A Randomized Clinical Trial comparing the clinical fit of CAD/CAM monolithic zirconia Fixed Dental Prostheses (FDP) on ti-base abutments based on digital or conventional impression techniques. One year follow-up.

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Purpose: To compare the fit and clinical performance of screw-retained monolithic zirconia implant fixed dental prostheses (FDPs) based on either intraoral optical scanning (IOS) or conventional impressions. Materials and Methods: Patients with two posterior tissue-level implants (Straumann Regular Neck) replacing two or three adjacent teeth were recruited. Impressions were taken with both IOS (True Definition Scanner, 3M ESPE) and a conventional (polyether) pick-up impression. Double-blind randomization was performed
after impression-taking, and patients were to receive an FDP based on either the digital or the conventional impression. The fit was evaluated, and the time required for adjustments was recorded. Additionally, survival and technical complication rates with a follow-up of 1 year were documented. **Results:** A total of 38 patients requiring 45 FDPs were included: 24 FDPs in the test (IOS) and 21 in the control (conventional) group. The average adjustment time was 6.92 minutes (SD: ± 10.84, range: 0 to 49 minutes) for digital vs 12.38 minutes (SD: ± 14.52, range: 0 to 54 minutes) for conventional impressions ($P = .090$). A proper fit (no adjustments) was achieved in 33.3% of the digital and 28.6% of the conventional group. Forty-two FDPs could be placed within the two planned appointments, and 3 FDPs exhibited an unacceptable fit and required an extra appointment. Eight technical complications occurred during the first year of function. The overall restoration survival rate was 100%. **Conclusion:** The clinical fit of CAD/CAM FDPs based on digital impressions is comparable to conventional impressions. Screw-retained monolithic zirconia FDPs on Ti-base abutments show low major complication and survival rates in the short term. *Int J Prosthodont 2021. doi: 10.11607/ijp.7074*

**INTRODUCTION**

The use of CAD/CAM technology to produce dental implant restorations is widely applied and considered daily routine by many dental laboratories (1, 2). The introduction of intraoral optical scanning (IOS) has made these workflows even more efficient since the data necessary to create a digital design (CAD) is directly available (3). It makes the scanning of the analogue model obsolete. Also, most patients prefer IOS if compared to conventional impressions (4). For solitary restorations, IOS is currently widely applied and reported as a promising alternative for conventional techniques (5, 6). However, the accuracy of these digital impression systems is less important for solitary implant restorations than for multiple implant restorations. Since abutments are fabricated in the same industrial environment as the
implants – and should therefore fit together in a perfect manner - the only possible clinical issue with an inaccurate impression is the relative positioning of the crown to the implant. The latter can thus only lead to a too tight or loose interproximal- or occlusal contact or a rotated or tilted crown causing functional or esthetic concerns. For multiple-implant reconstructions, such as multi-unit Fixed Dental Prostheses (FDP), the accuracy of the chosen impression technique is more demanding. Not only the fit of the restoration on the implant is of significance but also the implant's position and angulation in relation to the other implants. Although individual components might have a perfect fit, two (or more) misinterpreted implant positions inevitably lead to an impassive fit. Especially for screw retained fixed implant restorations – which have become increasingly popular (7) – the achievement of a passive fit and thus an accurate impression is key (8). When screwed down into place a misfit can not be compensated for by, for instance a cement space and in the case of misfit, tension is introduced on the abutments and implants. For cement retained multi-implant restorations the cement space between the abutments and the FDP can compensate for a minimal misfit between the restoration and the abutment.

The introduction of monolithic CAD/CAM materials and their use in the digital workflow has opened the opportunity to increase efficacy in the dental laboratory (5, 9). In addition to the elimination of time-consuming anatomic ceramic veneering (10), the mechanical strength is improved because of the absence of these veneering materials. Veneering ceramics have a tendency to chip or fracture from their framework and high clinical complication rates have been reported in clinical studies (11, 12). These restorative technical complications might occur more frequently on implants than on natural teeth, since implants lack the flexibility of a periodontal ligament (13). Monolithic zirconia has promising characteristics as a restorative material for FDPs on implants (14). Its high flexural strength makes it less likely to fracture or
chip (15). Additionally, polished monolithic zirconia is said to be the least abrasive ceramic restorative material available (16-19). Nevertheless, clinical data to support the use of monolithic zirconia on implants is limited. Therefore, the objective of this randomized controlled clinical trial is to compare the fit and evaluate the clinical application of posterior CAD/CAM monolithic zirconia screw-retained FDPs on implants luted on ti-base abutments which have been produced on either IOS (digital impressions) or conventional (analogue) impressions. The hypothesis of this study was that digital implant impressions lead to shorter clinical adjustment times if compared to similar monolithic zirconia restorations made based on conventional impressions.

MATERIALS AND METHODS

Patient selection

The study was designed as a randomized controlled clinical trial. The test group comprises of restorations based on IOS, the restorations in the control group are based on conventional impressions. All patients were recruited at the department of Oral Implantology and Prosthetic Dentistry at ACTA, Academic Center for Dentistry Amsterdam. They had first undergone guided placement of soft-tissue level implants in the posterior area. The study protocol was approved by the regional ethical committee of VU-Medical Center, Amsterdam, the Netherlands (No. 2013-152NL43489.029.13). Patients provided signed written informed consents with permission to use their data for scientific purposes. All patient treatments were performed by the same clinician (WD). The study followed the CONSORT 2010 guidelines.

Patients were included based on the following inclusion criteria: 1) Partially edentulous adults. 2) Having two osseointegrated Straumann tissue level implants with an RN prosthetic connection in a quadrant, to replace two or three adjacent teeth in the posterior area.
Exclusion criteria were: 1) Signs of inflammation or peri-implant diseases at the time of implant impressions. 2) Implants that wouldn’t allow straight occlusal screw access within the contours of the future restoration. 3) Patients with known allergies to any of the used prosthetic components.

**Impression phase**

All patients underwent the same initial procedure since randomization was performed after the final impressions. All patients underwent a digital and a conventional impression procedure. First the digital impression was obtained: healing caps were removed, brand specific scan abutments (Straumann CARES RN Mono Scanbody) were screwed on the implants with 10Ncm (figure 2). Subsequently a thin layer of scan powder (3M High-Resolution Scanning Spray, Seefeld, Germany) was applied and a full-arch IOS was obtained using the True Definition Scanner (3M). Also a scan of the opposing arch, and a left and right bite scan in maximum intercuspation (MIP) were obtained. If the inter-occlusal space allowed, the scanbodies were left in place during the bite scan to facilitate more matching surface. After a thorough rinse, an open tray impression coping (Straumann RN synOcta impression cap) was placed and a conventional pick-up impression was taken using the earlier made individual tray (Lightplast base plate, Dreve Dentamid GmbH, Unna, Germany) and a polyether impression material (3M Impregum Penta) (figure 3). In case of an instable MIP or implants placed in Kennedy Class I or II patients (free-ending), a bite registration was obtained with 8mm RN bite registration aids (Straumann) using a vinyl polysiloxane bite registration material (Futar D, Kettenbach GmbH & Co, Eschenburg, Germany). The impression of the opposing arch was obtained using alginate (Cavex Impressional NS). Both the STL-file of the digital impression and the conventional impressions were sent to a dental laboratory and further processed within 24 hours.
Laboratory phase

After randomization a restoration was allocated to either the test- (IOS) or the control (conventional) group. Thus, the final restorations were all made based on only one of the two applied impressions methods. For the restorations in the conventional group, Straumann Mono Scanbodies were placed on the created stone cast (Primus goldbraun, Klasse 4 Dental GmbH, Augsburg, Germany) and these were digitized with a desktop laboratory scanner (3Series, Dental Wings Inc., Montreal, Canada). For the restorations in the digital group the open-source STL-files were imported in the laboratory CAD software (DWOS, Dental Wings) and the workflow was started with a model builder to design a 3D printed model (Dreve Dentamid GmbH, Unna, Germany) in which special repositionable implant analogs (Straumann) could be placed.

The following entire technical digital design and production (CAD CAM) procedure for both research groups would be completely identical. Therefore, the only difference between the test and control group was the method of impression taking and its required processing. Monolithic zirconia (3M Lava Plus) screw-retained implant FDPs on specific ti-base abutments designed for bridges (Straumann Variobase for bridge RN) were used. These abutments are non-engaging and have a flattop cone prosthetic shape to be luted into the FDPs (figure 3). All FDPs were fabricated in the same centralized milling facility (Straumann CAD/CAM-Center, Leipzig, Germany). The dental laboratory finalized and individualized the restorations by applying a thin layer of glaze and staining on non-contact surfaces (IPS e.max Ceram, Ivoclar Vivadent, Schaan, Liechtenstein). Depending on the study group, the luting was performed on either the conventional cast- or the 3D printed models. After low-pressure ($\leq 2\text{bar}$) aluminium oxide ($\leq 50\mu\text{m}$) sandblasting of the internal part of the zirconia, luting of
the FDPs onto the ti-base abutments was performed with luting composite (Multilink Hybrid Abutment, Ivoclar Vivadent) according to the manufacturer’s instructions (figure 4).

**Restorative phase**

3 weeks after impressions the patients were scheduled for placement of the final restorations. The placement of the restorations was performed double blind: the clinician did not receive any information on which impression method was ultimately used for the production process of that specific FDP. One experienced clinician (WD) performed all fit examinations. After removal of the healing abutments the FDPs were tried in. First the screw resistance was checked to confirm passivity. If any increase in resistance was felt, while tightening the occlusal screw, before complete seating during hand tightening, the interproximal contacts were controlled with dental floss, corrected if necessary, and complete passive seating was assessed again. First, Waxed Floss (Reach, Johnson & Johnson, Brunswick, USA) was used. If this floss would not give enough tug-back a thicker Waxed Dentotape (Reach, Johnson & Johnson) was used. If this dentotape would give sufficient tug-back, the contact was quantified as being slightly weak but clinically acceptable. If not, the contact was too weak and deemed unacceptable. Additionally, a perpendicular periapical radiograph was taken to confirm proper seating (figure 5).

This was followed by checking the occlusion with 12µ occlusion foil and 8µ shimstock (Hanel, Coltène Whaledent, Langenau, Germany) to confirm occlusal contact. If there was imprint with the occlusion foil but no tug-back with the shimstock the occlusal contact was considered weak but clinically acceptable. If there was no coloured imprint of the occlusion foil the occlusion was deemed unacceptable.
If any corrections were deemed necessary on the contacts or occlusion a stopwatch was started and the time (in minutes) needed to perform these corrections was recorded. Corrections were performed with fine diamond burrs with a maximum grit size of 50µ (red ring) and copious water-cooling. The corrected surfaces were afterwards polished for at least 2 minutes per touched surface with a specific zirconia polishing kit (eZr, Garrison, Spring lake, USA). The correction and polishing was, where possible, performed extra-orphally. After final placement, the screw access channel was cleaned with a specific agent which removes phospholipids due to saliva contamination (Ivoclean, Ivoclar Vivadent). Subsequently teflon tape was applied to protect the occlusal screw, followed by the application of an MDP-containing bonding agent (Scotchbond Universal, 3M), and a dentin-shade occlusal composite restoration (Filtek Supreme XTE, 3M).

Directly after placement of the restoration the clinician filled in a questionnaire stating if it was either a 1) Proper fit (no adjustments required), 2) Adjustment-requiring fit, or 3) Unacceptable fit (laboratory intervention required). The location(s) of these corrections and the extra time necessary to perform the corrections and subsequent polishing were noted per restoration. An unacceptable fit was present in case of incomplete seating of one of the abutments, a complete lack of occlusion and/or interproximal contacts (see above), or such extreme over-contouring that corrections or complete remake in the laboratory were deemed necessary. In case of an unacceptable fit, a new set of digital and conventional impressions plus bite registrations was immediately taken. For these unacceptable fit cases the documented correction time for statistical purposes was determined at 40 minutes (the time lost by the extra appointment) plus the time of possible adjustments during the (extra) third session.
Follow-up

All patients were recalled 1 year after placement of the restorations. In addition to overall survival of the restoration the following possible restorative complications were documented:
1) Screw loosening, 2) Ceramic fracture, 3) Ceramic chipping, 4) De-cementation from the titanium-base abutments, and 5) Loss of the occlusal composite restoration.

Outcomes

A distinction was made between FPDs with Proper fit, Adjustment-requiring fit, or Unacceptable fit. The primary outcome variable was the time required (in minutes) for potential adjustments at the time of placement of the FDPs. Additionally, the locations of these adjustments were recorded (occlusal and interproximal: mesial and distal). As secondary outcome variable the survival and technical complications of these implant restorations during the first year of function were reported.

Sample size

Performing a proper sample size calculation was complicated since at baseline very limited comparable data was available. One study performed clinical fit comparison of conventional vs digital impressions for crowns on natural teeth (20). A difference of 20 µm in marginal gap fit of single crowns in favor of digital impressions (SD: 15 µm) vs conventional impressions (SD: 25 µm) was reported. The question remains if these differences are representative for the clinical evaluation of fit in our study. One of the parameters checked in our study is the occlusion. The thinnest occlusion foil used to judge if a restoration is too high is 12 µm thick. This would mean that the reported difference of 20 µm could be clinically significant. Based on this difference in precision of 20 µm, a power level of 0.90 and a probability level of 0.05 a minimum total sample size (two-tailed hypothesis) of 48 was calculated.
Randomization

Randomization was performed with a predesigned plan. Two groups of 25 sealed envelopes containing information to which study group a case was divided - were created. All envelopes were prepared by an independent researcher and marked with a randomly generated code. This code was used for all further registrations by the clinician. The list of codes and their associated research groups were only accessible by the statistician. Per implant restoration one of these sealed envelopes was randomly selected by the independent researcher and sent together with the impressions to the dental laboratory. The clinician was therefore blinded to which impression the dental technician would use to produce the subsequent restoration. If a patient would require more than one multiple implant FDP, the second FPD would be restored using the alternative impression technique. Any third FDP would be randomised again and a forth FDP would routinely be the different from the third again. Therefore, any patient included in the study with more than one FDP is inevitably included in both study groups. This was done to minimize potential patient factors.

Statistics

All data analyses were carried out according to a pre-established analysis plan. During data collection there was no knowledge about which research group the patient’s restoration was assigned to. The data was analyzed using SPSS version 24 (SPSS, Chicago, IL, USA). Data was analyzed at restoration level. For the primary outcome variable - the correction time in minutes per restoration – a Shapiro-Wilk test of normality was first performed to confirm - the expected - non-normal distribution. Further comparison between test and control groups – was performed using Wilcoxon rank sum tests (Mann-Whitney U). The secondary outcome variables were reported with descriptive statistics only.
RESULTS

Initially 41 patients requiring 48 two-implant-FDPs were initially recruited for the study. Three patients all with one FDP dropped out before placement of the final restoration: one patient was diagnosed with a life-threatening disease; one patient lost a neighboring tooth and the treatment plan was altered and one patient decided to withdraw from the study for personal reasons. With that, 38 patients with 45 two-implant-FDPs were eventually included in the study. Overall 21 splinted crowns (2-FDP) and 24 three-unit bridges (3-FDP) were produced. Of these 45 restorations, 22 FDPs had a neighboring tooth distal to the restoration (posterior support present) and 23 FDPs were created in a free-ending situation. The randomly assigned test group consisted of 24 and the control of 21 FDPs respectively. An overview of the included FDPs is given in table 1. Thirty one patients received one FDP and 7 patients received two FDPs. The inclusion- and randomization process was schematically illustrated in a flowchart (figure 7).

A proper fit - without any corrections – occurred in eight of the 24 (33,3%) FDPs in the test and six of the 21 (28,6%) FDPs in the control group respectively. In the test group, fifteen FDPs (62,5%) required adjustment prior to placement and were therefore classified as 'adjustment-requiring fit' vs. thirteen FDPs in the control group (61,9%) respectively. One FDP (a three-unit bridge) in the test group (4,2%) was classified as unacceptable because of a complete absence of occlusal contact. Two FDPs (both three-unit bridges) in the control group (9,5%) had an unacceptable fit: one didn’t have any occlusal contact, whereas the other had such high occlusion that chair-side correction was not deemed possible. The time required for adjustments in the test group ranged from 4-28 minutes, but with the second appointment required for the unacceptable fit case - and its subsequent adjustments - the range was 4-49
minutes. Eight of FDPs in the test group needed occlusal adjustment (33.3%), of one FDP the occlusion was slightly weak on one tooth but clinically acceptable and one – as stated above - had a complete absence of occlusion (8.3%). Ten FDPs in the test group had a too tight mesial contact (41.7%) and one (of the twelve FDPs that had distal neighboring tooth) needed distal contact correction (8.3%). For the FDPs in the control group, the correction times required ranged from 6-29 minutes, but 6-54 minutes with the unacceptable fit FDPs - and their subsequent second appointment – were included. Thirteen FDPs exhibited a too high occlusal contact (61.9%) and one – as stated above - had a complete lack of occlusion (4.8%). Nine had a too tight mesial contact (42.9%) and two (of the ten FDPs that had distal neighboring tooth) needed distal contact correction (20%).

The average adjustment time required in the IOS (test) group was 6.92 min (SD ±10.84, range: 0-49 min) vs. 12.38 min (SD ±14.52, range: 0-54 min) in the conventional impression (control) group. The differences between the adjustment time between the test and control group did not reach statistical significance (p=0.090). The clinical adjustment times and possible corrections are summarized in table 2.

During the first year of function eight technical complications occurred in the 45 included FDPs. The overall technical complication rate was therefore 17.8%. The most common complication was de-cementation of the zirconia FDP from the titanium abutments: six times overall (13.3%). In both test and control groups, it happened once on a two-unit and twice on a three-unit FDP (figure 6). The other two technical complications were a loss of the composite restoration sealing the occlusal screw access (4.4%), both happened in the test group. All complications could be solved within one appointment and were therefore classified as minor complications. No major complications - such as chipping or fracture - occurred. Therefore, the overall survival of the 45 included FDPs was 100% after one year of
function. The survival and complication rates of the FDPs recalled after one year are reported in table 3.

**DISCUSSION**

The aim of this randomized clinical trial was to compare the use of digital vs. conventional impression techniques for application in the digital workflow in the laboratory phase to produce monolithic zirconia screw-retained implant FDPs on two implants. The use of IOS as impression technique is gaining popularity especially when combined with monolithic CAD/CAM materials since the majority of the production process is digital (9). Our study evaluated the clinical adjustment times of these restorations based on either IOS or conventional impressions and demonstrated that IOS seems to perform at least similar to conventional impression techniques. The average adjustment times were actually lower in the IOS group than in the conventional group. Nevertheless, a statistically significant difference was not found since the values were so widely distributed: large differences in average adjustment time and corresponding high standard deviations were present in both groups. Therefore, the hypothesis that digital impression would lead to shorter clinical adjustment times could not be accepted based on these findings. Separate statistical test (Wilcoxon rank sum tests (Mann-Whitney U) was also performed to see if free-ending situations vs. restorations a with a distal contact and 2-unit FDPs vs 3-unit FDPs could have had an influence on the results (table 1). The only significant difference found was that in general (test and control groups combined) 2-unit FDPs on average had shorter clinical adjustment times than 3-unit FDPs ($p=0.027$).

The current study only focused on the time required for adjustment during placement of the restorations. In the entire workflow other possible time differences, such as time required for
the impression phase and the time required in the laboratory, are relevant too. Other studies have also focused on these time-related factors and showed higher efficacy for digital impressions and fully digital workflows (9, 21).

Occlusion appears to be the most challenging factor in achieving a proper fit. It was the reason for rejecting three of the 45 restorations (unacceptable fit) and was moreover a common location for required corrections. Especially in the conventional group most restorations that didn’t have a proper fit presented issues considering the occlusion. Of the fifteen FDPs without a proper fit in this control group fourteen exhibited issues with the occlusion. In the test group (IOS) this number was lower: ten of the sixteen FDPs without a proper fit had issues with occlusion. Although hard conclusions cannot be drawn from these figures the differences could be explained by the challenge of bite-registrations in the conventional workflow. Bite registrations in the digital workflow are not only performed intraorally but also directly saved accordingly. In conventional workflows bite registrations are also executed intraorally but the subsequent processing of the registered bite is performed in the laboratory. This means that any irregularity in the stone casts or bite registration material could prevent proper seating of the casts in MIP. Therefore, the bite could subsequently be digitized in a wrong position and further production will thus be affected. Still, bite registrations performed by IOS are not flawless either, even different scanners result in different occlusal registrations(22). Moreover, it is the authors opinion that free-ending situations with multiple missing teeth in one of the jaws complicates these bite registration scans and could therefore result in more error. Ongoing research (and development) is indicated to validate and improve these workflows.
In the current study full-arch intraoral scans were used in. Since the study deals with partial edentulism the application of partial scan would also have been a possible in selected cases. Retrospectively this might have been more accurate since recent data supports improved accuracy for partial scans (23, 24). This effect especially seems to influence the overall digitized shape of entire jaw in contrary to the local trueness. The occlusion is therefore more likely to be affected by this matter than the inter-proximal contacts. The possible beneficial effect of a digital bite registration in comparison to conventional impressions might have been even larger if partial impressions were used. Nevertheless, this is hypothetical and should be investigated with other clinical studies. Moreover, full arch impressions offer the possibility to perform dynamic occlusion simulations allowing corrections on working- and non-working sides. This effect should also not be neglected and needs further investigation for application in the digital workflow.

Implant angulation could play a role in the accuracy of implant impressions(25). In the current study the risk of bias due to differences in angular deviations between the implants was reduced by placing all implants utilizing computer guided surgery: all implants – within one restoration - were preferably planned parallel or - if anatomy demanded it - with a maximal deviation of 8 degrees.

Clinical fit, evaluated on occlusion and contacts, was the primary outcome of this study. Nonetheless, passivity also plays a key role in the fit of FDPs. Screw resistance and radiographs were used of confirm passivity and complete seating of the restorations. The best way to perform clinical evaluation of passive fit is however debatable (26). A well-angulated perpendicular periapical radiograph can be used to identify misfit as small as 12.7µm (27), nevertheless an acceptable marginal fit on an x-ray is not always proof of a passive fit (28).
What can be conceived retrospectively is that the relatively high number of de-cementations could have been an indication of non-passive fit in those restorations. The used ti-base abutments for bridges have very little mechanical retention due to its flat-cone prosthetic shape (figure 1). It is the author’s estimation that a prosthesis misfit could lead to tension in the luting cement layer ultimately (or immediately) leading to de-cementation of the abutment from the zirconia FDP. Probably this is only noticed when the other abutment also de-cements several days later. The rationale for this, is that all FDPs that de-cemented in the study were re-luted to the abutments intraorally, unscrewed and polished extra-orally and reconnected to the implants with screw-retention. This – by definition - leads to a more passive fit than luting on a cast (or 3D-printed model) and till date no second de-cementation was seen in these cases.

The less-retentive shape of the used abutments could be an explanation for the relatively high number of de-cementations. Using an abutment with a more retentive coronal shape could potentially decrease the chance of de-cementation. Nevertheless, a more retentive (stronger) ti-base to zirconia connection could ultimately lead to other – more dramatic - problems if tension is present. Currently the weakest link appears to be the connection between abutment and restoration. If this connection is reinforced, the restorative material or the implant itself might be "at risk".

An unacceptable fit is clearly the worst outcome when assessing clinical fit. It often means that a new impression or bite-registration needs to be obtained. In the current study an unacceptable fit occurred once in the digital- and twice in the conventional group respectively. Due to the relatively small group sizes and its rare occurrence it is impossible to draw statistical conclusions on this matter. In case of an unacceptable fit it was decided to
take new impressions immediately and perform the same clinical fitting protocol in an additional appointment. In this particular protocol the length of an appointment was 40 minutes, therefore this number was added to the second clinical fitting time. Although these 40 minutes are somewhat arbitrary since every clinician employs different appointment lengths, the same can be stated for the time required for corrections. Retrospectively the three cases with an unacceptable fit had adjustment times of 44, 49 and 54 minutes respectively and it remains disputable if these numbers give a realistic appreciation of such unfavorable event. To rule out if these figures influenced the statistics unrealistically the same statistical test was performed with these three restorations excluded, which also didn’t give a statistically significant difference between the two groups.

In the current study only one restoration was tried in (and placed). Alternatively, two restorations could have been made per implant pair which would have resulted in larger groups and - with that – more power. However, the study was specifically designed as a randomized clinical trial and long-term follow-up of the two groups (conventional and digital impression based) is planned. Therefore, it was decided to only create (and place) one restoration per implant pair instead of trying both and only placing the best fitting restoration.

The current study only presented minor technical complications. The loss of occlusal screw-access composite and de-cementation from the abutments are both complications that can be restored without any further compromise of the FDPs. No ceramic chipping or fractures were reported during the first year of function in the current study. This is in contrast to high numbers of chipping as reported in other clinical studies on FDPs (11, 29, 30). This difference could be attributed to the fact that these studies all used veneered zirconia restorations. In our study monolithic zirconia restorations were applied which might explain the absence of
chipping or fractures because of its high flexural strength. Nevertheless, also long-term clinical evaluation of this material is necessary since these other studies also showed complications occurring between 1 and 5 years after placement. These long-term evaluations are also deemed necessary to evaluate potential tooth wear and other antagonist complications.

Conclusions

Based on the findings in the present study, the following conclusions can be summarized:

- The clinical fit and required adjustments of two-implant CAD/CAM monolithic zirconia screw-retained FDPs based on full arch intraoral optical scanning (IOS) are comparable to conventional impressions.
- Screw retained monolithic zirconia FDPs supported by two implants exhibit low major complication rates and 100% restoration survival on the short term (one year follow-up).

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Figure 1. Digital impression (IOS) with Straumann Mono Scanbodies
Figure 2. Conventional impression posts for pick-up impression
Figure 3. Non-engaging ti-base abutment for bridges
Figure 4. Monolithic zirconia FDP luted on two non-engaging ti-base abutments.

Figure 5. Perpendicular periapical radiograph to confirm full seating of a FDP
Figure 6. Decementation of the three-unit zirconia FDP form flat-cone-shaped the abutments.
Figure 7. Flowchart of inclusion, randomization and follow-up

- 41 pt. / 48 FDPs recruited
- 3 pt. / 3 FDPs dropped-out
- 38 pt. / 45 FDPs included

- Both impressions applied
- Send to laboratory
- Casts of all pt. processed (poured & downloaded)

- Randomisation applied

- Test group
  - (Digital impression)
  - 24 FDPs

- Control group
  - (Conventional impression)
  - 21 FDPs

- 24 FDPs in test group fulfilled 1-year follow-up
- 21 FDPs in control group fulfilled 1-year follow-up

- 45 monolithic zirconia screw-retained 2-implant FDPs on ti-base abutments fulfilled 1-year follow-up
Table 1. Overview of included restorations with average adjustment times

<table>
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<th>AVG Adjustment time</th>
<th>P-values (test vs control)</th>
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<td>Total</td>
<td>45</td>
<td>9.47 min (SD ± 12.84)</td>
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<td>2-unit FDP</td>
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<td>Total</td>
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<td>4.43 min (SD ± 4.79)</td>
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<td>3.20 min (SD ± 3.01)</td>
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<td>5.55 min (SD ± 5.91)</td>
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<td>3-unit FDP</td>
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<tr>
<td>Total</td>
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<td>13.88 min (SD ± 15.88)</td>
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<td>9.57 min (SD ± 13.55)</td>
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<tr>
<td>Free-ending</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td>23</td>
<td>11.52 min (SD ± 15.13)</td>
<td>0.509</td>
<td></td>
</tr>
<tr>
<td>Test group</td>
<td>12</td>
<td>9.83 min (SD ± 14.43)</td>
<td>0.532</td>
<td></td>
</tr>
<tr>
<td>Control group</td>
<td>11</td>
<td>13.36 min (SD ± 16.35)</td>
<td>0.532</td>
<td></td>
</tr>
<tr>
<td>With distal tooth</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td>22</td>
<td>7.32 min (SD ± 9.80)</td>
<td>0.509</td>
<td></td>
</tr>
<tr>
<td>Test group</td>
<td>12</td>
<td>4.00 min (SD ± 4.35)</td>
<td>0.068</td>
<td></td>
</tr>
<tr>
<td>Control group</td>
<td>12</td>
<td>11.30 min (SD ± 13.00)</td>
<td>0.068</td>
<td></td>
</tr>
</tbody>
</table>
Table 2. Fit and possible adjustments of two-implant FDPs based on IOS (test) vs. conventional (control) impressions.

<table>
<thead>
<tr>
<th>Two-implant FDPs based on</th>
<th>Digital impression</th>
<th>Conventional impression</th>
</tr>
</thead>
<tbody>
<tr>
<td>Proper fit</td>
<td>8 (33,3%)</td>
<td>6 (28,6%)</td>
</tr>
<tr>
<td>Adjustment-requiring fit</td>
<td>15 (62,5%)</td>
<td>13 (61,9%)</td>
</tr>
<tr>
<td>Unacceptable fit</td>
<td>1 (4,2%)</td>
<td>2 (9,5%)</td>
</tr>
<tr>
<td>Location of adjustments/inaaccuracies</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Occlusal - too high</td>
<td>8 (33,3%)</td>
<td>13 (61,9%)</td>
</tr>
<tr>
<td>Occlusal - too weak</td>
<td>2 (8,3%)</td>
<td>1 (4,8%)</td>
</tr>
<tr>
<td>Mesial contact - too tight</td>
<td>10 (41,7%)</td>
<td>9 (42,9%)</td>
</tr>
<tr>
<td>Mesial contact - too loose</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Distal contact, if present - too tight</td>
<td>1/12 (8,3%)</td>
<td>2/10 (20%)</td>
</tr>
<tr>
<td>Distal contact, if present - too loose</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Average time required for corrections</td>
<td>6.92 min (SD ±10.84)</td>
<td>12.38 min (SD ±14.52)</td>
</tr>
<tr>
<td>Statistical analysis (Wilcoxon rank sum tests)</td>
<td></td>
<td>(p=0.090)</td>
</tr>
</tbody>
</table>
Table 3. Clinical performance of monolithic zirconia two-implant FDPs on ti-base abutments during the first year of function.

<table>
<thead>
<tr>
<th></th>
<th>Two-implant FDPs based on</th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Digital impression</td>
<td>Conventional impression</td>
<td>Total</td>
<td></td>
</tr>
<tr>
<td><strong>Baseline</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>n= 24</td>
<td>n= 21</td>
<td>n= 45</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Implants lost (without prosthetic reason)</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>One year follow-up</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>n= 24</td>
<td>n= 21</td>
<td>n= 45</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Complications:</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Screw loosening</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>- (0.0%)</td>
</tr>
<tr>
<td>Ceramic fracture</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>- (0.0%)</td>
</tr>
<tr>
<td>Ceramic chipping</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>- (0.0%)</td>
</tr>
<tr>
<td>Decementation from ti-base abutment</td>
<td>3</td>
<td>3</td>
<td>6 (13.3%)</td>
<td></td>
</tr>
<tr>
<td>Loss of occlusal composite restoration</td>
<td>2</td>
<td>-</td>
<td>2 (4.4%)</td>
<td></td>
</tr>
<tr>
<td><strong>Restoration survival (one year)</strong></td>
<td></td>
<td></td>
<td></td>
<td>100%</td>
</tr>
</tbody>
</table>