Clinical Fitting and Adjustment Time for Implant-Supported Crowns Comparing Digital and Conventional Workflows

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ABSTRACT

Purpose: The aim of this prospective cohort study was to investigate clinical and laboratory performance of implant-supported reconstructions comparing the digital to the conventional workflow.

Materials and Methods: Twenty study participants were treated in a cross-over design for single-tooth replacement in posterior sites, each with a customized titanium abutment plus computer-assisted design and computer-assisted manufacturing (CAD/CAM)-zirconia-suprastructure (test: digital workflow; $n = 20$) and a standardized titanium abutment plus PFM-crown (control: conventional pathway; $n = 20$). Evaluation of the 40 reconstructions included: 1) feasibility of laboratory cross-mounting of each abutment-crown-connection, and 2) assessment of adaptation time for clinical adjustments of interproximal and occlusal surfaces. Statistical analyses were performed using the exact *Wilcoxon rank sum tests*.

Results: Laboratory cross-mounting was feasible for three reconstruction pairings revealing a 15% *vice versa* transfer success rate. All implant crowns could be provided successfully within two clinical appointments, independently of the workflow used. The mean clinical adjustment time was significantly lower ($p < .001$) for test reconstructions from the digital workflow with 2.2 min (standard deviation [SD] ± 2.1) compared with the ones from the conventional pathway with 6.0 min (SD ± 3.9).

Conclusions: The digital workflow was almost threefold more efficient than the established conventional pathway for fixed implant-supported crowns. Clinical fitting could be predictably achieved with no or minor adjustments within the digital process of intraoral scanning plus CAD/CAM technology.

KEY WORDS: CAD/CAM, conventional, cross-mounting, dental implant crown, digital, intraoral optical scan, workflow

INTRODUCTION

Classical impression techniques with transfer posts in combination with plaster master casts and porcelain-fused-metal (PFM) crowns still represent the gold standard in the manufacturing process for fixed implant-supported reconstructions.[1] However, economic, technical, and patient-related compromises are associated with the conventional pathway: time-consuming and complex manufacturing steps with expensive manpower and equipment, a long list of materials with inconsistent quality, waste products as well as interference of the treatment steps during impression taking due to suffocation hazard, gagging and taste irritation.[2]

An alternative to the well-established conventional pathway is the digital approach.[3–5] The clinical patient situation is registered virtually with a contact-free transfer using an intraoral optical scanner (IOS) system.[6,7] Then, the scanning data are stored as standard tessellation language (STL) files and can be used for computer-assisted design and computer-assisted manufacturing (CAD/CAM) of milled models, customized abutments

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and suprastructures with high-performance materials.[8,9] Today, digital computer-assisted technologies allow a simplified and streamlined production of implant prosthetic components.[10]

Presently, only limited data are available in the dental literature concerning prosthetic implant workflows of digital processing with IOS and CAD/CAM-technology compared with the conventional pathway with classical impression taking, plaster casts, and lost wax technique. Studies focusing on precision of implant reconstructions are mainly designed as in vitro investigations with outcomes in the field of technical accuracy.[11] These investigations only report on single work steps, such as impression taking procedures or microscopic analyses of the final reconstructions, instead of evaluating the entire workflow.[12,13] Moreover, the transfer of these isolated stages to clinical situations and their medical relevance to the complete treatment protocol are still unanswered.

Within this context, the clinical outcomes of implant-supported reconstructions that were fabricated in a digital workflow is essential. A specific question arises for the performance with regard to chair-side adjustments and final placement of implant crowns manufactured digitally equivalent to the conventional pathway under clinical conditions.[2,14]

Therefore, the aim of this prospective clinical cohort study with cross-over design is to investigate the null-hypothesis that the process quality of implant-supported single-unit reconstructions in the digital workflow is comparable with the conventional pathway with regard to clinical and laboratory performance.

MATERIALS AND METHODS

Patients

The clinical trial was designed as a prospective single-cohort study with a sample size of 20 subjects (patient-implant-level $n = 20$), each with one implant (Tissue Level Implant System RN/WN, Institut Straumann AG, Basel, Switzerland). Demographic patient data showed a mean age of 55.4 years (ranged from 34.7 to 72.8 years) and 47.4% females. Inclusion criteria were defined as single edentulous spaces in premolar and molar sites with existing interproximal and antagonistic contacts.

Two implant-supported crowns per patient with cementable retention were produced, tried in, and evaluated clinically (reconstruction-level $n = 40$) as follows:

- Test: $n = 20$ customized titanium abutments plus CAD/CAM-zirconia-suprastructures;
- Control: $n = 20$ standardized titanium abutments plus PFM-crowns (Figure 1).

Baseline of the study was the start of the prosthetic therapy: clinical registration of the implants' three-dimensional positioning (Figure 2), technical manufacturing of the reconstructions (Figure 3), and conclusively, the prosthetic rehabilitation (Figure 4). Distribution of the clinical treatment and laboratory manufacturing sequences, whether starting with the digital or conventional approach, were randomly chosen per study participant by the envelope technique.

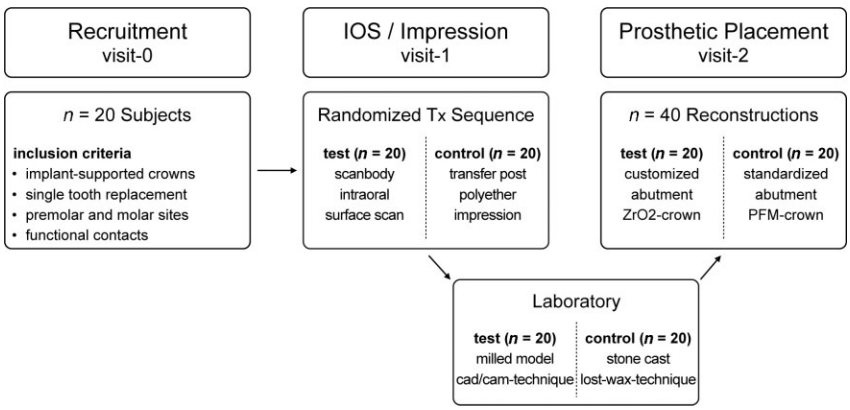

Figure 1 Study flowchart displaying prosthetic treatment sequences: recruitment (baseline), clinical appointment 1 for intraoral scan (IOS) and impression taking procedure, laboratory manufacturing process as well as clinical appointment 2 for prosthetic placement.

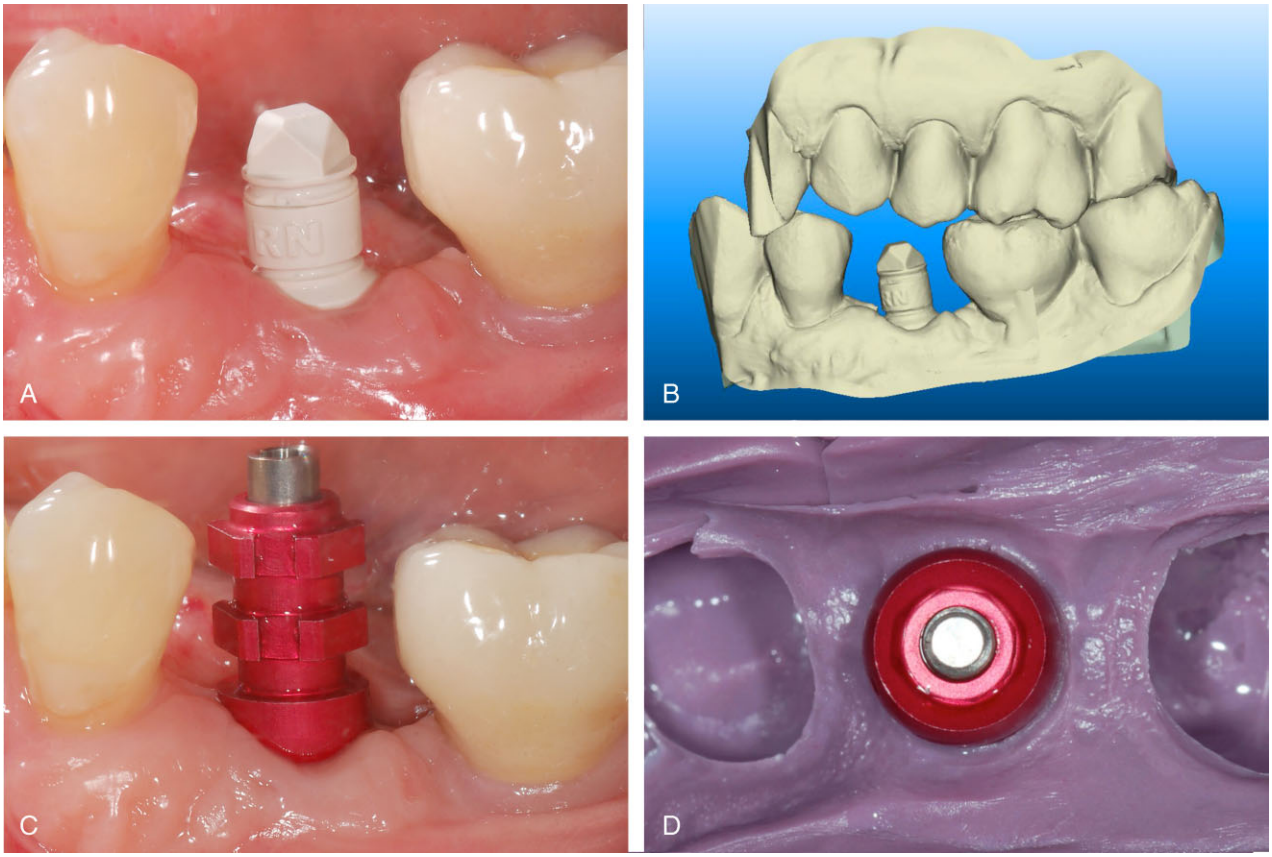

Figure 2 A–D. Patient #05 – first clinical appointment: capturing the three-dimensional implant position in the digital workflow with IOS using a scanbody to define the implant position (2A+D); conventional pathway with classical open tray impression technique (2C+D).

Digital and Conventional Workflows

All clinical work steps were performed by one experienced team of the same dentist/dental assistance, and only one dental master technician produced all test and control reconstructions. The test reconstructions were manufactured in the digital workflow including IOS (iTero Scanner, Align Tech Inc., San Jose, CA, USA) plus CAD/CAM-technology (CARES X-Stream, Institut Straumann AG; ceramic veneering material Noritake CZR, Kuraray Noritake Dental Inc., Tokyo, Japan), and compared with the conventional pathway with impression-plaster-cast-technique plus pre-fabricated implant abutment components (synOcta, Institut Straumann AG) in combination with PFM-crowns (gold alloy PX Premium C, PX Dental SA, Marin, Switzerland; ceramic veneering material Noritake EX3, Kuraray Noritake Dental Inc.) as controls.

For master cast fabrication of the test reconstructions, models were produced made of polyurethane (iTero modeling) in a professional off-house milling center (CAD/CAM-Center, Institut Straumann AG, Leipzig, Germany). Implant labor analogues were placed according to the STL-files taken from the IOS with implant-specific scanbodies. Master casts for control reconstructions were man-made conventionally with low-expansion die stone ISO Type 4 (Silky Rock, Whip Mix, Louisville, KY, USA) under consideration of the manufacturer's recommendations.

Laboratory Cross-Mounting

Outcomes were evaluated according to performance of the manufactured reconstructions in both groups: 1) feasibility of laboratory cross-mounting of each abutment-crown-connection, and 2) assessment of adaptation time for clinical adjustments of interproximal and occlusal surfaces.

For each study participant, the implant abutment-crown-constructions of one group were placed onto their corresponding model situations of the other group and vice versa. In addition, interproximal and occlusal

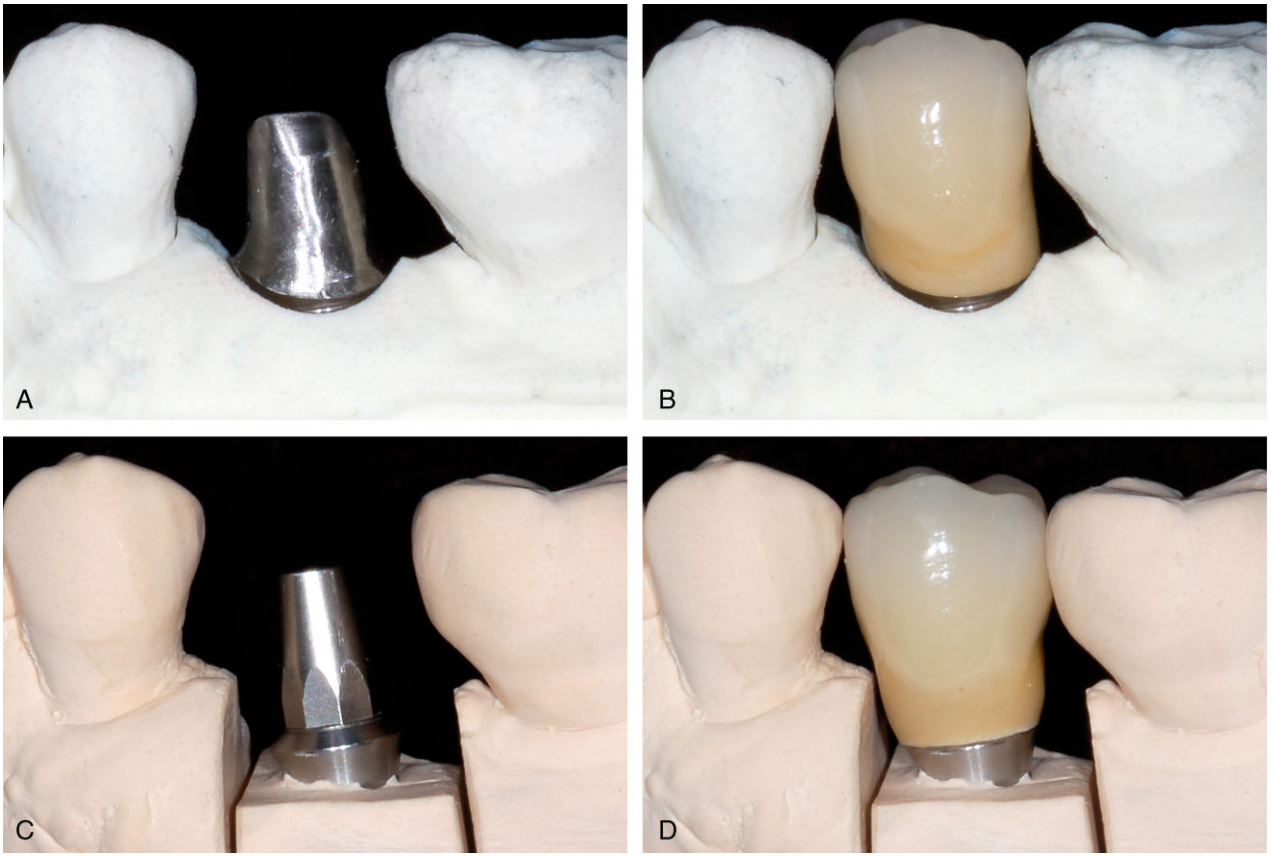

Figure 3 A–D. Patient #05 – laboratory manufacturing: milled model with customized titanium abutment and CAD/CAM-generated ZrO_2 implant crown (3A+B); stone master-plaster-cast with standardized titanium abutment and PFM-implant-crown (3C+D).

fitting of the implant reconstructions was evaluated according to dichotomic feasibility (yes/no).

Laboratory assessment for cross-mounting was independently double-checked by a second dental master technician and the responsible dentist. Calibration for evaluation of success criteria was performed prior to the clinical study including the dentist and the dental technicians. In this context, six model-reconstruction samples were used for calibration: three well-fitting and three misfitting pairings. Evaluation was performed separately by the dentist and the dental technicians including repetitions after 7 days. The results of calibration of all six model-reconstruction samples were reproducible and clear without any controversial assessments for the participants themselves as well as for inter-individual comparison of turn one and two.

Clinical Fitting and Adjustment Time

For clinical evaluation, the healing abutments were removed, and the abutment types were mounted with a manual torque control ratchet (35 Ncm) onto the implants with respect to the randomization process for the order of sequence. Then, the corresponding implant crowns were tried in. First, the interproximal fit and the seating of the entire reconstruction were assessed clinically. Identical continuity with dental floss was controlled for mesial and distal aspects. If applicable, corrections were made with diamond burs and silicone polishers to adapt the implant crown creating sufficient interproximal contacts. After succeeding interproximal contacts, the occlusal scheme was checked statically and dynamically with shimstock foil. Again, if applicable, modifications were made in the same way as described for interproximal corrections to achieve light occlusal contacts without dynamic interactions. Time was recorded for each clinical treatment step, separately for test and control group reconstructions. Finally, all test reconstructions were seated and included for a long-term follow-up study.

Statistics

Statistical analysis was calculated with the computer program "Software R" (R-Foundation, Vienna, Austria) (version 3.0.2). Exact *Wilcoxon rank sum tests* were used

Figure 4 A–D. Patient #05 – second clinical appointment: mounted customized titanium abutment and placement of the final CAD/CAM-fabricated ZrO_2 implant crown (4A+B); mounted standardized titanium abutment and PFM-implant-crown (4C+D).

for all comparisons in this randomized cross-over study. As no carry-over effects were expected, the data of both measurement-rounds were used for analysis of test and control groups, respectively. A p-value of <.05 was considered as statistically significant.[15]

The clinical single-cohort study was officially approved and registered by the Ethics Committee Bern, Switzerland (KEK-Nr. 053/12; http://www.kek-bern.ch).

RESULTS

Laboratory Cross-Mounting

All 20 test reconstructions were tried in to mount onto the corresponding conventionally produced plaster-master-casts and all 20 control reconstructions onto the digitally fabricated milled models. The results of this cross-over relocation revealed that a total of three pairings could be transferred successfully in this vice versa approach, reflecting a 15% transfer success rate for test reconstructions on plaster casts and control reconstructions on milled model, respectively. Failure modes for the remaining 17 pairings were characterized by interproximal and consecutively occlusal misfit of the implant-supported single-unit reconstructions.

Clinical Investigation

All crowns could be delivered successfully within two clinical appointments (IOS and delivery). Remakes were not necessary, neither in the test nor in the control group. However, needs for clinical adaptations were significantly lower for test group reconstructions compared with controls. Results for the mean total adjustment time, as the sum of interproximal plus occlusal adaptations, were 2.2 min (SD ± 2.1) for the digital workflow and 6.0 min (SD ± 3.9) for the conventional pathway ($p = .0002$). In addition, all implant-supported PFM-crowns required modifications to achieve a sufficient clinical fit; whereas in contrast, eight (40%) digitally fabricated implant-reconstructions could be inserted without any corrections and 12 crowns needed minor adjustments (Figure 5).

Detailed analysis for the interproximal adaptations revealed a significantly reduced mean chair-side time for

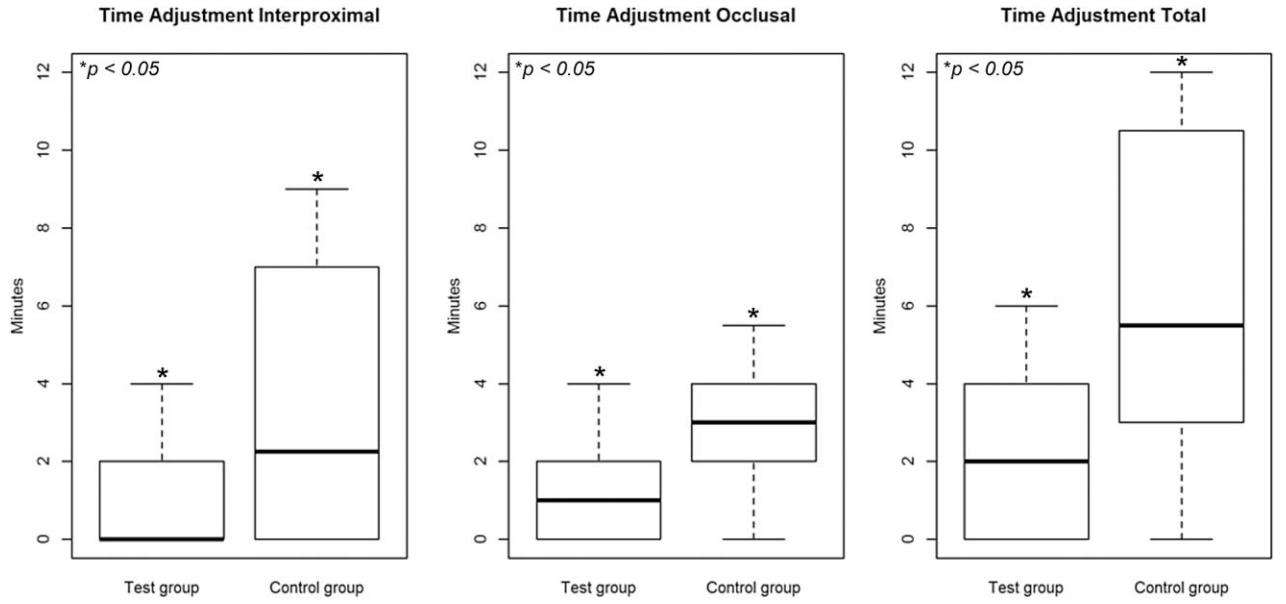

Figure 5 Box-plot diagrams for interproximal, occlusal and total needed adjustment time (in minutes) for the digital workflow (test) compared with the conventional pathway (control); analysis made with *Wilcoxon rank sum*.

the test group with 1.0 min (SD ± 1.2) compared with the control group with 3.2 min (SD ± 3.3) ($p = .006$), and for occlusal modifications 1.2 min (SD ± 1.3) and 2.8 min (SD ± 1.4), respectively ($p = .0002$) (Table 1).

DISCUSSION

The present study compared digital and conventional workflows with respect to specific technical and clinical performance in the production process of implant-supported crowns by means of laboratory cross-mounting and the need for chair-side modifications to place the final reconstructions. The meaning of performance was defined separately for laboratory evaluation and for clinical assessment. First, the transfer process of test and control reconstruction types to their corresponding model situations of the other group were examined ex vivo. Secondary, the need for clinical adjustments when placing the implant crowns in the patient was recorded in time units.

The outlined null-hypothesis – that both workflows would not show significant differences – had to be rejected. The results demonstrated a significantly shorter adjustment time required for the reconstructions produced by the digital workflow compared with the conventional pathway. The clinical fitting and adjustment time for the crowns was the key measurement tool for comparison. It has to be stated in particular that this type of assessment is highly subjective and as

TABLE 1 Need for Clinical Adjustment, and If Applicable, Mean Time for Chair-Side Correction Compared for the Digital Workflow (Test) and the Conventional Pathway (Control)

	Workflow	
	Digital (n = 20 reconstructions)	Conventional (n = 20 reconstructions)
Clinical Investigation ($n = 20$ subjects)		
Try-in successfully *without* adjustments	**8 (40%)**	**0 (0%)**
Try-in successfully *with* adjustments	**12 (60%)**	**20 (100%)**
Total mean time for adjustment ($p = .0002$)	**2.2 min (SD ± 2.1)**	**6.0 min (SD ± 3.9)**
• interproximal ($p = .006$)	1.0 min (SD ± 1.2)	3.2 min (SD ± 3.3)
• occlusal ($p = .0002$)	1.2 min (SD ± 1.3)	2.8 min (SD ± 1.4)

Bold letters sum of "interproximal" + "occlusal" adjustment time.

such could have partially affected the results, especially in light of the fact that the study is not double blinded for obvious reasons because the different abutment designs are easily recognizable. In addition, the subjective aspect of the adjustment time might also have heavily affected the final outcome, particularly considering that the mean time of adjustments was quite short.

In industrial processing, benefits of computerized engineering technology are associated with high precision, simplified fabrication procedures and minimized manpower resources.[14] Therefore, these advantages also favor the digital workflow for quality assurance, accurate production, and cost effective implementation in dental (implant) medicine.[4,5,8] Nevertheless, new treatment protocols have to be trained, and learning curves also have to be considered while implementing digital dental workflows in daily routine.[16] The correct application is a prerequisite and crucial for the success of the overall treatment. This includes equally the dentist, the dental assistance, and the technician as well.[17] Therefore, the performance heavily depends on operators' experience. It has to be considered that only one experienced team of the same dentist/dental assistance and a digitally well-trained master technician treated all included patients in this study.

For comparison, neither any retrospective nor prospective clinical studies were found reporting on competitive analyses of digital workflows and conventional production pathways for fixed implant prosthodontics in the current dental literature. Laboratory investigations assessed bending moments and technical failure modes of CAD/CAM-generated implant abutments made of titanium and zirconia. In general, these studies revealed promising results for high mechanical stability of implant-abutment-connections processed in the digital workflow.[18,19] Precision and circumferential accuracy of CAD/CAM-based crowns showed favorable findings with equivalence and even superiority to conventionally manufactured reconstructions.[20,21] For the transfer of the 3D implant position, the classical impression taking procedure was compared with IOS technology in laboratory trials. These investigations reported on accuracy and precision of different intraoral scanning devices with heterogeneous results for digital impressions, indicating a strong dependency on the used system.[22–24] However, the results also demonstrated a level of precision that was within the range of analogue impressions.[25,26]

However, compelling evidence from clinical trials demonstrating the dominance of digital dental protocols for the entire treatment protocol of fixed implant prosthodontics is still limited. One clinical case series could be identified that investigated fully anatomical implant-supported crowns for single-tooth replacement in posterior sites. Reconstructions were made of resin nano ceramic and bonded onto pre-fabricated (test) or individualized (control) titanium abutments. A complete digital approach was used for laboratory processing with partially quadrant-like IOS plus CAD/CAM-technology. Based on these results, it was concluded that patients would benefit from the presented digital workflow according to economic considerations.[10] In this context, the purchase factor also has to be taken into account. Initial investments for an IOS device, a personal computer system, and possible scanning fees as well as maintenance costs are more expensive than the equipment needed for the conventional approach.

For the first time, the results of this prospective cohort study showed the superiority of the digital workflow over the conventional pathway for clinical fitting of implant-supported crowns. The data presented are valid for cement-retained implant crowns and might not be transferable for screw-retained solutions. Based on the current literature, however, it can be speculated that IOS plus CAD/CAM-production for implant reconstructions seems to be more accurate than the classical lost wax casting technique for manufacturing of PFM implant crowns.[10] A possible explanation could be based on minimal human intervention and bypassing several manual fabrication steps in the digital workflow.[27]

The implementation of new technologies within the digital workflow enables the production of implant reconstructions in a computerized process. It has to be reflected, however, that additional time for model fabrication within the CAD/CAM-process is necessary. The overall laboratory work time in the digital approach would be longer, considering the time needed for production of the CAD/CAM-models, sending and milling the implant prosthetic components. On the other hand, demanding laboratory work steps may be simplified in the digital workflow, and the material-specific advantages are ensured due to standardized fabrication quality.[5,8] In addition, the need for chair-side corrections, such as secondary grinding and polishing, can be minimized or are not even necessary. This fact reduces

clinical work time but may also decrease the risk for cracks and chipping of veneer ceramics.

CONCLUSIONS

Based on the findings of the present prospective clinical study, the digital workflow for the production of implant-supported single reconstructions seemed to be more efficient than the established conventional pathway. Clinical fitting could be predictably achieved with no or minor adjustments within the digital process of IOS plus CAD/CAM-technology. Overall, digital processing was almost threefold faster for clinical adaptation than the conventionally produced reconstructions.

The digital workflow has the potential to streamline the clinical treatment in combination with high quality and precision in the field of fixed implant-supported single-unit reconstructions. Nevertheless, these findings are preliminary in nature and have to be confirmed in additional clinical trials. Further large-scale studies with long-term follow-up observations are necessary to investigate the clinical performance of the treatment concept of implant-supported crowns in the digital workflow. It should be mentioned though that several systems offer different workflow protocols. Most of these systems were developed for closed processes. Therefore, results reporting on one specific workflow sequence may not be transferable to other systems.

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