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Porous orbital implant after enucleation in retinoblastoma patients: indications and complications

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Abstract

This study aims to identify risk factors associated with complications in retinoblastoma patients following primary and secondary enucleations with porous implant placement.

A retrospective case-control study was performed between 2010 and 2015. Data pertaining to subjects' demographics, medical history, clinical, and pathological findings, implant characteristics and complications were collected.

The analysis included 103 eyes of 101 patients age 27.8 ± 21.9 months undergoing enucleation for retinoblastoma. Postoperatively, 19/103 (18%) eyes developed exposure, extrusion, or hematoma requiring subsequent surgery. Exposure was the most common postoperative complication (12/19, 63%). Age at enucleation 24 months or younger, Hispanic ethnicity, female gender, and intravenous chemotherapy prior to enucleation were associated with increased odds of implant complications. In contrast, patients who were given intravitreal melphalan (IM), subtenons carboplatin (SC), or external beam radiation therapy (EBRT) did not demonstrate an increased risk of complications.

In this cohort of retinoblastoma patients undergoing primary or secondary enucleation with porous implants, implant exposure was the most common postoperative complication. Our findings suggest that female gender, Hispanic ethnicity, age at enucleation 24 months or younger, and intravenous chemotherapy prior to enucleation may increase the risk of complications.

Keywords

Chemotherapy; complications; exposure; porous implant; retinoblastoma

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Disclosure statement

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Introduction

The clinical utility of an orbital implant following enucleation is to replace orbital volume, provide support for an ocular prosthesis, and aid in postoperative cosmesis.^{1–3} The ideal implant should also possess good biocompatibility, support for anophthalmic orbit growth, ease of surgical implantation, and low complication rates.⁴ Postoperative complications, including contraction of the socket, implant migration, exposure, and infection often require revisional surgery and additional anesthesia sessions, and thus pose increased risk to the patient.^{2,5}

Orbital implants are broadly divided into two types: porous and nonporous. Nonporous implants like silicone spheres are relatively inert, flexible, easy to use, and inexpensive, but have become utilized less frequently since the introduction of porous implants such as hydroxyapatite (HA), porous polyethylene (Medpor®), and aluminum oxide. This is because porous implants in theory promote fibrovascular ingrowth that allows them to integrate into the orbital tissue and thus have the promise of better prosthesis motility.^{4–7} Porous implants also allow for direct attachment of extraocular muscles, which may reduce the risk of implant migration while additionally improving prosthetic movement through the placement of a pegging system that couples the prosthesis with the implant.^{1,2,8,9} However, while porous implants have theoretical advantages over nonporous implants, there has yet to be conclusive data to support the use of one over the other.¹⁰ In fact, there are several studies which have failed to demonstrate any motility advantages of porous implants over nonporous implants.^{11–13}

Given the range of complications associated with orbital implant placement and the range of available implant types to choose from, it is important to develop a broad-based understanding of the possible risk factors for complications in all patient populations. In the pediatric population, most enucleations are performed secondary to trauma.⁶ Another common indication for enucleation is advanced retinoblastoma, and these patients are at increased risk of complication given their ocular and systemic therapy.^{1,14} This study aims to identify risk factors for complications following primary or secondary enucleation with porous orbital implant placement in retinoblastoma patients at a single institution over a 5 year period.

Materials and methods

Patients and procedures

In this retrospective, case-control study, patients with retinoblastoma who underwent enucleation with porous orbital implant placement between January 1, 2010, and July 1, 2015 were included. Enucleations within this time period were performed by more than one surgeon on the ocular oncology service with the choice of orbital implant type based upon surgeon preference. We obtained data from electronic medical records pertaining to subjects' demographic information, medical history, clinical and pathological findings, implant characteristics, and complications. Study data were collected and managed using REDCap electronic data capture tools hosted at the University of Southern California.¹¹

Surgical technique

Enucleations performed in children for retinoblastoma are similar to previously described techniques using porous implants. A 360 degree conjunctival periotomy is completed and Tenon's layer is dissected away from the sclera. All 4 rectus muscles are sequentially isolated with muscle hooks, secured with 5–0 Vicryl sutures and transected from the sclera. A blunt cannula is used to infuse a solution containing 1% lidocaine with epinephrine and Wydase into the intraconal space. The superior oblique and inferior oblique muscles are then isolated and transected from the sclera. Using traction on the medial rectus insertion site, the optic nerve is palpated and transected in the posterior orbit using long-tipped scissors. Cottonoids soaked in epinephrine and thrombin are placed into the intraconal space to obtain hemostasis. Orbital implant sizers are then used to determine the size of the porous implant used in the case. The porous implant is soaked in Bacitracin solution, then placed into the intraconal space using the provided introducer. All four recti muscles are then attached to the grooves in the anterior surface of the implant using the previously attached 5–0 Vicryl sutures. The anterior Tenon's layer is then closed with interrupted, buried 5–0 Vicryl sutures, and the conjunctiva is closed using a running 6–0 plain gut suture. A small plastic conformer is placed between the eyelids and a double eye patch and shield are used for the surgical dressing.

Statistical analyses

A multivariable logistic regression model was created in order to evaluate the independent effects of predictors of experiencing any complications from porous polyethylene orbital implant placement, while controlling for relevant demographic and clinical characteristics. All statistical analyses were conducted using Stata/SE 14.2 (StataCorp LLC, College Station, TX, USA).

Results

Demographic and clinical characteristics

A total of 103 eyes of 101 patients diagnosed with retinoblastoma underwent primary or secondary enucleation with a porous implant at CHLA between January 1, 2010, and July 1, 2015. Of these 103 implants, 99 were Medpor® smooth surface tunnel (SST), two were Medpor® multipurpose conical orbital implants (MCOI), and two were porous Alphasphere™ implants. Other demographic and clinical characteristics are reported in Table 1. Of note, all but one enucleated eye was either Group D or E.

Primary enucleation was performed on 70 eyes (68.0%) while 33 eyes (32.0%) received therapy prior to enucleation, including intravenous chemotherapy (33 eyes) and external beam radiation therapy (EBRT) (12 eyes).

Nineteen eyes (18.4%) experienced postoperative complications, including 12 implant exposures (11.7%) (Figure 1), and two instances of extrusion (in implants that were also exposed). The implant exposures were repaired via implant revision, implant exchange, and/or conjunctivoplasty. No patients with porous orbital implants experienced implant migration. Seven surgeries had minor complications, including postoperative hematoma or

hemorrhage (5/19), prolonged orbital inflammation (1/19), and minor conjunctival dehiscence without implant exposure (1/19).

Risk factors for complications in porous implants

In multivariate analyses, female sex (Adjusted OR = 7.61, 95% CI: 1.77–32.62, $p = 0.006$), Hispanic/Latino ethnicity (Adjusted OR = 4.62, 95% CI: 1.27–16.75, $p = 0.02$), and younger age (Adjusted OR = 1.06, 95% CI: 1.01–1.12, $p = 0.04$) were associated with greater odds of experiencing a complication of any type following implant placement (Table 1). In contrast, laterality (unilateral or bilateral disease; Adjusted OR = 0.49, 95% CI: 0.07–3.27, $p = 0.47$) and the presence of high-risk pathology on evaluation of the enucleated eye (Adjusted OR = 0.89, 95% CI: 0.10–7.87, $p = 0.92$) were not found to be significant factors associated with complications.

Patients who received intravenous chemotherapy prior to enucleation were also more likely to experience complications following enucleation (Adjusted OR = 7.32, 95% CI: 1.05–50.82, $p = 0.04$), however chemotherapy following enucleation was not associated with increased complications (Adjusted OR = 1.61, 95% CI: 0.23–11.57, $p = 0.63$). Other types of chemotherapy were not associated with complications; no patients who received Intravitreal Melphalan or Subtenons Carboplatin experienced any complications, and only one patient who received intra-arterial chemotherapy experienced complications. Furthermore, there were no observed complications in patients with a history of EBRT prior to enucleation.

We also examined age at critical cut-off levels for predicting complications, and determined that age at enucleation of 24 months or younger was significantly associated with complications, χ^2 (1, N = 103) = 5.44, $p = 0.02$, OR = 3.56.

We analyzed the length of resected optic nerve and incidence of blepharoptosis. We found an incidence of ptosis of 4/52 (7.7%) in optic nerve lengths less than 1.0 cm and 5/49 (10.2%) in lengths 1.0 cm or greater; the incidence of ptosis did not differ significantly between the two groups ($p = 0.66$).

Discussion

Retinoblastoma patients undergoing enucleation are unique given their young age and the concomitant systemic and ocular treatment they often receive before and after enucleation. In this cohort of retinoblastoma patients undergoing primary or secondary enucleation with porous implant over a 5 year period we found a 18% rate of postoperative complications, the most common of which was implant exposure in 12 of 103 patients (11.7%) in our cohort. These patients required subsequent surgery and comprised the majority of our observed complications. Our observed exposure rate of porous orbital implants in this cohort was comparable to previous studies on retinoblastoma patients that have found rates ranging from 0%–53% and greater than previously observed rates in adult patient populations or pediatric patients enucleated for a diagnosis other than retinoblastoma.^{3,14–19}

Factors thought to be related to the development of postoperative complications include implant material type, surgical technique and exposure to additional therapy such as chemotherapy and radiation therapy; the latter is particularly relevant to the pediatric retinoblastoma population.^{3,16,17,20–23} In part, this is due to the fact that exposure to chemotherapy or radiation therapy prior to or after enucleation can impact wound healing.^{16,22,23} Results from the literature on the impact of additional therapy on complication rates are mixed. Some studies have found that the risk for complications is slightly increased (16.7%–20.7% in those with therapy versus 5.7%–11.7% in those without), while others did not observe an increased risk from chemotherapy.^{3,16, 17,20–25} Our multivariate analysis observed a 7.3 times significantly greater increase in the odds of experiencing any type of complication if the patient received intravenous chemotherapy prior to enucleation, although the observed difference was less apparent with a 22% complication rate in those who received intravenous chemotherapy versus 17% in those who did not. While we recorded data on outcomes based on specific chemotherapy regimens, it is difficult to make conclusions regarding any difference in impact on complications due to the few numbers of patients who received other forms of local or regional chemotherapy.

Our observation that patients 24 months of age or younger at enucleation is associated with 3.6 times increased risk of experiencing complications is consistent with previous research.⁵ This increased risk may be due to the smaller orbital volume in younger patients.²⁶ Given the difficulty in performing an implant exchange with porous implants, there is motivation for placing an adult-sized (or near adult-sized) implant in young retinoblastoma patients undergoing enucleation. As such, it may be worthwhile considering smaller sized porous orbital implants in the younger patient population or perhaps choosing a larger nonporous implant.

The associations between implant placement complications and female sex and Hispanic ethnicity have not been previously reported, and reasons for these observations remain unclear. Parents of female patients may desire prosthetic placement earlier in the postsurgical period, although we did not record time to prosthesis fitting in this study and therefore this is simply a hypothesis. Another possible mechanism contributing to the noted increase in complication rates may be the slight differences in orbital anatomy between females and males.²⁶ The observed 4.6 times greater risk for complications in the Hispanic population may also be attributable in part to differences in orbital anatomy between ethnic populations, although studies in this regard have been limited to adults.^{27, 28} Ultimately, however it is difficult to make any definitive conclusions explaining these observations in demographics given limitations in the data collected.

Finally, we included an analysis of optic nerve length and the incidence of blepharoptosis to investigate the hypothesis of an increased chance of damage to the superior branch of the third nerve when obtaining a longer optic nerve stump during enucleation in children with retinoblastoma. However, our results did not show a correlation between the incidence of blepharoptosis and a longer optic nerve stump, and therefore this theory was not supported by our results.

A limitation of our study was that we were unable to compare the clinical results of nonporous (i.e., silicone) orbital implants to porous implants due to a small number of patients in our practice who received this type of implant. There have been several studies in adult patients that have compared the two types of implants directly, analyzing complication rates and prosthesis motility. Studies comparing the use of nonporous and porous implants on adult populations have found that complication rates are low and comparable, with acrylic implants possibly providing better prosthetic movement.^{11,12} A recent study by Mourits, et al.²⁰ directly comparing porous and nonporous implants in retinoblastoma patients found that the use of HA led to more exposures (12.7%) than nonporous acrylic implants (4.9%), although the difference was not statistically significant.²⁰ In non-comparison studies, the rates of complications with porous implants are generally higher than with nonporous implants.^{2,15,29} The evidence in the literature suggests that the purported advantages of porous implants remain theoretical, and the results of our current study demonstrate the risk of complications is even higher in the pediatric retinoblastoma population.

In conclusion, we found a significant rate of complications following primary or secondary enucleation with porous orbital implants in the pediatric retinoblastoma population, with implant exposure being the most likely complication observed after enucleation (11.7% in our cohort). While use of porous orbital implants has been generally considered a safe option, age at enucleation 24 months or less, female gender, Hispanic ethnicity, and intravenous chemotherapy prior to enucleation were found to have a statistically significant increase in complication rates. Chemotherapy after enucleation was not found to increase complication rates. Future studies directly comparing the use of porous orbital implants with alternative options such as nonporous implants and dermis fat grafts may be beneficial in elucidating the ideal management of the anophthalmic orbit following enucleation for retinoblastoma.

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Figure 1.
Photographs depicting two instances of orbital implant exposure.

Table 1.

Patient demographics and statistical analysis by outcome (N = 103 eyes).

Variable	All patients N (%)	Complications (n = 19)	No complications (n = 84)	Multivariable logistic regression results	
				OR (95% CI)	p-value
Sex					
Female	49 (48)	14 (74)	35 (42)	7.61 (1.77 – 33.62)	0.006
Male	54 (52)	5 (26)	49 (58)	1	
Ethnicity					
Hispanic or Latino	50 (49)	12 (63)	38 (45)	4.62 (1.27 – 16.75)	0.02
Not Hispanic or Latino	53 (52)	7 (37)	46 (55)	1	
Laterality					
Unilateral	68 (66)	11 (58)	57 (68)	0.49 (0.07 – 3.27)	0.47
Bilateral	35 (34)	8 (42)	27 (32)	1	
Enucleated eye side					
OD	56 (54)	10 (53)	46 (55)		^a
OS	47 (46)	9 (47)	38 (45)		
Group of Enucleated Eye					
B	1 (1.0)	0	1 (1)		^a
D	42 (41)	8 (42)	34 (41)		
E	59 (58)	11 (58)	48 (58)		
Age at enucleation					
Mean Months ± SD	27.8 ± 21.9	18.8 ± 9.6	29.9 ± 23.3	1.06 (1.01 – 1.12)	0.04
Age 0–24 months	51 (50)	14 (74)	37 (44)		
Age 25+ months	52 (51)	5 (26)	47 (56)		
History of chemotherapy before enucleation					
Systemic	32 (31)	7 (37)	25 (30)	7.32 (1.05 – 50.82)	0.04
Intra-arterial	5 (4.9)	1 (5.3)	4 (4.8)	32.86 (0.27 – 3933.41)	0.15
Intravitreal	4 (3.9)	0	4 (4.8)		^a
Melphalan					^a
Subtenons	5 (4.9)	0	5 (6.0)		
Carboplatin					
Post-enucleation adjuvant chemotherapy					
History of EBRT					
	26 (25)	5 (26)	21 (25)	1.61 (0.23 – 11.57)	0.63
	12 (12)	0	12 (14)		^a
High risk histopathologic features					
	21 (20)	3 (16)	18 (21)	0.89 (0.10 – 7.87)	0.92
Average implant size (Mean mm ± SD)					
Total	19.3 ± 1.0	18.9 ± 1.2	19.4 ± 1.0		^a
Age 0–12 months	17.8 ± 0.6	17.9 ± 0.5	17.6 ± 0.9		

Variable	Multivariable logistic regression results				
	All patients <i>N</i> (%)	Complications (<i>n</i> = 19)	No complications (<i>n</i> = 84)	OR (95% CI)	<i>p</i> -value
Age 13–24 months	19.3 ± 1.0	19.3 ± 1.0	19.1 ± 1.1		
Age 25+ months	19.9 ± 0.5	19.9 ± 0.5	20 ± 0.0		

CI: confidence interval; EBRT: external beam radiation therapy; OR: Odds ratio

Items in **bold** are those that were statistically significant at a level of *p* = 0.05 or lower.

^aThese variables were not included in the final multivariable logistic regression model due to lack of observed complications or lack of significance in univariate analysis.