

# Patient Satisfaction and OHRQL in Patients Receiving Definitive Obturators Fabricated from Combination of Polyetherether Ketone, Heat Cure PMMA, and Silicone-Based Soft Liners

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**Abstract Aim:** This clinical research designed to estimate Patient Satisfaction and Oral Health Related quality of Life in Partial Maxillectomy Patients receiving Definitive Obturators Fabricated from Combination of Polyetherether Ketone, Heat Cure PMMA, and Silicone-Based Soft Liners. **Materials and Methods:** 12 individuals with acquired maxillary defects were selected to undergo prosthetic rehabilitation with obturator fabricated from combination of PEEK framework, heat cured PMMA lined with silicone. Clinical Evaluation determined the classification and extension of maxillary defects. A grading method was used to assess how the definitive obturator is retentive and stable. The self-described effectiveness of definitive obturator was assessed using Obturator Functioning Scale and visual analogue scale. **Results:** Clinical results revealed that most of participants were classified as Class III Aramany classification and many of them expressed that their obturators were appropriately retentive and stable. There were close correlations in between the Aramany classification and the retention. The Obturator Functioning Scale expressed acceptable satisfying results regarding mastication, speech, and appearance. These results were improved during the follow-up periods after 3 and 9 months. The patients exhibited an average VAS score of 59.99 mm. (SD +19.46 mm, medium 65.00 mm, (0-100 mm)). **Conclusion:** A combination of PEEK framework and heat cure PMMA lined with silicone proved to be a successful and well-tolerated material for obturator fabrication with several advantages in terms of weight, biocompatibility, good retention and stability and patient's positive response and satisfaction.

**Keywords:** *peek, obturator function scale, visual analog scale, HRQL*

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## 1. Introduction

Maxillofacial defects could possess a profound effect on various characteristics of life, such as esthetics, speech, masticatory function, and overall comfort. These defects may result from either congenital conditions or acquired through trauma, surgery, or other medical interventions. The complexity of these defects, involving bone, muscle, cartilage, and mucosal layers, necessitates a comprehensive and multidisciplinary approach for effective reconstruction. [1] The use of a maxillary obturator is a crucial component in addressing such defects. This prosthesis plays a significant role in partially or completely filling the acquired or congenital defect, separating oral and nasal cavities, and restoring functional

and aesthetic aspects. By doing so, it contributes to improved phonetics, masticator efficiency, and overall comfort for the individual. [2] Reconstructive procedures for maxillofacial defects are often intricate and time-consuming, requiring collaboration among various medical professionals such as oral and maxillofacial surgeons, prosthodontists, otolaryngologists, and other specialists. [3] This multidisciplinary rehabilitation process is crucial for achieving comprehensive and satisfactory outcomes. This includes the patient's psychological, physical, and social aspects of life. The restoration of social standing is an important consideration in the rehabilitation process, as it helps individuals reintegrate into society with confidence and an improved quality of life. [4] The use of a maxillary obturator is one important aspect of this process, contributing to both functional and aesthetic restoration. A systematic rehabilitation strategy is essential to address

the multifaceted nature of these defects and to improve the overall well-being and social standing of the affected individuals [5]. The choice of the obturator materials has evolved over time. Traditionally, CoCr frameworks and heat cured PMMA have been commonly used. However, acrylic resin can sometimes cause irritation and may not always provide sufficient retention and comfort. One significant challenge of metallic obturators is its heavy weight in case of large defects. [3] This added weight can contribute to discomfort for the patient. Additionally, concerns related to allergic reactions and esthetics may arise in some cases. To address these challenges, various strategies have been explored. One approach involves the application of titanium and the making of a hollow bulb obturator. Castable titanium allows for a lighter framework while still maintaining the strength required for functional use. [6] An alternative material that has gained attention in dentistry, including in removable prosthodontics, is polyetheretherketone (PEEK). PEEK is an inert, nonallergic biocompatible material, with a smooth surface so inhibits accumulation of plaque. Furthermore, PEEK's modulus of elasticity and mechanical properties closely match bone making it a promising material to be used in obturator framework construction. [7] The use of metal frameworks combined with acrylic resin for maxillary obturators has been a common practice, but concerns related to weight, allergic reactions, and esthetics have prompted exploration of alternative materials. Castable titanium and PEEK have emerged as promising alternatives, with PEEK offering a combination of excellent biocompatibility, aesthetic properties, and mechanical strength for the fabrication of maxillary obturator frameworks. [8]

Health-related Quality of Life is described as personal, multifactorial constructs affected by the individual's internal frame of reference. Maxillectomy Patients are anxious regarding the anticipated post-resection QoL. This suggests that patient-reported experiences and perceptions play a crucial role in evaluating the effectiveness of obturator prostheses. It highlights the potential positive impact of well-designed obturators on QoL but acknowledges challenges, such as patient acceptance and issues with obturator fit. Additionally, the subjective assessment of obturator function is deemed significant, emphasizing the need to incorporate patient perspectives in evaluating rehabilitation outcomes. [9] Obturator Functioning Scale (OFS) considered one of the best utilized methods to grade OHRQOL evaluating self-testified objectives of an obturator. The OFS assesses masticatory efficiency, phonetics, and esthetics. It involves 15 subjects to evaluate eating speech esthetic results of obturator construction. All elements were graded on Likert scale that consists of 5-points. [10]

The aim of current clinical research was to estimate patient satisfaction and OHRQOL in partial Maxillectomy individuals receiving definitive obturators fabricated from combination of Polyetherether ketone, heat cure Polymethylmethacrylate, and silicone-based soft liners.

## 2. Materials and Methods

Twelve individuals, with age group between 37 and 55 years old, were designated in present investigation with

history of acceptable, healthy, stable, and hygienic acquired partial maxillary defects (Figure 1) and didn't receive chemotherapy or radiotherapy at least for one year.



**Figure 1.** Clinical Feature of Stable Partial Maxillary Defect

The patients did not undergo any prosthetic treatment before and looked for appropriate prostheses restoring their previous esthetic, speech, and masticatory functions. Prosthetic rehabilitation was premeditated and completed at Prosthodontic specialty clinics at Taif University dental hospital in following Helsinki Declaration. The treatment plans were explained in detail, then approved by the patient. Usual past-medical and past-dental histories were taken. Panoramic x-ray and CT of the defect site were conducted. An irreversible hydrocolloid impression material\* was used for the initial diagnostic impression. Undesirable Soft tissue walls were avoided, and the required modifications were made in the stock tray. This type of impression material is commonly used for its ease of use and accurate detail reproduction. The diagnostic cast, likely created from the diagnostic impression, was surveyed. Surveying involves the assessment of the cast to identify features like undercuts, tissue undercuts, and the overall topography of the oral structures. A tripod designs were chosen based on Aramany design principles [11], that guide the classification and treatment planning for maxillectomy defects. Any necessary adjustments or modifications to enhance the fit and function of the prosthetic device were done through mouth preparation. Then secondary impression was registered by Medium Flow material\*\*. Polyvinyl siloxane is known for its accuracy and stability, making it suitable for capturing the fine details required for the fabrication of dental prostheses. The framework pattern for the PEEK framework (Figure 2) was created on a duplicated model. This involves sculpting the pattern to match the desired design for the maxillary obturator.

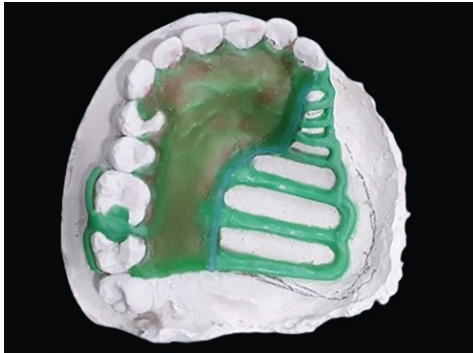
Spruing, investing, burnout procedures were done leaving a mold cavity that will be filled with PEEK\*\*\* during the pressing process at 400°C for 43 minutes. Then the framework underwent finishing and polishing. This step is crucial for ensuring a smooth surface, comfortable fit, and esthetic appearance of the framework. The completed PEEK framework was tried intraorally. This step involved placing the framework in its place to assess

\* Tropicalgin, Zhermack SpA, Bovazecchino, Italy.

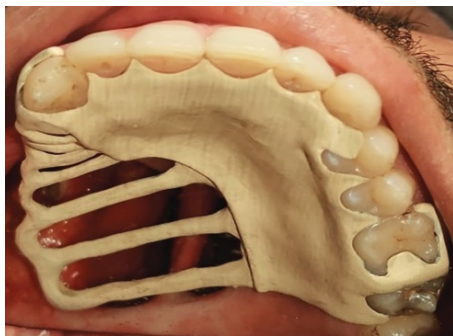
\*\* Variotime@Medium Flow Refill, Kulzer GmbH, Leipziger Straße 263450 Hanau, Germany.

\*\*\* BioHPP®, Bredent, Chesterfield, UK

fitness, retention, and overall comfort. Any necessary adjustments may be made at this stage to achieve the desired outcomes. (Figure 3)



**Figure 2.** tripod design Wax pattern based on Armany classification



**Figure 3.** PEEK frameworks try in

A special tray was manufactured over the maxillectomy area of the framework and green stick compound\*\*\*\* was used for border molding. This process enhances the border seal and records the antral part of the defect. Polyether medium body impression material\*\*\*\*\* was utilized to take the definitive impression, recording all the desired walls of the defect to enhance obturator retention. Recording maxillomandibular relationship were made and transmitted into a semi adjustable articulator\*\*\*\*\*. Setting up of artificial teeth was completed on the articulator. Occlusion, esthetics, and speech were checked at try-in step (Figure 4).

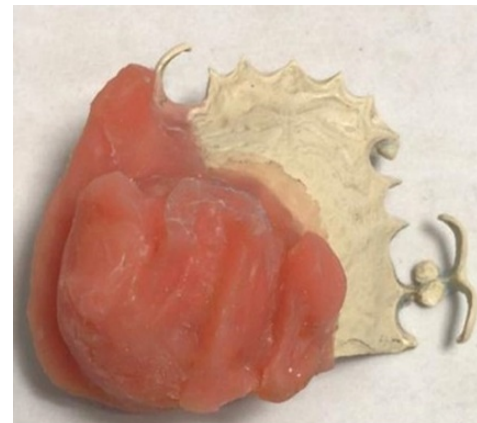
After that, the obturator part was manufactured from heat cured PMMA through typical procedures [12-15]. After finishing and polishing, Retentive slots and grooves were created on the bulb section for subsequent relining with soft liner\*\*\*\*\*. Cyanoacrylate adhesive\*\*\*\*\* were used ensure attachment between PMMA and silicone. [16] (Figure 5)

The definitive obturator was assessed to check retention, stability, and overall comfort (Figure 6). These factors are crucial for the successful functioning of the obturator and the patient comfort. The prosthesis weight was notably reduced, measuring 25.85 grams. This reduction in weight

is likely a positive outcome, addressing concerns related to the weight of prostheses in cases of maxillary defects. [17]



**Figure 4.** Wax try-in step



**Figure 5.** Definitive Obturator made from combination of PEEK Framework, Heat Cure PMMA, And Silicone Based Soft Liner



**Figure 6.** Definitive Obturator in place

Following the insertion of the obturator, postinsertion results showed improvement in several aspects: Enhancement in speech clarity, Improved ability to chew and masticate, Improved swallowing function, and Positive changes in the appearance of the prosthetic restoration. The PEEK framework was good tolerated by the oral tissues. This indicates that PEEK's application as a framework has been well-tolerated by the patient's tissues, suggesting good biocompatibility.

### 3. Evaluations

#### Clinical Evaluation

Determine the classification and extension of maxillary defects. A grading method was used to assess the degree of retention and stability of the definitive obturator. [18,19]

\*\*\*\* MAARC Green Tracing Sticks, IndiaMART InterMESH Ltd.Uttar Pradesh, India.

\*\*\*\*\* Variotime@Medium Flow Refill, Kulzer GmbH, Leipziger Straße 263450 Hanau, Germany.

\*\*\*\*\* A7 Plus C.S.A Articulator, CORIDENT,Chimsan-dong, Buk-gu Daegu, South Korea

\*\*\*\*\* RELINE II Soft Silicone-based Relining, GC Corporation, Tokyo, Japan.

\*\*\*\*\* GC Adhesive Universal, GC Corporation, Tokyo, Japan.



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المتغيرات	عدد المرضى	مطلقا	قليلًا	الى حد ما	كثيرًا	لاقصى حد
1						
صعوبة في مضغ الأطعمة						
2						
التسرب عند بلع الأطعمة						
3						
صوت مختلف عما كان عليه قبل الجراحة						
4						
صعوبة التحدث في الأماكن العامة						
5						
الكلام النقي						
6						
صعوبة في نطق الكلمات						
7						
الكلام صعب الفهم						
8						
صعوبة التحدث على الهاتف						
9						
يشعر بجفاف الفم						
10						
عدم الرضا عن المظهر						
11						
المضيق على الأسنان الأمامية ملحوظ						
12						
أي منطقة تشعر بالخدر						
13						
تجنب المناسبات العائلية أو الاجتماعية						
14						
صعوبة إدخال أو إزالة الطقم الجراحي						
15						
الثقة العليا تبدو مضحكة						

Figure 7. Arabic version of Functional Obturator Scale

### Obturator Functioning Scale

The self-described effectiveness of definitive obturator was assessed using Obturator Functioning Scale (OFS) [10] that assesses Patient satisfaction regarding mastication, phonetics, and esthetic. The Likert scale consists of 5-points was utilized (“never i.e., not at all, a little or minimum, slightly or somewhat, more difficulty, exceedingly difficult”). A translated form of the Obturator Functioning Scale into Arabic language (Figure 7) was created, and patients were requested to fill it. This questionnaires were presented at the time of insertion of the obturator, after 3 months, and after 9 months follow up period.

### visual analogue scale

This is a vertical ordered measurement with 10 mm. intervals. The scale assists individuals to define their health condition either good or bad. The patients were directed to mark the scale that actually exhibit the strength of their indicators. The findings were stated in mm. beginning with “0” to “100”. [20] All the questionnaire statistics were collected and analyzed using SPSS 19.

## 4. Results

### Clinical findings

33.3% of patients’ defects Class I Aramany classification while, 50% were classified as Class II, in contrast Class III (0%), Class IV (8.3%), and class VI (8.3%). Almost 75 % of patients had partial maxillary defects, while hemi- and subtotal maxillectomies were detected in 16.6 % and 8.3% respectively. About 58.3% of patients expressed that their obturators were appropriately retentive, 8.3% expressed little, 25 % medium, and 8.3% were not retentive. 41.6% of patients expressed good stability, 33.3% recorded that their obturators were somewhat stable and 25% no stability. There were close

correlations in between the Aramany classification and the retention.

Table 1 exhibits the patient replies of the questionnaire, At the time of delivery, 8.3 % of individuals described minimum or negative eating struggle. 16.6 % had negative or minor seepage during mastication. The mainstream (83.3%) described no speech problems prior to maxillectomies that contrasts with speech problems after maxillectomies, when two (16.6 %) individuals stated high struggle during speaking in community (even though 16.6 % described minimum or negative problems). Above 33.3 % believed that they developed minimum or negative nasal speech. vocabulary Phonation wasn’t an obstacle in 33.3% of patients. Four people, nearly 33.3 % thought that there were minimal or negative problems to understand their speech and 16.6 % (two individuals) registered exceptional problem during speaking on the phone. Xerostomia was noted as not present or minor in 8.3 % (one patient) and two (16.6%) stated critical xerostomia. Two individuals (16.6%) were highly disappointed regarding their look however and nearly 25% expressed negative or minimal replies. The anterior clasps were not described to be highly visible by any patient (0.0%) while the majority (about 75%) described negative or minimal results. Numbness was absent in 100% of patents. Family or community events weren’t avoided by 8.3% of individuals, while 16.6 % described minimal and 8.3% stated that they avoid these events completely. Difficulty during obturator placing and removal was not or minimally detected in 75% of individuals while no one displays extreme problems. Only one patient (8.3%) was unpleasant with the appearance of his upper lip and four (33.3%) were not concerned. These results were improved during the follow-up periods after 3 and 9 months.

### Visual analogue scale scoring (VAS)

The patients exhibited an average VAS score of 59.99 mm. (SD  $\pm$ 19.46 mm, medium 65.00 mm, (0-100 mm).

**Table 1. Patients' answers of Functional Obturator Scale at the time of delivery**

	Question	Not at all (Never)	A little (minimum)	Somewhat	Very much	Extremely (High)
1	Mastication Troubles	0	1	2	8	1
2	Leakage when swallowing foods	1	1	2	7	1
3	Voice different from before surgery	9	1	1	0	0
4	Difficulty talking in public	0	2	4	4	2
5	Speech is nasal	0	1	8	2	1
6	Difficulty pronouncing words	1	3	6	2	0
7	Problem in understanding speech	1	3	6	1	1
8	Difficulty talking on the phone	0	2	5	3	2
9	Mouth feels dry	0	1	4	5	2
10	Dissatisfaction with looks	1	2	3	2	2
11	Clasp on front teeth noticeable	1	8	3	0	0
12	Any area feels numb	0	0	0	0	0
13	Family and community events escaping	1	2	7	1	1
14	Obturator insertion and removal problems	8	1	3	0	0
15	Upper lip looks funny	1	2	7	1	1

## 5. Discussion

The combined approach of surgical reconstruction and prosthodontics rehabilitation, including the use of definitive obturators, provides a comprehensive and effective solution for patients with maxillary defects. Optimal management varies according to defect extension, patient preferences, and the healthcare team experiences. [21] The use of different materials in the obturator production has evolved over the years. Certainly, combination CoCr framework with acrylic resin has been a conventional choice due to its proven track record and clinical success. However, there is a growing interest in alternative materials, such as Polyetheretherketone (PEEK), for the fabrication of various prostheses, including obturators. [7] CoCr is known for its high strength and durability, biocompatibility, and it has been used in dentistry for many years without causing adverse reactions in the oral environment while PEEK is considered highly biocompatible, and it has been widely used in medical and dental applications. It is inert, meaning it doesn't react with bodily fluids or tissues, reducing the risk of allergic reactions or corrosion. PEEK can be more esthetically pleasing than metal frameworks, as it is tooth-colored and can blend well with natural dentition. PEEK has the same mechanical properties as bone compared to metal alloys, potentially reducing stress on the surrounding tissues. It is lightweight, which can contribute to patient comfort. The use of PEEK in dental prosthetics is relatively newer compared to traditional materials. Long-term clinical studies are needed to establish its performance and longevity in the oral environment. PEEK may be more expensive than traditional materials, and cost considerations can influence material selection. Consideration of the patient's specific needs, such as allergies, esthetic preferences, and overall health, is crucial in material selection. [8,22] Incorporating

PEEK into the framework of a maxillary obturator prosthesis is suggested to address issues related to increased weight and bulkiness, especially in cases of larger defects. This approach aims to improve patient comfort and esthetics while ensuring that the essential function of retention is maintained by acrylic resin. The statement reflects an understanding of the balance between material properties, functional requirements, and patient-centered outcomes in prosthodontic rehabilitation. [17] Artopoulou et al., [23] suggested positive outcomes associated with the use of PEEK mainly Improvement in the Patient-Reported Outcomes such as mastication, phonetics, and appearance. Both PEEK construction approaches (injection molding & CAD/CAM) offer efficient, precise procedures for fabricating PEEK frameworks for dental prosthetics. Technique choosing may differ according to the production scale, need for customization, and the available resources in a dental laboratory or manufacturing facility. [24]

PEEK does not form a chemical bond with acrylic resin. This lack of chemical affinity can pose challenges in ensuring a strong and durable connection between the PEEK framework and the acrylic components of the obturator prosthesis. Mechanical retention involves creating features in the PEEK framework, such as undercuts or grooves, that mechanically interlock with PMMA, enhancing overall obturator stability. The obturator portion can be relined with soft liner to improve the prosthesis fitness, and retention and stability by creating soft and comfortable interface between the obturator and soft tissues. [16] Numerous studies have investigated the Quality of Life of individuals following cancer treatment. This includes assessments across various domains, such as physical health, psychological well-being, social interactions, and overall life satisfaction. These studies contribute significantly to understanding the holistic impact of cancer and its treatments on patients [25]. Despite extensive research on cancer and its

treatments, there's a relative paucity of literature specifically addressing the OHRQL of those experienced maxillary defects and are using obturator prostheses. Maxillectomy has profound functional and aesthetic implications, and obturator prostheses play a crucial role in rehabilitation. The limited focus on obturator prosthesis users implies a potential gap in understanding of the specific needs, challenges, and outcomes associated with this patient population. Research in this area could specify precious visions of the efficiency of obturator prostheses in successful Quality of Life. [26] The primary focus of this clinical research was on the patient acceptance and tolerance of PEEK framework and on the Quality of Life (QoL). This suggested a patient-centered approach assessing various aspects in the patients' lives following rehabilitation with definitive obturators. The study employed a scoring system utilized by Kapur to evaluate obturator retention and stability. The choice of the Kapur scoring system suggested a practical and straightforward approach to assessing these aspects without the need for specialized instruments. This implied that the scoring system is user-friendly and can be easily implemented in a clinical setting, making it potentially accessible for a wide range of healthcare professionals. The criteria used in the Kapur scoring system may include factors such as the prosthesis fit and stability and overall patient comfort.

Absence of important correlations among the Obturator Functioning Scale results and Visual Analog Scale were noteworthy, and it's interesting to observe that this finding is unexpected and differs from previous studies [26-28] where OFS typically correlated significantly with other Quality of Life (QoL) measurements. Some possible considerations and interpretations for this unexpected results may be the Differences in Measurement Tools: (OFS) and (VAS) may capture different aspects of patient experience and satisfaction. The tools used to measure QoL can vary in their sensitivity to specific dimensions of patient outcomes. If the two scales assess different aspects, a lack of correlation might be expected. Also, the OFS might be more specific to certain functional aspects related to obturator use, such as speech, mastication, and swallowing while VAS is more general or encompasses a broader range of factors, it might not show a strong correlation with the specific aspects covered by the OFS. In addition, differences in the study population, cultural factors, or other demographic variables may contribute to variations in how patients respond to different measurement tools. Patient populations can vary in terms of expectations, experiences, and how they perceive and rate their own QoL. QoL is a complex and multifaceted construct, and variations in study designs can lead to different findings. There could be methodological issues in the current study, such as sample size, selection bias, or the timing of assessments. Small sample sizes, for instance, might reduce the statistical power to detect significant correlations. The design and characteristics of the obturator prosthesis itself may influence patient experiences. For example, differences in materials, fit, or design could impact patient satisfaction in ways not captured by generic QoL measures. Careful interpretation of study findings, acknowledgment of potential limitations, and consideration of the unique characteristics of the patient population are essential in advancing our

understanding of QoL in individuals using obturator prostheses.

## 6. Conclusion

Within the limitation of this study, A combination of PEEK framework and heat cure PMMA lined with silicone proved to be a successful and well-tolerated material for obturator fabrication with several advantages in terms of weight, biocompatibility, good retention and stability and patient's positive response and satisfaction. The observation underscores the need for further research dedicated to understanding the lived experiences and QoL outcomes of individuals using obturator prostheses after maxillectomy. Future studies in this area could explore aspects such as patient satisfaction, adaptation to prosthetic devices, social and psychological impacts, and long-term outcomes.

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