

DISSERTATION

How does the practice of evisceration for open globe injuries at Groote Schuur Hospital conform to international standards?

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Faculty of Health Sciences

UNIVERSITY OF CAPE TOWN

Principal Investigator: Dr Junaid Zondi

Student number: 1247253

Date submitted: 10 August 2016

Supervisor: Prof Nagib du Toit

Faculty of Health Sciences

Department of Surgery

Division: Ophthalmology

University of Cape Town

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Dr Junaid Zondi (MBCHB; DMH (SA); Dip Ophth (SA); FC Ophth (SA)).

Signature

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28/07/2016

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Glossary of Terms

Afferent pupillary defect- APD is a medical sign observed during the swinging-flashlight test whereupon the patient's pupils constrict less (therefore appearing to dilate) when a bright light is swung from the unaffected eye to the affected eye.

Cosmesis- An operation that improves appearance.

Enucleation- The surgical removal of the entire eyeball including the scleral shell.

Evisceration- The surgical removal of the contents of the globe, leaving the scleral shell and the extra-ocular muscles intact.

Extra-ocular muscles- The muscles that move the eye.

Globe- The globe of the eye, or bulbus oculi, is the eyeball apart from its appendages. A hollow structure, the bulbus oculi is composed of a wall enclosing a cavity filled with fluid with three coats: the Sclera, Choroid, and the Retina.

No Perception of Light- NPL is the inability to interpret the surrounding environment by processing information that is contained in visible light.

Ocular trauma- Refers to any injury of the eye. The injury may have been due to mechanical trauma (blunt or penetrating), chemical agents, or radiation (ultraviolet or ionising).

Open Globe Injuries- OGI is any full-thickness injury to the cornea, sclera, or both.

Posterior- Located behind a part or toward the rear of a structure.

Postoperative- During, relating to or denoting the period following a surgical operation.

Prolapsed- A term medically used to describe any interior tissue as it protrudes from an orifice on (but not limited to) the human body.

Retina- A layer at the back of the eyeball that contains cells sensitive to light, which trigger nerve impulses that pass via the optic nerve to the brain, where a visual image is formed.

Sclera- Also known as the white of the eye is the opaque, fibrous, protective, outer layer of the eye containing collagen and elastic fiber.

Sympathetic Ophthalmia- SO is a rare but devastating condition, which manifests as inflammation in both eyes following an OGI to one eye, and it can lead to blindness.

Uvea- The pigmented layer of the eye, lying beneath the sclera and cornea, and comprising the iris, choroid, and ciliary body.

Abbreviations and Acronyms

GSH	Groote Schuur Hospital
OGI	Open Globe Injuries
PR	Primary repair
PE	Primary evisceration
SO	Sympathetic ophthalmia
NPL	No perception of light
LP	Light perception
HM	Hand Movements
APD	Afferent pupillary defect
TAPD	Total afferent pupillary defect

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Protocol

INTRODUCTION

Penetrating ocular trauma can have devastating visual implications and is often a challenge to manage effectively. At Groote Schuur Hospital (GSH) we see a high incidence of open globe injuries (OGI) in comparison to other centres worldwide.¹The decision to perform a primary repair (PR) or primary evisceration (PE) following an OGI can be a difficult one.

Evisceration is the surgical removal of the contents of the globe, leaving the scleral shell and the extra ocular muscles intact. In the past, enucleation, which is the removal of the entire eyeball including the scleral shell, was favoured over evisceration due to the presumed lower risk of sympathetic ophthalmia (SO). SO is a rare but devastating condition which manifests as inflammation in both eyes following an OGI to one eye, and it can lead to blindness.

Recent studies have found that the risk of SO following evisceration is low,¹ and that enucleation is not necessarily the best protective measure against development of SO, since there are ample reports of SO occurring not just after evisceration but also after enucleation.² Furthermore the cosmetic outcome of evisceration as opposed to enucleation was found to be superior.³ PR of the injured eye, if it can be performed successfully, is preferred of course (as there is some potential for vision thereafter), but there are cases where trauma to the eye is so severe that PR is impossible or post-operative visual potential is extremely poor. In these cases a PE should be considered.

Before a PE can be considered, the following criteria need to be fulfilled.⁴

- The affected eye must have an acuity of no perception of light (NPL)
- A total afferent pupillary defect (APD) must be present
- There is prolapsed uvea and/or retina in the wound
- Wounds are longer than 20mm, or extend posterior to the equator of the globe
- The fellow eye is normal and the patient is able to give informed consent

These criteria have not changed over the years and are still regarded as a good guide in assisting the clinician in making the decision between PE and PR.⁴ All these criteria need to be met and the patient needs to be fully orientated in order to give informed consent, as making the decision to lose an eye is a difficult one to make both psychologically and for future cosmesis.

OBJECTIVES

This study aims to assess how closely our department at GSH conforms to these criteria or guidelines and at which point(s) do we stray from these guidelines.

Other subsidiary objectives/questions to be answered are:

What is the PE rate for ocular trauma at GSH?

What is the secondary evisceration rate at GSH?

In those patients who present with NPL vision and a total APD, what is the visual outcome if PE is not performed and does phthisis bulbi develop? In other words, is the PR justified in terms of visual outcome and cosmesis, and psychological reasons as well?

METHODS

Study Design

Type of study – Descriptive and analytical retrospective case series.

Sample Collection

Medical records of all those patients who were admitted to the eye department at GSH, presenting with OGI's following trauma to the eye from July 2009 to July 2011 will be collected for analysis.

Measurement

The records of all those that underwent PE will be analysed to see if the above criteria were met or not.

The records of those that underwent secondary evisceration after PR will also be analysed to determine the rate of secondary evisceration at GSH.

Furthermore the visual outcome and presence of phthisis bulbi (at three months) in the patients who presented with NPL vision and total APD will be analysed.

Descriptive Analysis

Data was analyzed using the statistical program stata version 12.1. The data will be collected as both numerical and categorical variables. Variables were described using means, medians and proportions as appropriate.

The main analyses focused on:

1. How closely each of the criteria were met.
2. At which points do we stray from the these guidelines.

ETHICAL CONSIDERATIONS

Clearance from the Human Research Ethics Committee (HREC) will be obtained prior to commencement of data collection.

All patients' names and medical record numbers will be kept confidential.

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Abstract

Background

Penetrating trauma can have devastating visual consequences and is often challenging to manage effectively, especially in the setting of severe trauma. The decision to perform a primary repair or a primary evisceration following an open globe injury can be a difficult one. Removal of an eye is not only traumatic but produces grief, anxiety and depression. It can result in a poor quality of life of the affected patients, and thus must be justified before it is performed. Before a primary evisceration can be considered, certain criteria need to be fulfilled. The affected eye must have acuity of no perception of light. A total afferent pupillary defect must be present. There must be prolapsed uvea and/or retina in the wound. Wounds should be longer than 20mm, or extend posterior to the equator of the globe. The fellow eye should be normal and the patient must be able to give informed consent. The primary evisceration rate at Groote Schuur Hospital appears to be higher than in other centers.¹ If we do conform to the required criteria, then we are justified in performing primary eviscerations, but if we do not conform, then we need to improve our adherence in order to meet the required standards and improve our management.

Purpose

- a. To determine if the above criteria for primary evisceration are met in those undergoing primary eviscerations at Groote Schuur Hospital, and at which point(s) we strayed from the guidelines.
- b. To determine the rate of primary and secondary eviscerations following ocular trauma.
- c. To evaluate the visual outcomes, at three months, in patients who present with no perception of light vision and total afferent pupillary

defect, who meet some of the criteria for primary evisceration, but primary evisceration is not performed.

Methods

A retrospective case series study was performed to identify all patients who were admitted to the ophthalmology ward at Groote Schuur Hospital following an open globe injury. The records of all patients who underwent primary evisceration were analyzed to evaluate whether or not the criteria were met and to determine the rates of primary and secondary evisceration.

Results

There was a total of 249 open globe injuries admitted during the designated two year period. Of these, 212 (85.14%) were males and 37 (14.86%) were females. The number of patients undergoing primary evisceration was 61(24.5%), the number of patients undergoing primary repair was 175 (70.3%) and thirteen (5.2%) had other procedures. Of the 61 patients who underwent primary evisceration, 10 patients had missing data in their folders directly related to the above- mentioned criteria and were thus excluded. Therefore, out of 51 patients in whom the required data was available, a total of 37 (72.55%) patients met all the criteria required for a primary evisceration to be performed.

A total of 11 (21.56%) patients did not meet the visual acuity criterion of no perception of light (10 were perception of light vision and 1 was hand movements vision). A total of 9 (17.6%) patients were documented to not have a total relative afferent pupillary defect. All patients had prolapsed uvea in the wound. Three patients (5.8%) had an “abnormally” seeing or poorly seeing fellow eye. Five (9.8%) were documented as irreparable, which refers to their wounds being more than 20mm in length. The informed consent

criterion was fulfilled in all patients. Secondary eviscerations accounted for 4.6% of surgeries done for open globe trauma. Of the patients that were eligible for primary evisceration, but instead had primary repair, the majority (77.7%) remained no perception of light vision and 88.8% had phthisis bulbi at 3 months.

Conclusion

The majority of our evisceration cases met all the criteria for a primary evisceration. The two criteria which we did not fully adhere to were the visual acuity of no light perception and the presence of a total relative afferent pupillary defect. Visual acuity testing in the trauma setting is challenging, but we should improve on the accuracy of our testing of these two entities, and clearer documentation of all the criteria in our open globe injury cases especially if undergoing a primary evisceration. A few patients had an abnormally seeing fellow eye and still underwent PE due to the injured eye being irreparable. Our primary evisceration rate reflects our resource-limited setting and the severity of our ocular trauma cases. The poor visual acuity and poor outcome in the form of phthisis bulbi at three months in those who did not have a primary evisceration despite poor acuity appears to support our rationale for performing primary eviscerations in those with poor prognoses, given our resource-limited setting.

Introduction

Penetrating ocular trauma can have devastating visual consequences which are often challenging to manage effectively. At GSH, we see a large number of OGI's in comparison to other centers worldwide.² The decision to perform a PR or PE following an OGI can be a difficult one.

Evisceration is the surgical removal of the contents of the globe, leaving the scleral shell and the extra-ocular muscles intact. In the past, enucleation, which is the removal of the entire eyeball including the scleral shell, was favored over evisceration due to the presumed lower risk of SO. SO is a rare but devastating condition, which manifests as inflammation in both eyes following an OGI to one eye, and it can lead to blindness.

Recent studies have found that the risk of SO following evisceration is low³ and that enucleation is not necessarily the best protective measure against the development of SO, since there are a number of reports of SO occurring not just after evisceration but also after enucleation⁴. Furthermore, the cosmetic outcome of evisceration as opposed to enucleation is thought to be superior.⁵

PR of the injured eye, if it can be performed successfully, is preferred due to the fact that there is some potential for vision thereafter. However, there are cases where trauma to the eye is so severe that PR is impossible or post-operative visual potential is extremely poor. In these cases a PE should be considered.

Before a PE can be considered, the following criteria should be fulfilled: ³

1. The affected eye must have an acuity of NPL.
2. A TAPD must be present.
3. There is prolapsed uvea and/or retina in the wound.
4. Wounds are longer than 20mm, or extend posterior to the equator of the globe.
5. The fellow eye is normal and the patient is able to give informed consent.

The criteria mentioned above have not changed over the years and are still regarded as suitable guidelines to assist the clinician in making the decision between PE and PR.³ All of the above criteria should be met and the patient needs to be fully orientated in order to give informed consent. Making the decision to lose an eye is a difficult one, both psychologically as well as for future cosmesis and has profound implications on the patient's quality of life.

The purpose of this study therefore, was to determine if the above criteria were fulfilled prior to performing a potentially life-changing event in the form of a primary evisceration. Also to ascertain the outcome if PR is performed instead, in patients who would otherwise qualify for a primary evisceration.

Literature Review

Penetrating ocular trauma resulting in an open globe can have devastating implications and can result in significant ocular morbidity.⁶ OGI's are defined as full-thickness wounds of the eye wall.⁷ The management of these OGI's remains controversial and challenging, and the decision to perform a PR versus a PE or primary enucleation remains a difficult one.⁸

Evisceration is the removal of the entire contents of the eye, while the scleral shell remains attached to the extra-ocular muscles.⁹ Enucleation on the other hand involves removal of the entire globe, with separation of all extra-ocular muscles and resection of the optic nerve from the globe.

Previously, enucleation was preferred over evisceration due to the small, but definite risk of SO. "It is thought that the risk of SO is eliminated if the severely injured eye is removed as a primary procedure, and decreased if secondary removal (following primary repair and within 10 -14 days after the initial insult) is performed. SO is a devastating condition that occurs bilaterally in the form of a pan-uveitis. The eye that has been traumatized is referred to as the 'exciting eye' and the fellow eye, which also becomes inflamed, is the 'sympathizing eye'.²

Recently though, a number of studies have found that the risk of developing SO following severe ocular trauma is negligible, it would seem that evisceration is a safe option with a very low risk of developing SO.²

Furthermore, evisceration is a technically easier surgery to perform, compared to nucleation, causes less disruption of the orbital anatomy and may have fewer post-operative complications.¹⁰ After evisceration/enucleation an implant is often placed into the orbit to replace the lost volume and to get better movement of the prosthesis. Prostheses serve an aesthetic and a

functional purpose. The artificial eye serves to mimic the natural eye and make the face complete in appearance but it also serves as volume substitution.¹¹ Evisceration has the potential for better mobility of the prosthetic implant leading to better cosmesis.¹²

Evisceration as a primary procedure is reserved as the very last resort following penetrating ocular trauma.¹³ It is a destructive procedure which ensures irreversible elimination of vision or the potential thereof. The effect that loss of an eye has on a patient cannot be understated. "The patient has lost a part of his body, like amputation of a leg or a hand, they have lost an eye – a part of their vision, a part of their face and for some, a part of their personality".¹¹

There are a number of clinical consequences that have been reported in the literature after eye amputation. Phantom eye syndrome is defined as any sensation that a patient reports as originating in the eye despite it being amputated, it includes phantom vision (visual hallucinations occurring without external stimulation of the relevant sensory organ), phantom pain (painful sensations the patient refers to the amputated eye, without a clinically significant cause for pain in the remaining orbit or surrounding structures) and phantom sensations.¹¹ In a study done in 2010 by Rasmussen, 42% of patients reported visual hallucinations, with some patients so visually disturbed that it interfered with daily life. Many of these patients were embarrassed to discuss their visual experiences, even with their relatives, for fear of being thought to have a mental illness.

In the same study 23% of the 173 interviewed patients reported phantom pain, with 31% of them experiencing pain every day. They further found that eye-amputated patients have a poorer health-related quality of life and more perceived stress than the general population.¹⁴

The eyes play a vital role in both communication and physical attractiveness.¹⁵ Patients using ocular prostheses report feelings of social anxiety and avoid social situations as a result of their altered facial

appearance, related to feelings of negative views they hold about the way they look.¹⁶

In a questionnaire investigation by Coday *et al.* in 2002 of 58 eye-amputated patients, 23% had changes in employment, 39% had changes in driving status, 40% were socially affected and 50% had difficulties with sports and hobbies.¹⁷

Even if a patient has good vision in one eye, quality of life is still adversely affected. Good vision in two eyes is associated with a substantially higher quality of life in patients with ocular diseases than does good vision in only one eye.¹⁸ This is an important factor to keep in mind when making the decision to assess the value and cost effectiveness of medical interventional therapies.

Current evidence shows that destructive ocular procedures are on the decline due to improved diagnosis and treatment of ocular trauma leading to increased globe preservation.¹³ Despite microsurgical improvements in the management of ocular trauma, there remain eyes that cannot be salvaged.¹⁹ There are situations where such a procedure, as a primary intervention, is the only solution.

Severe damage with dismal visual potential is one of the reasons. A severely damaged eye will usually be non-functional especially if vital structures *e.g.* ciliary body, retina and optic nerve are damaged. These eyes may also be removed with time as a secondary procedure due to post PR complications such as, a painful blind eye, severe infection in the form of post-traumatic endophthalmitis, the development of phthisis bulbi (a shrunken non-functioning and unsightly globe) and to reduce the possibility of SO.

Furthermore, failure to primarily eviscerate a severely traumatized globe with no visual potential, can have a devastating effect on the ability of allied

specialists to repair associated maxillofacial injuries for fear of damaging a repaired globe.¹⁹

Whenever possible, and more often than not, PR will be performed to try and spare a traumatised globe in an attempt to try and salvage any remaining visual potential from the affected globe. This also allows the patient to realize that the eye is no longer functional and can help make it easier for the patient to come to terms with that reality and consent to an evisceration. When closure is impossible, a primary enucleation/evisceration is indicated.³

The Western Cape is notorious for gangsterism and gangster-related violent crimes. It is one of the reasons our exposure to ocular trauma is not unusual. A number of ocular trauma-related studies have been conducted at our institution. At GSH, we see many cases of penetrating ocular trauma every year (two to three per week) a much higher incidence than that which occurs at other centers.² It is therefore of relevance that our management of these OGI's be examined and analyzed.

At our institution, a patient presenting with an open globe injury initially passes the Emergency area to be assessed for possible life threatening injuries which are then managed. Once those are managed or ruled out, the patient is then referred to the eye department where a more thorough ocular examination, including imaging in the form of CT scanning, is performed to assess the extent of the ocular trauma.

If an open globe is confirmed, the patient is then admitted to the eye ward and placed on prophylactic intravenous antibiotics for the prevention of post traumatic endophthalmitis. It is at this time that a decision needs to be made in terms of whether the traumatized eye potentially can be primarily repaired or may need to undergo an evisceration as a primary procedure. This decision is made in conjunction with the patient and is based on the clinical findings of the ocular examination.

There are internationally recognized criteria that must be met prior to making the decision to perform a primary evisceration.³ These are:

- The affected eye must have a visual acuity of NPL
- Presence of a TAPD
- There must be prolapsed uvea or retina in the wound
- The wound should be >20mm or extend posterior to the equator, this can only be confirmed intraoperatively
- The fellow eye should be normal and the patient should give informed consent

Most of these criteria relate to clinical features at presentation which are known to correlate well with the final visual outcome in OGI's according to the Ocular Trauma Score (OTS).⁷ The OTS uses specific diagnostic criteria to predict the visual prognosis in patients with ocular trauma. The score is based on initial visual acuity which is given a specific score. The presence of globe rupture, endophthalmitis, perforating injury, retinal detachment, and / or afferent pupillary defect is noted and points are then subtracted for these entities and the injury then scored. The lower the score, the worse the visual prognosis. OTS scores range from 1 (most severe injury and worst prognosis at 6 months) to 5 (least severe injury and least poor prognosis at 6 months). Each score is associated with a range of predicted post-injury visual acuities. It has a predictive accuracy of approximately 80%, which means that the OTS will be accurate 4 out of 5 times. The OTS provides guidance for the clinician before pursuing complex, sometimes expensive interventions, particularly in resource-limited settings.

In a retrospective study of 42 patients with penetrating ocular injury resulting from assault, Groessl *et al.* found that factors predictive of poor visual outcome were: "initial visual acuity of LP or worse; injury by a blunt object; posterior scleral lacerations (> 15 mm in length) and presence of vitreous haemorrhage, retinal detachment, and prolapsed uvea".²⁰

Since the loss of an eye has severe consequences for the patient, it is recommended that the above criteria are strictly adhered to.

The affected eye must have a visual acuity of NPL

Visual acuity of NPL implies that the affected eye sees absolutely nothing. A bright light stimulus is presented directly and from different quadrants in order to be certain that the stimulus is not perceived by the patient while the unaffected eye is occluded. Presenting visual acuity of NPL on its own is usually associated with a poor visual prognosis, and NPL because of trauma is a common indication for enucleation/evisceration.⁶

In a study done by Pieramici *et al.* on 290 OGI's, looking at prognostic factors for visual outcomes, presenting visual acuity was found to be a strong predictor of final visual outcome. In patients who presented with visual acuity better than 5/200, none underwent enucleation, whereas in patients who presented with visual acuity less than 5/200, sixty five (34%) underwent enucleation. In their patients who presented with NPL vision, only thirty (79%) underwent enucleation, whereas four (11%) actually obtained visual acuity better than NPL.²¹ In a study by Esmaeli *et al.*, predictors of poor vision were initial visual acuity of LP or NPL and they also found that factors predicting enucleation were similar to those predicting poor vision.²²

This variable, as significant as its presence is, cannot be used in isolation. There are reports in the literature of eyes that improved to LP vision or better following appropriate interventional measures. A study by Han *et al.* found that four out of twenty five (16%) patients regained some vision after presenting with NPL vision due to an OGI.²³ Sony *et al.* reported 17 out of 73 eyes (23%) with improvement to LP or better.²⁴

It should be borne in mind that visual acuity can be profoundly impaired to the extent of NPL in the presence of significant media opacity (e.g. corneal

oedema, hyphaema, cataract, dense vitreous haemorrhage), retinal detachment, associated sub-retinal or subhyaloid haemorrhage and even psychological factors (e.g. hysteria). Assessment of light perception is a subjective measure and not a fool-proof test, especially in the presence of severe media opacity.⁶

Therefore a post traumatic visual acuity of NLP alone should not be an indication for PE.⁶ It should be associated with other clinical findings supporting a poor prognosis.

Presence of a total APD (TAPD)

An APD is an indicator of damage to the optic nerve or the retina. The presence of a TAPD is the second prerequisite. A TAPD is elicited using a bright light stimulus and is indicated by absolutely no pupillary response to direct light. It implies that the anterior visual pathway has no function at all. A visual acuity of NLP is synonymous with a TAPD, every patient with definite NPL vision should, by definition, have a TAPD.²

Pieramici *et al.* reported in his study that the presence of an afferent defect at presentation was associated with a significantly worse visual outcome. In patients presenting with an afferent defect, 18% obtained better than or equal to 5/200 visual acuity, whereas 55% went on to enucleation.

However, in patients without an afferent defect on presentation, 79% obtained better than or equal to 5/200 visual acuity and only 7% had an enucleation.²¹ A retrospective study conducted by Rahman *et al.* identified statistically significant risk factors present on initial presentation of the trauma patient which were associated with eventual enucleation, which included blunt mechanism of injury, absence of a red reflex, presence of a lid laceration, and the presence of a RAPD. When all these predictors were

analyzed using binary logistic regression, it emerged that the presence of a RAPD was the strongest predictor.¹⁹

The presence of prolapsed uvea or retina in the wound

The prolapse of intra-ocular contents (e.g. uveal tissue, vitreous, and retina) in the wound is an indication of severe damage. It points to extensive disruption of intraocular anatomy. Its presence is important in terms of prognosis and decision making and should be clearly noted in examination and surgical notes. In a retrospective study by Yalcin Tök *et al.* of 313 patients, when using multiple logistic regression analysis of factors that most affected the prognosis, other than initial VA, retinal detachment and the presence of vitreous prolapse were identified.²⁵

A posterior OGI usually results in vitreous loss, vitreoretinal traction, and retinal detachment. Retinal detachment after posterior OGI's usually requires multiple surgeries and leads to poor vision or the loss of the eye.²⁵ Uveal prolapse into the wound has also been associated with a higher risk of post-traumatic endophthalmitis. In a retrospective clinicopathologic study by Lubin *et al.* they described 105 eyes with histologically confirmed SO, which all resulted from penetration of the globe with prolapse of uvea into the wound.²⁶

Therefore prolapse of uveal tissue and retina into the wound is an adverse prognostic sign both in terms of poor visual outcome and in terms of increasing the risk of post-traumatic endophthalmitis.

The wound should be >20mm or extend posterior to the equator

This criterion relates to the extent and location of the wound. When dealing with penetrating injuries, the globe is divided into 3 zones according to the ocular trauma classification group.⁷ Zone 1 injury involves the cornea up to the limbus, which is the transition between the cornea and the sclera. Zone 2 involves the region 5mm or less posterior to the limbus. Zone 3 is more than 5mm posterior to the limbus.

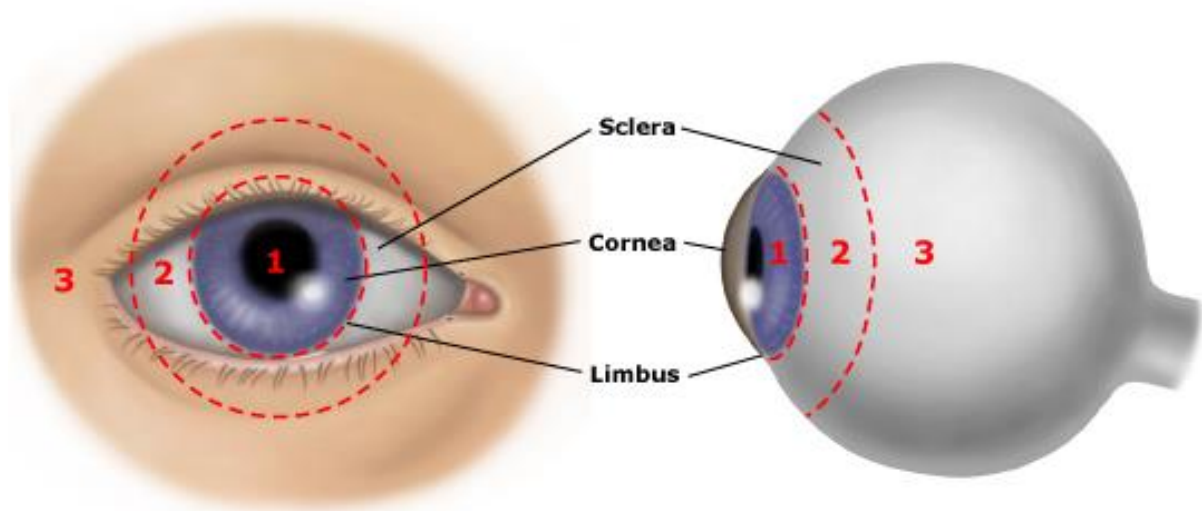
Zone 3 injuries are associated with a poorer prognosis due to retinal involvement in these injuries. A wound that is >20mm is likely to be in Zone 3, and if it extends beyond the equator it is by definition Zone 3. Rao *et al.* found length of the wound as the second important predictive factor for poor outcome, after initial presenting VA. Yalcin Tok *et al.*, found that “the risk of having a final VA worse than 20/200 was three times higher in Zone 2 injuries and 5.5 times higher in Zone 3 injuries when compared with Zone 1 injuries”.²⁵

Esmaeli *et al.* found that predictors of poor vision were initial visual acuity of LP or NPL, wounds extending posterior to rectus muscle insertion plane, wound length greater than 10mm, and blunt or missile injury. They further found that vitrectomy did not improve final vision, although it decreased the likelihood of enucleation.²²

Madhusudhan and coworkers found that patients who had a wound extending posterior to the equator had 20 times the risk of having a final visual acuity less than 3/60 when compared with those whose wounds were anterior to the recti insertions or restricted to the cornea.²⁷ Gilbert *et al.* found that 90% of eyes with wounds extending posterior to the rectus muscles were enucleated.²⁸

It is clear therefore that the longer the wound and the more posterior its location, the higher the likelihood of a poor visual outcome and globe removal, and the full extent of the wound can only be accurately determined intraoperatively.

FIGURE 1: Zones of the globe



- Zone 1** Injury to cornea or limbus
- Zone 2** Injury to anterior 5mm of sclera
- Zone 3** Full thickness injury more than 5mm posterior to limbus

Eye.hms.harvard.edu

The fellow eye should be normal

A normal seeing fellow eye is an important criterion to consider prior to performing a PE. Although monocular patients experience poorer health-related and vision-related quality of life than those with binocular vision,²⁹ losing vision in both eyes is much more significant. Visual acuity is the best variable to objectively quantify the “usefulness” of the fellow eye. Subjectively each individual differs in the apparent usefulness of his/her vision in accordance with their daily activities and visual demands, so this criterion is difficult to quantify. The World Health Organization (WHO) has developed a classification system that groups visual acuity into categories from normal to social blindness. A normal seeing eye should have visual acuity of 6/18 or less. According to the WHO, the classification of vision and visual impairment is as follows:

Table 1a World Health Organisation Categories of visual impairment

Visual Acuity	Category – taking into account visual acuity in better eye.
6/6 –6/18	Normal
<6/18-6/60	Visual impairment/Borderline
<6/60-3/60	Economic Blindness/Severe visual impairment
<3/60-NPL	Social blindness

Therefore a blind or extremely poorly seeing fellow eye that is not useful to the patient is a strong deterrent to performing a PE, in such a case a PR should be done unless it is absolutely impossible to repair the globe.

Informed Consent

The issue of informed consent seems like a straight forward one as surgery without informed consent is rarely performed. Consent is an act of reason; the person giving the consent must be mentally capable and have all necessary information in order to give valid, comprehensive and informed consent. Informed consent of a patient is based on the principles of autonomy and privacy. There are seven criteria which define informed consent: ³⁰

1. Competence to understand and to decide
2. Voluntary decision making
3. Disclosure of material information
4. Recommendation of a plan
5. Comprehension of 3 and 4
6. Decision in favor of a plan
7. Authorisation of a plan

One gives informed consent only if all these criteria are met. If all the criteria are met except that the person rejects the plan, the person is then making an informed refusal. Therefore merely having a signature on an informed consent form does not necessarily mean that fully informed consent has been given.

The concern in the setting of trauma is that, the injured patient may be unconscious, disoriented or under the influence of mind-altering substances, all these factors complicate the obtaining of true informed consent. Prior to

the patient being taken to surgery, the informed consent must clearly state that the eye may have to be removed and that there will not be any restoration of sight once the eye is eviscerated.³

As clinicians, we are mainly concerned with the clinical aspects of these injuries and their surgical management, and we are at risk of being insensitive as we have been desensitized by our regular exposure of these injuries, but for the patient, however, it is much more complex. Removal of an eye is a major event for any individual as it has physical, socioeconomic and psychological effects.⁹

The loss of a vital bodily organ such as the eye is not only traumatic but produces grief, depression and irreversible loss of function. Although the depression associated with loss of an eye is not unexpected, it can be distressing, therefore the mode of presenting information to the prospective patient for the destructive eye surgery should be with empathy and sympathy.³¹

Therefore, it is important that the patient is fully alert, fully informed and aware of the extent of the injury and all the possible outcomes, complications and consequences of performing or omitting a PE.

CONCLUSION

Clinicians and patients are faced with a number of decisions after severe OGI's. These are based on the prospects of globe preservation after the injury and the degree of visual preservation that is likely to be achieved.

As discussed above, the loss of the globe, and, by extension, vision whether monocular or binocular is a serious and life-changing event. It's an event that has both personal and social consequences. For the patient it has a traumatic, psychological and emotional impact, which can lead to feelings of anxiety, depression and low self-esteem, which can in turn result in a poor quality of life, job loss, and difficulties with daily activities and decreased social interaction. It is a huge decision that cannot be taken lightly and thus should be justified.

The criteria discussed above have been repeatedly shown to be highly accurate in predicting outcomes after penetrating ocular trauma. In a study by Man *et al.* which was aimed at comparing the OTS and the classification and regression tree (CART) as prognostic models of visual outcome after OGI, they found that the variables most predictive of visual loss were: **RAPD, poor initial vision, lid laceration, posterior wound**, and globe rupture. Furthermore the sensitivity to predict visual survival (LP or better) was 97.4% for OTS and 93.5% for CART. The specificity to predict no vision (NPL or enucleation) was 100% for OTS and 73.9% for CART.³²

Each of these criteria are independently associated with a poor outcome and if all are met it is justifiable to primarily eviscerate the globe in the trauma setting.³ Since losing an eye is such a profound event, it is recommended that all these criteria are strictly adhered to.

Due to the limited resources at our disposal, we are unable to undertake all out attempts at salvation on each and every OGI. Only selected cases that are thought to have a better prognosis undergo pars plana vitrectomy post trauma. Esmaeli *et al.* found no change in visual outcome post vitrectomy, although this decreased the likelihood of enucleation.²² At our institution we do a large number of PE's and thus it is important to assess whether we conform.

The majority of our OGI's are assault-related, and given the violent nature of these injuries, assault-related OGIs are expected to have a significantly worse functional and anatomical outcome compared to OGI's in general.^{20,33} Bauza and associates showed that initial VA of NPL, rupture or perforating injury, and Zone 3 injury may be related to poor visual outcome and the need for enucleation.³³

The importance of addressing all of the above prior to performing an evisceration is vital, as undergoing a limb destructive procedure is a major event for an individual. The full involvement of the patient in the decision making cannot be over emphasized. All the information should be available to the patient regarding the severity of the trauma, the possible complications and risks especially the risk of SO and the pros and cons regarding future cosmesis and functioning.

Aims and objectives

RESEARCH QUESTION

How closely does the decision to perform PE for OGI at GSH, Western Cape, South Africa conform to international standards?

AIM OF THE INVESTIGATION

The aim of the study was to assess how closely our department at GSH conforms to these criteria or guidelines and at which point(s) we strayed from these guidelines.

OBJECTIVES OF THE STUDY

- a. To determine if criteria for PE are met in those undergoing primary evisceration at GSH, and at which point(s) we strayed from the guidelines.
- b. To determine the rate of primary and secondary eviscerations following ocular trauma at GSH.
- c. To evaluate the visual outcomes, at three months, in patients who present with NPL vision and TAPD who meet some of the criteria for PE, but PE is not performed.

STUDY DESIGN

A descriptive and analytical retrospective case series.

STUDY POPULATION

The study population consisted of all adult patients who were admitted to the ophthalmology eye ward at GSH, presenting with OGI's following trauma to the eye from July 2009 to July 2011.

Sample size

A total sample of 249 adult patients, presenting for the first time with OGI's following trauma to the eye, were admitted to the ophthalmology eye ward at GSH during the specified period. 61 patients (out of the 249 patients) underwent PE and were initially included in this study.

SUBJECT IDENTIFICATION

- I. An existing ocular trauma database was used to identify all patients who underwent a PE following an OGI.
- II. The file numbers of all the patient files adhering to the inclusion criteria were recorded.
- III. Using the ethical approval letter of the study, an application was submitted to the records office at GSH to access and review the records of the file numbers recorded that adhered to the inclusion criteria.
- IV. The relevant information pertaining to this study was then collected from the requested patient records.

METHODOLOGY and DATA COLLECTION

For this study, the records of all patients that underwent PE were analyzed to see if the above criteria were met or not, and to determine the rate of PE at GSH. The records of patients that underwent secondary evisceration after PR were also analyzed to determine the rate of secondary evisceration at GSH. Furthermore the visual outcomes at three months in the patients who presented with NPL vision and TAPD were analyzed.

DESCRIPTIVE ANALYSIS

Data was analyzed using the statistical program stata version 12.1. The data will be collected as both numerical and categorical variables. Variables were described using means, medians and proportions as appropriate.

The main analyses focused on:

1. How closely each of the criteria were met.
2. At which points do we stray from these criteria.

FINANCIAL DISCLOSURE

No financial disclosures.

ETHICAL CONSIDERATION

The protocol was submitted to the Human Research Ethics Committee of the Faculty of Health Sciences, University of Cape Town and GSH for approval (HREC REF:603/2014). All personal identifying data was removed from our database. The investigator adhered to Good Clinical Practice (GCP) guidelines during the study period. Participation in this study did not affect the quality of care of the participant during or after the study.

Results

A total of 249 patients with OGI's were admitted during the designated two-year period. Of these, 212 (85.14%) were males and 37 (14.86%) were females. A total of 61 (24.5%) patients underwent primary evisceration, the number of patients undergoing primary repair was 175 (70.3%), and 13 (5.2%) patients underwent other procedures, including pars plana vitrectomies.

Out of the 61 patients who underwent primary evisceration, 10 patients had missing data. These patients were thus excluded from the study. Therefore, out of 51 patients in whom the required data was available, a total of 37 (72.55%) patients met all the criteria, as stated above, required for a PE to be performed.

A total of 11 (21.56%) patients did not conform to the first criterion of NPL vision. Ten of these were LP vision and one patient was HM vision.

A total of 9 (17.6%) patients did not meet the TAPD criterion. All of these patients did have an RAPD, but it was not recorded as a TAPD.

Five (9.8%) patients did not meet the criterion of the wound being > 20mm or extending posterior to the equator of the globe.

A total of 3 (5.8%) patients had visual impairment in the fellow eye (according to WHO guidelines). One patient was CF vision and the other two were 6/36 in the fellow eye.

All the patients included in the study had uveal prolapse through the wound documented in their records, and all patients had given informed consent prior to undergoing a primary evisceration. Table 1 summarizes criteria not met.

NPL	TAPD	IRREPARABLE (wound>20mm)	NORMAL OTHER EYE	UVEAL PROLAPSE
11 (21.56%)	9 (17.6%)	5 (9.8 %)	3 (5.8%)	0 (0%)

Table 1: No of patients not meeting the individual criteria.

Secondary eviscerations accounted for 4.6% of surgeries done for open globe trauma.

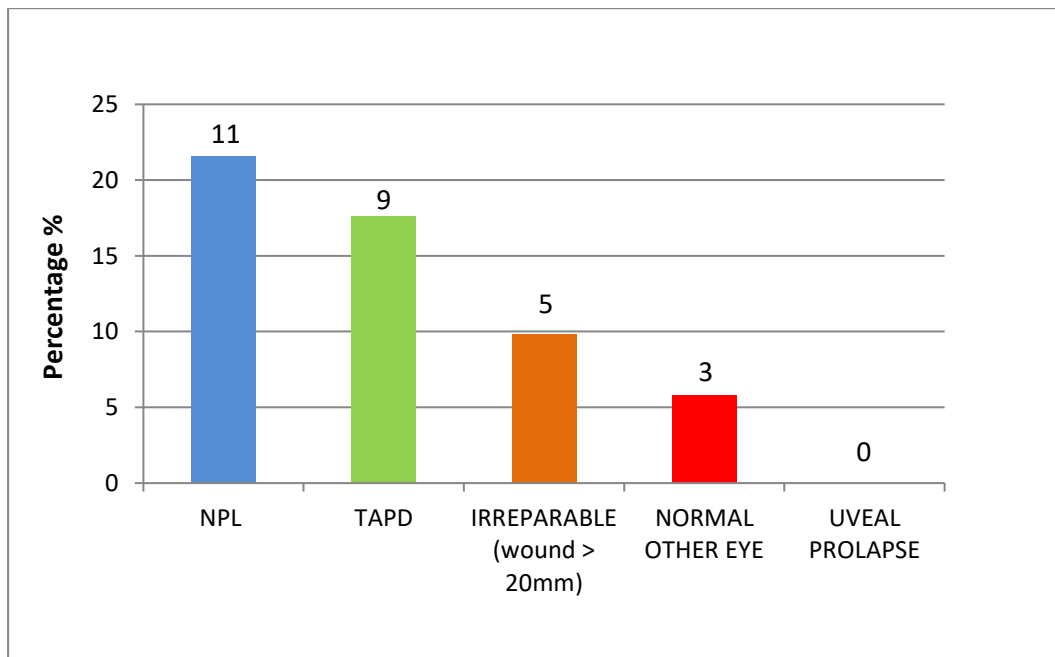


Fig 2: Percentage of patients not meeting criteria.

A total of 66 patients presented with NPL vision and a documented TAPD. Only 17 of these underwent PR. The other 49 underwent PE. Eight of the 17 patients were lost to follow up, therefore only nine of these patients had three month follow up data. At three months only two (22, 2%) of the nine improved to PL vision, with the remaining seven patients (77, 7%) remaining NPL. Figure 2 summarizes the visual outcome in these patients at three months if a PE was not performed.

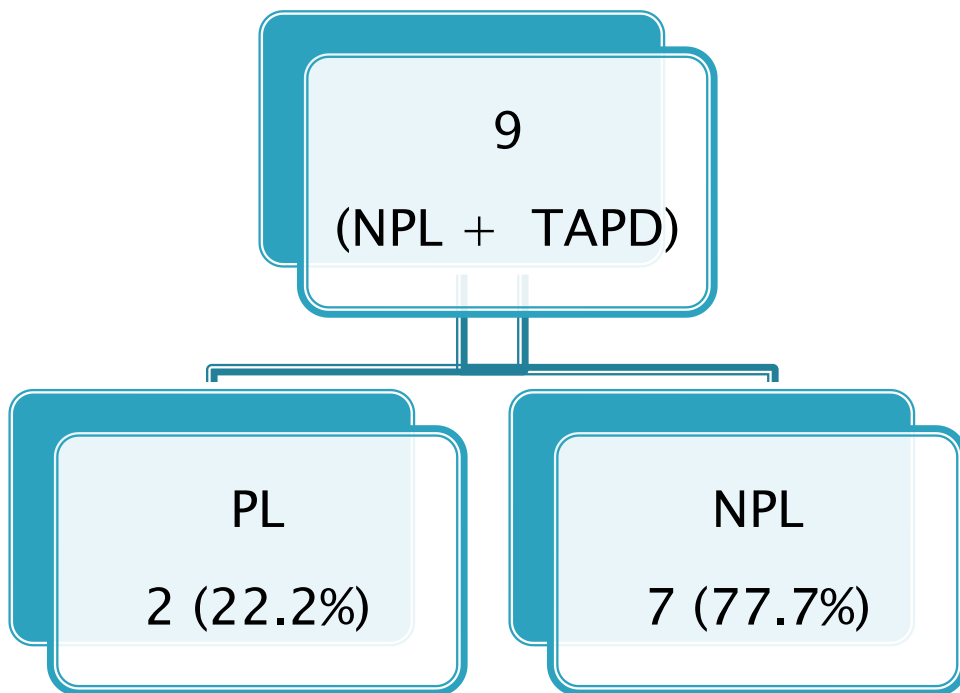


Figure 2: Visual outcomes at 3 months

Eight (88.8%) of the nine patients who had the three month follow up data were documented to have phthisis bulbi at three months, with one patient documented to have a corneal scar with a blind eye. Three of these patients had a secondary evisceration, assumed to be for cosmetic purposes as they had phthisis bulbi. Figure 3 summarizes patients that developed phthisis bulbi after being primarily repaired when they had qualified for a PE.

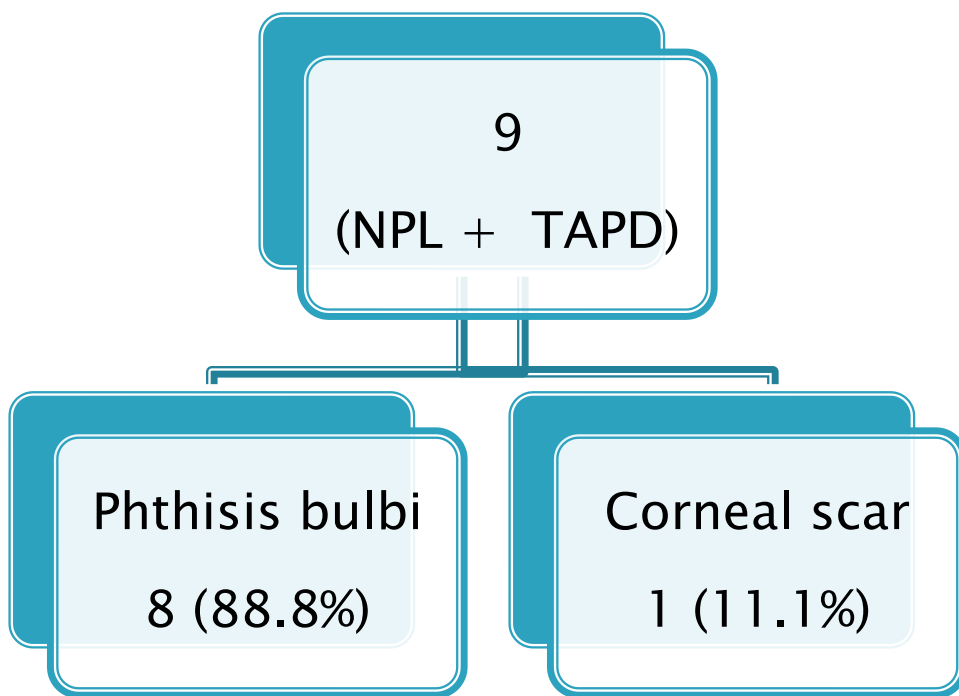


Figure 3: Development of phthisis bulbi at 3 months

Although these are small numbers, from this information, we can deduce that PR generally had poor outcomes in terms of visual acuity and cosmesis in patients that partially qualified for PE, but underwent PR instead.

Discussion and summary

OGI's can have devastating visual consequences and pose challenges in terms of management to the clinician. The standard practice of ophthalmologists is to perform a primary surgical repair to restore the structural integrity of the globe as soon as possible. Only subsequent to the initial repair is an evisceration / enucleation usually considered.¹⁹

Certain injuries, however carry a dismal prognosis regardless of how quickly and aggressively they are treated. In such unsalvageable cases primarily eviscerating/enucleating the globe can be justified. The advantages of PE are that, the possibly medically unstable patient need only be subjected to one anaesthetic and the risk of SO is eliminated.³ "Secondary enucleation requires additional anaesthesia, presents a higher risk of implant exposure and extrusion, and further compounds the already significant psychological effect of poor cosmesis".¹⁹

Evisceration is a major event for the individual with far reaching implications. It therefore needs to be justified before it is undertaken. Since we do a large number of PE's at GSH, it is important to assess whether we conform to international standards of the practice of evisceration.

In this study, 72.55% of patients met all the required criteria/guidelines prior to undergoing a PE. This is a substantial and significant proportion of patients in whom the guidelines were adhered to in full, though it is still below an acceptable level.

This is the first review of how closely the management of OGI's conforms to recognized guidelines. It is difficult to put a number or percentage to quantify as an acceptable figure, but obviously 100% conformity would be the ideal.

Normality has been functionally and differentially defined by a vast number of disciplines, so there is not one single definition. In general, 'normal' or conformity refers to lack of significant deviation from the average. "When looking at a specific behavior, one may use a Gaussian bell curve to plot all reactions, and a normal reaction would be within one standard deviation, or the most average 68.3%. In statistics, normal is often arbitrarily considered anything that falls within about 1.96 standard deviations of the mean".³⁴ Our conformity was greater than 70%, but less than the desired 95% or 100%. Therefore although we conform fairly closely to these criteria, it is still below an acceptable level.

When assessing each guideline individually:

Informed consent, as a signed document at least, was met in all patients. This does not need further discussion.

All our patients had uveal prolapse in the wound. This is not a surprising finding as most of our OGI's are severe in nature and are due to assault-related trauma. Uveal prolapse is indicative of disturbed anatomy. It is quoted in a number of studies as a significant predictor of a poor visual outcome.^{20,25} The fact that all of our patients who underwent PE had uveal prolapse noted in their records supports the notion that our ocular trauma cases are severe.

A total of 21.56% of patients did not have NPL vision. This is the guideline which we seemed to not conform to mostly. This can be explained in a number of ways. One of the factors could be examiner error due to the difficulty of accurately testing visual acuity in the injured patient as a result of pain and discomfort. During office hours, most of our presenting visual acuity measurements are done by our nursing staff, which could be a potential source of error. Some patients that were not NPL had a TAPD on examination. This by definition is incorrect, as only a truly NPL eye should have a TAPD. Although the clinician making the important decision would

check the visual acuity as well, these discrepancies are more likely due to patient unreliability in the acute trauma setting, which is common.

Furthermore, most of the patients that were not NPL, were documented as irreparable with extensive wounds past the equator. Therefore, as much as they had some vision (most had only LP vision) they had still suffered extensive trauma with irreparable globes, the extent of which was only discovered intra-operatively. Esmaeli *et al.* found that presenting visual acuity of NPL or LP was associated with poor final visual acuity and higher likelihood of enucleation.²²

All of our cases that were not totally blind had LP vision or HM vision, which suggests that even eyes with LP vision may be unsalvageable. This makes a strong point for the need to use all the specified criteria, rather than heavily relying on one specific criterion.

A total of 17.6% of patients did not have a TAPD. This is the second guideline which we tended to stray from. The testing for a RAPD requires skill and experience as previously mentioned. In the literature the presence of an RAPD is associated with a poor outcome.²⁰⁻²² All our patients had an RAPD, but some did not have a TAPD.

All these factors lead to poor vision in the long-term, and in a majority of cases, enucleation is eventually required.³⁵ Esmaeli and coworkers concluded from their data that “eyes with wounds longer than 20 mm, which extend posterior to the equator, will lead to poor final vision and subsequent enucleation in the overwhelming majority of cases, and that primary enucleation should be considered in eyes with such surgical findings”.²² Bauza *et al.* reported that reasons for primary enucleation in their study included irreparable globe and extensive injury with NPL vision and further stated that both Zone 3 injured eyes and eyes presenting with initial VA of NPL were likely to undergo enucleation.³³

Our PE rate is 24.5 %. This is similar to 28.6 % in a study by Groessel and coworkers looking at assault related OGI's. Bauza *et al.* reported 31.8% of eyes that underwent enucleation in their study. This is in contrast to previous studies looking at OGI's in the general civilian population with percentages ranging from 7.8 – 12.1%.¹⁹ The reason for this could be the fact that due to limited resources at our disposal, full on attempts at sparing the globe are reserved for those cases regarded to have a better prognosis.¹ This could also be explained by the more serious nature of our trauma cases as discussed previously.

Our secondary evisceration rate is 4.6 %. This is lower than the numbers quoted in recent literature.^{22,28} This is due to the fact that our PE rate is higher in comparison to the PE rates in these studies. Bauza *et al.* reported a blind, painful eye as the commonest reason for their secondary enucleations, other reasons were a phthisical eye, hypotonia and failed closure during PR.³³ With our high PE rate, we eliminated most of these reasons.

Our poor follow up rate led to small numbers of patients presenting for the three month follow up period, which is a short coming in our study. Almost half of this cohort of patients was lost to follow up. Reasons for our poor follow up rate include fear of eye removal, poor finances for transport and lack of insight.

Of the patients that were eligible for PE but instead underwent PR, a large percentage (78%) remained NPL, and 89% of these patients had developed phthisis bulbi at three months. Brakup *et al.* studied 50 eyes that had suffered severe globe rupture and were not removed within two weeks. Thirty of the 43 eyes (70%) that were followed up for two months became phthisical.³⁶ Therefore although the globe was salvaged, there was severe damage to vital structures that maintain the function and integrity of the globe. Phthisis results in a shrunken, deformed and unsightly orbit which becomes a reason for evisceration in any case.

Although these percentages are drawn from small numbers, from this information, we may deduce that PR generally had poor outcomes in terms of visual acuity and cosmesis in patients that qualified for PE, but underwent PR instead.

In conclusion, the majority of our PE's met all the criteria that need to be fulfilled prior to performing a PE. The two criteria which we did not fully conform to are the visual acuity of NPL and the presence of a TAPD, although all our patients did have an RAPD. Some eyes with LP vision, can still be unsalvageable. The importance of conforming to all these criteria in the decision making process is underlined. We should improve on the accuracy of our testing of these two entities and improve on the clear documentation of all the criteria in our OGI's. Our PE rate is a reflection of our resource-limited setting and the severity of our ocular trauma cases. The poor visual outcome and development of phthisis bulbi at three months in patients that were eligible for PE, but instead underwent PR, supports the idea that these severely injured eyes are likely to have poor outcomes and require evisceration later on in any case.

Methods of literature search

A search of the MEDLINE-PUBMED database was conducted using the key terms *open globe injuries, penetrating ocular trauma, enucleation, evisceration, effects of eye amputation* and *sympathetic ophthalmia*.

Additional references were taken from the bibliographies of these references, and evaluated for their relevance to the topic.

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Department of Surgery

Departmental Research Committee

Professor Anwar Suleman Mall

J-45 Room Old Main Building, Groote Schuur Hospital,
Observatory 7925, South Africa

Tel (021) 406 6168/6232/6227 Fax (021) 448 6461

Email: Anwar.Mall@uct.ac.za

22nd July 2014

Dr J Zondi
Department of Surgery
Division of Ophthalmology
University of Cape Town

Dear Dr Zondi,

RE: PROJECT 2014/064

PROJECT TITLE: How does the practice of evisceration for OGI at GSH conform to international standards

The above proposal was reviewed by the Department of Surgery Research Committee and I am pleased to inform you that the committee approved the study.

Please use the above project number in all future correspondence.

Yours sincerely

**PROFESSOR ANWAR S MALL
CHAIRMAN: RESEARCH COMMITTEE**

UNIVERSITY OF CAPE TOWN
Faculty of Health Sciences
Human Research Ethics Committee
Room E52-24 Old Main Building
Groote Schuur Hospital
Observatory 7925

Telephone [021] 406 6338 • **Facsimile** [021] 406 6411

Email: shuretta.thomas@uct.ac.za

Website: www.health.uct.ac.za/fhs/research/humanethics/forms

12 September 2014

HREC REF: 603/2014

DrNduToit

Ophthalmology

Surgery

J-floor, OMB

Dear Dr du Tait

**PROJECT TITLE: HOWDOESTHEPRACTICE OFEVISCERATION OF OGI
ATGSHCONFORM TO
INTERNATIONAL STANDARDS (MMeD candidate-Dr J Zondi) sub-study
of 227 /2008**

Thank you for your response to the Faculty of Health Sciences Human
Research Ethics Committee
dated 5 September 2014.

It is a pleasure to inform you that the HREC has **formally approved** the
above-mentioned study.

Approval is granted for one year until the 30th September 2015.

Please submit a progress form, using the standardised Annual Report Form if
the study continues

beyond the approval period. Please submit a Standard Closure form if the
study is completed within
the approval period.

(Forms can be found on our website:

www.health.uct.ac.za/fhs/research/humanethics/forms)

Please note that the ongoing ethical conduct of the study remains the
responsibility of the principal
investigator.

***We acknowledge that the MMed student, Dr Junaid Zondi will also be
involved in this study.***

Please quote the HREC reference no in all your correspondence.

Yours sincerely

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PROFESSOR M BLOCKMAN

CHAIRPERSON. FHS HUMAN ETHICS

Federal Wide Assurance Number: FWA00001637.

Institutional Review Board (IRB) number: IRB00001938

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