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# Effect of immediate all-digital restoration of single posterior implants: The SafetyCrown concept on patient-reported outcome measures, accuracy, and treatment time—A randomized clinical trial

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## Abstract

**Objective:** The SafetyCrown workflow facilitates the immediate restoration of posterior single sites with the one-abutment/one-time concept. This randomized clinical trial aimed to assess the direct effect of immediate restoration on dental patient-reported outcomes (dPROs), feasibility, implant accuracy, and time.

**Materials and Methods:** Participants with a single posterior edentulous site for late implant placement underwent optical impressions, shade selection, and cone beam computed tomography. After virtual treatment planning, they were randomized into the test group and the control group. For the test group, individual definitive hybrid abutments were prefabricated. The next step was a fully guided surgery with printed guides. After the implant was placed using guided surgery, the abutment was inserted. A chairside CAD/CAM workflow was used to provide the patient with a provisional restoration. Implants in the control group were left submerged to heal. Oral health-related quality of life (OHRQoL) was assessed using the OHIP-G14, and dPRO was measured using a 10-item visual analog scale (VAS) questionnaire. Additional measurements of implant accuracy and time were performed. Follow-up was performed 7 to 10 days after implant placement.

**Results:** Thirty-nine participants with 45 restorations were included (test group: 23, control: 22). Immediate restoration was successful in 21 out of 23 implants (91.3%) in the test group. Both groups exhibited decreased OHRQoL without significant intergroup differences, while patient satisfaction was high overall. Test group participants perceived higher benefits and satisfaction with immediate loading than participants in the control group. Implant accuracy averaged 0.60 mm at the shoulder and 0.95 mm at the apex. Operative time was longer in the immediate loading group (61.9 min) than in the control group (32.1 min) ($p < 0.001$).

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**Conclusions:** Considering the limitations, the immediate restoration of late placed posterior implants using the described workflow proved feasible in 21 out of 23 cases. Both groups achieved high patient satisfaction with no differences in OHRQoL during the first week. Patients who received immediate loading rated the benefits very highly and were satisfied with the provisional restoration during the healing period.

**KEYWORDS**
CAD/CAM, guided surgery, immediate restoration, OHRQoL, one-abutment/one-time, PROM, single implants, time assessment

**Summary box**

**What is known?**

- Immediate loading of a late placed posterior implant is a possible treatment option assuming sufficient primary stability.
- The impact of immediate restoration for a single posterior late placed implant on dental patient-reported outcomes is unknown.

**What this study adds**

- This is the first study assessing the direct impact of immediate restoration of a posterior single implant on dental patient-reported outcomes.
- Immediate restoration and subsequent provisional restoration on a prefabricated individual definitive abutment as the first part of the SafetyCrown workflow is a feasible treatment option with high patient satisfaction.

## 1 | INTRODUCTION

The restoration of a single missing posterior tooth is one of the most common clinical situations where implant-supported single crowns are usually the treatment of choice. Invasive preparation of adjacent teeth to support a fixed dental prosthesis (FDP) or a removable partial denture (RPD) can be avoided. However, the restoration of a missing tooth with an implant-supported crown is time consuming and stressful for the patients. Contemporary dentistry allows the immediate placement of dental implants after tooth extraction.[1–3] However, immediate placement is not universally possible, nor is it generally better, because it requires careful patient selection and assessment of the individual anatomy and risk profile.[2,4] Especially for replacing posterior missing teeth, many implants are placed after the bone has healed in a late approach. Whereas in the early days of dental implantology, a healing period of 3 to 6 months to await osseointegration was recommended before loading the implant,[5] this duration has been shortened because of improvements in implant surfaces and macro designs.[6,7] When implants are placed with sufficient primary stability, they can be immediately loaded[1,8–10] within 1 week of implant placement.[3,11] Clinical studies have shown high survival rates for this protocol in both the anterior maxilla and posterior sites.[1,4] Immediate loading with a provisional restoration shortens the duration of partial edentulism for the patient and eliminates the need for the second stage surgery after submerged healing. When immediately restored with a prefabricated, definitive abutment, the one-abutment/one-time approach provides a biological advantage in addition to fewer appointments and less treatment time.[12–16] Based on the combination of these aspects, the SafetyCrown protocol was developed for the restoration of single missing posterior teeth within an all-digital workflow,[17] aiming to improve patient satisfaction and shorten treatment time, while striving for stable surrounding soft and hard tissues. These two factors, time efficiency and improvement in the patient's perception of treatment,[18] are also reported by experts to be the key advantages of digital technology in implant dentistry. Patient perspective, referred to as dental patient-reported outcome (dPRO), has been the subject of investigation for single implant supported definitive crowns in relation to the loading protocol. The impact on oral health-related quality of life (OHRQoL) has been assessed and suggests a similar impact for immediate versus conventional restoration.[7,19–22] However, to the best of the authors' knowledge, research questions failed to focus directly on the immediate impact of the provisional restoration on patient satisfaction.[7,9,19,20,23–26]

This randomized controlled clinical trial (RCT) was designed to gather evidence on the performance of the workflow and immediate effects on dPROs in terms of patient satisfaction and perception of the healing process. Such evidence is essential for evidence-based decision making and patient information.[27,28] Its primary outcome was the assessment of the direct effect of the treatment option on dPROs. The null hypothesis states that there is no difference regarding patient-reported outcome measures (PROMs) between immediate implant restoration with a provisional on the definitive abutment (test

group) and conventional restoration after submerged healing (control). This was evaluated for the initial phase of the SafetyCrown workflow, from treatment planning to immediate provisional restoration on the prefabricated definitive abutment. In addition to dPROs, the secondary outcomes of feasibility of the treatment concept, implant accuracy, and treatment duration were assessed.

## 2 | MATERIALS AND METHODS

### 2.1 | Study design and participants

The present study was designed as a single-center, randomized, controlled clinical trial. The protocol was approved by the Institutional Review Board of the Medical Faculty, RWTH Aachen University, Germany (EK 136-22) before the start of the study and was conducted in accordance with the Helsinki Declaration of 1964 as revised in 2013. Written informed consent was obtained from all participants before treatment and the CONSORT guidelines were followed. All participants were recruited within the Department of Prosthodontics and Biomaterials, Centre for Implantology, University Hospital RWTH Aachen, Germany. The main inclusion criterion was a single edentulous posterior site with complete bone healing for performing graftless late implant placement with or without immediate restoration (ITI type 4A and 4C[3,11]). To reduce confounding regarding the primary outcome of dPRO, no further need for dental treatment had to be present at the time of inclusion. Some participants had undergone various treatments (e.g., fillings, crowns, systematic periodontal treatment) prior to inclusion. A washout period of at least 2 weeks before surgery was included without appointments and to allow for adaptation. A detailed list of inclusion and exclusion criteria is presented in Table 1. No changes were made to the protocol or eligibility criteria during the study.

**TABLE 1** Inclusion and exclusion criteria.

| Inclusion criteria | Exclusion Criteria |
|---|---|
| • Age 18 to 70 years<br>• Single edentulous posterior area or free-end situation, where an implant supported crown is an appropriate treatment plan (up to two per participant, not opposing)<br>• No further need of dental treatment/appointments scheduled other than the study intervention.<br>• Sufficient attached gingiva to reach 2 mm buccal to the future crown without soft tissue grafting.<br>• Sufficient bone volume and interproximal space to place minimum 3.75 × 8 mm implant.<br>• Healed site for late implant placement.<br>• Fixed opposing dentition.<br>• O'Leary plaque index ≤25%.<br>• Non-smokers, smokers with fewer than 10 cigarettes per day | • Systemic disease and/or use of medication that interfere with bone or soft tissue healing (e.g., antiresorptive medication)<br>• History of head and/or neck radiation<br>• Substance abuse<br>• Uncontrolled diabetes (HbA1c ≥7.0)<br>• Severe bruxism<br>• Probing pocket depth of ≥4 mm at teeth adjacent to the implant site, untreated periodontitis<br>• Pregnant or breastfeeding |

### 2.2 | Intervention

An overview flow-chart of the study intervention, as well as assessment tools and their timing are shown in Figure 1. At the first visit, full-arch intraoral optical impressions with buccal occlusal registration were obtained (Primescan, Dentsply Sirona, Charlott, NA) and exported as standard tessellation language (stl) files. The shade of the adjacent teeth was documented. Additionally, cone beam computed tomography (CBCT; Orthophos SL 3D, Dentsply Sirona) with a limited field of view was performed to avoid artifacts interfering with optimal matching yet reducing radiation to the minimum needed (single jaw, 8 cm × 8 cm or 5 cm × 5 cm). These reduced fields of view were possible because the participants exhibited only small restorations on the teeth adjacent to the implant site. Data were exported as a DICOM (Digital Imaging and Communication in Medicine) dataset.

Virtual implant planning was then performed using coDiagnostiX (Dental Wings, Montréal, Canada). The individual DICOM data set was segmented after import, and the panoramic curve was determined. For mandibles, the alveolar nerve was defined. Afterwards, the study jaw stl file was imported and aligned to the segmented jaw. The fit was visually checked in all cuts (axial, coronal, sagittal) and when needed manually adjusted to accomplish the best possible superimposition pattern. The opposing jaw was aligned by copying the spatial orientation of the study jaw, as aligned by the buccal occlusal registration. A virtual tooth setup for the edentulous area was performed using the tool provided by the software. A single implant type (BLX, Straumann AG, Basel, Switzerland) was selected throughout the study, with dimensions ranging from 3.75 to 4.5 mm in diameter and lengths from a minimum of 8 mm to a maximum of 14 mm. This was selected to target high primary stability and the predictable use of immediate restorations while still allowing implant placement through the surgical guide. The position of the implant shoulder was planned to be 0.5 mm below the crestal bone level. Drill sleeves were planned with a height of 4 mm above the intended implant shoulder. Drilling templates with index orientation were then designed within the software program and exported as stl files. All first visits, as well as all implant planning, were performed by one trained investigator (LW). For calibration and in critical situations, joint approval (SW and LW) of the design was obtained after completion.

An individual definitive abutment was prefabricated for the test group. An stl file of the jaw with a scan body representing the virtually planned implant orientation and position was exported from the planning software program. The dental laboratory technician designed a custom abutment from tooth-colored, high-strength 3Y-TZP zirconia (LavaPlus, 3 M, Saint Paul, MN) on a titanium base (Variobase,

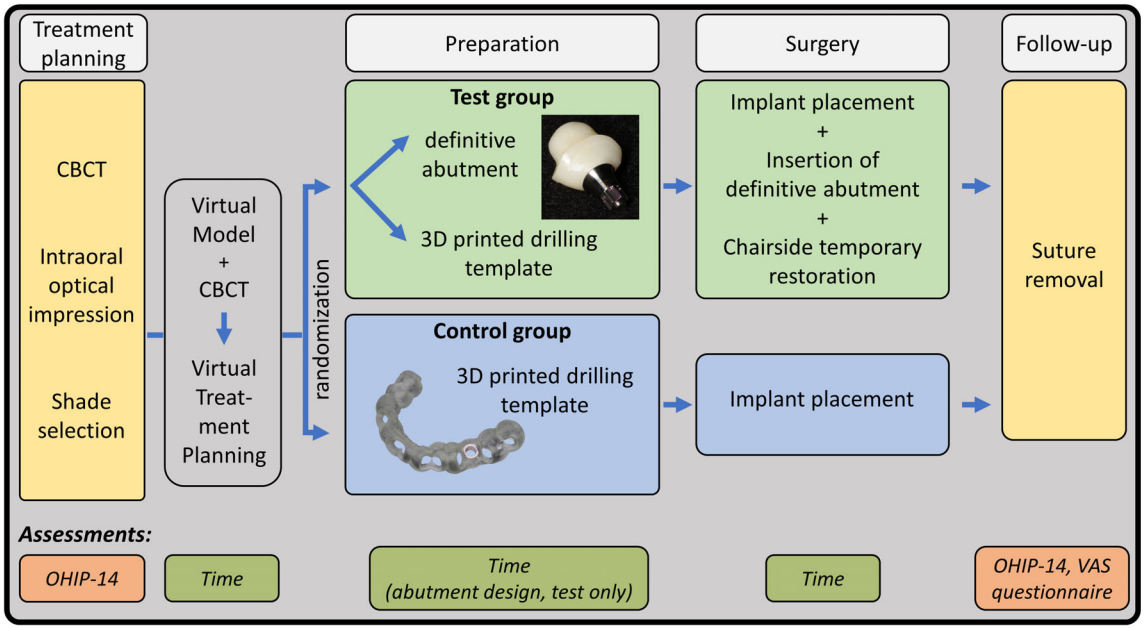


**FIGURE 1** Study flowchart with assessments. The subsequent treatment steps and follow-up intervals are not considered in this publication and are therefore not shown in the flowchart. For further information, see Waltenberger and Wolfart.[17]

Straumann AG) in a laboratory software program (Exocad 3.1, exocad GmbH, Darmstadt, Germany). A supragingival cementation line 1 mm above the prospective gingival margin was intended. The supragingival cementation line of the abutment may be visible for premolar positions in combination with a high smile line. Participants were informed prior to treatment. The abutment was then milled, sintered, and polished according to the manufacturer's instructions (equipment: PM5 and Programat S1, Ivoclar Vivadent, Schaan, Liechtenstein). The abutment was adhesively bonded to the titanium base using Multilink Hybrid Abutment (Ivoclar Vivadent) after sandblasting, cleaning, and applying a phosphate primer (Monobond Plus, Ivoclar Vivadent). No stain or glaze was applied to the abutment surface, only a high-gloss polish using a multistage polishing protocol that was completed with a diamond polishing paste (Zirkopol, Feguramed GmbH, Buchen, Germany). For both the test and control group, the drill guides were 3D printed, washed, and polymerized (Form 2; Form Wash; Form Cure, Formlabs GmbH, Berlin, Germany) using a surgery-grade resin (Surgery Guide Resin, Formlabs). The drill sleeve was then inserted into the template, and the template was autoclaved.

Participants took a prescribed single dose of 2 g of amoxycillin and clavulanic acid (e.g., Augmentan 875/125 mg, GlaxoSmithKline GmbH & Co. KG, Munich, Germany) orally 1 h prior to surgery. If a documented allergy to penicillin was present, a single dose of 600 mg clindamycin was prescribed. Furthermore, up to three doses per day of ibuprofen 600 mg was prescribed to be taken as needed.

Implant placement was performed in the second appointment under local anesthesia (Ultracain D-S forte, Septodont, Niederkassel, Germany). Before surgery, participants rinsed with 0.2% chlorhexidine mouthwash for 1 min. Both investigators (LW and SW) placed implants in the study. After the preparation of a full thickness flap, fully guided implant preparation was performed. The drill protocol was adjusted to the bone density aiming for sufficient primary stability (35–50 Ncm target range). Implants were placed through the drill guide to the desired height and index. Prior to placement, the proper final seating of the insertion tool at the desired depth was verified. Where marginal bone prevented the insertion tool from reaching the desired position, the bone was modified using a round ceramic bone drill (CeraBur, Komet, Brasseler GmbH, Lemgo, Germany). After implant placement and visual inspection for sufficient surrounding bone, the implant stability quotient (ISQ) was measured. For the test group, only implants equaling or exceeding an ISQ of 70 and 35 Ncm of torque were qualified for immediate restoration. The definitive abutment was tried in and inspected for proper fit with the implant and for tooth orientation. In addition, the space to the marginal bone, to the adjacent teeth and to the opposing dentition was checked. Interfering marginal bone was smoothed with a round ceramic bone bur. If all requirements were met, a scan body (Scanbody Cares Mono RB/WB, Straumann) was inserted and an optical scan of the study jaw was obtained in an additional file in the software program (Cerec 5.2, Dentsply Sirona, Bensheim, Germany). The definitive abutment was then placed. Minor corrections of the abutment were made, if necessary, using burs designed for shaping and grinding sintered zirconia (DCB burs, Komet). Polishing was required only if alterations of the emergence profile were necessary and was subsequently performed using the laboratory polishing procedure. The abutment was inserted and tightened with a torque of 15 to 20 Ncm to avoid the risk of implant movement when tightening to the full required torque. The screws were retightened later after osseointegration. Monofil polypropylene sutures (Prolene 5-0, Ethicon, Johnson & Johnson Medical GmbH, Norderstedt, Germany) were placed. The screw channel was

sealed with condensed sterilized Teflon tape. The previous optical scan in the area of the new restoration was then cut out, and the area rescanned with the abutment in place. A provisional polymethyl methacrylate (PMMA) restoration (TelioCAD, Ivoclar Vivadent) was designed, fabricated (Cerec 5.2), milled (MCXL, Dentsply Sirona), and polished using a chairside computer-aided design/computer-aided manufacturing (CAD/CAM) workflow. The restoration was designed without occlusal or proximal contacts. After try-in and checking the absence of proximal, static, and dynamic occlusal contacts, the restoration was cemented with a provisional cement (TempBond NE, KerrHawe S.A., Bioggio, Switzerland). In the control group, the implant was sealed with a closure cap. The marginal bone was further smoothed with ceramic round burs to avoid bone growth over the implant. Sutures were placed for closed healing.

The sutures were removed after 7 days, which was the follow-up period for this study.

## 2.3 | Outcome measures

### 2.3.1 | Assessment of dPROs and OHRQoL

Oral-health related quality of life (OHRQoL) was measured using the German short version[29] of the oral health impact profile[30] (OHIP-G14). It contains 14 questions about impairments within the last 7 days, with participants marking the frequency on a 5-point ordinal response scale ranging from "never" = 0 to "very often" = 4. A summary score is calculated with a possible range of 0 to 56. Lower numbers indicate less impairment, that is, higher OHRQoL. The OHIP-G14 was assessed at the first visit and before suture removal 7 to 10 days after implant placement. Participants receiving two implants completed one form.

There is currently no standardized approach for assessing dPROs of the interventions performed.[7,19] The authors designed a questionnaire to assess PROMs of the intervention. The questions were partly derived from a questionnaire used in a randomized controlled clinical trial comparing the PROMs of posterior single-implant crowns.[31] A preliminary version of this questionnaire was also used and reported in the pilot study of this RCT.[17] The participants filled out the questionnaire independently with staff present for assistance if needed. A visual analog scale (VAS) with scores ranging from 0 to 100 were represented by a horizontal bar of 10 cm. The participants marked the response with a vertical line. The response was visually quantified using a ruler. In cases of two interventions in one participant, always performed simultaneously, the two independent questionnaires for both groups were completed by the participant with staff assistance for differentiation. The questions asked were as follows:

1. *How stressful did you consider the implant placement operation?* (0 = "not stressful at all," 100 = "very stressful")
2. *How stressful did you consider the healing process from the operation to the removal of the sutures today?* (0 = "not stressful at all,", 100 = "very stressful")
3. *How satisfied are you with the course and the result of the operation?* (0 = "completely dissatisfied," 100 = "very satisfied")
4. *Do you consider the provision of an immediate provisional restoration and the omission of the second-stage operation as an advantage in the treatment process?* (0 = "no advantage at all," 100 = "great advantage")

Control group only:

5. *How important would it have been to you to get the tooth gap immediately restored with a provisional restoration during implant placement?* (0 = "totally unimportant," 100 = "very important")

Test group only:

6. *How satisfied are you with the general result of the provisional restoration?* (0 = "completely dissatisfied," 100 = "very satisfied")
7. *How satisfied are you with the function of the provisional implant crown?* (0 = "completely dissatisfied," 100 = "very satisfied")
8. *How satisfied are you with the aesthetics of the provisional implant crown?* (0 = "completely dissatisfied," 100 = "very satisfied")
9. *How satisfied are you with the cleanability of the provisional implant crown during daily oral hygiene?* (0 = "completely dissatisfied," 100 = "very satisfied")
10. *How important was the immediate restoration of the tooth gap with a provisional restoration after implant placement for you?* (0 = "totally unimportant," 100 = "very important")

The participants were further requested to document the healing process in terms of the intake of analgesics (yes/no, amount), the presence of swelling (yes/no, duration), as well as facial discoloration (yes/no, duration). Additional comments were entered in a free field.

### 2.3.2 | Assessment of implant accuracy

The optical scan made during surgery with a scan body was converted into an stl file and imported into the implant planning software program. The alignment based on the scanning software program was visually examined and adjusted manually only if an improved visual fit was determined to be possible. The treatment evaluation tool in the software program can detect the scan body, and the algorithm translates back to the achieved implant position. Angular deviation, depth deviation at the implant shoulder, and Euclidean distances of the body deviation at the implant shoulder and apex were recorded.

### 2.3.3 | Assessment of treatment duration

A specially designed case report form (CRF) was used to assess the duration of preparation and treatment. Times were recorded by the investigator using a stopwatch during preparation for treatment and by a second assistant during surgery. All implant planning was

performed by the same investigator (LW). Laboratory times were recorded by a dental laboratory technician who designed all the abutments. The times were recorded for the following treatment phases:

1. Implant planning and template design: Import of DICOM dataset from a DVD into the implant planning software, segmentation, determination of panoramic curve, stl-alignment of study jaw, import of opposing jaw, marking of alveolar nerve, virtual tooth arrangement, implant planning, sleeve selection, template design and export; export of virtual planning (only test group).
2. Laboratory preparation (only test group): Case imported into laboratory software program, abutment design.
3. Surgery
   - Test group: Raising flap, implant placement (excluding local anesthesia, ISQ measurement and accuracy scan), abutment try-in and insertion, suture, optical scan, chairside design of PMMA restoration (excluding milling and polishing in laboratory); try-in and cementation of PMMA restoration.
   - Control group: Raising flap, implant placement (excluding local anesthesia, ISQ measurement, and accuracy scan), suture.

### 2.4 | Sample size, randomization, and concealment

The sample size for the randomized clinical trial was calculated on the basis of a retrospective clinical pilot study[17] and computed for PROMs after definitive restoration as the primary outcome. The calculation showed that 38 restorations (19 per group) would be necessary to achieve the required power, as specified in a previous publication.[17] Treatment planning and recording patient information were performed before allocation. Randomization was conducted by the investigator immediately after implant planning by throwing one virtual die (random.org, Dublin, Ireland). Following Efron's biased coin,[32] the probability was $p = 0.5$ represented by numbers 1 to 3 and 4 to 6 of the virtual die allocating to the two study groups. The probability changed to $p = 1/3$ and $p = 2/3$, respectively, when there was no longer equal allocation to the two groups. The numbers 1–2 and 3–6 then determined the participant's allocation. This randomization method ensures favorable balancing properties, yet fully randomizes each individual.[33] For participants receiving two restorations, the first was randomized, and the second was allocated to the other group. The first restoration was determined by selecting clockwise according to the FDI tooth numbering scheme. Participants were informed about their allocation to the test or control group on the day of surgery. Later, blinding was only possible for the evaluation and statistical analysis of OHIP-G14 sum scores and implant accuracy because of the characteristics of the data sets for treatment duration and PROMs.

### 2.5 | Statistical analyses

Means and standard deviations were calculated for all outcomes scores. Minimum and maximum values were determined for the analysis of implant accuracy and treatment time. The statistical analysis recognized the dependence of outcomes from six patients receiving two restorations. All inferential analyses and comparisons were performed using the *t* test which is, without clustering, equivalent to conducting a linear regression of the outcome with treatment group as predictor variable. To account for clustering of restorations in some patients we obtained robust standard errors and *p* values by using the Huber–White–robust sandwich variance estimator (as implemented in with "cluster" options in Stata [Version 18, Stata Corp., College Station, TX]). The level of statistical significance was set at $p < 0.05$.

## 3 | RESULTS

### 3.1 | Characteristics of participants

A total of 45 implants were placed in 39 participants aged from 21 to 64 years (mean 44 years) at the time of surgery. Slightly more males (54%) than females were treated. After implant planning, 23 implant sites were allocated to the test group and 22 to the control group. Six participants requiring two restorations were included. The mandibular first molar was the most commonly restored site (62%), but implants were placed in premolar and molar sites in all four quadrants. Detailed demographic characteristics and implant locations are shown in Tables 2 and 3. Participants were recruited between August 2022 and November 2023. Three potential participants who met all eligibility criteria did not wish to receive an implant and were therefore not included. The participants were treated between September 2022 and December 2023. The detailed CONSORT flowchart of the study is presented in Figure 2.

### 3.2 | Application of the workflow and complications

The successful placement of the prefabricated definitive abutment immediately after implant placement, together with the delivery of a

**TABLE 2** Baseline demographic characteristics and restored sites of the included participants.

| Distribution of participants | | |
|---|---|---|
| **Total** | **Test group** | **Control group** |
| Participants | | |
| 39 | 23* | 22* |
| Implants | | |
| 45 | 23 | 22 |
| Age | | |
| 44.2 (SD 12.1; range 21–64) | 44.2 (SD 12.8; range 21–61) | 44.0 (SD 11.9; range 21–64) |
| Gender | | |
| 21 m (54%) | 13 m (57%) | 13 m (59%) |
| 18 f (46%) | 10 f (43%) | 9 f (41%) |

*Note*: *Six participants receiving both interventions are allocated to both groups totaling more than 39.

**TABLE 3** Location of study interventions in relation to the assigned group.

| Location of restorations (FDI) | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| **Maxilla** | **17** | **16** | **15** | **14** | **24** | **25** | **26** | **27** | **Total** |
| Total | 0 | 2 | 1 | 0 | 3 | 2 | 2 | 0 | 10 (22%) |
| Test group | | 2 | 1 | 0 | 1 | 0 | 0 | 0 | 4 (9%) |
| Control group | | 0 | 0 | 0 | 2 | 2 | 2 | 0 | 6 (13%) |
| Test group | 1 | 7 | 1 | 0 | 0 | 1 | 9 | 0 | 19 (42%) |
| Control group | 1 | 4 | 2 | 0 | 0 | 1 | 8 | 0 | 16 (36%) |
| Total | 2 | 11 | 3 | 0 | 0 | 2 | 17 | 0 | 35 (78%) |
| Mandible | 47 | 46 | 45 | 44 | 34 | 35 | 36 | 37 | |

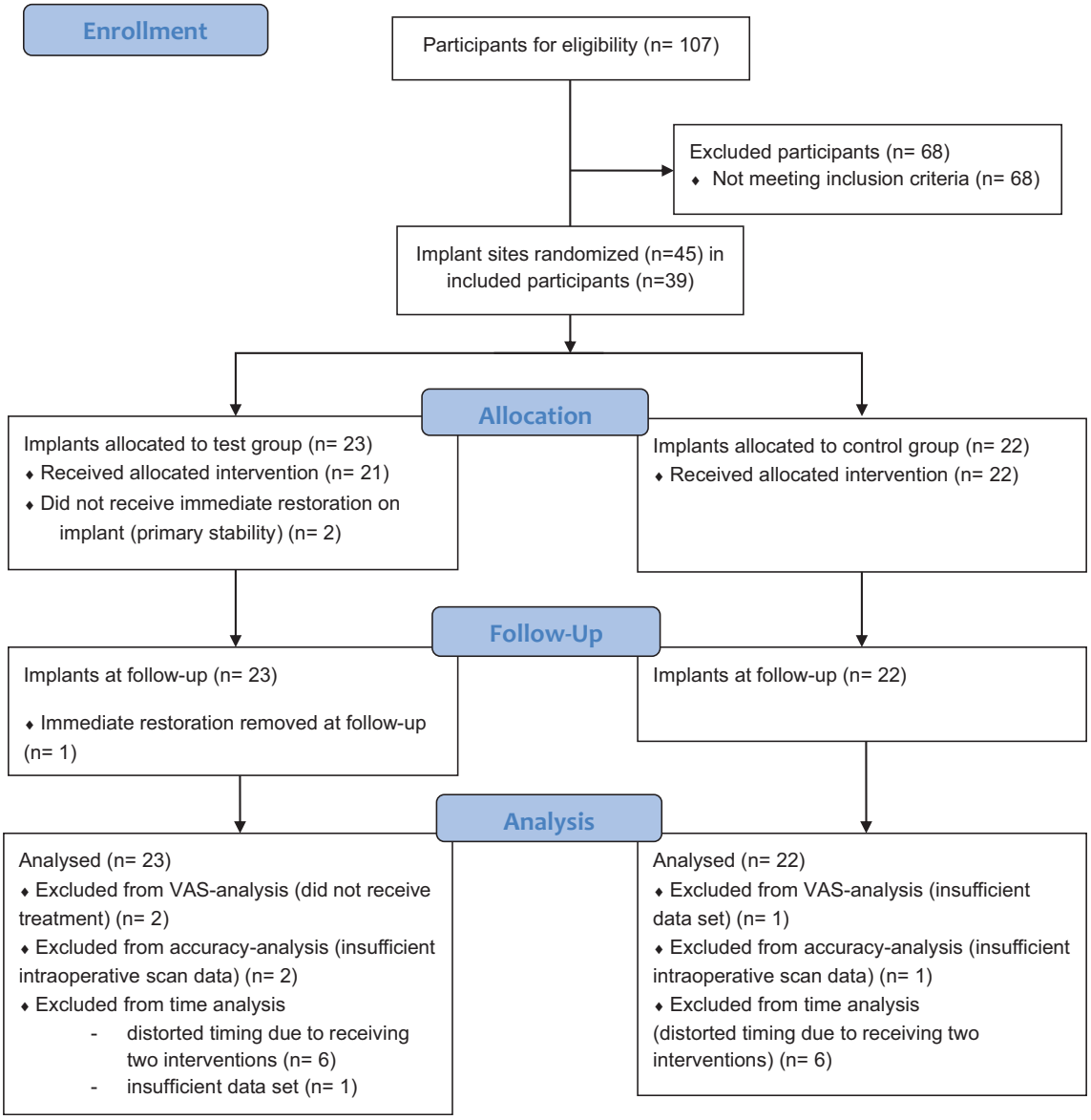


**FIGURE 2** CONSORT flow diagram of the study.

provisional crown, was possible in 21 of 23 cases (91.3%). Figures 3 and 4 illustrate successful workflows in the test and control group. A lack of primary stability inhibited immediate loading in two participants who received implants in FDI positions 36 and 47. These implants were sealed with a cover screw, and closed healing was initiated. No implants were lost during the study period. One male

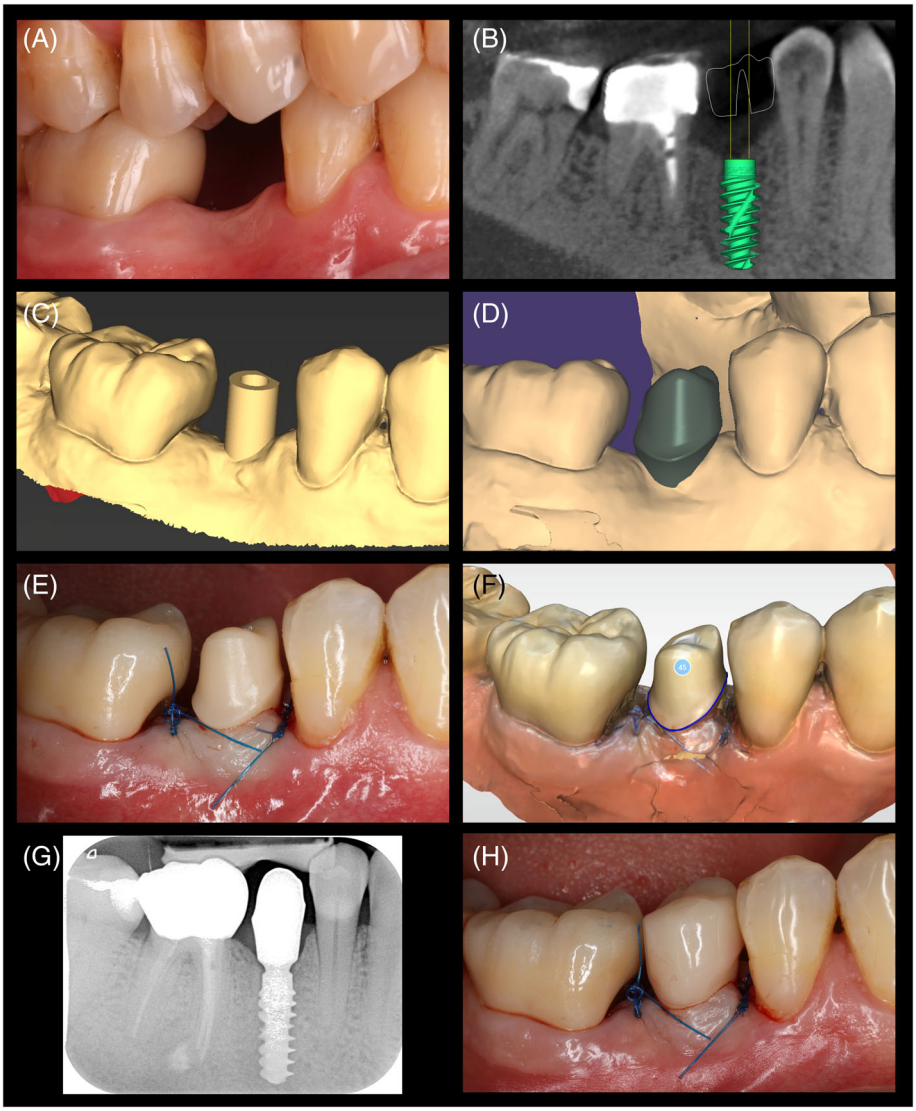


**FIGURE 3** Representative successful application of the workflow in the test group. (A) Pretreatment situation with missing FDI 45. (B) Virtual implant planning with tooth setup. (C) Virtual treatment export with scanbody representing the planned position. (D) Laboratory design of the definitive abutment. (E) Definitive abutment placed immediately after implant placement with sutures. (F) Chairside optical scan as the start of the design-workflow for the provisional restoration; (G) Radiographic examination after implant placement and immediate restoration with an individual radiographic holder; (H) Successful immediate provisional restoration with CAD/CAM chairside PMMA restoration seated on the abutment.

participant in the test group experienced local inflammation around the abutment accompanied by screw loosening in FDI position 16 (test group). In the same patient, local inflammation with delayed wound healing without dehiscence was present at follow-up at FDI 26 (control group). He had a history of severe diabetes years earlier, and the immediate restoration was removed rather than being retightened; a healing abutment was placed as a precaution. No other screw-loosening incidences occurred within the follow-up period. Sutures were removed after an additional 5 days of healing, and systemic antibiotics were prescribed. No significant pain or discomfort was reported by a participant.

### 3.3 | dPRO and OHRQoL

OHRQoL decreased in both groups from surgery to the 7-day follow-up, as evidenced by an increase in OHIP-G14 scores. In the test group, mean OHIP-G14 scores increased by 3.4 points from 1.4 (SD 2.1) to 4.8 (SD 3.7). In the control group, scores increased from 1.5 (SD 2.0) at baseline to 5.0 (SD 5.0). There was no significant difference between groups in the amount of increase in OHIP-G14 points between baseline and follow-up ($p > 0.870$).

A detailed overview of the results of the questionnaire is presented in Tables 4 and 5. The main findings are as follows.

Participants did not rate implant placement with immediate restoration as more stressful than participants receiving implant placement alone. VAS scores ranged from 14.1 (SD 18.4) for the test group to 18.5 (SD 20.9) for the control group. There was also no difference in perceived levels of stress during the healing period between the groups. Overall satisfaction with the outcome of surgery was very high in both groups.

The answers to question 4, however, were significantly different. Participants who had experienced immediate loading (test group) rated it strongly as an advantage in the treatment process along with the omission of a second stage operation (VAS 93.8; SD 8.2), whereas participants in the control group rated the advantage of the workflow medium (VAS 74.6; SD 27.2). This difference was statistically significant ($p = 0.005$). Participants in the control group rated the

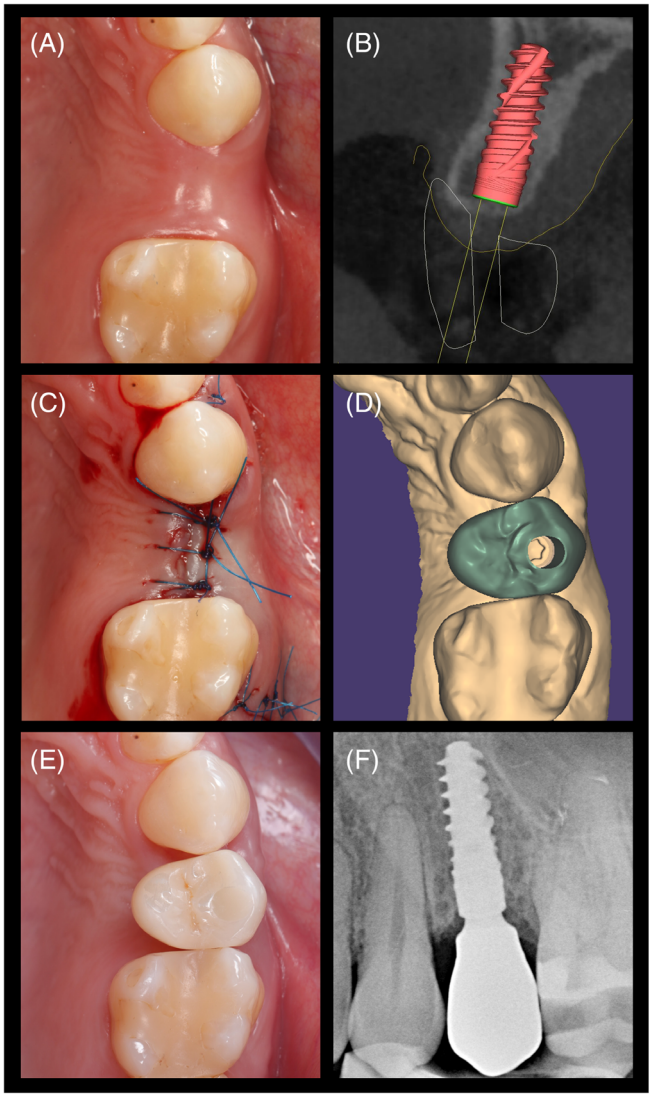


**FIGURE 4** Representative workflow for the control group. (A) Pretreatment situation with missing tooth FDI 24. (B) Virtual implant planning with tooth setup. (C) Implant placement with submerged healing. (D) Digital design of the restoration following optical implant impression after osseointegration and second stage surgery. (E) Final screw-retained restoration. (F) Radiograph after definitive restoration.

importance (question 5) of immediate restoration with a VAS score of 59.1 with a high standard deviation of 32.3. In contrast, test group participants rated the importance of the procedure as "very important" (92.2; SD 9.7). Overall satisfaction with the provisional crown in the test group was very high in terms of overall result, function, and aesthetics, with mean scores above 90. Only cleanability was rated slightly lower, with a mean of 82.3 points.

A total of 13 out of 22 participants in the control group and 13 out of 23 participants in the test group used low doses of analgesics. The highest dose reported was six doses of ibuprofen 600 mg over 3 days. Eight participants in the control group and eight in the test group reported mild swelling. Three participants (control only) reported slight discoloration. There was little further information on complications, and no self-reported major complication.

### 3.4 | Implant accuracy

None of the implants placed in the test group were unable to be immediately restored because of inaccuracy of implant placement. Accuracy was similar in the test and control group. Data from both groups are shown in Table 6. Overall accuracy resulted in an angular deviation of 3.2° (SD 2.0°). The 3D body deviation was 0.57 mm (SD 0.31 mm) at the implant shoulder and 0.95 mm (SD 0.5 mm) at the apex. Implant shoulders were placed on average 0.32 mm (SD 0.48) deeper than the planned position. Two implants exceeded the 2-mm discrepancy between planning and implant placement at the apex, with a Euclidean distance of 2.09 mm each. In the control group, two implants could not be placed through the surgical guide after a fully guided osteotomy (FDI 36, 47) because of limited mouth opening and were placed freehand without the template.

### 3.5 | Analysis of treatment duration

The duration of virtual implant planning was not statistically different, with 16.8 (SD 2.0) min in the test group and 18.4 (SD 4.0) min in the control group. Abutment design, which was only measured in the test group, took an average of 11.0 (SD 3.4) minutes. Surgery and immediate restoration in the test group took 61.9 min, significantly longer than surgery alone in the control group (31.9 min; $p < 0.001$). The surgeon had no significant effect on the duration of surgery ($p = 0.258$). Detailed results with standard deviations and minimum and maximum values are shown in Table 7.

## 4 | DISCUSSION

This randomized clinical trial demonstrated that late posterior implant placement with immediate restoration and subsequent provisional restoration using prefabricated individual definitive abutments proved successful in 21 out of 23 cases (91.3%). Perceptions of OHRQoL, stress, and the healing process after implant surgery with immediate loading did not differ from those of the control group. Overall satisfaction was very high. Participants who received immediate loading with the associated benefits of the workflow showed increased appreciation of the concept compared with the control group. The use of the tested workflow significantly increased treatment time, although second-stage surgery and impression-making were avoided in the subsequent process.

The immediate restoration of late placed posterior implants is considered a clinically documented and practical treatment approach, provided that primary stability is adequate, although survival rates vary by site.[1,8] In the posterior mandible, the documented cumulative implant survival rate was 97.0% (93.3%–97.5%) at a mean follow-up

**TABLE 4** Results of the dPRO questionnaire completed by participants using a visual analog scale.

| Question | Test group (mean) | Control group (mean) | *p* value* |
|---|---|---|---|
| (1) How stressful did you consider the implant placement operation? (0 = "not stressful at all," 100 = "very stressful") | 14.1 (SD 18.4) | 17.7 (SD 20.1) | 0.472 |
| (2) How stressful did you consider the healing process from the operation till the removal of the sutures today? (0 = "not stressful at all," 100 = "very stressful") | 11.5 (SD 16) | 11.0 (SD 14.4) | 0.877 |
| (3) How satisfied are you with the course and the result of the operation? (0 = "completely dissatisfied," 100 = "very satisfied") | 95.2 (SD 7.3) | 90.7 (SD 21.4) | 1.000 |
| (4) Do you consider the provision of an immediate provisional restoration and the omission of the second-stage operation as an advantage in the treatment process? (0 = "no advantage at all," 100 = "great advantage") | 93.8 (SD 8.2) | 73.8 (SD 26.1) | *0.005* |
| (5) How important would it have been to you to get the tooth gap immediately restored with a provisional restoration during implant placement? (0 = "totally unimportant," 100 = "very important," control group only) | | 59.1 (SD 32.3) | |
| (6) How satisfied are you with the general result of the provisional restoration? (0 = "completely dissatisfied," 100 = "very satisfied," test group only) | 94.5 (SD 8.5) | | |
| (7) How satisfied are you with the function of the provisional implant crown? (0 = "completely dissatisfied," 100 = "very satisfied," test group only) | 92.1 (SD 7.8) | | |
| (8) How satisfied are you with the aesthetics of the provisional implant crown? (0 = "completely dissatisfied," 100 = "very satisfied," test group only) | 90.5 (SD 11.8) | | |
| (9) How satisfied are you with the cleanability of the provisional implant crown during daily oral hygiene? (0 = "completely dissatisfied," 100 = "very satisfied," test group only) | 82.3 (SD 21.6) | | |
| (10) How important was the immediate restoration of the tooth gap with a provisional restoration during implant placement for you? (0 = "totally unimportant," 100 = "very important," test group only) | 92.2 (SD 9.7) | | |

*Note*: *derived using robust standard errors. Questions 1–4 were asked of all participants. Question 5 only to the control group, questions 6 to 10 only to the test group.

**TABLE 5** Participants' responses to the questionnaire about their use of analgesics and complications.

| | Test group | Control group |
|---|---|---|
| Intake of analgesics (1 dose equals 1 ibuprofen 600 mg p.o.) | 8× no dose<br>6× 1 dose<br>5× 2 doses<br>2× 5–6 doses | 8× no dose<br>6× 1 dose<br>6× 2 doses<br>1× 6 doses over 3 days |
| Presence of swelling | 8× minor;<br>13× absence | 7× minor, 14× absence |
| Presence of discoloration | None | 3× presence |
| Further complications (if any) | 1× "unpleasant feeling" | 1× "sutures irritate tongue"<br>1× "especially painful when lying down in the evening" |

of 30 months for immediate loading. This compares well with conventional loading at 95.0% (93.1%–100%) after 38.7 months. In the posterior maxilla, the data available from five studies (three RCTs) showed a survival rate of 95.9% (86.4–100%) after 13.8 months for immediate restoration. These data tended to be inferior when compared with the mean survival of 100% in four trials (two RCTs) at 33.1 months for conventional loading. The low survival rate (86.4%) in the posterior maxilla originated from an RCT using straight implants without aggressive threads for immediate restoration (Standard Plus, Straumann AG).[34] Therefore, we chose the BLX implant system because the macro design and workflow provided greater control of primary stability by adapting the drilling sequence to the bone density. Using this type of implant, the authors consider the protocol reliable for both the posterior maxilla and mandible. In addition, the internal tapered connection designed with six index orientations provided efficient control of primary stability at the required index orientation. This allowed the predictable achievement of primary stability in almost all cases.

Two participants in the test group could not be immediately restored because of a lack of primary stability. In both cases, the implants were placed deeper to achieve a subcrestal position of 0.5 mm on the buccal aspect of the implant shoulder because of the insufficient width of the alveolar process at the crestal tip, resulting in primary stability only being achieved in cancellous bone. During the drilling process, the bone quality was estimated to be dense based on the cortical aspect of the drilling sequence. Therefore, the drilling protocol was adjusted accordingly. The neck of the BLX implant has a reverse taper to reduce stress on the surrounding bone at high torque. Primary stability is then mostly provided by the friction of the aggressive helical threads. The authors conclude that when subcortical implant placement with immediate loading is planned with the BLX implant system, bone density should only be assessed in the cancellous part of the osteotomy. In two additional cases in the control

**TABLE 6** Angular and bodily deviation between the planned and achieved implant position at implant shoulder and apex.

| Deviation Group | Angular | Depth (mm) | 3D bodily @ shoulder (mm) | 3D bodily @ apex (mm) |
|---|---|---|---|---|
| Test group ($n = 22$) (SD; min–max) | 3.31° (1.30; 0.6–5.9) | 0.32 (0.48; −0.58 to 1.52) | 0.59 (0.33; 0.23–1.53) | 1.00 (0.45; 0.33–2.09) |
| Control group ($n = 20$) (SD; min–max) | 3.06° (2.61; 0.2–12.8) | 0.27 (0.40; −0.91 to 0.89) | 0.55 (0.30; 0.16–1.09) | 0.91 (0.56; 0.15–2.09) |
| Total ($n = 42$) (SD; min–max) | 3.19° (2.04; 0.2–12.8) | 0.30 (0.44; −0.91 to 1.52) | 0.57 (0.31; 0.16–1.53) | 0.95 (0.51; 0.15–2.09) |
| *p* value* | 0.690 | 0.689 | 0.733 | 0.565 |

*Note*: *derived using robust standard errors.

**TABLE 7** Results of the time measurement in the study.

| | Implant planning and surgical guide design incl. export (test only) (min) | Abutment design (min) | Implant placement (min): Test: Implant placement with insertion of abutment, suture, optical scan, design of provisional restoration, try-in and cementation Control: Implant placement, suture |
|---|---|---|---|
| Test group ($n = 15$) | 16.8 (SD 2.0; 12.6–20.1) | 11.0 (3.4; 6.5–22.1) | 61.9 (11.9; 47.8–90.7) |
| Control group ($n = 17$) | 18.4 (SD 4.3; 10.9–26.5) | | 32.1 (9.2; 20.6–53.5) |
| *p* value* | 0.282 | | *<0.001* |

*Note*: *derived using robust standard errors.

group (FDI 36 and 47), the implant osteotomy was fully guided, but placement had to be performed freehand because of limited mouth opening. The length of the insertion post, which adds to the implant length of the system, prevented safe placement without bringing the implant into unwanted contact with the surroundings. In addition to the lack of accuracy,[35] freehand implantation does not provide sufficient information about the index orientation. This may hinder the proper placement of a prefabricated individual abutment or result in stepwise adjustment of the implant orientation, increasing the risk of not obtaining proper primary stability at the planned implant depth. Although the limitation associated with mouth-opening for statically guided implant surgery is well known,[36,37] the severity increases with a prefabricated abutment. In this situation, the workflow was scheduled, and the patient informed accordingly.

Based on the experience of this RCT, the correct final fit of the insertion tool at the required depth must be verified before implant placement. The parallel walls of the insertion tool, given its ideal fit in the drill sleeve, begin only a few millimeters above the implant connection. When subcrestal placement is required, early contact of the insertion tool with the marginal bone can create friction and simulate increased insertion torque.

The OHRQoL showed a similar increase of approximately three OHIP-G14 points from baseline to control in both groups and was expected as the participants had to cope with wound healing. Analgesic use and patient-reported perception were comparable with those of other studies, although clinical data are scarce.[38–41] The intake of analgesics was selected as a surrogate parameter for pain. To gain an additional perspective, question 2 was asked about perceived stress throughout the healing process. Patients responded with a low level of stress. When data were extracted from the six participants who received two implants, the OHIP-G14 sum score showed no increased impact on OHRQoL compared with receiving one implant. Although not precisely measured in this clinical trial, the duration of implant surgery alone was also longer in the test group. The abutment had to be tried in, sometimes with the additional need for bone shaping. This did not result in lower OHRQoL, increased use of analgesics, or reduced satisfaction with treatment.

None of the prefabricated abutments were unable to be placed because of inaccuracy in implant placement. The described workflow provided high accuracy with average 3-D bodily deviations of approximately 0.6 mm at the implant shoulder and 0.95 mm at the apex. These data are at the more precise end of the spectrum in the literature.[35] However, the accuracy achieved was to be expected because implant locations in posterior single edentulous sites provide ideal support for the surgical guide without cantilevers or mucosal support.[42] In addition to the accuracy achieved, outliers exceeding 2 mm at the apex do occasionally occur, and safety margins should always be maintained.

Published comparisons of treatment time are sparse. Graf et al. systematically reviewed the literature for time associated with computer-guided implant planning and surgery.[43] Treatment planning for fully guided placement was comparable, with 15 min to around 17 min in this trial.[44] The duration of implant placement was comparable with the findings of other authors, but since the timing, number of implants, and implant systems were different, no clear comparison can be made.[41,43–47] The authors are unaware of previous studies that reported treatment times for the insertion of a prefabricated abutment with subsequent provisional restoration for single posterior

implants. Parallels can be drawn with a recent publication on four different workflows in the restoration of posterior implants. Guo et al. measured a similar duration for implant placement with approximately 30 min in posterior sites using a static guided implant workflow.[48] The time for rescanning immediately after implant placement was 4.6 min for the optical scan. A direct comparison with this study cannot be made as the increase of approximately 30 min for immediate restoration compared with the control included a longer procedure associated with the delivery of the abutment, rescanning of the placed abutment, and the digital design and placement of the provisional restoration.

The main strengths of the study were its design as a randomized controlled clinical trial with a large number of participants and its investigation of a novel digital treatment procedure. The study is reporting on multiple outcomes to give a comprehensive overview of the procedure. The intention-to-treat analysis of all implant placement procedures allowed in-depth discussion of shortcomings and challenges of the procedure.

Limitations of the study included that data were not available from all participants for all analyses, as specified in the consort flowchart. The unavailable data are unlikely to lead to distortion because of the high number of participants in each group. The outcomes and discussion of implant placement and the subsequent provisional restoration of the inserted definitive abutment originate in the implant system and components used and are therefore limited in transferability. Only two second molar positions were treated throughout the study. Full-guided insertion of the implant was possible in both cases. In consideration of applying the workflow for second molar positions, challenges may arise more frequently to successfully conduct full-guided implant placement due to mouth opening. Further limitation was the time measurement of the entire implant procedure without differentiating the individual steps. Implant accuracy was measured using the CoDiagnostiX software algorithm. Although this tool is easy to use and has been widely used,[35] the algorithm is not completely transparent.

## 5 | CONCLUSIONS

Given the limitations of the specific workflow, it is possible to immediately restore a late-placed posterior implant using a prefabricated individual definitive abutment and subsequent provisional restoration as part of the SafetyCrown workflow. However, this treatment option is restricted by the requirement for adequate primary stability and proper mouth opening to perform fully guided implant insertion. The workflows of both groups achieved high patient satisfaction without differences in OHRQoL during the first week. Patients who received immediate loading valued the benefits more highly and expressed high satisfaction with the provisional restoration during the healing period. Although the workflow may increase the duration of the surgical appointment, it can eliminate the need for additional appointments for second-stage surgery and subsequent optical impressions.

## AUTHOR CONTRIBUTIONS

Lukas Waltenberger: Conceptualization (equal), Data curation (equal), Formal analysis (support), Funding acquisition (equal), Investigation (lead), Methodology (equal), Project administration (lead), Visualization (lead), Writing—original draft (lead). Sven Reich: Conceptualization (equal), Funding acquisition (equal), Methodology (support), Validation (support), Writing—review and editing (support). Marcel Zwahlen: Formal analysis (lead), Writing—review and editing (support). Stefan Wolfart: Conceptualization (equal), Dara curation (equal), Funding acquisition (equal), Investigation (equal), Methodology (equal), Project administration (support), Resources (lead), Supervision (lead), Validation (lead), Writing—review and editing (lead).

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## CONFLICT OF INTEREST STATEMENT

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## DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available on request from the corresponding author. The data are not publicly available due to privacy or ethical restrictions.

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