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TREATMENT OUTCOMES OF INDIRECT VERSUS DIRECT DIGITALLY CONSTRUCTED COMPLETE DENTURES AS COMPARED TO CONVENTIONALLY CONSTRUCTED COMPLETE DENTURES: CROSS-OVER CLINICAL STUDY

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ABSTRACT

Purpose: This study aimed to measure retention force and evaluate patient satisfaction level as treatment outcomes of indirect versus direct digitally constructed complete dentures (CDs) as compared to conventionally constructed CDs. **Material and methods:** Eight completely edentulous patients were enrolled in this study to receive maxillary and mandibular complete denture (CD) sets made by conventional method. They wore these CDs for three months constituting the first group (Group I) followed by two weeks as a 1st wash out period. Then the patients received three dimensional (3D) printed computer aided design computer aided manufacturing CAD/CAM CD sets and wore them for another three months. These sets were made by indirect digital technique using extra- oral scan to capture patients' clinical data to be analogical-digital technique constituting the second group (Group II). Patients then left out these dentures for two weeks as a 2nd washout period after which they received 3D printed CAD\CAM CD sets made digitally by direct intra-oral scanning impression (IOSI) in combination with 3D face scan to constitute the third group (Group III). They again wore these sets for another three months. Retention force was measured as well as the patient satisfaction level was evaluated for every group two times, one and three-month post-insertion of each CD set. **Results:** The results of this study showed that there were significant differences between CD sets of Groups II and III when compared to conventional CD sets. However, Group II had significantly higher values of retention force as well as the best significant patient satisfaction as compared to Group I and Group III that showed generally the least potential retention force and patient satisfaction (with exception of esthetic satisfaction that was significantly the best for Group III followed by Group II). **Conclusion:** Within the limitations of this study, we can conclude that: 3D printed CDs digitally made by indirect method had better retention force and patient satisfaction level compared to conventionally made CD. However, 3D printed digitally made by direct method expressed the least retention force and patient satisfaction level compared to the other two groups. The esthetic satisfaction level was the best for CD sets made digitally by direct method due to the use of 3D face scan.

KEYWORDS: CAD/CAM CDs, intra-oral scan, face scan, denture retention, patient satisfaction.

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INTRODUCTION

Edentulism remains to be a major problem worldwide especially with epidemiological studies indicating that population lifespan has been increasing. In spite of the advancing treatment options of edentulism such as implant-supported CDs which are more efficient and more preferable option for edentulous patients, conventional CDs remain the first prosthetic choice for most of edentulous patients because of the least invasive procedures and financial restrictions. [1]

The conventional clinical protocol in CD construction involves prolonged multiple clinical procedures (about five clinical steps) that may be increased depending on accuracy of laboratory technician. Also the usual material used for fabrication of conventional CD has been the polymer polymethyle methacrylate (PMMA) material that is characterized by relative ease of processing and repair, biocompatibility, and esthetic acceptance by the patients, however PMMA has several drawbacks including high polymerization shrinkage and leaching of the monomer with accompanied porosity causing allergic reaction as well as microbial colonization from the oral environment. [2, 3]

CAD/CAM technology has updated the practice of dentistry in many fields including construction of CDs. Digital workflow of CDs has important advantages including modified and shortened clinical protocols and digital data archive where these points are especially critical for elderly medically compromised patients who may need copies or remake of their dentures. Also CAM fabrication of the denture bases reduces the hazards of human errors of processing heat cured acrylic resin of conventional CDs. Moreover, denture bases are dimensionally stable with less residual monomer and hence CAM made denture bases have more superior fit, retention and stability than that of conventional ones. [4-6]

There are two main digital fabrication processes for CDs construction; the subtractive and the additive. Subtractive (milling) method involves milling the denture base from a pre- polymerized resin block to provide highly accurate denture base with absolute dimensional stability, superior flexural strength and high fracture toughness. However, milling technique has limitations for use because it is very expensive due to the waste of a large portion of the block that remains unused and is discarded during this process. [7, 8]

Additive 3D printing or rapid prototyping (RP), incorporates techniques that utilize a photo polymerizable acrylic material and lithographic machine that polymerize a liquid where the liquid resin is cured layer by layer till the object is completely fabricated by using either light sources or lasers. Dentures can be fabricated in a one print-job where denture base and teeth are printed together as one piece (monolithic) in white acrylic and then stains are applied to base side of the monochromatic denture where, color stability of such stains is questionable. Alternatively, CDs can be printed in two steps as denture base is printed separately in pink-colored acrylic and then printed teeth or teeth from commercially available sheets are bonded to base via an adhesive bond or addition of liquid base material, which is then polymerized at a later stage. The output of printed denture base is one of high detail and smooth surface. [9, 10]

CAD/CAM technology encompasses three basic stages that are: data acquisition (image scan), data processing (CAD) and prosthesis manufacturing (CAM). Data acquisition forming virtual master model can be done by one of two methods either indirect or direct method.

Indirect method involves extra-oral scanning of clinical analogical records of patient where the functional impression of the edentulous ridges is made to obtain master casts followed by making occlusal rims to get jaw relation record during either first or second visit of patient. Extra-oral scan can be made for the impressions or master cast and then made for occlusal rims using either an intra-oral scanner (in the clinic by the prosthodontist) or an extra-oral

laboratory scanner in the lab by the technician. It is then sent to a CAD software for designing of virtual maxillary CD and mandibular CD in occlusion. The design is revised by the prosthodontist who approves the design for CAM stage either by 3D printing or milling technique. [8, 11, 12]

Direct method depends on capturing the patient's edentulous arches using intra-oral scanners and making digital direct impressions. IOSI can offer several advantages such as, patients comfort (no gag reflexes, reduced chairside) and dentures fabrication in a nearly fully digital workflow to facilitate the laboratory procedures (cast preparation, handling and shipping) without the need of physical casts. ISOI might be combined by recording the patient' face in three dimensions using a facial scanner to replace conventional facebow allowing accurate positioning of occlusal plane as well as esthetic design of CDs. It was found that the combination of intraoral and face scans permitted successful restoration of fully edentulous patients with maxillary overdentures supported by four implants and a CAD/CAM PEEK bar. [13] Complete digital centric relation is not attainable up to date and hence recording of centric jaw relationship using occlusion blocks must be done then, the occlusion blocks are scanned by the intraoral or lab scanner. [9, 14-17]

CAD/CAM dentures provided by four different manufacturers (AvaDent, Merz Dental, Whole You, Wieland/ Ivoclar) that were generated from extraoral scanning of the master cast and occlusion rims (indirect workflow) have produced dentures with better fit than conventional ones and so clinically there is enhanced retention and lower traumatic ulcers frequency and better masticatory efficiency.[10]

IOSI are routinely used in fixed restorations with high precision when compared to conventional methods. The use of IOSI in removable prosthesis has still questionable reliability and reproducibility especially in the absence of functional border molding of limiting structures making their clinical outcome of fitness and retention to be suspicious. [18] Evidence related to the adaptation of CDs using intraoral digital scanners is scarce, as the few published literatures were in vitro and compared the trueness of intraoral scanning compared to physical impressions for edentulous arches. [19-21] Although some reports confirmed comparable accuracy in registering hard tissues using either intraoral scans or conventional impressions. [22, 23] ,other in vitro studies established that scanning edentulous arches leads to less accurate trueness. [14, 24] However few clinical cases that were made by direct capturing of edentulous jaw using intra oral scans provide a dimensionally accurate complete denture with sufficient retention. [19, 25]

So the aim of this study was to compare the clinical outcome regarding retention and patients' satisfaction of CDs that was made by indirect digital workflow versus that was manufactured by direct digital workflow (using IOSI and 3D face scan) as compared with the same outcomes of conventionally made CDs. Null hypothesis was that there would be no significant differences either in retention values or patient satisfaction level between the two digitally fabricated dentures and the conventional ones.

MATERIAL AND METHODS

Eight completely edentulous patients (6 females and 2 males) were selected from the outpatient's clinic of removable prosthodontic department, Faculty of Dentistry, Beni-Suef University. Patients age ranged from 55-65 years with an average of 60 years .

Participants selection Criteria:

Patients were selected according to certain inclusion and exclusion criteria . Included patients had to have moderately developed residual alveolar ridges covered with firm mucosa (especially the mandibular ridges), Class I Angle maxillomandibular relationship, and should be capable of reading and answering a written questionnaire. Patients with any systemic or temporomandibular joint diseases or had maxillary and mandibular ridges with abnormal

anatomic landmarks (e.g. tori and prominent raphe) or irregularities (e.g. severe undercuts or bony exostosis) were excluded from the study. Uncooperative patients and those who were unable or unwilling to continue till the end of the study were also excluded. Patients had been informed about the details concerning the treatment steps and follow up periods of this study. They had signed written informed consents. All research protocol was approved by the Research Ethics Committee (R.E.C) of the Faculty of Dentistry, Beni-Suef University. Patients medical and dental history were recorded in his file along with his clinical examination.

All patients received maxillary and mandibular conventional CDs for three months (**Group I**), then patients were asked to take off the denture for two weeks as a washing -out period. They then received CAD/CAM CDs made by the indirect method. Patients wore dentures for another three months (**Group II**). Then all the patients took off their digitally manufactured dentures for another two weeks as a 2nd washing out period during which the 3rd cross-over dentures (**Group III**) were made by direct digital procedures and face scan method and they wore dentures for another three months.

Evaluation of treatment outcomes were done two times for each cross-over denture that was evaluated for the amount of retentive force and patients' satisfaction one and three months after insertion of each set of dentures.

Prosthetic procedures of conventional CDs: (Group I)

Conventional CDs were constructed as usual in five visits where in the 1st visit primary impressions for both maxillary and mandibular arches were made using Alginate irreversible hydrocolloid (Cavex impression material, Holland). In the 2nd visit secondary impressions were performed using rubber base material (thixoflex M, medium, Zhermack, Italy) after making border molding using low fusing modeling green stick compound (Cavex, Holland). Impressions were boxed and poured into stone master casts (Zesus Dental Stone hard type, Italy) that were duplicated (for Group II dentures later on) . Jaw relation records were then done in the 3rd visit through which the maxillary cast was mounted by a facebow record and the mandibular cast was mounted using the centric relation wax record at the predetermined vertical dimension of occlusion. A protrusive wax record was then made to adjust the horizontal condylar guidance of a semi-adjustable articulator (Hanau wide view, Whip mix- USA). All these records were scanned using a laboratory scanner (Medit, extra-oral scanner, Seoul, Korea) (for Group II dentures later on). Conventional steps continued by setting up the artificial semi anatomic acrylic teeth (Vita, Acrylic teeth, Germany) on the articulator, followed by try-in of the trial dentures and taking the patient's approval for denture esthetics. Trial dentures were then waxed-up and processed using heat cured acrylic resin (Acrostone, Manufacturing and import co., Egypt) through conventional lost wax technique. Dentures were finally delivered to the patients after refinement of occlusion by laboratory remounting and selective grinding as a balanced occlusal scheme was used. The patients were recalled after three days and then one week to deal with any patient complaint. Any necessary adjustments were made to ensure that the patients will wear their dentures comfortably for three months. (Fig.1a, b, c)

Prosthetic procedures of rapid pro-typing (3D printed) CDs using indirect digital workflow: (Group II)

Before scanning, proper orientation of the cast to be parallel to the floor ensuring a proper scanning process. A Laboratory scanner (Medit, extra-oral scanner, Seoul, Korea) was used to scan the master casts that were duplicated earlier to create virtual models on the CAD software EXOCAD where maxillary and mandibular virtual models were analyzed and related to each other by the previously scanned jaw relation record on which the level of occlusal plane, central line and two canine lines were previously determined. When scanning was

Fig. 1a, b, c: Conventional complete denture (Group I); **1a** Master casts, **1b** teeth setup and try-in, **1c** delivered dentures

completed, the 3D image of the scanned cast was displayed and stored with an extension of standard triangulation language (STL) files.

After designing extensions of denture base on the virtual models and determining areas of relief, artificial anterior teeth were selected from the teeth library option in the EXCOCAD software according to the available width in between the two canine lines, followed by setting of teeth on the virtual denture bases and balancing of occlusion using the virtual articulator. The CAD design of the virtual denture was exported as STL file to a three dimensional printer (DENT 2 DLP 3D Printer). Printing of denture base and teeth as one unit in white acrylic resin (Next- Dent Try-in) to be used for try-in of occlusion, esthetics and denture extensions.

After approval of the trial dentures, the final denture base was printed (Next-Dent 3D Print) according to Digital Light Projection (DLP) technology having already the sockets of artificial teeth that were previously selected from the artificial teeth library and then were brought from the dental supplier with its specific adhesive (Visio bredent, Germany). After the whole printing process was completed, the printed denture bases were rinsed in 95 % isopropyl ethyl alcohol to remove residual monomer on the surface of printed dentures. After cleaning and drying of the printed denture bases they were placed in an UV-light curing device for fifteen minutes for the post- curing treatment. The support structures were then removed, and the printed denture bases were finished by fine bur and rotary tool then polished using Abraso-gum acryl.

The CAD-CAM dentures were delivered after refining the occlusion. The same follow-up schedule was proceeded as mentioned for the conventional CDs. (Fig. 2a, b, c)

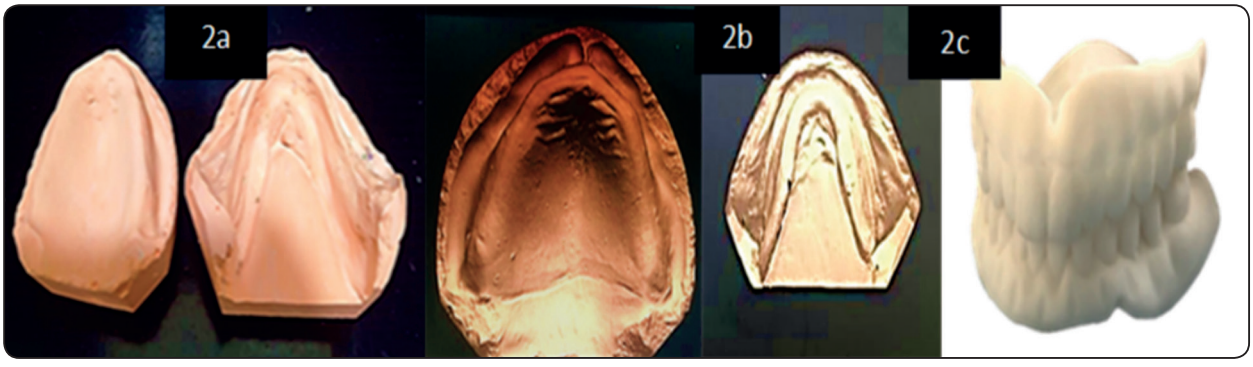

Fig. (2a, b, c): Steps of complete denture construction by indirect digital workflow (Group II)**; 2a** Master casts, **2b** Casts indirect scanning, **2c** Teeth setup and try-in.

Prosthetic procedures of rapid pro-typing CDs using direct digital workflow and facial scanning: (Group III)

A digital workflow using a facial and intraoral scanners and CAD CAM technology [26] was used for this group as follows:

First clinical appointment:

Fully digital impressions of both maxillary and mandibular completely edentulous arches were made using the TRIOS3 intraoral scanner having standard resolution (3Shape, Copenhagen, Denmark, Software version 1.4.7.5). Firstly, each edentulous jaw was cleaned, saliva was wiped dry before scanning. The scanner head was retracting the lip and cheek, while stretching and fixing the vestibular area with the retractor. The maxillary ridge was scanned from the left maxillary tuberosity to the right one to pass again to the left tuberosity along the posterior palatal seal; then, the posterior palatal region was scanned and proceeded anteriorly till the rugae folds. Lastly the labial and buccal vestibules were captured as deep as possible. Similarly, the mandible was scanned from the retromolar pad on one side to the contralateral side along the residual ridge, followed by buccal and labial vestibular depth scanning; finally, the lingual vestibule was scanned from lingual pouch of one side proceeding anterior till reaching the pouch on other side with retraction of the tongue giving special attention to the width and depth of the lingual pouch. [27] The scanned data were saved in Standard Tessellation Language format (STL file) to obtain maxillary and mandibular virtual models.

Facial scanning

The patient's face was digitized by using a facial scanner (Bellus3D Face Camera Pro; Bellus 3D). Three facial scans were made: [28]. Three facial scans were needed: reference, rest, and smile. First, place the forehead marker or extra-oral scan bodies (Scan Body Face; AFT Dental System) on the patient's forehead. For the reference scan, position the intraoral scan marker (Scan Body Mouth; AFT Dental System) in the patient's mouth. Intraoral face scan marker is a device with three available sizes (small, medium and large) and it looks like the bite frame but it has central extended portion outside the mouth having scan bodies, on that extension, there is vertical line that should coincide with the midline of the patient face.

Occlusal wax rim was then fitted on the upper portion of this scan marker (bite frame) and two V-shaped notches were cut bilaterally on the maxillary wax rim, then the mandibular wax rim was softened and fitted on the lower portion of the scan bite frame and the patient was guided to close in centric relation at the predetermined vertical dimension of occlusion. A reference facial scan was made while the patient was closing in centric position with the intra-oral scan bite frame. The bite was then removed and scanned extra-orally using Trios 3-shape intraoral scanner. The intraoral marker was removed from the patient's mouth and taking a new facial scan of the patient at the rest position then the third smile scan was completed while the patient was smiling. The STL file virtual models and the 3D facial scans were imported into a dental CAD software program (EXOCAD Dental CAD; EXOCAD GmbH) where the different facial scans were superimposed using the forehead marker as the common landmark, then virtual models were related to each other by the scanned centric relation attached to the intra-oral marker, finally the facial scan was superimposed to the virtual models using both the intra-oral and forehead scan markers.

Computer-aided design (CAD) procedures of CD started by analyzing the virtual casts and selecting artificial teeth from the EXOCAD library. Smile Design Creator of EXOCAD software was used to make virtual setting of maxillary anterior teeth following the smile curve of the patient with adjustment of dental midline according to the facial scan I. Incisal line was adjusted parallel to the interpupillary line, two canine lines went in parallel with two lines passing through inner canthi of the

eyes and ala of nose bilaterally, then virtual setting of maxillary posterior teeth was done following an occlusal plane that should be parallel to the ala-tragus lines on the profile views of the patient's face scan. (Fig.3, Fig.4a, b, c)

Second clinical appointment: STL files of the virtual CDs were imported to the 3D printer (DENT 2 DLP 3D Printer) to pro-type the try-in which was done to check for esthetics, centric relation and vertical dimension of occlusion as well as denture base extensions. Squash wax bite was made in a protrusive position, then scanned using a laboratory scanner (Medit, extra-oral scanner, Seoul, Korea) to be transferred to the EXOCAD software and balance the occlusion on the virtual articulator(Fig.5). Then the designed dentures were printed following the same steps that previously mentioned in Gr II .

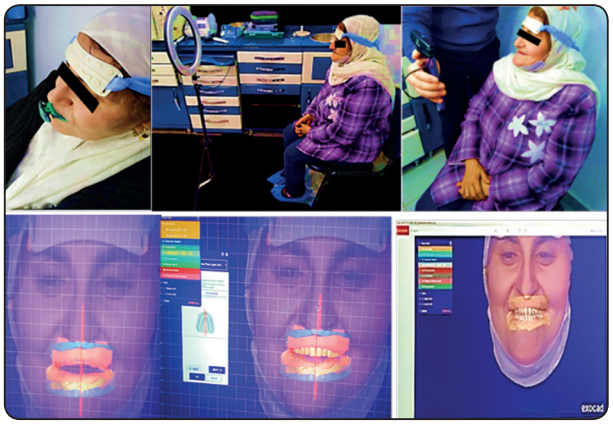

Fig. (3): Facial scanning for group III digital CDs. Three facial scans were made: reference, rest, and smile scans

Third clinical appointment: delivery of CAD-CAM CDs after refining of occlusion by selective grinding and then follow-up three days and one-week post-insertion to manage all patients' complaints. (Fig.5)

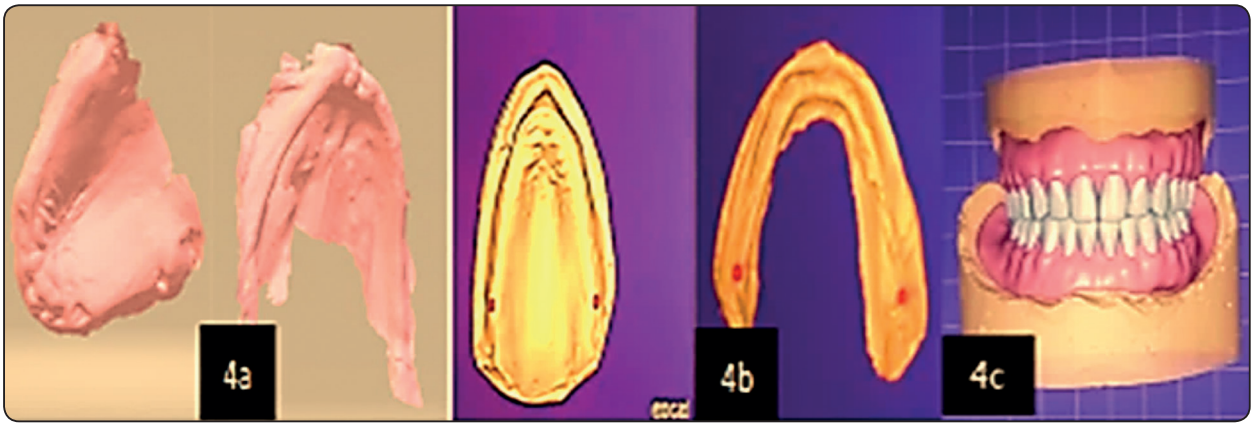

Fig. 4a, b, c: Digital image of the scanned arches by direct digital workflow and complete denture design. (Group III); 4a Intra oral scanning, 4b Virtual Casts resulting from IOSI, 4c Design of teeth setup

Fig. (5): Try-in and delivery for group III direct workflow digital complete denture

Assessment of Complete Denture Retention

A- Assessment of maxillary CDs retention: One month after denture insertion, retention was measured using digital force gauge (Extech Digital push pull Gauge Force Gauge Taiwan). The device unit of measurement was chosen to be in Newton and the peak hold option was selected. Self-cure acrylic resin was used to attach a metallic ring to the polished surface at the geometric center of the maxillary denture palatally at the intersection of two lines: the first (vertical midline) extended between the incisive papilla anteriorly and fovea palatine posteriorly and the second (horizontal line) extended between the contact of second premolar and the first molar bilaterally. Every patient wore his\her maxillary denture after rinsing the mouth with water. Dentures were left intra-orally for 5 minutes to allow settling of denture. The patient was positioned upright in the dental chair with his mouth open and the lips relaxed so that the palate and the maxillary ridge were nearly 45 ^{0} to the horizontal plane and the mandible nearly parallel to the floor. Metallic tip of the force gauge was attached to the metallic ring at the mid-palatal area and the display before measuring force was adjusted to be zero via the zero button. The maximum force needed to dislodge the denture was determined as the retention force (Fig.6). The procedure was repeated three times by the same investigator and the average value was calculated and recorded.

B- Assessment of mandibular complete denture retention: The same procedures of measuring retention of maxillary denture were followed for measuring retention of mandibular one with the exception that the metallic ring was fixed to the mid-lingual area of the polished surface (Fig.6).

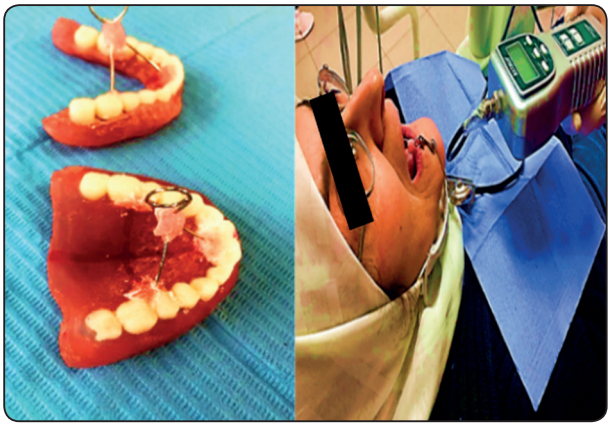

Fig. (6): Assessment of Complete Denture Retention

Assessment of patient satisfaction:

Quantitative assessment of patient's satisfaction levels was done by using Visual analogue scale (VAS) questionnaires. [(29)] Each VAS consisted of a 100 mm horizontal line on which patients drew a vertical line through to record their response. The VAS is anchored with totally unsatisfied at one end and highly satisfied at the other end. This instrument measured patients' satisfaction covering 6 priorities including stability, ability to masticate several types of food, esthetics, ability to speak, ease of cleaning and liability to maintain clean denture base without stains, comfort and general satisfaction, following the verbal questions listed in **(Table 1)**. These questions were asked to every patient within each group twice, one and three months after denture insertion. The mean values for each item of VAS were calculated at follow-up times, recorded and statistically analyzed as VAS score percentage.

TABLE (1) Questions of visual analogue scale:

Item	Questions asked in questionnaire
1- Comfort and General satisfaction	Are you generally satisfied and feeling comfortable with your dentures?
2-Stability	Do you feel that your dentures are stable in their place?
3- Esthetics	Are you satisfied with the appearance of your dentures?
4-Ability to speak	How difficult is it for you to speak because of your dentures?
5-Ease of cleaning?	How difficult is it to clean your dentures and mouth?
6- Ability to chew	How much difficulty do you find to chew different types of food with your dentures?

Statistical Analysis:

Data were presented as means and standard deviation (SD) values. Retentive force showed normal distribution.. Repeated measure ANOVA test followed by Bonferroni test was used for between group comparison. Paired sample t-test was used for within group comparison. Kruskal Wallis Test used to compare between the different tested groups within each follow-up time for VAS score. The significance level was set at $P \leq 0.05$. Statistical analysis was performed with IBM® SPSS® (SPSS Inc., IBM Corporation, NY, USA) Statistics Version 22 for Windows. All data were recorded , tabulated and statistically analyzed.

RESULTS

- Statistical analysis revealed that at both follow-up periods, both maxillary and mandibular CD sets of Group II expressed significantly the highest retentive forces followed by Group I. While CD sets of Group III showed the lowest retentive forces. However, from one to three months, retentive forces improved significantly for all CD sets in the three tested groups **(Table 2)** (Fig.7a, b)

TABLE (2): Mean retentive force (in Newton) of all tested groups at both follow-up periods.

Item	Follow-up Period	Conventional (Group I) Mean ± SD	Indirect printed (Group II) Mean± SD	Direct printed (Group III) Mean ± SD	P1-Value
Maxillary arch	**One month**	14.79±0.50 A a	19.19±0.70 B a	11.77±0.48 C a	**< 0.001**
	Three months	16.11±0.40 A b	21.18±0.68 B b	13.78±0.46 C b	**< 0.001**
	P2-Value	<0.001	<0.001	<0.001	
Mandibular arch	**One month**	6.97±0.45 A a	11.37±0.76 B a	4.06±0.32 C a	**< 0.001**
	Three month	8.96±0.44 A b	13.55±0.0.57 B b	6.05±0.30 C b	**< 0.001**
	P2-Value	**<0.001**	**<0.001**	**<0.001**	

Means with different letters within each row are significantly different at p≤0.05 (P1).

Different letters within each column are significantly different at p≤0.05 (P2)

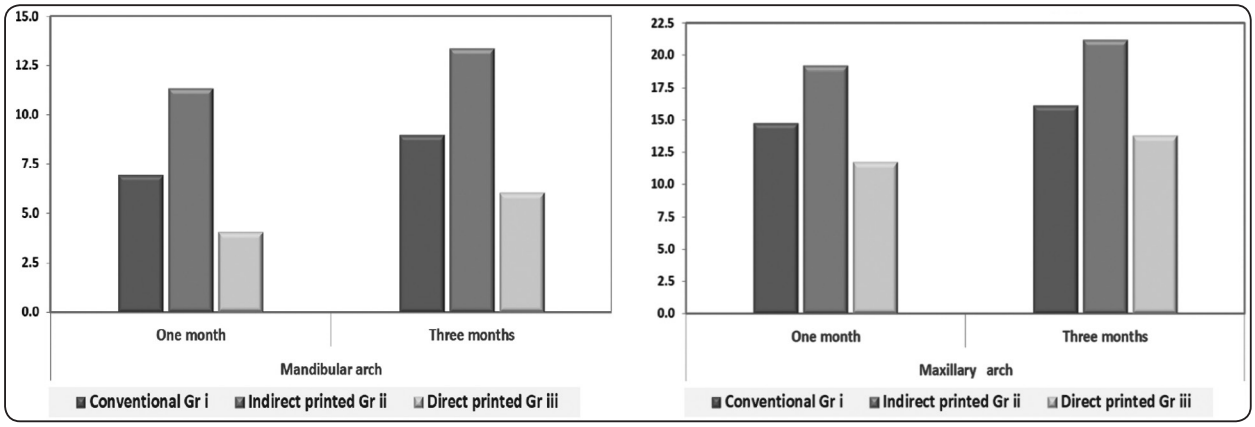

Figure7a&b: Mean retentive force (in Newton) of all tested groups as both follow up periods a- for mandibular arches b- for maxillary arches

- At both follow-up periods, patients wearing Group III CD sets recorded the highest significant VAS score percentage for esthetics and natural smile appearance, followed by Group II then Group I CD sets. However, VAS score recorded for ease of hygiene and liability to maintain clean denture base was significantly higher for Group II followed Group III then Group I at both follow-up periods.

-VAS score percentage for other investigated items (stability, masticatory ability, speaking ability and comfort) of patient satisfaction showed significant differences among the three groups at both follow-up periods, where satisfaction levels were significantly higher with Group II CD sets followed by - Group I CD sets. While patients' satisfaction levels for these items was significantly the worst for Group III CD sets. **(Table 3)** (Fig. 8a &b)

Table (3): Mean and SD for VAS Score percentage for different follow -up periods for all tested groups.

Item	Follow-up Period	Group- I Mean ± SD	Group- II Mean ±SD	Group- III Mean ±SD	P. value
1- Stability Of Both Dentures Together	One month	60.06 ±2.41^{B}	72.75 ±1.71^{A}	25.52 ±3.28^{C}	**< 0.001**
	Three months	70.97 ±1.31^{B}	82.79 ±1.75^{A}	39.05 ±4.43^{C}	**< 0.001**
2- Masticatory Ability of different food types	One month	59.76 ±4.51^{B}	66.18 ±3.32^{A}	30.74 ±4.52^{C}	**< 0.001**
	Three months	78.34 ±3.17^{B}	81.93 ±5.29^{A}	41.90 ±4.40^{C}	**< 0.001**
3- Esthetic and Smile Appearance	One month	54.20 ±3.23^{C}	64.95 ±2.53^{B}	71.40 ±1.46^{A}	**< 0.001**
	Three months	63.50 ±5.01^{C}	75.21 ±2.74^{B}	82.26 ±0.48^{A}	**< 0.001**
4- Ability To Speak Easily	One month	58.64 ±2.89^{B}	67.10 ±2.16^{A}	28.91 ±2.64^{C}	**< 0.001**
	Three months	66.21 ±2.32^{B}	78.97 ±2.74^{A}	36.13 ±2.80^{C}	**< 0.001**
5- Ease of Hygiene and Liability of Denture Base To Preserve Clean Appearance.	One month	45.79 ±6.61^{C}	65.65 ±2.51^{A}	61.72 ±2.56^{B}	**< 0.001**
	Three months	60.74 ±6.63^{C}	86.85 ±1.26^{A}	80.59 ±2.59^{B}	**< 0.001**
6- Comfort And General Satisfaction	One month	57.58 ±1.68^{B}	68.86 ±2.13^{A}	32.18 ±1.69^{C}	**< 0.001**
	Three months	70.37 ±1.89^{B}	79.88 ±2.11^{A}	45.69 ±2.09^{C}	**< 0.001**

Means with different letters within each row are significantly different at p≤0.05.

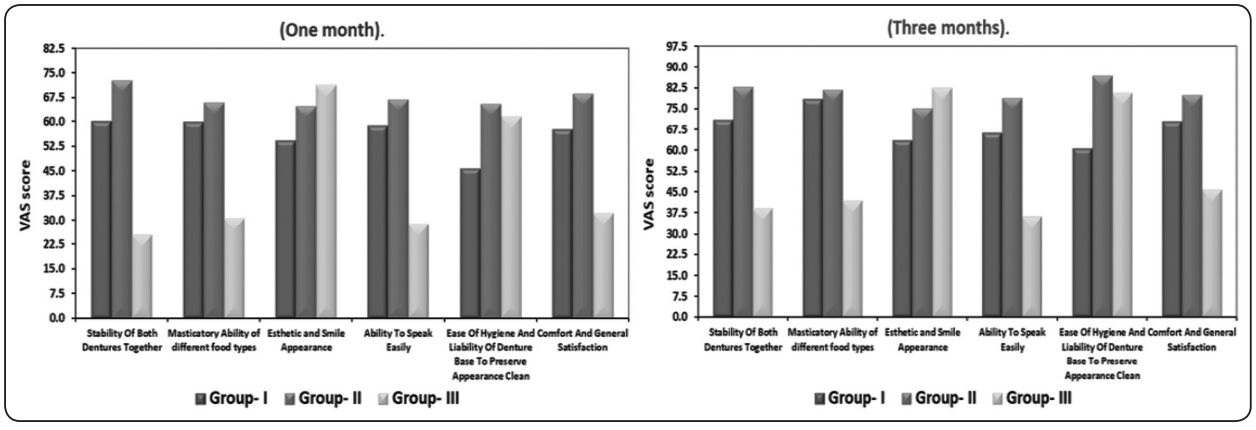

Fig. (8) a & b: Mean and SD for VAS score for different follow up periods for all tested groups a- One month b- Three month

DISSCUSSION

This study investigated the retention values and satisfaction levels of digital dentures constructed by the indirect and direct methods and compared them to conventional CDs as a control group.. Results of the current study revealed significant differences between the three groups for the two tested outcomes and hence the null hypothesis was rejected.

The results of retention of either maxillary or mandibular CD of Group II showed significantly higher retentive forces compared to conventional dentures. This could be attributed to better congruence, precision trueness and hence better fit of printed CD using the indirect digital method. Denture base to the underlying soft tissues than conventionally made denture base [10,30,31], as tissue congruent denture fit is the crucial factor for good retention in removable CDs. CDs of Group II were made by extra-oral scanning of master casts then CAM printing of the denture bases hence achieving maximal tissue congruence compared to conventional ones, as the dimensional changes of materials used during conventional processing of heat cured acrylic resin are unavoidable. Moreover, the possible human (technician) errors are presented as a causative factor for the poor fit of denture bases and artificial teeth displacement. [32-35] On the other hand however, the additive manufacturing technique used for 3D printing of CD sets is done by successive layering of photosensitive resin then UV light polymerizing it, hence the dimensional changes of each layer are compensated for by addition of the successive resin layer allowing material conservation as well as printing complex geometries with reasonable dimensional accuracy. [32, 36, 37]

Also Goodacre et al. [38] have demonstrated that pressure-requiring processing techniques produce more tooth movement and denture base distortion than CAM technology which is superior in acrylic resin processing. This explained other results of in-vitro studies that indicated that 3D printed CD using the indirect digital method bases (whether maxillary or mandibular) has better tissue adaptation and hence better retention than conventionally made CDs. [39- 41] In addition to less dimensional changes of CAM CD base, all CAD/CAM PMMA are more hydrophilic than conventional heat-cured PMMA. Hydrophilicity has long been known to play a role in increasing denture retention. [42-45] Also, this study results were consistent with that obtained by the clinical research that was conducted by Kattadiyil et al [46], who mentioned that indirect digitally made maxillary CD had higher retention scores than conventionally made ones.

On the contrary digital CDs made by direct scanning of oral tissues (Group III), recorded the least significant retention force compared to both conventional (Group I) and digitally made by indirect technique (Group II). These results may be due to lack of adequate border seal, as the intra-oral scanning impression (IOSI) could be described as mucostatic impression technique [25] where all movable tissues of edentulous arch were not captured in its compressed functional form, as during the scanning procedure the labial and the buccal mucosa had to be permanently retracted and these areas are of major importance for the retention of a CD where the borders must be near the tissues to prevent ingress of air and food particles.

In-vitro studies comparing the accuracy of different impression techniques of edentulous arches, indicated that there were no significant differences between open mouth conventional impression and (IOSI) in supporting areas of maxillary and mandibular arches, however the highest incidence of e discrepancy was detected in the anterior border seal, movable tissues such as lingual vestibule and soft palate that were very unstable in some cases. [47- 49]

Moreover, results of IOSI is dependent on the resolution of the used intra-oral scanner (IOS) as well as the technique of the oral scan. In the current study the IOS (Trios 3-shape) [50-- 54] scanner was used and the same scanning impression sequence that was used in a few clinical studies [26] that

investigated IOSI for completely edentulous arches was followed. However, the recorded amount of retention for Group III CD sets could be attributed to 3D printing (rapid prototyped) denture base having a higher technique accuracy, where reasonable retention is attained by the close mucosal contact of the denture base. [26, 55- 57] Also some clinical literatures have reported that good retention of CD manufactured by a digital workflow using direct scanning even if not functional impression, could be attributed to the surface tension between the denture bases and underlying tissue that plays a bigger role than the sealing effect by means of custom formed denture borders. [16, 57]

Recorded patient satisfaction levels followed the same trend as the retention results except for the esthetic item that was statistically the best in CD sets of Group III. In that group tried to digitally capture all clinical data as much as possible, so IOSI was made in combination with 3D facial scans that replaced the face bow record and created a virtual dental patient during CAD procedures, to be used for digital acquisition of esthetic facial references (such as the bi- pupillary line and oral line). This was done to enable the creation of a smile design during setting of anterior teeth and virtual placement of the occlusal plane based on esthetic and functional principles. The facially driven design is a technique which considers the facial esthetics, facial profile, proportions, and harmony for the oral rehabilitation, and uses digital smile design to make aesthetically pleasing faces enhancing smiling, self-esteem, and self-confidence of patients. [58- 61]

On the other hand, the semi-adjustable articulator and face bow records that were used in the construction of CD sets of Group I and II, are based on average values and cannot be individualized unless the fully adjustable articulator is used, which also needs high technical skills requirements and so errors from the users may also lead to questionable accuracy. [62]

It is worthy to mention however that patients were more satisfied with the aesthetics of their Group II sets than their Group I conventional sets. These results may be attributed to the inevitable dimensional changes of materials used for processing of heat cured acrylic resin in addition to potential mistakes of laboratory technicians that may cause possible tooth movement disturbing esthetics, occlusal plane, centric relation and vertical dimension of occlusion. [63] All the hazards of materials and errors of technicians could be avoided by CAM manufactured CD sets producing less tooth movement. [64]

Denture retention affects greatly the masticatory performance, speaking ability and reduced traumatic ulcers and hereby has a strong impact on the patients' quality of life. [65, 66]

So VAS scores of stability, masticatory ability, speech feasibility and general comfort were the best for Group II followed by Group I. These results were very realistic and could be attributed to the proper fit and retention quality of these two groups. Patients' satisfaction levels also improved throughout the study and that paralleled that of increased retention values throughout the follow-up times. This may be supported by a study [67] which found that the prosthesis which produced by indirect 3D printing technology, adheres tightly to the tissue enhancing its retention, stability and transferring loads equally to the tissue. Moreover, recent studies using surface matching software, revealed that higher soft tissue deformation was found in the conventionally made dentures than that found in 3D printed CDs. [11, 68, 69]

The findings of this study were consistent with a research [70] which conducted that the surface quality of the 3D printed part showed high quality and the patient was satisfied during delivery. However, a systematic review [71] showed that higher patient satisfaction and preference for the digital CDs may be due to the lack of blinding of patients which could have influenced their responses in favor of the new digital denture. On the other hand, the study of

Inokoshi et al. [55] showed that the 3D printed CD and the conventional ones were equally rated by the patients with respect to comfort and esthetics of denture, and overall satisfaction. [55, 71]

The least VAS scores for these categories were recorded for Group III. As mentioned earlier, the prolonged success of a prosthesis relies not only on the optimum fit attained between the denture base and the underlying tissue but also on a good border seal to provide good retention. Hence these functional qualities were reduced for Group III who showed the least retentive forces. [72-74]

As regards, the ease of oral hygiene and liability to maintain a clean denture base and preserve good appearance without stains, VAS scores for Group II were significantly the highest followed by Group III. While, Group I showed the lowest scores. These results may be due to residual monomer release in conventionally made CD bases which results in porosity and eventually allowing the impaction of food debris.

CONCLUSIONS

Within the limitations of this study (reduced sample size and short follow-up period), we can conclude that:

1- Digital 3-D printed CDs constructed using the indirect method had significantly better retention than both the conventional and the digital 3-D printed CDs constructed using the direct method which were the least retentive.

2- In general and in almost all aspects, patients were significantly more satisfied with their digital CDs made by the indirect method, as compared to their conventional and digital CDs made by the direct method. The only exception was for the aesthetic aspect.

3- The incorporation of 3D face scan in the rehabilitation of completely edentulous patients produced the most esthetic placement of artificial teeth and hence the best esthetic patient satisfaction.

RECOMMENDATIONS

Intra-oral scanning impression for completely edentulous arches has several advantages for both clinicians and patient and it is accurate to capture supporting structures. However, its main limitation is to record the functional border tissues. This can be overcome by more advances of IOS to be able to record the different depths of lining mucosa. Until this advance of IOS has been reached out, retention of CD made by direct scanning could be increased by either chair side relining using soft liners or laboratory relining, both of them could be tried in future clinical studies.

The incorporation of 3D face even with extra-oral scanning technique is very successful to produce superior esthetic to allow possibility of virtual try-in session predicting the final outcome of digital CD workflow.

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