

Orbit

The International Journal on Orbital Disorders, Oculoplastic and Lacrimal Surgery

ISSN: (Print) (Online) Journal homepage: www.tandfonline.com/journals/iorb20

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To cite this article: Tarjani Vivek Dave, Anthony Vipin Das, Sameer Mohapatra, Oshin Bansal & Anasua Ganguly (2022) Outcomes and complications of evisceration with primary implant: an electronic medical record driven analytics of 1800 cases, *Orbit*, 41:6, 717-725, DOI: [10.1080/01676830.2021.1998915](https://doi.org/10.1080/01676830.2021.1998915)

To link to this article: <https://doi.org/10.1080/01676830.2021.1998915>



Published online: 16 Nov 2021.



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ORIGINAL INVESTIGATION



Outcomes and complications of evisceration with primary implant: an electronic medical record driven analytics of 1800 cases

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ABSTRACT

Purpose: To describe the surgical outcomes and implant complications in 1,800 patients undergoing evisceration with primary implant

Methods: An Electronic Medical Record-driven analysis of 1,800 patients undergoing evisceration with primary implant between 2013 and 2019. Implant sizing was performed intra-operatively to place the largest implant without tension on the wound closure. Outcome measures included implant complications, prosthesis measurements, and incidence of a good aesthetic outcome. Good outcome was defined as <2 mm enophthalmos and grade 1 or less superior sulcus deformity with a custom ocular prosthesis.

Results: Eighteen hundred eyes of 1800 patients were included. The mean age at surgery was 36 ± 21 years (median 32 years). Implants used were poly(methyl methacrylate) (PMMA) in 1737 (97%) and porous polyethylene in 63 (3%) patients. Two-petal sclerotomy was performed in 1512 (88%) and four-petal sclerotomy in 165 (10%) patients. The mean diameter of the implant used was 19.35 ± 1.18 mm (median 20, range 10–22 mm). The implant extrusion rate was 3% (56) and implant displacement was seen in none. The mean prosthesis volume and thickness were 2.22 ± 0.67 ml (median 2, range 1–6.5 ml) and 6 ± 1 mm (median 6, range 2–9 mm). The mean difference in prosthesis projection on Hertel's exophthalmometer was 0.28 ± 1 mm (median 0, range 0–1 mm). Good outcome was observed in 93%. The mean follow-up period was 351 ± 386 days (median 194).

Conclusion: Evisceration with empirically selected primary orbital implant placement is associated with minimal implant complications and gives a good aesthetic outcome in 93% of the patients.

ARTICLE HISTORY

Received 20 April 2021

Accepted 23 October 2021

KEYWORDS

Big data; electronic medical records; epidemiology; evisceration; exposure; extrusion; implant; migration; orbit; prosthesis; ptosis; risk factors; socket

Introduction

Over the years, evisceration has replaced enucleation as a preferred surgical technique for end-stage painful blind eyes.^{1,2} It is advantageous over enucleation when an intra-ocular tumor has been ruled out as it requires lesser surgical dissection, making the surgery quicker and cost-effective. As compared to enucleation, evisceration also tends to give better motility to the prosthesis since the extra-ocular muscles are preserved and hence a better cosmesis.^{3,4} The complications following evisceration include decreased motility, cosmetically unacceptable enophthalmos (due to inadequate volume replacement), infection, implant migration, exposure and extrusion.^{5,6} Implant extrusion forms the most significant complication following evisceration. Several techniques of evisceration have been described over the past two decades to allow the placement of an adequately sized orbital implant without increasing the risk of implant extrusion.^{5–13} Similarly,

literature is replete with the outcomes of different implant materials used in evisceration.^{14–16} The general consensus, however, has been that the implant material does not increase the implant motility unless pegging of the orbital implant is performed and that adding sclerotomies with disinsertion of the optic nerve helps in placing an implant with a larger diameter.^{17–21} Hence, the choice for the implant material is largely based on individual preferences and availability.^{18–20}

The largest data set available in the literature describing the implant complications is the series by Yoon JS that studied complications of HA implants in 802 cases undergoing evisceration, enucleation and secondary implant surgeries.²² The largest series reporting implant outcomes specifically in evisceration included 354 patients.²³ This represents a relatively small number with respect to the general footfall of patients undergoing evisceration over the world. Although abundant

literature exists on porous implant outcomes, large data on implant outcomes with a non-porous implant in evisceration are scarce. In the present age of data informatics, it is possible to extract large volumes of data from electronic medical record systems, which can assist further understanding of management outcomes. In the current communication, we report the surgical and implant outcomes of patients undergoing evisceration and implant across our tertiary eye care network, a big data analysis retrieved from an indigenously developed electronic medical record system. We also compare and contrast our data with other large data subsets on evisceration and implant carried out around the globe.

Methods

Study design

This is a retrospective cross-sectional hospital-based interventional study. Patients undergoing evisceration and implant between January 2013 and October 2019 at four of our tertiary eye care centers located in 3 different states of the country are selected for the study. The patient or their parents or guardians filled a standard consent form for electronic data privacy at the time of registration. None of the identifiable parameters of the patient were used for analysis of the data. The study adhered to the Declaration of Helsinki and was approved by the Institutional Ethics Committee. Each patient underwent a comprehensive ophthalmic examination and the clinical data were entered into a browser-based electronic medical record system (eyeSmart EMR).²⁴

Data retrieval and processing

The data of 1,345,480 patients were retrieved from the electronic medical record database and segregated into a single excel sheet. A total of 2071 patients underwent evisceration during the study period. Of these, 271 patients underwent evisceration without a primary orbital implant and were excluded. The 1,800 eligible eviscerations with primary orbital implant patients in this group were segregated for analysis and included in this study. The columns with data on ocular diagnosis, surgical notes, complications and prosthesis outcomes were exported for analysis.

Outcome measures

The outcomes were analyzed for the rate of implant and surgical complications such as implant exposure, extrusion and migration, post-operative ptosis, superior

sulcus deformity, anophthalmic enophthalmos, contracted socket, conjunctival cysts and lower eyelid retraction. Implant migration was classified into implant displacement and implant decentration as described earlier by our group.²⁵ The superior sulcus deformity and Hertel exophthalmometry were assessed with the prosthesis in the eye socket. Superior sulcus deformity was classified from grade 0 to 4 as described previously.²⁵ The color match of the prosthesis was classified based on our previous work.²⁶ The motility of the prosthesis was classified as excellent, good, fair and poor based on the movement of the prosthesis from the midline. Excellent represented 75% or more movement of the prosthesis past the midline, good represented 50 to 75% movement of the prosthetic eye from the midline, fair represented 25% to 50% movement of the prosthesis from the midline and poor represented 25% or less movement of the prosthesis from the midline. The custom ocular prosthesis volume was calculated using the translation of the water column in a pre-fabricated beaker (Figure 1a,b). A prosthesis volume of 2.2 ml or less was considered ideal.²⁷ The thickness of the prosthesis was measured at the center of the pupil using a caliper (Figure 1c,d). A prosthesis thickness of 7 mm or less was considered ideal.²⁷ The final aesthetic outcome of the surgery was considered good if enophthalmos was <2 mm and superior sulcus deformity was grade 1 or less (Figure 2). The patient satisfaction with the aesthetic

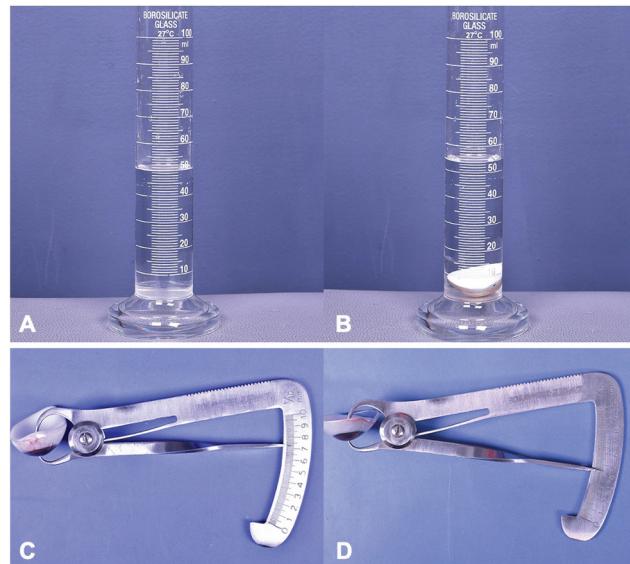


Figure 1. Volume and thickness measurements of prosthesis: (A) pre-calibrated beaker with water column till 50, (B) after the placement of the prosthesis, water column rises to 50.4 estimating the volume to 4 cc,³ (C) prosthesis thickness measure estimating the thickness to 7.3 mm (D) prosthesis thickness measurement for a different patient estimating the thickness to 4.4 mm.

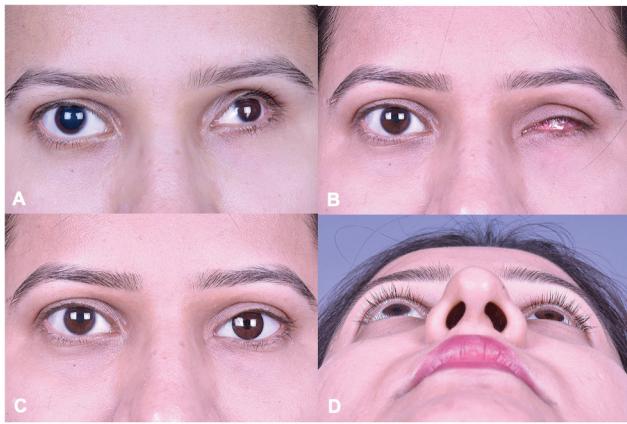


Figure 2. Assessing the aesthetic outcomes of evisceration and implant: (a) pre-operative appearance with left phthisis bulbi, (b) 6-weeks after left evisceration with 20 mm implant, (c) post-operative appearance with left prosthetic eye and grade 0 superior sulcus deformity and (d) post-operative appearance in Birds view with left 1 mm enophthalmos.

appearance of the prosthesis and the socket was graded on a linear 10-point scale where 1 was the least and 10 was the maximum satisfaction with the prosthesis.

Statistical analysis

Descriptive statistics using mean (\pm standard deviation) and median (\pm range) were calculated and reported using Microsoft Excel (Microsoft Corporation, Redmond, USA).

Results

Demographics

This study included 1,800 patients who underwent evisceration with implant. The majority of patients were male 1150 (64%). The mean age at surgery was 36 ± 21 years (median 32, range 3 months to 96 years). Children constituted 285 (16%) of the cases. The risk factors for evisceration included trauma in 47%, infection in 25%, intractable glaucoma in 11%, post-ocular surgery in 8%, congenital causes in 5% and other causes. The surgical indication included were painful blind eye in 731 (41%), phthisis bulbi in 533 (30%), staphyloma in 207 (12%), open globe injury in 195 (11%), disfigured blind eye in 98 (6%) and microphthalmos with poor visual potential in 36 (2%) patients. The mean follow-up period was 351 ± 386 days (range 289 to 2283 days).

Surgical techniques

The commonest surgical technique used was evisceration with a two-scleral flap sclerotomy in 1512 (88%)

cases. Four-flap sclerotomy was performed in 165 (10%) patients and relaxing anterior sclerotomies without optic nerve disinsertion were performed in 42 (2%) patients. The surgical technique of two-flap evisceration was as described by Massry et al⁷ and the four-flap evisceration was performed as described by Sales-Sanz et al.⁹ Optic nerve was released 360 degrees posterior to the equator approximately 3 mm from the optic nerve head in these cases to allow a tension-free closure.

Implants

Implants used were polymethyl methacrylate implant in 1737 (97%) and porous polyethylene (medpore spherical implants) implants in 63 (3%) patients. The mean diameter of the implant used was 19.35 ± 1.18 mm (median 20, range 10–22 mm). The choice of the implant diameter was an intraoperative decision. The largest sphere that could be placed within the scleral shell after the sclerotomies, without undue tension on the wound closure, was selected.

Complications

Implant complications in the PMMA group included implant exposure in 49 (3%) (Figure 3a,b), implant extrusion in 56 (3%) (Figure 3c,d) and implant decentration in 30 (2%). A flowchart on the management of complications is depicted in Figure 4. Of the 49 patients with implant exposure, 39 progressed to develop implant extrusion. 10 patients underwent implant exchange with a smaller implant. In 8 of these patients, the implant was retained without additional complications over the followup period. In 2 of these 10 patients, there was recurrent implant extrusion. One patient underwent dermis fat graft and the other was offered a hollow prosthesis. In 36 (64%) patients, the implant extrusion was treated with a secondary implant and a good prosthetic outcome was achieved without additional implant complications in 32 of these 36 patients. Four patients (7%) developed implant migration after secondary implant surgery. Two of these 4 patients underwent implant removal with DFG and 2 were managed with implant removal followed by a hollow prosthesis. The remaining 20 (36%) patients did not opt for a revision surgery for additional volume augmentation and were offered a hollow prosthesis.

Thirty patients had a decentered implant with the maximal convexity of the implant not centered in palpebral fissure on clinical examination. They were managed by prosthesis modification alone. None of the patients developed an implant migration after primary implant placement (displacement outside the muscle cone) that



Figure 3. Implant complications. Each horizontal panel is an individual patient: (a) left evisceration with implant for panophthalmitis, (b) left high-magnification socket image with nasal PMMA implant exposure, (c) right spontaneous implant extrusion 5 weeks after evisceration with PMMA implant performed for an open globe injury after road traffic accident, (d) right high-magnification socket image with the empty scleral shell, (e) right phthisis bulbi and a pre-existing ptosis, (f) right persistent ptosis post-evisceration with a 20 mm implant, (g) left evisceration with implant for anterior staphyloma, (h) left lower eyelid retraction with a custom ocular prosthesis, (i) right prominence of custom ocular prosthesis 6 months following evisceration and implant and (j) right high-magnification socket image with a bluish subconjunctival cyst.

required a second procedure for correction of the implant position. The implant exposure, extrusion and migration rates in the porous implant group were 0%.

Contracted socket was seen in 87 (5%) patients. A preoperative diagnosis of an open globe injury was elicited in 38 of these 87 patients (44%). Contracted socket was graded as grade 1 in 49 (56%), grade 2 in 21 (24%) and grade 3 in 17 (20%) patients. A mucus

membrane graft was performed for surface augmentation in 28 (32%) of these patients with a good prosthetic outcome post-operatively. Lower eyelid laxity was seen in 22 (1%) patients (Figure 3g,h). Of these, 12 (55%) patients underwent a lateral tarsal strip procedure. Conjunctival cysts were seen in 25 (1%) of these patients (Figure 3i,j). All these patients underwent a cyst aspiration and sclerotherapy with sodium tetradecyl sulphate and had a stable prosthesis post-operatively.

Ptosis was noted in the post-operative period in 357 (20%) cases. A pre-operative diagnosis of staphyloma with an increased pre-tarsal show of the eyelid was documented in 207 (58%) patients. All these patients developed ptosis post-operatively. Most of the cases in this series had trauma or infection as the reason for evisceration. Ptosis in these cases could have been pre-existing due to the above reasons. Of these, 64 (18%) patients with anophthalmic ptosis opted for surgical correction of the ptosis with a good correction post-operatively. The reason for evisceration had a bearing on the complications noted. About 65–70% of all complications occurred in cases where the reason for evisceration was either trauma or infection.

Aesthetic outcomes

The prosthetic outcome was graded objectively in 679 patients following the introduction of a dedicated socket proforma in the year 2017. (Appendix 1). The mean prosthesis volume was 2.22 ± 0.67 ml (median 2, range 1–6.5 ml). Five hundred and thirty-five (79%) patients had a prosthesis volume of 2.22 ml or less and 96% (651) of the patients had a prosthesis volume of 3 ml or less. The mean custom ocular prosthesis thickness was 6 ± 1 mm (median 6, range 2–9 mm). An ideal thickness of 7 mm or less was seen in 604 (89%) patients. The mean difference in prosthesis projection on Hertel exophthalmometry between the two sides was 0.28 ± 1.43 (median 0, range 0–1 mm). The mean superior sulcus deformity (SSD) was grade 1 (median grade 1, range grade 0 to 4). The mean motility of the prosthesis was graded as fair. The mean color match of the prosthesis was graded as L1 for the limbal shading, V2 for the Vascular hue and P2 for the pupil and iris shading. The final aesthetic outcome of the surgery was considered good if enophthalmos was <2 mm and superior sulcus deformity was grade 1 or less. Good aesthetic outcome (enophthalmos < 2 mm and grade 1 or less SSD) was seen in 93% of the patients. A multivariate logistic regression analysis revealed that the odds of a good aesthetic outcome were significant in a non-trauma etiology, non-infectious etiology and in cases where a larger implant was used (Table 1). The mean patient

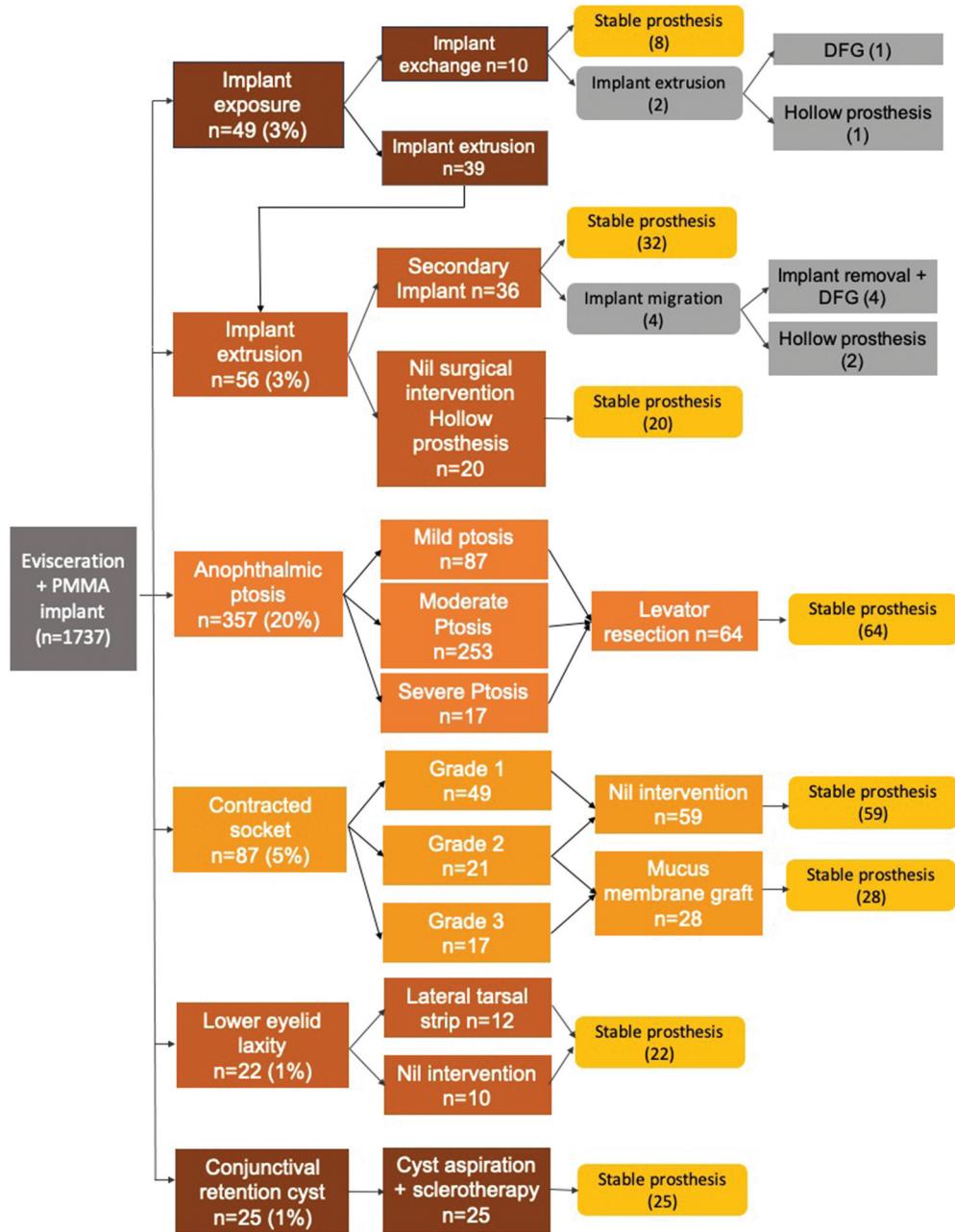


Figure 4. Flowchart of implant complications and management of the complications.

satisfaction score with the prosthesis was 7.79 ± 0.66 (median 8, range 3–10).

Discussion

This study of 1,800 patients undergoing evisceration and primary orbital implant placement suggests that the technique of making 2 scleral flaps with disinsertion of the optic nerve is a common surgical technique of evisceration. The use of a PMMA implant is associated with implant complications comparable to that published in

the literature.^{7,28} The commonest post-operative complication noted was the prevalence of ptosis in 20% of the patients post-surgery. Based on the results of this study, the use of an implant of diameter 20 mm is associated with a good aesthetic outcome in 93% of the patients and the volume of the custom ocular prosthesis falls in the ideal volume range in 96% with the ideal thickness in 89% of the patients.

The choice of surgical technique in evisceration has evolved over the last two decades with the increasing number of physicians preferring techniques that involve

Table 1. Logistic regression analysis showing the effect of various factors determining good aesthetic outcome.

	Bivariate analysis			Multivariate analysis		
	Odds ratio	95% CI	P value	Odds ratio	95% CI	P value
Age	0.99	0.98 to 1	.2	0.99	0.97 to 1	.15
Female gender	1.11	0.76 to 1.61	.57	1.11	0.73 to 1.68	.62
Non-infectious etiology	1.12	0.78 to 1.6	.51	0.87	0.57 to 1.33	.54
Non-trauma etiology	1.71	1.18 to 2.47	.004	1.1	0.64 to 1.87	.72
Non-trauma and non-infectious etiology	2.65	0.64 to 4.26	.0001	3.67	1.84 to 7.31	.0002
4 petal technique over 2 petal technique	1.15	0.63 to 2.12	.63	1.01	0.52 to 1.96	.98
Increasing Implant size	1.99	1.71 to 2.31	<.0001	2.21	1.87 to 2.63	<.0001

disinsertion of the optic nerve from the scleral shell in an attempt to address the volume loss associated with evisceration adequately. The most significant change following the adoption of surgical techniques that involve scleral flaps and disinsertion of the optic nerve has been a reduction in the implant extrusion rates from 22% when sclerotomies are not performed²⁸ to 0% with the advent of sclerotomies.^{7,9} The modification of Kostick and Linberg⁵ included relaxing incisions and posterior sclerotomies, so a large sphere could be accommodated without tension on the wound. Massry and Holds⁷ performed 2 full-thickness sclerotomies from the anterior limbal incision to the optic nerve in the inferonasal and superotemporal quadrants to create 2 scleral flaps. Sales-Sanz and Sanz-Lopez⁹ described the 4 petal sclerotomy technique that can be used in phthisical eyes as well to expand the scleral surface area. A concern regarding increased implant migration prevailed with the use of the sclerotomy techniques, especially in the setting of a non-porous implant, as the implant can slip into the extraconal space between the scleral flaps. In a previous study,²⁹ we addressed this concern and reported a 0% migration rate with the use of the two scleral flap technique. In the current large series of 1800 eyes, we report an implant exposure rate of 3% and an implant extrusion rate of 3%. The implant decentration rate was 2% with the PMMA implant. None of the cases had an implant displacement that required a second procedure for correction of the implant position or hindered the prosthetic outcome. We also report a 0% implant complication rate with the use of the porous polyethylene implant comparable to the published literature.³⁰

The commonest post-operative complication noted in our series was the presence of post-operative anophthalmic ptosis in 357 (20%) of our patients. The incidence of ptosis after socket surgery ranges from 4% to 54%.^{7,31} The large variation in the incidence of post-operative ptosis is due to the fact that a definite subset of patients have pre-operative ptosis that is often missed and inadequately documented. Mechanisms postulated for anophthalmic ptosis include sub-optimal percentage volume augmentation during surgery and a greater

number of years of prosthesis wear.³² In our cohort, the average implant diameter used was 19.35 ± 1.18 mm with a median implant diameter of 20 mm. However, trauma was the commonest aetiology for evisceration in our series and additionally, we also noted the presence of staphylomas in 12% of our patients. In the presence of staphylomas, a pre-operative diagnosis of ptosis is generally missed until attention is paid to an increased pre-tarsal show in this subset of patients. Often, in the presence of a phthisical eye, the vertical palpebral fissure is narrow due to the relative enophthalmos, making the diagnosis of ptosis difficult. Hence, estimation of the exact incidence of new onset post-operative ptosis remains a challenge. In our series, an increased pre-tarsal show was documented in all patients with a diagnosis of staphyloma accounting for pre-existing ptosis in 207 (58%) patients. This brings the incidence of new onset ptosis to 8% (150) patients. Table 2 shows a comparison of complications noted in our series as compared to other large data sets (> 50 cases with similar techniques of sclerotomies and optic nerve release) of evisceration outcomes.

Kaltreider et al.²⁷ described the formula of axial length-2 mm for the calculation of the ideal implant diameter. They subtracted 1 mm from the implant diameter for evisceration and for hyperopia and reported excellent aesthetic results, with less than grade 1 SSD and 2 mm enophthalmos in 85% of patients. The median implant diameter in our study was 20 mm. The average axial length in Indian subjects has been reported to be 23.5 mm. Using the Kaltreider formula, our patients should have received an implant diameter of 22.5 mm. However, with the use of a median 20 mm implant, we achieved a good aesthetic outcome in 93% of our patients using the same assessment criteria as described by Kaltreider et al.²⁵ This could be due to the racial differences in the axial length between Caucasian and Asian eyes since Asian eyes are known to be smaller in axial length.^{33,34}

Whilst the volumetric outcomes of evisceration have been discussed in terms of sulcus deformity and enophthalmos,^{7,35} the implant prosthesis correlation has been poorly addressed. Kaltreider et al.²⁷ described

Table 2. Comparison of implant complications with the global literature.

Sr no	Study, year	No. of cases	Surgical technique	Mean implant diameter (mm)	Implant types	Implant exposure (%)	Implant extrusion (%)	Implant migration (%)	Anophthalmic ptosis (%)	Contracted eyelid	Enophthalmos (%)	SSD (%)	LL laxity (%)	Conjunctival cysts (%)	Mean follow-up (months)
1	Massry GG, 2001	70	2-petal	20	PMMA, PP and HA	0	0	0	Pre-existent 54, new onset 4	NA	NA	16	Pre-existing 13, new onset 4	NA	34
2	Sales-Sanz, 2007	73	4-petal	20	PP	0	0	0	NA	0	NA	1.3	3	43	
3	Masdottir S, 2007	62	2-petal	18	Silicone	5	3	2	NA	28	NA	13	5	90	
4	Shoamanesh A, 2007	147	360 oblique relaxing sclerotomy	18	HA, PP and silicone	3	NA	0	NA	9	10	2	NA	NA	
6	Yoon JS, 2008	229	Anterior relaxing with circumferential equatorial	18	PP	3	0	NA	8	3	NA	2	NA	0.4	50
7	Huang D, 2009	154	4-petal	20	PP	0	0	NA	NA	NA	NA	0	NA	NA	42
8	Kim KH, 2011	92	Anterior relaxing and posterior 330° relaxing	19	PP	0	0	NA	NA	6.5	NA	9	NA	4	60
9	Smith RJ, 2011	201	2-petal	20	HA, PP, AO	1	0	NA	NA	NA	NA	NA	NA	5	32
10	Lin CW, 2016	89	Anterior relaxing with circumferential posterior	NA	HA, PP, AO	21	NA	NA	NA	4	2	NA	6	NA	109
11	Nadal J, 2018	133	Evisceration with posterior autogenous scleral graft within the modified scleral shell	17	AO	2	NA	NA	NA	8	NA	9	NA	2	57
12	Dave TV, present study	1800	2-petal and 4-petal	19	PMMA and PP	3%	3%	0	20*	5	7	11 [#]	1	1	12

SSD: Superior sulcus deformity, PMMA: Poly(methyl methacrylate), HA: Hydroxyapatite, PP: Porous polyethylene, AO: Aluminium oxide.

* An accurate estimation of new-onset ptosis could not be made since many had ptosis due to volume loss.

[#]This is the only study to give an objective grading to the SSD.

the ideal prosthesis to have a volume of 2.2 ml or less and a thickness of around 7 mm. In our series, we found the mean prosthetic volume to be 2.22 ml or less in 79% of the patients and thickness of 7 mm or less in 89% of the patients, making it comparable to the data presented by Kaltreider et al.²⁷

The strengths of this study include the large number of cases enrolled with data spread over 7 years and a reasonably long follow-up period. Another strength is the presentation of the prosthetic outcomes in a large subset. One of the limitations of our study is the relatively smaller number of patients undergoing a porous polyethylene implant to allow comparison of data between the PMMA and the porous implant groups. This can be explained by the surgeons' choice of implant and the higher cost of the porous implants. Also, 54% of our patients belonged to the lower socioeconomic group. Another limitation is the possible observer bias in calculating the prosthesis outcomes. To conclude, we present the largest series of patients undergoing evisceration and implant in tertiary referral practice. Based on the results of this study, evisceration with implant, performed using a mean implant diameter of 20 mm, is associated with minimal complications and gives a good aesthetic outcome in 93% of the eyes.

Disclosure statement

No potential conflict of interest was reported by the author(s).

Funding

This work was supported by the Hyderabad Eye Research Foundation.

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