

Patient-Centered Evaluation of Silicone Ocular Prostheses Fabricated by Two Different Techniques

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Abstract Aim: Assessment of the effect of prosthodontic rehabilitation with silicone ocular prostheses fabricated from two different techniques on patient satisfaction using a modified questionnaire **Material and Methods:** 14 participants grouped into two groups; Group A: Planned to receive conventional silicone ocular prosthesis and Group B: receiving silicone ocular prosthesis lined with PVC thermoplastic sheet (Sof-tray sheets). After 9 months of using the orbital prosthetic device, the patients replied to a 10 items survey including aesthetics, self-assurance, retention, awareness of the prosthesis, insertion and removal problems, prosthetic home cleaning, restriction of social events, distress, and inflammation of the soft tissues, and advising others to try this technique. Responses were conveyed into a modified 100-mm horizontal visual scale. Answers means were transferred into a % proportion to characterize the index of individual satisfaction. A Friedman trials were utilized to judge answers between the two groups. **Results:** Excellent satisfaction indexes were displayed for all questions by most of patients in both groups, regarding group (A), silicone ocular prosthesis without lining, the lowermost proportion was the awareness of the prosthetic device, and the maximum proportion was the easiness of prosthesis elimination from its position. For group (B), silicone ocular prosthesis with PVC lining, maximum proportion was the advising others to use this method of rehabilitation, and the lowermost proportion was the prostheses awareness. There were excellent improvements in group (B) compared to group (A) regarding tear resistance and fungal resistance. Statistically significant improvement in group (B) than group (A) ($p > 0.05$) regarding ease of prosthesis cleanup, inflammation of underlying soft tissues, and retention. The other variables showed no significant difference. **Conclusions:** Great rate of patient satisfaction displayed that ocular prostheses constructed from silicone alone (Group A) and silicone lined with PVC liner (Group B) are good methods for rehabilitation of patients with ocular defects. The advantages of PVC liner include improved fungal resistance, increased tear resistance

Keywords: silicone, PVC, ocular prosthetic devices, patient satisfaction

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1. Introduction

The demand for prosthetic restoration of facial parts and tissues has been on the rise, driven by various factors such as congenital conditions, traumatic injuries, tumors, and diseases. The restoration of facial defects poses a complex challenge that often requires a multidisciplinary approach involving surgeons, prosthodontists, and other specialists [1]. Orbital deformities indeed have profound implications for individuals beyond the loss of vision. These deformities often extend beyond functional limitations to impact aesthetic appearance and social interactions, significantly affecting the overall quality of life [2]. The orbital region presents unique challenges for surgical reconstruction compared to other areas of the face. While plastic surgery procedures have made significant

advancements in repairing and reconstructing various facial features, the orbital region poses specific difficulties, particularly after extensive tumor resections, such as complex anatomy, limited tissue availability, functional considerations, cosmetic and aesthetic challenges, and risk of complications [3]. Prosthodontic rehabilitation faces several challenges, and limitations such as ineffective materials, the dynamic nature of skin and muscles, lack of underlying structures for support and retention especially in large defects, and patient satisfaction [1]. Advancements in 3D printing technology and computer-aided design have also contributed to improvements in facial prosthetics. These technologies allow for more precise customization of prostheses to match the patient's unique facial anatomy [4,5]. Silicone could be utilized in the construction of maxillofacial prosthesis as they are durable, flexible and have lifelike texture and color. However, silicone prostheses come with certain limitations related to

longevity, maintenance, low tear resistance, replacement necessity, and fungal growth affinity [6]. Numerous studies [1] [7-11] have been published to enhance silicone properties such as adding polyurethane sheets and polypropylene fibers. Polyurethane (PU) Liners provide a supportive substructure on the tissue-bearing surface of the prosthesis. This added support can contribute to improved durability, improvement in edge tear resistance, increased fungal resistance which is important for maintaining hygiene and preventing complications. Despite the advantages, PU liners come with certain limitations, including technique sensitivity during fabrication. Additionally, concerns about yellowish discoloration and the metameric effect (color changes under different lighting conditions) have been reported. Incorporating the Polyurethane sheets at the processing step of a definitive prosthesis may preclude the possibility of a try-in for fitting surface evaluation. This can be a limitation in ensuring optimal fit and patient comfort [7-9]. The use of Polyvinyl chloride (PVC) liners to reinforce silicone was suggested to improve the properties of silicone and at the same time overcome the disadvantages of PU liners [10-11].

2. Materials and Methods



Figure 1. Careful examination of the defect side

14 patients were selected from the prosthodontic specialty clinics in Taif university dental hospital. These patients were referred from departments of ophthalmology in several hospitals in Taif governorate as community services for the region of Taif. Patients were asked to contribute to this research. The consent forms were signed by Contributing individuals. This research was authorized by the Committee of Research Ethics in Taif University, Taif city, KSA. Four patients refused to publish their photos, so the decision was taken to complete their rehabilitation without publishing their photos. Detailed history and Careful clinical examination of the defect were done (Figure 1) including of the cause of the defect, examination all the walls of the defect detecting undercuts, degree of healing of the defect, presence of pain, discomfort[3]. Patients grouped into two groups; Group A: Planned to receive conventional silicone ocular prosthesis and Group B: receiving silicone ocular prosthesis lined

The QOL is a well-articulated multi-dimensional and subjective concept which covers several features of a person's acceptance in different areas of life. The dynamic concept of QOL may be affected by different elements, involving ethnic, community, financial factors. Additionally, individual perspectives on what constitutes a high quality of life may differ based on personal values, cultural background, and life experiences [12]. The evolution of aesthetic reconstruction for orbital deformities, especially using orbital prostheses, has indeed undergone significant advancements [12,13]. Assessing satisfaction of patient represent a necessary evaluation of the clinical value of these techniques. Beyond technical considerations, improvements in quality of life are important indicators for the success of these prosthetic interventions [14].

So, this research aimed to evaluate and compare satisfaction of patients with silicone ocular prostheses fabricated from two different techniques, silicone alone and silicone lined with PVC sheets through a modified QOL questionnaire.

with PVC thermoplastic sheet (Sof-tray sheets). For both Groups, Fabrication of ocular prosthetic device includes the subsequent steps: Primary impression, special tray construction, definitive impression, hemi-facial impression, selection of Iris, try-in of the waxed or clay pattern and Construction of definitive prosthetic device [6]. The patients were placed on the dental chair with the back rest parallel to the floor so that the defects were facing up, and the defects were painted with separating medium or Vaseline to facilitate impression removal. The defective area was surrounded with boxing wax¹ (Figure 2) then, impressions of the defective area were made by thin, soft mix of irreversible hydrocolloids². The impressions were reinforced with a piece of gauze or by pre-bent L- shaped

1 Technowax®-Baseplate, Protechno, Girona, Spain
2 Kromalgin, Vannini Dental Industry, Italy.

paper clips and a layer of plaster. The whole constitutions were removed, taking care about undercut direction to avoid tear of the impression [1].



Figure 2. Boxing And Primary Impression of The Defect

Plaster Study models were cast and utilized to create special trays. This custom-made trays were produced by adjusting the mixing tips of light body impression by adapting auto polymerized polymethylmethacrylate³ on the study cast to form a concavity with several escaping perforation and groves then attaching mixing tip (Figure 3a.). Final impressions were taken with Light flow rubber base⁴ (Figure 3b) and participants were requested to do eyeball functional movements. Hard type IV dental stone⁵ were used to pour the master casts. For simple repeated re-orientation of clay or wax sculpture, all borders (upper, lower, medial, and lateral)of the master cast were written on the cast. In addition to the defect impression, it is preferred to have impressions of the upper half of the face (hemi-facial). This area was boxed using modelling wax and thin, extra soft mix of Alginate impression materials were applied over the entire area. As alginate set, wet gauze was applied over it and stone mixes were painted over the gauze to support alginate throughout the casting process. Hollow tubes were placed in the patient's nose during the impression registration to maintain breathing. Type III gypsum products⁶ were used to prepare refractory cast for facial moulage (Figure 4) For Group B, Soft, thin PVC sheets were adapted on the orbital defect master cast (Figure 5) and gently strip it off to Verify its fit and the need of any adjustments on the patient defect . Featheredge the liner borders to certain integration of the margins with surrounding skin. Clay Orbital Prosthesis were then Sculpted using the linear measurements from the pupil center to the midline of the face[15]. The eye outer and inner canthus were drawn on the facial moulage to aid detecting the proper iris position (Figure 6). Vernier calipers were used to measure the iris sizes of normal eyes

that helped selection suitable and similar colors and sizes from the available readymade irises and put them in its place in the clay pattern. The eye clay pattern was tested on the patient face to guarantee that it was a mirror image of the healthy eye, checking prosthesis insertion, removal, fitness, precise horizontal alignment. Any esthetic corrections , accurate locations of irises, colour matching, dimensions, and quantity of visible sclera, in comparison with normal eyes were completed at that time .Then tried-on clay - pattern were flaked and processed conventionally to produce mold cavity to receive silicone.(Figure 7) The definitive ocular prostheses were constructed from silicone elastomer giving it a very natural appearance. Manufacture's recommendations were followed during handling of the material. MDX4-4210-base and catalyst were blended in weight proportion of 10:1 in a Vacuum deaeration to decrease entrapment of air. After that, silicone was packed into the mold [1]. As different parts of facial features vary in colour, different parts of the prosthesis were shaded in different colors by both intrinsic and extrinsic procedures [16].

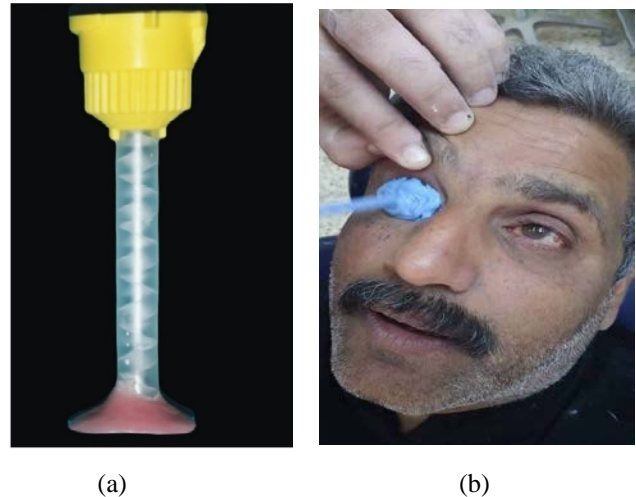


Figure 3. (a). Modified Mixing tip, (b):Final Impression of the defect

After finishing the processing, the prostheses were deflaked, carefully removed, and completed using specific silicone refining tools. Thin layers of Pros-Aide Adhesive⁷ were applied on the prostheses and inserted on the defects. Detailed repetitive information about the importance of home care was given to the patient. Regular recall visits were approved to gauge ocular prosthesis handling and concern. [1]

Because of small number of participants in such research, slight modifications, and changes in Sloan et al's questionnaire [17] were utilized to assess the patient's feelings about their ocular prostheses, the first modification was creation an accurate Arabic version (Figure 9) of the survey to guarantee more clearance of the original questionnaire items. The second modification was the using of a visual analogue scale (VAS) varying between zero and one hundred mm. expressing patient's responses. The survey included ten items that evaluated the grade of patient response concerning several points:

³ Eco-cryl cold. Protechno, Girona, Spain.

⁴Variotime@Light Flow Refill, Kulzer GmbH, Leipziger Straße 263450 Hanau, Germany.

⁵ Durguix, Protechno, Girona, Spain

⁶ ACUAVEST, Protechno, Girona, Spain

⁷ Factor II, Inc., Lakeside, Ariz., USA.

aesthetics, retaining the prosthesis in position, prostheses Conspicuousness, self-assurance, easiness of insertion, removing and cleaning the prosthesis, restriction of participating in social events, lack of distress and inflammation of the underlying soft tissues, and advising other patients to go through this method of rehabilitation.



Figure 4. Master cast of the facial moulage



Figure 5. Polyvinyl chloride liner applied on master cast



Figure 6. Clay pattern of sculpted on the facial moulage



Figure 7. The dewaxed duplicated cast

The Arabic versions of the Survey were handed to participants and the assistant clarified every item, explain the range of answers (Not satisfied at all which corresponded to 0-20mm on the VAS horizontal line, little satisfied corresponded to 21-40 mm on the VAS horizontal line, somewhat satisfied corresponded to 41-70mm on the VAS horizontal line, very satisfied corresponded to 71-85 mm on the VAS horizontal line and extremely satisfied corresponded to 86-100 mm on the VAS horizontal line). Contributors responded to each item by choosing only one point that exactly represented their satisfaction degree. Data were collected and arranged and the mean of the VAS responses in mm of every answer was transferred into % of satisfaction regarding every question. Participants were allowed to make remarks on every item that were recorded and evaluated to improve our data of individual responses [18-20].

3. Results

Participants displayed superior satisfaction levels for all survey questions in both groups. Regarding group (A), silicone ocular prosthesis without lining, the lowest rate being 78.5 % for Conspicuousness of the prostheses and the highest being 93.7% for easiness of prosthesis removal. Superior levels were found concerning easiness of insertion (92.4%), Recommendation to others (90.2%), retention efficacy (87.2%), Enhancement of self-assurance (84.6), lack of distress and inflammation of the underlying soft tissues (83.2%), ease of cleaning (82.4%), No limitation to activities (80.5%), and Appearance (79.9). For group (B), silicone ocular prosthesis with PVC lining, highest rate being 94.1% for Recommendation to others, and the lowest rate being 80.2 % for Conspicuousness of the prostheses. High satisfaction rates were obtained regarding lack of distress and inflammation of the underlying soft tissues (90.5%), retention efficacy (90.3%), Enhancement of self-assurance (89.7%), Easy placement (88.2%), Ease of cleaning (87.6%), Ease of removal(86.7%), No limitation to activities(83.2%) and appearance (82.2%). There were statistically significant improvements ($p < 0.05$) in group (B) than group (A) regarding Ease of cleaning, lack of distress and inflammation of the underlying soft tissues, and efficiency of retention while it was insignificant ($p > 0.05$) regarding the rest of survey questions (Table 1).



Figure 8. Final prosthesis inserted in position

 						
<p>استبانة مدى رضاه المريض وجودة الحياة المتعلقة بصحة الفم لدى المرضى الذين يستخدمون جهاز تعويضي للعين</p>						
ملاحظات	م	غير راضي على الإطلاق	راضي قليلا	راضي الى حد ما	راضي كثيرا	راضي لأقصى حد
		مقياس التناظرية البصرية (٢٠٠٠)	مقياس التناظرية البصرية (٤٠-٢١)	مقياس التناظرية البصرية (٧٠-٤١)	مقياس التناظرية البصرية (٨٥-٧١)	مقياس التناظرية البصرية (١٠٠-٨٦)
	١					
	٢					
	٣					
	٤					
	٥					
	٦					
	٧					
	٨					
	٩					
	١٠					

Figure 9. Arabic version of the patient satisfaction and QOL questionnaire

Table 1. patient perception with both groups

Variable	% of VAS + SD		P-Value
	Group A	Group B	
Appearance	79.9 +8.9	82.2 + 12.4	0.07
Efficiency in retention	87.2 +12.2	90.3 +8.3	0.003*
Conspicuousness of the prostheses	78.5 +9.4	80.2 + 10.5	0.09
Improvement of self-confidence	84.6 +11.3	89.7 + 9.1	0.04
Ease of placement	92.4 +1.5	88.2 + 8.2	0.09
Ease of removal	93.6 +3.4	86.7 + 5.3	0.07
Ease of cleaning	82.4 +11.2	87.6 + 7.9	0.002*
No limitation to activities	80.5 +7.6	83.2 + 6.7	0.07
lack of distress and inflammation of the underlying soft tissues	83.2 +12.1	90.5 + 10.8	0.002*
Recommendation to others	90.2 +3.5	94.1 + 7.0	0.07

* Significant ($P < 0.05$)

4. Discussion

Rehabilitation of patients with facial defects is a multidisciplinary approach involving collaboration between surgeons, prosthodontists, psychologists, and other healthcare professionals. Advances in surgical techniques, materials, and prosthetic technologies continue to improve outcomes, but the inherent complexities of facial reconstruction make it an ongoing challenge in the field of maxillofacial rehabilitation [1]. Development and selection of prosthetic materials for replacing facial tissues involves careful consideration of various biological and mechanical standards to ensure optimal outcomes for patients. While there are several materials available for maxillofacial prosthetics, finding the standard substance for restoring movable soft tissues remains a challenge. Each material has its own set of advantages and limitations, and the selection often relies on the specific patient's needs, defect location, and the functional and aesthetic reconstruction objectives [6].

This study suggested the use of PVC as a liner to silicone ocular prosthesis can overcome the drawbacks related to silicone alone or silicone relined with PU. The use of PVC as a lining material is said to offer improved fungal resistance compared to other materials and can reduce tearing during prosthesis placement and removal. The Polyvinyl chloride is stated to have advantages over a polyurethane liner, including better resistance to tear, less color changes, more available, decreased expense, technique simplicity, and easiness of manufacturing and allow prompt recognition of incongruities in retention and stability at the try-in stage [10,11].

Patient satisfaction has been a critical measure of the success of prosthetic rehabilitation, particularly in individuals with maxillofacial defects. This aspect is paramount not only for assessing the technical success of the prosthetic device but also for understanding its impact on the patient's overall well-being, aesthetics, and social reintegration. The satisfaction of patients with maxillofacial prostheses is often subjective, relying on the individual's perception of comfort, appearance, and functionality. While subjective evaluations are valuable in capturing the patient's personal experience, they can also be influenced by various factors such as expectations, psychological state, and social context. Therefore, it is essential to approach patient satisfaction assessments with

a comprehensive understanding of these factors [18]. Ocular prostheses play a crucial role in aesthetic rehabilitation for individuals with facial defects. The satisfaction of patients with ocular prostheses goes beyond mere cosmetic considerations; it is intricately linked to their ability to re-socialize and reintegrate into society [2,19]. The eyes, being a prominent facial feature, significantly contribute to one's appearance and expressions. Therefore, a satisfying ocular prosthesis not only addresses the physical aspects of rehabilitation but also contributes to the psychological and social aspects of the patient's life [14]. Studies have demonstrated the direct correlation between patient satisfaction [12,13] with ocular prostheses and the level of reintegration into society. A well-designed and well-fitted ocular prosthesis can positively influence self-esteem, confidence, and interpersonal interactions. Conversely, dissatisfaction with the prosthetic device may lead to psychological distress and hinder the individual's ability to participate fully in social activities. To enhance the effectiveness of prosthetic rehabilitation, it is crucial for healthcare providers to adopt a patient-centered approach. This involves considering not only the technical aspects of the prosthetic device but also understanding and addressing the patient's expectations, concerns, and psychological well-being. Open communication, realistic expectations setting, and ongoing support contribute to a more positive rehabilitation experience and, consequently, higher levels of patient satisfaction [19].

The consideration of the American Academy of Maxillofacial Prosthesis's recommendation regarding the simplicity and straightforwardness of questions is noteworthy. This approach is essential for ensuring that the questionnaire is user-friendly and does not impose undue burden on the patients, especially considering the potential challenges faced by individuals undergoing maxillofacial prosthetic rehabilitation. The utilization of the modified Sloan et al's questionnaire, adapted to the Saudi population, represents a methodologically sound approach to objectively assess patient satisfaction in maxillofacial prosthetic rehabilitation. The careful considerations given to cultural adaptation, translation, and the simplicity of the questionnaire contribute to the robustness of the study's methodology. The positive outcomes and the absence of doubts during interviews further support the effectiveness of the chosen questionnaire for evaluating patient satisfaction in this study [12]. The belief that the questionnaire used is direct, precise, and

apparent so that it could be utilized in next research, reflects a level of confidence in the tool's reliability and validity. This confidence is vital for the ongoing use of the questionnaire in research and clinical settings.

The superior satisfaction levels reported by participants in both groups, particularly regarding the appearance and retention of the prostheses, highlight the positive impact of the prosthetic intervention. Esthetics, being subjective in nature, can be influenced by a range of internal and external variables. This recognition is crucial in understanding that patients may perceive satisfactory results differently than an external observer. Despite not restoring vision, the prosthesis contributed to the recovery of the ocular defect, promoting greater social acceptance among patients. This information is valuable for guiding future research and refining clinical practices to better meet the needs and expectations of patients undergoing such rehabilitation. The integration of 3D technology and digital impressions represents a promising avenue for enhancing the design and customization of ocular prostheses, bringing them nearer to meet the high prospect of patients. This anticipation of future advancements underscores the dynamic nature of healthcare and the ongoing quest for innovative solutions to improve patient outcomes [4,5]. Also, the study focused on individual confidence and community perceptions provides valuable insights into the psychosocial aspects of maxillofacial prosthetic rehabilitation. The concern expressed by patients about being identified solely as a "defective being" or someone carrying an abnormality reflects the profound impact that facial defects can have on individuals' self-perception and societal interactions. The desire for patients to feel inconspicuous and avoid being defined by their facial abnormality emphasizes the importance of achieving not just physical but also psychological and social rehabilitation. Superior satisfaction rates, represent a positive outcome. It suggests that prosthetic intervention successfully facilitated patients' ability to blend into society without drawing undue attention [17].

The high satisfaction levels related to the easiness of positioning, removal, prosthesis adaptation underscore effectiveness of prosthetic intervention. The consideration of patients with visual or motor difficulties reflects a patient-centered approach in prosthetic design. The awareness of challenges faced by users of adhesive prostheses highlights the need for ongoing improvements in prosthetic technology and fitting processes to enhance the overall experience for individuals undergoing maxillofacial prosthetic rehabilitation.

The analysis of the patient's free remarks revealing that the use of a PVC liner improved patient satisfaction and facilitated adequate adaptation is a significant finding. The positive impact on patient satisfaction underscores the importance of technological advancements and innovative solutions in the field of maxillofacial prosthetics. Patients' ability to carry out daily activities without significant limitations is a key indicator of the success of prosthetic intervention and the study suggested that the adhesive use contributed to overcoming these limitations. This finding suggests that advancements in materials and techniques, such as the use of a PVC liner, contribute to enhancing the overall quality of life for individuals with facial prostheses.

5. Conclusion

Within study limitations, it is suggested that both silicone and silicone lined with a PVC liner are effective approaches for the prosthetic rehabilitation of ocular defects patients. The advantages associated with the PVC liner make it a promising option, addressing functional, practical, and early detection considerations. The study's insights contribute to the continuing upgrading of prosthetic procedures and materials, ultimately enhancing life quality and satisfaction for individuals undergoing maxillofacial prosthetic rehabilitation.

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