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# Effect of different fabrication workflows on the passive fit of screw-retained bar splinting two interforaminal implants: a parallel blinded randomised clinical trial

Bassant Sherif Gamal Eldin<sup>1\*</sup>, Ingy Amin Talaat<sup>1</sup>, Noha Helmy Hassan Nawar<sup>1</sup> and Ahmed Mostafa Abdelfattah Mohamed<sup>1</sup>

## Abstract

**Background** To clinically compare the effect of the conventional and the digital workflows on the passive fit of a screw retained bar splinting two inter-foraminal implants.

**Methods** The current study was designed to be a parallel triple blinded randomised clinical trial. Thirty six completely edentulous patients were selected and simply randomized into two groups; conventional group (CG) and digital group (DG). The participants, investigator and outcome assessor were blinded. In the group (CG), the bar was constructed following a conventional workflow in which an open top splinted impression and a lost wax casting technology were used. However, in group (DG), a digital workflow including a digital impression and a digital bar milling technology was adopted. Passive fit of each bar was then evaluated clinically by applying the screw resistance test using the “flag” technique in the passive and non passive situations. The screw resistance test parameter was also calculated. Unpaired t-test was used for intergroup comparison. P-value < 0.05 was the statistical significance level. The study protocol was reviewed by the Research Ethics Committee in the author’s university (Rec IM051811). Registration of the clinical trial was made on clinicaltrials.gov ID NCT05770011. An informed consent was obtained from all participants.

**Results** Non statistically significant difference was denoted between both groups in all situations. In the passive situation, the mean  $\pm$  standard deviation values were  $1789.8^\circ \pm 20.7$  and  $1786.1^\circ \pm 30.7$  for the groups (CG) and (DG) respectively. In the non passive situation, they were  $1572.8^\circ \pm 54.2$  and  $1609.2^\circ \pm 96.9$ . Regarding the screw resistance test parameter, they were  $217^\circ \pm 55.3$  and  $176^\circ \pm 98.8$ .

**Conclusion** Conventional and digital fabrication workflows had clinically comparable effect on the passive fit of screw retained bar attachments supported by two dental implants.

**Keywords** Dental impression technique, Dental marginal adaptation, Computer-aided design

\*Correspondence:

Bassant Sherif Gamal Eldin  
Bassantsherif@dent.asu.edu.eg

<sup>1</sup>Oral and Maxillofacial Prosthodontics Department, Faculty of Dentistry,  
Ain Shams University, Organization of African Unity Street, Cairo, Egypt



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## Background

A statement was produced in 2002 McGill conference that the first choice for the standard of care for the edentulous mandible was an overdenture retained by two implants [1]. Various types of attachments can be used in such overdentures as the bar ones that offer high retentive capacities and help with load distribution [2]. Bars may be either screw or cement retained. Screw retained bars are easier to be retrieved and show better results in the terms of bleeding on probing and low plaque index [3]. However, their passive fit is essential to avoid the biological and mechanical failures as well as the transmission of unfavourable stresses to the bone-implant interface [4].

Several factors contribute to the passive fit of screw retained prosthesis. Such factors include the relative parallelism between the implants, implant number, impression material and technique, in addition to the method of prosthesis fabrication [5]. In a study conducted by Narayane et al., they concluded that the more parallel the implants, the more accurate the impression with less deviation of the implant analogs [6]. Michelinakis et al. also reported that less implant deviations were encountered in the short span edentulous sites with a smaller number of implants compared to the long span or the completely edentulous sites having a greater number of implants [7]. Moreover, it was reported that the two-step polyvinyl siloxane impression was significantly less accurate than the one-step putty and light-body combination one [8]. Khan et al. also reported that such combination of impression materials was more accurate than the medium-body polyether impression material. Furthermore, the open top splinted impression technique was stated to be more accurate than the closed top and the non splinted ones [9]. However, a systematic review found no clear evidence that supports the accuracy of one impression technique rather than the others [10]. On the other hand, recent advances in the digital technology within the dental field have innovated the impression techniques. Some studies concluded that the digital impressions were as effective as the conventional ones for the fabrication of the full arch implant supported restorations. However, superior results were attained for the digital ones in case of severe implant angulations [11, 12]. Similarly, another study reported that in cases involving four implants, the digital impressions were found to be more accurate than the conventional ones. Meanwhile, in situations involving a maximum of three implants, the conventional impression was found to be more accurate than the digital one [13].

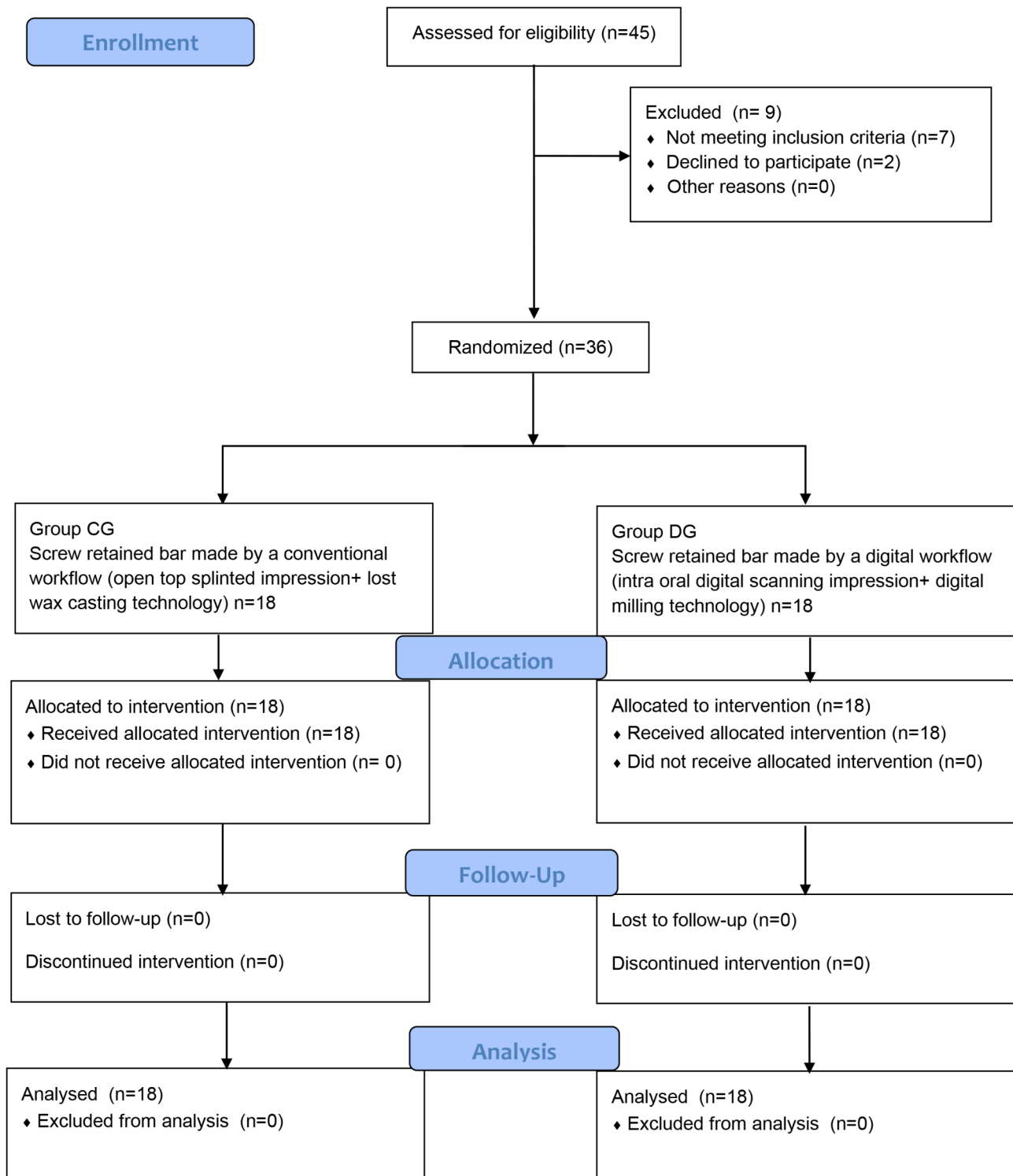
Screw-retained restorations can be fabricated by the conventional lost wax casting technology. However, they can be also fabricated by a digital technology using an additive method such as laser sintering or a subtractive

one such as milling, or combination techniques [14]. The accuracy of the conventional process is limited by the dimensional stability of the various materials used. Furthermore, the wax pattern fabrication is a time-consuming and a labour-intensive step [15]. Therefore, errors during fabrication of the restoration may result and affect its passive fit. To overcome such a problem, digital technology techniques were advocated in the literature [16, 17]. De Franca et al. and Roig et al. concluded that the digitally fabricated screw retained frameworks exhibit better fit when compared to the conventionally fabricated ones [18, 19]. On the other hand, a systematic review reported that the existing scientific clinical evidence does not allow clear conclusions to be drawn about the superiority of the digital technology over the conventional one with respect to the marginal accuracy [20]. Moreover, Abdel-Azim et al., stated that the conventional impression/fabrication workflow resulted in a smaller marginal discrepancy for the single-implant frameworks compared to the digital one that showed better results for the full-arch ones [21, 22].

Various methods are mentioned in the literature for clinical evaluation of the screw retained prosthesis misfit as the alternate finger pressure, radiographic examination and explorer tip. However, such methods are subjective [23, 24]. Rutkunas et al. selected the screw resistance test parameter (SR) in an objective way to evaluate the passive fit of implant-supported restorations clinically. The SR parameter was calculated as the difference of the rotation angles of each screw in the passive and the non passive situations. However, they compared the clinical effect of the impression techniques only with no relevance to the whole workflow [25]. So, the aim of the current study was to clinically compare the passive fit of the screw retained bars fabricated by the conventional and the digital workflows. The null hypothesis tested in this study was that both workflows had no difference in their effect on the passive fit of screw-retained bar attachments.

## Methods

The current study was designed to be a parallel assigned triple blinded randomized clinical trial following the CONSORT 2010 guidelines. Figure 1 Thirty-six completely edentulous patients were selected to share in the current study. Sample size calculation was based on 95% confidence interval and power 80% with  $\alpha$  error 5% (MedCalc® version 12.3.0.0 program, Ostend, Belgium) in the light of a study conducted by Alikhasi et al. [26]. For each patient, two implants were placed in the mandibular right and left canines and received a screw retained bar. Patients were simply randomized using a computer-generated list (Random Alloc, Software informer, Informer Technologies Inc) and allocated into two groups; conventional group (CG) and digital group



**Fig. 1** Study flow diagram following the CONSORT guidelines

(DG). For concealment, each patient selected an opaque sealed envelope and the code was revealed to determine the patient’s group. For the group (CG), the bar was fabricated following a conventional workflow that included an open top splinted impression technique coupled

with casting technology. However, in the group (DG), a digital workflow including a digital impression and a digital bar milling technology was adopted. Passive fit of each bar was then evaluated intraorally using the screw resistance test [27]. The study protocol was reviewed

by the Research Ethics Committee in the author's university (Rec IM051811). Registration of the clinical trial was made on clinical trials.gov ID NCT05770011 on 15/03/2023. An informed consent was obtained from all participants.

Patients with uncontrolled systematic diseases, heavy smoking habits and conditions that may affect implant osseointegration were excluded. For implant placement, a complete denture was made for each patient. Gutta-percha markers (Meta Biomed, Chungcheong Buk, South Korea) were placed at the mandibular canines to act as radio-opaque markers and a Cone Beam Computed Tomography (CBCT) (i-CAT™ FLX V8, Kavo, California, USA) scan was made for each patient while wearing the denture. A surgical guide was then designed (Blue Sky Plan software, Illinois, USA), printed, stabilized in the patient's mouth and sequential drilling of the implant sites under copious irrigation then followed [28–30]. The dental implants (Neobiotech Co Ltd, Seoul, Republic of South Korea) were placed in the osteotomy site and three months later the patients were recalled for the second stage surgery and bar fabrication.

For bar fabrication in the group (CG), closed-top primary impressions were made using putty and light addition vinyl polysiloxane impression material in one step (Zermack company, Badia Polisine, Italy). The open top impression posts were then attached to the lab analogs in the study cast and splinted with autopolymerizing acrylic resin (Hard Denture Liner, Promedica GMBH, Germany). The splint was then split, and the impression posts were resplinted again in the patient's mouth. The open-top secondary impression was then made using regular body polyvinyl siloxane impression material (Zermack company, Badia Polisine, Italy) [16, 31]. Impressions were made by a single trained operator.

Non engaging titanium bases were then screwed to the implant analogs in the master cast (Neobiotech Co Ltd, Seoul, Republic of South Korea) [32]. Readymade wax pattern of the bar (OT bar Rhein83, Bologna, Italy) was then attached to the plastic sleeve of the titanium base and adjusted in position. Lost wax casting technique was then adopted using Co-Cr alloy (BEGO Medical GmbH, Bremen, Germany). The fitting surface of the bar copings was sandblasted using 110 µm aluminum oxide articles (BEGO sandblaster, BEGO Bremer GMBH, Germany) and primed (Z prime, Bisco, United states of America). Self-cured adhesive resin was then used to cement the bar to the non-engaging Titanium bases (SuperCem, Self adhesive resin cement, Republic of South Korea) [33].

For bar fabrication in the group (DG), the healing abutments were removed from the implant fixtures in the patient's mouth. Dryness of the scanning field was essential during the intraoral scanning procedures. Moreover, the patients were instructed to avoid any movements during scanning [34, 35]. Scanning of the lower arch was done using an Omnicam (Dentsply Sirona, Germany) intraoral scanner. Scanning was done by a single calibrated operator who was trained on the intraoral scanning techniques. The scanning process was observed on the computer desktop and if there were any missing data, additional scanning was made. The scan bodies (Neobiotech Co Ltd, Seoul, Republic of South Korea) were then screwed to the implants and scanning was done. Figure 2 [36]. Both scans were previewed on the computer desktop and superimposed together. The Standard tessellation language (STL) file was then exported, downloaded and previewed in Inlab Exocad software (Exocad GmbH, Damastadt, Germany). The implant system was selected from the software library and the restoration type was designed as Rhein 83 OT Bar-A (OT bar Rhein83,

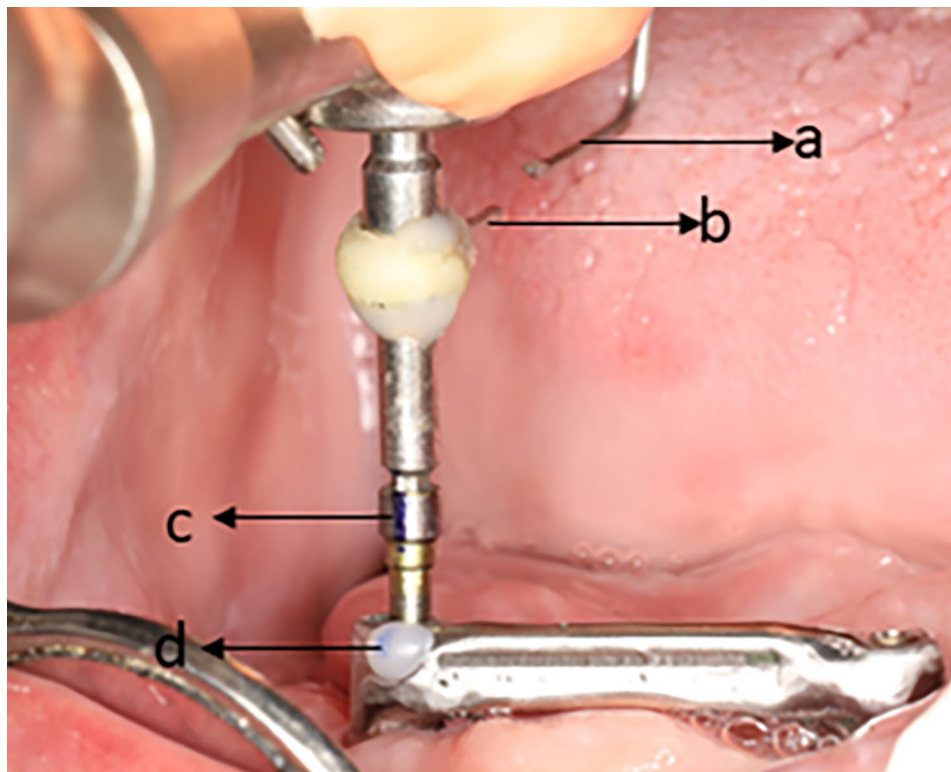


**Fig. 2** Scan bodies were screwed to the implants ready for intraoral scanning

Bologna, Italy). Computer assisted design/computer assisted manufacturing (CAD/CAM) titanium bases (Neobiotech Co Ltd, Seoul, Republic of South Korea) type were selected from the software library. The position of the bar was adjusted in accordance to the titanium bases and the gingiva. The STL file was then exported to the milling machine (Icam v5 imes-icore, Hessen, Germany) and milling of the Co-Cr bar (BEGO Medical GmbH, Bremen, Germany) was done. Sandblasting and priming of the bar copings and the titanium bases were done in the same steps followed for the group (CG). The bar was then cemented to the non-engaging titanium bases [33, 37].

Passive fit of each bar was assessed intraorally. Blinding during measurement was done with the help of a third party rather than the outcome assessor. The bars were given to a third party who coded them. The coded bars were given to the trained outcome assessor and the measured values were returned back to the third party to reveal the codes. The screw resistance test was used to evaluate the passive fit of each bar intraorally by using the “flag” technique [27]. The SR parameter was calculated as the difference of the rotation angles of each screw in the passive and the nonpassive situations by the formula:  $SR = SR_{\text{passive}} - SR_{\text{nonpassive}}$  [25]. Tightening of the screws was done using a motor driven screwdriver. One

pointer (pointer a) was attached to the head of the hand piece denoting the starting position. A second pointer (pointer b) was attached to the shank of the screwdriver using flowable composite. Both pointers were aligned together at an angle  $0^\circ$  on a protractor. Then, the marks (c and d) were made on the labial surface of the screw and the abutment respectively to be used as a starting point for tightening the screw. Figure 3 First, the right screw was tightened at a torque of 15 Ncm without tightening the left screw to record the SR value in the passive situation [25]. The number of turns rotated by the screw driver’s pointer (pointer b) was counted. The degree of rotation of the last turn was measured by a  $360^\circ$  protractor. For measurement of the last turn degree, the pointer (a) was aligned with the zero degree of the protractor and the angle referred to by the pointer (b) was recorded. The SR passive was calculated by summation of the number of the turns added to the degree of rotation in the last turn. This step was repeated three times and an average reading was recorded. The right screw was then retrieved, and the left screw was tightened at a torque of 15 Ncm. Afterwards, tightening of the right screw was done at a torque of 15 Ncm and the angle of rotation was recorded for the right screw. This value represented the SR value in the nonpassive situation. This step was repeated three times and an average angle was recorded (Video 1).



**Fig. 3** Adjusting the starting position of the pointers for intraoral assessment of the passive fit of the bar using the flag technique. Pointer (a) attached to the head of the hand piece denoting the starting position. Pointer (b) attached to the shank of the screw driver. Point (c) a mark made on the labial surface of the screw. Point (d) a mark made on the labial surface of the abutment

Intra group comparison of the SR passive and non passive situations was done. Inter group comparison of both situations was done as well. Pick up of the bar clips in the reinforced over denture base was made using autopolymerizing acrylic resin [38].

Statistical analysis was performed using the statistical package for social sciences (version 21.0 SPSS Inc; IBM Corporation, Chicago, USA). Shapiro Wilk test revealed normal distribution of the resultant data. Paired t-test was used for the intra group comparison of the SR passive and non passive situations. Unpaired t-test was used for the intergroup comparison for both situations as well as the SR parameter. P-value < 0.05 was considered to be the statistical significance level.

## Results

All participants attended the second stage surgery with no implant loss. The participants in the group (CG) were 9 females and 9 males with average age  $67.1 \pm 5.6$  while in the group (DG), they were 11 females and 7 males with average age  $66.1 \pm 5.03$ . Paired t-test showed statistically significant difference for the intra group comparison of the passive and the non passive situations in both groups ( $T=17.1$ ;  $P<0.001$  for group (CG),  $T=7.1$ ;  $P<0.001$  for group (DG)). On the other hand, Un Paired t-test showed non-statistically significant difference for the inter-group comparison of the passive and non passive situations in both groups. For the passive situation, the T-value was 0.44 while the P-value was 0.33. However, for the non passive situation, the T-value was 1.41 while the P-value was 0.08. Similarly, the Un Paired T test showed non-statistically significant difference for the SR parameter ( $T=1.533$ ;  $p=0.07$ ). The mean and standard deviation values are listed in Table 1.

## Discussion

The screw retained bar attachment was used in the current study as it allows better stress distribution, provides good retention and can be retrieved easily if biological or technical complications occur [3]. However, the passive fit of such restorations is essential to avoid biological and mechanical complications [4]. So, the current study was performed to clinically compare the passive fit of such attachments fabricated by the conventional and

the digital workflows. The null hypothesis that there was no difference between them was accepted as there was no statistically significant difference. Such insignificant difference could be related to the proper selection of the impression materials and techniques, precise steps of bar construction, number of implants and their parallel placement as well as selection of the abutments.

Regarding the impression technique in the group (CG), primary impression was made using the one step putty and light body polyvinyl siloxane impression technique which was reported to be significantly more accurate than the two step one and the medium-body polyether impression material [8, 9]. The adoption of the open top splinted impression coupled with intraoral impression coping resplinting may have prevented individual coping movement during the impression-making procedure and decreased the polymerization shrinkage of the splint material ending up with improved fit of the bar [16, 31]. On the other hand, the inherent limitations in the digital impressions despite being controlled in the group (DG) may have negatively affected the accuracy of such impressions. The humidity of the oral environment, presence of saliva, head movements in addition to accumulation of the registration and angulation errors may have negatively affected the impression's accuracy as reported in the literature [34, 39]. Moreover, several studies in the literature found no significant differences in the accuracy between both impression techniques. A further randomized clinical trial concluded that the digital impression technique was found to be as effective as the conventional impression technique [12]. Rech. et al. in their study concluded that the conventional impression technique could be more accurate than the digital one for restorations receiving less than three implants [13]. Papaspyridakos et al. also suggested that the digital impressions appear to have comparable three dimensional accuracy with the conventional implant impressions [40]. Furthermore, Rutkunas et al. showed non statistically significant difference between both impression techniques on the passive fit of the implant supported restorations [25]. In another study, it was stated that the accuracy between both impression techniques was found to be comparable in the parallel placed implants; a further reason for the results in the current study as the implants were placed parallel

**Table 1** Comparison between the groups CG and DG in the passive, non passive situations and the SR parameter using unpaired T-test

	Group CG		Group DG		T-test value	P value
	X°	SD	X°	SD		
Passive	1789.8°	20.7	1786.1°	30.7	0.44	0.33
Non passive	1572.8°	54.2	1609.2°	96.9	1.41	0.08
SR parameter	217°	55.3	176°	98.8	1.53	0.07

X: mean; SD: standard deviation; CG: conventional group; DG: Digital group; SR parameter: screw resistance test parameter (difference of rotation angles in the passive and nonpassive situations: SR=SR passive – SR nonpassive)

by the help of surgical guides [6, 28]. On the contrary, Roig et al., concluded that the fit of frameworks fabricated by the digital impression technique was better than the conventional one. Such results were owed to the use of a prefabricated auxiliary device in their technique [19].

Regarding the bar construction technology, a systematic review reported that no clear conclusions can be drawn relative to the marginal adaptation about the superiority of the CAD-CAM milling technology as opposed to the conventional casting technique [20]. On the other hand, De Franca et al., stated that the CAD/CAM fabricated frameworks exhibited better fit when compared to the conventionally fabricated ones [18]. However, in such study three implants were placed rather than two as in the current study. Moreover, it was not clear if the implants were aligned parallel in their study as the relative parallelism of the implants could affect the passive fit of the overlying prostheses. Furthermore, Lin et al. concluded that the digital fabrication technology compared to the conventional one resulted in no difference in the accuracy for the parallel placed implants. However, better accuracy was reported for such technology for implants placed at 30 and 45 degrees; a finding that highlights the effect of the parallel placed implants in the current study [41].

Moreover, the cementation of the bars over the non-engaging abutments in both workflows may have accounted for the attained results [32]. Furthermore, the passive fit of the screw retained bar is affected by the number of supporting implants; the less the number of the implants supporting a prosthesis, the more passive the fit as concluded by Katsoulis et al. [42]. So, the smaller number of implants used to support the bar in the current study may account for the statistically insignificant difference between both workflows. Furthermore, Abdel-Azim et al., stated that the conventional impression/fabrication workflow resulted in a smaller marginal discrepancy for the single-implant frameworks compared to the digital one that showed better results for full-arch ones [21, 22].

Such less number of the implants used to support the bars in the current study could account for the study limitations. Therefore, further clinical studies evaluating the passive fit of conventionally fabricated screw retained bars supported with more number of implants are recommended. It is also recommended to recruit a larger number of participants in the future studies. Moreover, it has been reported that the use of the nonengaging abutments as in the current study, can produce greater stress in the abutment screws and the implant-abutment interface when forces are applied [43]. Thus, the passive fit in case of using the engaging abutments should be evaluated too. Furthermore, only one type of intraoral scanner has been used in the current study. Therefore, it is also

recommended to compare between different types of intraoral scanners with different scanning technologies regarding their effect on the passive fit in the future studies. However, the conventional workflow is cheaper when compared to the digital one. Moreover, intraoral scanners and milling machines are not available in all dental operatories. So, the conventional workflow may provide a cheaper acceptable standard of care for the completely edentulous mandible receiving a two implant retained overdenture, accounting for the clinical relevance of such workflow and matching the 2002 McGill conference statement.

## Conclusion

Conventional and digital fabrication workflows had clinically comparable effect on the passive fit of screw retained bar attachments supported by two dental implants.

## Supplementary Information

The online version contains supplementary material available at <https://doi.org/10.1186/s12903-024-04157-1>.

Supplementary Material 1

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Not applicable.

## Author contributions

Bassant sherif Gamal Eldin: Conceptualization, methodology, writing-original draft, writing- review and editing, data curation. Amin Talaat: Methodology, writing original draft, analysis, writing- review and editing. Noha Helmy Hasan Nawar: Conceptualization, methodology, writing- review and editing, data curation. Ahmed Mostafa Abdelfattah: Conceptualization, methodology, writing original draft, writing- review and editing, data curation.

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## Data availability

The data are available from the corresponding author upon request once the research article becomes published.

## Declarations

### Ethical approval

Approved from the Research Ethics Committee in the author's university Faculty of Dentistry Ain Shams University Research Ethics Committee (FDASU-Rec IM051811). Registration of the clinical trial was made on clinical trials.gov ID NCT05770011)

### Consent to participate

Informed consent was obtained from participants.

### Consent for publication

Not applicable. As there are no identifiable images of the participants.

### Competing interests

The authors declare that they have no competing interests.

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