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A study comparing patient satisfaction and retention of CAD/CAM milled complete dentures and 3D printed CAD/CAM complete dentures versus conventional complete dentures: a randomized clinical trial

Um estudo comparando a satisfação do paciente e a retenção de próteses totais fresadas em CAD/CAM e próteses totais 3D impressas com tecnologia CAD/CAM versus próteses totais convencionais: um ensaio clínico randomizado

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Abstract

Objective: To compare the three different methods of complete denture fabrication assessing patient satisfaction and retention after insertion for six months' follow-up period. **Material and Methods:** The study was conducted in the Prosthodontic Department where a total of forty-eight patients were recruited from the outpatient clinics fulfilling the inclusion criteria. This study was designed as a randomized controlled clinical trial. All patients followed the steps of complete denture construction till jaw relation record. Then, all eligible patients were randomized to intervention and control groups. For intervention groups digital scanning, designing, manufacturing of complete dentures was done; 3D printing for first and milling for second intervention. For the comparator group, complete dentures were manufactured the conventional way. After 2 weeks of delivery of the dentures, patients received a patient satisfaction questionnaire, retention was measured by retention force gauge. Both readings were also recorded after 3 months and at 6 months. The mean and standard deviation values were calculated for each group in each test. The significance level was set at $P \leq 0.05$. **Results:** No statistical difference was found in terms of patient satisfaction and retention between the three groups at different time intervals. **Conclusion:** The manufacturing technique seemed to have no influence on patient satisfaction and retention with milled showing the least results.

KEYWORDS

Computer-aided design; Denture, Complete; Denture retention; Patient satisfaction; Printing, Three-dimensional

Resumo

Objetivo: Comparar três métodos diferentes de fabricação de prótese total avaliando a satisfação do paciente e a retenção após a inserção por um período de acompanhamento de seis meses. **Material e Métodos:** O estudo foi conduzido no departamento de Prótese onde um total de quarenta e oito pacientes foram recrutados das clínicas ambulatoriais atendendo os critérios de inclusão. Este estudo foi designado como um ensaio clínico randomizado controlado. Todos os pacientes seguiram as mesmas etapas de confecção de prótese total até o registro da relação maxilo-mandibular. Então, todos os pacientes qualificados foram divididos de forma aleatória nos grupos de intervenção e grupo controle. Para os grupos de intervenção foram realizados escaneamento digital, projeto e fabricação de próteses totais; Impressão 3D para o primeiro e fresagem para o segundo grupo de intervenção. Para o grupo de comparação, próteses totais foram feitas com o método convencional. Depois de 2 semanas após a entrega das próteses os pacientes receberam um questionário de satisfação e a retenção foi mensurada com um medidor de força de retenção. Ambas as leituras também foram registradas após 3 e 6 meses. Os valores de média e desvio padrão foram calculados para cada grupo em cada teste. O nível de significância foi estabelecido em $P \leq 0,05$. **Resultados:** Nenhuma diferença estatística foi encontrada em termos de satisfação do paciente e

retenção entre os três grupos em diferentes intervalos de tempo. **Conclusão:** A técnica de fabricação pareceu não ter influência na satisfação do paciente e retenção da prótese, com o grupo fresado apresentando o mínimo de resultados.

PALAVRAS-CHAVE

Design assistida por computador; Prótese total; Retenção de prótese; Satisfação do paciente; Impressão tridimensional

INTRODUCTION

Conventional complete dentures are considered to be the most common treatment option for edentulous patients for many decades despite the fact of reported problems of discomfort, lack of retention, and polymerization shrinkage of Polymethyl methacrylate that could have a direct impact on patient satisfaction. CAD-CAM technology has been introduced in the construction of complete dentures (CDs) in the early 90s. It has overcome the encountered problems with conventional dentures which resulted in low polymerization shrinkage, improvement of fitting and retention of dentures utilizing digital workflows, reducing patient visits, and also facilitated the storage of 3D data to be utilized anytime for denture construction. Two major digital techniques for manufacturing dentures are currently available subtractive (milling) and additive as rapid prototyping. Milling techniques are used to manufacture computerized three-dimensional (3D) data obtained by digital scanning and designing, then subtracting restoration material from blocks through a computerized numerical control machining. Rapid prototyping is to fabricate restoration prototypes in an additive or layering manufacturing of the 3D object creating final restorations. [1]

PMMA blocks are characterized by high impact quality that enhances the fracture resistance and increases the longevity of the denture for the patient. The industrial manufacturing process ensures a homogeneous material quality with no porosities or air bubbles in the material, with no possibility of harbouring bacteria or candida infections on its surface producing a high-quality denture base.

Recently, no published study has investigated patient satisfaction and retention of CAD-CAM complete dentures utilizing the mentioned digital techniques of manufacturing in comparison to conventional dentures, thus a question arises whether patient satisfaction and retention will differ through CAD-CAM fabricated dentures?

The null hypothesis was that when comparing between three methods of complete denture fabrication; conventional versus CAD/CAM milled versus 3D printed, there will be no difference between the three methods of fabrication regarding patient satisfaction and denture retention.

MATERIALS AND METHODS

PICO and research hypothesis

Population: Completely edentulous Patients

Intervention 1: CAD/CAM milled complete dentures

Intervention 2: CAD/CAM 3D-printed complete dentures

Control: Conventional complete dentures

Primary outcome: patient satisfaction

Secondary outcome: retention of maxillary denture

Ethics approval and patients' selection

This study was designed as a randomized controlled clinical trial with three-arm parallel groups with an allocation ratio of 1:1:1. The study was approved by the Ethics Committee of Scientific Research of the University (Approval number 17-9-8). The protocol was registered in clinicaltrial.gov (ClinicalTrials.gov ID: NCT 03281603).

The study was conducted in the Prosthodontic Department, (Faculty of Dentistry Cairo University, Cairo, Egypt) from October 2017 to January 2020 where a total of 48 patients were recruited from the outpatient clinics fulfilling the inclusion criteria.

Subjects for the inclusion criteria included completely edentulous patients ranging from age 55 to 75 years, Angle's Class I skeletal relationship, a well-developed ridge with U-shaped palatal vault and adequate firm mucosa, last extraction took place six months ago, and normal facial symmetry.

Subjects presented with Temporomandibular disorders, uncontrolled diabetes, flabby tissues or sharp mandibular residual ridge, the patients with neuromuscular disorders, patients on chemotherapy or radiotherapy, severe psychiatric disorders, and Angle's class II & III skeletal relationship were excluded.

Continuous response variable from independent control and experimental subjects with one control(s) per experimental subject was planned based on a previous study by Kattadiyil et al [2], the difference in patient's satisfaction score is 0.5 ±0.45. Using power 80% and 5% significance level we will need to study 14 in each group. To compensate for dropouts, a 25% increase was added for a total sample size of 16 patients per group. Sample size calculation was achieved using PS: Power and Sample Size Calculation Software Version 3.1.2 (Tennessee, USA).

Eligible Patients signed a written consent to be enrolled in the trial. General preparations were made for patients till bite blocks for bite registration which was recorded at the proper vertical dimension utilizing the wax wafer method to record the jaw relation in centric relation. Two arbitrary points were made on the centre of the nose and the chin, then vertical dimension at rest was recorded at the physiological rest position of the patient. The vertical dimension of occlusion was obtained by the difference between the rest position and occlusion by knowing the freeway space. An earpiece face bow records were taken to mount the upper casts on the semi-adjustable articulator (Bio Art A7 Dental Equipment, Brazil). Lastly, lower casts were mounted according to centric relation records.

Randomization

Allocation sequence generation was run via a computer-generated program for randomization (www.random.org) to allocate eligible patients to intervention and control groups with an allocation ratio of 1:1:1. Allocation concealment was done using opaque sealed envelopes. Inside each envelope, there was a code that was not known by the principal investigator.

Blinding

In this trial, the patients were blinded as the final appearance of dentures manufactured by the three techniques was the same as the participants who weren't able to recognize which denture was manufactured by either technique. The principal investigator couldn't be blinded as the trial included digital designing of complete dentures on the CAD software and in the steps of the manufacturing techniques. Also, the outcome assessor could be blinded for the questionnaire.

Intervention groups

All bite records with their corresponding mounted master casts were digitalized using an extraoral desktop 3D scanner (Freedom HD scanner, DOF, Seoul, Korea). First, the order was created. The scanning step was done in three stations, scanning the upper cast, the lower cast then the bite registration. Acquisition of intermaxillary recording was done by point alignment of the bite scan and the arch scan to be properly superimposed in their correct position. The resultant scans were then exported into three files with an extension of standard triangulation language (STL) files.

All STL files were imported to digital design software in full denture modules (exocad GmbH, Germany). Starting the designing step, intraoral landmarks were virtually marked on both arches (Figure 1).

Afterward, teeth were chosen from the teeth library on the software according to each subject sex, character, and recorded inter-arch space. Automatically, the setting of teeth was done by the software following the crest of the alveolar ridge, also followed the facial guidelines recorded from each patient (Figure 2).

In the next step, the software automatically blocked the undercuts on the master casts then the permanent denture bases with their characterization by digital waxing up were designed (Figure 3). After finishing the design four STL files were produced consisting of two socketed denture bases and two sets of teeth for both arches exported as STL files to be ready for manufacturing (Figure 4 and 5).

In the production step, Try-in was done utilizing photopolymerizable PMMA liquid resin for try in procedures (NextDent, Netherlands) printed by 3D printer (Mogassam digital dentistry, Egypt) by rapid prototyping to be printed together with their perspective teeth as monolithic dentures (Figure 6).

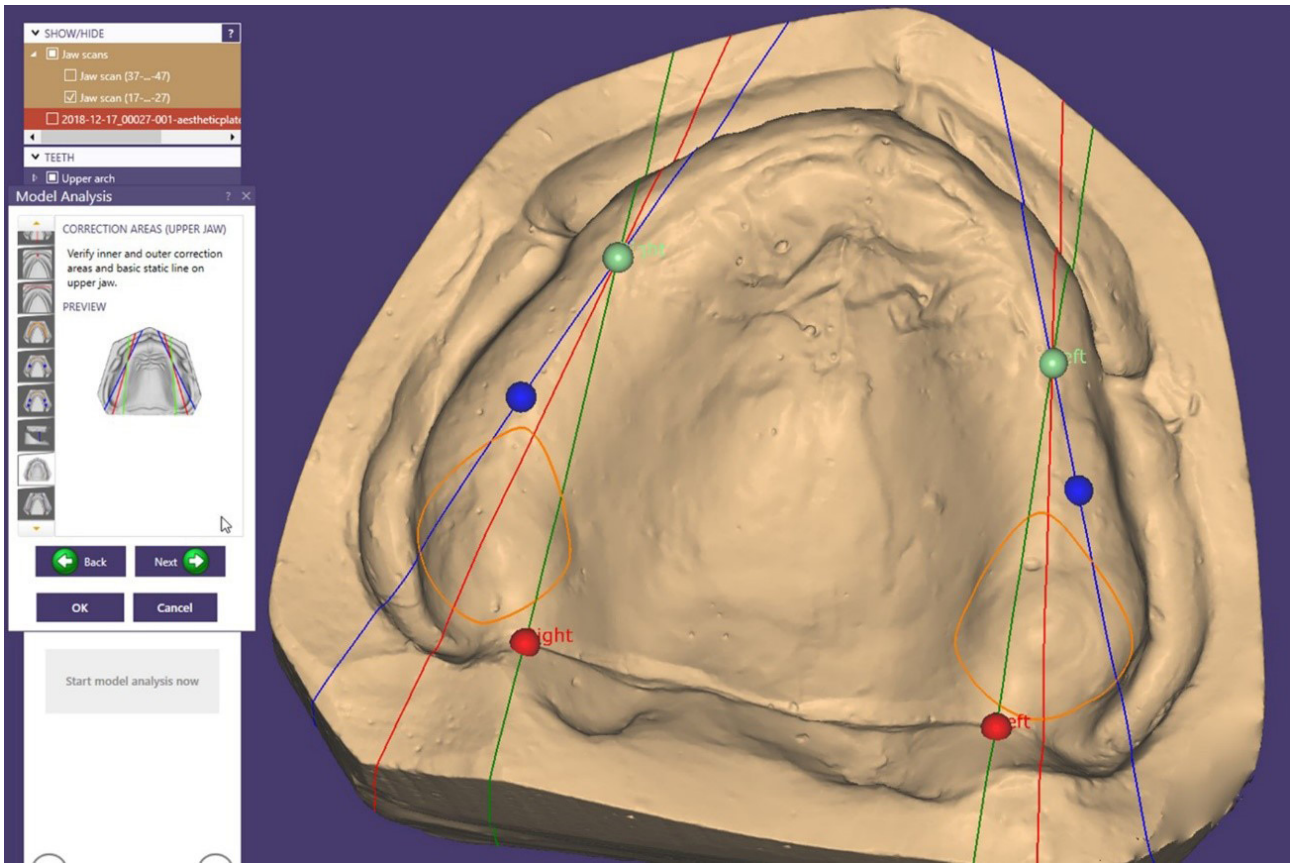

Figure 1 - Summary for maxillary arch analysis of landmarks.

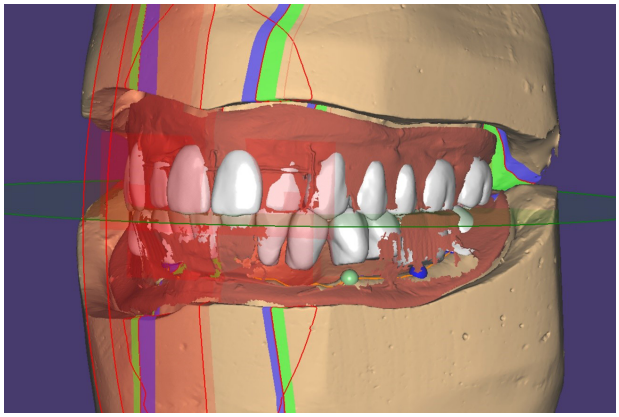

Figure 2 - Finalizing setting guided by the occlusion rims.

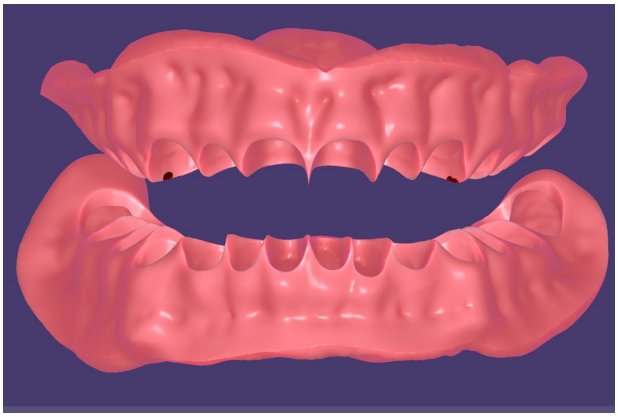

Figure 4 - Final stls for socketed denture bases.

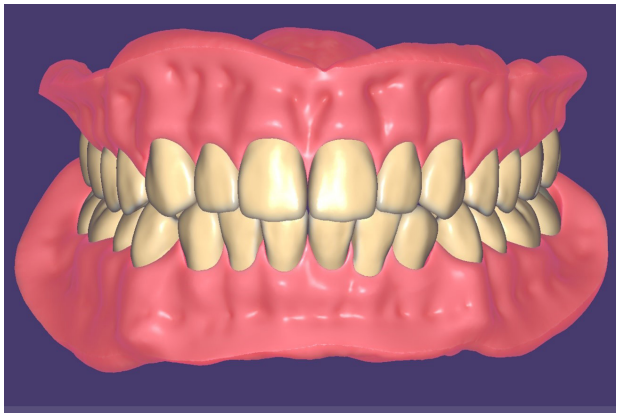

Figure 3 - Dentures after digital waxing up.

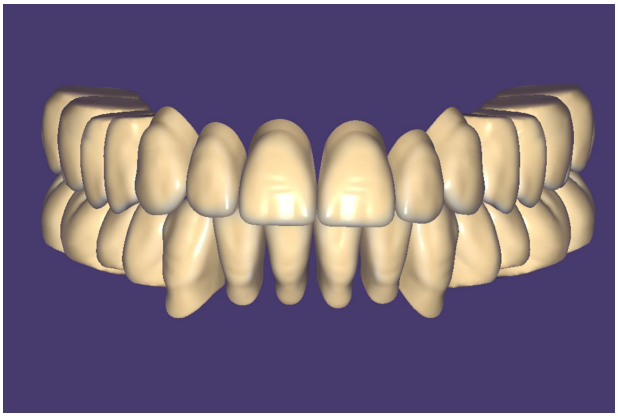

Figure 5 - Final STLs for teeth.

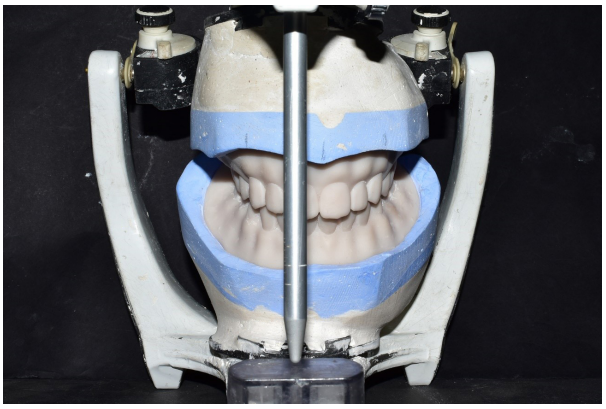

Figure 6 - Printed monoblock trial full dentures on the articulator.

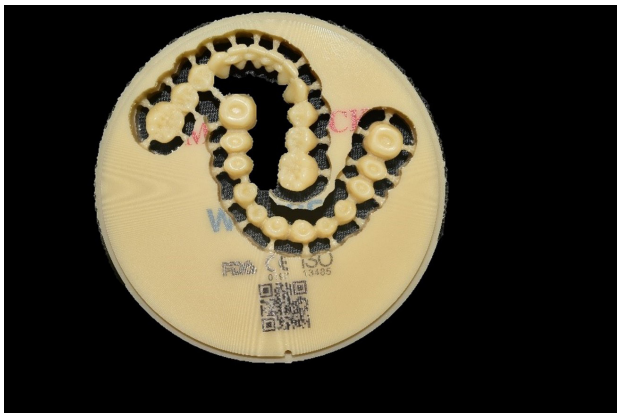

Figure 7 - Milled complete set of artificial teeth.

For the final teeth production, teeth STL files were drily milled by a 5-axis milling machine (Eco-Mill 5x, SHERA, Germany) from PMMA blank (Dental CAD-CAM blank, WIESSEN, Germany) with the suitable teeth shade then finished and polished to be ready for bonding them to their perspective sockets of the denture bases (Figure 7).

First Intervention printed group

The designed denture bases were exported as STL files and sent to the 3D printer software. The printer was calibrated to receive the liquid resin for a permanent denture base (NextDent, Netherlands). The printing process was done, the bases were then removed from the platform and rinsed in 99% of isopropyl ethyl alcohol by agitation and brushing then drying, cleaning and finally cured in the light curing device (Brelux, Bredent, Germany) for fifteen minutes (Figure 8).

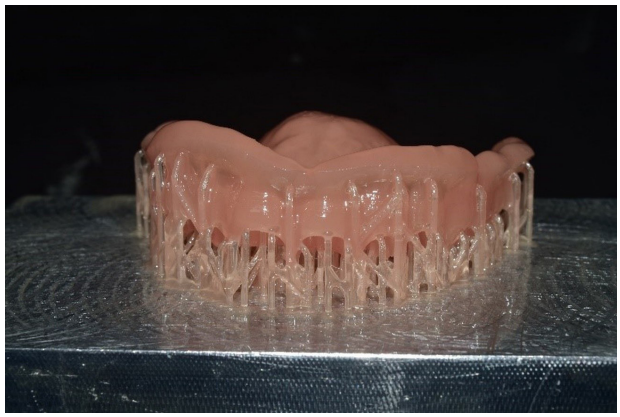

Figure 8 - Printed upper denture base (polished surface).

Second Intervention milled group

The denture base STL files were drily milled of PMMA blank (Dental CAD-CAM blank, WIESSEN, Germany) using a 5-axis milling machine. The milled bases were then finished and their fitting was tried on the master casts (Figure 9).

Figure 9 - Milled denture base.

Bonding of teeth to denture bases, finishing & polishing

The next step was bonding the already milled artificial PMMA teeth for both intervention groups to their perspective denture base sockets. The produced denture base sockets were cleaned by steam jet then sandblasting was done for sockets by aluminum oxide (grit size 110 μm) and a pressure of 3 to 4 bar for 10 seconds according to the manufacture instructions and the same procedure was done to the teeth neck.

A bonding agent (VISIO-Link, Bredent, Germany) was then applied on the denture base sockets, together with the teeth necks, and light-cured for 90 seconds. The teeth were then cemented to their denture base sockets using resin cement (Combo-lign, Bredent, Germany) and then light-cured for 180 seconds (Figure 10).

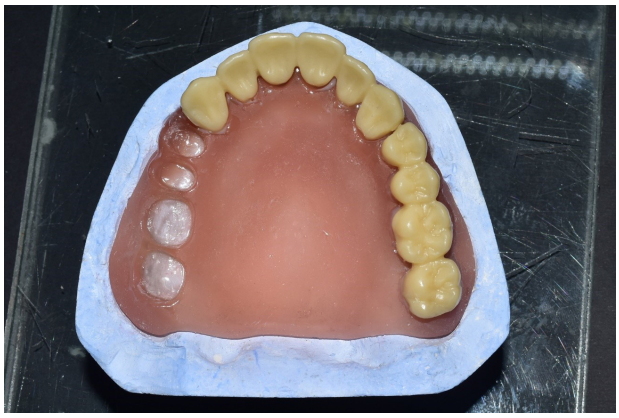

Figure 10 - Cementing the teeth in their perspective sockets.

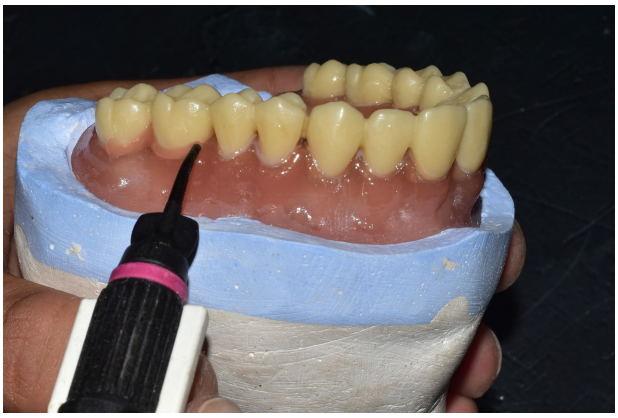

Figure 11 - Obtaining Gum and gingival characteristics on polished surface by Crea-lign.

Characterization of the teeth in their sockets obtaining gum margins and the full denture bases were painted with Gum materials (Crea-lign, Bredent, Germany) and then light-cured for 180 seconds (Figure 11). The full dentures were then finished and polished and inserted for each patient checking their retention, stability, and occlusion, and post-insertion instructions were given.

Conventional group

All steps for conventional complete dentures were constructed traditionally with heat-cured polymerizable resin (Acrostone medical and dental supplies, Egypt).

Primary outcome: patient satisfaction through patient questionnaire

A designed patient questionnaire was given to each subject at baseline (after 2 weeks of the delivery day), three and six months according to Borerrigter's [3] method in assessing patient satisfaction with complete dentures. The questionnaire included five main domains as follows: Functional complaint about the denture, overall masticatory ability, masticating ability for different types of food, the effect of mental and daily life, and overall denture satisfaction. Each domain concerned with the number of questions as domain one consisted of thirteen questions, domain two of six questions, domain three of three questions, domain four of seven questions, and the last domain of nine questions.

For the first two domains scores were given from 1 to 4 as: (1 = never; 2 = sometimes; 3 = often; 4 = always). Domain three scored from 1 to 3 as: (1 = well; 2 = moderately; 3 = badly). Domain four scored from 1 to 5 as (1 = never; 2 = hardly ever; 3 = occasionally; 4 = fairly often; 5 = very often) the last domain scored by the visual analog scale and its last two questions were by yes or no. All scores were recorded and averaged then sent to the statistician for data analysis.

Secondary outcome: retention

First, after 2 weeks of denture insertion, the denture was taken from each patient then the geometric center was detected by placing the produced dentures on their casts then drawing a line joining the cusp tip of the right canine to the left ptergomaxillary notch and another line joining the cusp tip of the left canine to the right ptergomaxillary notch [3], [4]. The intersection of these two lines was marked at a point in the center of the denture which denoted the point to place the snap hook.

A small fissure bur was used to grind a hole in the detected geometric center which had a diameter slightly larger than the diameter of the hook. Then a mix of clear self-cured acrylic resin was applied in the hole on which the hook was placed before the resin sets. A stainless steel wire of a fixed length of 20 cm was used to engage the hook on the denture, and the other side of the wire engaged the gauge of the force gauge device. The hook was kept in each patient's file and used again in the follow-up periods (Figure 12).

The retention force gauge (Extech, U.S.A.) device engaged the hook of each denture through the stainless steel wire. A pull action was done perpendicular to the occlusal plane with the patient's head in an upright position and the amount of retention was denoted in Newton on

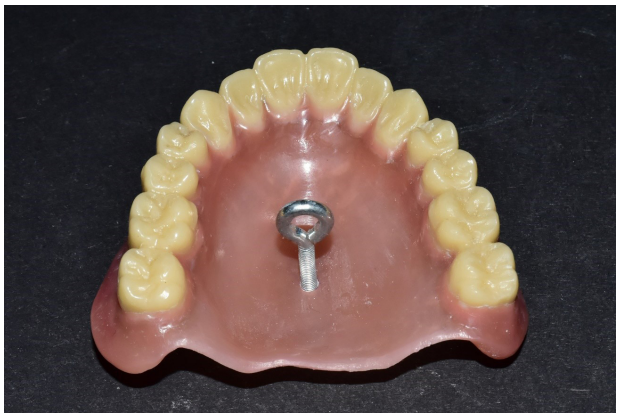

Figure 12 - Inserting the hook for measuring retention in the determined geometric centre.

the device three times and the average of the three readings was recorded. After the readings were taken, the hook was removed and sealed by clear self-cured acrylic resin so that at the next follow-up period the hook was placed at the same place. The readings of all constructed dentures at baseline, after three months, and after six months were tabulated and statistically analyzed.

Statistical analysis

The mean and standard deviation values were calculated for each group in each test. Data were explored for normality using Kolmogorov-Smirnov and Shapiro-Wilk tests, data showed non-parametric distribution. Kruskal Wallis was used to comparing between more than two groups in non-related samples. Mann-Whitney test was used to compare two groups in non-related samples.

Friedman was used to comparing between more than two groups in related samples. Wilcoxon test was used to compare two groups in related samples. The significance level was set at $P \leq 0.05$. Statistical analysis was performed with IBM® SPSS® Statistics Version 20 for Windows.

RESULTS

Primary outcome: analysis of patient satisfaction for the five domains

Question category 1: Functional complaints about the dentures

No statistically significant difference was found between (3D printed), (Milled), and (Conventional) complete dentures at baseline, after 3 months and after 6months where (P=0.170), (P=0.400) and (P=0.210) respectively.

Question category 2: Evaluation of overall masticatory ability

No statistically significant difference was found between 3D printed, milled, and conventional complete dentures at baseline, after 3 months and after 6 months where (P=0.206), (P=0.128) and (P=0.396). respectively.

Question category 3: Evaluation of masticating ability for different types of food

No statistically significant difference was found between 3D printed, milled, and conventional complete dentures at baseline, after 3 months and after 6 months where (P=0.069), (P=0.131) and (P=0.458) respectively.

Question category 4: Effects on mental and daily life

No statistically significant difference was found between 3D printed, milled, and conventional complete dentures at baseline, after 3 months and after 6 months where (P=0.103), (P=0.811) and (P=0.292). respectively.

Question category 5: Analysis of overall denture satisfaction

No statistically significant difference was found between 3D printed, milled, and conventional complete dentures at baseline, after 3 months and after 6 months where (P=0.231), (P=0.656) and (P=0.080) respectively.

For all the categories, the highest mean score (least satisfaction) was found in milled groups followed by conventional, while the lowest mean score (highest satisfaction) was found in the 3D printed group (Table 1).

The secondary outcome; retention of maxillary denture

No statistically significant difference was found between 3D printed, milled and conventional groups at baseline, three months, and 6 months where P=0.348, P=0.097, and P=0.085 respectively. However, the highest mean retention value was found in 3D printed group (17.2±3.49 Ncm at 2weeks), (19.6±0.55 Ncm at three months), and (22.6±1.5 Ncm at 6 months). This was followed by conventional group showing

Table 1 - Patient satisfaction scores along the five domains (mean deviation ± standard deviation)

		cconventional		Milled		3D printed	
		SD	MD	SD	MD	SD	MD
Domain 1	BL	3.36	29.6	1.67	32.4	0.84	27.2
	3M	3.83	28.2	2.17	31.2	2.05	26.2
	6M	0.84	24.8	3.63	29.8	4.3	22
Domain 2	BL	2.83	14	2.68	16.8	3.78	12.6
	3M	1.41	12	2.3	14.4	2.74	11
	6M	0.84	10.8	2.59	12.2	2.4	9.4
Domain 3	BL	1.1	5.2	1	6	0.55	4.4
	3M	0.84	5.8	0.71	6	0.71	5
	6M	0.84	5.2	0.55	5.4	0.84	4.8
Domain 4	BL	1.3	15.2	1.34	16.6	0.84	14.8
	3M	0.84	15.2	2.59	16.2	1.67	14.6
	6M	0.89	13.4	2.17	13.8	1.3	12.2
Domain 5	BL	0.89	5.4	0.84	5.8	0.84	4.8
	3M	0.89	6.6	1	7	0.89	6.4
	6M	1.34	4.4	0.55	5.4	0.7	4

BL: baseline; 3M: three months; 6M: six months; MD: Mean deviation; SD: standard deviation.

(15.2±3.49 Ncm at two weeks), (18.2±2.49 Ncm at three months), and (21.4±1.52 Ncm at six months). While the lowest mean retention value was found in milled group (13.2±1.10 Ncm at two weeks), (17.8±1.3 Ncm at three months), and (20.2±1.3 Ncm at six months).

A statistical significant difference was found within the same group (i.e. effect of time within the same group) between baseline and six months where (P=0.008), (P=0.008) and (P=0.0211) for printed, milled and conventional groups respectively (Figure 13).

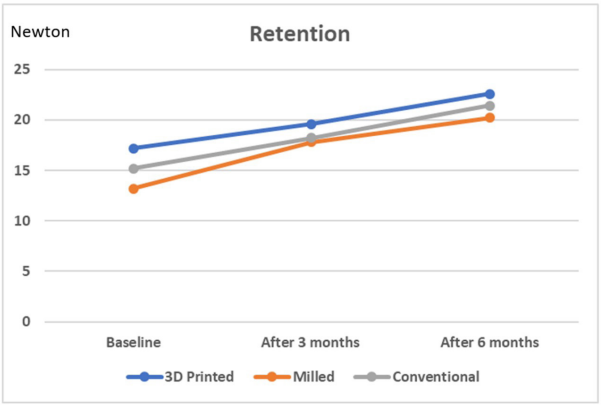

Figure 13 - Bar chart representing effects of time on the retention of all groups.

DISCUSSION

Patient satisfaction is considered to be an important outcome that would evaluate the success of any prosthesis in terms of; retention, stability, function, esthetics, and psychological comfort [5]. Retention is also an important factor that would greatly influence patient satisfaction, that was the reason it was recorded together with patient satisfaction [6].

Over the six-month follow-up period, there tends to be a statistically significant improvement in patient satisfaction for all of the three different dentures, showing the least satisfaction at baseline and the highest satisfaction at six-month follow-up for all of the five domains. The six-month follow-up led to the understanding of whether the patient's adaptation to new dentures influences any discrepancies in the proposed treatment. In addition, any differences in discomfort or discrepancies may not be significant anymore if addressed after six months, disclosing that functional adaptation, tissue settling of the denture base, and neuromuscular coordination of the new situation may have alleviated some of the patients 'complaints [7].

Patient satisfaction was recorded in the present study using a validated questionnaire which consists of five domains [3]. When comparing the patient satisfaction scores for each of the five domains there tends to be no statistically significant difference between the

printed denture, milled denture, and conventional dentures. These results were consistent with a study that reported no significant differences between conventional and digital methods utilizing 3D printing of CD fabrication in terms of overall satisfaction [8].

In the present clinical trial, there tends to be no statistically significant difference for patient satisfaction scores for all of the 3 different complete dentures for all 5 domains but patients were mostly satisfied with printed dentures, followed by conventional dentures, and least satisfied with milled dentures. This might be attributed to the inherent limitation in the milling technology being not able to mill severe undercuts greater than 25-30 degrees depending on the milling machine used that is only limited in a 5 axis motion and the bur size that cannot cut through complex geometries and undercuts. Moreover, the milled denture fitting surface resulted in a very smooth surface that hinders better retention and border seal and adaptation to the tissues by physical means. This might have affected the retention regarding the milled group and subsequently compromising patient satisfaction [9], [10].

An in vitro study in 2017 concluded that the trueness of the fitting surface of digital 3D printing and conventional techniques seems to remain within a clinically acceptable range in terms of adaptation and fit that directly affects the retention of dentures, which seems to explain the reason printed and conventional dentures were more retentive than milled ones [11].

When considering the retention scores of the three groups there tends to be no statistically significant difference between the three groups in retention over the six-month follow-up period. In the present study; although no significant difference was found; printed dentures have recorded the highest retention, followed by conventional and milled dentures which have reported the least retention which is similar to the results of patient satisfaction. From the results of the present study, there tends to be a correlation between patient satisfaction and retention. Furthermore, retention of the three different dentures have significantly improved from baseline over the six-month follow-up period, the reason for this might be related to the settling of the denture base, functional adaptation, and neuromuscular coordination of the patient. In this trial, retention records were performed on maxillary arches as for the large surface area compared to lower arches, posterior palatal seal feature, and palatal tissue surface design. Variety of retention force gauge devices in the literature that utilized a pulley system with a weighing pan, spring balance, spring gauge, and strain gauge force transducer were designed to deliver the dislodgment forces in a vertical direction perpendicular to the occlusal plane when the patient is sitting in an upright position. In lower arches, the presence of unfavorable surface areas, teeth setting in the neutral zone, and difficulty in centralizing forces because of the presence of the tongue has contributed to the study complexity, therefore further studies with special designs are recommended to consider problems for the lower arch in the future [12].

In Studies comparing simplified protocol for reducing the number of visits versus traditional protocols, two studies concluded that the simplified protocol results in a positive response of patent's satisfaction of treatment outcomes similar to the traditional protocol which matches the results of our study upon using digital versus conventional methods of fabrication [13], [14].

A study compared functional aspects of speech, mastication, and esthetics of digital milled CDs and conventional CDs and revealed no pronounced differences between the functional aspects and esthetic outcomes of both dentures which directly affects patient satisfaction and matches the results of our study [15]. On the other hand, other studies [2], [16], [17] observed different results that were not following the results of our study. These studies compared the digital milled denture bases from Avadent system versus the conventional denture bases in terms of patient satisfaction, retention, and adaptation of denture bases and reported high predictable results over the conventional dentures. They also reported that the accuracy of digital data obtained from the impression scan is much accurate than those obtained from cast scans.

The overall results of the present study showed no statistically significant difference between the 3 fabricated dentures over the 6 months' follow-up period. However, within each group, there was a statistically significant difference for both patient satisfaction and retention outcomes from baseline to the 6 months' follow-up period. Although the results of our study showed an insignificant difference, the printed group showed the best values regarding

patient satisfaction and denture retention while the milled group showed the least values.

CONCLUSION

There was no statistically significant difference according to patient satisfaction and retention between CAD-CAM printed, milled, and conventional complete dentures. The manufacturing technique seemed to not influence patient satisfaction and retention. Further studies are required to evaluate the outcomes on different types of arch form and residual ridges.

Author Contributions

The primary author was responsible for Literature search, Clinical study, data acquisition and analysis, statistical analysis as well as manuscript preparation.

The second and third authors were responsible for design of the study, data analysis and manuscript editing and reviewing.

Conflict of Interest

The authors declare no conflicts of interest.

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Regulatory Statement

This study was conducted in accordance with all the provisions of the local human subject's oversight committee guidelines and policies of the Faculty of Dentistry Cairo University, Cairo, Egypt. The study was approved by the Ethics Committee of Scientific Research of the University (Approval number 17-9-8). The protocol was registered in clinicaltrial.gov (ClinicalTrials.gov ID: NCT 03281603).

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