ASDJ
AINSHAMS DENTAL JOURNAL

Print ISSN 1110-7642
Online ISSN 2735-5039

AIN SHAMS DENTAL JOURNAL
Official Publication of Ain Shams Dental School
September 2024 Vol. 35

Retention of Maxillary Denture Bases Fabricated from Traditional and Thermoplastic Tray Impressions: A Randomized, Crossover Clinical Trial

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Aim: to compare the retention, dentist and patient satisfaction of maxillary 3D-printed dentures fabricated from thermoplastic tray impressions to those made using conventional final impressions.
Materials and Methods: Eleven completely edentulous patients were recruited for this double-blind, randomized, crossover clinical trial. Participants were randomly assigned to receive dentures fabricated from either conventional tray final impression or thermoplastic tray final impression for 14 days before switching to the other pair. Outcomes assessed were maxillary denture retention patient and dentist satisfaction with dentures. The outcomes were measured at baseline, and 14 days after denture insertion. After crossover, a similar protocol was implemented. For statistical analysis, a paired sample t-test with α=0.05 was used.
Results: The trial was successfully completed by all participants. No significant difference in peak retention values was measured between the two groups at baseline ($p = 0.27$) and 14 days after denture insertion ($p = 0.55$). However, after 14 days of denture insertion, there was a statistically significant increase in retention values for both the conventional tray impression ($p = 0.016$) and the thermoplastic impression ($p = 0.022$). Regarding patients' satisfaction, there was a statistically significant difference in overall patient satisfaction favoring dentures fabricated from the thermoplastic tray, recording 3.40 ±1.23 ($p = 0.021$). There was no significant difference in overall dentist satisfaction with the denture in both groups. ($p = 0.77$)
Conclusion: A simplified approach for maxillary denture fabrication using thermoplastic trays could have comparable outcomes with dentures made from conventional trays.

Keywords: Complete denture, Dental impression technique, Patient satisfaction, Dentist Satisfaction, Denture retention

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Introduction

Complete edentulism is a worldwide phenomenon that occurs because of biological disease processes. Edentulism may lead to impaired chewing, speech, aesthetic concerns, or negative self-perception and hence negatively impact the quality of life.[1] Conventional CDs have been used for years as a treatment option for edentulous patients as they are economical and easy to fabricate. They provide an acceptable level of esthetics and function for many patients have been proven to improve life quality significantly. [2] However, patients often complain about the lack of optimal denture retention. [3]

Retention is regarded as a significant factor in the success of a complete denture, which is also enhanced by maximum coverage and excellent adaptation to the basal tissues. [4] Denture retention is directly proportional to the surface area of the prosthesis and the intimate fit of the denture base to soft tissues. [5]

The accuracy of the impression depends on the impression material, the type of impression tray, and the impression technique, which in turn affect the degree of contact with denture-bearing tissues, patient satisfaction, and quality of life. [6]

There was a general agreement among authors on using conventional acrylic custom trays for the final impression in complete denture construction. [7] Studies have demonstrated that they are widely used in complete denture impressions, with 75-98% of participating dentists using them. [7,8]

Advantages of custom trays include that they can adapt to any anatomic anomaly, including large tori; they are more stable than stock trays; and they can be used again for the same patient. Hence, it was chosen to be the comparator in this trial. However, conventional acrylic custom trays require a preliminary impression to be constructed, which wastes time, effort, and materials.

Although conventional impression techniques in CD therapy have served the profession well throughout the years, the recent introduction of new materials and devices presents an opportunity to reconsider conventional wisdom. Intraoral scanner systems have made it possible for clinicians to directly collect data from the mouth without taking a traditional impression and pouring a cast. [9]According to several studies, edentulous jaw scanning techniques can produce complete dentures without conventional records being transferred to the dental laboratory. These techniques record edentulous mandibular and maxillary arches in a similar way to conventional impressions. [9]

Other investigators found that IOS can capture tissues in a passive state, resulting in a true mucostatic impression; nevertheless, recording denture borders and the posterior palatal seal for marginal sealing of the CD using IOS alone was problematic.[10]

It may be challenging and time-consuming to scan an edentulous area with an IOS device, as edentulous areas are smooth and lack obvious anatomical structures. Thus, clinicians have described using artificial markers to overcome these limitations. [11] Additionally, there may be problems with image stitching, particularly in the palatal region, due to mucosal movement during scanning. [12]

Therefore, multiple investigators concluded that intraoral scanners are only used to produce a 3D-printed custom tray or stable trial denture base to be modified to the desired border extension using conventional reline impression technique. [9,13] Additionally, attempts were made to manufacture 3D printed custom trays which can be designed based on a digitized cast. [14]

Novel thermoplastic materials and anatomically developed stock impression tray systems allow for the creation of precise, pressure-controlled, definitive impressions that can function as custom trays in the patient's mouth without the need for custom impression trays, reducing the

number of visits and saving chairside time. [15]

In an in vivo study done to compare the retention of DBs fabricated from selective pressure, functional, and Massad's impression techniques, it was concluded that the retention of the DBs manufactured from the selective pressure impression technique was the highest, followed by the functional and Massad's techniques. No statistically significant difference was found between the mean load to dislodge DBs for selective pressure and Massad's techniques. However, all impression techniques showed an adequately retentive permanent denture. [16]

Moreover, the denture base fabrication method affects the fit between the base and mucosal tissue, which is important for complete denture retention. 3D printing has many advantages over conventional processing for the fabrication of complete dentures, which include faster manufacturing time, being more economical, and putting fewer burdens on dentists and dental technicians. [17]

However, research on the retention of denture bases (DBs) made from thermoplastic tray impressions is insufficient. Therefore, this study aimed to compare the retention of dentures fabricated from thermoplastic tray impressions to those made using conventional final impressions. The null hypothesis of the study was that there would be no difference in denture retention, patient satisfaction with their prosthesis, as well as the clinical quality of the dentures as assessed by the dentist obtained by the two impression techniques.

Materials and Methods

PICO

- Population: Completely editing patients to receive complete dentures.
- Intervention: 3D printed complete denture constructed from definitive impression using prefabricated thermoplastic tray.
- Control: 3D printed complete denture constructed from definitive impression using conventional acrylic resin custom tray.
- Primary outcome: Retention of maxillary denture.
- Secondary outcome: Dentist and patient satisfaction.

Trial Design

This study was designed as a double-blind, randomized, crossover, clinical trial with two groups of 1:1 allocation ratio distributed as eleven patients in each arm. The end point is set to be 14 days after the complete denture insertion. This study was approved by the Ethics committee of Scientific Research of Cairo University (#4.4.21). The protocol was registered in clinicaltrials.gov (ClinicalTrials.gov ID: NCTT04982510). This trial is self-funded by the primary investigator. Patients were recruited from an outpatient clinic in the Department of Prosthodontics (Faculty of Dentistry, Cairo University), where a total of eleven patients fulfilling the inclusion criteria were recruited by SA.

The inclusion criteria included, a complete edentulous patient, ranging from 50 to 70 years of age, well- or moderately developed ridges, a healthy attached mucosa with adequate thickness without inflammation, the last extraction occurring six months ago, and facial symmetry. The study excluded individuals with Parkinson's disease, xerostomia, resin allergy, residual ridge pathological changes, severe undercuts, irregular bony exostosis, flabby or flat ridges, and medical or psychological conditions hindering cooperation.

Randomization

Simple randomization using sequentially numbered opaque sealed envelopes was conducted. Every participant chose an opaque sealed envelope from a box to ensure allocation concealment. Envelopes have been assigned to KZ who was neither involved in the denture construction procedure nor the

data collection. Randomization dictated the initial denture impression protocol, either the conventional or thermoplastic one. The two dentures were delivered in a randomized order with a two-week gap between them for washout.

Blinding

This trial was double blinded as the patient could not recognize the difference between the two maxillary dentures constructed using different impression techniques. Additionally, the investigator MA conducting the denture assessment and measuring dentist satisfaction was not involved in randomization or denture construction.

Denture Construction

The interventions and possible harms of the study were discussed with patients by the principal investigator, SA. Patients willing to participate signed a written informed consent in Arabic to be enrolled in the study. Patients' relevant medical, social, and dental histories were recorded, and a clinical examination was conducted.

A preliminary impression was obtained with irreversible hydrocolloid (Tropicalgin, Zhermack) in stainless steel impression stock trays (Aluminum tray, Misr Dental, Egypt), which borders were individualized with pink wax (Cavex set-up regular pink wax, Netherlands). Maxillary and mandibular study casts were obtained. Custom trays were fabricated on the preliminary casts with self-curing acrylic resin (Cold Cure Special Tray Material, Acrostone Co., Egypt). The participants were randomly assigned into 2 groups according to the maxillary final impression technique: conventional tray impression and thermoplastic tray impression. On the second visit, the final impression was made according to the randomization, using selective pressure impression technique. [18]

Final Impression

Conventional Tray Final Impression

After custom tray disinfection, it was examined intra-orally for adaptation, fit, and proper extensions. Trays' borders were painted with tray adhesive material (Universal Tray Adhesive, Zhermack, Italy), and then heavy body addition silicone (Aquasil Ultra+ Heavy Fast Set Tray Material, Dentsply Sirona, United States) was used as border molding material (Figure 1A). Afterwards, the tray was painted with tray adhesive material, and the final impression was obtained with medium body addition silicone (Aquasil Ultra+ Medium Body Tray Material, Dentsply Sirona, United States) (Figure 1B).

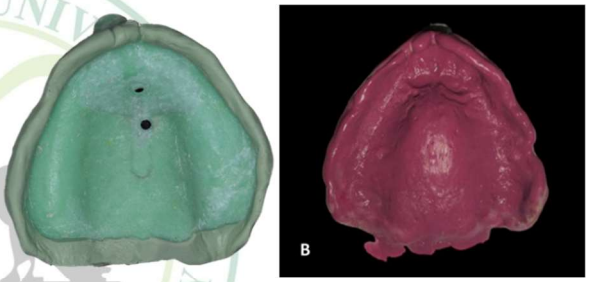

Figure 1: A: Conventional custom tray fitting surface. B: Final impression in conventional custom tray

Thermoplastic Tray Final Impression

Thermoplastic trays (Wagner tray, bigjawbone LLC, United States) are available in a single standard size that can be intra-orally molded to fit the arch shape (Figure 2A). This was accomplished by heating for one minute in a hot water bath. If the tray borders were too short, the tray was lengthened by adding the thermoplastic material supplied with the tray. After completion of tray adjustment and checking the tray to be 2 mm short of the vestibule, the trays' borders were painted with tray adhesive material, and then heavy body addition silicone was used as a border molding material. The tray's fitting surface opposite the rugae and median palatine raphe was scrapped using a dental carver to create space for the selective pressure impression technique (Figure 2B). Afterwards, the tray was painted with tray adhesive material, and the final impression was obtained with medium body addition silicone (Figure 2C).

For patients in both groups, the mandibular arch impression was done using an acrylic resin special tray. Border

molding was done by green stick impression compound (Hiflex tracing sticks, Prevest, India) and the final impression was obtained by medium body addition silicone (Aquasil Ultra+ Medium Body Tray Material, Dentsply Sirona, United States).

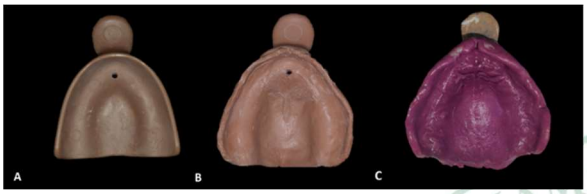

Figure 2: A: Unmodified thermoplastic tray. B: Thermoplastic tray after intraoral molding and modification. C: Final impression in thermoplastic tray

All final impressions were boxed and poured using hard dental stone (Denston 4, Ata Plaster, Turkey), which was mixed following the manufacturer's recommended water/powder ratio (30 ml/100 g) for 30 seconds in a vacuum mixer. Impressions were poured over the vibrator, and the dental stone was left to set in the impression for an hour before separation. The casts were left to set for 24 hours before being scanned using an extraoral scanner (FREEDOM HD, DOF - Degree of Freedom, South Korea).

The obtained STL files were imported into specialized CAD software (Exocad Gmbh Julius-Reiber, Germany). Splint module was selected, followed by the orientation of the cast according to a vertical path of insertion. Undercuts were allowed up to 0.1mm. The outline of the denture base was drawn by dots along the full depth of the vestibule on the virtual cast. The thickness of the denture base was set to be 2mm. The denture base was exported in the form of an STL file.

The denture base STL files were imported into free-form software (Blender software, Blender Foundation, Netherlands). The geometric center was determined using a software tool (set center to geometry). The geometric center was virtually annotated by (+) on the polished surface, to which a cylinder shape was attached. The finished denture base with the cylinder representing the geometric center mark was exported in the form of an STL file (Figure 3A).

The designed denture base was imported into 3D printing preprocessing software (CHITUBOX, CBD-Tech, China). The denture base was centralized on the building platform using the X, Y, and Z axes. The denture base was oriented at 45º in relation to the building platform. Medium-sized support arms were added to the denture base's polished surface. The curing time was set according to the manufacturer's instructions, and the layer thickness was set to 50 µm.

The STL file was exported to a stereolithography 3D printer (Phrozen Sonic Mini 4K 3D Printer, Taiwan) to fabricate denture bases using pink denture base resin (NextDent Denture 3D+ Resin - Dark Pink, Netherlands).

The printed denture base was placed in the wash and cure machine (Anycubic wash and cure machine 2.0, China). First, the denture base was rinsed from the uncured residual resin in 99% alcohol using an ultrasonic bath for no longer than five minutes. Then, post-curing was done in a UV-light curing box for 10 minutes. Afterward, the supporting arms were removed, and the outer surface was polished using a rag wheel with pumice.

Wax occlusal rim was added to the maxillary printed denture base to be used as an occlusion block. Then it was inserted into the patient's mouth to check lip and cheek support and adjust occlusal plane height and inclination. The upper cast was mounted using facebow records, and the lower cast was mounted in the appropriate vertical dimension using a centric relation record.

Artificial teeth were attached to the printed denture base using wax, following the guidelines of conventional complete denture construction. The maxillary and mandibular dentures were tried in the patient's mouth to assess the tooth shape, size, arrangement, vertical dimension, lip

support, and centric relationship of the jaws.

Denture was flasked and the wax was eliminated. To avoid subjecting the printed denture base to additional heat, self-cure acrylic resin was used to attach the artificial teeth to the obtained denture base to avoid subjecting the printed denture base to additional heat, which could lead to dimensional distortion. The denture was then finished and polished and inserted into patient mouth. [19]

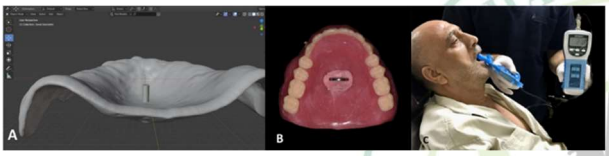

Figure 3: A: Cylinder representing the geometric center. B: Stainless steel wire loop attached to denture's base geographic center with self-cure acrylic resin. C: Patient position during retention measurement

Measurement of Primary Outcome: Retention

Retention was measured on denture insertion and 14 days after insertion and settling. A stainless-steel wire loop was attached to the denture base's geographic center by self-cure acrylic resin, which was determined digitally and denoted by a cylinder on the polished surface (Figure 3B). The patients were set in a semi-upright position in the dental chair. Hence, the palate was almost 45 degrees to the floor, which allowed the administered dislodging force to be perpendicular to the denture. The patients were asked to partly open their mouths so that the nylon thread did not come into contact with their tongues and lips (Figure 3C). [20]

Patients were instructed to rinse their mouths with water before and after each test to ensure a consistent quantity and quality of saliva. Each fabricated maxillary denture was seated intraorally and allowed to remain for a settling time of 3 minutes before measuring vertical pulling force.

Retention was measured using a digital force gauge device (Digital Force Gauge, Extech Instruments, Nashua, New Hampshire), applying a pulling action on a snap hook attached to the geometric center of denture bases. The device was prepared first, the unit of measurement was chosen to be Newton, and the peak hold option was selected.

A total of five measurements (pulls) will be made for each base. The angle and distance between the denture base and the digital force meter were maintained throughout the study.

Measurement of Secondary Outcome: Dentist & Patient Satisfaction

After 14 days of denture use, a validated questionnaire was used to obtain patients' ratings of the prosthesis on a Likert scale. [21] The questionnaire is based on different domains, including aesthetics, phonetics, mastication, and comfort, while the dentist assessed the denture regarding the quality of fit (retention), extension, vertical relation, and occlusion.

The dentists and the patients rated their dentures using a Likert scale ranging from 1-5 (5=very satisfied; 4=satisfied; 3 = neither satisfied nor dissatisfied; 2=dissatisfied; 1=very dissatisfied).

Statistical analyses were conducted using IBM SPSS Statistics (v2.0; IBM Corp). Since the Kolmogorov-Smirnov test of normality revealed no significance in the distribution of values, parametric statistics were used to describe the data, and data were described using mean and standard deviation (SD). For normally distributed data, a paired sample t-test with α=0.05 was used to compare the effect of time and the effect of group. For patient and dentist satisfaction scores, Wilcoxon signed-rank test was used.

Results

I. Complete denture retention

Denture bases constructed from the thermoplastic impression technique showed higher baseline retention values 20.54±7.82 in comparison to denture bases constructed from the conventional impression technique 19.84±7.36 (

Table 1). However, there was no statistically significant difference between the studied groups.

After two weeks, there was no statistically significant difference in retention values between the two studied groups (p-value > 0.05).

After two weeks of denture insertion, there was a statistically significant increase in retention values for the both studied groups recording p-values of 0.016* and 0.022* for the conventional tray impression technique and the thermoplastic impression technique respectively (Table 1).

Table 1: The mean, standard deviation (SD) of retention

Groups	Retention				
	Baseline		After 2 weeks		*p-value*
	Mean	SD	Mean	SD	
Conventional Tray Impression	19.84	7.36	21.91	8.14	19.84
Thermoplastic Tray Impression	20.54	7.82	22.62	8.56	7.36
p-value	0.276 N. S		0.055 N. S		

*: Significant (p<0.05). N.S.: Non-Significant (p > 0.05)

II. Patient satisfaction

There was a nonsignificant difference in all the patient satisfaction domains except for comfort recording a significant p-value of 0.048. For the comfort domain, the thermoplastic tray impression recorded a higher value of 4.43±0.6 in comparison to conventional tray impression which recorded 4.23±0.8.

The paired sample t-test showed that there was a statistically significant difference in overall patient satisfaction recording 3.31 ±1.25 and 3.40 ±1.23 for conventional tray impression and thermoplastic tray impression respectively (**Error! Reference source not found.**2).

Table 2: The mean, median and standard deviation (SD) of patient's satisfaction by the denture in different groups

	Patient's satisfaction						
	Conventional Tray Impression			Thermoplastic Tray Impression			*p-value*
	Mean	SD	Median	Mean	SD	*Median*	
Aesthetic	2.82	1.41	2.5	2.88	1.37	5.5	0.180
Phonetics	3.68	1.08	4	3.77	1.08	4	1.000
Mastication	2.94	1.1	3	3.01	1.13	3	0.317
Comfort	4.23	0.8	4	4.43	0.6	4.5	0.048*
All over	3.31	1.25	3.5	3.40	1.23	3.5	0.021*

*: Significant (p<0.05). N.S.: Non-Significant (p > 0.05)

III. Dentist Satisfaction

The paired sample t-test showed that there was a non-significant difference in overall dentist satisfaction between the two studied groups (Table 3).

Table 3: The mean, standard deviation (SD) of denture assessment by the dentist in different groups

	Denture Assessment by The Dentist				
	Conventional Tray Impression		Thermoplastic Tray Impression		*p-value*
	Mean	SD	Mean	SD	
Retention	4.2	0.632	4.1	0.738	0.78
Extension	4.4	0.516	4.5	0.85	0.678
Vertical Relation	4.1	0.876	4.1	0.876	1.000
Occlusion	4.5	0.85	4.4	0.516	0.678
Overall satisfaction	4.3	0.723	4.28	0.751	0.868

*: Significant (p<0.05). N.S.: Non-Significant (p > 0.05)

Discussion

The impression material and technique affect the quality of DB intimate contact, which affects denture retention, patient satisfaction, and quality of life. Impression accuracy is affected by the impression materials and the type of impression tray used.

The recent introduction of thermoplastic materials and anatomically designed stock impression tray systems that could be easily adapted as custom trays in the patient's mouth where though to enable the creation of precise, pressure-controlled definitive impressions. The Wagner tray, developed by Dr. Stephen Wagner, is considered a novel thermoplastic tray. It has the advantage of being non-perforated and closely resembling the conventional resin custom tray. This tray is used in

AvaDent's three-appointment workflow to record final impressions.[22] In another trial, this tray was used to simultaneously record the final impression and the neutral zone, facilitating the virtual teeth setup and enhancing phonetics outcomes. [23]

Therefore, the main objective of the present study was to compare dentist satisfaction, patient satisfaction, and retention between printed DBs constructed from conventional impression trays and novel thermoplastic trays.

The trial included completely edentulous patients exhibiting facial symmetry and well-developed ridges. Patients with flabby tissues or severely resorbed ridges were excluded as they require impression-making modifications, either in trays, impression material, or post-insertion tissue conditioning application, all of which would subsequently add to the trial's variables. [24]

The denture bases were designed to have a minimum thickness of 2mm in order to produce a denture base with acceptable flexural properties. [25]

It has been established that measuring complete denture retention is best accomplished by pulling the denture from its geographic center [20]. Digital determination of the denture geometric center was carried out using CAD software in order to standardize results and control variables. [26]

A stereo-lithography printer was chosen in this study as it was shown to produce an intaglio denture surface with better trueness than DLP printers [27,28]. Regarding the printing parameters, a layer thickness of 50 µm was chosen since it has been demonstrated to produce less dimensional discrepancy and variation. [29]

A 45° printing build angle was chosen to print the denture bases as it was found to produce the highest fitting accuracy by many authors. [27,30]

Medium-sized support arms were chosen instead of large support arms since the latter are more difficult to remove in the post-processing process, which might have led to denture distortion. [31]

All efforts were made to standardize the retention measurement process. The patient was seated in a semi-upright position in the dental chair with his mouth open, lips relaxed. A digital force gauge was used to measure retention. The vertical dislodging force was applied to the denture and increased gradually until the denture was dislodged. Retention force was measured as the maximum force needed to completely dislodge the maxillary denture.

As with any complete denture, a settling in period begins with its insertion. This period is thought to last between one to three weeks, at the end of which the denture sits more closely to its supporting tissues than when it was first delivered [32,33]. Because of this intimate contact with the underlying tissue, the load was evenly distributed across the denture intaglio surface. Therefore, an evaluation period of maxillary denture retention after two weeks of denture insertion is thought to produce sufficient retention. [34]

In this study, the secondary outcome was patient satisfaction. Presenting the patients' thoughts aids in the establishment of a standard to enhance the health care quality of patients and the quality of life following prosthetic tooth replacement. A validated questionnaire was used in the current clinical study to evaluate the dentist and patient satisfaction. It was chosen as it is a comprehensive self-assessment questionnaire meant to assist dentists in evaluating the final complete denture. [21]

Functional complaints about the denture were assessed by questions about phonetics, the presence of any sore spots related to the dentures, denture loosening, or even difficulty eating. Facial aesthetics were also assessed by asking the patients whether they were satisfied with their facial appearance with dentures and whether they were satisfied with the size, shape, and color of the teeth.

For the dentist's satisfaction, the denture assessment was done based on retention, extension, vertical relation, and occlusion. The results revealed a statistically insignificant difference in overall dentist satisfaction between the two groups (4.3±0.7 for control group and 4.2±0.7 for test group, *p*-value >0.05) investigated, with the denture extension receiving the highest mean dentist satisfaction score (4.4±0.5 for control group and 4.5±0.8 for test group). This finding might indicate the ability of the thermoplastic tray's impression to produce dentures of acceptable and comparable quality to those produced by the traditional method.

Moreover, dentures constructed from thermoplastic tray impressions showed higher overall patient satisfaction scores (3.4±1.23). There was a statistically non-significant difference in all the patient satisfaction domains between the two studied groups except for the comfort domain, the thermoplastic tray recorded a higher value (2.94±1.1 and 3.01±1.13 for control group and test group respectively, *p*-value<0.05). This was in agreement with previous studies and could be due to the enhanced denture base fit along with the presence of fewer sore spots. [35,36]

Another reason for justifying the improved comfort in the thermoplastic tray group could be because of the tray material itself on impression accuracy. The chemically cured acrylic resin custom tray has the disadvantage of polymerization shrinkage and stress relaxation, which could induce deformation of the final impression, resulting in final prosthesis inaccuracies. [37]

Regarding retention, denture bases constructed using the thermoplastic impression technique showed higher baseline retention values (20.5±7.8 mean SD) in comparison to denture bases constructed using the conventional impression technique (19.8±7.3 mean SD). However, there was no statistically significant difference between the studied groups (*p*-value 0.2).

The acceptable and comparable retention values observed for both groups could be explained by the thermoplastic tray's ability to capture accurate border molding and impression to ensure adequate border seal analogous to the conventional tray. [4,16]

Furthermore, after two weeks of denture insertion, there was a statistically significant increase in retention values for both studied groups. The reason for this might be related to the settling of the denture base into the underlying resilient mucosa [33]. The improvement in denture retention with time emphasized the importance of the patient's neuromuscular coordination established with function. [38]

This may be backed by research that indicates the prosthesis fabricated using 3D printing technology attached firmly to the tissue, improving its retention and stability and distributing stresses evenly on the tissues. [39]

One limitation of this study is that it focuses on the upper arch only. Hence, further in vivo studies with a larger sample size and longer follow-up period are recommended, specifically focusing on the mandibular arch. Additionally, it is suggested to locally manufacture thermoplastic tray to reduce costs and enhance its accessibility for dental clinicians.

Conclusions

Based on the results of the current study, it can be concluded that:

1. Dentures made from thermoplastic trays have similar retention values with those made from conventional tray.
2. Thermoplastic trays dentures were more comfortable for the patients than conventional ones.
3. Dentures from both groups were similarly satisfactory from the clinician's point of view.

Funding:

This study was self-funded by the primary investigator.

Data Availability:

Data is available from the corresponding author upon request.

Declarations:

Ethics approval and consent to participate:

This study was approved by the Ethics committee of Scientific Research of Cairo University. The protocol was registered in clinicaltrials.gov (ClinicalTrials.gov ID: NCTT04982510). The main investigator, SA, discussed the interventions and possible adverse effects of this study with patients. The patients willing to participate in the study signed a written informed consent in Arabic. Patients signed an informed consent to give permission to use their images or other clinical information to be reported in a medical publication.

Competing interests:

The authors declare no conflicts of interest.

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