete digital workflow: A randomized control trial. *Journal of Prosthodontics*, *31*, 405–411. https://doi.org/10.1111/jopr.13447
Richert, R., Goujat, A., Venet, L., Viguie, G., Viennot, S., Robinson, P., Farges, J. C., Fages, M., & Ducret, M. (2017). Intraoral scanner technologies: A review to make a successful impression. *Journal of Healthcare Engineering*, *2017*, 8427595. https://doi.org/10.1155/2017/8427595
Sailer, I., Benic, G. I., Fehmer, V., Hammerle, C. H. F., & Muhlemann, S. (2017). Randomized controlled within-subject evaluation of digital and conventional workflows for the fabrication of lithium disilicate single crowns. Part II: CAD-CAM versus conventional laboratory procedures. *Journal of Prosthetic Dentistry*, *118*(1), 43–48. https://doi.org/10.1016/j.prosdent.2016.09.031
Sailer, I., Gottnerb, J., Kanelb, S., & Hammerle, C. H. (2009). Randomized controlled clinical trial of zirconia-ceramic and metal-ceramic posterior fixed dental prostheses: A 3-year follow-up. *International Journal of Prosthodontics*, *22*(6), 553–560.
Sailer, I., Muhlemann, S., Kohal, R. J., Spies, B. C., Pjetursson, B. E., Lang, N. P., Gotfredsen, K. L., Ellingsen, J. E., Francisco, H., Özcan, M., Hassan, B., Esteve-Pardo, G., Bardaji, J. A., Kraus, R. D., & Wennerberg, A. (2018). Reconstructive aspects: Summary and consensus statements of group 3. The 5(th) EAO consensus conference 2018. *Clinical Oral Implants Research*, *29*(18), 237–242. https://doi.org/10.1111/clr.13302
Schincaglia, G. P., Marzola, R., Giovanni, G. F., Chiara, C. S., & Scotti, R. (2008). Replacement of mandibular molars with single-unit restorations supported by wide-body implants: Immediate versus delayed loading. A randomized controlled study. *The International Journal of Oral & Maxillofacial Implants*, *23*(3), 474–480.
Spies, B. C., Pieralli, S., Vach, K., & Kohal, R. J. (2017). CAD/CAM-fabricated ceramic implant-supported single crowns made from lithium disilicate: Final results of a 5-year prospective cohort study. *Clinical Implant Dentistry and Related Research*, *19*(5), 876–883. https://doi.org/10.1111/cid.12508
Testori, T., Galli, F., Capelli, M., Zuffetti, F., & Esposito, M. (2007). Immediate nonocclusal versus early loading of dental implants in partially edentulous patients: 1-year results from a multicenter, randomized controlled clinical trial. *The International Journal of Oral & Maxillofacial Implants*, *22*(5), 815–822.
Ting-Shu, S., & Jian, S. (2015). Intraoral digital impression technique: A review. *Journal of Prosthodontics*, *24*(4), 313–321. https://doi.org/10.1111/jopr.12218
Zhang, Y., Tian, J., Wei, D., Di, P., & Lin, Y. (2019). Quantitative clinical adjustment analysis of posterior single implant crown in a chairside digital workflow: A randomized controlled trial. *Clinical Oral Implants Research*, *30*(11), 1059–1066. https://doi.org/10.1111/clr.13519
Zimmermann, D., Ferreira de Almeida, D. C., Velloso, G., & Moraschini, V. (2022). Digital replication of the peri-implant soft tissue contour of implant-supported crowns: A dental technique. *The Journal of Prosthetic Dentistry*, *128*(1), 8–12. https://doi.org/10.1016/j.prosdent.2020.12.025

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