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PATIENT SATISFACTION FOR THREE-DIMENSIONAL PRINTED VERSUS CONVENTIONAL HEAT-CURED ACRYLIC COMPLETE DENTURE: A RANDOMIZED CONTROLLED TRIAL

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KEYWORDS

3D printing, complete denture, patient satisfaction, digital denture

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ABSTRACT

Introduction: Complete denture rehabilitation remains the most common choice for treating edentulism. 3D printed dentures have evolved as a new treatment modality to decrease fabrication time increase the predictability of the patient and accost an effective option compared to the milled denture. **Aim:** The study aimed to compare patient satisfaction of 3D printed complete dentures to conventional ones. **Materials and Methods:** After sample size calculation and ethical committee approval, 20 patients were selected, then randomly and equally distributed into two groups (n=10): Group A received a conventional heat-cured acrylic complete dentures and Group B received 3D printed complete dentures. Participants answered a denture satisfaction questionnaire after three months of denture delivery. **Results:** Printed maxillary denture wearers were significantly more satisfied than acrylic wearers with aesthetics and retention (p-value 0.05 ≤), while there was no significant difference between 3D printed and acrylic complete denture wearers for denture satisfaction, comfort, and speech (P-value ≥ 0.05). **Conclusions:** Within the limitation of this study, it was concluded that 3D printed dentures showed better patient satisfaction compared to conventional heat-cured acrylic dentures, but this difference was not statistically significant for some patient satisfaction criteria such as general satisfaction, comfort, and speech.

INTRODUCTION

Edentulism is an irreversible condition. Complete teeth loss prevalence has declined over the last decade, but edentulism remains the most common disease, especially in old age [(1)].

Complete dentures as a prosthetic treatment option remain the most common one. Studies showed that denture wearing continues to increase due to the increase in the population age [(2)].

Edentulism can lead directly to the inability to do some functions and physical, social, and psychological problems. Thus, the impact of edentulism on general health depends on a lot of health variables: physical symptoms and functional capacity, social functioning, and perception of being well [(3)].

Complete denture rehabilitation remains the most common choice for treating edentulism. This is because complete dentures are

cost-effective, easy to process and repair, and introduce acceptable esthetics and function to a lot of patients[4].

For more than 80 years, the polymer polymethyl methacrylate (PMMA) has been the most widely used material in the production of traditional full dentures. This is due to its relative simplicity of processing and repair, biocompatibility, high mechanical strength, modulus of elasticity, and aesthetic properties. On the contrary, PMMA has many disadvantages such as high polymerization shrinkage, lack of radio-opacity, liability to microbial colonization from the oral environment, allergic reactions mostly due to leaching of the monomer, degradation of mechanical properties over time, and low wear resistance [5].

With increased patient age in the future, the need for complete dentures as a treatment modality is recognized. When weighing cost versus time, the key factor is the reduction in chairside, laboratory, and total working time for dentists, technicians, and patients [6].

3D printed dentures appeared as a new treatment modality to decrease fabrication time and increase the predictability of the patient and cost-effective options compared to the milled denture [7].

Satisfaction with dentures improves dental health and quality of life for edentulous patients. Several in vivo studies using removable full dentures evaluate patient satisfaction in terms of speech, mastication, chewing efficiency, and post-insertion visits [8].

The effects of many aspects including age, the patient's psychological status, the dentist's experience, the technique employed, and communication with the patient on the success of complete dentures were investigated [9].

Patient satisfaction and patient-dentist communication rather than the quality of prostheses are very important for denture success [10].

The patient's psychological state also influences denture satisfaction. Nervous patients report lower levels of satisfaction. Patients who are satisfied in their everyday lives are happy with their dentures, although negative repercussions such as impatience, boredom, wrath, loneliness, and helplessness create denture intolerance, while positive results as pleasure, peace, and usefulness produce denture acceptance [11].

MATERIALS AND METHODS

Ethical consideration

The study was approved by the Research Ethics Committee (REC) at Suez Canal University Faculty of Dentistry on 18/3/2021 no (318/2021) and clinical trial gov registration on 18/10/2022 (NCT05585008), All patients provided written informed consent before enrollment in the study, while all methods were performed following the Declaration of Helsinki as well as relevant guidelines and regulations.

Participants selection

Twenty healthy completely edentulous patients with ages ranging between 50-65 years old who were seeking the construction of maxillary and mandibular dentures were selected from the outpatient clinic of the Prosthodontics Department faculty of Dentistry, Suez Canal University. The patients were selected according to the following inclusion criteria: The selected patients, had maxillary and mandibular edentulous ridges covered with healthy firm and dense mucosa with no remaining roots, no severe bony undercut, or

local pathological lesions. Patients had no previous dentures. Patients were free from any systemic disease that may affect the rate of bone resorption e.g., diabetes mellitus patients with no history of bad habits e.g. severe clenching, The cases were selected with no T.M.J disorders and with skeletal Angle Class I relation.

The following patients were excluded: patients with xerostomia, high palatal vault, and short or hyperactive lips.

Ethical considerations: regarding patient well-being and confidentiality were undertaken. Informed consent was signed by the patients before commencing the study explaining all clinical examinations, procedures, and follow-ups.

Study design.

This was a prospective randomized, controlled trial. All treatments were performed by an experienced prosthodontist, and he was blinded until the try-in and denture delivery phase.

Patients were divided randomly and equally with the aid of a randomization website *(randomizer.com)* and according to the method of denture fabrication into two groups:

Group A patients received the conventional pack and press heat cure acrylic dentures.

Group B patients received three-dimensional (3D printed complete dentures)

The recruitment and flow diagram of patients is presented in Fig .1

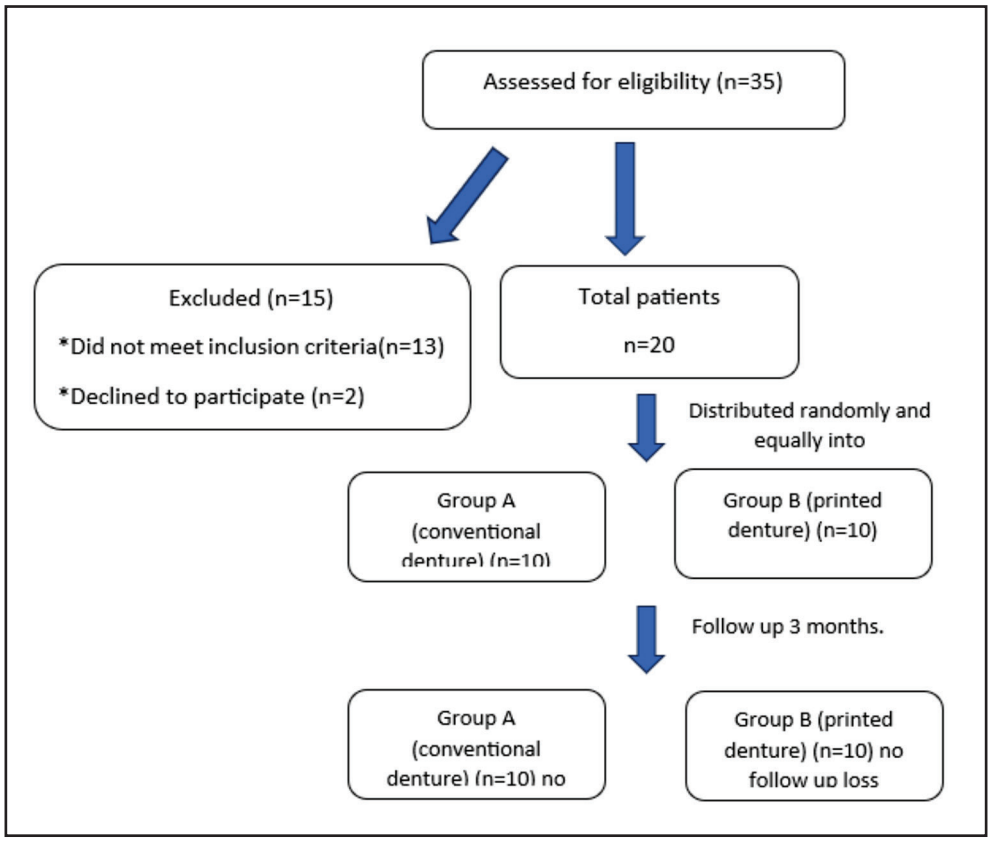

Fig. (1) Shows the recruitment and flow diagram of the patients.

Clinical procedures

Group A(conventional heat cure acrylic denture): Irreversible hydrocolloid alginate impression material was mixed as was prescribed by manufacturer instructions and was loaded onto the modified stock trays. Secondary impressions were created utilizing the open-mouth technique with a modeling compound (Impression compound, Kerr, Italy) as the border tracing material and zinc oxide impression material (Cavex outline, Cavex, Netherlands) as the final imprint. The master cast was created by pouring the final imprint of type IV stone (Elite Rock, Zhermack, Italy). A biting occlusion block was created using the master cast and evaluated in the patient's mouth for retention, stability, and correct border extension.

The maxilla's position relative to the hinge axis was recorded using an earpiece arbitrary facebow (bio-art elite face bow, bio art, Brazil), and the maxillary cast was put on a semi-adjustable articulator (bio-art A7plus, bio art, Brazil).

To determine the resting vertical dimension (RVD), two dots were put on the most prominent parts of the nose and chin, and the mandibular rim was adjusted to meet the maxillary occlusal rim uniformly at a maxillomandibular vertical dimension 3 mm smaller than the RVD. The maxillomandibular horizontal relation was measured using a manually guided retruded contact position. The midline, smile line, and location of the canines were all noted. Protrusive recordings were created. The lower cast with occlusion blocks was placed on the articulator.

Artificial acrylic teeth with suitable size, shape, shade, and have 33º cuspal angle were set according to the patient's gender, age, and arch shape. The selected artificial teeth were arranged following the bilateral balanced occlusion concept. Trial dentures were evaluated in the patient's mouth for phonetics, aesthetics, occlusal vertical dimension, and centric relation.

Processing of acrylic dentures was done from heat-cured acrylic (Heat cure acrylic, Acrostone, Egypt) using the conventional hot water path long cycle method (70˚ for 9 hours). After deflasking, the denture and the corresponding master cast were separated from the flask with caution. Laboratory remounting and occlusal refinement were done. Dentures were finished, polished, and then delivered to the patients. Clinical remounting was done by taking new interocclusal records in the patient's mouth and mounting the dentures on an articulator to correct errors made during the initial records. Selective grinding was then used to refine the occlusion based on the remount records.

Group B (three-dimensional printed denture): The same impression technique, bite registration, and articulator mounting for group A were done.

Since computer aided design (CAD) software (Exocad Dental CAD 3.0, Exocad GmbH, Germany) does not enable virtual carving of the post-dam area in the 3D virtual edentulous models, The post-dam area was trimmed on the actual master cast. On the master cast, a line was drawn between the pterygomaxillary notches on both sides and the points 2mm behind the foveae palatinae. A cutting line 1 to 1.5 mm deep along the vibration line was made using a carver. A layer of the cast was removed from the area covering this cutting line to 5mm before this line.

Generation of 3D digital edentulous models and transfer information on the articulator to the design software and virtual articulator: The master cast attached to the articulator plate was scanned and saved in standard tessellation language (stl) format under the name of mounted printed denture master

cast. The occlusion block was scanned and saved in stl format under the name of the scanned occlusion block. Scan upper cast, lower cast, and occlusion blocks stl files were imported to CAD software. The software automatically detected the orientation of the maxillary cast by matching the attached plate to the virtual articulator plate. The lower master casts were oriented virtually by superimposition on scanned occlusion block.

The path of insertion was determined. The CAD software supports the determination of the occlusal plane for the scanned maxillary cast. Three points were selected on the contacting plane of the maxillary cast. Feature points were selected at the Incisive papilla. The maxillary tuberosity, median palatine raphe, and canine region of the maxillary arch, the retromolar pad, midline, and canine area of the mandibular arch. Borders of the baseplates were designed to meet the requirement for complete dentures and form the base for complete dentures. The labial and buccal borders ended at the mucobuccal fold between the alveolar mucosa and the labial and buccal mucosa, avoiding the labial/buccal frenulum; the lower jaw ended at the lingual frenulum, avoiding the lingual frenulum; the rear margin of the upper jaw ended at the line of pterygomaxillary notches on both sides and the points at 2mm behind the foveae palatinae. A 1 to 1.5-mm-deep cutting line was created along the vibration line using a sculpt knife. This region gradually shallowed, resulting in a bow shape parallel to the palate's mucosal surface.

Using the CAD software, the arrangement of artificial teeth was achieved by moving the teeth in sagittal, horizontal, and coronal planes during the modeling. The length, width, height, and shape of the dentition could be adjusted. For each tooth, modifications/adjustments could also be made to match the particular shapes of the patient's arches.

The denture design was free-formed to allow for better adjustability. The CAD program can simulate the movements of occlusion, laterotrusion, pro/retrusion, and side shift. During the virtual occlusal correction, the contacting locations were recorded in distinct colors for each movement. Those interfering spots were eliminated practically. Following this occlusal correction process, the creation of virtual 3D full dentures was completed.

Then the teeth and denture base were exported as two separate stl files to the slicing software (Chitu box, China). The printing angle was set at 45 degrees with the incisal edge toward the printing bed for teeth and the fitting surface away from the printing bed for denture bases. Supports were set using the auto support function. For teeth and denture base printing, after printing the printing supports were removed using a special cutter and low-speed rotary instrument.

The printed parts (teeth and denture base) were washed with ethyl alcohol (95%) to remove excess resin for two minutes and rinsed in a water bath at 50°c. The denture teeth were reassembled and fixed with unfilled resin in their position in the denture base lacunae. Post-curing for printed parts was done with a post-curing machine that has a wide range of wavelength (370-500nm) fit and 130 watts of lamp power for 30 minutes at 50°c (brelux Power Unit 2, bredent, Germany).

Clinical assessments

Participants answered a denture satisfaction questionnaire after three months of denture delivery (as is shown in Table 1) Possible answers for each question and respective scores were: unsatisfactory =0, regular =1, and good =2 [12].

Table (1) *Shows the denture satisfaction questionnaire*

Questions	Original criteria
How do you rate the overall quality of your dentures?	General satisfaction
How do you rate the ability to chew with your dentures?	Comfort of wearing
How do you rate the ability to speak with your dentures?	Speech
How do you rate the appearance/aesthetics of your dentures?	Aesthetics
How do you rate the retention of your maxillary denture?	Retention of the maxillary denture

Statistical analysis

Sample size calculation was performed using **G*Power version 3.1.9.2**(University Kiel, Germany). The effect size was 1.6 using an alpha (α) level of 0.05 and a Beta (β) level of 0.05, i.e., power = 95%; the estimated minimum sample size (n) was a total of 20 samples.

The results were collected, tabulated, and statistically analyzed using SPSS Statistics Version 20 for Windows (SPSS, Inc., an IBM Company, USA).

RESULTS

The results of each question about denture satisfaction were evaluated separately and described by counting frequencies. The results showed no normal data distribution and were described by non-parametric methods. Data from each question were compared using the Wilcoxon test.

The results of patients' assessment of their Maxillary denture satisfaction are shown in Table2 , Fig.2, and Fig. 3 The printed denture group showed high grades for all variables (satisfaction, comfort, speech, aesthetics, and retention).

As the data were not normally distributed, the Mann-Whitney test was used. The significant differences in patients' satisfaction between the acrylic denture and printed denture wearers are shown in Table 3.

Table (2) *Shows the frequency of answers to the patient satisfaction questionnaire.*

	Grades					
	Unsatisfactory		*Regular*		*Good*	
	Acrylic	*Printed*	*Acrylic*	*Printed*	*Acrylic*	*Printed*
Satisfaction	*2*	*0*	*6*	*4*	*2*	*6*
Comfort	*2*	*0*	*6*	*4*	*2*	*6*
Speech	*1*	*0*	*7*	*4*	*2*	*6*
Esthetics	*1*	*0*	*7*	*3*	*2*	*7*
Retention	*1*	*0*	*7*	*3*	*2*	*7*

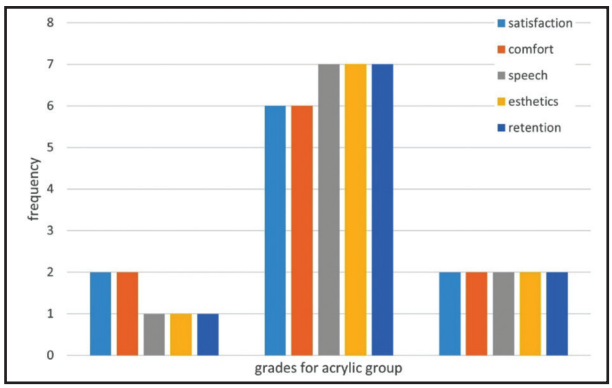

Fig. (2) Shows the acrylic group frequency answers for satisfaction.

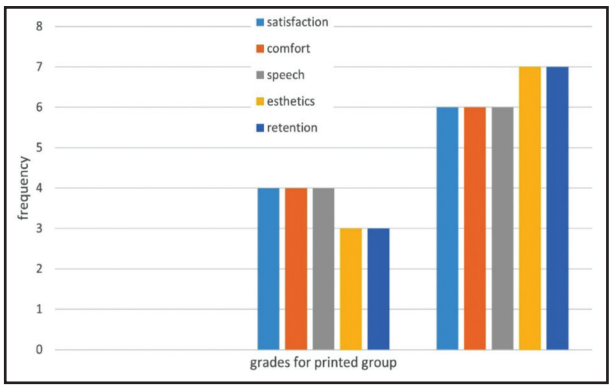

Fig. (3) Shows the printed group frequency answers for satisfaction.

Table 3 *shows the Significance of the differences in satisfaction between acrylic and printed denture wearers' satisfaction assessments (the significance level was set to 0.05)*

	Satisfaction	*Comfort*	*Speech*	*Esthetics*	*Retention*
p-value	*0.075 ns*	*0.075 ns*	*0.105 ns*	*0.043**	*0.043**

ns=non-significant p-value≥ 0.05. **=p-value< 0.05(significant)*

Printed maxillary denture wearers were significantly more satisfied than acrylic wearers with aesthetics and retention (p-value <0.05), while, there was no significant difference between printed and acrylic maxillary complete denture wearers for denture satisfaction, comfort, and speech (P-value ≥ 0.05).

DISCUSSION

Denture bases undergo dimensional changes during processing which may adversely affect their support, stability, retention, and subsequent decreased patient comfort [13].

CAD CAM 3D printed denture fabrication technique is proposed to decrease such dimensional changes and get the balance between biocompatibility, aesthetics, minimal distortion, and adaptation [14].

In this study, the selected patients had ages ranging from 50-65 years old as the prevalence of edentulism over the age of 50 years is high. Patients over 65 may have bone resorption and systemic diseases[15].

The selected patients had healthy and firm mucoperiosteum without any signs of inflammation as inflammation causes edema of the soft tissue and changes their natural size, especially at the time of impression making which may affect the retention of the denture when the inflammation subsides [16].

Patients with flappy tissues were rejected because an excessive amount of moveable soft tissue may allow the denture to move about the bone, preventing denture base stability and decreasing the retentive quality of the denture bases [17].

The patients had no bone or soft tissue undercuts to remove the influence of mechanical variables on denture base retention [18].

Furthermore, patients with significantly resorbed maxillary ridges and torus palatinus were eliminated to prevent the unfavourable influence on denture base adaptation and retention [19].

Patients suffering from xerostomia were excluded from the study, as the salivary flow rate and viscosity are important factors for denture retention [20].

Uncooperative patients and those with limited mouth opening, neuromuscular, or TMJ disorders were excluded to facilitate the intraoral procedures as well as the denture base retention evaluation [21].

The goal of the whole denture imprint method is to precisely record all possible denture-bearing surfaces so that a stable retentive prosthesis may be created. Upper and lower impression and jaw relation records were made to give the data necessary to design and construct the denture foundation and fabricate a full denture to support each patient's oral rehabilitation [22].

The open-mouth tray mucocompressive impression technique was used in both acrylic and 3D-printed denture groups to get better denture retention [23].

For the 3d printed denture group, the mucocompressive technique was used instead of the intraoral scan, as the intraoral scanner has a lot of disadvantages in complete denture workflow like making the impression in mucostatic, not in mucocompressive condition, difficulty in scanning with tissue retraction to obtain proper border seal. All those disadvantages may alter denture retention[24].

3D printing for denture building is a novel digital additive manufacturing technology that is currently being studied in comparison to the heat-cured fabrication approach, which is assumed to be the primary technique for denture base creation. This technology was chosen because it provides for material conservation and the ability to print complicated shapes with decent dimensional accuracy [14].

The incisive papilla and hamular notches were used to determine the midline in the virtual design of the printed denture since they are permanent landmarks whose placements do not alter with bone erosion [25].

Bonded teeth printed denture was used instead of monolithic dentures because it is more cosmetically acceptable and monolithic dentures require a farther cut back in denture foundation to add tissue color resin [26].

The results of 3d printed denture satisfaction were better than conventional heat-cured acrylic dentures due to better adaptation, accuracy, and retention which give the patient self-confidence and acceptance for his denture.

In the current study, the results showed that there is no statistically significant difference between printed and acrylic maxillary complete denture wearers for denture satisfaction (P-value ≥ 0.05).

The patient satisfaction results of the current study differ from a study in which 3D-printed dentures showed enhanced overall satisfaction concerning conventional dentures. This may be attributed to the small sample size used compared to the current study [27].

Printed denture wearers were significantly more satisfied than acrylic denture wearers with esthetics satisfaction (p-value<0.05), and this differs from a study that found that printed denture satisfaction regarding esthetics has less statistically significant value compared to a conventional acrylic denture, However, this study was registered at 18 months for aesthetic evaluation. This was explained by the changes of acrylic resin color in the oral cavity as a result of slowdown water absorption [28].

CONCLUSIONS

Within the limitation of this study, it was concluded that 3D printed dentures showed better patient satisfaction compared to conventional heat-cured acrylic dentures, but this difference was not statistically significant for some patient satisfaction criteria such as general satisfaction, comfort, and speech.

Availability of data and materials: The datasets used and/or analyzed during the current study are available from the corresponding author upon reasonable request.

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

Author contributions: A.H. did the clinical steps, participated in data analysis, and participated in the design of the study. M.E. and M.M.T. drafted the manuscript and followed up the work. M.E. and S.E. drafted the manuscript. All authors gave final approval for publication.

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