Original Article

Risk factors for orbital implant exposure after evisceration: A case control study of 93 patients

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Purpose: The study aims to analyze risk factors for exposure of orbital implants after evisceration by comparison of patients with and without exposure of implants. **Methods:** This is a case control study in retrospective interventional case series; Group A- implant exposures after evisceration, Group B - Patients on follow up after evisceration with implant, without exposure, with matched duration of follow up. The sample size is calculated for a power of 80. **Results:** Group A comprised 32 sockets with implant exposure, presenting at median 18 months after surgery; Group B included 61 eviscerated sockets, without implant exposure, with follow up median 36 months. Odds Ratio (OR) was calculated; infected eyes -OR 1.3, $P = 0.6$; phthisical eye - OR 1.4, $P = 0.43$; multiple prior surgeries- OR 1.55, $P = 0.33$. Group A had 59.3% porous implants, Group B 55.7%, - OR 1.3, $P = 0.5$. Mean implant size in Group A 19.06 mm, Group B 18.78 mm- showed no statistical difference. Multiple logistic regression analysis showed no significant risk factor for exposure. Surgeon factor was not analyzed since there were multiple surgeons. **Conclusion:** This is the first study with calculated sample size, comparing implant exposure patients to a control group. Porous implant material, presence of infection, phthisical scleral shell, and prior surgery showed higher trend of exposure (Odds ratio >1), but none was conclusive. Larger size of implant was not a risk factor for exposure. Eliminating the role of several factors in implant exposure allows the surgeon to make better surgical choices: such as place an implant of appropriate size, of a material of surgeon's choice, and do primary placement of implant in a patient with evisceration post-corneal ulcer or endophthalmitis. A hypothesis and a recommendation is that meticulous attention be paid to surgical technique.

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Evisceration of the eye is undertaken for several indications such as a painful blind eye, severe open globe injury, endophthalmitis or panophthalmitis, or in a deformed blind eye prior to fitting a prothesis.[1] Implants have been used for volume replacement after evisceration since 1885.[2] Multiple materials and designs have been used in orbital implants, and there are standard guidelines for selecting the appropriate size.[3-7]

Implant exposure is a known complication of placement of an orbital implant. Implant exposure leads to discharge and infection and needs further surgical management. The reported rate of implant exposure after evisceration ranges from zero to 67%[4-6,8-17] Multiple studies have described exposure rates after evisceration, but the causes of implant exposure after evisceration have been addressed by very few of these studies.[12,15] Published reports have analyzed enucleation and evisceration together for complications.[14,18] This study evaluates the various known risk factors for implant exposure following evisceration surgery, comparing patients with implant exposure to matched controls without exposure.

Aims and objectives

Our study aims to assess the postulated risk factors for implant exposure by comparing the pre-operative and intraoperative characteristics of patients who had implant exposure to those who did not.

Methods

A retrospective review of records was undertaken for all consecutive patients with implant exposure after evisceration, operated between January 2009 and April 2014. Informed consent for surgery had been provided by all patients.

All consecutive patients with exposure of implant were selected; the mean interval from surgery to presentation with implant exposure was 20 months (Group A). Consecutive patients undergoing evisceration with implant in the same time period, with a minimum follow up of one year, without implant exposure at any visit, were included as controls (Group B). The records were accessed as per the Helsinki declaration and Institutional Review Board (IRB) approval was taken. The sample size calculation for unmatched case-control study showed a power of 80 and alpha error of 0.05, for sample size of 28 in the cases (exposure group) versus 55 in the control (non-exposure group). (http://www.openepi.com/SampleSize/SSCC.html).

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Patient details including age, gender, the indication for surgery, implant material, implant size, surgical technique, and any post-operative complications were noted from the medical records. Orbital implant exposure was defined as loss of integrity of anterior socket tissues, conjunctiva, Tenon's capsule and sclera, such that the implant is visible on the surface. Any dimension of gaping was considered exposure, including extrusion of the implant. In patients with exposure of implant, the time interval since the surgery, and any presence of symptoms like pain, bleeding, or discharge was noted.

The evisceration surgery was performed under general or local anesthesia, with 360° peritomy, keratectomy, removal of the intraocular contents. The scleral shell was swabbed with absolute alcohol and irrigated. Anterior radial sclerotomy with peri-optic nerve sclerotomy, or four-petal sclerotomy, was performed as per surgeon's choice. The implant was placed after assessment with a sizer. One of the following implants was placed- hydroxyapatite (FCI Ophthalmics, Pembroke, USA), alumina (FCI Ophthalmics, Pembroke, USA), porous polyethylene (Biopore Surgicals, Mumbai, India), or silicone (Surgiwear, Shahjahanpur, India). The scleral opening was closed with interrupted 6-0 polygalactin or 5-0 polypropylene suture and conjunctiva was closed with continuous 6-0 polygalactin. No patient underwent wrapping of implant or pegging. An appropriate size conformer was inserted and the patient was prescribed analgesics, oral antibiotics, and topical steroid and antibiotic eye drops. The surgeries were performed by various surgeons with varied level of skill and experience, including residents, trainees and trained oculoplasty surgeons.

Statistical analysis was performed using the commercially available software Medcalc v16.4. The Z test was performed to compare pre-operative characteristics. Student's T test was used to compare implant sizes in the two groups. Chi square test was used to compare use of indigenous implants in the two groups. Odds ratio and multiple logistic regression were analyzed to evaluate the effect of the other factors like type of implant, indication for surgery, prior history of multiple ocular surgeries.

Results

A total of 93 eyes of 93 patients were included in the study. Group A comprised patients who had implant exposure, 32 eyes with median follow up of 18 months, mean 20 months, range 1-61 months. Group B (control group) comprised patients post-evisceration, without exposure, 61 eyes with median follow up of 36 months, average 37 months, range 12–65 months. The pre-operative data of the two groups are presented in Table 1.

Table 2 shows the implant characteristics. In Group A, 17 out of 32 (53%) presented with socket related symptoms; nine (28%) presented with pain, eight (25%) with discharge and five (15.6%) patients presented with bleeding from the socket. Several patients had more than one symptom.

On calculation of Odds Ratio, for the type of implant (porous versus non-porous), presence of previous infection, presence of phthisical eye, and history of multiple previous surgeries – all showed Odds ratio greater than one, but none was conclusive. Multiple logistic regression analysis did not show any factor to be significant [Table 3]. Two tailed T test was performed between the two groups for the size of the implants used, with $P = 0.3$, and no significant difference [Table 2]. Chi square test on the usage of indigenous porous polyethylene implant did not show a difference between the groups ($P = 0.87$). Use of a larger implant (20 mm or larger) in a phthisical eye, was also not significantly commoner in the exposed group by Chi square test ($P = 0.17$).

Table 1: Preoperative characteristics in the two groups

Characteristics	Group A	Group B	*P*
Mean age in years (range)	41.5 (16-80)	32.1 (3-77)	*P*=0.3
Standard deviation	19.87	18.36	
Gender distribution (male:female)	16:16	38:23	*P*=0.26
Commonest Indications for surgery			
Phthisis bulbi	20	33	
Post infection	6	9	
Post-trauma	4	15	
Post multiple surgery	12	17	

Table 2: Implant characteristics in the two groups

	Group A	Group B
Mean implant diameter	19.06 mm (CI 18.71-19.41)	18.78 (CI 18.45-19.11)
Range of implant diameter	18-20 mm	16-22 mm
Non-porous implants	13 (40.6%, CI 23.6-57.6)	27 (44.2%, CI 31.8-56.7)
Silicone	12	27
PMMA	1	
Porous implants total	19 (59.3%, CI 42.4-76.4)	34 (55.7%, CI 43.3-68.2)
Hydroxyapatite	2	3
Aluminium oxide	6	11
Indigenous porous polyethylene	11	20

Table 3: Odds ratio for hypothetical risk factors for exposure

	Odds ratio	*P*
Infection	1.3	0.6
Phthisical eye	1.4	0.43
Multiple prior surgeries	1.55	0.33
Porous implant	1.3	0.5

Discussion

Multiple studies have evaluated the factors that play a role in implant exposure post evisceration or enucleation. Variables like type of surgery,[4] type of implant used,[19] wrapping of implant,[6,20] use of pegging,[12,15] technique of surgery,[6,8,11] multiple prior surgeries,[14] ocular comorbidities and infections,[3,21] and surgeon skill[22] have been evaluated. However, in these studies, the entire cohort of eviscerated and/or enucleated patients has been studied; the exposed and non-exposed implants have been compared, but without adequate sample size. Many of the publications have analyzed evisceration and enucleation together. The number of cases

in the group with implant exposure has been small in these series. A case control study of exposed versus non-exposed implants with calculated sample size has not been published previously.

We evaluated the known risk factors for exposure in patients undergoing evisceration with implant based on previous literature. Several studies have differentiated between the rates of implant exposure, wound dehiscence and implant extrusion. We feel that all three refer to loss of integrity of the tissues anterior to the implant, thereby leaving the orbital implant open to the surface. In this study we have grouped all three entities together for the purpose of analysis of data.

Many studies have compared outcome of different material and designs of implants used in evisceration. Porous implants allow fibrovascular ingrowth into the implant, which reduces implant migration. Non-porous implants have a higher rate of implant migration, while the integrated porous implants have a higher rate of exposure.[1] Our surgeons preferred porous implant over non porous implants. We found that the material of implant was not a risk factor for implant exposure. Based on anecdotal information, we particularly analyzed a newer brand of porous polyethylene implant, indigenously produced in our country. This implant was also insignificant as a risk factor.

We found no difference in the implant sizes placed in Group A versus Group B. Though the average size of implant in group A was higher, it was not statistically significant. The average size of implants used in this series was similar to those in multiple published series.[6,8,11]

The primary placement of orbital implant after evisceration in infected eyes has been studied.[3,21,23] Our study showed no increase in exposure when implant was placed in eyes with endophthalmitis, panophthalmitis or perforated corneal ulcer. This was similar to the findings of other studies that placement of an implant in panophthalmitis does not lead to greater implant exposure.[3,21,23] However, in a retrospective study, we were unable to assess the health of the sclera; the health of the sclera is essential for an uncomplicated implant placement. Bee published a study concluding that higher leucocyte count pre-operatively may give higher risk of implant exposure.[24] However, Bee's study reported an exposure rate of 12.5%, which is well within the other reported rates of exposure.

In this series the most common indication for surgery was phthisis bulbi. Placement of an adequately sized implant into a phthisical scleral shell needs meticulous surgical technique and relaxing sclerotomies, to place the implant well into the muscle cone. Lack of care in this step may cause exposure of the implant. With this hypothesis, we tested the groups for presence of phthisis bulbi, which was not significant. We also tested for the combined effect of phthisis bulbi and larger implant (20 mm or larger). The juxtaposition was not a significant risk factor.

Integrity of the conjunctiva is paramount in maintaining the health of the socket. A history of multiple prior surgeries has been reported as a risk factor for exposure.[14] We hypothesized that multiple prior surgeries may scar the conjunctiva and lead to a greater exposure rate. We found this hypothesis was not substantiated in our study, and the history of multiple prior surgeries was not a significant factor. Neither of the groups included any patient with previous history of chemical injury or radiation to the orbit, which are also causes of scarring.

Skill and experience of the operating surgeon have been noted to be of significance in determining outcomes.[17,22] While surgeon factor has been reported to cause a 12-fold difference in the rate of complication by McElnea *et al*., this report combined cases of enucleation and evisceration.[22] Enucleation is a more complex surgery, and further outside the comfort level of the general ophthalmologist; including enucleation may have skewed the result.

Surgical technique has been found to have an impact on the outcome. Kostick and Linberg have stressed on use of relaxing sclerotomies for deeper placement of a larger orbital implant.[25] Other recent publications on evisceration focused on techniques of surgery which allow placement of a larger orbital implant deep into the socket.[8,11,26] Placement of an implant posterior to posterior sclera showed less exposure as compared to radial sclerotomies.[26] The four-petal technique has also been reported as having low rate of exposure. On review of the surgical notes, all patients in our series, both exposed and non- exposed, had radial relaxing sclerotomies, with placement behind posterior sclera, or four petal evisceration performed.

As mentioned, there were surgeons with varying levels of skill and experience operating our set of patients. There were two trained experienced oculoplastic surgeons whose cases were included in this series; however, even for them, all surgeries were assisted by trainees or residents; from the surgical notes, we could not determine which steps of the surgery were performed by the residents, and the levels of training of the concerned residents. Hence the skill of surgeon was not amenable to analysis.

Patients who had exposure were identified during routine reviews, or when they presented with symptoms. More than half the patients had symptoms like bleeding, discharge, and pain. This highlights the need for long-term follow up.

We found that implant exposure may occur as late as 18 or 20 months after surgery. Previous studies have pointed out that longer follow up may reveal more cases of implant exposure.[4,14] We have chosen a control group with median follow up which is comparable to, or longer than the implant exposure group. We can be reasonably certain that potential implant exposures in the control group have not been missed due to inadequate follow up duration.

This is the first large study which uses uncomplicated evisceration with implant as a control group to determine risk factors for implant exposure. An appropriate sample size has been used to give a power of 80. This study does not include enucleation, which has a completely different technique, and is unsuitable for comparison. Third, we have combined the incidents of implant exposure, extrusion and dehiscence. In all three, the anterior surface of the implant is no longer covered by the tissues of the socket. Similar pathophysiologic principles would apply in all three conditions, and the conditions should be analyzed together. We have analyzed multiple risk factors for implant exposure. The Odds ratio and multiple logistic regression do not indicate culpability of any particular factor. While this is a study with adequate power, a larger still sample size may have shown significance of some risk factor.

From the largely negative findings of our study, we arrive at several interesting conclusions.

The material of the implant is not germane to implant exposure. Rather than being driven by the industry, the surgeon can select the implant he/she feels is most appropriate. Use of a larger implant does not predispose to increased implant exposure. The surgeon should use an adequately sized implant for volume replacement after evisceration, and not undersize the implant. Multiple prior surgeries do not make the eye more susceptible to implant exposure. Although the conjunctiva would be scarred and adherent, careful handling of the conjunctiva will allow successful placement of implant. Placement of an implant into an eye eviscerated for infections such as endophthalmitis, does not increase the rate of exposure. It is acceptable to place an implant at the primary surgery, and not subject the patient to a second surgery. Implant exposure can occur years after the primary surgery. More than half the patients presented with symptoms of pain, discharge and bleeding in the socket, and the surgeon should be aware of these indicators of exposure.

We put forward the following hypothesis: since the only factor we did not analyze was level of surgeons' skill, and all other putative factors emerged non-significant, perhaps the most critically important factor is the surgeon skill. The hypothesis is difficult to prove definitively: a randomized trial would not be ethical. A retrospective study comparing "non-oculoplastic surgeon" to "oculoplastic surgeon" would not garner sufficient numbers in the first arm, and other conditions would not remain comparable.

We urge adequate training in evisceration at the level of residency in ophthalmology; as well as urge any ophthalmologist to focus on meticulous surgical technique in performing evisceration with implant.

Conclusion

Porous implant material, presence of infection, phthisical scleral shell, and prior surgery showed a higher trend for implant exposure in our study, but none was conclusive. Larger implant size was not a risk factor for exposure. Based on these results, the surgeon can make appropriate surgical choices regarding the size and the material of the implant and whether to perform primary implant following evisceration in patients with corneal ulcer or endophthalmitis.

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Conflicts of interest

There are no conflicts of interest.

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