Retention, Accuracy, Electromyographic Activity and Patients Satisfaction of 3-D Printed compared to Conventional Complete Dentures: A Randomized Crossover Study

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Abstract

Objective: Analyzing and comparing the retention, accuracy, EMG, and patient satisfaction of maxillary complete denture base fabricated by rapid prototyping compared to conventional techniques. Material and Methods: Ten completely edentulous patients were enrolled in the study. An upper and lower conventional complete denture were provided and used by each patient for a 3-month follow-up. A 2 week washout period by avoiding the use of the conventional dentures was followed by another 3 months of wearing a digitally 3D-printed upper denture and a conventional lower denture. Patients were followed-up in a visit interval of 1 week, 1 month and 3 months after wearing each of the denture types. Retention, accuracy, EMG activity, and Patient satisfaction were measured. Results: Compared to traditional dentures, 3D-printed dentures had a higher average retention that was statistically significant. The accuracy of 3D-printed dentures was also significantly better than that of traditional dentures. The EMG results indicated that the muscle activity was significantly lower for 3D-printed dentures than for traditional dentures at various follow-up periods. The median satisfaction score for 3D-printed dentures was also significantly higher than that for traditional dentures.

Conclusion: According to the current study, the 3D printed dentures showed positive outcomes for both the patients and the clinicians in terms of how well they fit, how precise they are, how they affect muscle activity, and how satisfied the patients are with them.

KeyWords:**3D printed, retention, accuracy, EMG and patient satisfaction**.

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Introduction.

Individuals may experience aesthetic issues as a result of losing their natural teeth, but masticatory function may also be gravely affected. Long-term edentulism may eventually lead to muscular hypotonicity, tempro-mandibular dysfunction, or bone resorption, all of which can directly harm the masticatory process. Due to its affordable price, simple manufacturing process, and acceptable aesthetics, the full denture has been a standard therapy for individuals who are entirely edentulous.

One of the most common materials for making conventional complete dentures is the polymer **poly(methyl methacrylate) (PMMA)** (1). This material is popular among patients because it is easy to produce and repair, compatible with the body, and has good aesthetics (2). However, PMMA also has some limitations, such as large shrinkage during polymerization, tendency to be colonized by microbes, lack of radiopacity, allergic reactions mainly caused by the release of monomers, loss of mechanical properties over time, and poor resistance to wear in human saliva. These limitations have led to the development of new materials and fabrication methods—both subtractive and additive—for dentures (3, 4).

Constructing conventional complete dentures requires a complicated restoration technique, and inexperienced dentists frequently struggle to achieve complete dentures that are retained, stabilized, and occluded properly in some elderly patients who have severe alveolar ridge resorption. Digital full denture systems have been created recently, which can increase the precision and effectiveness of denture production while lowering the necessary number of clinic visits (5, 6). These systems call for two to five clinical visits and utilize various protocols for clinical and laboratory procedures.

Three-dimensional (3D) printing is an advanced manufacturing technique that uses digital models created with computer assistance to automatically generate customized 3D objects. Due to its quick manufacturing, high accuracy, and ability for individual customisation, 3D printing provides benefits in process engineering (7) as compared to conventional wax loss technology and subtraction computer numerical control systems. Additionally, the use of 3D printing in dentistry enables practitioners to provide patients more individualized and cost-effective treatment while also reducing the labor-intensive process of creating dental appliances (9). However, there is limited data on clinical outcomes of dentures fabricated by both techniques. Therefore, it was necessary to address the comparison between 3D printed maxillary dentures and conventional dentures in terms of improving retention, accuracy, EMG activity, and patient satisfaction in complete denture wearers.

Material and Methods

Ethical Considerations

The protocol of the current randomized controlled crossover study was approved by the Research Ethics Committee (REC) of the Faculty of Oral and Dental Medicine of Al-Azhar University for Girls and registered on clinicaltrials.gov with an identifier number of NCT05834530.

Sample Size Calculation

The sample size calculation was performed using GraphPadStatMate 2.00 and ten completely edentulous patients were found to be a suitable sample number based on a previous study (10) with a power set to 80% to detect the difference between the retention's group mean and the hypothetical mean of 9.35 with a significance level (alpha) of 0.05 (two-tailed) and 95% confidence intervals.

Patient Recruitment

The Removable Prosthodontic Clinic of the Faculty of Dental Medicine at Al-Azhar University for Girls recruited ten fully edentulous patients (n = 10) who agreed to prosthodontic treatment with a removable denture (RD) and randomly assigned them. The inclusion criteria were having firm, thick, and compressible mucosa on the ridges and no signs of TMJ disorders, such as limited mouth opening or mandibular movement, muscle spasm, pain, or mandibular deviation. Each patient signed a written consent form after being fully informed of every step of the trial. The selected fully edentulous patients initially received their conventional dentures for both maxilla and mandible, which they used for three months, then they were instructed to stop wearing them for two weeks as a washout period before receiving their maxillary 3D printed dentures.

Patient Preparation

For each patient, initial impressions of the maxilla and mandible were obtained using Cavex alginate, a dust-free, high consistency irreversible hydrocolloid impression substance. Amsterdam B. V.)Preliminary stone (Moldano. Bayer, W. Germany) castings were poured in a perforated, suitable-sized stock tray, and customized trays were made using self-curing acrylic resin (Cold cure denture base material, Acrostone, England). With the help of a border molding tool (Tracing stick, Pyrax Polymers, U.K.), a secondary imprint was made, and a zinc oxide/eugenol impression paste (White imprint Paste, England), the final impression was made. In order to create master castings for both 3D-printed and traditional full dentures, imprints were packed and poured into dental stone.

I. 3D Printed Dentures Fabrication

A. Data Acquisition and Scanning Procedure

The poured master castings for the maxilla and mandible were placed in their final positions before being sprayed with a specialized scanning spray (BiLKi, Occlusion Spray Red-BK286, Germany). The inEOS X5 (SironainEos X5 Digital Dental Scanner) was used to scan the plaster casts. When the scan was finished, the 3D scanned data was shown and saved as an STL file (Standard Tessellation Language).

B. Designing Dentures

The Exocad software (Exocad Dental CAD; Exocad GmbH) was used to develop a PMMA full denture. Master casting STL files and jaw relation information were imported, virtually mounted, and aligned before analysis. Upper and lower virtual models were analyzed and created after the defined occlusal plane, midline, incisive papilla, maxillary tuberosity, median palatine raphe, lateral incisors, canines, buccalfrenum area, first premolars and molar regions, and position of the retro molar pad were marked. Points were added to the denture borders in Figure 1A to depict the denture borders.

C. Virtual Teeth Setting

Software was used to automatically establish the position of the teeth, basing on previous studies. Moving and turning each tooth separately allowed for further adjustments to the location of the teeth. The borders of the posterior analysis were maintained by moving the posterior teeth in a grouped block. By adjusting the interdental papilla and simulating the tooth roots, the program also permits denture foundation characterisation. Various knives and brushes of various sizes and shapes were used as virtual instruments for material addition or removal. Then, the software's settings were changed to "3D printing" as the production method.

D. Finalizing the Design

An exported STL file for each denture base, upper and lower, was set to be ready for denture manufacturing (*Figure 1B*).

Figure 1AMarking the virtual cast. 1B Finalizing the denture

E. Denture Manufacturing

Utilizing a desktop 3D printer and additive manufacturing, dentures were manufactured. Denture bases STL files were loaded to the printer software to automatically build supporting arms, and a new file on the Photon S Desktop 3D Printer Machine was stored for each denture. Pink denture the base resin (NextDent Denture 3+, Netherlands) and white teeth printing resin (NextDent Teeth, Netherlands) were poured into the machine's reservoir to begin the printing process. The bases of printed dentures and the responding teeth were twice cleaned in alcohol for a total of three minutes, followed by a two-minute cleaning bath. The supporting arms were taken off after printing, and then they were polished using an abrazo-gum acryl polishing kit from BredenJmbH& Co.KG in Seden, Germany. In the final step, teeth were precisely fixed to the 3D-printed denture base in recessed holes using resin. The denture was then thoroughly cleaned, dried, and placed in a post-curing unit for 15 minutes. After carefully inspecting the denture's fit and occlusion, the 3D-printed denture was delivered.

II. Conventional Complete Denture Fabrication

The poured maxillary master casts were mounted on a semi-adjustable articulator (Bio-Art equipamentosdontolgicostda articulator and face-bow, Brazil) utilizing occlusion blocks that were built on the acquired master casts, and jaw relation registration that was done using a face-bow record. Using the wax wafer technique to mount the mandibular cast, the centric occluding relation was noted at a suitable vertical dimension. Based on aesthetic criteria, anatomically cross-linked acrylic resin teeth were built up, and waxed denture bases were tried in before traditional denture production using heat-cured acrylic resin (Vertex-B.V., Netherlands). Last but not least, the patients tried on the final dentures and evaluated them for correct extension, stability, retention, aesthetics, phonetics, and occlusion. In case any adjustments were needed, clinical remounting was done. After giving the patient home-care instructions, the dentures were delivered.

Outcome Measures

Patients were asked to wear their conventional complete dentures first, and outcome measures were recorded at different time intervals for each measured outcome. After 3 months of wearing the conventional complete dentures, the patients were asked to stop wearing their dentures for a washout period of 2 weeks, and then their maxillary conventional dentures were replaced by 3D-printed dentures to wear them for another 3 months.

1.Retention record

Utilizing the universal testing device, retention was evaluated and recorded for each patient on the day of delivery (baseline), one and three months later. In maxillary dentures, two tiny metal tubes with a diameter of 3 mm were positioned a few millimeters above the laterals using self-curing acrylic resin. A measured orthodontic wire was used to confirm that the right tube and left tube were equally spaced from the geometric center. The patient was told to sit up straight and maintain a fixed posture for his chin on a chin support. The denture and the attachment portion of the universal machine were both rigidly linked to the bar. Up until the denture was completely out of position, the device was exposed to a gradually rising vertical load (10 mm/min). An audible tuck signaled the dislodgement of the weight, which was corroborated by a rapid drop that was recorded in Newton using the computer's software. Five repetitions of the exam were administered before calculating the mean of all data was done.

Accuracy record

Each upper denture was finished, and then before delivery, the fitting surface was sprayed and scanned. After turning the denture's fitting surface to mimic the cast surface, the resultant STL file was saved. The STL file of the flipped fitting surface of the denture was chosen as the measured data, and the STL file of the master cast was chosen as the reference data. By clicking the "best fit alignment" icon, the two files were automatically aligned. Each denture base's correctness was assessed at sixty different sites, and a generated color map was produced based on the 3D divergence between the denture base and reference data. Green represents measured deviation below 0.2mm, yellow to red indicates positive deviation (misfit with space), and blue indicates negative deviation (tissue compression). The correctness of the upper denture bases for both 3D-printed and traditional dentures was assessed using this geomagic program (Figures 2A and 2B).

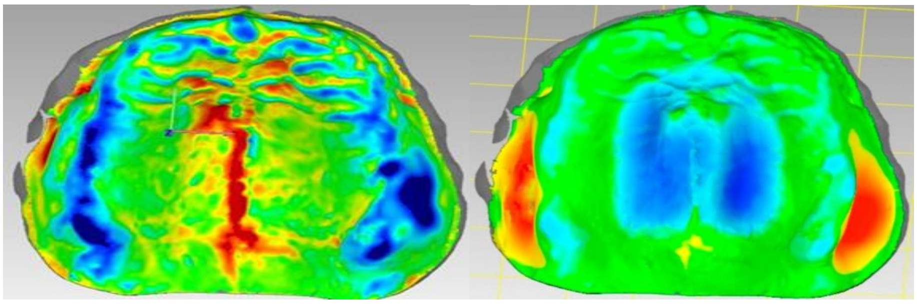

Figure 2: A. Color mapping for a conventional denture B. Color mapping for a 3D printed denture

Electromyographic activity

The electromyographic activity was recorded for each patient by Nemus 2 machine which was performed by measuring muscle activity of the masseter muscle on both sides, for both dentures at the end of the first week (base-line), then after 1 months and 3 months follow-up periods for each denture type measured with two types of standardized size of 1cm3of the test foods (carrot as hard food, and banana as soft food) for 10 seconds on the right and left sides. Patients were seated in a naturally erect position without supporting their heads. Bipolar electrodes placed on the muscles' bellies parallel to the direction of the fibers were used to record the masseteric myoelectric activity on both sides. The recording electrodes were spaced around 20 mm apart. After a 2-minute pause, a similar treatment was carried out on the anterior temporalis muscles on both the right and left sides.

Patient Satisfaction

The researchers used a survey that was previously employed by Boerrigter et al. (11) to collect data on patient satisfaction. They measured patient satisfaction with a visual analogue scale (VAS), where patients scored their responses from 0 to 10 (low/worst to high/best). The patient received the questionnaire after wearing each type of denture for one and three months.

Statistical Analysis

The researchers used a survey that was previously employed by Boerrigter et al. (11) to collect data on patient satisfaction. They measured patient satisfaction with a visual analogue scale (VAS), where patients scored their responses from 0 to 10 (low/worst to high/best). The patient received the questionnaire after wearing each type of denture for one and three months.

Results

1.Retention

In comparison to conventional dentures, 3D printed dentures had statistically greater mean retention at the baseline, one month, and three months (P-values = 0.019, 0.026, and 0.034, respectively) than did conventional dentures. A statistically significant change in mean retention values over time was seen in both types of dentures after follow-up (P-value <0.001). After one month and three months, the mean retention values in both groups increased statistically significantly, according to pair-wise comparisons of follow-up times (Table 1).

Table (1): comparison between retention of the two denture types with different interactions of variables.

Time	3D Printed	Conventional	P-value
Base line	21.35± 2.74	17.65± 3.67	0.019*
1 month	22.84± 3.47	19.21 ± 3.21	0.026*
3 months	23.91± 2.67	21.35 ± 2.32	0.034*
***P-value* (Between times)**	<0.001*	<0.001*	

Independent t-test *Significant at P ≤ 0.05*

2. Accuracy

The 3D printed denture exhibited a statistically significant lower median deviation (better accuracy) than the traditional denture, which was determined by measuring accuracy at all locations as well as the overall deviation of both denture types (Table 2).

Table (2): comparison between deviation values (mm) of the two denture types

Site	3D Printed	Conventional	P-value
Border	0.071 ± 0.019	0.554 ± 0.141	<0.001*
Crest	-0.029 ± 0.112	0.61 ± 0.198	<0.001*
Suture	0.051 ± 0.101	0.402 ± 0.174	<0.001*
Posterior palatal seal	0.032 ± 0.009	0.163 ± 0.157	0.017*
Lateral ridge	-0.025 ± 0.038	0.164 ± 0.214	0.013*
Palate	0.052 ± 0.031	0.395 ±0.147	<0.001*
Total	0.026 ± 0.019	0.374 ± 0.098	<0.001*

Independent t-test *Significant at P ≤ 0.05*

3. EMG Activity

The (mean± SD) values of masseter and temporalis muscles showed a statistically significant difference of EMG records between both dentures at all follow-up intervals except for the records of the masseter muscles upon chewing soft food and the EMG records of the temporalis muscle upon chewing hard food at 1 and 3 months follow up, which showed insignificant difference between both dentures as indicated by two-way ANOVA (Table 3).

Table (3): EMG activity of the two denture types with different interactions of variables.

			CCD No. = 10	RP No. = 10	P-value
1 week	Clenching	Masseter	234.72±34.28	179.12±10.94	0.001
		Temporalis	130.26±6.29	110.96±2.73	<0.001
	Soft food	Masseter	172.35±19.35	118.88±10.48	<0.001
		Temporalis	136.32±7.42	97.52±6.17	<0.001
	Hard food	Masseter	217.15±23.38	171.9±14.43	<0.001
		Temporalis	164.72±9.13	116.3±6.98	<0.001
1 month	Clenching	Masseter	264.18±36.77	215.97±24.59	0.003
		Temporalis	192.73±6.82	132.62±8.12	<0.001
	Soft food	Masseter	210.05±12.12	197.93±30.99	0.264
		Temporalis	175.82±15.82	127.87±17.97	<0.001
	Hard food	Masseter	290.45±16.78	264.75±23.89	0.012
		Temporalis	205.22±7.31	198.3±10.16	0.097
3 months	Clenching	Masseter	343.5±23.30	228.35±14.97	<0.001
		Temporalis	214.07±10.35	213.36±5.75	0.852
	Soft food	Masseter	260.20±30.11	242.5±19.29	0.135
		Temporalis	195.13±12.96	160.65±23.79	0.001
	Hard food	Masseter	347.43±24.73	312.15±14.13	0.001
		Temporalis	243.82±15.57	236.56±8.15	0.208

P> Independent t-test *Significant at P ≤ 0.05*

4. Patient satisfaction

There was no statistically significant difference between each item of satisfaction scores with the two denture types either after one or three months (Table 5), however; 3D printed denture showed a statistically significant higher median of the overall satisfaction score than that of the conventional denture at both follow-up periods (P-value <0.001).

Table (4): comparison between the two denture types according to patient satisfaction scores

Item	3D Printed	Conventional	P-value
Functional complaints	1.37 ± 0.33	1.54 ± 0.42	0.327
Overall masticatory ability	1.38 ± 0.28	1.67 ± 0.48	0.116
Masticatory ability with food types	1.25 ± 0.18	1.32 ± 0.29	0.525
Effect on daily life	1.68 ± 0.16	1.53 ± 0.41	0.295
Overall satisfaction	7.92 ± 0.36	5.14 ± 0.49	<0.001

Independent t-test *Significant at P ≤ 0.05*

Table (5): comparison between the two denture types according to patient satisfaction scores with the two denture types after three month

Item	3D Printed	Conventional	*P*- value
Functional complaints	1.37 ± 0.32	1.61 ± 0.45	0.186
Overall masticatory ability	1.28 ± 0.42	1.56 ± 0.62	0.252
Masticatory ability with food types	1.27 ± 0.26	1.36 ± 0.45	0.591
Effect on daily life	1.48 ± 0.31	1.62 ± 0.52	0.474
Overall satisfaction	7.98 ± 0.49	5.41 ± 0.62	<0.001

Independent t-test *Significant at P ≤ 0.05*

Discussion

Complete dentures are now being made using digital methods like CAD-CAM and rapid prototyping technologies. Digital technology offers various benefits, including accurate design of the denture frame components, quicker manufacture, better functional and esthetic outcomes, and better fit (12, 13). Therefore, the purpose of this study was to compare and evaluate the fit and retention of full denture frameworks made using traditional and digital fabrication methods.

This study's initial assessment of maxillary denture retention occurred one week after denture installation because that amount of time is the bare minimum required for a denture to settle and adapt to the underlying tissues and achieve acceptable retention (14). The noted good adaptation of denture bases (15) may be responsible for the acceptable and equivalent retention levels obtained for both groups. Multiple comparisons between each of the two follow-up periods showed a significant difference in retention values between the groups. The influence of the patient's neuromuscular coordination that has grown with function is amplified by the reported rise in denture retention over time (16).

The effectiveness of therapy depends on the precision of full dentures because retentive forces require close contact between the denture base and the underlying tissues. Since polymers were first used to manufacture denture bases, polymerization shrinkage has been an unavoidable part of the process. Checking the overall shape and fit of the intaglio surface is crucial for accuracy in prosthesis manufacturing (17). One of the most important factors for evaluating prostheses is fit, which refers to the correspondence between the denture base intaglio surface and the master cast. Fit directly influences maxillary full denture retention **(18, 19)**. Denture base adaptation has been assessed utilizing misfit measurement employing an examination of the overlay image of the scanned denture base and the master cast. An evaluation of the denture base's full fitting surface was conducted as an alternative to employing geometric reference points for surface matching**(20)**.

With recent advancements in CAD-CAM technology in dentistry, it is critical to look at the effects of various CAD-CAM parameters on the fabrication characteristics of prosthetics. This study looked at the typical printing materials and processes used to create 3D-printed dentures and demonstrated that there were substantial impacts on printing accuracy. The findings of this study showed that removable full dentures made using digital (CAD-CAM and RP) procedures fit more accurately than those made using traditional methods. The current study found that when compared to dentures made using traditional methods, CAD-CAM and 3D-printed dentures had clinically acceptable gaps and fit correctness. The use of CAD-CAM and 3D-printed dentures is expanding, however they are still in the early stages of development. To evaluate their accuracy with clinical performance in removable prosthodontics, more research is needed.

Numerous studies have recently compared the accuracy of CAD-CAM milling versus traditional techniques. In the maxillary full denture, encompassing the palate, the posterior palatal seal region, and the crest of the alveolar ridge, the CAD-CAM milling approach demonstrated less misfit than the injection molding method, according to the study by Goodacre et al. (18). According to various prior studies, due to the form and location of the mid palatal suture area, the mismatch caused by the polymerization shrinkage and the internal strains after the polymerization is rather significant in this area when using injection molding techniques. PMMA-based conventional procedures should take polymerization shrinkage into account, whereas the milling method is handled by removing a PMMA blank (puck) that has been industrially pre-polymerized and has final dimension **(19).**

One of the goals of this study was to compare the muscular performance of 3D printed and traditional dentures as well as to assess the muscle activity involved in the process of mastication and swallowing of meals with various textures in older adults. A safe, simple, and non-invasive approach that enables accurate measurement of the muscle's energy was what led researchers to use the surface EMG as a testing parameter for recording the masticatory function **(21)**.

This study used EMG activity of the masseter and anterior temporalis muscles, which are thought to be the most powerful, largest, and superficial masticatory muscles accessible to surface EMG examination (22). The patients were sitting upright throughout EMG recording in the current investigation in order to assure masticatory muscle relaxation and to prevent postural effects on the recorded muscle activity (23). To capture the peak electrical activity of the muscle, the disposable bipolar electrodes were placed on the belly of the muscle in a straight line parallel to the fiber orientation **(24)**. Our findings demonstrated a statistically significant decrease in bioelectric activity in both muscles following the use of a 3D-printed denture. The findings of the current study thus suggest that wearing a 3D-printed denture results in physiological adaptations to oral situations.

It was also determined what factors edentulous patients may change to improve their satisfaction and quality of life. At three months compared to one month, there was a substantial improvement in the patients' oral health-related quality of life (OHRQOLs). Similar findings were made in a prior research, when patients with full dentures showed an improvement in OHRQOL from baseline through the first and third months following denture placement **(25)**. These results were in opposition to those of the experimental study by Subramanian et al., which revealed that a longer period of time wearing dentures lowered patient satisfaction (26). It is important to note that OHRQOL at 3 months was linked to dental communication abilities. This can be linked to the general level of care that patients valued from the dental team during their departure interviews. Examples of care that affects OHRQOL include recognizing needs or goals, resolving questions, following up often, motivating patients, and assuring compliance. It was found that when patients were communicated effectively, anxiety and complaints decreased leading to satisfaction improvement and better adherence to any provided instructions and advice **(27)**.

The quality of life is related to how the therapy affects the health of the patients, and satisfaction is directly related to the therapy (28).

Both are affected differently by many causes. The level of satisfaction varies depending on the patient's choices, expectations, and the accuracy of the information provided by the healthcare professional. OHRQOL regularly fluctuates as a consequence because other factors outside treatment techniques also have an impact on it. The patient satisfaction data suggests that the function of the denture, independent of any other demographic factors, determines how satisfied edentulous patients are after having a full denture. The quality of life of denture users may also be influenced by the dentist's competence level, which should be further investigated in future research.

Conclusions

The 3D printed dentures have demonstrated good short-term clinical performance and favorable patient-related results in terms of retention, accuracy, EMG, and satisfaction with care, according to the findings of the current study, which has certain limitations. Additionally, the production of entire dentures using the 3D printing method demonstrated an effective modality alternative to conventional approaches.

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