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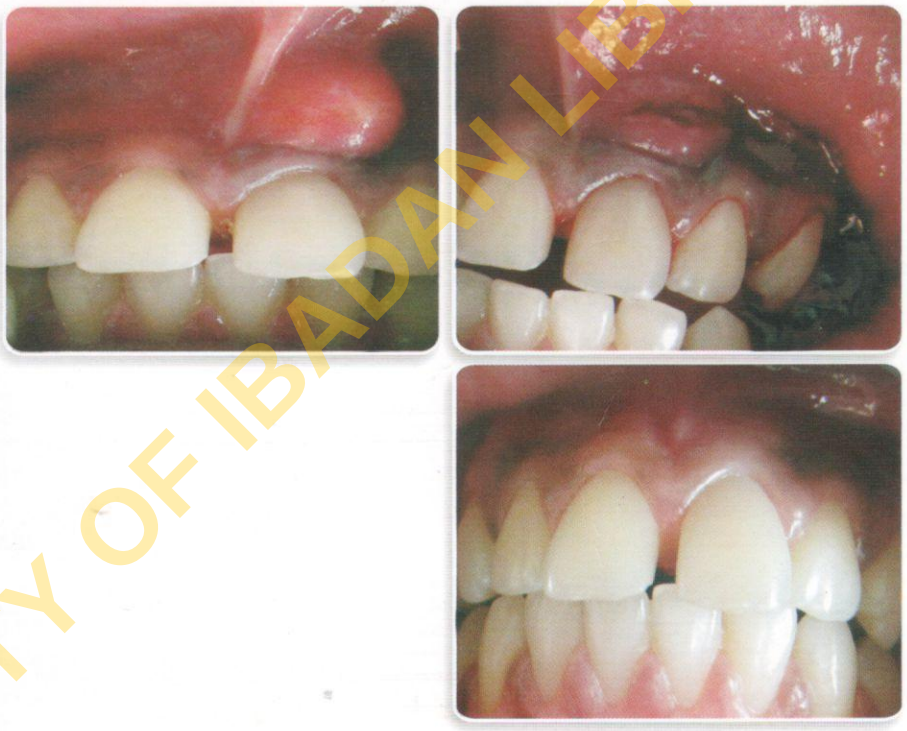

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Influence of resilient obturator material on self reported obturator function in individuals with maxillectomies

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Key words: Maxillectomy, silicone liner, acrylic, function, quality of life

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Abstract

Objectives: Removable maxillary obturators are the standard of care in rehabilitating individuals who have had maxillectomies in most specialist healthcare facilities in Nigeria. The rehabilitation of these individuals should emphasise quality of life rather than normative standards by the healthcare professional. This study sought to examine the relationship, if any, between the materials used for obturator fabrication and self - perceived quality of life as reported by the individuals rehabilitated. *Materials and methods:* Twelve individuals with maxillary defects participated in the trial. They were provided with two definitive obturators each after undergoing post surgical rehabilitation. One of the obturators had a hollow all acrylic bulb while the other had a hollow acrylic bulb with an outer layer of silicone resilient denture liner. The participants wore each prosthesis for a two - week period and crossed over to the other without wash out. The adapted Obturator Functioning Scale questionnaire was administered after the patient had worn each prosthesis. Paired t-test was employed to compare mean obturator functioning scores. The level of significance was set at $p<0.05$. *Results:* The mean modified obturator functioning score for the silicone lined obturator was 4.25, while that for the all acrylic obturator was 8.00. The standard deviations were 3.05 and 4.29 respectively. The difference in mean scores was significant at $p<0.05$. *Conclusion:* Silicone lined obturators improved the self reported quality of life of participants in this trial much more than all acrylic obturators.

Maxillary obturators have been used since the sixteenth century in France for the mechanical obliteration of palatal defects .[1] The development of obturators has been in tandem with the development of the materials available to the prosthodontist for the fabrication of these prostheses.[2] The maxillary obturator is essentially a denture with a component called a bulb or obturator component that fits into the defect in the palate.[3] These prostheses have been classified based on the period during rehabilitation in which they are used.[3,4] They have been classified as surgical obturators (or feeding plates) given during or just after surgery, interim (or temporary) obturators given after initial healing and during the period of tissue remodelling; and as definitive obturators given after tissue remodelling. Definitive obturators are usually given about 6 months post surgical ablation.[3,4]

The aetiology of maxillary defects was mainly infection in the past, but is now mainly due to iatrogenic resections to eradicate neoplasm (which may be benign or malignant).[1,5] A significant cause of palatal defects or palatal resections today is the fulminating fungal infection: mucormycosis which is typically seen in the immuno-compromised patients.[6] However, irrespective of the cause of the defect, the individual living with a maxillary defect is fraught with the challenge of integrating socially in his/her community. They also face the emotional challenge of the memory of their pre-morbid appearance and the psychic reaction this may elicit.[7] This challenge is increasingly being taken into cognizance in modern rehabilitative medicine and dentistry. The emphasis in the management of individuals requiring disfiguring surgical resections has shifted from a mere consideration of surgical end points to a more holistic concern with the quality of life of the individual.[8] This no doubt brings medical and dental practice closer to the WHO ideal for health.[9]

There are several materials available today for the fabrication of obturator bulbs.[10,11] The two commonly used materials historically have been methyl metacrylate and silicone rubber.[11] These materials have their merits and demerits, but are both acceptable from a biocompatibility perspective.[10,11] The commonest material used in Nigeria is methyl metacrylate,[12] and bulbs made from this material may be lined with a resilient silicone denture liner to maximise the physical properties of the bulb while making use of the resilience of the silicone rubber.[13]

The WHO defines quality of life as "the individual's perception of their position in life in the context of the culture and value system in which they live and in relation to their goals, expectations, standards and concerns".[14] The quality of life of individuals who have had medical or surgical intervention to relief pathologies is usually assessed with the administration of questionnaires. Many of these

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questionnaires have been developed in different communities, and are detailed and may even be said to be cumbersome, for instance, the DOESAK questionnaire developed for German speakers contains 143 questions.[15] While this may suggest comprehensiveness, individuals who have undergone a major life changing event like a maxillectomy are prone to poor concentration and memory lapses.[7] This is likely to lead to inaccurate data collection. Shorter and more concise questionnaires avoid this drawback.

The functioning of obturator prostheses has been suggested as a significant factor in the quality of life of individuals who use them.[8, 16, 17] This observation has been validated by applying a simple, short but concise questionnaire to test obturator functioning using the Obturator Functioning Scale.[16] This is a fifteen-point questionnaire scored on a Likert scale with lower scores signifying better function. This instrument has been adapted in this study to suit the cultural realities of a typical south western urban Nigerian society. The present study was to evaluate the self reported functioning of definitive maxillary obturators using the adapted obturator functioning scale questionnaire in a cohort of 12 individuals living with surgically acquired maxillary defects.

Materials and methods

Twelve individuals participated in the study. The statistical formula comparing paired means was applied to the results of a similar study to determine this sample size.[18,19] The individuals recruited into this study met stringent inclusion and exclusion criteria. These criteria included being biological adults (16 years or older), having maxillectomy defects which left at least 4 contiguous standing teeth unilaterally, and having maxillectomy defects that were deemed stable as far as tissue remodelling was concerned (individuals who had maxillectomies at least 6 months before recruitment into the study). All participants provided informed consent before recruitment. Where prospective participants expressed a desire to be included in the study before this basic condition was met, they were provided with the necessary prosthetic treatment including the provision of interim and temporary obturators which were adjusted as required before recruitment into the study.

Other criteria included the completion of any radiotherapy at least 6 months before recruitment, the absence of any radiation mucositis or clinical evidence of recurrence of the ablated tumour, and xerostomia. The participants were also required to be free of caries and periodontal disease and all had prophylactic periodontal consultations before recruitment.

Institutional Review Board approval was obtained from the University of Ibadan/University College Hospital Ethics Committee, and all participants filled out written informed consent forms before recruitment. Consecutive participants were recruited into 2 groups A and B and crossed over to the alternate group after 2 weeks without wash out. Participants in Group A were fitted with the all methyl metacrylate resin obturators first and crossed over to Group B where they were fitted with silicone lined methyl metacrylate obturators which they wore for 2 weeks. There was no washout period as the participants could not be left without prosthesis for any length of time. The participants recruited into Group B experienced the reverse process from the beginning. The adapted Obturator Functioning Scale questionnaire was completed by the participants after each 2 week period.

Diagnostic casts were made from irreversible hydrocolloid impressions (Jeltrate; Dentsply Intl). These were first surveyed to determine the need and extent of tooth preparation. Mandibular casts were also made to facilitate the recording of the participants' occlusion. The diagnostic casts were used to fabricate PMMA special trays. All necessary tooth preparations were made and 2 definitive impressions were obtained with medium body polyvinylsiloxane (Aquasil; Dentsply Intl) with a single mix technique. The working models were then poured in Type III gypsum (Labstone; Dentsply Intl). These working casts then had a final survey to facilitate the design of the framework. The gypsum casts were duplicated in refractory material (Meavest;Dentsply Intl) to produce 2 cobalt chromium (Vitallium; Dentsply Intl) metal frameworks for each participant. After a clinical evaluation to certify the fit, the frameworks were finished and polished.

The framework for the all methyl metacrylate resin obturator was incorporated into occlusion registration bases with auto polymerizing methyl metacrylate base plates and hard modelling wax (64102005W; Dentsply Intl) rims. The base plates followed the shape of the defect after adequate block out of excessive undercuts. This was to prevent rocking of the record blocks during occlusal registration. The registration bases were then used to register the occlusion of the participants. The bases were placed in the mouth after softening the wax rims and the participants were guided into centric occlusion as confirmed by normal intercuspation in the dentate areas. The bases were then retrieved and aligned with the mandibular diagnostic casts. The maxillary definitive casts were then carefully placed over the record blocks and the whole assembly was mounted on average value articulators (Contact A; Heraeus Kulzer).

The framework for the silicone-lined PMMA obturator was treated similarly, but the definitive cast for this obturator was first modified to create space for the resilient lining material. The inner surface of the defects on the casts was lined with 6 layers of aluminum foil before the base plate was made in auto-polymerizing methyl metacrylate (Prevest Dent Pro; Hiflex). The occlusion was recorded in a similar manner for these obturators.

The acrylic resin teeth were arranged on the articulator and the wax trial denture was clinically evaluated. The evaluation assessed occlusion, esthetics, and the participants' acceptance of the appliances. The participants commented on their expectations and minor adjustments that could be made at the chair side were made.

The hollows in the base plates were filled with a mixture of Type 2 gypsum (Lab Plaster; Dentsply Intl) and pumice (No 3 med; Kerr Corp) and the base plate was completed with auto polymerizing methyl metacrylate to bridge the defect filled in with the plaster/pumice mixture. The wax dentures with their auto-polymerizing methyl metacrylate bulbs were flasked and the denture portion was processed in heat polymerizing PMMA (Trevalon; Dentsply Intl). The working casts were liberally painted with separating

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medium before investment to facilitate the retrieval of the models after the dentures had been processed.

The dentures were retrieved after processing. The all methyl metacrylate obturators were finished immediately. However, the obturators for silicone lining had the aluminium foil spacer removed, and the bulb was lined with a self curing silicone resilient definitive soft liner (Easysoft; Karlin Technologies) following the manufacturer's instructions. These dentures could not be removed from the cast after the lining due to considerable engagement of undercuts and the dentures were retrieved after fracturing the casts.

The obturators were then trimmed, polished, and finished appropriately. The silicone lined obturators were coated with a layer of the sealant (Easysoft; Karlin Technologies) provided by the manufacturer according to manufacturer's instructions. The obturators were delivered to the participants. The questionnaires were filled out by each patient after the 2 week period spent in each group.

The data generated were fed into a personal computer and analyzed with software (SPSS INC v 19; IBM Corp). The obturator functioning scale questionnaire was adapted by a reduction of the items examined to 12 issues which were deemed to be culturally relevant to Nigerians. The scores were recorded from zero where there was no difficulty to four where there was extreme difficulty. The intervening queries were a little difficult, somewhat difficult and very much difficult. The scores were recorded for each patient for both appliances and fed into a personal computer where they were analyzed. The item that seeks to assess nasalance of speech was omitted as some Nigerian languages were deemed to have nasal words and some Nigerians speak the English language with a nasal accent; the item assessing difficulty to pronounce words was omitted as it was deemed to be too subjective and the item asking about the appearance of the upper lip was omitted as it was considered superfluous as there was already an item which asked about satisfaction with appearance. Data were analysed using the paired t-test on mean obturator functioning scores. The level of significance was set at $p < 0.05$.

Results

Twelve individuals participated in the trial. There were 5 males and 7 females. The ages of the participants ranged from 21 to 66 years with a mean age of 39.67 years and a standard deviation of 14.39. All the participants fulfilled the criteria for enrolment in the study.

The results of application of the modified obturator functioning scale questionnaire were as shown in Tables I and II. For the silicone soft liner lined obturator bulb group 8 patients (66.7%) claimed not to have any problems with chewing, while 4 (33.3%) reported a little difficulty with chewing. Ten (83.3%) had no difficulty with leakage from the appliances while swallowing, while 2 (16.7%) reported a little difficulty.

Three (25%) had no difficulties with differences in their voice quality as compared to pre-operative quality, while 7 (58.3%) reported a little difficulty and 2 (16.7%) reported very much difficulty. Eleven (91.7%) had no difficulty talking in public while 1 (8.3%) had a little difficulty talking in public. All (100%) claimed that their listeners had no difficulty understanding their speech. While 11 patients (91.7%) had no difficulty talking on the phone, 1 patient (8.3%) experienced a little difficulty with phone calls.

Ten (83.3%) experienced no difficulties with dry mouth, 2 (16.7%) reported a little difficulty with dry mouth. Seven

Table I: Reported difficulties with silicone lined obturators.

	Not at all. Score (0)	A little difficult. Score (1)	Somewhat difficult. Score(2)	Very much difficult Score (3)	Extremely Difficult Score(4
1. eating problems					
-Difficulty in chewing foods	9(75%)	3(25%)	0(0%)	0(0%)	0(0%)
-Leakage when swallowing	10(83.3%)	2(16.7%)	0(0%)	0(0%)	0(0%)
2. Speech problems					
- Voice different from before surgery	3(25%)	7(58.3%)	0(0%)	2(16.7%)	0(0%)
-Difficulty talking in public	11(91.7%)	1(8.3%)	0(0%)	0(0%)	0(0%)
- Speech is difficult to understand	12(100%)	0(0%)	0(0%)	0(0%)	0(0)%
-Difficulty talking on the phone	11(91.7%)	1(8.3%)	0(0%)	0(0%)	0(0%0
3. Other items in scale					
- Mouth feels dry	10(83.3%)	2(16.7%)	0(0%)	0(0%)	0(0%)
-Dissatisfaction with looks	7(58.3%)	2(16.7%)	3(25%)	0(0%)	0(0%)
- Clasp on front teeth noticeable	3(25%)	9(75%)	0(0%)	0(0%)	0(0%)
- Any area feels numb	10(83.3%)	2(16.7%)	0(0%)	0(0%)	0(0%)
- Avoidance of family or social events	6(50%)	3(25%)	2(16.7%)	1(8.3%)	0(0%)
- Difficulty to insert or remove obturator	12(100%)	0(0%)	0(0%)	0(0%)	0(0%)

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(58.3%) had no difficulty with their appearance, 2 (16.7%) had a little difficulty. while 3 (25%) found their appearance somewhat difficult to cope with. Four (33.3%) had no difficulty with anterior clasps showing while 8 patients (66.7%) found this a little difficult. Ten (83.3%) had no difficulties with numb areas while 2 (16.7%) had a little difficulty with this.

Half of the patients 6 (50%) reported no difficulty with appearing at public functions, 3(25%) found this a little difficult, 2 (16.7%) found this somewhat difficult while one patient (8.3%) found this to be very much difficult to do. All the patients (100%) had no difficulty with inserting and removing the appliances.

For the all acrylic bulb group, Table II, two patients (16.7%) had no difficulty with chewing, 5 (41.7%) experienced a little difficulty. Two patients (16.7%) found chewing somewhat difficult while 3 (25%) found chewing very much be somewhat and very much difficult respectively. Eight patients (66.7%) had no difficulty talking in public, 3 (25%) had a little difficulty while 1 (8.3%) found talking in public to be very much difficult. 11 (91.7%) claimed they had no difficulty with their listeners understanding them, while 1 (8.3%) experienced a little difficulty with his listeners. Ten (83.3%) had no difficulty talking on the phone while the other two (16.7%) experienced a little difficulty and found this somewhat difficult respectively.

Ten (83.3%) had no difficulty with dry mouth while 2 (16.7%) experienced a little difficulty in this regard. Four patients (33.3%) had no difficulty with their looks, 4 (33.3%) had a little difficulty with their looks, 2 (16.7%) found their appearance somewhat difficult to accept and the other 2 (16.7%) were very much dissatisfied with their looks even after optimum prosthetic rehabilitation possible. Three (25%) had no difficulty with anterior clasps showing, 7

Table II: Reported difficulties with all acrylic obturators

	Not at all Score(0)	A little difficult Score(1)	Somewhat difficult Score(2)	Very much difficult Score(3)	Extremely difficult Score(4)
1. eating problems					
-Difficulty in chewing food	2(16.7%)	5(41.7%)	2(16.7%)	3(25%)	0(0%)
- Leakage when swallowing	5(41.7%)	2(16.7%)	2(16.7%)	3(25%)	0(0%)
2. Speech problems					
- Voice different from before surgery	3(25%)	6(50%)	2(16.7%)	1(8.3%)	0(0%)
-Difficulty talking in public	8(66.7%)	3(25%)	1(8.3%)	0(0%)	0(0%)
- Speech is difficult to understand	11(91.7%)	1(8.3%)	0(0%)	0(0%)	0(0%)
-Difficulty talking on the phone	10(83.3%)	1(8.3%)	1(8.3%)	0(0%)	0(0%)
3. Other items in scale					
- Mouth feels dry	10(83.3%)	2(16.7%)	0(0%)	0(0%)	0(0%)
- Dissatisfaction with looks	4(33.3%)	4(33.3%)	2(16.7%)	2(16.7%)	0(0%)
- Clasp on front teeth noticeable	3(25%)	7(58.3%)	2(16.7%)	0(0%)	0(0%)
- Any area feels numb	10(83.3%)	1(8.3%)	1(8.3%)	0(0%)	0(0%)
- Avoidance of family or social events	6(50%)	4(33.3%)	1(8.3%)	1(8.3%)	0(0%)
- Difficulty to insert or remove obturator	12(100%)	0(0%)	0(0%)	0(0%)	0(0%)

Table III: Comparison of functioning scores between silicone lined and all acrylic obturators

	N	Mean(SD)	Paired T value	P value
OFSS1	12	4.25 ± 3.05	4.07	0.002
OFSACR	12	8.00 ± 4.29		

difficult. Five (41.7%) had no difficulty with leakage, 2 (16.7%) found this a little difficult, another 2 (16.7%) found this a somewhat difficult problem and 3 (25%) found this to be a very much difficult problem.

Three (25%) reported no difference in the voice quality as compared to pre-surgical voice quality, 6 (50%) found this a little difficult; 2 (16.7%) and 1 (8.3%) found the problem to (58.3%) had a little difficulty while 2 found this to be somewhat of a problem. Ten (83.3%) had no difficulties with numb areas while 1 (8.3%) had a little difficulty. The last patient reported having a somewhat difficult time with numb areas.

Six (50%) had no difficulty with attending social functions, 4 (33.3%) had a little difficulty, 1 (8.3%) found attending

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social functions somewhat difficult and 1 (8.3%) found this extremely difficult. All the patients (100%) had no difficulty inserting and removing the appliances.

The mean modified obturator functioning score for the silicone lined obturator was 4.25, while that for the all acrylic obturator was 8.00. The standard deviations were 3.05 and 4.29 respectively, Table III. The data was subjected to a two tailed paired sample t-test, $p = 0.002$.

Discussion

There have been several studies undertaken to assess the quality of life of rehabilitated maxillectomy patients and most of these studies have involved the administration of questionnaires.[8, 15, 16, 17] Kornblith et. al. proposed the Obturator Functioning Scale (OFS) and propounded the theory that obturator function was the single most important factor in the determination of quality of life of the rehabilitated patient.[16, 17] They went on to further postulate based on an analysis of the results they obtained from their studies that specific aspects of obturator functioning which most significantly affected adjustment of the patient were less difficulty in swallowing, chewing and in pronouncing words and less change in post surgical voice quality.[8, 16] This gave a guide in modifying this scale to suit the Nigerian cultural values.

The OFS has been used as the only questionnaire for the assessment of quality of life among patients that had prosthetic obturation as the sole rehabilitative procedure.[20, 21] It has been used to assess the impact of obturation from different centers on patients [20] and also used to compare the level of subjective patient satisfaction to an objective technical assessment of the quality of patients speech.[21] Based on these studies, this instrument was used as the sole means of assessing the patients' satisfaction with each type of obturator bulb material.

This study found that majority of the patients were more satisfied with the performance of the silicone lined obturators with regards to chewing and swallowing than with the acrylic obturators. About 67.7% and 83.3% of the patients reported no difficulty in these regards with the silicone lined prostheses respectively as against 16.7% and 41.7% with the all acrylic prostheses respectively. Most of the patients reported high levels of dissatisfaction with the all acrylic prostheses with regards to mastication. Three patients or 25% of patients reported "very much difficulty" with these prosthesis for both chewing and swallowing as compared to none with the silicone lined prostheses. These results are in keeping with the observations of previous investigators.[22, 23] Kanazawa et. al.[22] called attention to the resilience of silicone which potentially makes obturators lined with this material more retentive and stable by engaging undercuts in the defect. This potentially will facilitate easier mastication as the appliance is likely to be more comfortable for the patient to chew on without the fear of embarrassment. The softer nature of this material will also cushion the impact of the masticatory force on the delicate tissues within the defect.

The ability of the silicone to engage the tissues of the defect more intimately also ensures a better seal and reduces the likelihood of leakage during swallowing. The seal obtained in this way with the silicone material would be impossible with the acrylic bulbs as excess undercuts must be blocked out before the appliance can be inserted and removed by the patient.

The self-reported impact of obturators on speech problems shows similarity in patients' perception of the effect of both types on obturators on their speech. Identical number of patients (25%) had no difficulty with their present voice as compared to their pre-surgical voices. A higher number of patients (91.7%) were more comfortable talking in public with the silicone lined appliances than those who reported no difficulty with the all acrylic obturators (66.7%). This could be explained from the extra confidence that they would feel from a better fitting and more stable silicone lined obturator.

The scores for the level of people understanding patients' speech and that for the ability to converse on the phone was taken as an effective representation of the ability of the Nigerian patient's ability to pronounce words properly. The scores for these parameters were similar within and across the groups. The foregoing points to the fact that the material used in obturation has less impact on patients speech.[24] The results also suggest that patients have increased confidence with the silicone obturators probably due to an apparently better level of retention and stability that may be obtained with these appliances.

The responses to the other questions in the questionnaire were generally similar and in certain areas almost identical. The mean score for the silicone obturators with the modified OFS was 4.25 while that for the acrylic obturators was 8.0. These scores were subjected to a paired t-test and were found to be significantly different, $p < 0.05$. This clearly shows that most of the patients studied preferred the silicone lined obturators to the acrylic obturators. This preference was mainly due to the greater ease with which they could feed with the former and probably the greater confidence they obtain from its better retention and stability.

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