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RESEARCH

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Effect of primary versus secondary splinting impression techniques on the passive fit of screw-retained implant prosthesis: a randomized clinical trial

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Abstract

Background The utilization of splinting techniques for impression copings is commonly advised for complex implant-supported prostheses, as it can enhance the fit of these prostheses. However, there is limited understanding regarding the impact of the secondary splinting of implant analogues, on the passive fit of the prostheses. Limited data are available on the secondary splinting of implant analogues before pouring the impression and its comparison with the primary technique of intraoral splinting of impression copings prior to impression making.

Objectives This study's objective was to determine the impact of the primary versus secondary impression splinting techniques using resin on the passive fit of screw-retained prosthesis.

Material and methods This randomized clinical trial (RCT) involved two parallel groups consisting of 14 completely edentulous patients, with seven patients in each group. Each patient received a total of eight implants, four implants per arch, resulting in a total of 28 screw-retained prostheses. Two different impression splinting techniques were employed. Group (1) utilized the primary splinting technique, where the impression copings were splinted before taking the impression. In contrast, Group (2) utilized the secondary splinting technique, where the implant analogues were splinted before pouring the impression material. To evaluate the passivity of the screw-retained prostheses in both groups, a single-screw test (one-screw test) was used. Additionally, supplementary methods, including the screw resistance test, were employed.

Results The findings of this RCT revealed higher passivity scores for secondary splinting impression pouring technique with a statistically significant difference ($P = 0.082$). There was a 2.2-fold greater frequency of non-passivity in the primary splinted method. In group (2), the likelihood of non-passivity was four times higher for upper arches prostheses, while there was no significant difference ($P = 0.5$) observed in both groups for lower arches prostheses.

Conclusions The study found that using the secondary splinting impression pouring technique resulted in greater passivity of the implant prostheses compared to the primary splinting impression technique.

Keywords Passive fit, Screw-retained prostheses, Primary splinting, Secondary splinting, Single-screw test

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Background

Implant-supported prostheses have become the most popular treatment choice for the functional and aesthetic rehabilitation of edentulism due to advancements in implant technology, new innovations in procedures and materials, and the long-term effectiveness of the implant (Richi et al. 2020). The accuracy of the prosthodontics procedures can influence the long-term success of implant-supported restorations (Rutkunas et al. 2020; Revilla-Leon et al. 2018).

When the prosthesis–implant interface is maximally congruent, a prosthesis supported by implants that is passively fitted causes no strains on the prosthesis, implant, or surrounding structures (Katsoulis et al. 2017). One of the most crucial aspects of a treatment plan's effectiveness is the passive fit of implant-supported prostheses (Richi et al. 2020). To ensure a passive fit or a strain-free superstructure, it may be necessary for a framework to exert zero strain on both the implant components it supports and the surrounding bone (Peixoto et al. 2020; Karl and Taylor 2016).

In general, screw-retained and cement-retained superstructures are used in implant-supported fixed prostheses. It can be challenging to create a passive fit for implant-supported restorations, particularly when using multi-unit restorations. Impression material and dental stone distortion, and metal castings are potential contributors to this issue. On the other hand, because of the die spacer, which can give about 40 μm of cement space, cement-retained implant prostheses have the potential to be passive (Pjetursson et al. 2015; Lee et al. 2008; Anitua and Alkhraisat 2019).

In a systematic review with meta-analysis, Gaddale et al. (2020) noticed that, when comparing screw retention to cement retention, the fixed prosthesis type had an impact on the frequency of biological and technical difficulties. In contrast to screw-retained prostheses, cemented restorations showed higher biological issues (implant loss, bone loss > 2 mm). Both fixations had varied effects on clinical outcomes. Screw-retained restorations offer the advantage of easier removal compared to cemented restorations, which can facilitate the treatment of both technical and, eventually, biological issues. For this reason, due to their enhanced biological compatibility, these restorations are preferred for this reason.

Manufacturing accurate models and well-fitting complete implant-supported prostheses has been challenging (Vieira et al. 2023). The distortion equation, encompassing cumulative distortions throughout the entire fabrication process, is responsible for the misfit in the superstructure of implant-retained prostheses. Ideally, a distortion equation with a cumulative value of zero would result in a completely passive fit, representing the optimal scenario. The distortion equation involves multiple clinical and laboratory processes, such as impression technique, master cast production, wax pattern manufacturing, framework fabrication, and final prosthesis delivery. Attaining a passive fit is possible when the sum of the distortion equation equals zero (Araujo et al. 2015).

It is possible to splint the impression copings by joining them with resin material before taking an impression. A rigid tissue mimic substance can also be used to link the implant analogues inside the impression before pouring the impression (Del'Acqua et al. 2008).

Branemark (Branemark 1985) was the first to develop the use of hard material to splint impression copings during the impression technique in order to stabilize and prevent rotational, horizontal, and vertical movements. Since then, many splinting methods and materials that are employed to hold the impression copings tightly have been researched.

Arora et al. (2019) analyzed the precision of implant-supported castings produced using splinted and non-splinted impression procedures with several parallel and non-parallel implants. According to the study's findings, for both parallel and angulated implants, the use of the splinted impression technique was more precise than non-splinted method.

Kavadia et al. (Kavadia et al. 2019) examined how the open-tray method of splinting the impression copings affected the accuracy of the cast. According to their argument, there is no clinical benefit to splinting the impression copings for parallel implants. Splinting of the impression copings, on the other hand, can improve the precision of the cast when the implants are not parallel.

Del'Acqua et al. (2008) In a conducted study, an evaluation was done using a stone index and three different impression techniques (tapered impression copings, squared impression copings, and squared impression copings splinted with acrylic resin) to compare the precision of three pouring techniques (conventional, pouring using latex tubes fitted onto analogues, and pouring after joining the analogues with acrylic resin). They revealed that the squared coping impression approach was the most precise. They continued by saying that the best pouring method for creating impressions with tapered or squared copings involved pouring after joining the analogues with acrylic resin using latex tubes.

We have suggested to convey that splinted impression techniques can be performed in two ways. The first method, known as the "primary splinted technique," involves intraoral splinting the impression transfer copings before making the impression. The second method, referred to as the "secondary splinted technique," involves splinting the implant analogues before pouring the impression. Additionally, there are scanty data regarding the impact of splinting implant analogues prior to pouring the impression on the passivity of screw-retained prostheses. Therefore, the primary versus secondary splinted technique's impact on the passivity of screw-retained implant prostheses was the subject of this randomized clinical investigation.

The null hypothesis under evaluation was that there is no difference in the passive fit of the screw-retained implant prosthesis when comparing the primary splinted technique and the secondary splinted technique.

Methods

Ethics approval and consent to participate

The study proposal has been registered and exempted by the institutional review board organization IORG0010868, Faculty of Oral and Dental Medicine, Ahram Canadian University, Egypt, no IRB00012891#80. Patients were informed about the research work, and consents were obtained.

Sample size, study design, and recruitment of participants

A sample size of 14 patients (seven patients in each group with 28 screw-retained prostheses) was considered enough based on a priori power analysis ($\alpha = 0.05$, power—0.8) (Richi et al. 2020).

Randomization process

Following clinical examinations for all eligible patients, 14 patients were randomly divided into two groups, each consisting of seven patients (two arches for each patient), using the research randomizer website (https://www.randomizer.org/), a specialized site dedicated to randomization processes: There were discovered to be two impression splinting methods.

Group (1): 14 master casts were created using the primary splinting approach by splinting the impression copings prior to taking an impression. Group (2): 14 master casts were created using the secondary splinting approach by splinting the implant analogues prior to pouring the impression.

To assess the passivity, the single-screw test (also known as the "one-screw test") was combined with a screw resistance test and other supporting techniques.

All patients were selected for the current study according to specified inclusion criteria; patient's ages ranged between 50 and 70 years, with completely edentulous upper and lower arches with angle's class I maxillo-mandibular relationship, free from any systemic disease that can prevent the osseointegration or installation of dental implants, and have adequate interarch distance more than 22 mm for both arches. Heavy smokers and patients with parafunctional habits were excluded. Figure 1

All patients went through total maxillary and mandibular rehabilitation by screw-retained prosthesis with four implants installed with metal framework, applying a delayed loading protocol.

Virtual planning and surgical guide fabrication

For all patients who were included, upper and lower full dentures were made using standard procedures. Laboratory duplication silicone (Zetaplus. C-silicone putty. Zhermack business—Italy) was used to reproduce the finished dentures. German-made radiopaque acrylic resin, often known as X-resin or radiopaque paste material, is employed as a duplicating substance. For both the upper and lower jaws, a cone beam computed tomography (CT) image was taken. BlueSky Software (BlueSky-Plan 4; BlueSky Bio) was then used to finish the implant planning. The rapid prototyping team processed the 3D virtual stent using specialized software. Figure 2.

Surgical procedures and screw-retained abutment installation

Dental implants with a root form and a tapered thread (S-clean tapered dental Implant fixtures, Dentis, Korea) were chosen. Osteotomy was performed with three drills

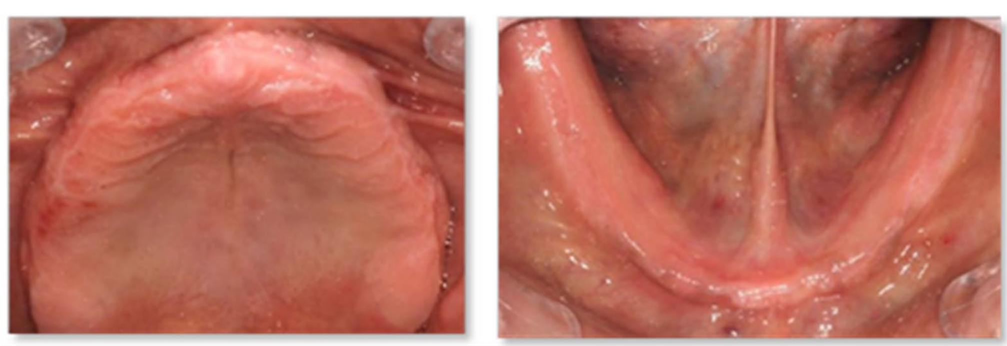

Fig. 1 Shows preoperative intraoral photographs of the maxillary (left) and mandibular (right) arches

Fig. 2 Displays the lower (left) and upper (right) final surgical guides

of increased diameter. After four months, the patients were recalled. The implants were exposed by punching out the covering soft tissue. A torque ratchet was used to secure the permanent short transmucosal titanium abutments (Transmucosal Octa abutment, DENTIS-Korea) over the implant fixtures and torque them to 35Ncm.

Impression making and master cast fabrication

Primary alginate impressions were made and study models were poured. Two acrylic open custom trays for each patient were made with a window cut through over the implant, one for the upper jaw and one for the lower jaw. Two primary impressions were carried out for the same patient. Impression transfer copings were screwed to the octa abutments using long fixation screws (Titanium fixation screw, Dentis implant system, Korea).

For group1, the impression copings were splinted using prefabricated acrylic bars that connected together to the impression copings using Duraly (Reliance Dental Manufacturing Company—Chicago—USA). The final impressions were taken with a silicone impression material (Medium consistency addition silicone, elite HD+, Zhermack, Italy).

For group (2), the impression copings were non-splinted. The final impressions were taken with a silicone impression material (Medium consistency addition silicone, elite HD+, Zhermack, Italy). Over the transfer copings, the dental implants lab analogues (Lab analogue, sub octa system, DENTIS company—Korea) were installed. Before pouring the impression through, the implant analogues were splinted using low shrinkage cold cure acrylic resin (Bredent, Multisil-mask, cold cure gingival mask resin, Germany) using a cartridge dispenser. The resin was injected around each implant analogue until it reached a suitable thickness and covered a portion of the implant analogues. Figure 3.

After an hour, Kimberlit, Type IV Dental Stone, Protechno-Spain's extra-hard type IV dental stone was used to pour the primary and secondary splinted impressions. The master casts obtained from the two different splinting techniques were used to fabricate two metallic

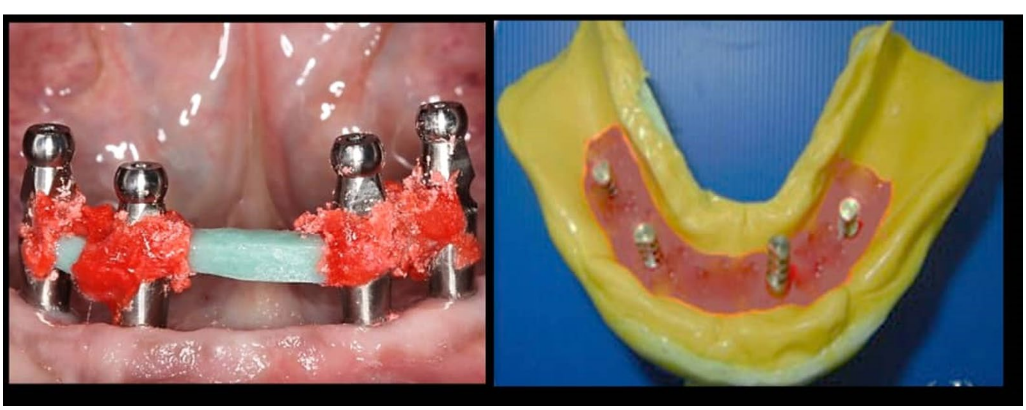

Fig. 3 Displays primary splinting copings (left) and secondary splinting analogues (right)

verification jigs (indexes) in order to evaluate the passivity of both techniques.

The resulted master casts for each group were:

Group (1): master casts produced from splinting the impression copings before impression making (primary splinting technique) without splinting the implant analogues before pouring.

Group (2): master casts produced from splinting the implant analogues before pouring the impression (secondary splinting technique) without splinting the impression copings.

Verification jig construction and passive fit evaluation

Both master casts were verified for accuracy using the metallic verification jig constructed of chrome cobalt alloy (Metal Brealloy, CO-CR alloy, Breadent—Germany). The cast cylinders were connected together with prefabricated metal bars with duralay (Reliance Dental Manufacturing Company—Chicago—USA) and then soldered (Soldering metal rods, You dent—USA) together. Accuracy was checked using single-screw test aided by screw resistance test (tightening every screw individually until initial finger resistance was achieved).

Both primary splinted and secondary splinted master cast jigs were examined for passivity using the single-screw test. The four abutments of verification jig were denoted sequentially from left to right Fig. 4. Single-screw test involves measuring the vertical gap that is formed on implant abutment c or d as a result of manual tightening of the retaining screw on implant abutment a. A piece of dental floss was wrapped between implant abutment and prosthetic abutment of the jig. The most distal abutment was next tightened down with a prosthetic fixation screw using just finger pressure. The jig's abutment will grab the floss and prevent it from slipping between two surfaces if it is less than the thickness of the implant abutment. In this instance, a gap and rocking motion were noticed during the verification jig's gentle seating, indicating that the master model did not accurately depict the intraoral condition.

Fabrication of the definitive prosthesis

After evaluation of passivity, the accurate master casts were chosen for the definitive prosthesis fabrication. Using the single-screw test, the finished metal framework was tired inside the patient's mouth to ensure passive fit. The final prosthesis was fabricated from prosthetic teeth (Visio-Light cured veneering composite resin, Germany) and light cured gingival composite material (Light cured modeling resin, Compoform U V. Bredent, Germany). Figure 5.

Results

Using SPSS, a statistical analysis of the study's findings was conducted. Chi-square test was performed to determine percentages and relative risk. This study's aim was to assess the impact of various impression splinting methods on the passive fit of screw-retained prosthesis. The results of this investigation revealed that all groups had discrepancies in the screw-retained prosthesis' passive fit. The study's findings were revealed as: 1 for passive prosthesis and 0 for non-passive prosthesis.

Percentage and relative risk of passivity for both groups.

In group (1), the passivity percentage was 35.71% passive and 64.29% non-passive. In group (2), the rate was 71.4% passive and 28.6% non-passive. In group (1), the risk of non-passivity was 2.2 times higher than group (2). The outcome demonstrated increased percentage passivity for group (2) with a statistically significant difference ($P=0.082$). According to Table 1, Fig. 6 the 95% confidence interval ranged from 0.9 to 5.6.

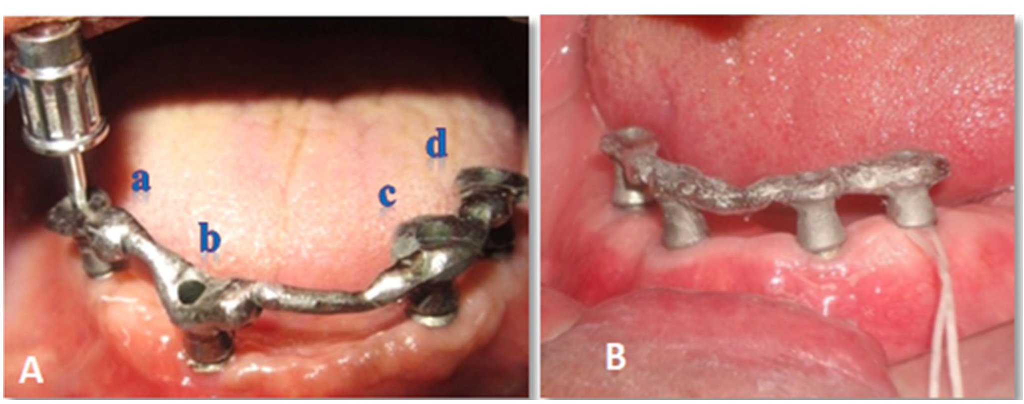

Fig. 4 Shows the process of prosthetic fixation screw insertion (**A**) and the assessment of the gap using dental floss (**B**)

Fig. 5 Shows the metal framework try-in, featuring passively fitting frameworks for upper arch (left) and lower arch (right)

Table 1 Percentage and relative risk of passivity for both groups

Variables	Group-1 (Primary splinting)		Group-2 (Secondary splinting)		Relative risk	CI 95%	*p* value
	Count	%	Count	%			
Passive	5	35.71	10	71.4	2.2	0.9–5.6	0.082*
Non-passive	9	64.29	4	28.6			

*P value < 0.05 indicates statistical significant differences

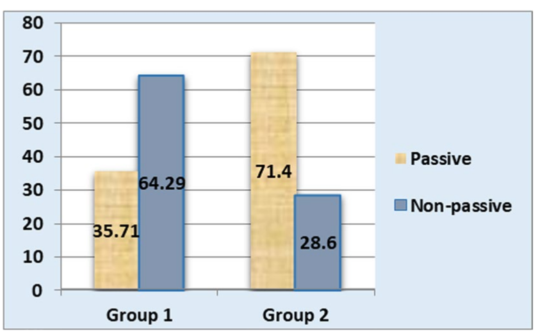

Fig. 6 Bar chart showing percentage of passivity

Comparison between groups (1) and (2) in the upper arch.

In group (1), the upper arches prosthesis had a 28.6% passive and a 71.4% non-passive rate. The rate for group (2) upper arches prostheses was 85.7% passive and 14.3% non-passive. In group (1), the probability of being non-passive was four times higher. According to the results, group (2) demonstrated a higher percentage passivity with a statistically significant difference ($P=0.09$). As can be seen in Table 2, Fig. 7 the 95% confidence interval ranged from 0.3 to 6.3.

Comparison between groups (1) and (2) in the lower arch.

Lower arches prosthesis in group (1) had a 42.9% passive and a 57.1% non-passive rate. In group (2), the percentage for lower arches prosthesis was 57.1% passive and 42.9% non-passive. In group (1), the chance of non-passivity was 1.3 times higher. For lower arches prosthesis, the results revealed a non-statistically significant difference ($P=0.5$) in both groups. As can be seen in Table 3, Fig. 8 the 95% confidence interval ranged from 0.45 to 3.88.

Table 2 Percentage and relative risk of passivity for both groups in the upper arch

Variables	Group-1 (primary splinting)		Group-2 (SECONDARY splinting)		Relative risk	CI 95%	*p* value
	Count	%	Count	%			
Passive	2	28.6	6	85.7	4	0.3–6.3	0.09*
Non-passive	5	71.4	1	14.3			

*P value < 0.05 indicates statistical significant differences

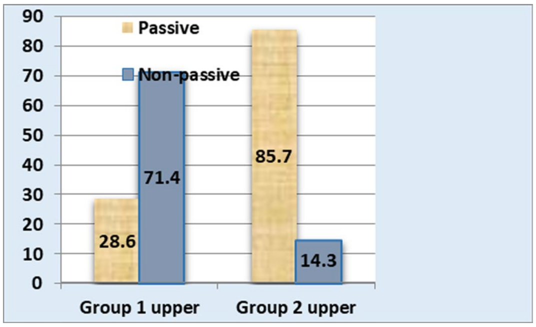

Fig. 7 Bar graph depicting the percentage of passivity for upper arch

Discussion

Considering that there were variations between the research groups, the null hypothesis regarding the passive fit was rejected. Furthermore, in the first group (primary splinting impression technique), there were differences in passivity between the maxillary and mandibular prosthesis.

Full-arch fixed prostheses supported by implants have been reported to exhibit a high success rate and have received positive feedback from patients (Barootchi et al. 2020; Malo et al. 2019; Luna Gomes et al. 2019; Mohamed et al. 2022). For patients who are edentulous, the All-on-4 concept is a very effective treatment option with great clinical results. This is accomplished without substantial grafting, its costs, and the attendant surgical morbidity (Malo et al. 2019).

Using an open-tray approach for a secondary impression eliminates the need to reposition the coping in its respective space in the impression. This reduces the effect of implant angulation and significantly affects the impression accuracy (Tafti et al. 2019).

To obtain accurate impressions using the splint technique, it is important to minimize acrylic resin shrinkage (Lee et al. 2008). Coping movement in multiple implants can lead to inaccurate impressions in both clinical and laboratory phases (Agnihotri et al. 2023). To achieve optimal accuracy, some authors have emphasized the importance of intraorally splinting impression copings together before taking an impression. Alternatively, other authors have suggested dividing the splint material into thin sections and rejoining them using minimal original material to minimize polymerization shrinkage (Elshenawy et al. 2018).

Rajendran et al. (2021) conducted a study comparing the accuracy of two types of impression materials, vinyl polyether silicone and polyvinyl siloxane, when used for taking impressions of multiple implants in simulated edentulous mandibles. The impressions were taken using both non-splinted and splinted direct open-tray techniques. The study concluded that regardless of the splinting method, both materials showed similar dimensional accuracy for fabricating casts.

In order for implant-supported prostheses to achieve a passive fit, it is necessary to confirm the accuracy of the master cast prior to casting the metal framework (Papaspyridakos et al. 2017). A commonly employed method to enhance the precision of the master cast and ensure a proper fit of the framework is through the use of a verification jig. The verification jig is utilized to confirm the position accuracy of the implant abutment analog on the master cast, thereby reducing the potential for complications related to implants and prosthetics (Blasi et al. 2022).

The single-screw test has been widely recognized as a standard clinical method to assess misfits in implant prosthesis (Slauch et al. 2019). The clinical satisfaction of the prosthesis is determined by ensuring that the screw on the terminal abutment can be fully tightened without any visible marginal gap at other locations, either through visual examination or the use of dental probes (Al-Meraikhi et al. 2018).

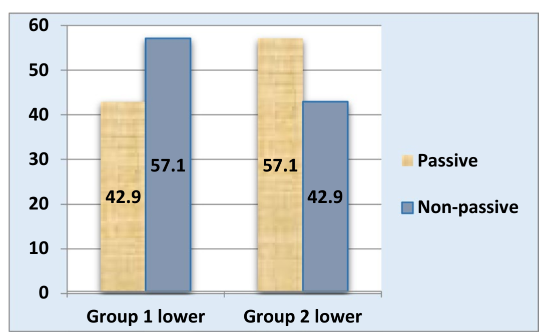

Fig. 8 Bar graph depicting the percentage of passivity for lower arch

Table 3 Percentage and relative risk of passivity for both groups in the lower arch

Variables	Group-1 (Primary splinting)		Group-2 (Secondary splinting)		Relative risk	CI 95%	*p* value
	Count	%	Count	%			
Passive	3	42.9	4	57.1	1.3	0.45–3.88	0.5
Non-passive	4	57.1	3	42.9			

In this study, the results showed greater passivity scores for secondary splinting impression pouring technique with statistically significant difference ($P=0.082$). In the primary splinted approach, there was a 2.2-fold increased incidence of non-passivity. The results obtained indicate that splinting the implant analogous before pouring is crucial in preventing analogue displacement. The deformation of impression material that occurs during the removal of splinted impression copings is typically reversible because of the high elastic recovery exhibited by addition silicone materials. On the other hand, the distortion of non-splinted implant analogues produced by gypsum product expansion during setting is irreversible since the analogues in the set model will be permanently locked in the distorted position. As a result, it is essential to splint the implant analogues before pouring to prevent them from moving.

In the upper impressions of both groups, there was a highly notable statistical difference ($P=0.09$) indicating a higher percentage of passivity in group (2) compared to the other group. Both groups of the lower impressions showed no statistically significant difference ($P=0.5$) and were found to be less effective compared to the upper splinting technique. This finding could be attributed to the potential influence of medial mandibular flexure, which may impact the accuracy of the lower impression.

The study had several limitations. Firstly, the sample size was relatively small, which may limit the generalizability of the results. Secondly, patients with bruxism and habitual jaw clenching were excluded, potentially impacting the applicability of the findings to these specific patient groups. Lastly, the study evaluated the clinical and laboratory passive fit of the frameworks, but there was insufficient time for post-implantation patient observation. Longer follow-up periods would be necessary to assess the long-term success of the prostheses.

To overcome these limitations, it is suggested that future studies should employ a well-designed clinical trial conducted across multiple centers. This approach would allow for the inclusion of a larger and more diverse sample of participants selected sequentially. The study should encompass a comprehensive assessment of implant parameters, such as marginal bone loss and other potential complications. By doing so, more compelling evidence can be generated, providing a more precise evaluation of the clinical significance of the prostheses being examined.

Conclusions

Considering the limitations of this study and based on the laboratory and clinical evaluation results, the following conclusions were made:

Implant prostheses fabricated using the secondary splinting impression pouring technique exhibited greater passivity compared to those fabricated using the primary splinting impression technique.

The secondary splinting technique, involving the splinting of implant analogues before pouring, was found to be a reliable and simple approach for obtaining accurate master casts.

Recommendation

To gather more comprehensive and reliable evidence, it is recommended to conduct larger-scale RCTs that are expertly designed and implemented. These trials should have extended follow-up periods to assess the long-term outcomes and efficacy of interventions. It is important to incorporate a wide range of functional, prosthodontic, and patient-reported outcome measures in order to obtain a comprehensive understanding of the treatment's effectiveness. By conducting such studies, researchers can enhance the validity and generalizability of their findings, leading to more informed clinical decision-making.

Abbreviations

RCT	Randomized clinical trial
CT	Computed tomography
CO-CR	Cobalt chromium
SPSS	Statistical package for scientific studies

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RS, MH, and SA performed the clinical procedures, data collecting, statistical analysis, and manuscript preparation, HO, AA, and DA conducted data analysis, critical revision, and wrote the manuscript, and all authors evaluated and approved the final version of the paper.

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Availability of data and material
The corresponding author will provide the datasets created and/or analyzed for the current work available upon reasonable request.

Declarations

Ethics approval and consent to participate
The study proposal has been registered and exempted by the institutional review board organization IORG0010868 Faculty of Oral and Dental Medicine, Ahram Canadian University, Egypt, no IRB00012891#80. Patients were informed about the research work, and consent was obtained.

Consent for publication
Not applicable.

Competing interests
The authors declare that they have no competing interests.

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