



The Efficacy of Custom-designed, Light-weight Hollow Ocular Prosthesis

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Abstract

Objective: To determine the efficacy of custom-designed, light-weight ocular prosthesis in cosmetic rehabilitation of anophthalmic socket with regard to patient's satisfaction level, degree of motility, and less associated complications.

Study Design: Non-comparative interventional prospective study

Study Place and Duration: At Eye unit 3, Mayo Hospital, Lahore, for study duration of July 2006 to Dec 2022.

Material and Methods: After taking IRB approval, 100 patients of either age and gender, with anophthalmic socket following evisceration or enucleation where orbital volume was sufficiently restored and the fornices were adequately formed, enrolled in this study. Custom-designed and light-weight ocular prosthesis were fabricated by the ocularist and follow up were done. Patient's satisfaction score, degree of motility of ocular prosthesis and associated complications were recorded on proforma. Statistical analysis was performed using SPSS v 25.

Results: Out of 100 patients, 36% were male and 64% were female. Majority of patients (63%) had evisceration previously and the highest percentage for its cause was endophthalmitis (33%). Mean patient's satisfaction score at one month was 4.96 ± 1.25 that further improved to 5.21 ± 0.68 at 6 months follow up with a significant p-value of 0.032 (< 0.05). Degree of prosthetic eye movement was fair in majority (43%) and the most common complication was mucous discharge that too only in 17%.

Conclusion: In conclusion, custom designed and light-weight ocular prosthesis are very effective in achieving the higher satisfactory score of patients, better ocular motility and reducing the prosthesis related complications that help patients in maintaining the better quality of life.

Keywords: Custom-designed; Light-weight; Ocular Prosthesis; Anophthalmic Socket

Introduction

The loss of an eye can be very traumatic event in a person's life. The disfigurement associated with loss of an eye can cause significant physical and emotional problems [1]. The rehabilitation of patient following anophthalmic socket requires a prosthesis that will provide optimum cosmetic and functional result. The patient wants the ideal ocular prosthesis, natural looking, that friends and family don't know about. From the medical point of view this means eyelids in normal position, the ability to blink, eyelashes in normal position, symmetrical with the healthy eye, good motility, custom prosthesis [2].

The history of ocular prosthesis dates back to 2900-2800BC when first evidence of use of ocular prosthesis was found in an Iranian woman [3,4]. It was 2.5cm in diameter made up of light material probably Bitumen paste. Romans and Egyptian priests were known to have produced artificial eyes as early as fifth century constructed from painted clay [5]. Germans introduced the art of making artificial eyes from glass and later in USA artificial eyes of acrylic paste were used.

Now-a-days wide varieties of ocular prosthesis are available. Unlike stock-based prosthesis which is not individualized for each

patient, custom designed prosthesis is prepared with exact measurement of size and shape with help of accurate instruments. It is an innovative design which offers exact fitting of prosthesis on orbital socket providing improved motility [6].

Another important change added to ocular prosthesis is weight reduction that is achieved by making it hollow. The weight of prosthesis imparts special problems with the motility and discomfort. Socket discomfort has tremendous impact on the quality of life and also influences social interaction in everyday life [7-18].

The rationale of this study was to determine the behavior of custom designed, light weight ocular prosthesis in terms of its motility, comfort and reduced prosthesis related complications. As many patients present to our oculoplastic unit for cosmetic rehabilitation of anophthalmic sockets, this study would be of tremendous help in improving the quality and reducing the prosthesis related complication.

So, the objective of this study was to determine the efficacy of custom-designed, light-weight ocular prosthesis in cosmetic rehabilitation of anophthalmic socket with regard to patient’s satisfaction level, degree of motility, and less associated complications.

Materials and Methods

After getting approval from Ethical Review Board and getting written informed consent from every patient according to the Declaration of Helsinki, Non-comparative interventional prospective study was conducted at Eye unit III, Institute of Ophthalmology, Mayo Hospital, Lahore for study duration from July 2006 to Dec. 2022 using non-probability Purposive sampling. This study included 100 patients of either age and gender, with anophthalmic socket following evisceration and enucleation where orbital volume was sufficiently restored and the fornices were adequately formed. Exclusion criteria was patients who have not completed 6 months follow up period following ocular prosthesis rehabilitation, who had surgical time of less than 6 weeks following evisceration/enucleation, patients with contracted/ infected/ inflamed socket, patients with residual disease who need further treatment or intervention (like radiotherapy for residual tumor), and the eyes where peri-ocular tissue was sacrificed due to disease activity.

Patients fulfilling the inclusion criteria were included in this study. Ocular prostheses were fabricated 6 to 8 weeks following

the surgery to allow for healing of socket. During that time, a conformer was worn to help the fornices well-formed and to avoid the contracture. The steps involved in making custom designed PMMA ocular prosthesis were to take the exact impression through selected trays, socket impression for exact scleral shell preparation, precise iris positioning and iris color matching. The weight of these prosthesis then reduced by making them hollow from inside (Figure 1). These were 99.5% monomer free prosthesis where bio-incompatible residual monomers removed through specialized heat activated polymerization. In monomers of PMMA, the addition of 2% glycoldimethacrylate (GDMA) makes it hydrophobic and thus inert in nature that make it comfortable for patient’s ocular surface.

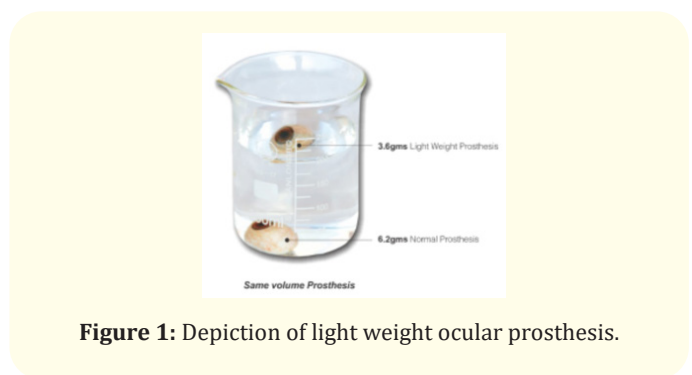


Figure 1: Depiction of light weight ocular prosthesis.

Thus custom-designed and light weight ocular prosthesis fabricated and fitted by the ocularist.

The patients were followed up at 1 month and 6 months after prosthesis fitting. At each follow up, motility of prosthesis, satisfactory score (Table 1), and complications recorded on preformed proforma. Consultations and follow up of these patients were made with ophthalmologist as well as ocularist.

Table 1: Satisfaction score.

	Scales
1	Highly satisfactory
2	Satisfactory
3	Moderately satisfactory
4	Moderately unsatisfactory
5	Unsatisfactory
6	Highly unsatisfactory

Degree of movement of prosthetic shell is an important parameter regarding cosmetic acquaintance with ocular prosthesis and it was assessed subjectively from patient’s/guardian’s feedback and categorized into good, fair and poor as follow.

Statistical analysis was performed using SPSS version 25 software. Categorical data was presented as frequency and percentage while numerical data was presented as Mean ± SD. Chi square test was used to detect the difference between scores at different follow up periods. Significance was considered at p value < 0.05.

Grading of degree of movement	Defining characteristics
Good	When prosthetic eye has nearly same degree of movement as that of normal eye
Fair	When ocular prosthesis has almost 50% movement compared to normal eye movement
Poor	When ocular prosthesis has less than 50% movement compared to normal eye movement

Table 2: Grading of degree of movement of ocular prosthesis.

Results

100 patients were included in our study. Out of which 36% were male and 64% were female. Right eye was involved in 45% and left eye was involved in 58% and bilateral involvement in 2%. The mean age of patients in our study was 30.5 ± 2.26 with a range of 15-45 years.

Age group	No. of patients	Percentage
15-25	35	35%
25-35	40	40%
35-45	25	25%

Table 3: Demographic variables.

Out of 100 patients who were enrolled for ocular prosthesis, 63% of the patients had evisceration, 25% had enucleation and in remaining 12% anophthalmic socket was either congenital or following pthiasis bulbi. The causes of anophthalmic socket following evisceration and enucleation are described as follow.

Satisfaction score was determined from every patient/guardian after ocular prosthesis implantation at a scale of 1-6 at various intervals of time. The mean satisfaction score at one month was 4.96 ± 1.25. The mean satisfaction score further improved to 5.21 ± 0.68 at 6 months follow up with a significant p-value of 0.032 (< 0.05).

Degree of movement	Percentage
Good	37%
Fair	43%
Poor	20%

Table 5: Degree of movement of the prosthetic eye.

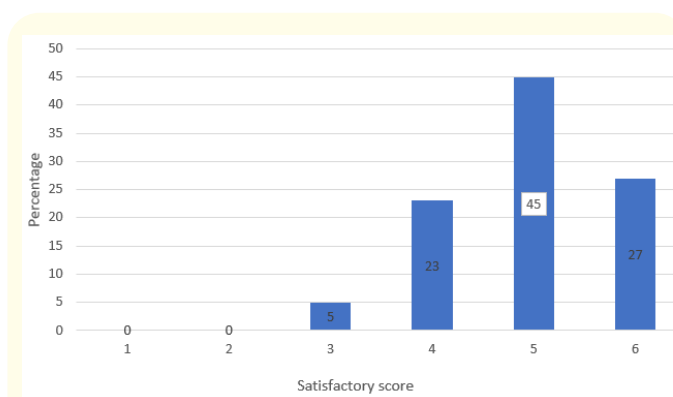


Figure 2: Bar Chart showing percentage of satisfactory score at 6 months following prosthesis fitting.

The degree of movement of the prosthetic eye also improved significantly with customized lightweight approach. Following paragraph indicates the feedback of degree of movement of prosthetic eye by the patients.

In this study, weight related complications of ocular prosthesis were reduced by 20-64% while continuous wearing time of prosthesis had a range of 30-180 days. Ocular prosthesis can cause various complications that can impact the patient’s well-being. The different kinds of complications associated with custom designed hollow prosthesis are shown as follow.

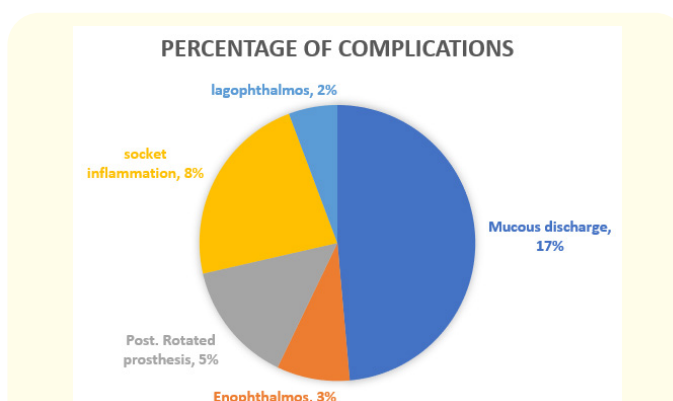


Figure 3: Pie chart showing percentage of complications associated with custom-designed light weight ocular prosthesis.



Figure 4: Above picture showing Right Anophthalmic socket following enucleation that was cosmetically corrected by custom-designed light weight ocular prosthesis in below picture.

Discussion

The efficiency of a prosthesis can really be judged by the similarity it has with the real, natural organ. In case of ocular prosthesis, it needs to be such that the cosmetic appearance is comparable to the healthy eye so that it may not be a hindrance in the daily social and recreational activities, reducing the psychological trauma (Figure 4). Along with this outward perspective, there is an inward perspective i.e. the degree of comfort and reduction of complications associated with it and this purpose is achieved by custom designed and low weight ocular prosthesis upon which our study is based.

The mean age of participants in our study was 30.5 ± 2.25 years. Out of this 36% were reported to be males and 64% were reported to be females. A similar study on ocular prosthesis was conducted by Pine., *et al.* [13] in which the mean age of the participants was 58 years, out of which 67% were males and females were 33%. The difference in being higher percentage of females in our study compared to males, is because cosmetic appearance is more concerned for females in our society specially when it comes to their marriage and mean age of 30 years in our study also augments this point. A study conducted by Nicola., *et al.* [14] also pointed out that female patients are more concerned about the cosmetic aspect of it.

Our study highlighted the importance of custom designed ocular prosthesis as compared to the stock prosthesis. This has proven

to be more cosmetically efficient providing symmetry to patient's face. A similar study conducted by Imam., *et al.* [20] showed the improvement in psychological and emotional status of patients of anophthalmia following implantation of ocular prosthesis.

The weight of the ocular prosthesis is also an important factor discussed in our study which can cause real problems for the patients like discomfort, lower lid sagging, discharge and ptosis etc. Lowering the weight of the prosthesis by making it hollow or using a light material like cryolite as compared to polymethyl methacrylate as discussed by Alexander., *et al.* [21] is a useful progress in this domain that reduces these weight related complications.

The custom designed hollow ocular prosthesis is more efficient in terms of degree of movement of the eye because of its close adaptation to the socket of the individual. Moreover, this has been proved to be better for tissue health because it eliminates any stagnating spaces as highlighted by Maretaningtias., *et al.* [22] in his study.

There are always some complications associated with the use of regular stock ocular prosthesis or conventional solid ocular prosthesis like lower lid distortion and asymmetric alignment of the palpebral fissure. The frequency of these complications has shown to be decreased by the use of custom designed hollow ocular prosthesis in our study. One such study was conducted by Vishvath., *et al.* [19] in which these complications were shown to be decreased by the use of custom designed hollow ocular prosthesis.

There are some gaps in our study in which further work can be done. First of all, this was a single-centered study, this can be improved by conducting a multicentred research in future. Secondly, a study comparing the effectiveness of custom designed hollow ocular prosthesis versus the conventional stock based ocular prosthesis side by side would be more helpful in future.

Conclusion

In conclusion, custom designed and light-weight ocular prosthesis are very effective in achieving the higher satisfactory score of patients, better ocular motility and reducing the prosthesis related complications that help patients in maintaining the better quality of life.

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