INDICATIONS AND OUTCOME OF SCLERAL BUCKLE SURGERY IN RHEGMATOGENEOUS RETINA DETACHMENT AT THE PCEA KIKUYU HOSPITAL-EYE UNIT

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DECLARATION

I declare that this dissertation is the result of my own work and has not been submitted either wholly or in part to any other university for the award of any degree or diploma. Research material and contributions by others have been properly acknowledged.

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LIST OF ABBREVIATIONS

BCVA	Best Corrected Visual Acuity
UCVA	Uncorrected Visual Acuity
KEU	Kikuyu Eye Unit
PDR	Proliferative Diabetic Retinopathy
PPV	Pars PlanaVitrectomy
PVD	Posterior Vitreous Detachment
PVR	Proliferative Vitreoretinopathy
SB	Scleral Buckle
SP	Scleral Pocket
ST	Sclera Thinning
IOL	Intraocular Lens
SRF	Subretinal Fluid
VA	Visual acuity
RD	Retinal Detachment
RRD	Rhegmatogenous Retinal Detachment

ABSTRACT

Background: Scleral buckling is one of the preferred surgical techniques for RRD repair at KEU. Beside the fact that this technique has been used for many years in this center, the outcomes are unknown and worldwide studies have shown a high success rate and improvement on visual acuity after surgery.

Objective: To identify the indications and outcome of scleral buckle surgery in RRD at the KEU.

Study design: Retrospective case series

Methods: In this study 75 RRD cases that underwent scleral buckling at KEU from 1st January 2012 to 31stDecember 2017 were identified and their social demographic data, the indication for surgery as well as the outcome measures in terms of BCVA and retinal reattachment at 6 months were entered into a data abstraction tool, then analysed using SPSS version 23.0. Factors associated with re-detachments were determined using chi square.

Results: Seventy-five (75) eyes of 73 patients were analysed but, only 30(40%) patients had 6 months follow up. The median age was 31 (IQR 22-46) years. Majority of patients (61.3%) were males, and right eye was involved in 62.7% of the cases. The mean duration of symptoms experienced prior to presentation was 35.6 (SD ± 30.2) days. In this study scleral buckling was done in 94.7% phakic eyes with inferior RRD in 72% without or with mild PVR associated with macula on in 98.7% cases. Less than 3 breaks were identified in 70.4% cases, associated with atrophic holes in 70.7% of cases. The final anatomical success rate was 96.7% at 6 months. The visual outcome improved in 19 (63.3%) eyes by more than 2 Snellen lines. In this study only 6.7% of eyes had re-detachment but no factors were identified to be associated with re-detachments.

Conclusion: Scleral buckling is safe and effective for uncomplicated RRD. Appropriate training of SB surgery for RRD is necessary and justified in view of the favourable results especially in phakic patients

CHAPTER ONE

1.0 Introduction

Scleral buckle surgery is an ophthalmic technique that has been used to repair rhegmatogenous retinal detachments for over 60 years(1). Retinal detachment is described as the separation of the neurosensory retina from the underlying retinal pigment epithelium (RPE). It can be classified into three main types: rhegmatogenous, traction and exudative retinal detachment. Combined forms such as tractional rhegmatogenous detachment may also occur but, the most common is the rhegmatogenous, where liquefied vitreous humor penetrates into the sub-retinal space following a retinal tear(2).

RRD occurs mainly due to physiological degeneration of the vitreous scaffold in the presence of a retinal break. The degeneration starts early in life and over time results in hardening of the collagen fibrils hence posterior vitreous detachment due to the progressive loss of elasticity(2). Early symptoms of acute detachment may include tiny dark floaters that are linked to photopsia (flashes). Loss of visual field is a late complication as a result of accumulation of subretinal fluid causing a corresponding loss of peripheral vision. In addition, patients can be asymptomatic until involvement of the macula(2).

Surgery is the only effective treatment and scleral buckle (SB) surgery is one of the most widely surgical techniques used to repair RRD (3). This surgical procedure is classified into radial, segmental circumferential and encircling circumferential buckling. The preferred type of buckle to use depends on its indication(4). Functional closure of all retinal breaks and relief of vitro-retinal traction is the main objective of sclera buckling(5). The sclera buckle(SB) procedure results in anatomic reattachment lasting up to 20 years with significant longevity in many cases(6).

The aim of the study is to assess retrospectively the indications and the anatomical success rates of buckling performed for RRD at KEU and also to establish the visual outcome following the surgical procedure.

CHAPTER TWO

2.0 Literature Review

2.1Rhegmatogenous retinal detachment

Rhegmatogenous retinal detachment (RRD) is the most common indication for surgery in vitreoretinal specialty(7), however, the presentation varies from uncomplicated detachment with a single localized break to total detachments associated with multiple breaks, giant tears or proliferative vitreoretinopathy (PVR) [4].

Ware in 1805, Wardrop in 1818 and Panizza in 1826 first described the retinal detachment by relying mainly on pathological observations(8). Various other people in history have also played a role by contributing to the current success rate of managing retinal detachments (RDs) that stands at more than 90%. The evolution of RD is divided into pre-Gonin and post-Gonin eras that were named after Jules Gonin(9). In the pre-Gonin era, though retinal breaks were associated with RD, the focus was on the RD without much attention to the causative break. Different theories and respective treatments were put forward with the first one showing that RD was spontaneous due to abnormal leakage from the choroid. Breaks in the retina were due to increased pressure from fluid generated behind the retina. Therefore, treatment was to puncture the sclera and retina to relieve the pressure.

Draining the subretinal fluid (SRF) resulted in failure as a result of use of various modalities such as chemical retinopexy and galvanocautery. In the second theory, hypotony and associated circulatory alterations were thought to be the cause of RD. Many treatments like injection of materials such as rabbit vitreous and gelatin to increase intraocular pressure were used. Osmotic agents such as saline, cane sugar, glycerin and mercury salts were also injected into the subconjunctival space with the hope of reducing SRF. Leber and Nordenson postulated alterations in the vitreous generated secondary traction on the equatorial retina forming retinal tears with RD. Non-surgical methods such as dietary modifications with salt restriction and bilateral compression bandages with bed rest that increases intraocular pressure were also used(9).

Jules Gonin (1870-1935) demonstrated the role of the retinal break in the pathogenesis of RD in which retinal breaks were localized pre- and intra-operatively. Under local anesthesia, the subretinal space was entered after making a radial sclera incision near the break while SRF was drained.Thermocautery was then introduced to create retinopexy in which Gonin reported a 63% success rate(9).

In subsquent decades, different modifications of retinopexy were developed and used to treat the retinal break. Chemical cauterization for retinopexy using potassium hydroxide introduced by Guist and Lindner in 1931 and diathermy to bare the sclera (surface diathermy) or after trephining the sclera (penetrating diathermy) was used. In this case, drainage of the SRF was performed along with diathermy. Complications of diathermy led to the search for other modalities for retinopexy. The current use of cryotherapy is credited to Harvey Lincroff and Amoils who created a specially designed cryo-probe by use of liquid nitrogen. Charles Schepens described the use of scleral depression and devised the first clinical head mounted indirect ophthalmoscope in 1947. He later modified it by incorporating the light source and viewing system on the headband as is currently known(9).

Shortening of the globe by scleral resection was the first step towards scleral buckling. Creating an inward ridge for supporting a break was initially achieved either by full or partial thickness sclera resection with SRF drainage and putting mattress sutures across the defect. Ernst Custodies performed the first scleral buckling procedure using an episcleral exoplant in 1949 while Charles Schepens did the first scleral buckling surgery in the USA in 1951. Harvey Lincoff in 1965 modified the original procedure by Custodis. The changes included use of silicone sponge, use of improved scleral needles and use of cryotherapy instead of diathermy for retinopexy. Silicone sponges were used in a radial or circumferential fashion depending on the clinical scenario(9).

2.2 Risk factors for rhegmatogenous retinal detachment

Typical risk factors for RRD includes, family history, increasing age, trauma to the eye, prior cataract surgery (pseudophakia or aphakia), fellow eye retinal detachment and shortsightedness (myopia) which is the main risk factor(2,5). An Indian study reported that prior cataract surgery was the most common identifiable risk factor at 40% (10).

2.3 Surgical interventions

RRD is successfully repaired by scleral buckle surgery, pars plana vitrectomy with retinopexy and internal tamponade and pneumatic retinopexy. None of the studies done previously has shown superiority of one technique over another in terms of anatomic or visual outcomes. The choice of technique used depends on the experience and preference of the surgeon combined with the type(s), number and distribution of retinal break(s) as well as the nature and extent of RRD(5).

2.4 Scleral buckle surgery

Scleral buckle surgery is a procedure in which a band of silicone, plastic, rubber or sponge is placed and sewn outside the sclera at the site of a retinal break to create an indentation of the sclera toward the retinal break. It holds the retina against the sclera until formations of scar tissue at the site of chorioretinal irritation by laser or cryotherapy is complete(10). The shortening of the sclera was introduced by Mueller in 1903 to decreases the globe volume, however, Jess became the first person to use a foreign substance to create an indentation in 1937 where a temporary tampon of gauze was placed beneath Tenon's capsule over the retinal break. Ernst Custodis was the first person to do scleral buckling using retained explants(9).

Scleral buckle (SB) procedure came to revolutionize the treatment of patients with retinal detachment and has been in place since 1957 with anatomic reattachment success of up to 94%.The procedure also gives longevity lasting 20 years or more in many cases(6).

Vitrectomy technique has become popular for the treatment of RRD due to the advent of outpatient ambulatory surgery, improvement in technology, instrumentation, and viewing systems(11). However, SB is still the primary procedure for many surgeons in young phakic patients with RRD(12).

Scleral buckling involves various techniques such as encircling buckles and segmental buckles that can be placed radically, circumferentially or even obliquely(4). The choice of the scleral buckle used depends on the location, number and size of the retinal breaks. It also depends on the phakic status, distribution of SRF, presence of proliferative vitreoretinopathy (PVR), the amount of vitreous traction, the state of the sclera and available eye volume.

There are three main SB techniques; they include the radial SB indicated for large U-shaped tears and posterior breaks, the segmental circumferential SB indicated for small to medium size breaks in the same location, the encircling circumferential SB used for more complex RD. This includes large and multiple breaks in three or more different locations, extensive RD without visible breaks, lattice degeneration in three or more locations, mild PVR, aphakic RD, excessive drainage of SRF and after segmental SB failed. It confers a permanent 360-degree scleral indentation(7).

General or local anesthesia can be used to perform scleral buckling and the procedure involves conjunctiva opening performed at either the limbus or several millimeters posterior in patients with filtering blebs or recent limbal wounds. In many cases, radial conjunctiva relaxation incisions are suggested to prevent tearing. A 360^0 peritomy is necessary if more than two quadrants are to be buckled. Conjunctiva and Tenon's capsule can be reflected in the required quadrants using curved Steven's scissor and only the appropriate muscles are isolated. After the peritomy, the space between Tenon's capsule and sclera is then entered, muscle tendon is later engaged with a muscle hook, and the connections to Tendon's capsule are identified and separated from the muscle.

A traction suture using 4.0 braided silk sutures is placed around the muscle, after all rectus have been isolated, the surface of the sclera is inspected for evidence of thinning, staphyloma, and anomalous vortex veins(13). The locations of any abnormalities are noted before scleral depression is started or retinal breaks are marked. Using indirect ophthalmoscopy and scleral indentation all breaks are localized and the anterior edge is marked, that consist of an area of most vitreoretinal traction that has to be opposed. The breaks are then sealed with cryopexy trans-sclerally and marks placed on the sclera to localize the breaks which act as guides to secure the buckle. The buckle is positioned beneath the rectus or over intact sclera and secured with 5-0 polyester sutures on spatulated needle placed parallel to the buckle going through partial sclera thickness or within intrascleral tunnels that will add the surgery duration but the risk of extrusion of the buckle decreases. If a non-drainage technique is chosen, it is necessary to use medical or surgery techniques (anterior chamber paracentesis) to counter intraocular pressure elevation. This usually occurs in cases of encircling bands due to their higher potential to reduce the eye ball volume. If a drainage approach is chosen, the SRF drainage is carried out by use of scleral cut down and a 30G needle perforates the choroid. Once adequate fluid removal occurs, the sclerotomy can be closed

with 5-0 nylon suture. Restoration of vitreous volume is achieved with air, gas (SF6 or C3 F8) or fluid if the eye becomes too soft from the amount of fluid drained. The buckle position and pulsation of central retinal artery is then checked and the conjunctiva closed with 8/0 vicryl.Subconjunctival injection of antibiotic and steroid are then given and temporary eye patch is placed (14,15).

During SB surgery for RRD, drainage of SRF can be done using an incision parallel to the limbus in a scleral pocket (SP) or through a simple radial scleral thinning (ST). A study reported that during surgery, choroidal detachments were observed at a higher percentage in the SP group and at the end of the surgery a certain amount of SRF behind the buckle was significant in the ST group. The study thus concluded that SP drainage technique appeared to be an effective and safe method to drain SRF (16,17).

Drainage of SRF is a critical stage in scleral surgery for RRD that is carried out to facilitate the localizations of breaks, to visualize the retinal attachment to the buckling band during surgery. It also allows reduction of the extent of retinal-choroidal-cryo-applications hence a smaller risk of pigment dispersion in to the vitreous and vitreoretinal retraction processes(16). However, drainage of subretinal fluid during scleral buckling is controversial with most cases being managed without draining while others believe that it is a crucial part of the technique. Two reasons for draining are to decrease the intraocular volume allowing elevation of the buckle without elevating intraocular pressure (IOP) and to remove fluid from the subretinal space allowing the retina to settle on the elevated buckle (13,16).

The most significant complications occurring during SRF drainage are subretinal or choroidal hemorrhage, retinal perforation, vitreoretinal incarceration, ocular hypotony and choroidal detachment. The occurrence of any of these complications can cause surgery to be unsuccessful (16). A study reported complications related to drainage of subretinal fluid in 5.6% of the 556 eyes in which drainage was attempted. Small sub retinal hemorrhage was the most common complication in 3%, retinal incarceration occurred in 2% and was associated with an iatrogenic retinal hole in three cases and loss of formed vitreous in two cases. Hyphema was observed during

drainage in a single eye with an anterior chamber IOL and an atypical endophthalmitis seen in one case in which uncomplicated drainage had been performed(17).

2.5 Indications for SB surgery

Scleral buckle surgery procedure is recommended in; RRDs in young and phakic patients with no posterior vitreous detachment (PVD), retinal dialysis, atrophic or round holes, breaks anterior to the equator, inferior breaks and certain complex retinal detachments with PVR. However, SB is contraindicated when detachment is due to significantly posterior breaks, in cases of opaque media (vitreous hemorrhage) and when it is associated with significant traction such as diabetic tractional detachments and PVR(18). It is also contra-indicated in patients with vaso-occlusive disease (sickle cell anemia) to avoid possible anterior ischemia caused by buckling(15). A study done in Nigerian included all phakic RD patients for buckling (19).

2.6 Surgery success rates

Rhegmatogenous retinal detachment has a high reattachment success rate in 90 percent of cases following surgery with success rates nearing 100% after secondary surgery(5). Anatomical success is a reattachment of the retina 6 months after primary surgery with reoperations included(3). In a retrospective study carried out in USA, 1226 cases with follow up over 1-year reported a success rate of 86%for scleral buckling, 90% vitrectomy and 94% for combined vitrectomy and scleral buckling and 63% for pneumatic retinopexy surgery(20).While in Norway, scleral buckling achieved a success rate of up to 86% reattachment without reoperation and 99% with reoperation in 6 months(3). In Japan,93.7% primary anatomical success and 100% final anatomical success in 271 eyes treated using SB surgery was reported(21). In Pakistan, a final re-attachment rate of 82% was also reported(22). In a Nigerian study, anatomical attachment was seen in 95.6% of patients on the operation table, 90.9% patients at first day postoperatively and 86.5% of patients at six weeks after surgery(19).

Several factors have been identified in previous studies linked to anatomical success or failure of SB surgery for RRD. Preoperative factors identified in previous studies include proliferative vitreoretinopathy, opacity of the media, pseudophakia, and in complicated RRD with multiple breaks. Primary anatomical failure was found more frequently in older patients with lower VA

with p <0.001(12). In a study carried out in India, it was reported that the commonest cause of failure was a missed break in 32.4%(23) while the prognostic factor for anatomic and visual acuity success was associated with macular detachment in most cases(15).

2.7 Visual outcomes

Scleral buckling procedure has a good visual outcome when performed in fresh retinal detachment(19).Visual acuity improves significantly after surgical intervention and there is no difference between various techniques used to repair rhegmatogenous retinal detachments(20). Various pre-operative characteristics determine the post-surgical visual outcomes, for instance, in old age (>70 years) severe PVR, detachment more than 7 days prior to surgery, and macular detachment are the most important predictive factors in restoring visual acuity. The most reliable predictive factors for poor postoperative outcome are the extent of initial macular involvement, poor preoperative visual acuity and intraoperative hemorrhage(15).Only 40% to 60% of patients with macula-off detachments have visual acuity restored to 20/50 or better. In detachments however, sparing the macula visual restoration is much higher. In a surgery carried out in one large series indicated that 90% of patients with macula-on detachments had vision of 20/50 or better(5).Similarly, in Japan, study findings showed a significant improvement on BCVA in patients with phakic and macula-off detachments and no change for those with pseudophakia or macula-on detachments(21).In Pakistan, a mean change in refractive spherical equivalent of -1.478 + or - 0.698 D in which the final BCVA achieved in 62% of the treated eyes was> 6/60(22).A retrospective non-comparative case series of 65 patients carried out in Scotland showed a significant improvement in BCVA from 29% of patients with preoperative VA of 6/6 to 56% with VA 6/6post-operatively(24).

Several other pre-operative characteristics have been identified to have a significant influence on post-operative visual outcome. Younger patients achieved significantly better visual outcome and had shorter duration of symptom compared to the older patients. This was reported in a Korean study with older age (35 years and older) being a prognostic factor for anatomical failure in SB for uncomplicated RRD(12).Positive prognostic factors for visual acuity that have also been shown to be important were better preoperative visual acuity with fewer quadrants involved by the detachment due to lack of high myopia(15).

In Nigeria, a study reported good visual outcome at 38.8% and the primary anatomic reattachment was at 80.5% while final anatomic success was at 90.2%. VA of 6/60 and better preoperative, mild PVR, and achievement of primary anatomic success favorably influenced a good visual outcome after surgery for RRD(25). In another study carried out in Nigeria, over 51.1% of patients reported an improvement of visual acuity, 20% remained the same and 28.9% got worse six weeks after scleral buckle surgery and at the end of the follow up 66.7% had BCVA > 3/60. Late presentation and PVR may have been associated with poor outcome in some patients in which vitrectomy in these patients helped to improve their visual outcome. It was noted advising the population on the importance of early presentation and adequate awareness of scleral buckle surgery for RRD could result in better outcome in sub-Saharan Africa(19).

In summary, the main factors that predict poorer visual function after surgery include poor preoperative visual acuity, more than three quadrants involvement, multiple breaks, breaks localized inferiorly, macula-off RRD, proliferative vitreoretinopathy of any grade (PVR) and intraoperative hemorrhage(5).

2.8 Complications

There is relatively low potential for intra and postoperative complications of SB surgery. Immediate and early postoperative discomfort, entrapment of rectus muscle leading to strabismus, explants extrusion, anterior segment ischemia especially after using encircling bands and increased axial length, decreased equatorial diameter leading to refractive error which is the most common complication. Other early complications include high IOP resulting from reduction of total globe volume leading to glaucoma if long standing, macular edema or macular pucker, diplopia, choroidal bleeding and infection of the buckle(26). Diplopia and strabismus were reported early after operation in around 15% of cases. Buckle infection was found in 0.3% of cases and buckle migrates into the eyeball was found in <0.01% of cases(2). In Pakistan, a study reported that at least one intra-operative complication was found in 32% of the patients. This included 2% associated with iatrogenic scleral break, 8% inadvertent drainage of sub retinal fluid, 2% with choroidal hemorrhage, 14% sub retinal hemorrhage, 2% retinal incarceration, vitreous hemorrhage in 6%, 4% with high intraoperative IOP, 2%, with very low IOP and hyphema in 2%, 22% high

IOP and 16% vitreous hemorrhage. Twenty-four percent of patients who developed these complications had with systemic complications. (22). Complications reported in a Nigerian study included raised intraocular pressure and reopening of breaks in five patients(19).

2.9 Factors associated with re-detachments

There are various risks that are mainly associated with anatomical failure and re-detachment of scleral buckling like pre-retinal membrane, undetected retinal tear, inadequate sclera buckle, new retinal tear, inadequate chorio-retinal reaction, iatrogenic retinal tear and loss of buckle height(27). A drain-air injection-cryo-exoplant (DACE) procedure can also cause too many air bubbles that interfere with proper localization of the break as well as appropriateness of the buckle location. There is a general tendency to choose buckles of narrow width which makes it easier to pass mattress sutures. However, this should not be at the expense of inadequate coverage of the break. Another issue that can compromise the outcome is a sub-retinal bleed at the conclusion of SRF drainage due to cauterization of the knuckle of the choroid that does not always prevent the bleed. One way to deal with this is controlled drainage.

There are other factors that can affect outcome like inadequate cryo-induced chorio-retinal adhesion around the retinal break and fish mouthing. The latter is common after placing circumferential buckles for large horseshoe tears(28).In a USA study,1088 consecutive operations for retinal detachment were done, it was found that that pre-retinal membrane, accounted for 33% of failure (27). Re-detachment was found to occur after a mean period of 13.6 months with a median of 3 months. 55 (12.6%) eyes had re-detachment within the first 3 months after the primary surgery. In addition, 68 out of 436 eyes (15.6%) had developed re-detachmentat 6 months and 80 out of 436 eyes (18.3%) after 1 year(29).

2.10 Rationale

Scleral buckling is a treatment of choice in patients with uncomplicated RD associated with round holes and in retinal dialysis. In detachments affecting the macula, 40 to 60% of patients improve their visual acuity to 20/50 or better. Worldwide studies have shown high sucess rate nearing 100%(5). In Kenya, despite the fact that the SB surgery has been done for many years at KEU no studies have been done to find out the indications and outcomes of SB surgery in RRD hence it is

necessary to determine the proportions of reattachment, the level of visual acuity after surgery and factors associated with the outcome then to establish the effectiveness of the SB surgery in our setting.

2.11 Research Questions

1. What are the indications of scleral buckle in rhegmatogenous retinal detachment among patients attending the Kikuyu Eye Unit (KEU)?
2. What are the retinal reattachment success rates following scleral buckling among patients attending the KEU?
3. What is the visual outcome 6 months after scleral buckling among patients attending the KEU?
4. Which factors are associated with re-detachment among patients attending the KEU?

2.12. General objective

To determine the indications and outcome of scleral buckle surgery in rhegmatogenous retinal detachment among patients attending the Kikuyu Eye Unit.

2.12.1 Specific objectives

1. To identify the indications of scleral buckle surgery in rhegmatogenous retinal detachment among patients attending the KEU.
2. To determine the retinal reattachment success rates 6 months following scleral buckling among patients attending the KEU.
3. To determine visual outcome 6 months after scleral buckling among patients attending the KEU.
4. To identify factors associated with re-detachment among patients attending the KEU.

CHAPTER THREE

3.0 MATERIALS AND METHODS

3.1 Study design

This was a retrospective case series.

3.2 Study site

The study was carried out at KEU at the Kikuyu Hospital situated in Kiambu County located in the Central region of Kenya. Kiambu County is one of the 47 counties in Kenya. It borders Nairobi and Kajiado Counties to the South, Machakos to the East, Murang'a to the North and North East, Nyandarua to the North West, and Nakuru to the West. Kikuyu sub-county covers 175.8 km^2 with an estimated population of 292,022 (Kiambu County, 2018).

The Kikuyu eye unit is a referral center and handles 70-80,000 patients a year (Kikuyu Eye Hospital, 2018). A total of 176 RRD is seen by year with an average of 18 scleral buckle surgeries for RRD done per year all by one vitreoretinal surgeon.

Figure 1**:** Kikuyu in Kiambu County in Kenya (Source: map data Google 2018)

3.3 Study population

This study included all case notes of patients with rhegmatogenous retinal detachment (RRD) who had scleral buckling done at the KEU from 1st January 2012 to 31st December 2017.

3.4 Eligibility criteria

3.4.1 Inclusion

1. Case notes of patients with rhegmatogenous retinal detachment patients who underwent scleral buckle surgery between 1st January 2012 to 31st December 2017

3.4.2 Exclusion

1. Cases notes of patients with rhegmatogenous retinal detachment who were treated using combined procedures other than SB surgery only.
2. Missing files after surgery.

3.5 Sample size

Averages of 2 SB surgical cases were carried out every month at the Kikuyu Eye Unit translating to approximately 20 cases per year. In this study we review records of 6-year period hence the total number of cases is estimated was 120. A representative sample was drawn from the finite population and sample size was determined using the formula for finite populations (less than 10,000). The calculation as follows:

$$n' = \frac{NZ^2P(1-P)}{d^2(N-1)+Z^2P(1-P)}$$

Where

n' = sample size with finite population correction,

N = size of the target population = 120

$Z_{1-\alpha/2}$ - Two-sided significance level (1-alpha)-95% = 1.96

P – Estimated proportion of patients with successful retinal reattachment after SB surgery = 86% (Schaal *et al.*, 2011)

d – Precision error = ±5%

$$= \frac{120 \times 1.96^2 \times 0.86 \times 0.14}{0.05^2 (120-1) + 1.96^2 \times 0.86 \times 0.14}$$

n = 73

A minimum of 73 records will be sampled to estimate within a 5% level of precision.

3.6 Sampling procedure

Hospital registers were used to identify all the case notes of patients who had undergone SB surgery. All files that fit the criteria within the study period were retrieved and reviewed from the records using the inpatient numbers and included in the study. All missing file or those not meeting inclusion criteria were excluded. Data collection was carried out over a period of one month.

3.7 Data collection methods

3.7.1 Study tools

A structured data abstraction tool (Appendix 2) was used to collect the demographic and medical information about the patient's characteristics, SB procedure, intra- and post-operative complications, surgical outcome and post-operative visual acuity.

3.7.2 Data abstraction

The data was collect by the investigator and information from the files was entered in the data abstraction tool. We ensured completeness of the information collected as much as possible. Those files with inadequate information for the study's objectives were excluded. Patients' records were allocated study numbers and recorded in the data abstraction tool. To ensure non-duplication of patients' records in the study database, colored stickers with study numbers written were placed on top of every file at the end of abstraction for identification.

3.8 Data management and analysis

The data from the questionnaires was entered and managed in a pre-designed Microsoft Access database. Data entry was done continuously in the course of data collection. At the end of data entry, this data was cleaned and analyzed using SPSS version 23.0. The study population was described by summarizing categorical data into proportions and continuous data into means or

medians. The visual outcome, indications of scleral buckling, complications arising during and after surgery, retinal reattachment rates was presented as proportions. Factors associated with reattachments were tested using Chi-square test and odds ratios were presented to show the estimated risk ratio associated with independent variables. All statistical tests were performed at 5% level of significance (95% confidence interval). The findings of this study were presented using tables and graphs.

3.9 Ethical considerations

Ethical approval for this study was sought from KNH/UON ethics research committee. In addition, permission to conduct the study was sought from Kikuyu hospital through the health information department. Confidentiality was assured at all times by not using patients' identifiers in the data collection tools or in any data set or publication. Patients' files were not be photocopied or names of clinicians/surgeons recorded. The research documents were only accessible to investigators and the statistician.

CHAPTER FOUR

4.0 RESULTS

A total of 91 scleral buckle surgeries were done between 1st January 2012 and 31st December 2017 and retrieved from the theatre record book, however, only 75 cases were analysed. Those that were not analysed consisted of 10 files that were missing from the records filing storage and 6 files had missing pages with no theatre notes as shown in the flow chart below.

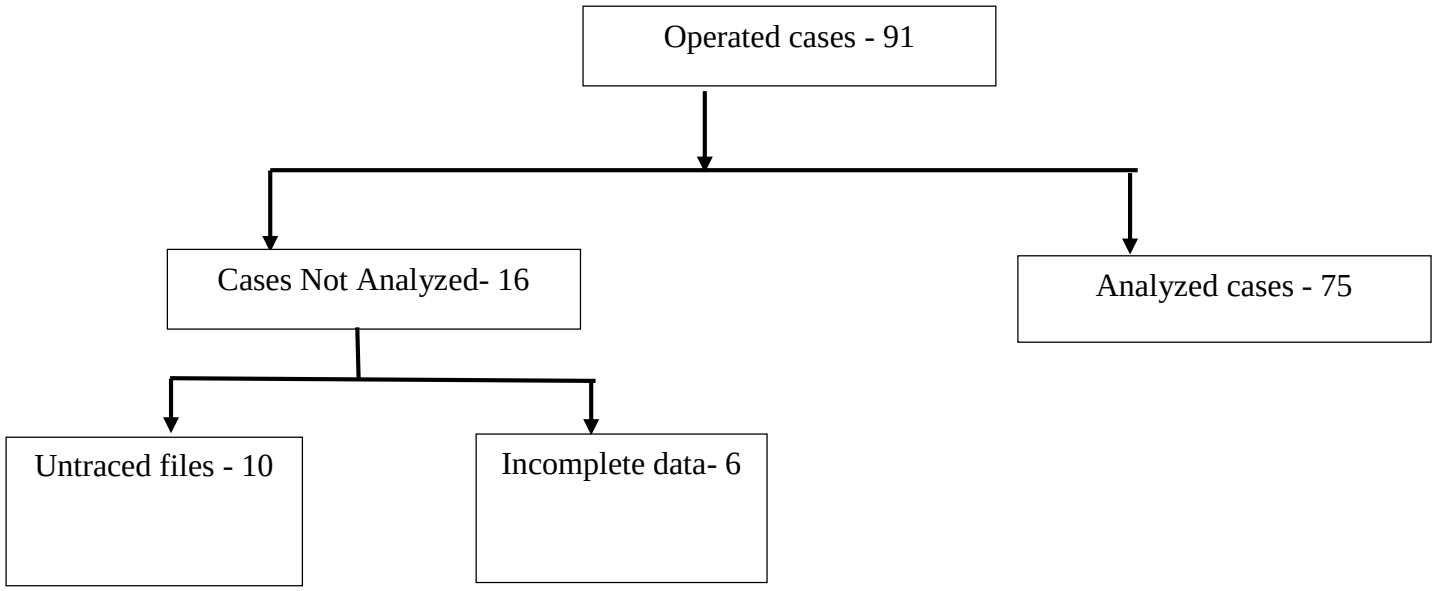

Figure 2 **: Flow-chart of operated cases**

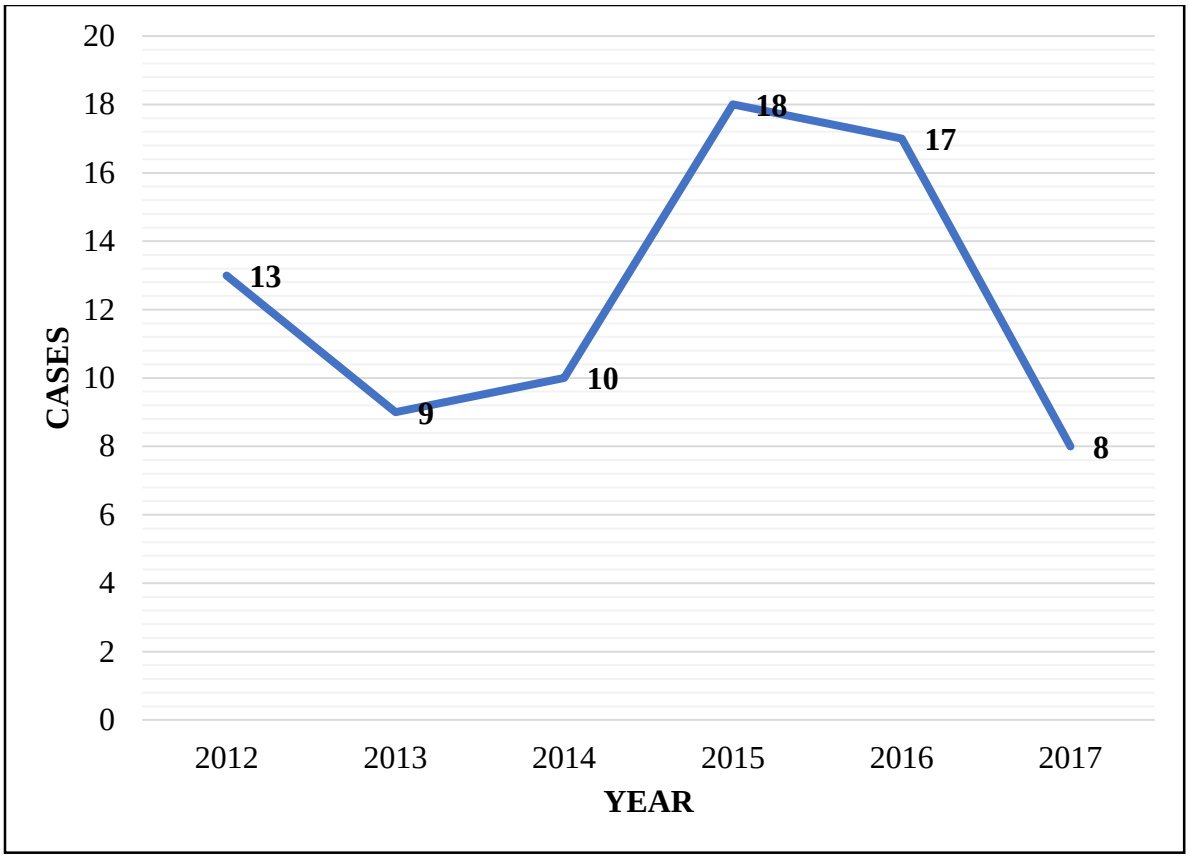

Figure 3**: Number of eyes operated by year (n=75)**

The average number of surgeries done per year was 13 and all surgeries were performed by the same surgeon.

Table 1**: Baseline characteristics (n=75)**

	Frequency(n)	**Percent (%)**
Age (years)	31(IQR 22-46)	
Sex		
Male	46	61.3
Female	29	38.7
Eye Operated		
Right eye	47	62.7
Left eye	28	37.3
Lens Status		
Phakic	71	94.7
Pseudophakic	4	5.3
Time from diagnostic to surgery (in days)		
<7	8	10.7
≥7	67	89.3

The age of presentation ranged from 5 to 72 years and the right eye was involved in 62.7% of patients. Majority of eyes operated were phakic in 94.7%. The mean duration from diagnosis to surgery experienced was 35.65 (SD ± 30.2) days, the median duration was 30 days and the range was 1 to 188 days. 96% of the eyes operated had a single operation done.

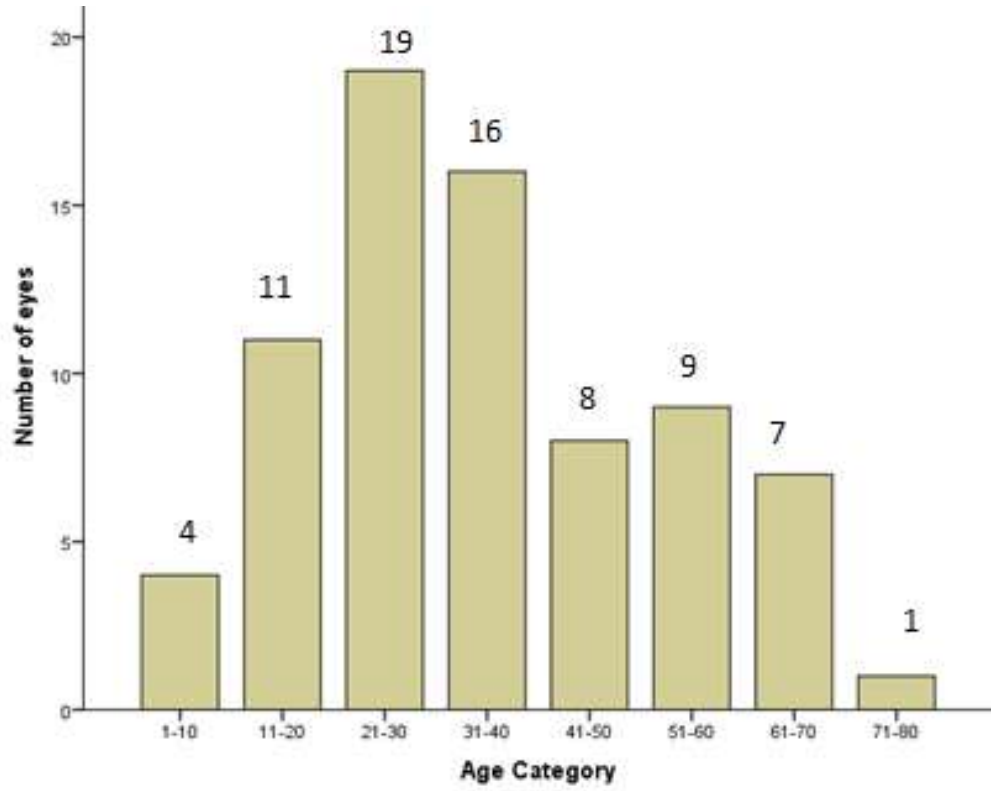

Figure 4: **Age distribution (n=75)**

Majority of patients in 25.3% where at age group of 21to 30

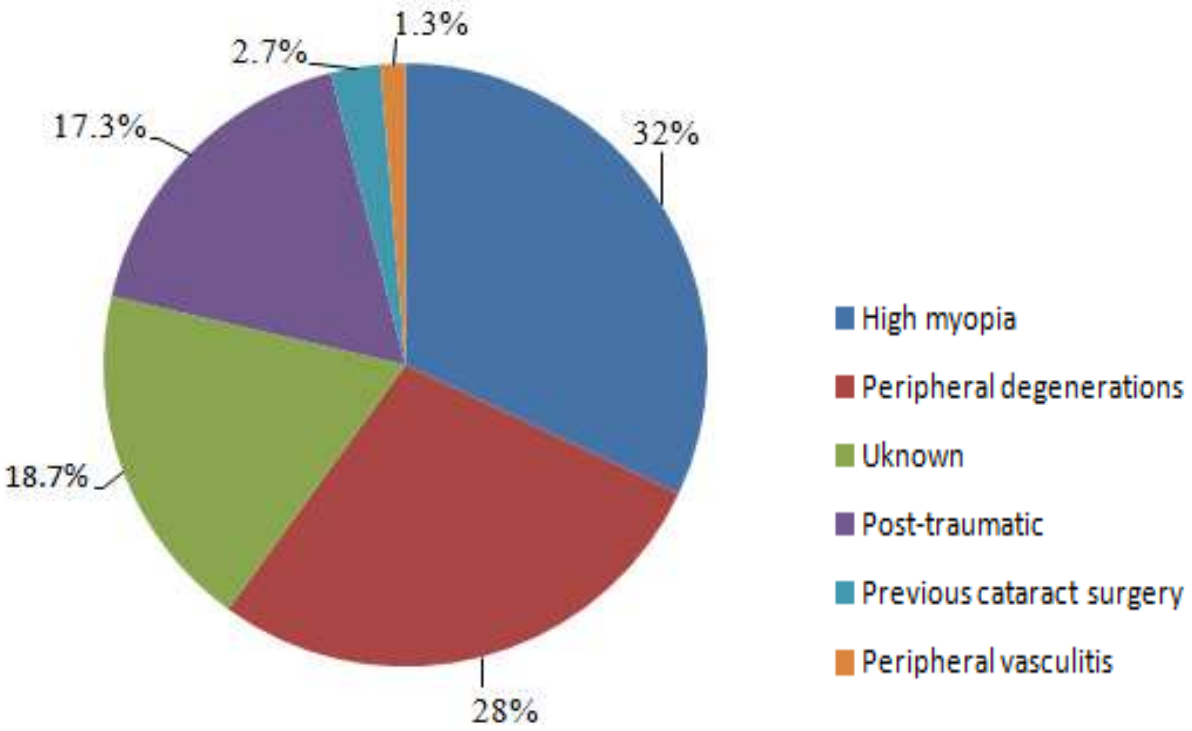

Figure 5: **Risk factors for RRD**

Myopia was the most common risk factor for rhegmatogenous retinal detachment in 24 eyes (32.0%) followed by peripheral degeneration. RRD associated with atrophic hole were identified in 50 eyes (70.7%). Unknown causes in 14 eyes (18.7%) contributed to a significant number of the retinal detachments.

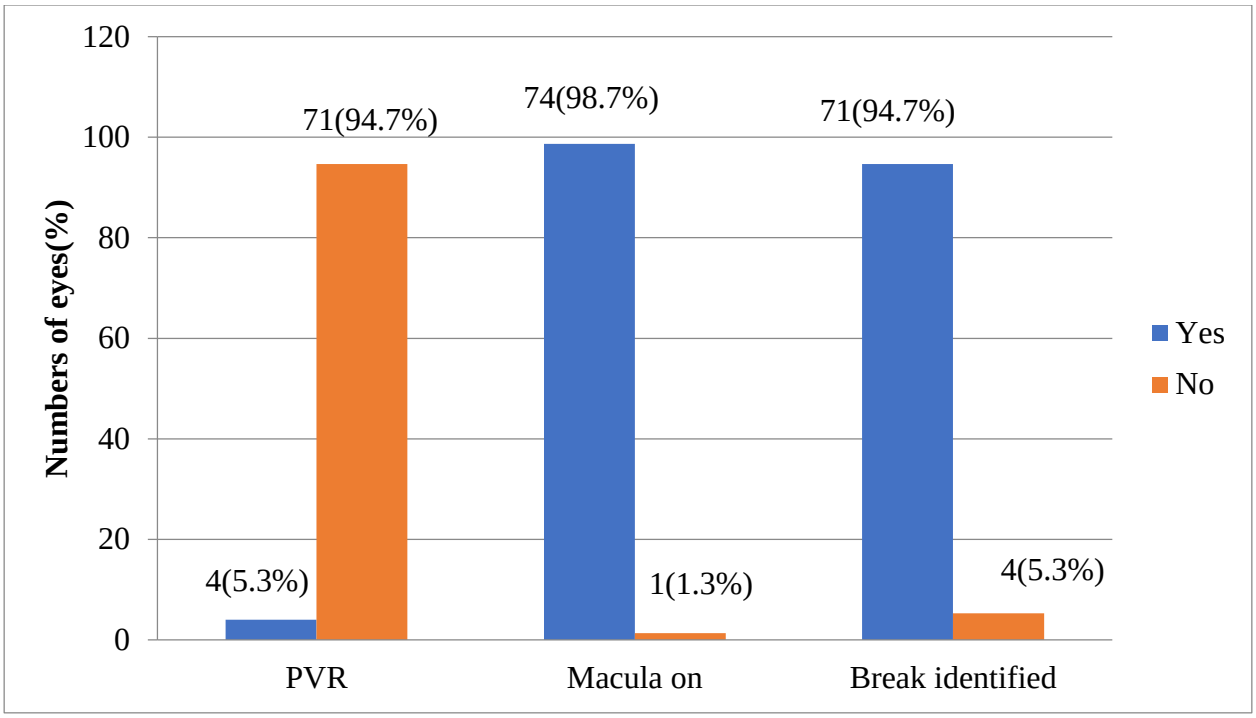

Figure 6: **Characteristics of RRD (n=75)**

Macula was attached in 98.7% of cases and retina breaks were identified in 94.7% of eyes. There was proliferative vitreoretinopathy grade A (tobacco dust) in 4 eyes (5.3%).

Table 2**: Characteristics of RD**

	Frequency (n=75)	Percent (%)
Number of breaks		
1-3 breaks	49	65.3
4-6 breaks	18	24.0
>6 breaks	7	9.3
Missing	1	1.3
Types of breaks		
Atrophic hole	53	70.7
Retinal tears	15	20.0
Dialysis	6	8.0
Missing	1	1.3
Location of Breaks		
Inferior	54	72.0
Temporal	14	18.7
Nasally	4	5.3
Superior	3	4.0

Majority of eyes 72.0% had inferior RD associated with atrophic hole. Note that one eye was not documented the type and number of retina breaks.

Table 3**: Types of scleral buckling**

	Frequency(n=75)	Percent (%)
Segmental circumferential	68	90.7
Encircling	5	6.7
Missing	2	2.7
Sub-retinal fluid drainage		
Yes	72	96.0
No	3	4.0

Every eye in the study underwent cryotherapy. Internal tamponade with gas or other agent was not applied to any of the cases.

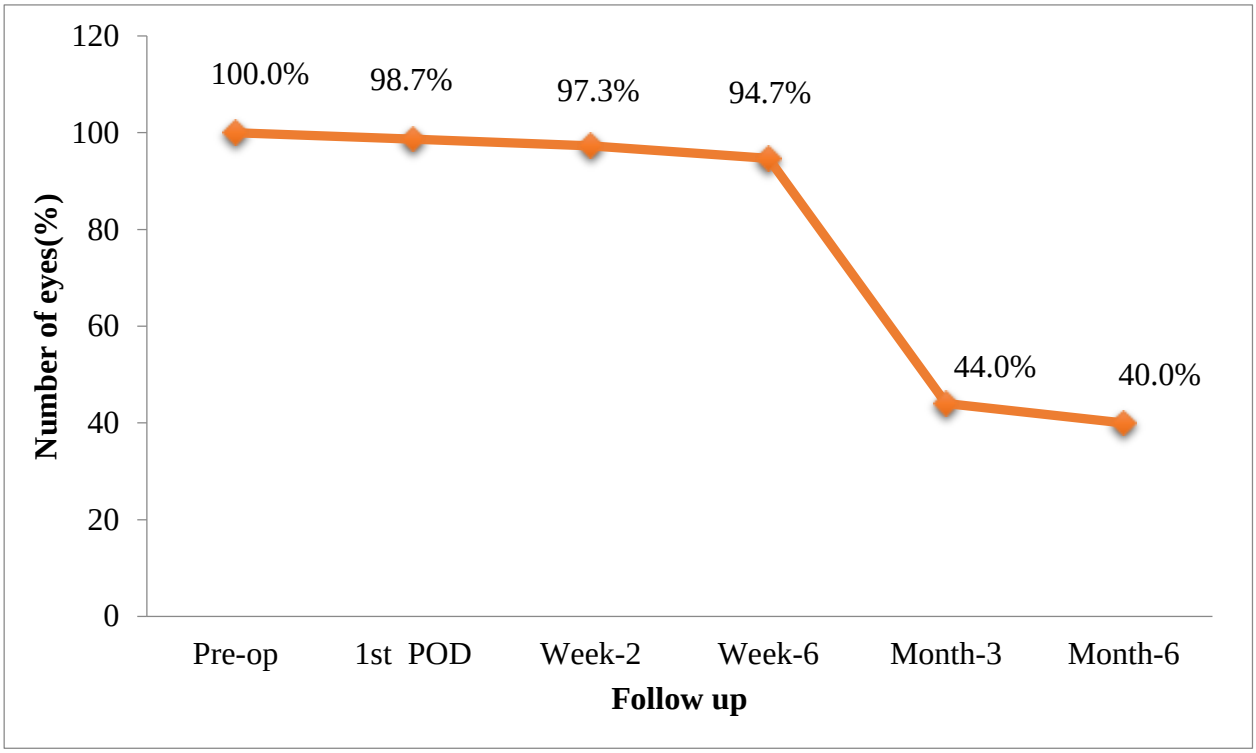

Figure 7: **Loss to follow-up**

Postsurgical follow-up is important in that it ensures that the retina is in place and at the same time, it also helps to identify unsuccessful cases for repeat surgery. The shortest postoperative follow-up period was 2 weeks, while the longest postoperative follow-up period was 6 months for 30(40.0%) eyes.

Table 4**: Trend of anatomical outcome**

Retina attached	On table	Day 1	6 weeks	3months	6 months
Yes	75(100%)	72(96.0%)	68(90.7%)	32(44.7%)	29(38.7%)
No	0(0.0%)	2(2.7%)	3(4%)	1(1.3%)	0(0.0%)
Missing data	0(0.0%)	1(1.3%)	4(5.3%)	42(56%)	46(61.3%)

Final anatomic success rate was 96.7% at 6 month follow up.

Table 5: **Anatomical outcome at last follow up**

	Frequency(n=75)	Percent (%)
Retina attached	70	(93.3%)
Re-detachment	5	(6.7%)

Primary anatomic success rate was 93.3%.

Re-detachment was found in 5(6.7%) eyes after surgery, male/female ratio 3:2.

In all the eyes in which the break was identified the macula was on and there was no PVR and Cryotherapy and drainage of sub retinal fluid were done and duration of symptoms was more than 7 days

Three eyes were associated with myopia and two were post-traumatic. One eye was pseudophakic and had re-detachment at day one after surgery, two eyes had re-detachment within one month of surgery two eyes had re-detachment secondary to new retinal breaks at three months period. Three of the re-detached eyes were re-operated and two were observed because they were inoperable.

For the eyes that underwent re-operation, one eye underwent additional buckling, the other underwent buckle replacement and the final one underwent pars plana vitrectomy.

Final anatomic success rate was 97.3% after re-operations based on last follow up.

Table 6: **Visual acuity trend**

BCVA	Preoperative	Postoperative			
		2weeks	**6 weeks**	**3 months**	**6 months**
Mild or no visual impairment (6/6 – 6/18)	10(13.3%)	8(10.7%)	9(12%)	7(9.3%)	8(10.7%)
Moderate visual impairment (<6/18 – 6/60)	23(30.7%)	30(40%)	19(25.3%)	14(18.7%)	13(17.3%)
Severe visual impairment (<6/60 – 3/60)	3(4%)	4(5.3%)	3(4%)	3(4%)	3(4%)
Blindness (<3/60)	39(52%)	27 (36%)	13(17.3%)	8(10.7%)	6(8%)
VA not recorded	0	6(8%)	31(41.3%)	44(57.3%)	46(60%)
Total	**75**	**75**	**75**	**75**	**75**

Only 30 cases (40%) had visual acuity data at 6 months follow up. The rate of loss to follow-up was high after 2 weeks.

Table 7: **Comparison of preoperative and post-operative BCVA at last follow up**

	Number of eyes	
	Preop BCVA	**Postop BCVA**
Mild or no visual impairment (6/6 – 6/18)	10 (13.3%)	13 (17.3%)
Moderate visual impairment (<6/18 – 6/60)	23 (30.7%)	36 (48%)
Severe visual impairment (<6/60 – 3/60)	3 (4.0%)	5 (6.7%)
Blindness (<3/60)	39 (52.0%)	21 (28%)
Total	**75 (100.0%)**	**75 (100.0%)**

Postoperative BCVA has been measured at the last follow-up for each patient.

At presentation, 42 eyes (56%) had VA worse than 6/60, 33 eyes (44%) had VA between 6/6 and 6/60. The proportion of eyes with VA better than or equal to 6/60 increased from 44% pre-operatively to 65.3% post-operatively and the proportion of eyes with VA worse than 6/60 decreased to 34.7% by the last follow up.

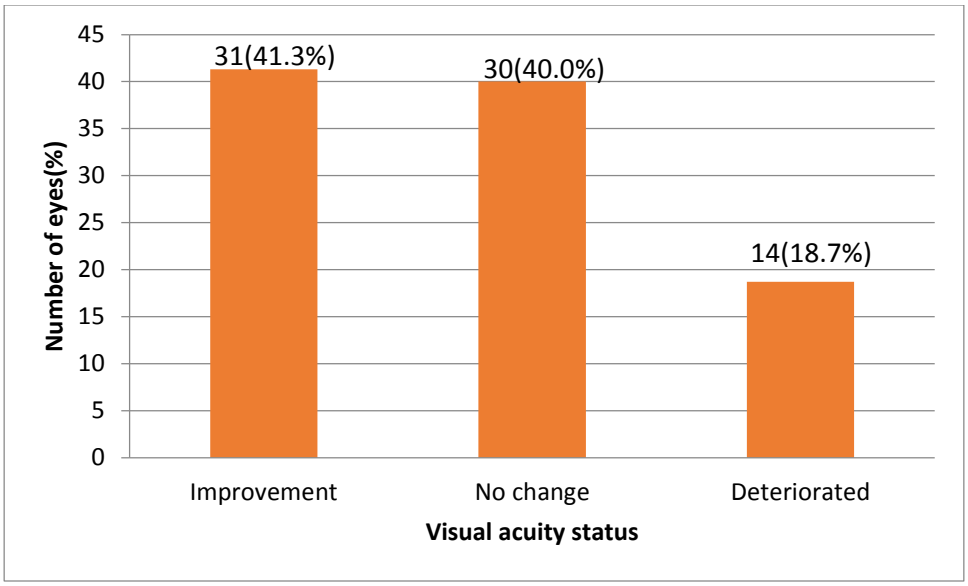

Figure 8: **Visual acuity status at last follow-up**

Majority of eyes operated 31 (41.3%) showed improvement in 4.6 (average) in Snellen line from their pre-operative visual acuity.

Table 8: **Comparison of preoperative and post-operative BCVA at 6 months**

	Number of eyes	
	Pre-op BCVA	**Pos-top BCVA**
Mild or no visual impairment (6/6 – 6/18)	5 (16.7%)	8 (26.7%)
Moderate visual impairment (<6/18 – 6/60)	5 (16.7%)	13 (43.3%)
Severe visual impairment (<6/60 – 3/60)	2 (6.7%)	3 (10.0%)
Blindness (<3/60)	18(60.0%)	6 (20.0%)
Total		30(100%)

The proportion of eyes with 6 months post-operative BCVA ≥6/60 increased from 33.3% pre-operatively to 70% post-operatively and the proportion of eyes with VA<6 /60 decreased to 30.0% from 66.7%

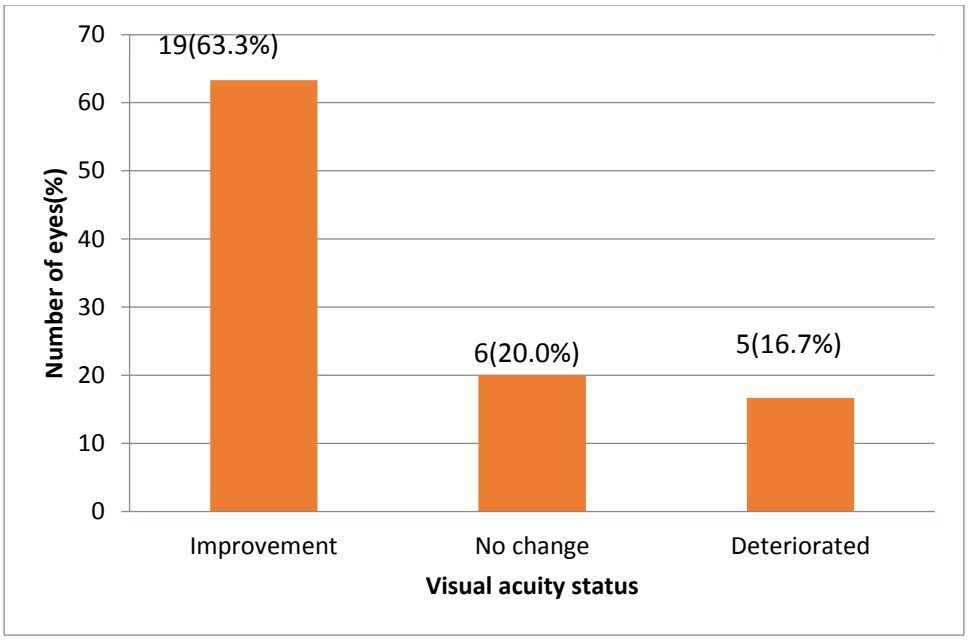

Figure 9: **Visual acuity status at 6 months**

Majority of eyes operated 19 (63.3%) showed improvement in 4.8 (average) in Snellen line from their pre-operative visual acuity.

Table 9: **Complications of scleral buckling**

	Frequency (%)
Intraoperative complications	**9 (12%)**
Retinal incarceration	5(6.7%)
Retina Folds	3(4%)
Vitreous hemorrhage	1(1.3%)
Postoperative early complications	**2 (2.7%)**
Infection of explants	1(1.35%)
Retina folds	1(1.35%)

Complications were identified in 14.7% of eyes. Of these 12% were noted in the intra-operative period and retinal incarceration was found in 5 eyes (6.7%) and was the commonest intra-operative complication. Postoperative early complications were found in 2 eyes (2.7%) but there were no late complications seen in patients with 6 months data.

Table 10: **Factors affecting re-detachment**

	Attached	Re-detachment	OR (95% CI)	P value
Duration of symptoms				
≤ 7 days	8(11.4%)	0(0.0%)		
> 7 days	62(88.6%)	5(100.0%)	NA	
Age				
< 35 years	32(45.7%)	2(40%)		
≥ 35 years	38(54.3%)	3(60%)	1.26(1.99-8.03)	0.589
PVR				
Yes	3(4.3%)	0(0.0%)		
No	67(95.7%)	5(100%)	NA	
Lens status				
Phakic	67(95.7%)	4(80%)		
Pseudophakic	3(4.3%)	1(20%)	5.58(0.46-66.5)	0.246
No. of retinal breaks				
1-3 breaks	45(62.2%)	4(80%)		
>3 breaks	24(37.8%)	1(20%)	0.46(0.50-4.43)	0.657

There was no significant factor which was associated with retinal re-detachment as shown in the table above.

5.0 DISCUSSION

Scleral Buckle is one of the surgical techniques used for repairing RRD at KEU. A total of 91 files were identified from the theatre records, but only 75 cases were analyzed. Those not analysed consisted of 10 files that were missing from the records filing store and 6 files with missing pages as show in flow chart 1. All patients were operated on by a single surgeon and 96% of the eyes had a single operation done. The standard procedure was a SB technique where all patients received an encircling tire.

The decision of an encircling or segmental buckle to use was made based on the size and location of the retinal tear. Drainage of subretinal fluid was performed in 72(96%) eyes when judged necessary by the surgeon. Cryo-coagulation was performed in all cases and no intravitreal tamponade was used.

Follow up

All eyes were examined on the first day post-operation but the number of patients subsequently decreases at two weeks follow up to 98.7% and 40% at 6 months as shown in figure 7. That was similar to a study done by Shakal et al that showed the shortest postoperative follow-up period was 2 weeks, while the longest postoperative follow-up period was 6 months(24). Postsurgical follow-up is important in that it ensures that the retina is in place and at the same time, it also helps to identify unsuccessful cases for repeat surgery

Demographics

Most patients who had surgery were males at 61.3%. The mean age of presentation was 34.7 (SD± 17.1) years with the range being 5 to 75 years. These findings were almost similar to those in a study done at Khyber Institute of Ophthalmic Medical Sciences in Pakistan by Khan et al, who found more male patients with rhegmatogenous retinal detachment at 66.04% mean age at presentation of 38.87 ± 8.7 years with a range 5 to 90 years(30).

The mean duration from diagnosis to surgery experienced was 35.65 (SD ± 30.2) days, the median duration was 30 days and the range was 1 to 188 days. This was found to be different with majority of studies done that showed early presentation. A study done by Oluleye et al in Nigeria found that the median duration before surgery was 3 months, range: 5 days – 156 months(19).

The most identified risk factor for RRD was myopia in 24(32%) eyes and was the leading indication for sclera buckling. This may be due to the fact that myopia causes stretching of the eyeball with consequent peripheral tears and it is easier to tamponade with sclera buckling. This was comparable to a study done by Koc et al in Beyoglu Eye Training and Research Hospital, Istanbul that showed the most common risk factors were idiopathic causes and myopia, each found in 34.7% of eyes, and trauma in 18.8% (31).

Indications for Scleral buckling

In this study the majority of eyes were phakic in 94.7%, associated with inferior RRD in 54(72%) of eyes with mild or without PVR. Majority had macula on 74(98.7%) associated with atrophic holes in 70.7% eyes and less than 3 breaks in 50(70.4%) eyes were identified as shown in Table 2. This was similar to a study done by Haritoglou et al where 90.2% of eyes were phakic with no PVR in 49.2% and less than 3 breaks in 89.5%. This could be because the visual prognosis is better(32).

Outcomes of scleral buckling

Anatomical

Primary anatomic success rate was 90.0% that was defined as retina reattachment after one surgery and final anatomic success rate was 96.7% at 6 month follow up. This was found to be better in comparison with the MUSTARD study, one of the largest studies done on scleral buckling in Europe that showed macula on detachment had a success rate of up to 88.24% and the overall success rate of all 4325 MUSTARD patients was 83.98%(33). This was comparable to many studies, in particular, a study done in Nigeria by Oderinlo et al that found primary anatomic reattachment was achieved in 83 eyes (80.5%), while final anatomic success was achieved in 93 eyes (90.2%). Quinjiro found a success rate of 96% in primary surgery and 100% in secondary although his study was in phakic uncomplicated detachments(34) while Noori had 100% in young patients(35).

Functional

The visual outcome at last follow-up period revealed improvement in 41.3% of eyes, 40% remained the same and 18.7% had vision deterioration as shown in Figure n^0 8. This results are almost similar to a study done by Oluleye et al in Nigeria that showed at 6 weeks, there was an improvement in visual acuity in 23 eyes (51.1%), while visual acuity remained the same in nine eyes (20%) and was worse in 13 eyes (28.9%), (19).

The proportion of eyes with 6 months post-operative BCVA ≥6/60 increased from 33.3% pre-operatively to 70% post-operatively and this was better compared to a study done in Pakistan by Abdullah AS, et al, that showed final BCVA of > 6/60 was achieved in 62% of the subjects in the treated eyes (22). At final follow-up, improvement in visual acuity was achieved in 63.3% of eyes with an average of 4.8 with a mean of two or more Snellen lines and this was also comparable to a study done in Ireland that showed an improvement of two or more Snellen lines from presenting acuity in 10 (35.7%) eyes, and 16 (57.1%) of the operated eyes exhibited no change in vision, whereas a deterioration of two or more Snellen lines was seen in two (7.1%) eyes(36).

Complications

In this study complications were identified in 11(14.7%) eyes as shown in Table 9. This was comparable to a study done by Haritoglou et al. in Munich that showed 9.6% of eyes suffered complications(32). Retina incarceration seen in 6.7% was the most frequent intra-operative complication and 1(1.35%) had buckle infection in the post-operative period. This was found to be different to a study done in Nepal where the intraoperative complications included vitreous hemorrhage (1.96%) and post-operatively where rise in IOP above 21 mmHg was seen in 17 eyes (33.3%) and buckle infection (1.96%) (37).

No late post-operative complication (6-weeks to 6-months), was noted. This may be related to the number of patients who dropped out and may also be related to the facts that the surgery is safe and effective with few late complications.

Factors affecting re-detachment

In this study only 5(6.7%) eyes had re-detachment. Age, lens status, PVR, number of breaks and duration of symptoms were assessed and were found not to have any statistically significance on the rate of retinal re-detachment as shown in the Table 12. In a study done by Park et al in Korea it was shown that older age (≥35) was an independent prognostic factor for primary anatomical failure in SB for uncomplicated RRD (12).

6.0 LIMITATIONS

1. A high attrition rate was noted in this study and is a major limitation on the study especially in establishing the long term functional and anatomical outcomes of SB and the complications.
2. This being a retrospective study only 30 files had complete post-operative visual acuity recorded at sixth month review visit. This reduced the number of files with complete post-operative visual acuity data for analysis of visual acuity outcomes.

7.0 CONCLUSIONS

1. Scleral buckling was mostly done for younger phakic patients with macula-on RD, inferior RD and no PVR.
2. Majority (96.7%) of the eyes achieved high success rate at 6 months follow up.
3. Improvement of BCVA at 6 months follow up was archived in 41.3% of the eyes.
4. There were no factors found to be associated with retinal re-detachment

8.0 RECOMMENDATIONS

1. Scleral buckling should continue to be indicated for phakic patients with uncomplicated inferior RRDs.
2. A study to attempt to establish the reasons why there is a low turnout for post-operative review visits should be done.
3. Scleral buckling technique should continue to be emphasised in vitreoretinal training because it has been shown to be safe and effective in treatment of uncomplicated RRDs.

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10. TIME FRAME

	March-Aug/18	Sept-Dec/18	Jan.2019	Feb-March	April	May
Proposal writing						
Ethics approval						
Data Collection						
Data Analysis						
Report writing						
Thesis Defense						

11. Appendix 1: BUDGET

Items	Quantity	Unit cost (Kshs)	Total (Kshs)
Proposal development			
Printing	6	1,000.00	6,000.00
Binding	6	500	3,000.00
Internet		5,000.00	5,000.00
Ethics committee fee	1	2,000.00	2,000.00
Subtotal			**16,000.00**
Data collection			
Printing data tools	1	5,000.00	5,000.00
Contracted services			
Statistician	1	40,000.00	40,000.00
Transport to Kikuyu		2,000,00	2,000.00
Accommodation= 28 days		28x2000	56,000.00
Food		28x2000	56,000.00
Other expenses	1	15,000.00	15,000.00
Subtotal			**174,000.00**
Data analysis	1	30,000.00	30,000.00
Report writing			
Internet		5,000.00	5,000.00
Printing	10	1,000.00	10,000.00
Binding	10	500.00	5,000.00
Subtotal			**50,000.00**
Grand Total			**240,000.00**

11.1 Appendix 2: Data Abstraction Tool

1) Patient number: _____

2) Eye operated Right ☐ Left ☐

3) Sex Male ☐ Female ☐

4) Age ☐ Year of birth ☐☐☐

5) Duration of symptoms at time of surgery: days_____ weeks_____ months _____ years_____

6) Visual acuity at admission (UCVA) ☐

(BCVA) ☐

7) Lens status

   i. Phakic ☐
   ii. Pseudophakic ☐
   iii. Aphakic ☐

8) Etiology of detachment:

   i) Post traumatic ☐
   ii) Myopia ☐
   iii) Previous cataract surgery ☐
   iv) Peripheral degenerations ☐
   v) Previousintravitreal injections ☐
   vi) Unknown ☐
   vii) Others _____

9) Rhegmatogenous retinal detachment

   With PVR Yes ☐ No ☐
   Macular ON Yes ☐ No ☐
   Retinal breaks identified ☐ Yes ☐ No

i. Number of breaks ☐
ii. Size of breaks ☐
iii. Types of breaks ☐
iv. Location of breaks _____

10) Type of Scleral buckling done
i. Encircling ☐
ii. Segmental radial ☐
iii. Segmental circumferential ☐

11) Cryotherapy Yes ☐ No ☐

12) Sub-retinal fluid drainage Yes ☐ No ☐

13) Internal tamponade
i. Yes ☐
a) Air ☐ b) SF6 ☐ c) C3 F8 ☐
ii. No ☐

14) After surgery:

Retina attached

	Time	Yes	No
i.	On the table		
ii.	Day 1		
iii.	1 months		
iv.	3 months		
v.	6 months		
Vi	12 months		

15) New breaks ☐ Re-detachment ☐ No ☐

	Time	Number of tears	Location of tears
i.	Day 1		
ii.	1 months		
iii.	3 months		
iv.	6 months		
v.	12 months		

16) Re-operations

i) Additional buckle or buckle replacement, ☐

ii) Pneumopexy ☐ SF6 ☐ C3F8 ☐

iii) Vitrectomy ☐

17) Visual acuity

		(UCVA)	(BCVA)
a)	After surgery:		
i.	2 weeks	☐	☐
ii.	6 weeks	☐	☐
iii.	3 months	☐	☐
iv.	6 months	☐	☐

18) Complications

a) Intraoperative:

i. Choroidal detachment ☐

ii. Vitreous hemorrhage ☐

iii. Choroidal hemorrhage, ☐

iv. Subretinal hemorrhage, ☐

v. Retinal incarceration, ☐

vi. Raised IOP, ☐

vii. Hyphema ☐

viii. Vitreous incarceration ☐

ix. Lens damage ☐

x. Corneal damage ☐

xi. Retinal tears ☐

xii. Others ☐

b) Postoperative early complication (24h-6 weeks):

i. Keratitis ☐

ii. Endophthalmitis ☐

iii. Exposure of explants ☐

iv. Infection of explants ☐

v. Elevation IOP ☐

vi. Muscle entrapment ☐

vii. Re-detachment ☐

viii. Others ☐

c) Late complications:

i. Cataract formation ☐

ii. Glaucoma ☐

iii. New break ☐

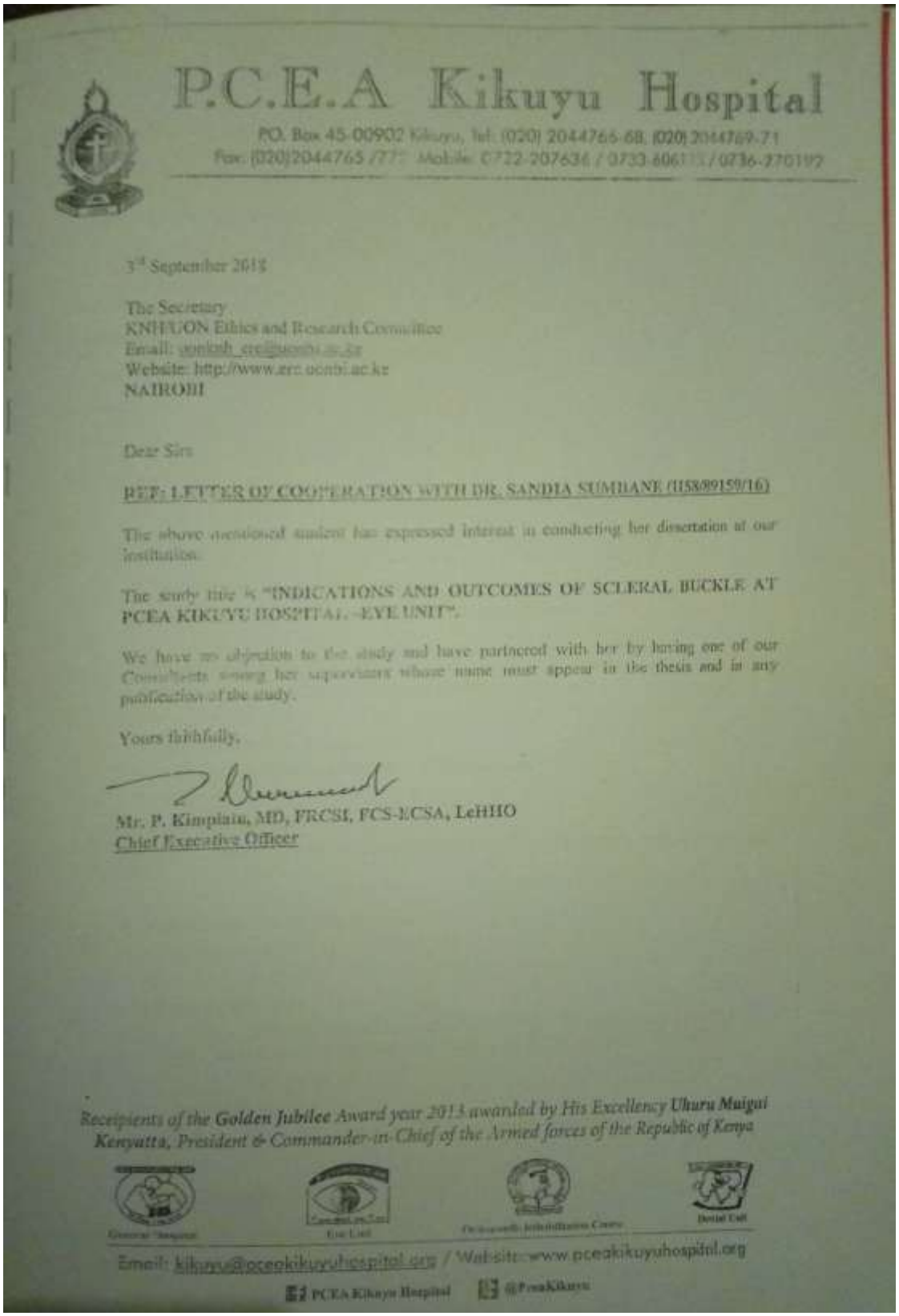
iv. Proliferative vitreoretinopathy ☐

v. Re-detachment ☐

vi. Cystoid maculopathy ☐

ix) Others ☐

11.2 Appendix 3: Collaborating letter



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3rd September 2018

The Secretary
KNH/UON Ethics and Research Committee
Email: uonknh_erc@uonbi.ac.ke
Website: http://www.erc.uonbi.ac.ke
NAIROBI

Dear Sirs

REF: LETTER OF COOPERATION WITH DR. SANDIA SUMBANE (H58/89159/16)

The above mentioned student has expressed interest in conducting her dissertation at our institution.

The study title is "INDICATIONS AND OUTCOMES OF SCLERAL BUCKLE AT PCEA KIKUYU HOSPITAL –EYE UNIT".

We have no objection to the study and have partnered with her by having one of our Consultants among her supervisors whose name must appear in the thesis and in any publication of the study.

Yours faithfully,

Mr. P. Kimpiaiu, MD, FRCSI, FCS-ECSA, LeHHO
Chief Executive Officer

*Recipients of the **Golden Jubilee** Award year 2013 awarded by His Excellency **Uhuru Muigai Kenyatta**, President & Commander-in-Chief of the Armed forces of the Republic of Kenya*

Email: kikuyu@pceakikuyuhospital.org / Website: www.pceakikuyuhospital.org

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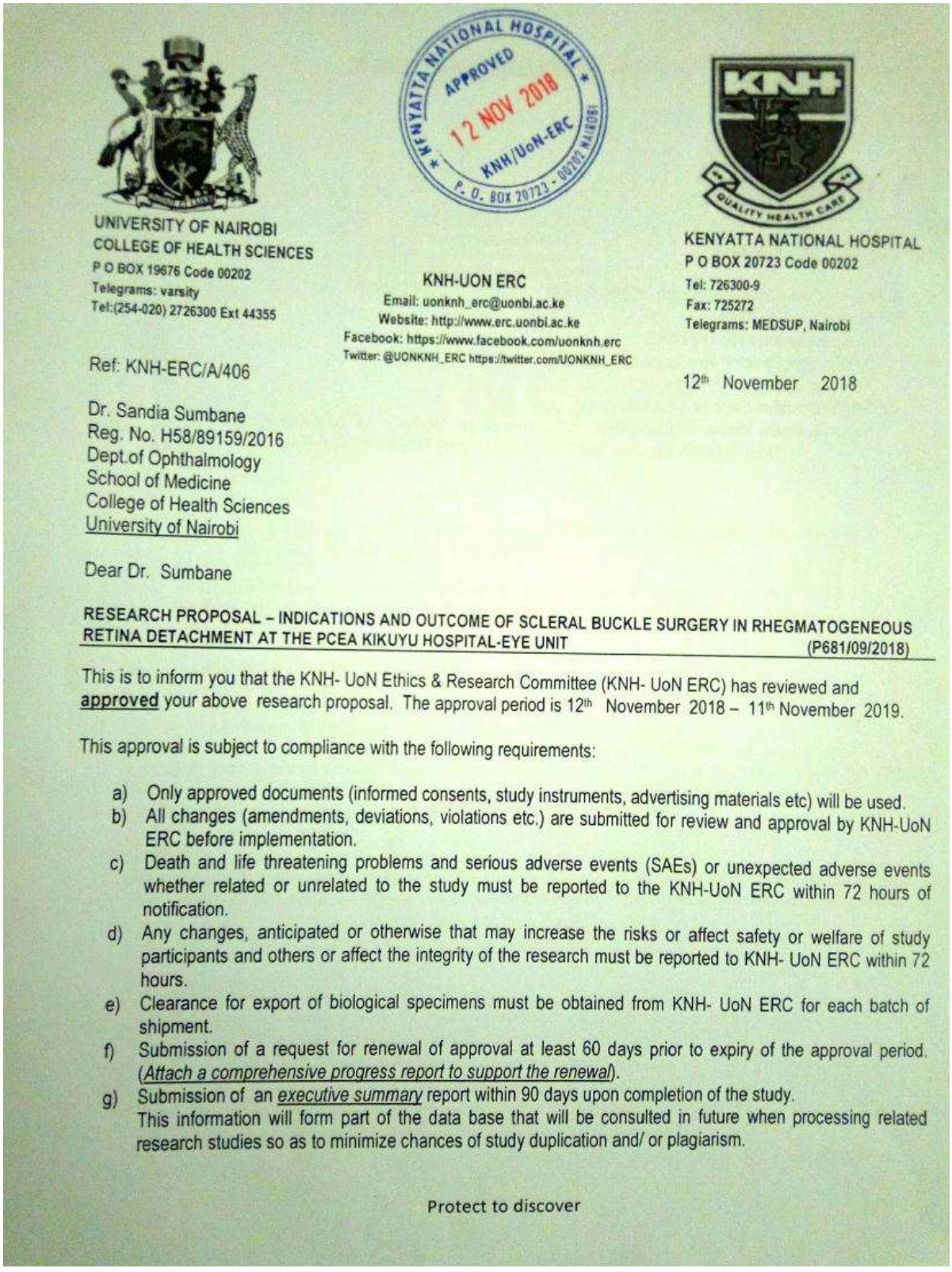
11.3 Appendix 4: Ethics Approval



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Ref: KNH-ERC/A/406

12th November 2018

Dr. Sandia Sumbane
Reg. No. H58/89159/2016
Dept.of Ophthalmology
School of Medicine
College of Health Sciences
University of Nairobi

Dear Dr. Sumbane

RESEARCH PROPOSAL – INDICATIONS AND OUTCOME OF SCLERAL BUCKLE SURGERY IN RHEGMATOGENEOUS RETINA DETACHMENT AT THE PCEA KIKUYU HOSPITAL-EYE UNIT (P681/09/2018)

This is to inform you that the KNH- UoN Ethics & Research Committee (KNH- UoN ERC) has reviewed and **approved** your above research proposal. The approval period is 12th November 2018 – 11th November 2019.

This approval is subject to compliance with the following requirements:

a) Only approved documents (informed consents, study instruments, advertising materials etc) will be used.
b) All changes (amendments, deviations, violations etc.) are submitted for review and approval by KNH-UoN ERC before implementation.
c) Death and life threatening problems and serious adverse events (SAEs) or unexpected adverse events whether related or unrelated to the study must be reported to the KNH-UoN ERC within 72 hours of notification.
d) Any changes, anticipated or otherwise that may increase the risks or affect safety or welfare of study participants and others or affect the integrity of the research must be reported to KNH- UoN ERC within 72 hours.
e) Clearance for export of biological specimens must be obtained from KNH- UoN ERC for each batch of shipment.
f) Submission of a request for renewal of approval at least 60 days prior to expiry of the approval period. (*Attach a comprehensive progress report to support the renewal*).
g) Submission of an *executive summary* report within 90 days upon completion of the study. This information will form part of the data base that will be consulted in future when processing related research studies so as to minimize chances of study duplication and/ or plagiarism.

Protect to discover

For more details consult the KNH- UoN ERC website **http://www.erc.uonbi.ac.ke**

Yours sincerely,

PROF. M.L. CHINDIA
SECRETARY, KNH-UoN ERC

c.c. The Principal, College of Health Sciences, UoN
The Director, CS, KNH
The Chairperson, KNH-UoN ERC
The Assistant Director, Health Information, KNH
The Dean, School of Medicine, UoN
The Chairperson, Dept. of Ophthalmology , UoN
Supervisors: Dr. Muchai Gachago(Dept. of Ophthalmology, UoN), Dr. Millicent Kariuki (Dept.of Ophthalmology, UoN), Dr. Shafiq Jafferji Shabbir,Kikuyu Eye Unit)