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QUALITY OF LIFE AND MASSETER MUSCLE ACTIVITY IN PATIENTS WITH DIGITAL COMPLETE DENTURES CONSTRUCTED USING COMBINED INTRA-ORAL AND FACE SCANNING VERSUS THE INDIRECT METHOD AS COMPARED TO CONVENTIONAL DENTURES: A CROSSOVER STUDY

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Aim: The aim of this crossover study was to evaluate oral health-related quality of life (OHRQoL) and masseter muscle activity in patients with digital complete dentures constructed using combined intra-oral and face scanning versus the indirect method as compared to conventional complete dentures.

Materials and methods: Twelve completely edentulous patients were selected. All participants received three complete dentures: a conventional complete denture (CCD), a digital complete denture constructed using intra-oral and face scans (IFDD), and a digital complete denture constructed using the indirect method (INDD). A crossover study design was followed. The sequence of wearing dentures was random. The masseter muscle activity and OHRQoL results were measured after three months of using each denture type.

Results: There were insignificant differences in OHRQoL scores and masseter muscle activity between INDD and IFDD, while significant differences between conventional and digital dentures were found. INDD showed the lowest oral health scores (2.31±0.65), followed by IFDD (2.44±0.63), and CCD showed the highest scores (3.20±0.40). The INDD group showed the highest masseter muscle activity, followed by IFDD, while the lowest activity was measured in the CCD set.

Conclusion: Within the limitations of this study, OHRQoL and masseter muscle activity were better in patients with digital complete dentures than conventional dentures. Also, the indirect method of digital complete denture construction led to a slightly better quality of life and higher masseter muscle activity than intra-oral and face scanning.

Keywords: Face scanning, intra-oral scanning, digital complete denture, indirect technique, oral health-related quality of life, masseter muscle activity.

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Introduction

A well-established treatment protocol is the restoration of the edentulous patient using conventional complete dentures. The utilization of computer-aided design and manufacturing (CAD-CAM) technique in the production of digital complete dentures, on the other hand, has lately developed popularity.[1,2] Denture retention, mechanical properties of materials, patient satisfaction, laboratory and clinical time, clinician acceptability, and procedure time and cost are all improved when digital technologies are used to construct complete dentures.[3-7]
For digital denture design and production,8 different manufacturer-dependent systems9 and treatment workflows[1] have been developed. Some of these treatment protocols employ traditional clinical processes that are afterwards digitalized in a way that is most appropriate for a certain system.[10,11] According to Saponaro et al,[12] the average number of clinical sessions required for digital complete denture manufacture is two to three visits, while traditional workflow requires at least five appointments.

In digital complete dentures, the clinical records of the edentulous ridges are obtained in the form of conventional impressions or digital records. The records are then uploaded to dental software, where the digital complete denture is virtually created.[13,14] Then the dentures become ready for placement. Despite the fact that this technology is just getting started, it has great promise to assist elderly patients in different ways. As they are fabricated in fewer clinical sessions and with claims of greater fit and material characteristics when compared to conventionally constructed dentures.[15,16]
Several studies advocate using intra-oral scanning to produce a well-fitting digital complete denture. Digitizing edentulous jaws is challenging due to problems with scanning soft tissue dynamics.[17] It has been observed that good digital denture adaptation and retention findings could be accomplished utilizing a retractor to fixate and retract the vestibules, cheeks, and lips while using intra-oral scanners.[18] Using intra-oral scanning has been advised in situations where conventional impressions were impossible, as in severe lip tightness or microstomia. However, before using intra-oral scanning as a replacement for conventional impressions, long-term validation of digital complete denture performance is needed.[19,20]

Clinical findings have shown that edentulous jaws may be completely digitized. The utilization of intra-oral scanners for digital complete denture manufacturing may give further benefits by enhancing patient comfort. As it reduces gag reactions, treatment sessions and chairside time. The laboratory phase is reduced due to the elimination of procedures required for impressions and casts. Also, there are no allergic responses to the impression materials.[18,21] It has been stated that intra-oral scans are sufficiently accurate for digital denture construction,[22,23] and a proof of concept has been provided for the production of a digital full denture through the use of intra-oral scanning.[18,24]

Digital face scanning is a fast-expanding technology in many disciplines such as biomedical engineering, industrial design, and 3D animation. In dentistry, it is used with the growing CAD/CAM technologies, which have enabled the virtual design and fabrication of complete dentures in a completely digital approach.25 The process of fabrication of digital dentures with facial scanning provides a three-dimensional simulation and preview of the teeth arrangement in relation to the patient's profile. It supplements or even substitutes traditional clinical assessment of a conventional teeth setting. Also, facial scanning enhances patient communication and minimizes errors and problems in previewing treatment findings.[26,27]
The facial scanning technique provides a virtual patient record that is required for prosthetic restoration by providing external patient profile information. The “virtual patient” can be created by combining the collection of as much data as feasible about the edentulous ridges, anatomical landmarks, and facial profile with the advancement in processing these data digitally.[28]
It is still not easy to combine all the data without shared landmarks in each dataset. Data alignment is easier in a dentulous subject because of the presence of teeth, with an edentulous patient, however, an artificial object for alignment is needed.[29]

The combined use of intra-oral and face scanning to create a digital complete denture may improve the precision of prosthetic restoration in completely edentulous patients, making them more comfortable and enhancing their appearance while minimizing treatment costs and chair time.[24,30] Different techniques for combining face scans with intra-oral scans have been published, with the goal of coming up with a protocol for making CAD/CAM complete dentures that satisfies patients' needs.[31]

There has been few published research on the benefits of adopting facial scanning technology in dental applications. Rangel et. al.[32] proposed merging digital casts with facial scans in patients with intact teeth, suggesting that this setup may be effective for orthodontic procedures. Rosati et al33 tested the validity of combining virtual teeth and face scans on eleven patients and concluded that this technique is technically viable and reliable. Joda and Gallucci[34] published a clinical report in which they discussed how they used cone-beam computed tomography, face scan, and intra-oral digital impressions for restoring a patient who had two implants in the aesthetic region. Hassan et al[26] were the first clinical trial to use the "virtual patient" concept to restore totally edentulous individuals. They recommended that future studies should focus on proving the accuracy of this method and expanding its potential uses.

Reviewing the literature, it was found that there are some clinical studies that compared digital to conventional complete dentures or evaluated the different techniques and workflows for making digital complete denture.[35-38] Furthermore, few clinical reports have evaluated the technique of using intra-oral and face scans.[26-28] Only one clinical study compared both types of scanners regarding retention and patient satisfaction.39 To the best of the authors' knowledge, there have been no clinical trials that compared the effects of intra-oral and face scans on masseter muscle function or on OHRQoL.

The aim of this study was to evaluate oral health-related quality of life (OHRQoL) and masseter muscle activity in patients with digital complete dentures constructed using combined intra-oral and face scanning versus the indirect method as compared to conventional complete dentures. The first null hypothesis was that there would be no difference in OHRQoL and masseter muscle activity between digital complete dentures constructed using intra-oral and face scanning and the indirect method of digital construction. The second null hypothesis was that there would be no difference between the digital dentures and the conventional complete dentures in OHRQoL and masseter muscle activity.

Materials and methods

I- Participants selection and study design:

Twelve patients from the Removable Prosthodontic Department's outpatient clinic were selected for this study: nine men and three women, with an average age of 61.17± 4.06 (ranging from 55 to 69 years). Patients were chosen based on a set of predetermined inclusion and exclusion criteria. Patients who met the inclusion criteria had to be class I or class II patients according to the Prosthodontic Diagnostic Index of the American College of Prosthodontics.[40] Participants also had a Class I Angle maxillo-mandibular jaw relation and were able to complete a written questionnaire. Patients were excluded if they had a systemic illness, temporomandibular joint dysfunction, hard, resistant areas in the denture-bearing region like tori and prominent raphe, bony exostosis, or severe undercuts, or if they didn't want or couldn't attend the follow-ups.

The sample size calculation was based on the results of a prior study trial,[36] with similar outcomes (0.85 effect size, α=0.05, β=0.95). The initial sample size of 10 patients was raised to 12. This was done to account for probable dropouts. The sample size was calculated using a power analysis (G. Power 3.1.5).

Treatment procedures and expected durations of the study and follow-ups were explained to patients. The patients signed informed consent forms after getting their approval to be included in the study. The local ethical committee approved all of the study's procedures. The study followed both the Helsinki Declaration and the recommendations of CONSORT (Consolidated Standards for Reporting Trials).

The crossover study design used in this study involved each patient receiving a variety of prostheses. This design allows the patient to act as a self-control. As a result, standardization of patients' parameters that may influence the treatment outcomes. All participants received three complete dentures: a conventional complete denture (CCD), a digital complete denture constructed using intra-oral and face scans

(IFDD), and a digital complete denture constructed using the indirect method (INDD). Participants were randomly assigned to either CCD, IFDD, or INDD and were instructed to use it for three months before switching to the other set. The following denture was inserted for the patient after a two-week washout period from the removal of the previous denture. The order of denture insertion was randomized to limit the influence of denture order on the measured outcomes. Six blocks of two patients were created in a random manner using a random generation tool in a Microsoft Excel spreadsheet. Each block has a unique set of sequential dentures. The following were the six probable successions: (1) CCD-INDD-IFDD; (2) CCD-IFDD-INDD; (3) INDD-CCD-IFDD; (4) INDD-IFDD-CCD;(5) IFDD-CCD- INDD; (6) IFDD-INDD-CCD. Blinding of the participants to the group allocation was done. Three months after each type of denture was used, the masseter muscle activity and OHRQoL results were measured. At the study's end, patients were asked to select which of the three dentures they liked and wanted to continue using.

II- Prosthodontic procedures:

The previous medical and dental history and clinical examination were performed and documented in the patients' file. The following procedures were performed for all patients.

1. ***Prosthetic procedures for construction of the conventional complete dentures (CCD):***

The conventional complete dentures were fabricated using the conventional technique. Upper and lower primary impressions were taken (Alginate, Cavex impression material, Holland). Definitive impressions were done using a rubber base impression material (3M ESPE St. Paul, USA) following molding of the trays' borders with green stick compound (Cavex, Holland). Boxing of the impressions was done, then they were poured into master casts (hard type, Zeus Dental Stone, Italy). After registering jaw relations, both casts were mounted on a semi-adjustable articulator (Hanau wide view, Whip mix-USA). The upper cast was mounted using a facebow record, while mounting the lower cast was done using a centric jaw relation record. The sagittal condylar guidance of the articulator was then adjusted using a protrusive record.

The artificial semi-anatomic teeth (Acrylic teeth, Acrostone, Egypt) were set up. The trial dentures were tried intra-orally for extension, retention, stability, esthetics, phonetics, vertical dimension, jaw relationship, and occlusion. Waxing up the trial dentures and then processing with the lost wax method using heat-cured resin (Acrostone, Manufacturing and Import Co., Egypt). Laboratory remounting and selective grinding were done until a balanced occlusion was achieved ***(Fig. 1).***

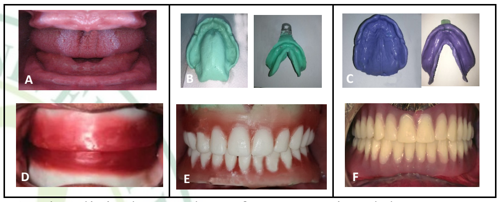

Fig.1: The clinical procedures for conventional denture construction in CCD group; A: intra-oral view of the edentulous ridges; B: primary impressions; C: definitive impressions; D: centric jaw relation; E: try-in of the trial dentures; F: delivery of the finished dentures

2. ***Prosthetic procedures for the indirect method of fabricating digital complete dentures (INDD group):***

The construction procedures started with scanning of both the master cast and the jaw relationship, obtained in the CCD group, with a desktop scanner (Medit, Seoul, Korea). The virtual models were created using CAD/CAM designing software (exocad GmbH, Darmstadt, Germany). Maxillary face bow (Hanau, engineering company, Inc., Buffalo, New York) record was taken. This was followed by setting the virtual articulator using the face bow record and the scanned jaw relation records. The digital representations of the casts and the jaw relation records were saved using the Standard Tessellation Language (STL) file format.

The denture base extension was designed digitally with maximum coverage and extension. The areas of relief were determined. Artificial teeth were selected from the teeth library option in the software (exocad GmbH, Darmstadt, Germany). Virtual setting-up of the teeth was done on the denture bases, and the occlusion was balanced using the digital articulator present in the software. The design of the digital complete denture was exported as STL to the 3D printer (Elegoo Mars 3 ultra 4k mono LCD 3D printer) ***(Fig. 2)***.

The trial denture was printed using white acrylic resin (Next- Dent Try-in). Denture extension, retention, stability, esthetics, phonetics, vertical dimension, jaw relationship, as well as occlusion, were checked intra-orally, and any necessary adjustments were done and scanned. The final STL file of the denture was prepared by subtracting the teeth from the denture base using reverse engineering software (Meshmixer Autodesk, California, USA), to create tooth sockets in the base. The denture bases with the sockets of artificial teeth and the teeth of the digital complete dentures were then printed using acrylic resin (Next-Dent 3D Print). The teeth were bonded to the base using adhesive (Visio Bredent, Germany). The denture bases were cleaned with 95% alcohol and dried before undergoing the post-curing procedure of being exposed to ultra-violet light for 15 minutes. The 3D-printed denture bases were finished and polished, and the occlusion had been fine-tuned ***(Fig. 3)***.

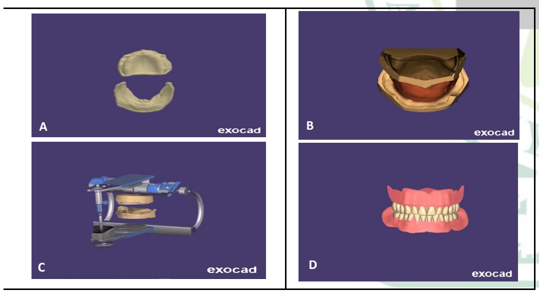

Fig. 2: Designing the digital complete denture in INDD group using CAD software; A: scanned master casts; B: scanned centric jaw relationship; C: virtual articulation; D: designed digital denture

Fig. 3: The intra-oral view of the trial denture in INDD group.

3. *Prosthetic procedures for construction of digital complete dentures using intra-oral and face scanning (IFDD group):*

The intra-oral scanner (TRIOS3, 3Shape, Copenhagen, Denmark) was used to create the digital impressions of both edentulous arches. Before scanning, the edentulous ridges were flushed and dried. A cheek retractor was used to stabilize the tissues and avoid their over-extension. The intra-oral scanning started with the upper edentulous ridge that was scanned from the left to the right maxillary tuberosity, then back to the left along the posterior palatal seal. After that, the posterior palatal seal area was scanned, then the scanning was progressed anteriorly until reaching the rugae region. This was followed by scanning the buccal and labial vestibules as thoroughly as feasible, and finally the palatal region was scanned by moving the head of the scanner in a zigzag pattern. In a similar manner, the lower edentulous ridge was scanned from one retromolar pad to the pad on the opposite side across the residual ridge, then the labial and buccal vestibules were scanned. Finally, the lingual sulcus was scanned from the pouch on one side to the contralateral side with tongue retraction.[41]

The scanned digital information was stored in STL files. The virtual casts were created using CAD designing software (exocad GmbH, Darmstadt, Germany). The recording bases were designed to be adapted over the virtual casts, and they were printed using a 3D printing machine (Elegoo Mars 3 ultra 4k mono LCD 3D printer). Wax occlusal rims (Modeling wax, Cavex, Haarlem, Holland) were attached to the recording bases. The recording base and the wax occlusal rim were used for recording the functional impression. As border molding was done with modeling plastic compound (Perfectin, S.A.I.C., Hubac, Buenesaires, Argentina), followed by making the functional impressions using a medium-body rubber base (Impregum Penta; 3M ESPE). The maxillary recording base was reseated in the mouth, then the lip support and height of the occlusal plane were adjusted. The occlusal plane was aligned parallel to the interpupillary line anteriorly and the Camper's plane posteriorly. The midline, high lip line, and canine lines were marked. The mandibular recording base was seated intra-orally, and the vertical jaw relationship was adjusted. This was followed by registering the horizontal jaw relation at the predetermined vertical dimension using the wax wafer method. This resulted in upper and lower impressions and the maxilla-mandibular jaw relationship record being combined into one intra-oral record.[13] The jaw relation record with the functional impression assembly was scanned with a desktop scanner (Medit, Seoul, Korea) and digitized to an STL file. The virtual models were created and aligned to the impression-jaw relation assembly using the designing software (exocad GmbH, Darmstadt, Germany). ***(Fig. 4)***

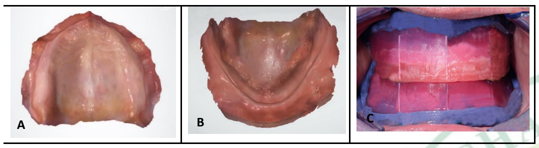

Fig. 4: IFDD group; A, B: intra-oral scanning of the edentulous ridge. C: the upper and lower impressions and the maxilla-mandibular jaw relationship record were combined into one intra-oral record.

A three-dimensional face scan (Proface Face Scanner, Pro Max 3DMid, Planmeca, Helsinki, Finland) was performed to produce a 3D "virtual patient" replica. The patient face was scanned in three different positions: reference position with the intra-oral scan body fixed to the occlusion blocks, rest position with lips closed, and smiling position with slightly opened lips. The three face scans were aligned virtually by the software (Planmeca Romeis Viewer, Planmeca, Helsinki, Finland) using the scan body and the forehead region as references and then transferred to an STL file ***(Fig. 5).*** The face scan was aligned with the virtual model, obtained from aligning intra-oral scan with impression-jaw relation assembly, using the record block attached to the reference scan. The virtual casts were placed on the virtual articulator to balance the occlusion. ***(Fig. 6)***

The complete dentures were digitally designed, as the denture bases had maximum coverage of the denture-bearing areas and the denture flanges had maximum extension to attain adequate stability and retention of the digital complete denture.

The virtual tooth selection was done by selecting artificial teeth from the digital library of the CAD software (exocad GmbH, Darmstadt, Germany). The selection and arrangement of the teeth was done with the aid of intra-oral and extra-oral anatomical landmarks data obtained from intra-oral and face scans. Using the smiling face scan as a guide, the models and virtual wax pattern were arranged in the correct coordinate system allowing for the clinical evaluation step to be done virtually. The resulting file was sent to a 3D printer (Elegoo Mars 3 ultra 4k mono LCD 3D printer) to produce a trial denture (Next- Dent Try-in) to resemble the conventional try-in assessment.

The denture extension, retention, stability, esthetics, phonetics, vertical dimension, jaw relationship, and occlusion were evaluated at the try-in visit. The necessary adjustments were done by design modification in light of new findings obtained during the clinical try-in. The final STL file of the complete denture was prepared. The teeth were subtracted from the denture base using the software (Meshmixer Autodesk, California, USA), to create tooth sockets in the base. The denture base and the teeth were printed in acrylic resin (Next-Dent 3D Print) using a 3D printer (Elegoo Mars 3 ultra 4k mono LCD 3D printer). Similar to the procedures done in INDD; The teeth were bonded to the base, The 3D-printed denture bases were finished then polished and the occlusion was adjusted. ***(Fig. 7)***

For each patient, the three dentures (CCD, INDD, IFDD) were delivered according to the sequence of denture insertion. The patients were recalled three days after denture delivery and then after one week to address any patient complaints. Any required adjustments were done to guarantee that the patients could wear their dentures comfortably during the follow-ups. Participants were instructed to use each denture for three months before switching to the other.

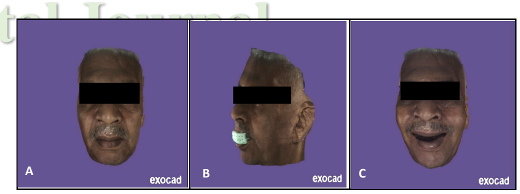

Fig. 5: Face scans of IFDD group in three positions; A: rest, B: reference, C: smiling.

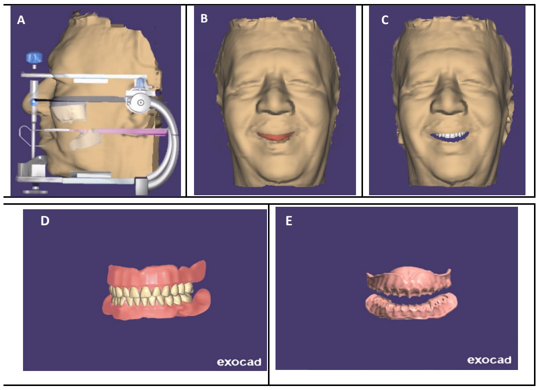

Fig. 6: Designing the digital denture in IFDD group using face scans and CAD software, A: virtual articulation, B: adjustment of wax occlusal rim, C: arrangement of artificial teeth. D: designed digital denture; E: the digitally designed denture base after removal of the teeth.

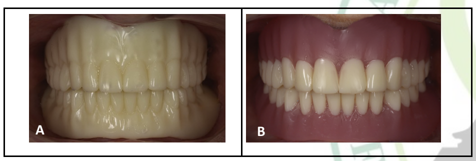

Fig. 7: Intra-oral views of IFDD group; A: trying in the trial denture; B: insertion of the printed digital denture.

III- Outcomes measurements:

1. *OHRQoL assessment:*

OHRQoL was measured by means of the Oral Health Impact Profile (OHIP-14) questionnaire. The questionnaire was divided into seven limitations: either functional, which involved taste sensation and sound production, or physical pain, which comprised pain or discomfort during eating and any sense of painful aching. The psychologic discomforts (feeling self-conscious or uncomfortable), physical disabilities (unsatisfactory or disturbed eating), psychologic limitations (difficulty relaxing, disappointment), social disabilities (irritability and job difficulty), and functional handicaps (inability to function generally in life). Each item was given a score, with the lowest ratings indicating the greatest improvement in overall quality of life. Using a forward-backward method, the questions were translated into Arabic. Two separate translators came up with a common translation.[42] Then the questionnaires were given in Arabic and explained to the patients. Three months after each type of denture was used, the OHRQoL results were measured.

2. *Masseter muscle activity:*

Electromyographic (EMG) evaluation of masseter muscle activity was evaluated using a previously reported technique.[43] The patient's electromyographic activity of the masseter muscle was monitored while in an upright position. Patients were told to relax and keep their gaze forward. Two surface electrodes were taped to the skin overlaying the masseter muscle. The first electrode is positioned in the middle of the superficial part of the masseter, parallel to the muscle fibers. The other electrode was positioned in front of the first one. The third electrode is the reference one, which is attached to the patient's forehead. The three electrodes were plugged into EMG machine (Nihon Kohden, Tokyo, Japan) ***(Fig. 8).***

The skin area on which the electrode was placed was shaved so that the electrode was in close contact with the skin. Adhesive tapes were used to secure electrodes to the skin. EMG measurement was done for both sides. Both hard (carrot) and soft (cake) meal samples (3x1x1 cm) were chewed thoroughly until they were ready for deglutition. Randomization of the sequence of chewed samples was done. EMG device sensitivity was set to 200 V at a speed of one second. Signals were amplified, filtered, then smoothed. One expert operator, who was blind to the treatment groups, analyzed EMG data utilizing the device's software.

Each patient had a transparent template prepared with markings for electrode placement relative to known facial landmarks such as the outer canthus of the eye, the tragus of the ear, and the corner of the mouth. In the following evaluation sessions, the transparent template was utilized to precisely place the surface electrodes ***(Fig. 8).***

Electromyographic (EMG) results that were assessed in the form of amplitude (µV) which is the variation between negative and positive peaks. Four peaks of the EMG signal were examined at each time, and the average was utilized for the statistical analysis. The test was performed five times for each type of food, with a 2-minute rest in between. The average of three readings taken on the same day was utilized for statistical analysis. Three months after each type of denture was used, the masseter muscle activity was measured.

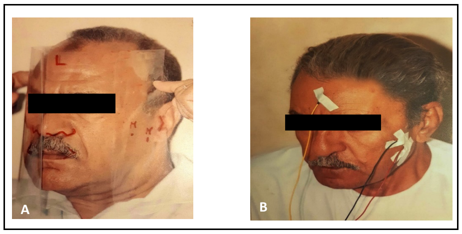

Fig. 8: Masseter muscle activity measurement. A: The transparent template used during the follow-ups. B: The electrode of the electromyogram is attached to the patient's face.

IV- Statistical analysis:

Statistical analysis revealed that the data were not normally distributed so non parametric tests were used. Kurskal-Wallis test was used to compare OHRQoL and masseter muscle activity between groups, followed by Dunns post hoc test. Wilcoxon's signed rank test was used to compare between the types of food within the group. P value is considered significant if it is smaller than 0.05. Data analysis was performed using software (SPSS, the statistical package for social science, version 22, IL, USA).

Results

All the patients completed the study and the follow-up with no drop-outs. Regarding the measured study outcomes, the statistical analysis between subjects revealed insignificant differences between the six treatment sequence groups, which had different sequences of successive denture types. This indicates that there was no statistically significant carryover effect. So, the average of the six groups' findings was calculated. Moreover, statistical analysis indicated that the difference in EMG amplitude between the right and left sides was insignificant. As a result, the mean of both sides was determined and statistically calculated.

I- Results of OHRQoL:

The mean scores of OHIP-14 domains and questions of quality of life for the three denture types are shown in ***Tab. 1.*** The average total scores of OHIP-14 were shown in ***Fig. 9.*** The statistical analysis revealed insignificant differences in OHRQoL scores for all domains and questions of OHIP-14 between INDD and IFDD. Regarding the difference between conventional and digital dentures, there were significant differences in total OHIP-14 scores and in all domains of OHRQoL (P<0.0001). INDD showed the lowest oral health scores (i.e. the highest quality of life, 2.31±0.65), followed by IFDD (2.44±0.63), and CCD showed the highest scores (i.e. the lowest quality of life, 3.20±0.40).

II- Results of masseter muscle activity:

The results of masseter muscle activity (µV) using soft and hard food for the three denture types (CCD, INDD, and IFDD) are shown in ***Tab. 2.*** The statistical analysis revealed insignificant differences in masseter muscle activity (µV) between IFDD and INDD groups. However, there were significant differences in masseter muscle activity between digital dentures (IFDD and INDD) and conventional ones (CCD) when chewing soft food (P=0.008) and hard food (P<0.0001). The INDD group showed the highest masseter muscle activity, followed by IFDD, while the lowest activity was measured in the CCD set. When chewing hard food, masseter muscle activity was significantly higher than when chewing soft food in each group.

Table 1: Results of OHIP-14 scores for the three denture types (CCD, INFD, INDD).

Domain	CCD n=12 Mean ± SD	IFDD n=12 Mean ± SD	INDD n=12 Mean ± SD	Kruskal Wallis test P value
Functional limitation				
Sound production	$2.88^{a} \pm 0.24$	$2.04^{b} \pm 0.64$	$1.96^{b} \pm 0.61$	<0.0001*
Taste sensation	$3.47^{a} \pm 0.19$	$1.97^{b} \pm 0.66$	$1.72^{b} \pm 0.58$	<0.0001*
Mean	$3.18^{a} \pm 0.36$	$2.00^{b} \pm 0.65$	$1.84^{b} \pm 0.61$	<0.0001*
Physical pain				
Pain or discomfort during eating	$3.36^{a} \pm 0.34$	$2.54^{b} \pm 0.42$	$2.18^{b} \pm 0.65$	<0.0001*
Painful aching.	$3.29^{a} \pm 0.40$	$2.23^{b} \pm 0.49$	$2.33^{b} \pm 0.64$	<0.0001*
Mean	$3.33^{a} \pm 0.37$	$2.39^{b} \pm 0.48$	$2.25^{b} \pm 0.65$	<0.0001*
Psychologic discomforts				
Self-conscious	$2.55^{a} \pm 0.34$	$2.45^{b} \pm 0.50$	$2.18^{b} \pm 0.59$	<0.0001*
Uncomfortable	$3.10^{a} \pm 0.18$	$2.24^{b} \pm 0.53$	$2.13^{b} \pm 0.52$	<0.0001*
Mean	$2.83^{a} \pm 0.39$	$2.35^{b} \pm 0.52$	$2.15^{b} \pm 0.56$	<0.0001*
Physical disabilities				
Unsatisfactory eating	$3.53^{a} \pm 0.21$	$2.19^{b} \pm 0.53$	$2.08^{b} \pm 0.55$	<0.0001*
Disturbed eating	$3.33^{a} \pm 0.25$	$2.84^{b} \pm 0.53$	$2.45^{b} \pm 0.35$	<0.0001*
Mean	$3.43^{a} \pm 0.25$	$2.52^{b} \pm 0.62$	$2.27^{b} \pm 0.50$	<0.0001*
Psychologic limitations				
Difficulty relaxing	$3.47^{a} \pm 0.19$	$1.94^{b} \pm 0.57$	$1.82^{b} \pm 0.46$	<0.0001*
Disappointment	$3.10^{a} \pm 0.18$	$2.20^{b} \pm 0.67$	$2.20^{b} \pm 0.67$	<0.0001*
Mean	$3.28^{a} \pm 0.26$	$2.07^{b} \pm 0.64$	$2.01^{b} \pm 0.61$	<0.0001*
Social disabilities				
Irritability	$3.25^{a} \pm 0.44$	$3.03^{b} \pm 0.48$	$3.00^{b} \pm 0.51$	0.0033*
Job difficulty	$3.18^{a} \pm 0.36$	$2.68^{b} \pm 0.30$	$2.78^{b} \pm 0.44$	0.0036*
Mean	$3.21^{a} \pm 0.40$	$2.86^{b} \pm 0.44$	$2.89^{b} \pm 0.49$	0.0036*
Functional handicaps				
Generally, in life	$3.27^{a} \pm 0.43$	$3.02^{b} \pm 0.46$	$2.85^{b} \pm 0.45$	0.0001*
Failure to perform function	$3.02^{a} \pm 0.38$	$2.72^{b} \pm 0.15$	$2.68^{b} \pm 0.17$	0.0001*
Mean	$3.14^{a} \pm 0.43$	$2.87^{b} \pm 0.37$	$2.77^{b} \pm 0.35$	0.0001*

*SD: Standard deviation. *Significant at p<0.05*
Different letters within the same raw indicated a significant difference between each two types of dentures.
CCD: Conventional complete denture, IFDD: digital denture constructed using intra-oral and face scanning, INDD: Digital denture constructed using indirect method.

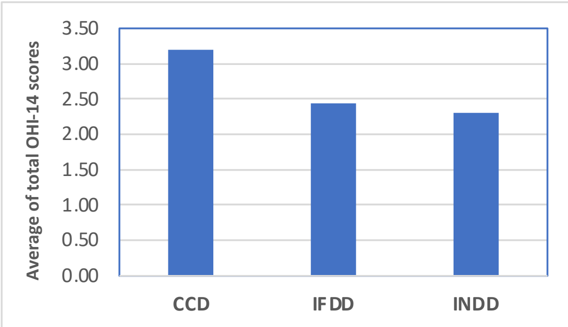

Fig.9: The average of total HIP-14 scores in the three denture types CCD: Conventional complete denture, IFDD: digital denture constructed using intra-oral and face scanning, INDD: Digital denture constructed using indirect method.

Table 2: Results of masseter muscle activity (µV) using soft and hard food for the three denture types (CCD, INDD, IFDD).

	Soft food					Hard food					Wilcoxon signed rank test P value
	Mean	SD	Median	Min	Max	Mean	SD	Median	Min	Max	
CCD n=12	172.53^{a}	19.82	170.85	145.30	205.40	273.41^{a}	17.08	278.00	242.80	297.10	0.0005*
IFDD n=12	199.73^{b}	15.63	197.50	179.20	227.50	318.13^{b}	28.71	310.50	283.20	393.30	0.0025*
INDD n=12	209.89^{b}	17.67	201.30	186.40	240.70	347.63^{b}	29.61	340.20	303.70	393.50	0.0005*
Kurskal-Wallis test P value	0.008					<0.0001					

SD: Standard deviation Min.:minimum Max.: maximum
**Significant at $p<0.05$*
Different letters within the same column indicated a significant difference between each two types of dentures.
CCD: Conventional complete denture, IFDD: digital denture constructed using intra-oral and face scanning, INDD: Digital denture constructed using indirect method.

Discussion

In dentistry, there have been recent paradigm shifts in the prosthetic treatments and technology solutions utilized to restore patients with total edentulism. Because there are many kinds of CAD/CAM technology, it is possible to design and fabricate a digital complete denture. The soft tissue profile data that comes from 3D facial scanning is a great addition to the data that is already available from traditional scanning methods.[44] When facial scan data is combined with data from intra-oral scanning, prosthesis designs can properly represent the aesthetic needs required by the external profiles of patients while conforming to prosthetic limits. This will result in improving the interaction between prosthetic and aesthetic planning, benefiting both the patient and the practitioner. But because the technology and its prosthodontic implications are still new, more clinical studies are needed to investigate their potential. [26,27]

The cross-over design used in this study allowed patient and denture characteristics to be standardized. It also improved the accuracy of the comparison between the three types of dentures in terms of OHRQoL and masseter muscle activity. Another benefit of this design is the use of a reduced number of patients. In addition, the patients experienced and compared the three treatment designs on their own.[45,46]

This study was done to evaluate the effect of incorporating 3D facial scanning data to the intra-oral scanning in the workflow to construct digital complete dentures for patients with total edentulism. Our study's workflow comprised intra-oral scanners for registering the edentulous ridge. A growing number of research has recently focused on reporting the methodology for the manufacturing of complete dentures utilizing intra-oral scanners and CAD/CAM systems.[2,17,18] No markers were used during intra-oral scans because it was just recently found that the intra-oral scanners can scan the edentulous ridges without the need for markers.[47]

In addition to the intra-oral scan of the edentulous ridges, an intra-oral record with the impression-occlusal rim assembly was taken to combine digital and traditional workflows. This was done because it was reported that combining digital and traditional workflows makes digital dentures with better retention than using only digital workflows. This is due to the optical impressions' failure to provide peripheral seal.[35] Furthermore, the intaglio surface of the trial denture base was used for superimposition with the edentulous ridge data obtained using the intra-oral scanner.[47]

In the current study, three face scans were done at three different positions: reference position with the intra-oral scan body, rest with lips closed, and smiling with slightly opened lips. This was done for the virtual articulation and arrangement of the teeth with the aid of extra-oral anatomical landmark data obtained from face scans. In addition, to facilitate the virtual try-in, as a “virtual patient” was created. This is in accordance with Kortam et al[39] who used the direct digital workflow with the aid of a face scanner taken in the same three positions. Schweiger et al.[13], on the other hand, replaced the reference facial scan with a cheek retractor face scan taken while the patient was wearing the intra-oral record of the impression-occlusal rim and the cheeks were retracted.

By integrating the virtual tooth arrangement with the face scans, the inspection of the prosthesis can be done immediately while taking facial appearance into account. As tooth size and position and the occlusal scheme can be modified while observing the aesthetic appearance of the face.[48] This would enhance the existing clinical approach of the aesthetic try-in, lower chairside time, and make it easier for the dentist and the lab to communicate with each other. [27] A lab technician who usually just sets up teeth on the articulator and look at few patient images could get more benefits from the virtual tooth arrangement. Also, it improves the case communication as well. [29] Furthermore, because the virtual setup is saved digitally, it can be used again to make a new prosthesis, cutting down on the time and cost of treatment if the prosthesis needs to be changed.[14]

The masseter muscle activity was assessed because it plays an important role in mastication and is more accessible to the surface electrode, which could detect a significant number of motor units in a contracting muscle. It was also suggested that the electrodes be placed parallel to the muscle fibers so that more eclectic connectivity could be recorded.[49-51]

To the authors' knowledge, no clinical studies have compared the influence of digital dentures constructed using combined face and intra-oral scanning on OHRQoL or EMG muscle activity in edentulous patients. Because of this, the results of this study can't be compared to the findings of another study that was done in a similar way.

The findings of the present study revealed that the first null hypothesis, that there would be no difference in OHRQoL and masseter muscle activity between IFDD and INDD, was accepted. There were no differences in the overall or individual domains of OHIP-14 scores and masseter muscle activity between the two groups of digital dentures (IFDD, INDD). As both dentures constructed using the same CAD/CAM production technique, designing software, 3D printer, printing technique and the type of printed resin.

The slightly better quality of life and higher masseter muscle activity of INDD than IFDD might be attributed to the inaccuracies of intra-oral scanners in recording the edentulous ridge and fabricating a complete denture with functional borders. Fang et al[17] et al concluded that the techniques for the direct intra-oral scanning of edentulous ridges do not cover the functional mucosal reflection due to the inability to make a true digital functional impression.[52] In our study, functional reproduction of the edentulous ridge was done by taking intra-oral records consisting of impressions of the edentulous ridges and jaw relationship. As some authors suggested, this record was performed using the trial denture base and a wax rim assembly, then the record was digitized and superimposed over the edentulous ridge data obtained from the intra-oral scanner. [1,13,47]

In our study, the use of a facial scanner aligned with the intra-oral scanner didn't improve the measured outcomes than the indirect technique. This could be attributed to the absence of facial scanning with cheek retraction while wearing the intra-oral record. It was recommended by Schweiger et al[13] that the cheek-retraction facial scanner improves the alignment with the intra-oral scan and thus might improve the results. Furthermore, the use of facial scanning to produce a "virtual patient: to increase the accuracy of the virtual articulation and try-in stage didn't improve the patients' quality of life. This might be due to one of the limitations of facial scanning, which is the inaccurate record due to patient movement while scanning. Also, the smile facial scan may change the position of facial lines, which could affect the alignment process of the three facial scans. [13,28,31]

The second null hypothesis, that there was no difference in the assessed outcomes between digital (IFDD and INDD) and conventional complete dentures (CCD), is rejected. The statistical analysis revealed significant differences in OHIP-14 and EMG of the masseter muscle between both types of dentures. The digital denture showed higher quality of life and EMG recordings of the masseter muscle than conventional dentures. This finding could be attributed to digital dentures' superior retention and stability over conventional dentures, as have been reported in several studies.[53-55] As CAD/CAM design and production of digital dentures (IFDD and INDD) decreases inaccuracies that may occur in the fabrication technique of conventional dentures (CCD). Moreover, the dimensional accuracy of the printed digital dentures that were used in the study comes from additive manufacturing and consecutive resin layering. This process compensates for the dimensional shift of each layer by adding the next layer, allowing for material conservation as well as printing with excellent dimensional accuracy. [56-58] On the contrary, Alkhodary et al.[35] discovered that conventional dentures retained significantly more than digital dentures.

The higher OHRQoL scores of digital dentures than conventional dentures were in accordance with a crossover study evaluated patient satisfaction and OHRQoL between traditional and digital complete dentures and discovered that patients rated CAD/CAM dentures higher regarding oral health status, general satisfaction, ability to talk and clean the prosthesis, aesthetics, and stability.[59] Cristache et. al.[60] assessed the OHIP-EDENT scores in many aspects before and after treatment at one week, twelve and eighteen months. They discovered that after eighteen months of wearing dentures, OHIP-EDENT scores were much better than before treatment with digital dentures. In a clinical prospective study, Mathew et. al.[61] compared the treatment outcomes of CAD/CAM and conventional complete dentures. The results revealed statistically significant higher rating scores for CAD/CAM complete dentures relative to the different denture parameters that include extension, fit, retention, stability, and base contour. The superior fit due to the absence of polymerization shrinkage might explain these observations.

Some studies have found that digital complete dentures have much higher masseter muscle activity than conventional complete dentures. Mohamed and Shaheen[36] found that after 30 days of wearing dentures, the masseter and anterior temporalis muscles were much more active in people who had CAD/CAM dentures than in people who had conventional dentures. They attributed this finding to the increased stability and retention of CAD/CAM dentures rather than conventional denture.[7] Previous research that evaluated the effect of complete denture retention, fit, and stability on masticatory muscle activity gives credibility to the hypothesis that there is a direct positive association between these variables.[62] Several studies have found that digital dentures are more retentive than conventional ones because they fit better to the tissues underneath.[7,63,64] However, Kattadiyil et al[65] observed unsatisfactory retention of digital dentures as one of its problems, which was assumed to be related to optical impressions' failure to provide peripheral seal of selective pressure impression technique as proposed by D'Arienzo et al.[66]

The study has some limitations; another facial scan was required using a cheek retractor to expose the labial surfaces of the edentulous ridges while retracting the cheek, allowing the virtual casts and facial scans to be aligned as a common fixed reference. Patient-related factors like salivary flow, facial hair, and movement during the scan may all have an impact on the scanning and registration procedure's accuracy. Also, the small sample size and short follow-up period are other limitations for the study. Further studies that consider these limitations are recommended to confirm the results of this study.

Conclusion

Within the limitations of this study, OHRQoL and masseter muscle activity were better in patients with digital complete dentures than conventional dentures. Also, the indirect method of digital complete denture construction led to a slightly better quality of life and higher masseter muscle activity than intra-oral and face scanning.

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