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DIFFERENT MANUFACTURING TECHNIQUES ACCURACY OF PALATAL OBTURATOR FOR ACQUIRED PALATAL DEFECT IN TREATMENT OF POST COVID-19 ASSOCIATED MUCORMYCOSIS (CAM)

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ABSTRACT

The purpose of this study was to evaluate the fit and accuracy of conventional lost wax technique and selective laser melting printing technique for fabrication of palatal obturator for acquired palatal defect in treatment of post coronavirus disease associated Mucormycosis (CAM).

Twelve patients had two CoCr alloy frameworks constructed with two different manufacturing techniques. The conventional lost wax and selective laser melting printing techniques. The fitting surfaces of both frameworks were scanned. The master cast of the maxillary defect was scanned by desktop scanner. The Standard Tessellation Language file of the master model was inverted, and the fitting surface scan was superimposed with a best-fit alignment using surface matching software to evaluate the adaptation of the frameworks between the superimpositions with the virtual model. The color maps were calculated at rests, clasps and palate.

Statistically significant difference between the two studied groups at the palate and defect lines area. While at the rests and clasp areas no significant difference was recorded.

The selective laser melting printing technique for fabrication of palatal obturator of acquired palatal defect in treatment of CAM was found to be comparable regarding the fit and accuracy to those fabricated with the conventional lost wax technique.

Clinical Relevance The accuracy and fit of palatal obturator manufactured by 3D printing technology.

KEY WORDS :SLM printing, obturator, CAM, palatal defect, post COVID-19

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INTRODUCTION

The recent Severe Acute Respiratory Syndrome Corona virus (SARS-CoV-2) infection was correlated with a broad clinical range of clinical manifestations ranging from asymptomatic to severe illness manifestation that demanded the admission to intensive care hospital units (ICU). [1-3]

Although vaccine campaigns started worldwide to end the pandemic condition, however, more regions of the world begun to endure a fatal complication of this disease. Expanded cases of COVID-19 Associated Mucormycosis (CAM) had been reported in India. [4-6] Other countries reported spikes in the fungal infection rates during the viral pandemic including, Chile, and Iran. [7-8]

This phenomenon was also documented in Egypt and most of these patients had imaging findings of suspicious fungal infections in maxillary and para nasal sinus associated with bone destruction after a verified COVID-19 disease. [9]

Several studies [10-12] reported acute invasive fungal rhinosinusitis (AIFR) as a rare condition that must be early diagnosed, observed, and rapidly treated to prevent life-threatening complications. The hospitalized COVID-19 patients particularly those with immunocompromised diseases like diabetes, renal failure and those usually administered steroids had a high-risk potential for fungal infections like aspergillosis and mucormycosis. Mucormycosis was an angioinvasive fungal infection that can cause ischemic necrosis of the infected regions with high morbidity rate. [13]

COVID-19 Associated Mucormycosis CAM could be clinically manifested by partial loss of neurological function and gradual necrosis due to thrombosis of blood vessels and infarction in conjunction with organism invasion. This may lead to a high fatality rate due to involvement of cranium region. [14]

Surgical resection and debridement of the necrosed areas of involved maxilla to solve the problem could results in massive acquired maxillary defect with oral and maxillary sinus communication that might involve the floor of nasal cavity, part of hard and soft palates and alveolar ridge. Those patients with extensive resection of maxilla could represent a challenging condition for an appropriate treatment planning protocol that usually included extensive surgical procedures followed by prosthetic rehabilitation involving maxillary obturators construction. [15]

The presence of those cases was reported in Egypt in several studies during the third pandemic wave. Fouad et al [16] reported that 96.2% of the studied patients had diabetes mellitus and 76.9% had previous history of corticosteroid treatment. Alfishawy et al [9] reported 21 patients evaluated in 11 different hospitals in Cairo, Egypt. Diabetes Mellitus was present in 19 patients and all of them got imaging findings of bony destruction and fungal sinusitis.

The aim of this study was to evaluate the fit and accuracy of both, conventional lost wax technique and selective laser melting printing technique (SLM), for fabrication of CoCr alloy palatal obturator of acquired palatal defect in treatment of post COVID-19 Associated Mucormycosis (CAM).

MATERIAL AND METHODS

Patients' selection

Twelve patients, 7 males and 5 females with age range between 45 to 65 years old, from outpatient clinic of Prosthodontic Department, faculty of Oral and Dental Medicine in both, Future University in Egypt and Ainshams University were enrolled in this study. Uncontrolled diabetes mellitus patients with acquired palatal defects due to post resection and total recovery from (CAM), full opposing mandibular dentate, adequate mouth opening, and intact soft palate were selected for this study. The definitive obturators were constructed at least three months after the surgical procedures. The palatal defects were either, sub-total maxillectomy type, where defects caused oro-nasal or oro-antral fistula but did not disturb the orbital wall of maxilla or total maxillectomy types, where these defects were characterized by absence of complete maxilla including orbital floor, but the orbital contents remained intact. [17]

Completely edentulous patients and patients with edentulous pre-existing congenital maxillary defects or acquired defects from gun shots and malignancies were excluded from the study. Patients were thoroughly informed about the study and each patient signed a written informed consent form. The study followed the declaration of Helsinki for the ethical principles concerning human participants and was approved by the ethics committee with registration number (FUE.REC No. (22)/9-2022). Eight cases (5 males and 3 females) completed the study. Unfortunately, four patients could not complete the study. Two patients died while other two suffered recurrency of CAM and didn’t complete the treatment plan.

Construction of obturator

Clinical procedures

All undesirable undercuts of the maxillary defects were blocked out using small pieces of gauze coated with petroleum gel. An appropriate stock tray was selected and slightly modified to reach maximum extension of the defect. Primary impressions were obtained for the maxillary and mandibular arches with irreversible hydrocolloid impression material (Alginmax, Major Prodotti Dentari SPA, Moncalieri, Italy). A Definitive hollowed closed bulb obturators were designed with tripodal principle to insure providing stability, retention, and load distribution.

Mouth preparation was done in the patient’s mouth for the planned occlusal rests and guiding planes. Definite maxillary impressions insured maximum distribution of forces to all available teeth, remaining hard palate, lateral walls of the defect and remaining alveolus were made with polyether impression material (Impregum F, ESPE, Germany). Master cast was obtained by pouring with dental hard stone. (Ultra rock; Kalabhai, India),

Digital designing and grouping

The master cast was fixed on the scanner table and scanned using 3Shape scanner (D850, 3Shape, Copenhagen, Denmark). The STL files were imported, and the partial denture framework was designed using 3Shape software program (3Shape A/S, Copenhagen, Denmark). The software was used to construct a meshwork design for a framework to control the angulation of the cast, measure the amount of undercut, and to determine the insertion and removal direction. For each patient two Co-Cr alloy frameworks were constructed by two different manufacturing techniques following the planed design. First manufacturing technique fabricated with conventional lost wax technique (group A) while the second manufacturing method (group B) fabricated by selective laser melting printing technique (SLM)

Accuracy and dimensional changes evaluation

All the fitting surfaces of the two frameworks conventional and printed ones were scanned by a single examiner. The STL file of the master reference model was inverted, and the inner surface scan was superimposed with a best-fit alignment using surface matching software (Geomagic Control X, 3D Systems, Canada) to evaluate the adaptation and correspondence of the frameworks with the virtual model. The software computed the vertical distances between the superimpositions.

The results were in the form of color maps calculated at specific 40 measuring points distributed in each of the sixteen frameworks at rests, clasps, and palate areas. Data was collected, tabulated, and statistically analyzed. The minimum required sample size was found to be 8 metal frameworks per group (number of groups =2) (total sample size = 16 metal frameworks). The sample size was calculated using G Power version 3.1.9.2.

Fabrication of final obturator

The finished and polished frameworks were tried in the patient's mouth to check the adaptation and fit. Maxillomandibular relationship was recorded with wax wafer technique. Teeth setting were made and wax try-in performed. Processing of the waxed-up obturator was made in heat cured acrylic resin (Vertex Regular and Vertex Implacryl, Vertex Dental B.V., Zeist, Netherlands). Both obturators were delivered to each patient.

Statistical methodology

Data was recorded and entered to the IPM SPSS ver. 25 (Statistical Package for Social Science) software. The Shapiro-Wilk test of normality revealed normal distribution of the variables, so data were described using mean, standard deviation. Comparisons were carried out between the two independents normally distributed variables using Independent Samples T- Test. An alpha level was set to 5% with a significance level of 95%, and a beta error accepted up to 20% with a power of study of 80%.

RESULT

Different color maps of the surface matching differences between the two manufacturing techniques and the casts on which they were fabricated are displayed in Figure (1-4). The areas ranging from yellow color to red color showed impingement of different fitting surfaces with the cast.

In contrast, areas ranging from light to dark blue color indicated space between different fitting surfaces and the cast. The green color demonstrated no processing deformation and ideal adaptation and fit of fitting surface studied against the cast giving zero value measurement.

The Independent Samples T-Test shows statistically significant difference between the two studied groups with P. Value of 0.000* at the palate and defect lines area. While there was no statistically significant difference between the two studied groups with P. Value of 0.228, and 0.783 at the rest and clasp areas respectively.

The two different manufacturing techniques within the four different locations of the metal framework of the obturator were observed in fig (5).

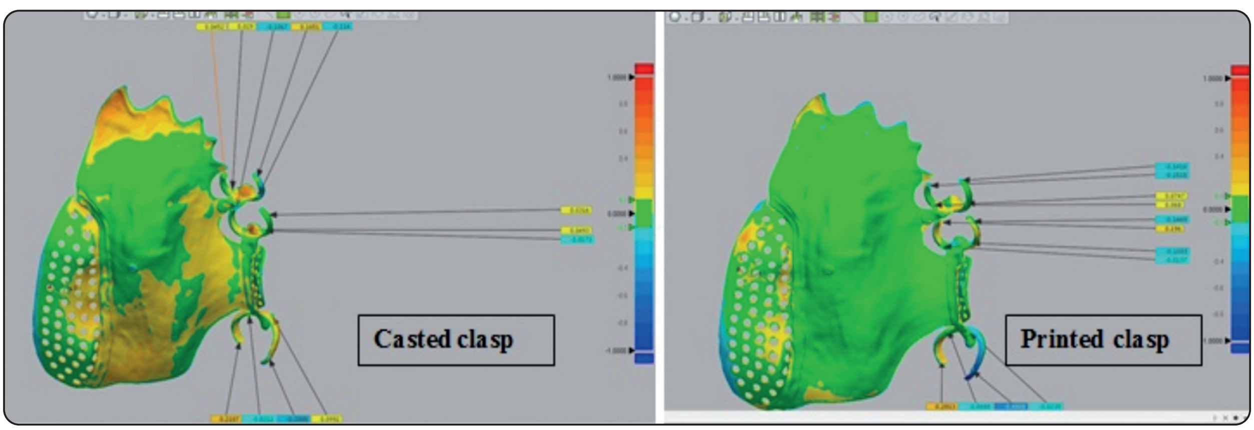

Fig (1): Different color maps of the surface matching differences at the clasps arms among the two manufacturing techniques and the cast

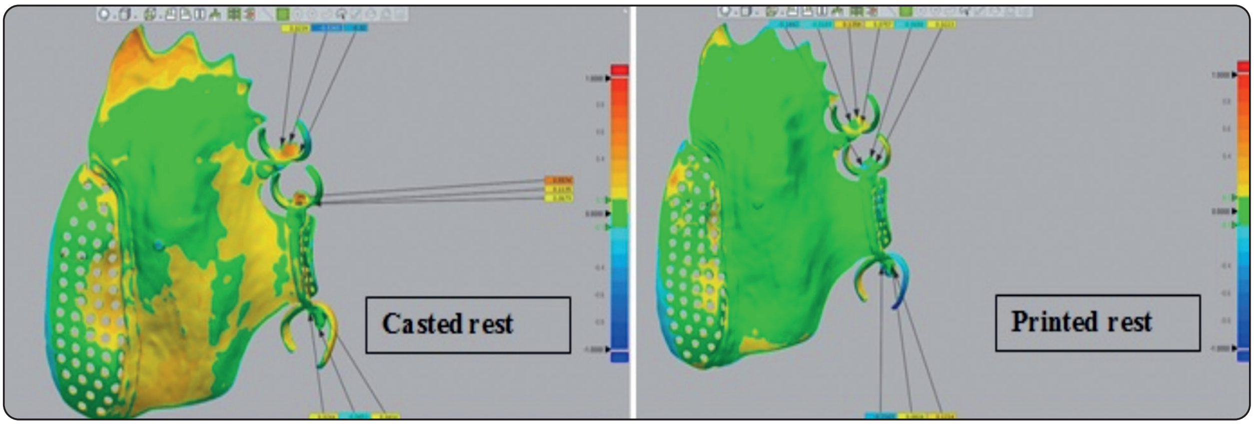

Fig (2): Different color maps of the surface matching differences at the occlusal rests among the two manufacturing techniques and the cast.

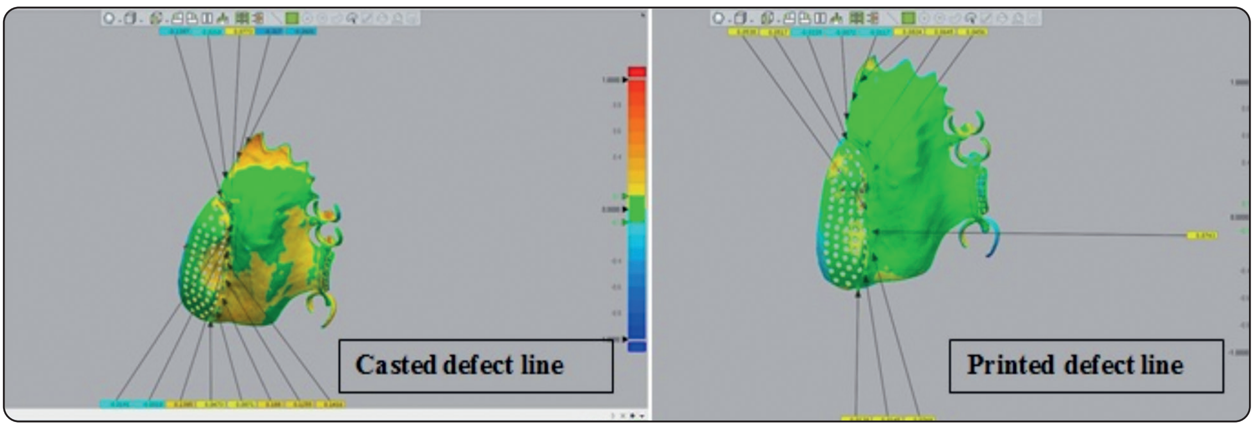

Fig (3): Different color maps of the surface matching differences at the defect line among the two manufacturing techniques and the cast.

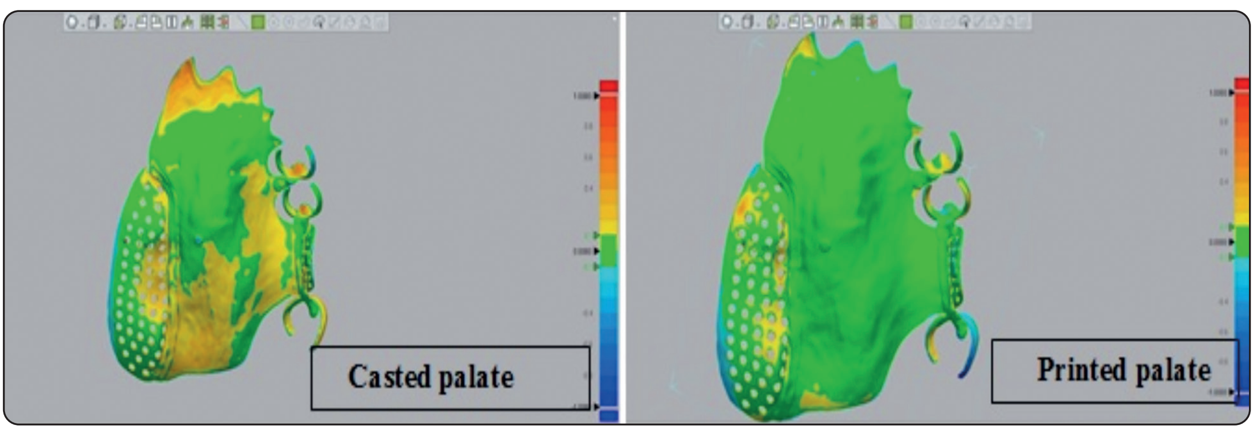

Fig (4): Different color maps of the surface matching differences at the palatal major connector among the two manufacturing techniques and the cast.

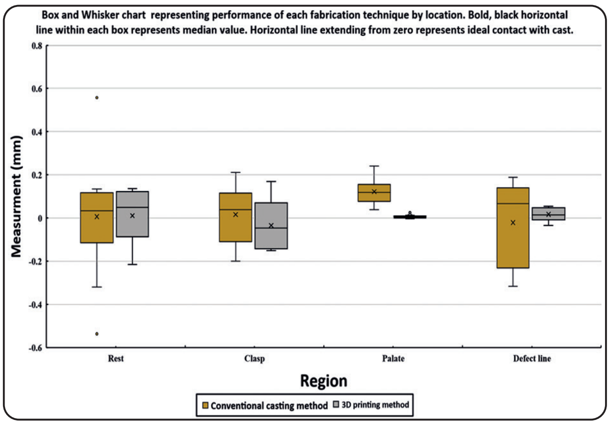

Fig. (5): Boxplot chart representing the performance of each fabrication technique by location.

The Independent Samples T- Test in table (1) shows statistically significant difference between the two studied groups with P. Value of 0.000* at the palate and defect lines area. While there was no statistically significant difference between the two studied groups with P. Value of 0.228, and 0.783 at the rest and clasp areas respectively.

TABLE (1) Comparing the adaptation between the two different fabrication methods at different areas.

Different areas of measurements	Conventional Cobalt Chromium casting method	Cobalt Chromium 3 D printing method	P. value
Rest	0.187 ± 0.209	0.101 ± 0.060	0.228
Clasp	0.104 ± 0.069	0.097 ± 0.055	0.783
palate	0.122 ± 0.058	0.007 ± 0.008	0.000*
Defect line	0.167 ± 0.081	0.027 ± 0.019	0.000*

: Statistically significant ($p<0.05$)
S: Statistically not significant ($p\geq 0.05$)

Both the accuracy (median distortion) and the reproducibility (interquartile range; IR) results for both techniques are listed in Table (2) for the different studied locations. The closer the value is to zero indicating more accuracy and reproducibility of manufacturing technique performed.

TABLE (2) Accuracy and reproducibility of metal framework in different fabrication methods based on location.

Different areas of measurements	Rank of Accuracy: Proximity to zero (median)		Rank of Reproducibility: (Interquartile Range)	
	Conventional casting	**3D printing method**	**Conventional casting**	**3D printing method**
Rest	0.034	0.049	0.232	0.209
Clasp	0.038	-0.046	0.224	0.212
palate	0.119	0.004	0.077	0.009
Defect line	0.067	0.014	0.371	0.055

DISCUSSION

All patients included in the study suffer from uncontrolled diabetes mellitus with acquired palatal defects due to surgical intervention to execute black fungus post covid 19.Although several classifications for maxillary defects had been proposed such as Armany's, Spiro's, Liverpool classification by Brown et al, Cordeiro's, and Okay's, however the classification of maxillary defects by Durrani et al., in 2013 were followed in cases selection. The classification seemed to be applicable to related clinical stages of mucormycosis.

The treatment of maxillary defects includes either using reconstructive surgeries or rehabilitation with an obturator prosthesis. Literature review regarding treatment of mucormycosis and osteomyelitis in the maxilla for post COVID-19 showed limited case reports. El Charkawi H and El Sharkawy O [18] reported a clinical report of two patients with post COVID-19 that required maxillectomy followed by scheduled rehabilitation. A 3Ds printing reconstruction of the skull and designing of rehabilitative mesh supporting the prosthesis were carried out. The patients endured modified maxillectomy followed by an immediate prosthetic obturator that was later replaced by a delayed one. Paliwal et al [19] reported the use of magnet to retain immediate prosthetic obturator.

The choice of proper line of treatment will depend on each individual case, taking into consideration that the ideal procedure should always seal the defect, close interweaving between mouth and nose, reestablish the physiological functions of chewing, swallowing, and speech, beside restoring the facial appearance. The use of obturator prostheses offers an ideal treatment option, being a simple and non-surgical procedure to close oronasal communication and restoring the physiological functions. [20-21] Metal framework obturator prosthesis provides longevity of the prosthesis and sensitive thermal conductivity of metal with less bulk and weight. [22]

In recent years, a wide shift from analog to digital workflow has been employed into maxillofacial rehabilitation. Although the use of intraoral scanners is considered the primary step for digital-based planning regardless of whether conventional treatment modalities are later used in rehabilitation stages. However, it is required to combine the use of cone beam computed tomography and three-dimensional (3D) printing to record the extent of defected areas in maxillary defects. [23-24]

Park et al. evaluated the trueness of the intra oral scanner impression compared to the conventional impression procedure. The obtained stone cast from conventional impression showed better details in the palatal tissues. [25] The use of desk top scanners to scan master cast obtained from secondary impression was preferred in this study.

Oh et al.,[26] evaluated the accuracy of metal 3D printed frameworks of removable partial dentures in comparison to that of frameworks produced by the conventional cast method by digital superimposition. The mean internal discrepancies on palate areas were 292.92 μm and 250.72 μm. Although this result didn't match our result. However, in the rest seat area the results were in conjugation with the result of this study. The mean internal discrepancies were 240.12 μm and 211.91 μm suggesting no statistically significantly difference among the fabrication methods ($p = 0.558$ and 0.542).

The selective laser melting (SLM) 3D printing technique showed statistically significant difference between the two studied groups at the palate and defect line areas. These results contradicted results of Salim et al, [27] reporting that the physico-mechanical properties including surface adaptation of Co-Cr RPD palatal major connectors fabricated by SLM compared with those fabricated by conventional casting. The surface adaptation and surface roughness of SLM 3D printing Co-Cr connectors were inferior compared to those produced conventionally. The overall volumetric and linear discrepancies were significantly higher (*P*<0.05) in the 3D printing group.

Chen et al [28] compared the tissue surface adaptation of four different designs of removable partial denture frameworks fabricated by an SLM technique with each other beside frameworks constructed by lost-wax casting technique as control group. Average gaps and maximum gaps between frameworks and models were measured using the silicone impression material. The study concluded that SLM printed frameworks accomplished an adequate adaptation. However, among frameworks with a larger span and relatively complicated designs including more retainers and clasps, the adaptation of those constructed by casting technique was slightly superior to those printed by the SLM technique.

This may explain that some of studied areas at the palate and defect lines showed statistically significant difference between the two studied groups while at rests and clasps there was no statistically significant difference between the two studied groups. Although numbers of present study were toward better adaptation of SLM printed framework in the four studied areas against conventional cast manufacturing technique.

The distribution or range of measurements recorded of median data is important in determining the ability of the two manufacturing techniques to produce a framework with accurate and uniform adaptation. Those values represented the reproducibility of the manufacturing technique to create a well-adapted framework each time it is constructed using that specific technique. The capability of the manufacturing techniques to produce a framework that is accurate, creating a median value close to zero and to be reproducible, producing the smallest interquartile range possible, determines the better technique.

3D printing method had the narrowest distribution of dimensional distortion as shown in table 2 which was located closest to zero at palate and defect line giving the indication of high reproducibility of the technique in this area. But results regarding rest and clasp area the conventional cast method showed slightly better results. The contradiction of results was reported in different literatures. Bajunaid et al., [29] evaluated the accuracy of conventional lost wax and 3D printed manufacturing techniques, were thirty RPD metal frameworks were fabricated over a mandibular Kennedy class III, modification 1 dental arch models. Polyvinyl siloxane impression material was painted in the rest seat representing the gap under the rest and was measured using a digital microscope. Comparison between the two techniques for each abutment tooth showed that the conventional lost wax technique had better fit in one tooth, while the SLM 3D printed technique showed a better fit in two teeth for the same framework.

Furthermore, Tasaka et al. studied the two previous manufacturing techniques by scanning frameworks of partially edentulous mandibular models. The frameworks were designed by using CAD software. 3D scanning of fabricated two types of frameworks was performed, and these data overlapped with design data. In the clasp arm area, lateral displacement was noted at the tips of the Akers and ring clasps for the conventional cast framework while medial displacement was reported at the tip of the RPI clasp as an infrabulge clasp. Similar results were achieved in a study of Akers clasps alone without framework fabricated by 3D-printed manufacturing. [30-31]

One of the limitations of this study was the presentation of all participants after complete surgical intervention. Although the main major challenges in post-surgical defects of mucormycosis over those results from tumors are the unpredictable and inexpressible progression of the fungus which require extra debridement procedure that might be unplanned prior to surgical intervention. However, complete utilization of full digital workflow requires the starting from medical scanning (CT, MRI and CBCT), face capture and intraoral scanner for teeth or surrounding bone structures for an acquisition of the three-dimensional data of the patient even before the any surgical intervention.

More short and long term experimental and clinical trials are needed to evaluate the new digital construction techniques for framework fabricated by conventional, milling and 3D printing or SLM techniques including patient satisfaction, mechanical properties, and biological outcomes.

CONCLUSION

Within the limitation of this study, the selective laser melting printing technique for fabrication of palatal obturator of acquired palatal defect in treatment of CAM was found to be comparable regarding the fit and accuracy to those fabricated with the conventional lost wax technique.

Declarations Section

A. Ethics Approval and Consent to Participate

The informed consent obtained from study participants was written and approved by ethics committee with registration number (FUE.REC No. (22)/9-2022)

B. Funding

No funding was given for the research it is self-funded by the authors.

C. Conflict of Interests

No conflict of interests

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