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Original Article/นิพนธ์ต้นฉบับ

Predisposing Factors and Timing of Orbital Implant Exposure/Extrusion Following Enucleation or Evisceration: An 11-year Study

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Abstract

Purpose: Enucleation and evisceration are surgical procedures to remove a diseased eye. An extrusion/exposure of the orbital implants is the most common post-operative orbital implant-related complication. This study aimed to identify the incidence, timing, and possible risk factors of orbital implant exposure/extrusion in patients who underwent enucleation or evisceration.

Methods: The medical records of patients diagnosed with "exposure/extrusion orbital implant" following enucleation or evisceration at Chiang Mai University Hospital between January 2007 and December 2017 were retrospectively reviewed. Multivariable regression analysis was performed to identify the possible predicting factors.

Results: Overall, 466 patients underwent either enucleation (313/466, 67.17%) or evisceration (153/466, 32.83%). Most of the surgeries were performed by ophthalmology residents. Three hundred twelve patients (312/466, 67.16%) were male. The age ranged between 0 and 94 years. The incidence of exposure/extrusion was 12.14% (38/313) in the enucleation group and 17.65% (27/153) in the evisceration group. The most common indication for surgery was ocular infections (218/466, 46.78% patients). Using multivariable regression analysis, older age ($p = 0.008$) and HIV infection ($p < 0.0001$) were significantly associated with the occurrence of exposure/extrusion in patients who underwent enucleation but not the evisceration.

Conclusion: The incidence of extrusion/exposure of the orbital implants following enucleation or evisceration was not uncommon. We identified older age and HIV infection as possible risk factors of orbital implant exposure/extrusion in patients who underwent enucleation. In most cases, the complications occurred within a month following the enucleation (18/38, 47.37% patients) and during 1-12 months following the evisceration (16/27, 59.26% patients), suggesting the appropriate follow-up frequency and period.

Keywords: Orbital implant exposure/extrusion, Enucleation, Evisceration

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Introduction

Enucleation and evisceration are surgical procedures to remove unsalvageable diseased eyes, mainly to save the patient's life and rescue the fellow unaffected eye from sympathetic ophthalmia.[1-2] In an enucleation technique, an entire globe and its intraocular contents are removed, while in an evisceration technique, the sclera, extraocular muscles, and optic nerve remain intact.[1,5] Therefore, indications for surgery, surgical techniques, surgical outcomes, and possible complications are somehow different.

In previous studies, the common indications for enucleation include intraocular malignancy, severe eye trauma, panophthalmitis, painful blind eye, and some congenital anomalies[1-2], whereas the common ones for evisceration are endophthalmitis and perforated corneal ulcer.[1,5] In most circumstances, an orbital implant is inserted at the time of surgery to replace the orbital volume, thus creating an excellent functional socket for future ocular prosthesis implantation.[1-5,9,10] In general practice, at 4-8 weeks following the surgical procedures, the orbital prosthesis is considered for acceptable cosmetic confidence.

However, post-operative orbital implant-related complications are not uncommon, ranging from eye discharge, conjunctival dehiscence, giant papillary conjunctivitis, shallowness of conjunctival fornix, contracted socket, infection, and exposure/extrusion of the orbital implants.[2,7] Of these, the orbital implant exposure/extrusion is the most common, possibly leading to a malpositioning or, eventually, a displacement of the orbital prosthesis.[2,7] Viswanathan P et al. reported the incidence rate of exposure/extrusion to be 4% and 3% in patients who underwent enucleation and evisceration in the UK, respectively.[4] Possible factors contributing to the complications were the types and size of the orbital implants, surgical techniques, infection, and the surgeons' experiences.[1,4,6]

The materials of orbital implants are also associated with the exposure/extrusion rate. In the United States, a comparative study revealed that hydroxyapatite and polyethylene implants were more prone to orbital implant exposure/extrusion than non-porous ones.[1,2,5,8] A study from China found that previous eye surgery and wound closure techniques were the significant contributing factors.[2]

This study aimed to identify the incidence and the possible risk factors of orbital implant exposure/extrusion in patients undergoing enucleation or evisceration from various etiologies, mainly infections. The results will benefit doctors and patients regarding post-enucleation or evisceration follow-up time, management, and medical counselling.

Materials and Methods

The study was approved by the Ethics Review Board of the Faculty of Medicine, Chiang Mai University, and was performed in accordance with the tenets of the Declaration of Helsinki. The medical records of patients diagnosed with "exposure/extrusion orbital implant" who received the procedural treatments (either enucleation or evisceration) at Chiang Mai University Hospital between 1 January 2007 and 31 December 2017 were retrospectively reviewed.

Demographic data and clinical characteristics were collected, including duration of symptoms, causes of enucleation or evisceration, type of implant, type and size of suture, surgeon, and the presence of infection before exposure/extrusion of orbital implants. All patients had the orbital implant inserted at the time of

enucleation or evisceration.

Study objectives

Main objectives

To study possible risk factors for the occurrence of orbital implant exposure/extrusion in patients who underwent enucleation or evisceration in Chiang Mai University Hospital.

Secondary objectives

To study the timing of orbital implant exposure/ extrusion in patients who underwent enucleation or evisceration in Chiang Mai University Hospital.

Surgical techniques

Enucleation is a surgical technique to remove the entire globe and its intraocular contents. The orbital implant is inserted into the eye socket following the surgery to maintain the orbital volume. In this study, the orbital implant was made of glass, sizing from 14, 16, and 18. At the final wound closure step, the Tenon's capsule and conjunctivae were sutured with either Surgidac 5-0 or Vicryl 6-0 or 8-0 in continuous or interrupted fashion based on surgeons' preference. Evisceration was a technique to remove the intraocular contents, including the lens, vitreous, and uveal tissues, then leave the sclera, extraocular muscles, and optic nerve intact. Next, the sclera was sutured with either Surgidac 5-0 or Vicryl 6-0 in an interrupted fashion. The sutures of Tenon's capsule and conjunctivae were similar to the enucleation technique.

Definition of orbital exposure/extrusion

Orbital implant exposure was defined as the orbital implant with any exposed areas, and orbital implant extrusion was defined as the orbital implant being extruded from the eye socket.

Statistical analysis

Descriptive analysis was used to describe the patient's demographics and clinical characteristics. Multivariable regression analysis was used to analyze the associations between patients' clinical data and the occurrence of exposure/extrusion. Statistical analysis was performed using R packages version 3.4.4 (2018).

Results

During the study period, enucleation or evisceration with primary orbital implants was performed in 466 patients. Of 466 patients, 313 patients (67.17%) were in the enucleation group, and 153 patients (32.83%) were in the evisceration group. The surgeries included the ophthalmology resident, the oculoplastic fellow, and the staff.

Of 466 patients, 312 (67.16%) were male. The age group ranged between 0 and 94 years. Similarly, the most common indication for enucleation or evisceration was ocular infection (145/313 (46.33%) patients for the enucleation group and 73/153 (47.71%) patients for the evisceration group). (Table 1) Other causes were trauma, tumor, and miscellaneous.

The orbital implant exposure/extrusion rate was 12.14% (38/313) of patients in the enucleation group and 17.65% (27/153) in the evisceration group.

Surgical techniques in the orbital implant exposure/extrusion patients

Of the patients with orbital implant exposure/ extrusion following enucleation, 24 of 38 (63.16%) eyes were sutured with combined Surgidac 5-0 and Vicryl 8-0, and 14 eyes with Vicryl 8-0. Considering the

Table 1 Demographics and baseline clinical characteristics of the patients who underwent enucleation or evisceration.

Demographics and clinical characteristics	Enucleation group		Evisceration group	
	Orbital implant exposure/extrusion (N = 38)	No exposure/extrusion (N = 275)	Orbital implant exposure/extrusion (N = 27)	No exposure/extrusion (N = 126)
Gender				
- Male (N, (%))	29 (76.32)	187 (68)	16 (59.26)	80 (63.49)
- Female (N, (%))	9 (23.68)	88 (32)	11 (40.74)	46 (36.51)
Age (Years)	30.26	41.88	48.26	50.45
Underlying diseases				
- DM (N, (%))	2 (5.26)	29 (10.55)	5 (18.52)	17 (13.49)
- HT (N, (%))	4 (10.53)	45 (16.36)	4 (14.81)	32 (25.4)
- HIV infection (N, (%))	3 (7.89)	2 (0.73)	0 (0)	3 (2.38)
- Others (N, (%))	1 (2.63)	34 (12.36)	8 (29.63)	32 (25.4)
Indications for anophthalmic surgery				
- Ocular infection (N, (%))	19 (50)	126 (45.82)	13 (48.15)	60 (47.62)
- Trauma (N, (%))	8 (21.05)	64 (23.27)	1 (3.7)	19 (15.08)
- Tumor (N, (%))	9 (23.68)	57 (20.73)	0 (0)	1 (0.79)
- Others (N, (%))	2 (5.26)	27 (9.82)	13 (48.15)	46 (36.51)

suture techniques, 29/38 (76.32%) eyes were sutured with combined interrupted and continuous fashion, 7/38 (18.42%) eyes with an interrupted fashion, and 2/38 (5.36%) eyes with a continuous fashion.

For the evisceration group, 21 of 27 (77.78%) exposure/extrusion eyes were sutured with combined Surgidac 5-0 and Vicryl 8-0, 3 eyes with Vicryl 8-0, and 1 eye with Surgidac 5-0. For the suture techniques, mainly the combination of interrupted and continuous sutures was applied (19/27 (70.37%) eyes), followed by the solely interrupted (3/27 (11.11%) eyes) and continuous ones (2/27 (7.4%) eyes).

Orbital implant size in the orbital implant exposure/extrusion patients

In the enucleation group, the patients with orbital implant exposure/extrusion, 3 of 38 patients (7.89%) were inserted with orbital implant size 14, 17/38 (44.74%) patients with size 16, and 18/38 (47.37%) patients with size 18. In patients who underwent evisceration with subsequent orbital implant exposure/extrusion, 1 of 27 (3.7%) patients were inserted with orbital implant size 14, 13/27 (48.15%) patients with size 16, and 13/27 (48.15%) patients with size 18.

Time to exposure or extrusion

In the enucleation group, 1 of 38 (2.63%) patients was diagnosed with orbital implant exposure/extrusion as early as within the first week following the enucleation. However, most complicated cases occurred within a month following the surgery (18/38, 47.37% patients). Only 15/38 (39.47%) patients had the orbital implant exposed/extruded between 1-12 months after the enucleation, and 4/38 (10.53%) patients at

more than a year afterward (Table 2).

In the evisceration group, 4 of 27 (14.81%) patients were diagnosed with orbital implant exposure/ extrusion between 1-4 weeks after evisceration and 7/27 (25.93%) patients at more than one year. Most of the cases (16/27 (59.26%) patients) had orbital implant exposure/extrusion at some points during 1-12 months following the surgery (Table 2).

Risk factors of orbital implant exposure/ extrusion

Using the multivariable regression analysis, older age, and HIV infection were the significant predicting factors for the occurrence of exposure/extrusion in the enucleation group (older age, $p < 0.001$ and HIV infection, $p = 0.008$) but not in the evisceration group (older age, $p = 0.268$ and HIV infection, $p = 0.364$) (Table 3).

Table 2 Time to orbital implant exposure/extrusion following the enucleation or evisceration

	Time to orbital implant exposure/extrusion			
	<1 wk.	**1 wk- 4 wk**	**1 mo – 12 mo**	**>1 yr**
Enucleation group	1 (2.63%)	18 (47.37%)	15 (39.47%)	4 (10.53%)
Evisceration group	0	4 (14.81%)	16 (59.26%)	7 (25.93%)

Table 3 Multivariable regression analysis for clinical characteristics associated with the occurrence of exposure/extrusion

	Enucleation group Coefficients (T value)	***P* value**	**Evisceration group Coefficients (T value)**	***P* value**
Age	-2.667	0.008	-1.112	0.268
HIV infection	3.275	< 0.001	-0.640	0.364

Discussion

In this study, the percentages of exposure/ extrusion of the orbital implant following enucleation or evisceration were approximately 15% (12.14% for the enucleation group and 17.65% for the evisceration group), whereas, in previous studies, the incidence of orbital implant exposure/extrusion widely ranged from 3% to 20%.[4,11] The relatively high percentages in the study may partially be explained by the major indication for ongoing procedures as infection (46.33% in the enucleation group and 47.71% in the evisceration group), compared to the indications of painful blind eyes from glaucoma or trauma in previous studies.[4] Additionally, the type of orbital implant used in this study is made of glass and non-porous. The non-porous orbital implant was previously reported as a material with a higher incidence of orbital implant exposure/ extrusion[3,6] In this study, most cases of evisceration or enucleation were performed by ophthalmology residents.

Regarding the timing, most of the incidences of exposure/extrusion happened in the first month following the enucleation (47.37%) and between 1-12 months following the evisceration (59.26%). In this study, the most common indication was an uncontrolled infection, in which fungus was a relatively common pathogen; therefore, the use of antifungal medications was prolonged following the enucleation or evisceration. Therefore, the different times to exposure/extrusion may guide the appropriate frequency and period of follow-ups. Additionally, as exposure/extrusion rarely happened after one year (10.53% in the enucleation group and 25.93% in the evisceration group), the follow-up period should be outlined for a year at least.

Using multivariable regression analysis, age, and HIV infection were the significant predicting factors for the orbital implant exposure/extrusion following enucleation. However, the primary indication for patients who underwent the enucleation in this study was an infection. Therefore, older age and HIV co-infection probably worsened the ocular infections and delayed the wound healing process by themselves, which altogether may weaken the integrity of the eye socket for the orbital implant, resulting in the exposure/extrusion as early as the first week following the operation.

Similar associations were also expected in the patients who underwent evisceration but may be underestimated due to fewer cases. Although other possible predicting factors, which included surgical techniques and orbital implant materials, were mentioned in the previous studies[3,5-7], these factors were of limited information and variation in this study. The type of orbital implant material in the study site was mainly made of glass, and the surgeons were ophthalmology residents in the majority. These unintentionally controlled circumstances may further emphasize the significant findings of aging and HIV infection as strong predicting factors for exposure/extrusion following enucleation.

Due to the retrospective nature of the study, some information, in particular the operative note, was somehow unavoidably missed. Moreover, due to advances in ophthalmology treatments, the conditions of unsalvageable orbital diseases are decreasing, thus limiting the prospective study in this field.

Conclusion

The incidence of orbital implant exposure/extrusion was approximately 15% (12.14% in the enucleation group and 17.65% in the evisceration group). Most cases of exposure/extrusion happened within a month following the enucleation and within the first year following the evisceration, which may outline the timing and period of follow-ups. Patients with older age or HIV co-infection should be advised regarding the higher risk of orbital implant exposure/extrusion following the procedure, in particular for the indications of ocular infection.

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ปัจจัยและระยะเวลาในการเกิดภาวะวัสดุใส่หนุนลูกตาเทียมโผล่ (Exposure) หรือหลุด (Extrusion) หลังจากการผ่าตัดเอาลูกตาออก (Enucleation) หรือการผ่าตัดที่ควักเฉพาะเนื้อในลูกตาออก (Evisceration): การศึกษา 11 ปี

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บทคัดย่อ:

วัตถุประสงค์: การผ่าตัดเอาลูกตาออก (Enucleation) หรือการผ่าตัดที่ควักเฉพาะเนื้อในลูกตาออก (Evisceration) เป็นการผ่าตัดเพื่อนำตาส่วนที่มีปัญหาออก แล้วแทนที่ด้วยการใส่วัสดุใส่หนุนลูกตาเทียม ภาวะวัสดุใส่หนุนลูกตาเทียมโผล่ (Exposure) หรือหลุด (Extrusion) เป็นภาวะแทรกซ้อนหลังการผ่าตัดเกี่ยวกับใส่วัสดุหนุนลูกตาเทียมที่พบได้บ่อยที่สุด การศึกษานี้มุ่งที่จะหาอุบัติการณ์ ระยะเวลา และปัจจัยเสี่ยงที่เป็นไปได้ของการเกิดภาวะวัสดุใส่หนุนลูกตาเทียมโผล่ หรือหลุดในผู้ป่วยที่ทำการผ่าตัดเอาลูกตาออกหรือการผ่าตัดที่ควักเฉพาะเนื้อในลูกตาออก

วิธีการเก็บรวบรวมข้อมูล: ศึกษาข้อมูลจากบันทึกการรักษาผู้ป่วยที่ได้รับการวินิจฉัยภาวะวัสดุใส่หนุนลูกตาเทียมโผล่ หรือหลุด หลังจากได้รับการผ่าตัดเอาลูกตาออก หรือการผ่าตัดที่ควักเฉพาะเนื้อในลูกตาออก ณ คณะแพทยศาสตร์ มหาวิทยาลัยเชียงใหม่ ระหว่างเดือนมกราคม พ.ศ. 2550 ถึง เดือนธันวาคม พ.ศ. 2560 โดยการใช้การวิเคราะห์การถดถอยพหุ (Multivariable regression analysis) เพื่อหาปัจจัยเสี่ยงที่เป็นไปได้

ผลการศึกษา: ผู้ป่วยทั้งหมด 466 คน ที่ได้รับการผ่าตัดเอาลูกตาออก (313/466, 67.17%) หรือการผ่าตัดที่ควักเฉพาะเนื้อในลูกตาออก (153/466, 32.83%) แบ่งเป็นผู้ชาย 312 คน (312/466, 67.16%) อายุระหว่าง 0-94 ปี อุบัติการณ์ภาวะวัสดุใส่หนุนลูกตาเทียมโผล่ หรือหลุด 12.14% (38/313) ในกลุ่มผู้ป่วยที่ได้รับการผ่าตัดเอาลูกตาออก และ 17.65% (27/153) ในกลุ่มผู้ป่วยที่ได้รับการผ่าตัดที่ควักเฉพาะเนื้อในลูกตาออก ข้อบ่งชี้ที่พบบ่อยที่สุดของการผ่าตัดคือ ภาวะลูกตาติดเชื้อ (218/466, 46.78%) การวิเคราะห์การถดถอยพหุพบว่า อายุที่มากขึ้น (p = 0.008) และการติดเชื้อ HIV (p < 0.001) สัมพันธ์กับการเกิดภาวะวัสดุใส่หนุนลูกตาเทียมโผล่ หรือหลุด ในผู้ป่วยที่ได้รับการผ่าตัดเอาลูกตาออกอย่างมีนัยสำคัญ

สรุป: อุบัติการณ์ของการเกิดภาวะวัสดุใส่หนุนลูกตาเทียมโผล่ หรือหลุดหลังได้รับการผ่าตัดเอาลูกตาออกหรือการผ่าตัดที่ควักเฉพาะเนื้อในลูกตาออกพบไม่บ่อย อายุที่มากขึ้นและการติดเชื้อ HIV เป็นปัจจัยเสี่ยงที่เป็นไปได้ที่ก่อให้เกิดภาวะวัสดุใส่หนุนลูกตาเทียมโผล่ หรือหลุดในผู้ป่วยที่ได้รับการผ่าตัดเอาลูกตาออก ส่วนมากภาวะแทรกซ้อนจะเกิดขึ้นภายใน 1 เดือนหลังจากการผ่าตัดเอาลูกตาออก (18/38, 47.37%) และระหว่าง 1-12 เดือนหลังการผ่าตัดที่ควักเฉพาะเนื้อในลูกตาออก(16/27, 59.26%) โดยควรได้รับการติดตามด้วยความถี่และระยะเวลาที่เหมาะสม

คำสำคัญ: *ภาวะวัสดุใส่หนุนลูกตาเทียมโผล่, ภาวะวัสดุใส่หนุนลูกตาเทียมหลุด, การผ่าตัดเอาลูกตาออก, การผ่าตัดที่ควักเฉพาะเนื้อในลูกตาออก*

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