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Rehabilitation of Maxillectomy Defect with Palatal Obturator Using Digital Technology: A Review

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ABSTRACT

This systematic review aimed to evaluate the masticatory, fonetic, aesthetic and psychological functioning of palatal obturator prosthesis fabricated using digital technology in patient with maxillectomy defect. According to Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines, an electronic search of the PubMed, PMC, Science Direct and Wiley databases was carried out in January 2022. The titles and abstracts of all articles were screened by two independent reviewers. The references of the subsequently selected studies were further screened for potential articles. Assessment of the selected full texts was performed independently according to established inclusion and exclusion criteria. A total of 10 studies were included with total of 251 patients. Obturator Functional Scale (OFS) for evaluation of the function was analyzed in 7 studies. Accuracy and dimensional differencies were analyzed in three other studies. From the limited number of studies, the patients showed good results in all fields of functional outcomes and social acceptance. The OFS scores were comparable with those reported in other studies using conventional method. CAD/CAM also tend to produce more extended dimension compared to original design, meanwhile conventional heat-cured PMMA palatal obturator show an overall reduction in dimensions with no significant difference and constant accuracy. CAD with RP technology in conclusion could possibly be an alternative and feasible method for manufacturing palatal obturators for patients after maxillectomy. It has shown significant clinical value, particularly with excellent accuracy and efficient working time.

Keywords: *Maxillofacial Prosthetic, Palatal Obturator, Digital Technology*

INTRODUCTION

Prosthodontic rehabilitation of the maxilla requires both the esthetic and functional restoration of the surrounding tissues. Extensive abnormalities of the maxillary basal bone might be congenital, such as cleft palate, or acquired as a result of trauma or surgical tumor excision. Patients with these severe impairments often result in oroantral communication that could cause hyper nasal speech, nasal fluid leakage, masticatory dysfunction, temporomandibular joint disorder and facial disfigurement.1,2Prosthodontists have a

significant role in the rehabilitation of their deformities by using obturator prostheses to restore the separation between the oral and nasal cavities. The size and shape of these prostheses determine their retention, stability, and support.2

Existing approaches for maxillofacial prosthesis fabrication especially palatal obturator are technique-dependent, consume large amount of materials,and frequently result in a sealing area that is prone to leakage and discolouration. Another issue with this procedure is the amount of working time required, as well as the subsequent visits for adjustments to compensate for material distortion.2,3

During the last decade, the integration of computer-aided design (CAD) and computer-aided manufacturing (CAM) has revolutionized the field of maxillofacial prosthetics, with benefits such as precise planning, predictable outcomes, less clinical and laboratory time.4 These benefit are associated with patient satisfactory with less discomfort.1

Evidence-based research reported patients who have undergone maxillectomy tend to have increased sensitivity in terms of gag reflex. Digital technology such as intraoral scanning result in significantly less stimulation of the gag reflex in comparison to conventional impression. The additional advantage of intraoral scanner include reduced trauma to tissues that have undergone surgery, chemotherapy, and/or radiotherapy.1,5

Much of the digital dentistry workflow and available literature are related to fixed dental prostheses or dental implant, thus their integration into removable prosthodontics, especially maxillofacial prosthetics has been slower. There are few studies have reported application of digital technology in maxillofacial prosthetics. While literatures that specifically concern in maxillary defect or palatal obturator are still limited. Thus, this systematic review aimed to introduce and evaluate digital technology application in the construction of several variety of palatal obturators and compare them to conventional method for patients with acquired maxillary defects.

MATERIAL & METHODS

Search Strategy

This systematic review was conducted according to PRISMA (Preferred Reporting Items for Systematic reviews and Meta-Analyses) guidelines for reporting studies evaluating healthcare interventions. A focus question was designed following the PICO format as per the following patient/population, intervention, comparisons, outcomes: (P) patient treated with acquired or congenital maxillary defect; (I) the use of digital technique in prosthetic rehabilitation; (C) the conventional workflow in prosthetic rehabilitation; (O) type of digital technology applied for preoperative planning, designing and manufacturing of maxillofacial prostheses

Information Sources and Eligibility Criteria

The electronic search was performed by entering the combination of following MeSH terms: “maxillofacial prostheses” and “palatal obturator” and “computer aided design” and “computer aided manufacturing”. The following electronic databases were screened for potential studies limited to the past 10 years articles: Pubmed via Medline, PMC, Wiley and Science Direct. The results were limited to studies written in English. Moreover, a manual search of the issues published between January 2012 and December 2021 of the following journals was also carried out : The International Journal of Prosthodontics, Journal of Prosthodontics, The Journal of Prosthetic Dentistry and related research.

The inclusion and exclusion criteria in this systematic review were the following:

Inclusion Criteria
Clinical human studies, randomized control trials, cohort studies involving the digital technique in maxillofacial prosthetic fabrication Published in English

Exclusion Criteria
Systematic / narrative reviews
Animal studies
In vitro studies
Case report executed without digital planning software
Unaccessible full text

Selections of Study

The study selection was performed independently by two independent (ID and MJ) reviewers through titles and abstracts of all identified studies through an electronic search read individually by the authors. For the studies that appeared to fulfill the inclusion criteria or those studies that had limited data in the title and abstract to reach the final decision, the full record was gathered. Disagreements among authors were resolved after discussion.

Extraction of Data

The data from each included study were extracted according to the designed standard form: author's name, country, year of publication, prostheses designed and/or fabricated, fabrication technique (conventional or digital), purpose of using digital planning, data for digital planning, material used and post-operative evaluation. Contact was made with the authors for possible missing data.

Risk of Bias

Two independent reviewers (I.D and M.J) assess the methodological quality of the included studies. Therefore, study-specific critical appraisal tools of the Joanna Briggs Institute will be used. In case of disagreement, the results will be discussed and if needed be resolved by a third party. Next to the methodological quality. Critical tools of The Joanna Briggs Institute (JBI) were used according to the type of included articles. Finally, an overall appraisal was made to determine if the risk of bias is low (included), high (excluded), or uncertain (more information needs to be sought). We considered there to be a high risk of bias if the answers "no" were ≥50%, a low risk of bias if the answers "yes" were ≥50%, and an uncertain risk of bias if the "unclear" answers were ≥50%.

RESULT

Study Selection

The literature was searched using the above-mentioned terms through electronic database mentioned above. The flowchart of literature search and selection process is shown in Figure 1. As most of the advancement in virtual planning and printing software for maxillofacial rehabilitation has been seen since the last decade ; therefore, an initial search yielded 319 studies with time filter (January 2012– December 2021).

A total of 24 studies were excluded after being identified as duplicate records. Furthermore, 292 studies were screened according to the inclusion and exclusion criteria; therefore, an additional 228 studies were excluded based on their study design and rehabilitation techniques surgical reconstruction with titanium implants and prosthetic rehabilitation of extra-oral defects. A total of 10 studies involving 251 cases were included in this review (Table 1). Obturator Functional Scale (OFS) for evaluation of the function was analyzed in 7 studies. Accuracy and dimensional differencies were analyzed in three other studies.

Study Characteristics

Applications of Digitization Technology

The included studies had the following purposes for utilizing digital software during palatal obturator fabrication: digital impression with intraoral optical scanner (46 cases), digital design of appliance with CAD processing (52 cases), direct printing and rapid prototyping of palatal obturators (52 cases), meanwhile 199 cases using conventional method for palatal obturators fabrication.

Characteristic of patients

Clinical characteristics of patients are shown in Table 2. Sixty-nine percent of the patients were

men. Out of 131 maxillectomy defects patients that were classified according to Aramany Classification, 59 cases were Class I and 30 cases were Class IV as the most frequent diagnoses. Seventy-one patients had undergone treatment with radiotherapy and chemical treatment.

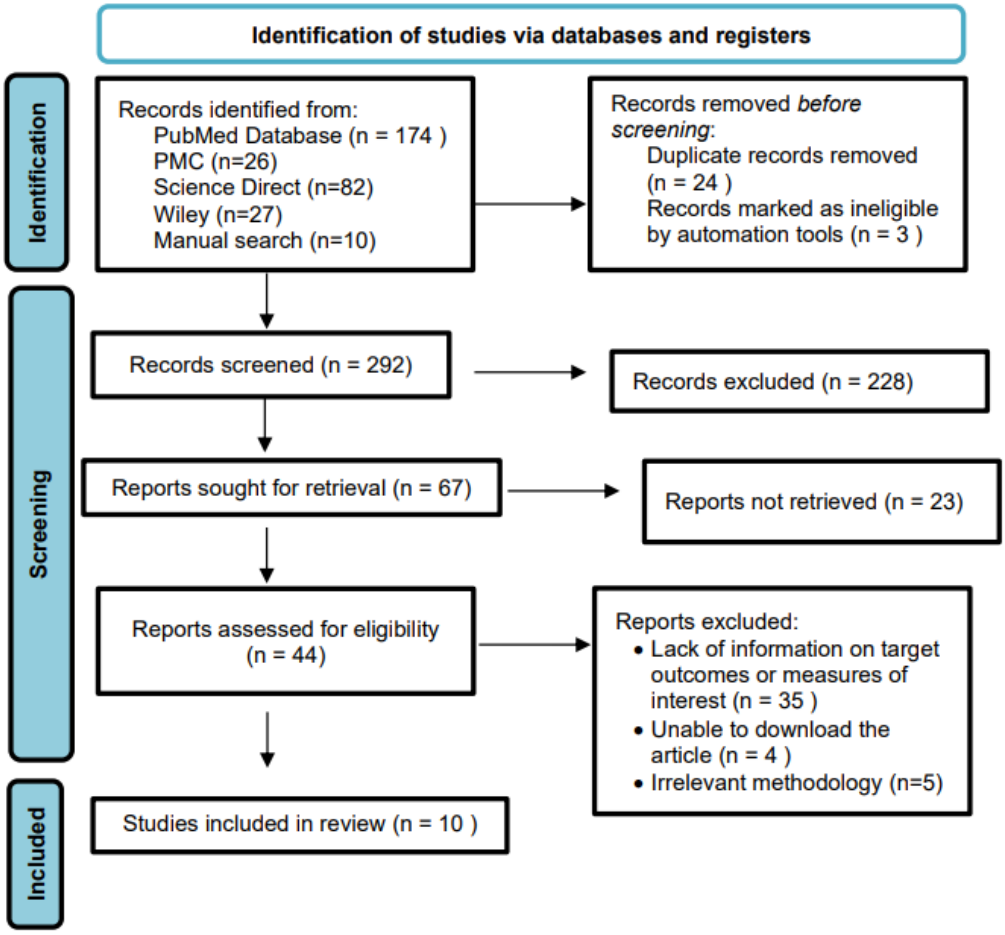

FIGURE 1: Prisma Flow Chart

TABLE 1: Included studies characteristic

Author	Country	No of cases	Follow-up Post Surgery	Technique		Purpose of software planning	Digitization Applied			Data for digital planning
				Digital	Conventional		Impression	Design	Manufacturing	
A. Neena et al.2 2020	Egypt	6	6 month	6	6	Design and fabricate an obturator prosthesis using a computer-aided design (CAD) and rapid prototyping (RP) technique	Conventional	Digital design with The 3D CAD Software [PlastyCAD, 3DIEMME. Italy. Autodesk Meshmixer, Autodesk Inc. USA]	3D print [Planmeca Creo, Planmeca. Finland] >> produce obturator base & teeth	Virtual model from optical scanner (SmartOptics activity 855, Smartoptics Sensortechnik GmbH. Germany)

H. Ye et al.6 2017	China	12	N/M	12	12	Generate 3D digital casts of maxillary defects	Intraoral optical scanner (TRIOS; 3Shape) + conventional impression (elastomer)	Software Geomagic Studio v2012; Geomagic Inc).	RP machine (Objet 30 Pro; Stratasys Ltd)	Spiral Computed Tomography (CT) + intraoral optical scanner
Z. Huang et al.7 2015	China	5	3 months	5	5	Fabrication of individual trays by computer-aided design (CAD) and rapid prototyping (RP)	MIMICS 10.0 (Materialise, Leuven, Belgium) from DICOM file	FREEFORMClay tools (Geomagic, Morrisville, NC)	3D printing (Weisteck, Shenzhen, China)	CT Scan (GE Lightspeed VCT xTE (GE Healthcare, Chalfont St. Giles, UK)

Author	Country	No of cases	Follow-up Post Surgery	Technique		Purpose of software planning	Digitization Applied			Data for digital planning
				Digital	Conventional		Impression	Design	Manufacturing	
F.-F. Jiang et al.8 2015	China	18	6 months	18		CAM to manufacture the polymethacrylate-based hollow obturator prosthesis.	3D Stereotropic model	CAD (Shanghai New Century Dental Materials Co., Ltd.)	CAM (Shanghai New Century Dental Materials Co., Ltd.)	CBCT Images
T. Jiao et al.9 2014	China	11	N/M	11		Fabrication obturator prosthesis	Digital Impression	Shape design (CAD processing)	Stereolithography (SLA) technology (ProJet HD 3500, 3D Systems)	(CT) scanner (GE Light Speed 16, GE Medical Systems)
M. Khan et al.10 2014	Pakistan	50	6-months	Conventional Method						
M. Ozdemir-Karatas et al.11 2018	Turkey	41	6 months	Conventional Method						
M. M. Ali et al.12 2018	Yemen	30	1 month	Conventional Method						
F. Naz et al.13 2019	India	50	6 months	Conventional Method						

J Popul Ther Clin Pharmacol Vol 30(9):e150–e160; 16 April 2023.

C. Chen et al.14 2015	China	28	1 year	Conventional Method

Obturator Functional Scale (OFS) Domains

The Obturator Functioning Scale (OFS) is a self-reported questionnaire used to assess the functioning of obturator.12 The OFS consisted of 15 items divided into five subscales: (1) Facial appearance, (2) speech ability, (3) mastication activity, (4) social interaction, and (5) subjective complaint, such as dry mouth, upper lip numbness, and difficulty inserting the obturator. Response categories ranged from 1 (not at all–a little difficult) to 5 (very much–extremely difficult).11 Points 1 and 2 stood for 'not at all difficult' and 'a little difficult' on the scale and were considered as 'Comfortable'. Points 3, 4 and 5 stood for 'somewhat difficult', 'very much difficult' and 'extremely difficult' respectively and were considered as 'Not Comfortable'.10

TABLE 2: Characteristic of patients

Variable		Number (No) of patients	Percentage (%)
Gender	Male	149	69,30
	Female	91	42,33
Aramany Classification	I	59	27,44
	II	18	8,37
	III	20	9,30
	IV	30	13,95
	V	-	-
	VI	4	1,86
Radiotherapy & Chemical Treatment	Yes	71	33,02
	No	57	26,51

The OFS was used to evaluate the quality of the obturator prostheses, OFS percentage of each included studies are shown in Table 3.9 The results indicated that majority of patient in each study that used digital-fabricated palatal obturator had minimal problems with eating, speech, and other functional items. Study conducted by Jiang et al8 showed that 82% patients felt comfortable with their facial appearance after using digital-fabricated palatal obturator and 95% of them had their speech ability improved after insertion.

Jiao et al9 reported better mastication ability with minimum leakage when swallowing in 91% patients, in terms of social interaction, all of the patients were satisfied with the prostheses and were able to reintegrate into their family and social interaction. Subjective complaint domain has the lowest percentage in both studies that utilized digital technology (67% and 52%), this include difficulty when inserting the obturator, upper lip feels numb, and dry mouth complaint.

Patient that used conventional obturator showed higher percentage in subjective complaint domain as reported by Chen et al14 with 79% of the patients feel comfortable with their palatal obturator along with minimum subjective complaint.

In our study we found that both Khan et al and Naz et al showed lowest percentage in mastication activity domain with respectively only 22% and 24% patient that feel comfortable with their chewing and swallowing ability. Included studies that assess OFS of conventional obturator showed some similarity especially in mastication activity domain, each studies almost have lowest level of comfort with lowest percentage compared with other domain in

percentage. These findings mean the most common complaint in patient with conventional palatal obturator are inability to eat, chew and swallow comfortably.

Dimensional Accuracy

The laboratory optical scanner was used twice to capture the geometries of both conventional and digital obturator, thus generating two separate 3D scans. Geometries of obturators were then compared to those of the 3D obturator pre-printing model using the measuring software package to obtain color maps of dimensional deviations. The ultimate purpose of the digital casts was clinical application, therefore, in addition to comparing them with conventional stone casts, dimensional difference was measured.6 Mean values of dimensional difference of the overall both digital and conventional obturator surfaces were then compared as shown in Table 4.

For CAD/CAM obturators measured by Neena et al2, the value of deviations were -0.26 ± 0.11, negative deviation values denoting that obturators were produced in more extended dimensions when compared to the original design. On the other hand, Ye et al6 results showed positive deviation values (0.28 ±0.69) indicating that the manufactured obturators were smaller in size than the original design. The level of discrepancy between the two casts from the same patient by Huang et al7 showed that the majority of cast areas discrepancies fell within the range of 0 to 1 mm.7 Due to the included studies' quality and data heterogeneity, meta-analysis could not be performed.

TABLE 3: Characteristics of The Included Studies in Obturator Functional Scale Domains

Method	Author & Published Year	Responses	OFS Domain				
			Facial Appearance	Speech Ability	Mastication Activity	Subjective Complaint	Social Interaction
Digital	Jiang et al (2015)	Comfortable	82%*	95%*	72%	67%	N/M
		Not comfortable	18%	5%	28%	33%	
	Jiao et al (2014)	Comfortable	75%	89%	91%*	52%	100%*
		Not comfortable	25%	11%	9%	48%	-
Conventional	Khan et al (2014)	Comfortable	59%	74%	22%	49%	52%
		Not comfortable	41%	26%	78%	51%	48%
	Ozdemir et al (2018)	Comfortable	64%	73%	65%	73%	74%
		Not comfortable	36%	27%	35%	27%	26%
	Ali et al (2018)	Comfortable	70%	82%	50%	76%	63%
		Not comfortable	30%	18%	50%	24%	37%
	Chen et al (2014)	Comfortable	65%	75%	64%	79%*	61%
		Not comfortable	35%	25%	36%	21%	39%
	Naz et al (2019)	Comfortable	63%	79%	24%	59%	52%
		Not comfortable	37%	21%	76%	41%	48%

TABLE 4: Characteristics of The Included Studies in Dimensional Accuracy

Author & Year Published	Dimensional Difference (mm)
Neena et al (2020)	-0.26 ± 0.11
Ye et al (2017)	0.28 ±0.69
Huang et al (2015)	less than 1 mm

DISCUSSION

Achieving success in retention and optimum stability of obturator prothesis by traditional techniques is challenging task for prosthodontist, as it requires several impressions to construct the diagnostic, master, and altered casts, which may be uncomfortable for patients with maxillary defects.15,16 Conventional impressions taking for obturators in maxillectomy patients also have high risk of aspiration, foreign body impaction, and impression deformation associated with large undercuts.17 Digital technology has been used in maxillofacial rehabilitation to plan surgical reconstruction and create surgical templates. Application of computer-aided design/ computer-assisted manufacturing (CAD/CAM) technology in dentistry has evolved to allow the creation of intraoral digital impressions from which high-resolution data of prepared teeth can be obtained directly.17

The application of CAD and selective laser sintering (SLS) technology in direct printing of prostheses potentially reduces further errors compared with the conventional method of fabrication. The results in this review as explained above indicated that majority of patient in each study that used digital-fabricated palatal obturator had minimal problems with eating, speech, and other functional items. Soltanzadeh et al18 also reported that clinically acceptable fit for metal frameworks could be achieved with rapid prototyping. This also along with improved mechanical properties, higher patient satisfaction in terms of denture cleaning, speaking, mastication, and comfort, reduced laboratory time, and availability of saved data for future prosthesis reproduction as some of the other advantages of the SLS technique.18

The preoperative data collection is the first step during software planning; therefore the quality and accuracy of these data significantly affect the accuracy of final outcome.4 In this review, the preoperative dataset consisted of CT scans, CBCT imaging and intraoral optical scanner. A total of 3 studies using CT scans for digital planning. The level of discrepancy between the digitally fabricated and conventional casts by Huang et al7 showed that the majority of cast areas discrepancies fell within the range of 0 to 1 mm.7 Rodney et al also reported the accuracy of the digitally fabricated surgical obturator was confirmed on the postmaxillectomy cast and the result proved to be adaptive intraorally and was undersized by approximately 2 to 5 mm.19

Advanced digital technology, including 3D scanning and printing, opens up the possibility of manufacturing maxillofacial prostheses more efficiently and with shorter lead times. The advantage of using a CBCT scanner is that the obturator can be scanned rapidly while the patient is sitting in the dental chair, which shortens scanning time. Furthermore, the patient can walk out the clinic with the obturator. The definitive obturator can be delivered in the second visit to the clinic, ultimately reducing the number of visits.6,20 Surgical reconstruction technique in maxillectomy has shown great progress, but it still cannot achieve satisfactory appearance. The patient's facial appearance has to be strengthened and improved.8 Palatal obturator that fabricated using digital technology in this study showed that majority of patients felt comfortable with their facial appearance after using digital-fabricated palatal obturator and 95% of them had their speech ability improved after insertion. Fei et al also stated that simultaneous repair of the defect with the CAD/CAM prosthesis after total maxillectomy for patients with maxillary sinus cancer has several advantages. It offers an individualized and accurate design protocol and relatively simple repair method, thus reducing trauma and complications. 8,10 Use of the CAD/CAM prosthesis improves the QoL of patients and achieves more precise repair after total maxillectomy, based on evaluations of the

facial profiles and functional recovery of postoperative patients.15,21

Subjective complaint domain has the lowest percentage in both studies that utilized digital technology, this include difficulty when inserting the obturator, upper lip feels numb, and dry mouth complaint. This possibly caused by the side-effect of surgery and radiotherapy of the oral cavity.22 Digital workflow for palatal obturator fabrication briefly described in Figure 2 start with registering computed tomography and magnetic resonance imaging images, which are used for maxillary defect delineation. Consequently, the 3D image of the maxillary defect exported as a stereolitography (STL) file and merged with a 3D image of the dental status. Based on these merged files, a personalized palatal obturator design is created and printed with 3D printing. An STL file of this final palatal obturator is created based on a scan of the relined obturator.23

Palin et al described that the advantages of this technique include the ability to capture craniofacial and oral anatomy without impression materials, easy duplication and manipulation of casts before printing, and a positive patient treatment experience. The disadvantages include the cost of the materials and printer, the availability of software and a 3D printer, radiation to the patient from the CBCT, and artifacts, distortion, and inaccuracies from the CBCT. Contraindications include allergies to silicone, patients with multiple metallic dental restorations, and general CBCT contraindications.24 CAD-RP technology was established as an alternate way for fabricating obturator prosthesis in this study. The findings showed that this strategy can meet the needs of patients while also improving their quality of life. An advantage of this method is the ability to offer "remote" prosthodontic expertise to local practitioners. Prosthodontists in other cities can conveniently send CT data to the authors' SLA facility to acquire the resin mold. It is hoped that oral cancer patients, especially those in developing countries, can benefit from this technique by reducing their medical expenses and the time and effort necessary to seek treatment.9,14,17

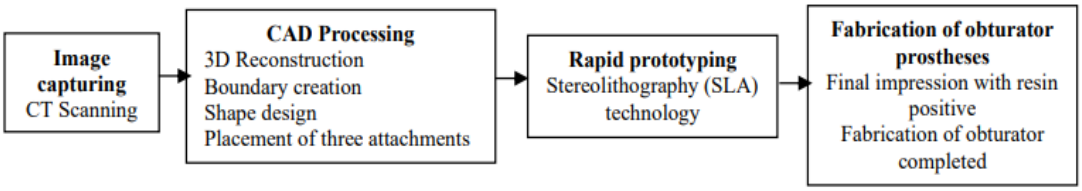

FIGURE 2: Schematic overview of the digital workflow for palatal obturator fabrication9

A shortcoming of the technique is the inability to capture functional movements at the posterior defect border. As it is not possible to predictably evaluate the speech and leakage at try-in of the resin mold, because the mold is not retentive within the defect.9 This could impact speech ability or could cause leakage while swallowing. OFS percentage in this study showed majority of patient in each studies that utilized digital technology felt comfortable with minimum complain in speech & mastication ability domain. This probably caused by relining procedure at additional appointment or application of tissue conditioner which took care of the concerns.

Included studies that assess OFS of conventional obturator showed some similarity especially in mastication activity domain, each studies almost have lowest level of comfort with lowest percentage compared with other domain in percentage. These findings mean the most common complaint in patient with conventional palatal obturator are inability to eat, chew and swallow comfortably. This result are in line with Khan et al10 that stated leakage while swallowing is a great concern in the patients with hemimaxillectomy even with their obturators in place.

CONCLUSION

Digital treatment planning with digital software for maxillary defects rehabilitation is the most reliable phase of the digital workflow, which saves clinical and laboratory time, reduces patient's visits and provides predictable outcome. Combined CAD with RP technology is able to be an alternative method for creating obturators for patients after maxillary resection as this method has shown significant clinical value that regained masticatory function, speech ability and swallowing.

CONFLICTS OF INTEREST

The authors declare no conflicts of interest.

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