Three-year follow-up of a Randomized Clinical Trial on screw-retained monolithic zirconia restorations on ti-base abutments based on digital or conventional impression techniques.

Wiebe Derksen¹, Daniel Wismeijer¹

1. Section of Oral Implantology and Prosthetic Dentistry, Academic Centre for Dentistry Amsterdam (ACTA), Amsterdam, The Netherlands

Authors Contribution: WD & DW conceived the ideas, WD collected the DATA, WD analyzed the data, and WD & DW led the writing.

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.

The study protocol was approved by the regional ethical committee of VU-Medical Center, Amsterdam, the Netherlands (No. 2013-152NL43489.029.13) and was performed in accordance with the Declaration of Helsinki guidelines on medical human research ethics.

Please address correspondence or requests for further information to:
Wiebe Derksen
Section of Oral Implantology and Prosthetic Dentistry
Academic Centre for Dentistry Amsterdam (ACTA)
Gustav Mahlerlaan 3004
1081 LA Amsterdam
The Netherlands
Tel. + (31) (0)20-5980412
e-mail: w.derksen@acta.nl

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Purpose: To report on the follow-up of two earlier published RCTs on the performance of screw-retained monolithic zirconia restorations on Ti-base abutments based on intraoral optical scanning or conventional impressions. Materials and Methods: A total of 54 patients receiving 89 restorations (44 single crowns [SC]), 21 splinted crowns [2-FDP], and 24 three-unit fixed partial dentures (3-FDP)] were included in the 1- to 3-year follow-up period. The
restoration survival and technical complications were documented. **Results:** A total of 50 patients with 84 restorations completed the 3-year follow-up. One 3-FDP from the IOS group was lost. This resulted in survival rates of 97.9% for the test and 100% for the control restorations and an overall survival rate of screw-retained monolithic zirconia restorations on implants of 98.8% after 3 years. There was no statistically significant survival difference between the test and control groups ($P = .362$). When evaluated separately, a 100% survival rate for SCs and 97.7% rate for 2-FDPs was reported. One decementation and three occurrences of screw loosening occurred over the 1- to 3-year follow-up. The multiple-implant restorations showed higher (23.3%) complication rates at the restoration level than the SCs (4.9%) after 3 years of function ($P = .026$). **Conclusion:** Screw-retained monolithic zirconia restorations on Ti-base abutments show promising survival rates after 3 years of function. Restorative complications of screw-retained monolithic zirconia restorations on Ti-base abutments are more likely to happen in the first year of function and are more common in multiple-implant restorations than solitary crowns. The impression (IOS or conventional) does not seem to influence these results. *Int J Prosthodont* 2022. doi: 10.11607/ijp.7891

**INTRODUCTION**

Zirconia-based CAD/CAM restorations used to restore dental implants are increasingly applied and considered daily routine for most dental laboratories (1, 2). The introduction of intraoral optical scanning (IOS) has made workflows involving CAD/CAM manufacturing protocols even more efficient since the data necessary to create a digital design (CAD) is directly available (3). Traditionally these zirconia-based restorations are veneered with ceramic to improve esthetics. Nevertheless, veneered ceramics have a tendency to chip or fracture from their framework and high complication rates involving the ceramics have been reported in clinical studies (4, 5). Recently tooth-colored monolithic zirconia restorations
have been introduced and these could potentially diminish the risk of ceramic chipping or fracture due to its high strength (6, 7). The latter can especially be beneficial for implant-borne prosthetics since implants lack the flexibility of a periodontal ligament (8). Therefore, the shock-absorbing mechanism of a natural root is missing and restorations might me more prone to chipping. Other monolithic materials, such as lithium disilicate, are also frequently used for solitary implant restorations (9). Nevertheless, monolithic zirconia – due to its higher flexural strength – also has promising characteristics as a restorative material for multiple-implant Fixed Dental Prostheses (FDP) (10).

Screw-retained implant restorations are increasingly popular due to their retrievability and -potentially - less biological complications (11). Screw-retained restorations however tend to show more technical complications such as porcelain fracture or chipping (12, 13). These conclusions however were all based on data on veneered restorations and could consequently been attributed to the impairment of the structural continuity of occlusal veneering porcelain due to the screw access hole. Therefore, a decreased resistance to ceramic-chipping - if compared to cemented restorations - could be expected. It is predicted that monolithic materials are more resistant to ceramic fracture and chipping, especially in screw-retained cases (7). This could be a potential benefit for the application of monolithic zirconia in solitary- and multiple-implant screw-retained restorations.

Long-term clinical data on the use of monolithic zirconia on implants is limited (14-18). Also, it is not known if monolithic zirconia restorations benefit from the application of a digital workflow - applying IOS – on the long term (16, 17).
Therefore, the objective of the follow-up of this randomized controlled clinical trial was to report on the three-year survival and complication rates of posterior CAD/CAM monolithic zirconia screw-retained SCs and FDPs on implants luted on ti-base abutments and to evaluate if the method of impression taking - conventional (control) vs digital (test) - has an influence on the long-term outcome. The null-hypothesis of this study was that the use of IOS leads to better long-term survival and reduced complication rates for monolithic zirconia screw-retained SCs and FDPs luted on ti-base abutments when compared to similar restorations made on conventional impressions. This study is a follow-up of the one-year data of two separately published RCTs on solitary crowns and multi-unit fixed dental implant prosthesis (16, 17).

MATERIALS AND METHODS

The inclusion criteria, treatment procedures and study protocols were specified previously in detail (16, 17). Both RCTs followed exactly the same treatment- and study protocol except for the indication: single tooth replacement vs partial edentulism requiring two implants supporting a FDP. In brief, a total of 55 patients were included, receiving 90 monolithic zirconia restorations on 135 implants: 45 solitary crowns (SC), 21 splinted crowns (2-FDP) and 24 three-unit bridges on two implants (3-FDP). All implants were tissue level implants with a 1.8mm collar and RN connection (Institut Straumann AG, Basel, Switzerland). The solitary restorations were monolithic zirconia (3M Lava Plus, Seefeld, Germany) screw-retained implant crowns luted on ti-base abutments (Straumann Variobase for crown RN AH 4mm). The multiple-implant restorations were both also screw-retained monolithic zirconia restorations (3M Lava Plus) but luted on specific non-engaging ti-base abutments (Straumann Variobase for bridge RN).
Impression phase

All patients underwent the same initial procedure since randomization was performed after the final impression taking. All patients underwent a digital- (IOS) and a conventional impression procedure. First the IOS was obtained with the 3M™ True Definition Scanner using Straumann Mono scanbodies. This was followed by a conventional pick-up impression with a polyether impression material (3M Impregum Penta). The randomization was hereinafter performed per restoration by an independent person. The clinician was blinded to which impression method was be used in the dental laboratory.

A restoration would either be made based on the IOS (test) or on the conventional impression (control).

Laboratory phase

The only difference between the test and control group was the method of impression taking and its required processing (i.e. the digitization of the poured conventional impressions vs. uploading the IOS). All restorations were subsequently designed using the same laboratory CAD software (DWOS, Dental Wings) and milled in a centralized milling facility (Straumann CAD/CAM-Center, Leipzig, Germany). The restorations were finalized in the dental laboratory and - depending on the study group - the luting was performed on either the 3D printed- (Dreve Dentamid GmbH, Unna, Germany) or the conventional cast models for the test and control groups respectively. After low-pressure (≤ 2bar) aluminium oxide (≤ 50μm) 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.

Restorative phase
3 weeks after impression taking the patients were scheduled for placement of the final restorations. Corrections, if necessary, were performed with fine diamond burrs with a maximum grit size of 50μ (red ring) and copious water-cooling. The corrected surfaces were then polished for at least 2 minutes per touched surface with a specific zirconia polishing kit (eZr, Garrison, Spring lake, USA). The screw access channel restorations were performed with a dentin-shade (2-3mm thick) occlusal composite restoration (Filtek Supreme XTE, 3M), after teflon tape application, cleaning of the screw access channel with a specific agent (Ivoclean, Ivoclar Vivadent), and the application of an MDP-containing bonding agent (Scotchbond Universal, 3M).

**Follow-up**

All patients were recalled 1 and 3 years after placement of the restorations. Additionally, all patients were instructed to visit our clinic if any complications would occur. Next to overall survival of the restoration the following possible technical complications were documented: 1) Screw-loosening, 2) Ceramic fracture, 3) Ceramic chipping, 4) De-cementation from the ti-base abutments, and 5) Loss of the occlusal composite restoration. The 1-year follow-up results were published earlier; only one patient with a SC dropped-out because of implant loss during this first year (16, 17). Because of this earlier dropped-out patient, 54 patients with 89 restorations were included in the currently studied 1-3-year interval.

**Statistics**

All data analyses were carried out according to a pre-established analysis plan. The three-year follow-up data of the monolithic zirconia restorations on implants is presented in descriptive statistics. The comparison between test and control groups was performed with a Chi-Square test. The comparison between different restoration types was performed using
the Fisher exact test. The level of significance was set at $\alpha = 0.05$. All statistical tests were performed at restoration level.

RESULTS

50 patients fulfilled the three-year follow-up. Two patients (both with a SC) couldn’t be reached and two other patients (with a 2-FDP and a 3-FDP) had moved to another country and were therefore unavailable for clinical examination. One patient with a SC received a different implant restoration because of the loss of her neighboring tooth. Since this patient had more than one implant-restoration included in the study, she did not dropout of the study since her other restorations were still included. Her dropped-out SC did not show any technical problems at the day of replacement by another reconstruction (14 months after placement). With that, 84 restorations were evaluated clinically during the 1-3-year interval and could be included in the analyses.

One 3-FDP from the digital group was lost during this interval due to repetitive de-cementation; it was decided to replace the bridge for a new reconstruction with a different abutment design. This resulted in a survival rate of 97.9% for test and 100% for control restorations and an overall survival rate of screw-retained monolithic zirconia restorations on implants of 98.8% after three years. There was no statistically significant difference between test and control group ($p = .362$). When evaluated separately (per type of restoration) 100% survival rate of solitary restorations and 97.7% for two-implant FDPs (splinted crowns and 3-unit FDPs combined) could be reported. The restoration survival rates were summarized in table 1.
In addition to the - in earlier publications reported (16, 17) – restorative complications during the first year of follow-up, some restorative complications also occurred during the 1-3 year interval. For the SCs there was only one event: a mandibular molar crown in the test group exhibited screw-loosening 1 year and 3 months after placement. For the FDPs, screw-loosening occurred two times, both in the control group, once on a 2-FDP and once on a 3-FDP after 2 years and 3 months and 2 years and 5 months respectively. Also, one de-cementation occurred on a 3-FDP in the digital group, 13 months after placement. Since de-cementation of this same bridge also occurred two months earlier – during the first year of follow-up – it was decided to replace the bridge; leading to the only restorative failure in this study. In three years of follow-up, ceramic fracture or chipping did not occur once. The details on the restorative complications - including the complications that had occurred during the first year of follow-up – are summarized in table 2.

Since some restorations had more than one complication, also the number of restorations that had (one or more) complications was calculated. In the test group 14.0% and in the control group 17.1% of the restorations suffered from one or more complication(s). Consequently 85.7% of the 84 monolithic zirconia restorations that met the three-year follow-up functioned without any technical complications. Most complications occurred between baseline and the one-year follow-up (10.1%) in contrast to the 4.8% complications in the 1-3-year interval. De-cementation of the ti-base abutment(s) - with 9.8% occurrence in 3 years - was the most common complication. This complication only happened once (2.4%) on a SC and seven times (16.3%) on a two-implant FDP. While de-cementation merely occurred in the first year of follow-up, screw-loosening was seen more often in the last follow-up interval: it happened once (1.1%) between baseline and one the year vs. three times (3.6%) in 1-3-years follow-up respectively.
The multiple implant FDPs showed statistically significantly higher (23.3%) complication rates at restoration-level than the SCs (4.9%) after three years of function \((p = .026)\). At restoration-level there was also a distinct difference between the splinted crowns and three-unit bridges: 15.0% vs 30.4% respectively. This difference however did not reach a statistical significance \((p = .294)\). During the 1-3-year period no loss of occlusal restorations was reported. The complications of 2-FDPs and 3-FDPs are summarized in detail in table 3.

At restoration-level there was no statistically significant difference \((p = .929)\) in the occurrence of complications between the test (14.0%) and control group (14.6%).

**DISCUSSION**

The initial aim of this RCT was to compare IOS vs. conventional impression techniques for the application of the digital workflow in the laboratory phase to produce monolithic zirconia screw-retained implant restorations. After earlier reporting on the initial results and short-term follow-up (16, 17) the current study focused on the 3-year follow-up of these restorations. Promising survival rates were reported, with 98.8% survival rate for all 84 restorations that fulfilled the three-year follow-up. SCs even demonstrated 100% survival rate, which is in line with high survival rates reported in other publications on monolithic zirconia solitary implant restorations (7, 14). Also the multiple-implant-FDPs showed very promising survival rates, which is in line with another prospective clinical study on the use of monolithic zirconia for multiple-implant-FDPs (15). Both this 5-year follow-up study and the current clinical trial showed no ceramic chipping. Nevertheless, one zirconia fracture occurred during the follow-up of the other study, for which no clear explanation could be given. Although the conclusions and clinical success might be similar to the current study, applied restoration
abutment is entirely different since they used a 'Cone-in-cone' connection instead of screw-retained or cemented restoration.

Direct screw-retention on implants for multiple-implant reconstructions - as applied in the current study - without a primarily placed separate implant abutment might result in more technical complications. Although very little is known about the consequences of impassive fit on the long term for implant survival, it is known that any implant impression leads to impassivity if multiple implants are splinted (19). This can be explained due to the fact that a master cast is never completely identical to the clinical situation (20). Some authors concluded that abutment screw-loosening more often occurred in screw-retained vs. cemented multiple-implant reconstructions (13). In combination with the theory that - produced under the same controlled conditions - cemented FDPs show a more passive fit than screw-retained FDPs, one could conclude that the abutment screw-loosening might have been caused by impassivity (21).

In the earlier published FDP article on this study cohort it was already advocated that the high number of de-cementations in the FDPs could have been caused by impassive fit of these restorations (17). Instead of abutment screw-loosening, the zirconia bridges de-cemented from the abutments. The non-retentive flat-cone abutments used in the current protocol might be the weakest link possibly explaining this phenomenon. As seen in the current study most de-cementations occurred in the first year of function and were - except for one abutment - re-cemented intra-orally. This one particular restoration could not be re-cemented in the patient’s mouth because of mucosal overgrowth and was therefore cementation was performed on the master cast. This particular restoration de-cemented again and resulted – after its second de-
cementation – in the only restorative failure of this study. All intra-orally (passively) re-
cemented restorations functioned uneventfully in the additional two years of follow-up.

Interestingly, screw-loosening did occur more frequent in the 1-3-year follow-up period. This
could, next to a lack of passivity, also have been caused by the lack of engagement of the
abutments. Some authors have emphasized that the use of an engaging abutment in contrast to
a directly screwed-down butt-joint connection (comparable to the current study) could lead to
less marginal gap formation (22). Less marginal gap formation ultimately means less micro-
movement, which in turn could prevent screw-loosening. It is hard to draw solid conclusions
on this matter, since the number of events is relatively small, but the usage of two non-
engaging abutments in this study could be related to the increase in abutment screw-loosening
after several years. Some authors have also suggested using a combination of an engaging and
a non-engaging ti-base abutment for similar screw-retained FDPs (23). This is an interesting –
and often technically possible - treatment option, and further investigation on this matter is
desirable.

Since the restoration-design of the test and control group in this RCT are completely identical
it could have been expected that the survival and complication rates were similar.
Nevertheless, the test and control groups were compared since the accuracy of the impression
and/or the printing or pouring of the models could play a role in the aforementioned passivity
challenges. Even so, no statistically significant differences were found between the
restorations that were produced based on either a conventional impression or an IOS.
Therefore, the null-hypothesis was rejected.

Conclusions
Within the limitations of the current RCT the following conclusions can be drawn:

- Screw-retained monolithic zirconia restorations on ti-base abutments show promising survival rates after three years of function and no chipping or fracture was observed.
- Restorative complications on screw-retained monolithic zirconia restorations on ti-base abutments seem to be more likely to happen in the first year of function and are more common on multiple-implant restorations than on solitary crowns.
- The method of the impression (IOS or conventional) does not seem to influence the long-term survival or occurrence of complications of these restorations.

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CONFLICT OF INTEREST AND SOURCE OF FUNDING STATEMENT:

The authors declare that they have no conflicts of interest.

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Table 1. Restoration survival percentages and follow-up details

<table>
<thead>
<tr>
<th></th>
<th>Total</th>
<th>Test (digital)</th>
<th>Control (conventional)</th>
<th>Test (SC)</th>
<th>Control (SC)</th>
<th>Test (FDP)</th>
<th>Control (FDP)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Included restorations (baseline)</td>
<td>90</td>
<td>47</td>
<td>43</td>
<td>23</td>
<td>22</td>
<td>24</td>
<td>21</td>
</tr>
<tr>
<td>1 year follow-up*</td>
<td>89</td>
<td>46</td>
<td>43</td>
<td>22</td>
<td>22</td>
<td>24</td>
<td>21</td>
</tr>
<tr>
<td>3 year follow-up</td>
<td>84</td>
<td>43</td>
<td>41</td>
<td>21</td>
<td>20</td>
<td>22</td>
<td>21</td>
</tr>
<tr>
<td>Restoration failure</td>
<td></td>
<td></td>
<td></td>
<td>1</td>
<td>(97.7%) a</td>
<td>-</td>
<td>(100%)</td>
</tr>
<tr>
<td>(3-year restoration survival percentage)</td>
<td></td>
<td></td>
<td></td>
<td>(98.8%)</td>
<td>(100%) a</td>
<td>(100%)</td>
<td>(100%)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>1</td>
<td>(95.5%)</td>
<td>-</td>
<td>(100%)</td>
</tr>
</tbody>
</table>

* Published earlier (16, 17)

a Statistically not significant difference (p=.362)
Table 2. Details on the restorative complications (including the complications that had occurred during the first year of follow-up).

<table>
<thead>
<tr>
<th></th>
<th>#</th>
<th>Screw loosening</th>
<th>De-cementation from ti-base</th>
<th>Loss of occlusal restoration</th>
<th>Total # of complications</th>
<th>Total # of restorations with complication(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>All restorations: 0-1 year interval*</td>
<td>89</td>
<td>1(1.1%)</td>
<td>7(7.9%)</td>
<td>2(2.2%)</td>
<td>10(11.2%)</td>
<td>9(10.1%)</td>
</tr>
<tr>
<td>All restorations: 1-3 years interval</td>
<td>84</td>
<td>3(3.6%)</td>
<td>1(1.2%)</td>
<td>-</td>
<td>4(4.8%)</td>
<td>4(4.8%)</td>
</tr>
<tr>
<td>All restorations: 0-3 years interval</td>
<td>84</td>
<td>4(4.8%)</td>
<td>8(9.6%)</td>
<td>2(2.4%)</td>
<td>14(16.7%)</td>
<td>12(14.3%)</td>
</tr>
<tr>
<td>SCs: 0-1 year interval*</td>
<td>44</td>
<td>1(2.3%)</td>
<td>1(2.3%)</td>
<td>-</td>
<td>2(4.5%)</td>
<td>1(2.3%)</td>
</tr>
<tr>
<td>SCs: 1-3 years interval</td>
<td>41</td>
<td>1(2.4%)</td>
<td>-</td>
<td>-</td>
<td>1(2.4%)</td>
<td>1(2.4%)</td>
</tr>
<tr>
<td>SCs: 0-3 years interval</td>
<td>41</td>
<td>2(4.9%)</td>
<td>1(2.4%)</td>
<td>-</td>
<td>3(7.3%)</td>
<td>2(4.9%)</td>
</tr>
<tr>
<td>FDPs: 0-1 year interval*</td>
<td>45</td>
<td>-</td>
<td>6(13.3%)</td>
<td>2(4.4%)</td>
<td>8(17.8%)</td>
<td>7(15.6%)</td>
</tr>
<tr>
<td>FDPs: 1-3 years interval</td>
<td>43</td>
<td>2(4.7%)</td>
<td>1(2.3%)</td>
<td>-</td>
<td>3(7.0%)</td>
<td>3(6.7%)</td>
</tr>
<tr>
<td>FDPs: 0-3 years interval</td>
<td>43</td>
<td>2(4.7%)</td>
<td>7(16.3%)</td>
<td>2(4.7%)</td>
<td>11(25.6%)</td>
<td>10(23.3%)</td>
</tr>
<tr>
<td>Test group 0-3 years</td>
<td>43</td>
<td>1(2.3%)</td>
<td>4(9.3%)</td>
<td>2(4.7%)</td>
<td>7(16.3%)</td>
<td>6(14.0%)</td>
</tr>
<tr>
<td>Control group 0-3 years</td>
<td>41</td>
<td>3(7.3%)</td>
<td>4(9.8%)</td>
<td>-</td>
<td>7(17.1%)</td>
<td>6(14.6%)</td>
</tr>
</tbody>
</table>

* Published earlier (16,17)

*Statistically significant difference (p=.026).

*Statistically not significant difference (p=.929).
Table 3. The complications of 2-FDPs and 3-FDPs compared

<table>
<thead>
<tr>
<th>Restoration</th>
<th>#</th>
<th>Screw loosening</th>
<th>De-cementation from ti-base</th>
<th>Loss of occlusal restoration</th>
<th>Total # of complications</th>
<th>Total # of restorations with complication(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>2-FDP: 0-3 years (Complication rate %)</td>
<td>20</td>
<td>1</td>
<td>2</td>
<td>-</td>
<td>3</td>
<td>3 (15.0%)</td>
</tr>
<tr>
<td>3-FDP: 0-3 years (Complication rate %)</td>
<td>23</td>
<td>1</td>
<td>5</td>
<td>2</td>
<td>8</td>
<td>7 (30.4%)</td>
</tr>
</tbody>
</table>

*aStatistically not significant difference (p=.294)*

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