

**ORIGINAL ARTICLE**

WILEY

Clinical and laboratory passive fit assessment of implant-supported zirconia restorations fabricated using conventional and digital workflow

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Abstract

Background: Long-term success of implant-supported restorations can be affected by the accuracy of the prosthodontic workflow which may differ between conventional and digital techniques.

Purpose: The purpose was to compare the fit of two-implant-supported restorations, fabricated using conventional and digital workflows and to assess the influence of distance and angulation between the implants on the passive fit of the prosthesis. The SR test was selected to evaluate the fit of two-implant-supported zirconia restorations.

Materials and Methods: Forty-eight zirconia two-implant-supported restorations were fabricated according to conventional (group C, n = 24) and digital (group D, n = 24) workflows. The SR parameter was calculated as a difference of rotation angles of each screw in passive and nonpassive situations. SR values between groups C and D were compared by performing measurements intraorally, on master and control casts.

Results: SR intraorally in group C ($16.25 \pm 15.52^\circ$) was higher than it was in group D ($13.85 \pm 10.78^\circ$), but the difference was not statistically significant ($P = .557$). While measuring SR on the master cast, group C SR ($6.04 \pm 7.43^\circ$) had lower values than group D ($13.12 \pm 13.86^\circ$) ($P = .0039$). No statistically significant correlations were found between SR measurements and inter-implant distance or angulation. Restorations with inter-implant angle higher than 10° differed significantly from those with less than 10° angulation.

Conclusions: Digital restorations had a better fit on the control cast, which was used as a reference in this study. Angulation of more than 10° between the implants could negatively affect the passive fit of the digitally fabricated restorations intraorally.

KEYWORDS

digital impression, implant, intraoral scanner

1 | INTRODUCTION

Oral rehabilitation with dental implants has become an indispensable treatment option in prosthodontics that is used in situations from single-tooth to full-arch reconstructions. Long-term success of implant-supported restorations can be affected by the accuracy of the prosthodontic workflow.¹⁻³ Achieving ideally fitting single-unit implant-supported restorations is less challenging than it is for splinted multiple-implant restorations.⁴ Also, splinting of implants instead of restoring each implant individually has been recommended in the literature.^{4,5}

The fit of a prosthesis has been defined mainly by marginal and passive fit.⁶ Marginal fit is determined as the marginal gap between the prosthetic component and the implant when the prosthetic screw is tightened.^{6,7} Several definitions of passive fit primarily describe it as an implant-supported restoration that produces no strains on prosthetic, implant or surrounding structures, when the prosthesis-implant interface is maximally congruent.⁷ Misfit of implant supported restorations may lead to technical and biological complications.⁸ The most frequent technical complications have been found to be the screw loosening and loss of retention of prosthetic components, while other complications also include chipping of the veneering ceramic and fractures of the framework.^{9,10} Biological complications such as mucositis or periimplantitis with crestal bone loss can be initiated by increased plaque accumulation and micro-movements at the implant-abutment connection. Such complications can also be induced by the increased strains in surrounding tissues.^{1,8} It has been reported, however, that nonpassive restoration of implants seems to have no negative impact on marginal bone, because of a possible bone adaptation mechanism.¹¹

While absolutely passive fit of the restoration is virtually impossible, various measures have been introduced to enhance the fit of the prosthesis. Clinical and laboratory methods of passivity assessment have been published in the literature, but they all have their limitations.^{4,12-14} Besides the most commonly used ones in the clinic (finger pressure, Sheffield test, etc.), tests employing the SR principle have been proposed by Jemt¹⁵ and Calderini.¹⁶ The study done by Jemt et al was based on the properties of the prosthetic gold screws of Nobel Biocare (Gothenburg, Sweden) and claimed that passive fit could be regarded when less than a 180° turn of the screw was needed to achieve final torque (10-15 Ncm). An OsseoCare device (Nobel Biocare) was used in the study by Calderini et al to analyze the torque dynamics of the prosthetic screw during the screw tightening process.¹⁶

The fit of cement- and screw-retained implant prostheses made from a conventional impression is well addressed in the literature.² With the advances in digital technology, more and more implant prostheses are fabricated using digital impressions obtained with intraoral scanners. Several clinical studies have reported the fit of single unit implant-supported restorations produced through digital workflow.¹⁷⁻¹⁹

There is however a lack of studies evaluating the fit of multiple-unit implant-supported restorations produced using digital workflow. With the use of digital workflow, implant-supported restorations can be fabricated on printed or milled master casts, or even without a cast.

Though, the accuracy of printed master casts for single-unit implant restorations show acceptable results,²⁰ they are still of insufficient accuracy for multiple implant restorations.^{3,21}

The aims of this study were:

1. to evaluate and compare the passive-fit of two-implant, supported zirconia restorations fabricated using conventional and digital workflows by measuring SR;
2. to assess the influence of distance and angulation between the implants on the passive-fit of the prosthesis.

2 | MATERIALS AND METHODS

The clinical study involved 24 cases of two-implant-supported (AnyOne, Megagen, Daegu, Korea) fixed partial restorations. The study follows the standards of the Declaration of Helsinki and all patients gave informed consent before inclusion in the study. Ethical approval for the clinical study was acquired from the Vilnius Regional Ethics Committee for Biomedical Research (No 158200-16-861-370). The restorations that were investigated were distributed as follows with regards to length: two-unit (n = 7), three-unit (n = 11), and four-unit (n = 6) bridges. Ten of them were in the mandible and 14 in the maxilla.

Forty-eight zirconia restorations were fabricated according to conventional (group C, n = 24) and digital workflow (group D, n = 24). For the conventional group vinyl-polysiloxane (Express, 3 M, Maplewood) open-tray dental implant impressions were made with splinted pick-up impression copings (Individolux, VOCO, Cuxhaven, Germany) with passivity verification after splinting.²² Master casts were poured using type IV plaster (Japan-Stone, Siladent, Goslar, Germany) according to the manufacturer's instructions and allowed to set at room temperature for 24 hours. The fabricated master casts were scanned with a D800 laboratory scanner (3Shape, Copenhagen, Denmark) using the original scan bodies attached to the implant analogues, and 24 bar-shaped, screw-retained restorations were designed by an experienced dental technician using CAD (computer-aided design) software (Dental System, 3Shape). The restorations were of simplified shape consisting of two cylinders connected with a bar. To avoid any interference with peri-implant tissues and neighboring teeth during seating, the restoration had a minimal diameter at the gingiva level and there were no contacts with adjacent or opposing teeth. Twenty-four restorations were milled from zirconia (Katana Zirconia, Kuraray Noritake, Dental, Inc., Osaka, Japan) using a 5-axis milling machine with 5 µm drill compensation (VHF Impression S1, VHF Camfacture AG, Ammerbuch, Germany). After zirconia sintering procedures, the restorations were cemented (Multilink Hybrid, Ivoclar Vivadent, Schaan, Liechtenstein) to original nonhexed titanium interfaces, which were screwed to the implant analogues embedded in the master casts. Twenty-four screw-retained zirconia restorations were made according to conventional workflow and formed study group C.

As for the digital (D) group of specimens, intraoral scanning with a Trios 3 (3Shape, version 1.3.4.2) intraoral scanner (IOS) was

performed using original scan bodies torqued to the implants at 15 Ncm. Digital impressions were taken according to the recommendations of the Trios 3 manufacturer. In the upper jaw, scanning started from the occlusal surface to buccal and palatal surfaces, while in the lower jaw scanning started from the occlusal surface to lingual and buccal surfaces. The data that was obtained was used for the fabrication of another 24 zirconia restorations, replicating the CAD/CAM process that was used for the conventional workflow. This resulted in zirconia restorations of identical shape for both groups. Since master casts produced using CAM or 3D printing technology are less accurate, cementation was done without the use of the master cast.

Having a reference in a clinical study concerning impression or restoration accuracy is always a very important objective. Traditional in-vitro techniques, such as when the reference cast is used to evaluate the fit of the restoration and when registration of 3D implant positions is done with an industrial scanner or coordinate measuring machines could not be applied, however. Assuming the evidence that for the most extensive cases conventional impressions with splinted impression copings and plaster casts are still considered the most reliable technique, group C was taken as the reference and group D was compared to it.^{1,23}

An alternate way of acquiring the best available reference by making an additional control cast from the splinted impression copings is reported in the literature.²⁴ This approach was used for 10 randomly selected cases. Using this technique, additional registration of implant positions was achieved with extra pick-up impression copings splinted intraorally (Individolux, VOCO). Immediately after the removal of the splints from the mouth, implant analogues were carefully attached to the copings and control casts were fabricated using type IV plaster (Japan-Stone, Siladent). These control casts were used as the best available reference, which helped to compare the accuracy of conventional and digital restorations.

2.1 | Primary evaluation of the passive fit

Restorations were checked intraorally, on the master casts, and control casts. They were evaluated for any major misfit or imbalance. After application of the Sheffield test, they were rated as passively fitting or having a clinically detectable nonpassive fit. During clinical evaluation, it was confirmed that specimens were not interfering with the gingiva, neighboring or opposing teeth, or restorations.

2.2 | Measurements of the SR parameter

SR of restorations in C and D groups was evaluated on three occasions: intraorally, on the master casts, and, for the limited number of cases, on the control casts.

Firstly, the prosthetic screw only on the mesial implant was torqued to 5 Ncm using an implant surgery unit and a handpiece (W&H Implantmed, W&H Dentalwerk, Bürmoos, Austria) (Figure 1). Then it was tightened to 35 Ncm with the original prosthetic ratchet adapted

with a goniometer (Saehan, Saehan Corporation, Bongamgongdan, Korea), which allowed measuring the rotation angle needed to achieve torque from 5 to 35 Ncm (Figure 2). This value was recorded as rotation angle representing SR of a passive situation (SR passive). Then the screw was untightened, the restoration was removed and repositioned, and the prosthetic screw on the distal implant was tightened to 15 Ncm. Then, the same technique was again applied to the prosthetic screw of the mesial implant, and rotation angle representing SR of a potentially nonpassive situation (SR nonpassive) was registered.

The SR parameter was calculated as the difference of rotation angles in passive and nonpassive situations by the formula:

$$SR = SR \text{ passive} - SR \text{ nonpassive.}$$

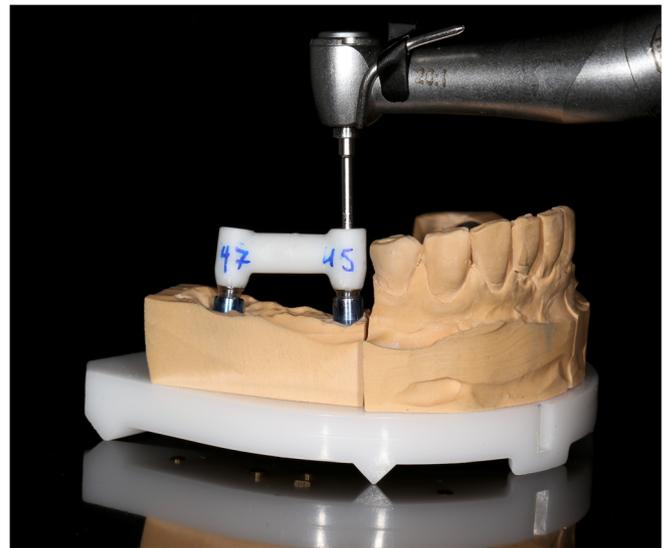


FIGURE 1 Initial torque of 5 Ncm was achieved with an implant surgery unit and a handpiece



FIGURE 2 A prosthetic ratchet equipped with a goniometer was used to estimate the rotation angle needed to achieve torque from 5 to 35 Ncm

Rotation angles and SR of the prosthetic screw of the distal implant were evaluated in the identical way.

SR represented the level of nonpassive fit of the restoration. Root mean squares of SR were used for further analysis. Ninety-six SR measurements were done with the frameworks of groups C and D intraorally. In addition, 96 SR measurements were performed on the master casts, and 40 SR measurements were performed on the control casts in the identical manner by the two calibrated operators.

To identify the average angle of rotation of the completely passive situation, the titanium base without a crown was tightened on the master cast from 5 to 35 Ncm with a ratchet and goniometer 10 times, each time measuring the angle. The average tightening angle was calculated ($87 \pm 5^\circ$) and used as a reference.

2.3 | Measurements of inter-implant distance and angulation

To find associations between measurements of SR and inter-implant distance and inter-implant angulation, the distance and angulation between the scan bodies were measured for specimens of groups C and D. Selected STL files of groups C and D were analyzed in reverse engineering software Rapidform 2006 (INUS Technology, Inc., Korea) according to the ICP (iterative closest point) algorithm (Figure 3). The

center point of the scanbody was chosen as the intersection between a selected center axis and the top plane of the scanbody. The distance between the center points of two scan bodies was measured. The angulation of the scan bodies was measured as the angle between two vectors representing the axes of the scan bodies in 3D space. Average linear and angular parameters were calculated by the formula $(D800 \text{ data} + \text{Trios3 data})/2$ and were used for further analysis.

2.4 | Statistical analysis

Statistical analysis was performed using R software ver. 2.3-2 (Lucent Technologies, Auckland, New Zealand). The Shapiro-Wilk test of normality was applied to the data. As most of the variables were not distributed normally, nonparametric tests were used.

The Wilcoxon signed rank test for paired data was used to compare medians of SR between groups C and D when measured intraorally, on the master, and on the control cast. Comparison was also made between overall SR measurements obtained intraorally and on the master cast.

All cases were also divided into two groups, depending on whether inter-implant angulation was below or above 10° . Differences in SR measurements obtained intraorally and on the master and control cast were compared between those groups.

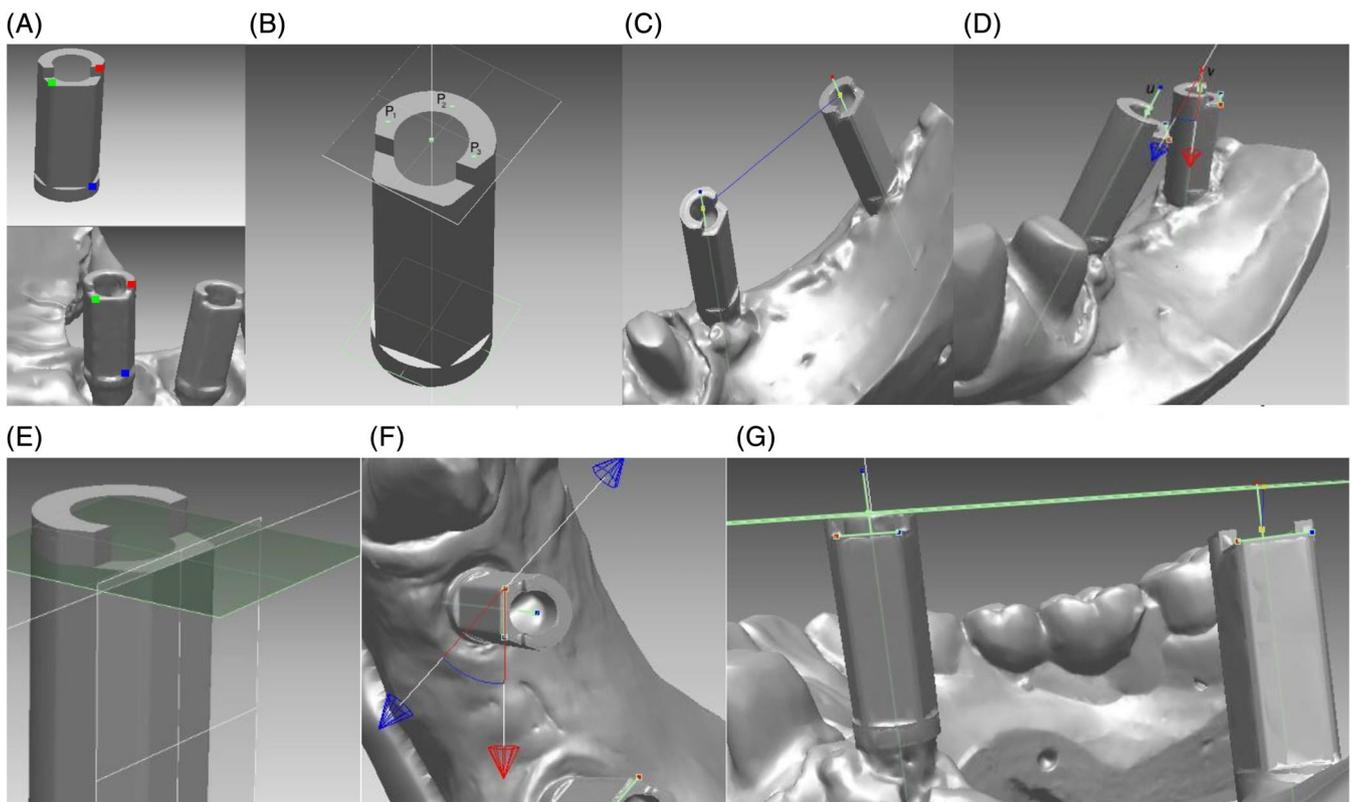


FIGURE 3 A, 3D computer models obtained using different scanning techniques. For coarse alignment, three corresponding points on the surface of each model are marked. B, The center point of the scan body is at the intersection between its axis and top plane. C, The Euclidean distance between the center points of two scan bodies. D, The angulation of scan bodies. E, Detecting the edge of the scan body. F, The rotation of one scan body in relation to the other one. G, The vertical shift of the scan body

TABLE 1 Number of restorations that were rated as not having optimal passive fit during the evaluation intraorally and on the master and control cast

Intraorally		Master cast		Control cast	
Group C	Group D	Group C	Group D	Group C	Group D
6	5	2	4	2	1

TABLE 2 Rotation angles (from 5 to 35 Ncm) of prosthetic screws in passive (P) and nonpassive (NP) situations

Intraorally		Master cast		Control cast	
Group C	Group D	Group C	Group D	Group C	Group D
P	NP	P	NP	P	NP
88 ± 17°	Q102 ± 25°	84 ± 15°	95 ± 15°	84 ± 13°	86 ± 20°
		83 ± 15°	85 ± 17°	87 ± 14°	90 ± 16°
				85 ± 13°	87 ± 14°

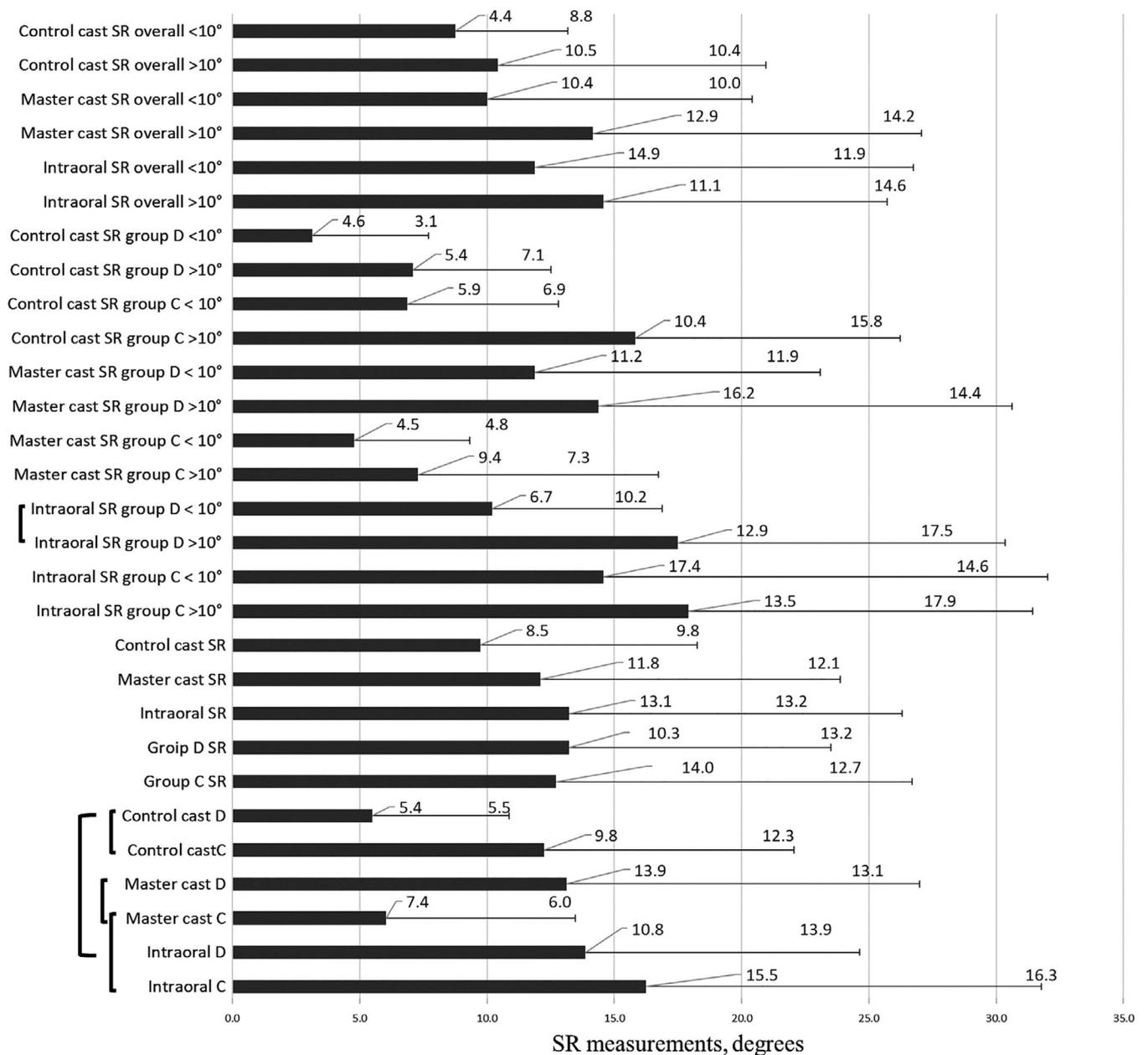


FIGURE 4 Screw resistance (SR) measurements of different groups of the specimens. Gray arches indicate statistically significant differences

To assess the associations between the SR measurements and distance or angle between the implants, the Spearman correlation test was applied.

3 | RESULTS

Based on the intraoral evaluation, all restorations were considered clinically acceptable. Six restorations of group C and five restorations of group D were considered to have less than optimal passive fit. Evaluation on the master cast revealed that two restorations of group C and four restorations of group D were rated as having suboptimal fit (Table 1). Rotation angle measurements obtained in passive and nonpassive situations are presented in Table 2.

TABLE 3 Screw resistance (SR) measurements of different groups of specimens

Variable	Mean \pm SD	Median (IQR) ^o
Group C SR intraoral	16.25 \pm 15.52 ^o	10 (10) ^o
Group D SR intraoral	13.85 \pm 10.78 ^o	10 (10) ^o
Group C SR on the master cast	6.04 \pm 7.43 ^o	5 (10) ^o
Group D SR on the master cast	13.12 \pm 13.86 ^o	10 (15) ^o
Group C SR on the control cast	12.5 \pm 9.79 ^o	10 (10) ^o
Group D SR on the control cast	5.5 \pm 5.35 ^o	5 (10) ^o
Group C SR overall	12.7 \pm 13.98 ^o	10 (15) ^o
Group D SR overall	13.22 \pm 10.28 ^o	10 (15) ^o
Intraoral SR overall	13.22 \pm 13.06 ^o	10 (15) ^o
Master cast SR overall	12.08 \pm 11.79 ^o	10 (15) ^o
Control cast SR overall	9.75 \pm 8.5 ^o	5 (8.75) ^o

TABLE 4 Comparison of subgroups with inter-implant angulation higher and lower than 10^o

Comparison groups	Wilcoxon signed rank test P value
Intraoral SR group C > 10 ^o vs Intraoral SR group C < 10 ^o	0.227
Intraoral SR group D > 10 ^o vs Intraoral SR group D < 10 ^o	0.037
Master cast SR group C > 10 ^o vs Master cast SR group C < 10 ^o	0.169
Master cast SR group D > 10 ^o vs Master cast SR group D < 10 ^o	0.336
Control cast SR group C > 10 ^o vs Control cast SR group C < 10 ^o	0.156
Control cast SR group D > 10 ^o vs Control cast SR group D < 10 ^o	0.103
Intraoral SR overall >10 ^o vs Intraoral SR overall <10 ^o	0.288
Master cast SR overall >10 ^o vs Master cast SR overall <10 ^o	0.145
Control cast SR overall >10 ^o vs Control cast SR overall <10 ^o	0.73

TABLE 5 Correlation of SR measurements to inter-implant distance and angulation. NS indicates not significant

Variables	Inter-implant distance	Inter-implant angulation
Intraoral SR group C	0.1 (NS)	0.18 (NS)
Intraoral SR group D	-0.19 (NS)	0.27 (NS)
Master cast SR group C	0.02 (NS)	0.05 (NS)
Master cast SR group D	0.17 (NS)	0.26 (NS)
Control cast SR group C	-0.03 (NS)	0.08 (NS)
Control cast SR group D	-0.15 (NS)	0.12 (NS)
Intraoral SR	-0.085 (NS)	0.22 (NS)
Master cast SR	-0.041 (NS)	0.31 (NS)
Control cast SR	-0.51	-0.2 (NS)
Group D SR	-0.14 (NS)	0.145 (NS)
Group C SR	0.067 (NS)	0.21 (NS)

Graphical representation and comparisons of SR values in different groups are represented in Figure 4. SR of C restorations measured intraorally (16.25 \pm 15.52^o) was higher than of D restorations (13.85 \pm 10.78^o) (Table 3), but the difference was not statistically significant ($P = .557$). While measuring SR on the master cast, group C SR (6.04 \pm 7.43^o) had lower values than group D (13.12 \pm 13.86^o), and the difference between them was statistically significant ($P = .0039$). Overall SR measurements intraorally (13.22 \pm 13.06^o) were found to be slightly higher than SR on the master cast (12.08 \pm 11.79^o), but the difference was not statistically significant ($P = .81$).

SR measurements intraorally of the group D restorations with inter-implant angle higher than 10^o statistically significantly differ from the SR measurements of the ones with an angle smaller than 10^o between the implants ($P = .037$) (Table 4). Also, no statistically significant associations between measurements of SR and inter-implant distance or angulation were found according to Spearman correlation coefficients (Table 5). The average distance between implants measured 15.8 \pm 5.76 mm and the average angle between implants was 9.98 \pm 5.7^o.

4 | DISCUSSION

The main objective of this study was to clinically evaluate the passive fit of two-implant-supported restorations manufactured using digital and conventional workflows.

The lead of the titanium prosthetic screw of the Ti base (the distance along the axis of the screw that is covered by one complete rotation of it) used in the study was 400 μ m. The gold prosthetic screw used in the Jemt et al study had a lead of 300 μ m.¹⁵ Thus, to achieve 15 Ncm of torque and close a 150- μ m marginal gap of the prosthesis, the screw had to be turned 180^o. In the current study, torque from 5 to 35 Ncm was achieved with approximately 90^o (exact value 87 \pm 5^o) angle of rotation, when a single Ti base was placed on the implant analogue. Therefore, 100- μ m vertical displacement

between implant and abutment is expected during final tightening with a completely passive fit. The average intraoral angle of rotation with group C restorations was $88 \pm 17^\circ$ in a passive situation and $102 \pm 25^\circ$ in a nonpassive situation. For group D, the average intraoral angle of rotation angle was $84 \pm 15^\circ$ in a passive situation and $95 \pm 14^\circ$ in a nonpassive situation (Table 2). SR differences measured intraorally between groups C and D were not statistically significant ($P > .05$), however. Difference in angle of rotation intraorally was 16° for group C and 14° for group D. This could lead to a $17.7\text{-}\mu\text{m}$ and $15.5\text{-}\mu\text{m}$ vertical displacement of the restoration respectively and clinically translate to a supra- or infra-occlusion situation. Any occlusal discrepancies higher than $8\text{ }\mu\text{m}$ of Shimstock foil can be sensed as an occlusion irregularity or have an effect on proximal contacts.²⁵ The differences in SR measurements between groups C and D on the control cast were statistically significant ($P < .017$). Since the control casts served as the best available reference, it can be assumed that restorations produced using a digital workflow had a better passive fit than ones fabricated with a conventional workflow. Also, angles of rotation of passive and nonpassive screws in groups C and D had similar measurements in an intraoral situation and on the control cast, suggesting that a control cast represented the intraoral situation better than the master cast.

Previous studies investigated the effect of angulation between implants on accuracy of impressions and restorations.²⁶⁻³⁰ Several authors have researched the impact of implant angulation on impression accuracy. Lin et al investigated parallel, 15° , 30° , and 45° divergence between dental implants situations and claimed that the divergence between implants significantly affected the accuracy of impressions and that the conventional method was more accurate than a digital one.²⁸ Similarly, Flugge et al found that increased inter-implant distance and angulation negatively affected the accuracy of dental implant impressions.³¹ Other studies, however, investigated the effect of angulations between the implants from 10 to 45° but were not able to find an effect on implant impression accuracy.^{26,27,29} No statistically significant difference was found in group C when restorations with higher and lower than 10° inter-implant angulation were compared. This was also the case intraorally and, on the master, and control cast. As for the group D restorations, SR mean in the group with more than 10° of inter-implant angulation was statistically significantly higher than for restorations with less than 10° of angulation ($P = .037$) intraorally. In group D, however, SR measured on the master and control casts was not significantly different between the angulation groups. Division of control cast cases into two groups based on the angulation leads to a very limited number of cases in each angulation group. Therefore, these findings should be interpreted with caution.

In this study, all correlations of SR intraorally and on the master cast and control cast to inter-implant distance or angulation were not statistically significant. Therefore, these factors had no impact on the passive fit of the restorations. Similarly, no statistically significant differences in axial displacement were detected between restorations on parallel and angulated implants after final fixation and cyclic loading in another study.³²

The limitation of the study is that different SR measurements can be achieved with distinct implant-abutment connection types. An

internal implant-abutment 11° conical connection was used in this study and is less able to prevent vertical displacement of the abutment during the tightening of the screw than external ones.^{32,33} SR measurements could also be affected by various types of prosthetic components that might or might not employ anti-rotational features. However, despite the type of implant-abutment connection, the stability of it is the crucial aspect to keep the implant surrounding crestal bone stable.^{34,35} Although the gap between the implant and abutment can cause colonization of microorganisms and further biological complications of peri-implant tissues,⁸ the nonpassive restoration itself cannot induce bone loss. Contrary, bone remodeling process have been observed near ill-fitting implant restoration.^{7,11,36} Nevertheless, no clinical threshold of the misfit of implant restoration can be defined, which could cause bone loss complications, because there are too many influencing factors and no reliable measures to evaluate their impact.^{7,37}

Though the use of prosthetic ratchets is considered a reliable method to tighten a prosthetic screw,³⁸ the angle of rotation had to be evaluated using the goniometer, which is not documented well in the dental literature. One measuring unit on the scale of the goniometer is 5° , which could limit the accuracy. As an alternative for measuring SR, an OsseoCare (Nobel Biocare) device, is described in the literature.¹⁶ This device, unless modified, is not able to record angles of rotation, however.

CAD/CAM fabricated restorations on dental implants have been proven to be more accurate than ones produced by the technique of casting.^{39,40} According to currently available research, the type of zirconia should have a negligible effect on the accuracy of the restoration.⁴¹ However, CAD design, milling, sintering parameters,^{42,43} and cementation techniques could influence the fit of the restoration.⁴⁴⁻⁴⁷ Cementing restorations on the cast could potentially compensate for undetected misfit with an increased cement gap, resulting in less optimal cementation and affecting the long-term stability of the restoration.^{45,48} In contrast to single unit implant crowns, cementation of multiple-unit implant restorations on a master cast could involve more technical challenges. In this study, the restorations of group D were produced via a completely digital workflow and cementation was performed without a cast, resulting in the best possible adaptation of the Ti base and zirconia restoration, which was controlled under a microscope. Resin-based cement has been proved to be the appropriate type for Ti base and crown cementation,^{49,50} but the preparation of the surfaces with air-abrasion should be carefully used, because it can damage the original geometry of the Ti base and weaken the bond of the surfaces.⁵¹ Due to the aforementioned considerations, all CAD/CAM and cementation processes were strictly standardized in both study groups.

5 | CONCLUSIONS

Within the limitations of this study, it can be concluded that:

- There is no difference in precision between conventionally and digitally fabricated restorations by means of passive fit, when measured intraorally.

- Angulation of more than 10° between the implants could negatively affect the passive fit of digitally fabricated restorations.
- Inter-implant distance does not seem to affect the passive fit of restorations, independent on if they are made digitally or conventionally.

CONFLICTS OF INTEREST

Authors declare no conflicts of interest.

AUTHOR CONTRIBUTIONS

V. R. contributed in study design, critical, and final revision of the article. C. L. contributed in critical revision and drafting of the article. P. V. S. and F. M. contributed in critical revision and drafting of the article. A. G. contributed in data analysis, interpretation, and drafting article.

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How to cite this article: Rutkunas V, Larsson C, Vult von Steyern P, Mangano F, Gedrimiene A. Clinical and laboratory passive fit assessment of implant-supported zirconia restorations fabricated using conventional and digital workflow. *Clin Implant Dent Relat Res*. 2020;1-9. <https://doi.org/10.1111/cid.12885>