A Clinical Study on Outcome of Polymethyl Methacrylate Orbital Implant (Mules orbital implant) Following Evisceration

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Abstract

Objectives: This present study was undertaken to assess the outcome of Mules PMMA orbital implant following evisceration.

Study Design: Interventional study

Study setting: Department of Ophthalmology, S.V.R.R.G.G. Hospital, Tirupati, Andhra Pradesh, India.

Materials and Methods: Modified technique of evisceration with anterior sclerotomy and double breasting of sclera along with primary placement of PMMA orbital implant was performed in 35 consecutive patients who presented with various causes of painful blind eye. The postoperative performance of the implant was assessed in terms of volume replacement, motility, extrusion rates and other complications.

Results: In the present study, degree of volume replacement was found to be good in 13 patients and fair in 22 patients. 24 of the 35 patients had a good movement of prosthesis (>20 degrees of horizontal movement) and 11 patients had fair motility (10 to 20 degrees). Extrusion rate was nil.

Conclusions: Evisceration with modified technique followed in the present study minimised the extrusion rates of PMMA implants with successful retention of the implant. In conclusion, evisceration with PMMA orbital implant can be an effective treatment for painful blind eyes with excellent postoperative outcome.

Keywords: evisceration, anterior sclerotomy, Mules PMMA orbital implant, good clinical outcome.

Introduction

Evisceration is a surgical procedure where all the intraocular contents are removed while preserving the outer scleral shell. This is a destructive procedure performed when all other treatment options have been exhausted, with the objective of safeguarding life of the patient and/or alleviating the symptoms.¹ ²

Evisceration of a non-seeing, painful eye leaves the patient with an empty or anophthalmic socket resulting in volume loss of 7-7.5 cm³ from the total orbital volume of 30 cm³. The common problems arising from anophthalmic sockets have been summarised by Tyers and Collins in 1985 in the clinical entity of ‘postenucleation socket syndrome’, the distinctive clinical features of which are ptosis/retraction of upper lid, deep superior sulcus, laxity of lower lid and enophthalmos.³

Arising from the need to compensate the loss of orbital volume in order to prevent the occurrence of enophthalmos, Mules, in 1885, proposed the use of glass implant(sphere) within the scleral cavity after removal of corneal button.⁴

Numerous orbital implants have been developed to rehabilitate the anophthalmic socket. The ideal implant should be easy to place, well tolerated, resist migration, extrusion and infection, not cause socket irritation, and be reasonably priced.⁵ ⁶ Solid sphere migration has been reported, but this may be technique-dependent.⁷

As we are encouraged to reduce the health-care costs when picking an implant, there will be increased pressure to use silicone or PMMA implants and not the more expensive porous polyethylene or hydroxyapatite implants if the benefit profile is not worth the extra cost.⁸ Viswanathan et al reported that acrylic spheres were the single most commonly used type of orbital implant in the United Kingdom.⁹

There is scarcity of literature on outcomes of Mules PMMA orbital implant in evisceration compared to enucleation. Based on the factors mentioned above, the present study was performed to determine the outcome of Mules PMMA orbital implant following evisceration in SreeVenkateswara Ram Narayan Ruia Government General Hospital (S.V.R.R.G.G.H) Tirupati.

Patients And Methods

In a prospective study between December 2012 and September 2014, 35 patients with painful blind eye secondary to perforated corneal ulcer or absolute glaucoma, anterior staphyloma and eyes with ocular trauma not amenable for salvage, who were found to be potential candidates for or evisceration, were included in the study. A second opinion was taken from another ophthalmologist before proceeding with the procedure. Out of 35 patients included in the study, 19 (54%) patients were male and 16 (46%) were females. Age group of patients was between 27 years to 75 years. Exclusion criteria included those patients less than 18 years of age and those not willing to participate in the study. This study was performed following the tenets of Declaration of Helsinki, and after approval by the Institutional Ethical Committee of S.V. Medical College, Tirupati. The type of procedure and the implant used, the characteristics, and benefits of each operation were explained to the patients.
informed written consent was obtained from each patient prior to the procedure.

**Surgical Procedure**

The evisceration procedure included a 360° peritomy followed by excision of the corneal button with corneoscleral scissors. An evisceration scoop was used to separate the uvea from the sclera and deliver the intraocular contents. The interior of the sclera was scraped to remove all visible uveal tissue remnants. Dehydrated (absolute) alcohol was used to remove residual pigment from the scleral wall. Anterior sclerotomy incisions were made in opposite oblique meridians between the vertical and horizontal muscles, at 2 and 8 o’clock positions. An appropriately sized PMMA sphere was placed in the scleral shell. Anterior scleral flaps were sutured with 6-0 Vicryl by double-breasting technique. The overlying Tenon capsule was closed with interrupted 6-0 Vicryl suture, and the conjunctiva was closed with a running 6-0 Vicryl suture. An appropriately sized conformer was placed in conjunctival cul de sac. Eye was patched for 24 hours. Postoperatively, intramuscular injection of 2cc dexamethasone (4mg/ml) was given daily for three days. Oral antibiotics (Tab. Ciprofloxacin 500mg twice a day) anti-inflammatory drugs (Tab. Diclofenac Sodium 50 mg twice a day), and antibiotic eye drops (Ciprofloxacin 0.3% QID) were prescribed for 5 days. Patients were followed up at first, third and sixth week postoperatively. Prostheses was given at 6 weeks after surgery. Implant was assessed in terms of motility and volume replacement at each visit with conformer in situ. At every follow up visit, quantitative and qualitative assessment of orbital volume was done in all cases. Quantitative assessment was done using Luede’s exophthalmometer. The replacement of orbital volume (with implant and prosthesis/conformer in situ) was assessed by measuring the axial displacement of the anterior aspect of the conformer/prosthesis and the readings were compared with the normal eye. Quantitative assessment was graded as good if the difference was <1mm, fair when the difference was 1-2mm and poor when it was >2 mm. Qualitative assessment was done in terms of the presence or absence of upper eyelid sulcus deformity like deep superior sulcus.9 Good horizontal motility was defined as symmetrical horizontal movement ≥20°. Fair motility was movement of >10° but <20° whereas poor motility was movement <10°.9 Wound was examined for signs of exposure or extrusion of implant.

**Results**

A total of 35 patients underwent evisceration with primary implantation of Mules PMMA intraorbital implant (Figure 1). Table 1 summarises the patient demographics. Reasons for evisceration can be seen in table 2. In the present study, 13 cases (37%) had good orbital volume replacement and 22 cases (63%) had fair replacement of orbital volume. Deep superior sulcus was noted in 17 cases (49%). The orbital implant used in 80% of the cases was 16 mm in size. This might be the cause for the mild enophthalmos produced in 63% of the cases. Good motility was noted in 24 (68%) cases and fair motility in 11 cases (32%). The current study recorded no extrusion, exposure or migration of the PMMA orbital implant.

![Figure 1: Mules PMMA implant](image)

**Table 1: Patient Demographics**

| Number of patients | 35 |
|-------------------|----|
| Number of eyes    | 35 |
| Age range (years) | 27 years-75 years |
| Mean age (years)  | 55.5 years |
| Sex ratio (Male : Female) | 19(54%) : 16(46%) |
| Eye (Right : Left) | 21(60%) : 14(40%) |
| 16 mm implant     | 28(80%) |
| 18 mm implant     | 7(20%) |

**Table 2: Indication for surgery**

| Indication                  | Percentage |
|-----------------------------|------------|
| Absolute glaucoma           | 1(2.85%)   |
| Anterior staphyloma         | 15(42.85%) |
| Expulsive choroidal haemorrhage | 1(2.85%) |
| Endophthalmitis             | 1(2.85%)   |
| Perforated corneal ulcer    | 16(45.75%) |
| Ocular trauma               | 1(2.85%)   |

**Discussion**

The evisceration technique has undergone several modifications with the goal of achieving a lower rate of exposure and allowing colonisation of the integrated implant by the receptor tissue. The purpose of these techniques was to improve surgical outcome and reduce complications like implant exposure, superior sulcus deformity, ptosis, enophthalmos and lower lid laxity. In this surgery, it is important to reduce volume loss and, at the same time, avoid excessive tension on the surgical wound. Many techniques have been recommended to achieve these goals like relaxing scleral incisions, posterior sclerotomies, scleral flaps, implant coverage by multiple scleral layers and others.10-12 The modified surgical technique was adopted in the present study. Many authors advocate removal of the uveal tissues with various instruments or gauze. Berens and Breakey were the first to use Metaphen to cleanse the scleral shell. Other authors have used absolute or 70% alcohol.12-13 In the present study, after the intraocular contents were scooped out, the scleral bed was wiped with cotton swabstick soaked with 100% absolute alcohol. Absolute alcohol denatures any residual uveal protein which minimises postoperative
inflammation. This was followed by saline irrigation. Anterior sclerotomy incisions were placed at oblique meridians between horizontal and vertical recti muscles, leading to significant override of the upper scleral lip over the lower scleral lip during wound closure. This provided double layer protection to the implant, averting the need for a graft and minimising the risk of extrusion. The importance of meticulous wound closure in preventing extrusion of implant was stressed by Liu et al in their study. Tenon’s layer was closed in a horizontal fashion, followed by closure of conjunctiva in vertical fashion, in order to maintain the fornices, for easy placement of conformer postoperatively and appropriately sized artificial shell at a later date. The mean age of surgery was 55.5 years in the present study. Similar results were obtained by Tajunisa et al while in a study by Tariq et al, 44.7% of patients undergoing evisceration were >41 yrs. The most common age group was above 60 years (52%) in a study by Babar. Males (54%) outnumbered females (46%) in our study, similar to that reported in other studies. Perforated corneal ulcer was the common cause of evisceration in our study (45.75%). This was comparable to Tajunisah et al (72%). Other studies have also reported ocular infections to be the most common factor leading to evisceration of the eye. As a general rule, it is wise to restrict implant size to 18 mm or less in (diameter) because large implants are sometimes difficult to cover adequately with the scleral shell. Standard evisceration techniques typically only allow placement of a 13- to 16-mm spherical implant. The average diameter of the PMMA implant used by Massry and Holds in their study was 20.2 mm while Kim et al used 18 mm sized implant in 43.4% of the cases in their study. The current study recorded good volume replacement in 13 cases (37%) (Figure 2) and fair in 22 (63%) of the cases. In 80% of the cases, a 16 mm implant was used. In our study, good motility was noted in 24 cases (68%) and fair motility in 11 cases (32%) (Figures 3). Kundu et al reported good motility in 14 patients (56%) and fair motility in 11 patients (44%). The current study had no cases of implant exposure. Previously reported extrusion rate varied according to the authors, from zero to more than 20% according to different surgical techniques. Recent studies using posterior sclerotomy or scleral quadrisection report lower implant extrusion rates. Other factors such as implant size, duration of antibiotic therapy and postoperative wound care regimen may play a role in implant extrusion. Zolli reported 6% (3 of 48) extrusion with alloplastic implants while Nunery et al reported less than 2% extrusion with alloplastic implants. Massry and Holds reported no extrusion in 50 cases of PMMA sphere implantation post-evisceration. In evisceration with hydroxyapatite implantation, an exposure rate as high as 67% has been reported by Buettner et al.

Conclusion

Therefore we support the view that evisceration with alloplastic sphere implantation can be an effective treatment for painful blind eyes, cosmetically unacceptable blind eyes, and medically uncontrolled endophthalmitis. Evisceration with anterior sclerotomy and double breasting technique followed in the present study, is a rapid and easy surgical procedure, which minimised implant extrusion, provided better implant excursion, and caused minimal orbital tissue damage. An additional advantage was with the lower cost of alloplastic spheres in comparison with their porous counterparts. Literature is scanty on evisceration with Mules PMMA implant compared to enucleation with PMMA implant. This pilot study should form a basis for a future examination of this issue by large, multicentered, randomized, prospective studies.

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