

EVALUATION OF MICROBIAL ADHESIONS AND QUALITY OF LIFE IN MAXILLECTOMY PATIENTS REHABILITATED WITH COBALT-CHROMIUM AND THERMOPLASTIC OBTURATORS

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ABSTRACT

Objective: The purpose of this study was to evaluate the oral microbial adhesions and quality of life in Maxillectomy patients after rehabilitation with two types of maxillofacial obturators: Thermopress & Cobalt- Chromium obturators.

Materials and Methods: Type of study: Randomized clinical trial (RCT) Ten hemimaxillectomy patients were taken from the out-patient clinic of the national Institute. Patients Grouping: Patients were randomly divided into two equal groups. Group-I: Five patients had received thermopress obturators. Group-II: patients were rehabilitated with cobalt chromium & polymethyl methacrylate obturators. - Microbial adhesions of viable microorganisms in the accumulating biofilm layer on Polymethylmethacrylate (PMMA) & Thermopress obturator bulb surfaces were determined along four weeks period & converted to Colonies Forming Units (CFU) per cm² unit surface area. -QOL was evaluated according to the Obturator Functioning Scale' (OFS). questionnaire by direct interviews with the patients at the end of four weeks period.

Results: The results of this study revealed that the microbial adhesions showed statistically significant increase in Group-I patients compared to Group-II; On the other hand, the patient's quality of life in Group-I recorded higher values in the examined domains than Group- II patients.

Conclusion: Within the limitations of this study; it may be concluded that: Thermopress material may induce more microbial adhesions than Cobalt chromium & PMMA ones. Thermoplastic obturators may provide maxillectomy patients better esthetics, speech & social interaction than metallic obturators with conventional PMMA.

KEY WORDS: Obturators, Thermopress, PMMA, microbial adhesion, QOL.

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INTRODUCTION

The term maxillectomy refers to partial or total removal of maxilla in a patient suffering from benign or malignant neoplasm.¹ Post-surgical maxillary defects predispose the patient to hyper-nasal speech, fluid leakage in the nasal cavity, impaired masticatory function, and, in some patients, various degrees of cosmetic deformity.²

Prosthetic restoration of functions and facial form by obturator prosthesis is an excellent method in the replacement of missing parts and restoration of contour. The surgical and interim obturators are constructed from acrylic resins to aid in healing during the recovery period and to shorten long-term rehabilitation.^{3,4} After the surgery by three to four months and after thorough evaluation of healing and tumor prognosis, definitive obturator prosthesis can be given.⁵

Such obturators may be colonized by microorganisms and function as a reservoir of infection. It has been estimated that at least 65% of all human infections are related to microbial biofilms.⁵⁻⁸ Several studies have been carried out on the adhesion of the yeast *Candida albicans* to denture acrylic resin.⁹⁻¹⁷ Denture soft-lining materials, and other silicone materials used in maxillofacial and voice prostheses are also susceptible to colonisation by *C. albicans* and other microorganisms, reducing the lifetime of these prostheses.¹⁸⁻²²

Oronasal communication that develops following tumour resection surgery, predispose the obturator prosthesis to a microflora that is different to that of the conventional partial and complete denture wearer. Prior to surgery, streptococci are the most common bacteria found in the oral cavity.²³ Following a maxillary resection, the obturators are also exposed to microorganisms of the nose and sinus. These include *Staphylococcus* spp., as well as corynebacteria, *Haemophilus* spp. and *Neisseriae*.^{24,25}

This altered microflora, in individuals who are immunocompromised from cancer therapy, and an environment that facilitates potentially virulent biofilm formation because of altered commensal flora, diet and saliva production, means that these patients may be at high risk for prosthesis-related infections.^{26,27} Such prosthesis-related infections can contribute to systemic bacterial and candidal infections, which, in patients who are immunocompromised as a result of management of a maxillary tumour, can occasionally result in the need for hospital admission to control local and systemic infections.^{26,28,29}

Polymethyl methacrylate (PMMA) resin has been the most commonly used material for denture bases and obturator prosthesis, despite its popularity, PMMA resin is far from ideal. Polymerization shrinkage and release of thermal stresses are the major disadvantages exhibited by the material. In an attempt to overcome dimensional inaccuracies of PMMA resin new thermoplastic resins and alternative processing techniques have been developed.³⁰⁻³³ One of these techniques is the injection molding technique; in which the polymerization shrinkage is compensated by continuously injecting resin at certain pressure through a carefully controlled procedure.³⁴

Several studies have revealed that injection molding techniques result in fewer dimensional inaccuracies and more accurate denture base than conventional processing techniques.³⁵⁻³⁷ They are stable and resist thermal polymer unzipping. They also exhibit high creep resistance and high fatigue endurance as well as excellent wear characteristics and solvent resistance. Thermoplastic resins typically have very little or almost no free monomer in the material. A significant percentage of the population is allergic to free monomer and these materials offer a new safe treatment alternative for these individuals.³⁸⁻⁴¹

Thermoplastic resins are used for a broad variety of applications from removable flexible partial

dentures, fiber-reinforced fixed partial dentures, temporary crowns and bridges, provisional crowns and bridges, orthodontic retainers and brackets, impression tray and border molding materials, occlusal splints, sleep apnea appliances, obturators and speech therapy appliances.³⁸ Direct retainers fabricated in a tooth-colored material and made from thermoplastic resin have been used to improve the appearance of metal clasp assemblies and are promoted for superior esthetics.⁴²⁻⁴⁴

Facial esthetics and oral functions are essential for social interaction and have an impact on individual's quality of life (QOL). QOL of patients with maxillofacial tumors is being considered to evaluate the patient's satisfaction. A strong correlation between obturator function and QOL have been shown in various recent studies.⁴⁵⁻⁴⁸

The purpose of this study therefore was to evaluate and compare microbial adhesion (Quantification and Identification) and quality of life in Maxillectomy patients after rehabilitation with two types of maxillofacial obturators: thermopress & Cobalt-Chromium obturators with PMMA bulb.

PATIENTS AND METHODS

Patients' Selection:

Inclusion criteria:

- Ten maxillectomy patients were selected in the age range of 40 -58 years from the out-patient clinic of the National Cancer. All patients had undergone surgery at least 6 months earlier.
- The defect corresponded to Class- II situation according to the Armany's Classification of defects. (*Fig. 1*) with the opposing mandibular arch is completely dentulous.
- Patients were thoroughly informed about the study and each patient has signed a written informed consent form.

Exclusion criteria:

- Patients with cleft lip and palate, completely edentulous patients and patients with traumatic defects were excluded.

Prosthetic Procedures:

For all selected patients the following prosthetic procedures were carried-out:

- Preliminary impressions of the maxillary & mandibular arches were made with irreversible hydrocolloid alginate (Alginmax, Major Prodotti. Dentari SPA. Moncalieri. Italy) after blocking-out the defect with petrolatum-laden gauze; (*Fig.1*)
- Diagnostic casts were poured with dental stone and diagnostic surveying was made.
- A definitive closed bulb obturator was planned as the design principles given by **Armany** for Class-II maxillary defects considering stability, retention and load distribution by the application of tripod design.⁴⁹
- Maximum support was gained from the remaining palatal tissue & retention was achieved from the embrasure clasps made on the remaining premolars and molars and I bar clasp was planned on the maxillary central incisor.
- Bracing was achieved by extending the major connector till the palatal surfaces of the remaining natural teeth. Guide planes should be designed to facilitate stability and bracing. Indirect retention was achieved by canine rest.^{49,50}
- Mouth preparation was made as determined by treatment plan. Master impression was made with **rubber base impression***. Precise impression of the defect is made for the fabrication of the prosthesis that allow maximum distribution of forces to all available teeth, remaining hard palate, lateral walls of the defect and remaining alveolus. (*Fig.2*)



Fig.1: Class II maxillary defect and Primary alginate impression



Fig.2: Final impression

- The master cast was prepared with die stone (Ultra rock; Kalabhai, India), surveying and block-out of undercuts on master cast were carried-out.
- Survey of the defect had aided in precise utilization of undercuts.
- Blocking of posterior & postero-lateral undercuts allowed anterior path of insertion. Minimum utilization of lateral undercuts prevented tissue trauma of fragile nasal mucosa. All undercuts not utilized for retention were blocked out to allow for a smooth insertion..⁵⁰
- The modified master cast was then duplicated.

Patients' Grouping:

Patients were randomly divided into two groups, each group included five patients.

Group I: Patients were rehabilitated with a maxillary thermopress proflex resin obturators .

Group II: Patients were rehabilitated with a maxillary definitive Ch-CO metallic framework obturators with conventional heat cured acrylic resin bulb (PMMA)

For group-I

- Occlusal relationship was obtained with the conventional wax wafer technique Setting- up of teeth was made & Try-in of the trial obturator was made. Waxing-up was completed, then the appliance was then invested in a special aluminum flask. Injection of Proflex Thermopress material* was made. Followed by curing of thermoplastic material , then. Finishing & polishing was carried out according to certain protocol.

For group II:

- On The duplicated Master cast , The wax framework was fabricated, sprued, invested and casting was made with Cr-Co alloy (Solidur Co-Cr; Yeti Dental, Germany).
- Finished and polished framework was tried in the patient's mouth for fit.
- Maxillomandibular relationship was recorded with wax wafer technique.
- Teeth setting -up 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, The Netherlands).

The obturators were delivered to the patients of both groups (**Fig 3**)

Microbial Sampling:

- Isolation of the microorganisms using gamma sterilized disposable cotton swabs was collected

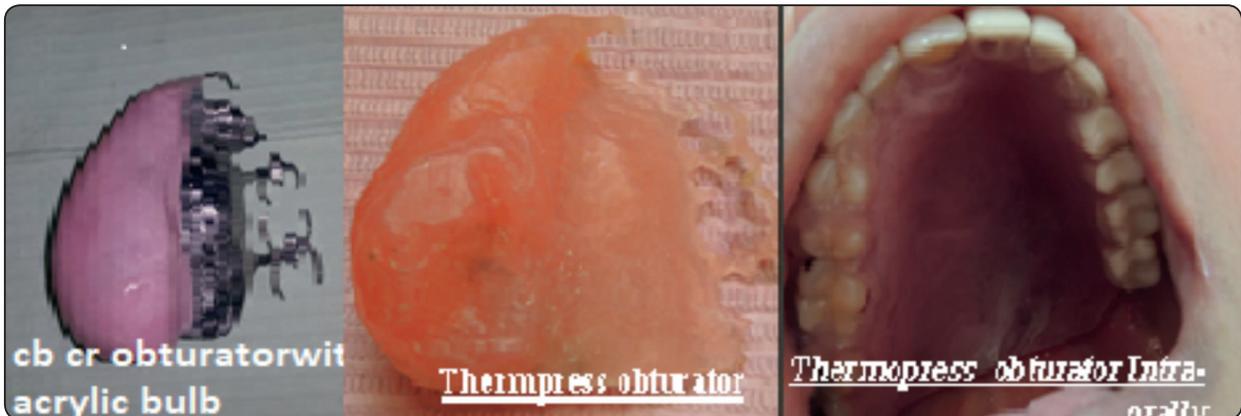


Fig.(3) definitive obturators for both group

after 1 week, 2 weeks and 4 weeks following obturator insertion.

- The swabs were taken from the bulb portion of the obturator
- For the bacteriological count, each swab was immediately inoculated into a tube containing 1ml. nutrient broth.

Culturing:

- After good shaking, this 1ml. was added to 9ml. nutrient broth in a sterile tube making a dilution of 1:10. The previous step was repeated to reach a dilution of 1:1000.
- Using the pre-adjustable micropipette 0.1 ml. (100 μ l) was transferred from the last dilution (1:1000), and plated in a sterile dishes containing nonselective blood agar medium using sterile glass rods (*Fig.4*).

Incubation procedures:

- The plates were covered & left for one minute to dry and then were inverted immediately before being placed in incubator for 24 hours at 37° C.

Counting of the colonies:

- After 24 hours, the plates were removed from the incubator. The counting was done by counting the number of colonies that appeared

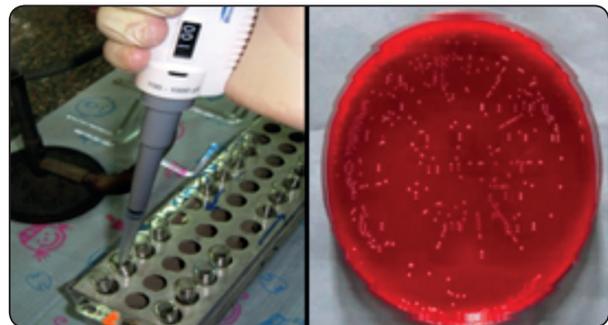


Fig.(4): Culturing of the samples and Counting the number of CFU

on the Petri dish (Colonies Forming Units per Sample), Then the Counts were converted into CFU/mL (*Fig.4*).

- The total number of colonies per stimulated saliva sample was determined by the following equation:
- $CFU/mL = \text{Total number of colonies counted in the plate} \times \text{inversion of the saline dilution} \times \text{inversion of the cultured volume} \times 1000.$

Quality of life:

- After insertion and adjustment of obturators, patients had undergone standardized questionnaire in personal interviews.
- The study sample consisted of 10 patients. 3 males and 7 females.

- The questions asked were based on a disease and domain specific QOL Questionnaire Obturator Functioning Scale' (OFS).
- This questionnaire has been utilized by other investigators.^{45,46,52,53}
- Nine domains in OFS questionnaires, including satisfaction with facial appearance, ability to speak, ability to speak in public, leakage with liquids and solids, dryness of mouth, insertion of obturator, chewing or eating, social-family interactions, and overall OFS were scored.
- Numerical value from 0 to 100 for each response in the questionnaires was used. A score of 0 indicates maximum suffering or dissatisfaction and score of 100 indicates that patient was asymptomatic or satisfied in that particular domain.⁵⁴

Statistical analysis:

Data from the two groups were collected, tabulated and statistically analyzed and illustrated in tables and figures. The data were summarized as means and standard deviations. Collected data were analyzed using a SPSS statistical package (Version 19, Chicago, IL, U.S.A.). Mean values were compared by independent t-test to compare between the groups. The ANOVA test used to compare the effect of time in different follow-up periods. The level of significance was set at 5% for all statistical analyses.

RESULTS

1- Microbial count

There were statistically significant differences of Microbial count means (CFU) at different follow-up periods for both group I and group II, as shown in table 1, (P<0.001). The mean values of CFU of bacteria showed statistically significant increase throughout the study period in the two studied groups.

When comparing the two groups, there were no statistically significant (P<0.05) differences between both groups at one and two weeks periods as indicated by independent t-test. However, group I showed statistically significant more Microbial count when compared to that of group II at the end of four weeks follow-up period (P<0.001) table 1.

2-Quality of life:

The sample of ten patients (3 Male, 7 Female), with a mean age of (54.1) years were included in this study. A total of 10 maxillary obturators were placed (five each group). The socio demographic and medical characteristics of the selected patients interviewed are presented in Table 2.

According to the OFS questionnaire, the Individual scores for specific domains were shown in Table 3, Graph-2

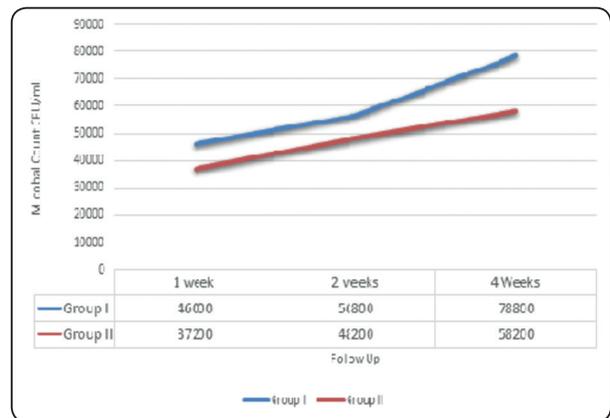
TABLE (1) Mean Values and SD for the Microbial count for both test Groups (CFU/ mL)

	1 week		2 weeks		4 week s		F-value	P-value
	Mean	SD	Mean	SD	Mean	SD		
Group -I	46000	7071	56800	10756	78800	5263	21.671	<0.001*
Group -II	37200	5403	48200	6648	58200	6180	14.830	<0.001*
Difference	8800		8600		20600			
t-value	2.211		1.521		5.674			
p-value	0.058		0.167		<0.001*			

TABLE (2) Socio-demographic and medical characteristics of patients (N=10)

Patient's characteristics	N (%)
Gender	
• Male	3 (30 %)
• Female	7 (70 %)
Age in years:	
• Mean	54.1± 9.07
• Range 38-65	
• > 60	4 (40%)
• 60 >	6 (60%)
Educational status	
• Educated	7 (70%)
• Not- Educated	3(30%)
Employment status	
• Retired	4 (40%)
• Not retired	6 (60%)
Tumor type	
• Squamous cell carcinoma	5 (50 %)
• Adenoid cystic carcinoma	2 (20%)
• Adenocarcinoma	3 (30 %)
Therapy	
• Surgery	1 (10%)
• Surgery +Radiation therapy	4 (40%)
• Surgery +Radiation therapy +chemotherapy	5 (50%)

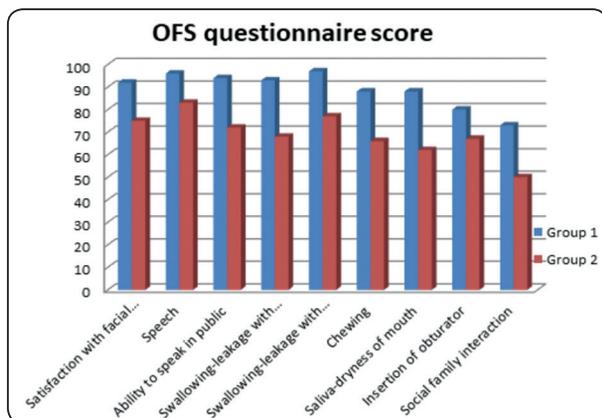
Group-I, showed statistically significant (P<0.05) more OFS score when compared to that of group II for all questionnaire domains as indicated by independent t-test.



Graph 1: A line chart showing the effect of time on the Microbial count for both test Groups (CFU/ mL)

TABLE (3) Comparison between the two groups regarding OFS questionnaire score

Domain	Group-I Mean ± SD	Group-II Mean ±SD	P- value
• Satisfaction with facial appearance	92±2.74	75±5.00	0.0002*
• Speech	96 ±4.18	86±4.47	0.0014*
• Ability to speak in public	94±6.52	72± 2.74	0.0001*
• Swallowing- leakage with fluids	93 ±2.74	68 ±5.7	0.0001*
• Swallowing- leakage with solids	97±4.47	77±4.47	0.0001*
• Chewing	88±5.7	66±6.52	0.0005*
• Saliva dryness in the mouth	86±4.07	62± 5.7	0.0001*
• Insertion of obturator	80 ±3.54	67± 10.37	0.03*
• Social family interaction	73±8.37	50±10	0.0043*



Graph (2) Bar chart showing the comparison between two groups regarding OFS questionnaire score

DISCUSSION

Rehabilitation with obturator prosthesis is functional, reliable, safe and easy to build. The palatal obturator restores: mastication, swallowing, articulation and intelligibility of speech.⁵⁵ This study was conducted to evaluate the effect of two different obturator materials on the microbial adhesions and quality of life in maxillectomy patients.

The results of the present study revealed that, in the two studied groups, there was a statistically significant increase in the mean bacterial counts throughout the whole study period (From 1-4 weeks after obturator insertion). This might be attributed to the presence of oro-antral communication following surgical resection with accumulation of oral and nasal flora on the nasal portion of the obturator with increased the countable bacteria in this area as reported by *Haug et al., 2002*⁵⁶

Furthermore, the acrylic surface of the obturator bulb have small micro porosities ,even it is properly cured and polished. These microporosities absorb oral fluids creating a favourable medium for the growth of microorganisms as reported by *Moura, J.S, 2006*.⁵⁷ Besides, the maxillectomy patient's diet decreased salivary flow & different salivary composition may enhance the microbial adhesion to the obturator' surfaces.⁽⁵⁸⁾

The results of this study had revealed no statistically significant difference in the oral microbial counts (QFU) of the two studied groups in the first two weeks following denture insertion. However, there was statistically significant increase in the microbial count in Group-I than Group –II, at the end of follow up period. This may be attributed to the slight rough surface of thermoplastic resin materials as they are not highly polished as of conventional acrylic resins. Consequently, their surfaces are more susceptible to microbial adhesions and formation of biofilm when they are exposed to the oral environment especially in presence of oro-antral communication in maxillectomy patients. The relatively higher roughness of thermoplastic resins might be related to the the different in polishing techniques used on the two studied materials that might have influenced their surface roughness and microbial adhesions.^[59]

Cosequently all patients should be instructed and motivated to remove the biofilm on the obturator surfaces with of adequate oral hygiene measures and extra-care motivated for maintaining a healthy oral mucosa minimizing the risk of oral and systemic infections. They must be informed that thorough oral hygiene is essential for long term service of their appliances as Biofilm may lead to deterioration of obturator surface and super infection of the oral surfaces in contact with obturators. They should be instructed to remove the obturator during brushing of their remaining teeth to minimize scratching of the obtuartor surface.

This study verified the impact of obturator on Quality of life (QOL) of maxillectomy patients. Overall well-functioning obturator prosthesis significantly improves the quality of life of maxillectomy patients by fulfilling their needs of mastication, speech and cosmetics. In this study, various demographic and medical characteristics have affected significantly the outcomes of QOL. It was documented that the QOL is multidimensional,

subjective and changes with time and circumstances, consequently it is not an easy work to evaluate. The results of the present study had revealed that patients of Group-I had overall better QOL compared to patients of Group –II. All items related to social activities as satisfaction with facial appearance & speech and speaking in public were much better in Group I than II.

These findings may be attributed to proflex Thermoplastic material used in obturator construction in Group-I. make the patients more stratified with their facial esthetics due to the absence of metallic display and the semi translucent property of the proflex resulting in better blending of prosthetic appliance with the color of the natural gingival tissue.

Patients were also more satisfied about their speech manner & less nasal tone with the thermoplastic obturator compared to the metallic as well. This finding may be explained as follows: the thermoplastic obturator may provide better retention compared to metallic one; as it is vacuformed to fit the model perfectly and the clasps may be easily modified to improve retention with warm water. The more retentive and secured qualities may lead to more intelligent speech.

The lack of metal display allowed the patients to speak with minimum fear of discovering the obturator in public. Theses caused may provide better social communications and consequently better QOL.

In the present study, the sample size was small and to some extent had comparable size of the maxillary defects.

Absence of pain due to the pressure spots that are commonly seen in acrylic resin after insertion of the appliance & which is considered the main annoying problem in maxillectomy patients leading to their withdrawal from the social activities & meeting relatives.

The better chewing ability and swallowing without leakage especially of liquids in Group I patients may be attributed to the more adaptation onto the defect, the better retention and the less pain during chewing. This results was in accordance with Keyf , 2001 and Shah D et al, 2012 who reported that Flexible denture base material helps to reduce the weight of the obturator, to decrease pressure to the surrounding tissues, to aid in deglutition and allowe more comfort and better speech pattern.

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