

**REVIEW OF OUTCOME OF HORIZONTAL
CHILDHOOD STRABISMUS SURGERY AT KENYATTA
NATIONAL HOSPITAL AND KIKUYU EYE UNIT – A
RETROSPECTIVE STUDY**

**A PROPOSAL FOR A DISSERTATION TO BE
SUBMITTED IN PARTIAL FULFILMENT OF THE
REQUIREMENTS FOR MASTERS OF MEDICINE IN
OPHTHALMOLOGY AT THE UNIVERSITY OF
NAIROBI**

Dr. Amberin Fatima Fazal (MBchB – UON)

H58/78551/2012

PRINCIPAL INVESTIGATOR AND DECLARATION

I hereby declare that this study is my original work and has not been presented for MMed Ophthalmology dissertation at any other university.

Dr. Amberin Fatima Fazal, MB ChB

Signature _____ Date _____

This dissertation has been submitted for examination with the approval of University of Nairobi supervisors.

SUPERVISOR'S

Dr. Kahaki Kimani, MB ChB, M.Med (Nairobi), MSC (London)), FEACO.

Senior Lecturer, Department of Ophthalmology

Signature: _____ Date: _____

Dr. Joseph Nyamori, MB ChB, M.Med (Nairobi), FEACO.

Lecturer, Department of Ophthalmology

Signature: _____ Date: _____

Dr. Daniel Mundia, MB ChB, M. Med (Nairobi), FEACO (E.A), PO/S (UCT)

Paediatric and Strabismus Consultant Ophthalmologist, Kikuyu Eye Unit

Signature: _____ Date: _____

DEDICATION

This work is dedicated to my family for their continued support and encouragement in my every
endeavour.

ACKNOWLEDGEMENT

I wish to acknowledge the contributions of the following individuals and group to the development of this research paper:

1. Dr. Kimani, Dr. Nyamori, Dr. Mundia and Dr. Njuguna for their contributed ideas, feedback and advice during the entire study period.
2. Alex Mukungu for assistance in preparation of the thesis.
3. My sponsors, Lions of Bavaria, for the financial support towards the budget of the study.
4. University of Nairobi, Kenyatta National Hospital and Kikuyu Eye Unit for permitting me to conduct the study.
5. My friends, who made their support available in a number of ways.

TABLE OF CONTENTS

PRINCIPAL INVESTIGATOR AND DECLARATION.....	ii
DEDICATION.....	iii
ACKNOWLEDGEMENT.....	iv
LIST OF TABLES.....	viii
LIST OF FIGURES.....	ix
DEFINITION OF TERMS.....	x
LIST OF ABBREVIATIONS.....	xii
ABSTRACT.....	xiii
INTRODUCTION AND LITERATURE REVIEW.....	1
1.1 Introduction.....	1
1.2 Literature Review.....	2
1.2.1 Incidence and prevalence.....	2
1.2.2 Classification of Strabismus.....	2
1.2.3 Aetiology.....	3
1.2.4 Assessment.....	4
1.2.5 Surgical Management.....	6
1.2.6 Complications.....	9
2.1 Justification.....	10
2.2 Broad Objective.....	11
2.3 Specific Objectives.....	11
METHODOLOGY.....	12
3.1 Study Area.....	12

3.2 Study population.....	12
3.3 Study period.....	12
3.4 Study Design.....	12
3.5 Sample Size Determination.....	13
3.6 Inclusion and Exclusion Criteria	13
3.6.1 Inclusion Criteria.....	13
3.6.2 Exclusion Criteria.....	14
3.7 Case Definition	14
3.8 Study Definitions	14
3.7 Data Management and Statistical Analysis	14
3.7.1 Data Collection and Storage.....	14
3.7.2 Data Analysis and Presentation.....	15
3.7.3 Missing Data.....	15
Ethical Considerations	16
Dissemination Plan	16
RESULTS.....	17
DISCUSSION.....	30
CONCLUSIONS	33
RECOMMENDATIONS	34
LIMITATIONS.....	34
APPENDICES	35
APPENDIX I: APPROVAL LETTER FROM ETHICS AND RESEARCH COMMITTEE	35
APPENDIX II: APPROVAL LETTER FROM KIKUYU EYE UNIT	37
APPENDIX III: QUESTIONNAIRE	38

APPENDIX IV: VISUAL ACUITY CONVERSION CHART	43
APPENDIX V: BUDGET (KENYA SHILLINGS)	44
APPENDIX VI: STUDY TIME FRAME.....	45
REFERENCES	46

LIST OF TABLES

Table 1: Demographic Characteristics	18
Table 2: Preoperative Refraction	21
Table 3: Types of Strabismus and Age at Diagnosis	21
Table 4: Types of Pre-operative Angles and Types of Strabismus.....	22
Table 5: Types of Surgery for Esotropia and Types of Pre-operative Angle	22
Table 6: Types of Surgery for Exotropia and Types of Pre-operative Angle	23
Table 7: Adjunct Surgeries	24
Table 8: Outcomes for Esotropia	25
Table 9: Overall Outcomes for Esotropia.....	26
Table 10: Outcomes for Exotropia.....	27
Table 11: Overall Outcomes for Exotropia	27
Table 12: Complications (post-op complications as a result of surgery)	28
Table 13: Second surgery and indication	29

LIST OF FIGURES

Figure 1: Flow diagram for reviewed records during the study period	17
Figure 2: Study Center (n=199)	19
Figure 3: Sex of Patients (n=199)	20

DEFINITION OF TERMS

Anisometropia: A condition in which the power of refraction in one eye differs from that in the other.

Astigmatism: A defect of vision in which the image of an object is distorted, usually in the vertical or the horizontal axis, because not all the light rays come to focus on the retina.

Denervation and extirpation: ablation of the entire portion of the muscle, along with its nerve supply, within the Tenon capsule.

Emmetropia: A state of refraction of the normal eye, in which parallel light rays are brought to focus on the retina with accommodation relaxed.

Esotropia: Convergent strabismus.

Exotropia: Divergent strabismus.

Hypermetropia: A condition in which parallel light rays are brought to a focus behind the retina when accommodation is relaxed.

Hypertropia: Vertical strabismus in which the eye is rotated so that the cornea is deviated superiorly.

Hypotropia: Vertical strabismus in which the eye is rotated so that the cornea is deviated inferiorly.

Marginal myotomy: cutting partway across a muscle, usually following maximal recession.

Myectomy: removal of a portion of a muscle.

Myopia: A condition in which parallel light rays are brought to a focus in front of the retina.

Myotomy: cutting across a muscle.

Posterior fixation suture (fadenoperation): attachment of a rectus muscle to the sclera 11-18 mm posterior to the insertion.

Recession: removal and reattachment of a muscle so that its insertion is closer to its origin.

Recession and anteriorization: movement of a muscle usually inferior oblique anterior to the inferior rectus insertion.

Resection: involves detachment of a muscle, removal of a portion of the distal end and reattaching it.

Tenotomy: cutting across a tendon.

LIST OF ABBREVIATIONS

BSV	-	Binocular single vision
ERC	-	Ethical Research Committee
KEU	-	Kikuyu Eye Unit
KNH	-	Kenyatta National Hospital
LR	-	Lateral Rectus
MR	-	Medial Rectus
PD	-	Prism Dioptres
Recess	-	Recession
Resect	-	Resection
SPSS	-	Statistical Package for Social Sciences

ABSTRACT

Background

Strabismus is the misalignment of the visual axis where the image in the fixating eye lies on the fovea and in the non-fixating eye lies on an extra-foveal region. Factors that contribute to ocular alignment include arousal and good vision in both eyes. Strabismus is an important paediatric ophthalmic condition and early diagnosis and proper management of strabismus is crucial for BSV development and prevention of amblyopia. There are no studies in Kenya on outcomes of strabismus surgery.

Objectives

To review outcome of childhood strabismus surgery in patients aged 0-15 years operated at the Kenyatta National Hospital and Kikuyu Eye Unit from June 2008 to June 2013.

Methodology

This study was a retrospective descriptive study carried out at KNH and Kikuyu Eye Unit. Files and theatre surgical registers were retrieved and identification of patients undergone strabismus surgery from June 2008 to June 2013 done. A questionnaire was used to collect data. Data obtained was analyzed using SSPS version 20.0. Analytical statistics and chi square was used to describe the strengths and deviations between the variables.

Results

199 children were operated, of whom 122/199 (61.3%) completed the 2-3 month follow-up. Average age at diagnosis was 6.2 yrs and average age at surgery was 9.6 years. 41/90 (45.6%) cases of esotropia and 19/32 (59.4%) cases of exotropia had a good outcome, while the poor outcome was 15/90 (16.7%) and 2/32 (6.3%), respectively. Bilateral medial rectus recession for esotropia had 12/34 (35.3%) good outcome and 6/34 (17.6%) poor outcome, while recess-resect procedure for esotropia had 27/53 (50.9%) good and 9/53 (17%) poor outcome. Bilateral lateral rectus recession for exotropia had 4/9 (44.4%) good and 1/9 (11.1%) poor outcome, while for recess-resect procedure for exotropia had 15/23 (65.2%) good and 1/23 (4.3%) poor outcome.

Conclusion: The most common (58.3%) surgery performed was a recess-resect procedure for all types of tropia. Exotropia had better outcomes than Esotropia as in other studies.

CHAPTER ONE

INTRODUCTION AND LITERATURE REVIEW

1.1 Introduction

Ocular alignment is the mechanism that ensures the fovea of the eye fixates on an object of interest in order to achieve normal binocular single vision (BSV). BSV is characterized by sensory and motor fusion. Sensory fusion is the cortical integration of slightly dissimilar images perceived by the two eyes into a single image¹. Motor fusion is the process by which bifoveal fixation is sustained by motor alignment.

Strabismus is the misalignment of the visual axis where the image in the fixating eye lies on the fovea and in the non-fixating eye lies on an extra-foveal region. Factors contributing to ocular alignment include arousal, good vision in both eyes, normal neuromuscular co-ordination of extraocular muscles to move the eye, functional cranial nerves III, IV, VI and brainstem supranuclear pathways. Any abnormality in these factors subsequently result in strabismus and consequently loss of BSV, depth perception and amblyopia in children². Childhood blindness is defined as a corrected visual acuity of less than 6/60 in the better eye in an individual aged 0-15 years³. Management of strabismus involves both non-surgical and surgical methods.

The management of strabismus dates back to several centuries ago when the condition was thought to be as a result of visitation of an evil spirit and was considered incurable. The earliest physicians proposed treatments like potions, purification and diet. By the 17th century masks were designed with the aim of reducing the visual axis. Variations in this mode of treatment are still advocated for in the form of sector occlusion.

The practice of strabismus surgery was began in 1739 by John Taylors⁴. Tenectomy of the Achilles tendon for treatment of club foot by an orthopaedic surgeon led Gibson to experiment with extraocular muscle transection for treatment of esotropia in 1818. It was in 1839 that Dieffenbach started modern strabismus surgery when he successfully performed a myotomy of the medial rectus on a 7yr old boy with esotropia⁵.

1.2 Literature Review

1.2.1 Incidence and prevalence

Globally the prevalence of strabismus is estimated to be between 1.3-5.7% of all children^{6,7,8}. The prevalence in Africa is similar but knowledge is limited to a few studies^{9,10}. In Kenya, Onsomu et al found a prevalence of 3% in nursery school children aged between 3-5 years; of which 94% had exotropia, 6% had esotropias and 56% had amblyopia¹¹. A study by Karimurio et al at Kenyatta National Hospital from 1989 to 1990 showed that 4.1% of all the eye patients attending the eye consultant clinics had strabismus¹².

1.2.2 Classification of Strabismus

Classification of strabismus is variable. Strabismus may be classified according to direction of gaze as either a vertical or a horizontal deviation, according to laterality as either unilateral or alternating and according to whether it is concomitant or non-concomitant. Alternative classifications of strabismus are based on time of onset; congenital or acquired. The recommended time to assess strabismus in children under five years old is between ages 3 and 6 months¹³.

Horizontal deviations include exotropia or esotropia. Esotropia or manifest convergent strabismus is characterized by the inward turning of one eye relative to another. Exotropia or manifest divergent strabismus is characterised by the outward turning of one eye relative to another^{14,15}. The vertical deviations are less common and include hypertropia or hypotropia. Hypertropia or manifest sursumvergent strabismus is characterised by the upward turning of one eye relative to the other while hypotropia, or deorsumvergent strabismus is characterised by the downward turning of one eye relative to the other. Incyclotropia is when the 12 o'clock meridian of the cornea of affected eye rotates towards the medial or nasal side while excyclotropia is a condition where the 12 o'clock meridian of the cornea of the affected eye leans towards the lateral or temporal side¹⁶.

Strabismus is unilateral if one eye consistently deviates, or alternating if either of the eyes can be seen to deviate¹⁷. Concomitant strabismus occurs when the size of the deviation does not vary by

more than a few prisms with changes in direction of gaze. In-concomitant strabismus occurs when the size of deviation varies with changes in direction of gaze¹⁸.

Concomitant esodeviation is further classified as, infantile esotropia syndrome, accommodative esotropia, monofixation esotropia syndrome, basic non-accommodative esotropia, esotropia and visual or neurologic abnormality (e.g., sensory esotropia), intermittent esotropia, divergence insufficiency esotropia (paresis, paralysis) and mixed (partially accommodative) esotropia. Concomitant exodeviations are further classified as infantile exotropia syndrome, intermittent exotropia, monofixation exotropia syndrome, basic exotropia, exotropia associated with visual or neurologic abnormality and convergence insufficiency exotropia. Non-concomitant esodeviations and exodeviations may be classified as secondary to cranial nerve disease, neuromuscular junction disease, muscular disease and orbital disease¹⁹.

Special types of strabismus include co-contractive retraction syndrome (Duane), co-contractive retraction with lower cranial neuropathy (Moebius), co-contractive retraction with jaw-eyelid synkinesis syndrome (Marcus Gunn), co-contractive retraction with exotropia (Synergistic Divergence and “Y” exotropia), restrictive hypotropia in adduction (Brown Syndrome), congenital fibrosis of the extraocular muscles.

1.2.3 Aetiology

Strabismus is a condition caused by a wide variety of etiologic factors and variable theories²⁰ have been described.

Defects in fusional facility

Binocular vision is necessary for depth perception. In early childhood the binocular reflexes (motor and sensory) are incompletely developed and any interruption in these reflexes result in strabismus²¹.

Refractive errors

Hypermetropia is a common refractive error in strabismus accounting for 80% or more in convergent strabismus and it is the most important factor in accommodative esotropia²². Anisometropia and astigmatism are also associated with strabismus²³.

Inheritance

Strabismus has a multifactorial inheritance pattern. A study by Pratt- Johnson et al, found 65% of the patients who had manifest strabismus to have a relative with the same condition²⁴.

1.2.4 Assessment

Diagnosis of strabismus is mainly clinical. Tests for strabismus range from screening tests to more accurate measurements. Accurate assessment is crucial prior to performing strabismus surgery in order to correctly plan for surgery.

Amblyopia is one of the most devastating effects of strabismus. Visual acuity testing is done to establish whether amblyopia is present or not, determine how well each eye is seeing and determine whether a refractive error is present. This testing is done by determining the smallest letters that can be read using standardized charts or the ability to fixate and follow objects in the very young children. Onsomu et al in Kenya found that 56% of the children with strabismus had amblyopia. Kalua et al found 40% of patients diagnosed with strabismus at KNH eye clinic had amblyopia²⁵.

Angular measurements for strabismus are done in order to determine the amount of deviation and are carried out using prisms or the Hirschberg's method. In 1886 Hirschberg devised the Hirschberg's test, which was defined as the ratio of the change in angular position of the line of sight to the change in location of the first Purkinje image relative to the pupil center. Although Hirschberg's method is considered a subjective method of assessment, it requires minimum equipment and little experience and renders accurate results²⁶. Wheeler et al mentioned in 'Objective Strabismometry in young children,' that Hirschberg's test is the most satisfactory method available for measuring squint deviation and concluded that the Hirschberg's test is a reliable approximate measure of the static angle of deviation²⁷.

The original formula suggested that 1mm or 7° was equal to around 13-17 Prism Dioptres (PD). More recent experiments by Brodie et al^{28,29} and Eskbridge et al^{30,31} suggest that the formula originally proposed should be modified from 1mm being equal to 13-15 PD to 1mm being equal to 21-22 PD. Jethani attempted an experimental study on an eyeball to determine the prism angular measurements using the Hirschberg's test and concluded that for each mm displacement there is around 19 PD change in corneal reflection test³². A study by Riddell et al was designed to determine empirically whether the adult value of the Hirschberg ratio (approximately 22 PD/mm) is a suitable value to use for all ages. The results suggested that the same average Hirschberg ratio can be used to estimate angle of strabismus across ages³³. The widely accepted measure of 1 mm of decentration of the corneal light reflection corresponding to 7° or 15 PD of ocular deviation of the visual axis was used by Satish et al where he studied surgery performed on all patients for large angle strabismus at a tertiary eye care centre³⁴.

Angular measurements using prisms are considered an objective tool in determining the angle of deviation. Measurements of the angle aid in determining which surgery to perform and to what extent the extraocular muscles can be manipulated in order to achieve ocular alignment. Post-operatively this measure is used to determine the reduction in the amount of angle. Mvogo et al in Cameroon studied surgical management of primary exotropia. Postoperative results were classified as consecutive esotropia being present in postoperative angles of ≥ 10 PD, residual exotropia with postoperative angle ≥ 10 PD and good operative results as either postoperative angles of consecutive esotropia being < 10 PD, orthophoria or exotropia of < 10 PD³⁵. In a study by Keenan et al at Birmingham Children's Hospital on outcome of strabismus surgery in childhood exotropia, a 'favorable outcome' was defined as a final alignment for near and distance within ± 10 PD of straight, or within ± 20 PD of straight with evidence of binocular single vision³⁶.

In a study in India by Gogate et al on patients with horizontal strabismus who underwent correction surgery with angles ≥ 20 PD, good outcome was classified as a patient having a residual deviation of ≤ 10 PD, 11 PD to 20 PD was borderline outcome, and > 20 PD was considered poor outcome³⁷. A study by Lau et al at Hong Kong Eye Hospital on surgical

outcomes for extra-large angle exotropia, a successful motor alignment was defined as either the patient being orthotropic or with an esodeviation or exodeviation between 1 and 10 PD^{38,39}.

Stereopsis is the ability to obtain an impression of depth by the superimposition of two pictures of the same object which have been taken from slightly different angles. Pre-operative sensorimotor testing is used to determine fusion potential. Following strabismus surgery, recovery of binocularity is inversely correlated to the duration of misalignment. Gogate et al on measuring stereopsis, found that 12% of patients who had no stereopsis before surgery recorded stereopsis after surgery, out of which 59.6% of patients achieved gross stereopsis, 21% of patients achieved stereopsis of 480-240 seconds of arc, 14% of patients achieved stereopsis of 240-120 seconds of arc, and 5.3% of patients achieved stereopsis of 60 seconds of arc. Kenneth et al measured stereopsis in 7 children aged between 13-19 weeks who had undergone strabismus surgery for congenital esotropia. The study showed that 71% of the patients achieved stereopsis however, also concluded that very early surgery resulted in high stereoacuity⁴⁰.

Loss of fusion resulting in diplopia (double vision) is a valid indication for surgery, hence it is important to establish that strabismus surgery leads to an improvement in sensory fusion⁴¹. Various tests are used to determine fusion including more commonly the Bagolini lenses and Worth 4-dot test. Kushner and Morton reported an increase in binocularity as determined by the Bagolini lenses and was correlated with long term postoperative ocular alignment⁴². In a study of 24 patients with long-standing strabismus, Morris and associates demonstrated improved ocular alignment as well as peripheral fusion at near using the Worth 4-dot⁴³. Scott and associates reported both a successful alignment and an improvement in sensory fusion in patients who developed strabismus both before and after visual maturity⁴⁴.

1.2.5 Surgical Management

The management of strabismus entails correct diagnosis and appropriate therapy. Strabismus is managed both non-surgically and surgically. Non-surgical methods involve use of orthoptic exercises, refractive error correction, use of prisms, occlusive therapy and filters⁴⁵. The aims of extraocular muscle surgery are to improve appearance by correcting the misalignment of the

eyes, possibly restore BSV, reduce abnormal head posture and centralize or expand the field of BSV⁴⁶.

Strabismus surgery is a day procedure with the patient spending only a few hours in the hospital with minimal preoperative preparation⁴⁷. The average duration for the surgery to be performed may be variable. In cases of residual deviation re-operations may be required. Resection of the muscles leads to more pain in the postoperative period than recession, with conjunctival injection that lasts longer and may cause some vomiting in the early postoperative period⁴⁸.

Common extraocular surgeries include loosening/weakening procedures, strengthening procedures, transposition/ repositioning procedures and adjustable suture surgery⁴⁹:

Loosening/weakening procedures

Procedures for weakening the actions of muscles are myotomy, myectomy, marginal myotomy, tenectomy, tenotomy, recession, denervation and extirpation, recession and anteriorization and posterior fixation suture (Faden operation). Recession is the most common weakening procedure and is the usual weakening procedure for rectus muscles⁵⁰.

Tightening/ strengthening procedures

Strengthening procedures tighten the muscle to offset the action of the antagonist muscle. Resection is the procedure frequently performed. Advancement and tucking are other types of surgeries.

Transposition/ repositioning

Transposition procedures involve redirection of the paths of extraocular muscles commonly for paralytic, A and V pattern strabismus. Complete palsy is treated by transposition of the superior and inferior recti to positions above and below the affected lateral rectus muscle. Partial paresis is treated by adjustable medial rectus recession and lateral rectus resection of the affected eye. Surgical intervention of the superior oblique should be considered for diplopia or abnormal head posture.

Adjustable sutures

This method employs using sutures that can be adjusted to reposition the muscle either by shortening or lengthening the muscle within the first postoperative day and hence increase the likelihood of success with one operation. However this procedure does not ensure long-term satisfactory alignment.

The study by Mvogo et al found 80% of the 41 patients with exotropia operated had bilateral recession of the lateral recti and resection of the medial rectus of the more squinting eye with 61.3% having good outcome.

Gogate et al found 44.6% of patients who underwent bilateral medial rectus recession for esotropia had good outcome and 26.7% poor outcome, while recess-resect procedures for esotropia had 61.7% good and 20% poor outcome. Bilateral lateral rectus recession for exotropia had 53.6% good and 21.4% poor outcome, while for recess-resect procedures for exotropia 55.7% good and 22.4% poor outcome. Large pre-operative deviations and amblyopic eyes accounted for 62.3% cases with poor outcome. They concluded recess-resect procedures had better outcome as compared to bilateral recess procedures.

A study by Satish et al in India on Large Angle Strabismus in 50 patients found 33 patients had two-muscle surgery with a success rate of 57.58%, while 17 patients had three-muscle surgery with a success rate of 64.71%.

Lau et al studied the surgical outcome of single-staged three horizontal muscles squint surgery for extra-large angle exotropia on 24 patients. Surgeries done consisted of bilateral lateral rectus recession for exotropia, unilateral medial rectus resection for residual angle. The success rate was found to be higher in the intermittent group 88.2% than the constant group 42.9% and finally patients with deviation of <80 PD had a 84.2% success compared with those with deviation ≥ 80 PD (40.0%).

Keenan et al found in outcomes of strabismus surgery in childhood exotropia, that 97.6% of the 42 patients operated had a unilateral lateral rectus recession or medial rectus resection, with or

without combined inferior oblique surgery. Favourable outcome were seen in 85.7%; this was observed at 3-6 months postoperatively. Good outcomes were more common in patients with constant exotropia with an alignment of within ± 15 PD. A study on outcomes of strabismus surgery in congenital esotropia, Keenan et al found that 37.5% of the 40 patients operated had bimedial rectus recessions while 17.5% had bimedial rectus recessions with conjunctival recessions and bilateral inferior oblique myectomies. Favourable outcome were seen in 57.5%⁵¹.

Gogate et al took the minimum post-operative follow-up at 6 weeks. A study in Cleveland by Mehta et al on outcomes of strabismus surgery with or without trainee participation as surgeon, a minimum post-operative follow-up of 8 weeks was taken⁵². Waqar et al in United Kingdom (UK) did a study on outcomes of horizontal strabismus surgery in newly appointed UK trained strabismologists and took a minimum post-operative assessment to be at 6 weeks⁵³.

1.2.6 Complications

Complications associated with strabismus surgery include; loss of vision, acute allergic suture reaction, chronic suture granuloma, reaction to synthetic absorbable suture, subconjunctival cysts, prolapse of tenon's capsule, suture abscess, dellen, lid fissure anomalies, ptosis, scleral perforation, slipped or lost muscle, anterior segment ischemia, hyphema, muscle-tendon rupture, posterior chamber haemorrhage, symblepharon, orbital haemorrhage, orbital cellulitis, endophthalmitis or operation on the wrong muscle. Jeong and Roh in Korea studied complications of strabismus and found 8.3% of the 599 patients operated experienced complications. Overcorrection had an incidence of 3.3% and was present in cases operated for both exotropia and esotropia. Prolapse of tenon's capsule (1.7%) and suture granuloma (2.8%) were found in resection procedures using the non-limbal approach. Dellen (0.5%) was seen in resection procedures using the limbal approach⁵⁴. Espinoza and Lueder on a study on conjunctival pyogenic granulomas after strabismus surgery found chronic suture granuloma in 2.1% of patients examined⁵⁵.

CHAPTER TWO

2.1 Justification

Strabismus surgery aims to improve the cosmetic appearance of the eyes and eventually reduce the negative psycho-social impact, possibly restore BSV and centralize or expand the field of BSV hence this study is of importance to determine whether we are achieving the aims of surgery. There is also no data on the strabismus surgery outcomes at KNH or KEU and the findings will act as a baseline and elucidate the type of surgeries performed at the unit.

2.2 Broad Objective

To review outcomes of childhood horizontal strabismus surgery in patients aged 0-15 years operated at Kenyatta National Hospital and Kikuyu Eye Unit from June 2008 to June 2013.

2.3 Specific Objectives

- To determine types of strabismus surgeries performed.
- To determine anatomical outcomes and complications of first strabismus surgery.

CHAPTER THREE

METHODOLOGY

3.1 Study Area

Kenyatta National Hospital is the national referral and teaching hospital with a bed capacity of 1800 patients. It has an active pediatric ophthalmology and strabismus clinic every Wednesday and Thursday morning that reviews an average of 17 patients every week. Strabismus surgery has been done by three paediatric ophthalmology and strabismus surgeons with theatre availability on Monday and Thursday every week. Surgeries done are bilateral recession and recession-resection with the average dosage ratio for exotropia being 1:1-1:1.5 and for esotropia 1:1.5.

Kikuyu Eye Unit has an active pediatric ophthalmology and strabismus clinic with consultants trained in this sub-specialty. The hospital manages around 70,000-80,000 patients annually. Surgeries done are bilateral recession and recession-resection with the average dosage ratio for exotropia being 1:1-1:2.5 and for esotropia is 1.5:1-2:1.

The data was reported collectively for KNH and KEU. Both institutions were being studied together as the facilities have ophthalmic paediatric and strabismus surgeons. The combined number of patients gave the study sufficient numbers for statistical analysis.

3.2 Study population

All patients 0-15 yrs who underwent strabismus surgery at KNH and KEU from June 2008 to June 2013.

3.3 Study period

1st January 2014 – 31st March 2015

3.4 Study Design

Retrospective descriptive study

3.5 Sample Size Determination

Sample size calculation for proportions

$$n = \frac{Z^2_{\frac{\alpha}{2}}(P(1-P))}{d^2}$$

Where

$Z_{\frac{\alpha}{2}}$ is critical value for 95% confidence interval = 1.96

P is the estimated prevalence of patients presenting to KNH and KEU for corrective strabismus surgery (30%)

d is the estimated level of precision = 10%

n is the number of patients required

$$n = \frac{1.96^2 (0.3(1 - 0.3))}{0.1^2} = 81 \text{ patient records}$$

The final sample size was calculated by Applying Finite Population Correction (FPC) to $n = 135$ which the estimated total number of eligible patients presenting to KNH and KEU for corrective strabismus surgery. The minimum estimated number of patient records n' required for this study within the proposed study period (2003 to 2013) is **51**.

$$n' = \frac{n}{1 + \frac{n}{N}} = \frac{135}{1 + \frac{135}{81}} = 51 \text{ patient records}$$

3.6 Inclusion and Exclusion Criteria

3.6.1 Inclusion Criteria

- All patients 0-15yrs who had corrective strabismus surgery at KNH and KEU from June 2008 till June 2013.

3.6.2 Exclusion Criteria

- Patients with paralytic and restrictive strabismus.
- Patients 16 years and older.
- Patients who were operated before June 2008 or after June 2013.

3.7 Case Definition

Any patient 0-15yrs of age, who underwent strabismus surgery at KNH and KEU and followed up at KNH and KEU after the surgery.

3.8 Study Definitions

- 1) Pre-operative size of angle was taken as:
 - Small 10 to ≤ 30 PD
 - Moderate >30 to ≤ 50 PD⁵⁶
 - Large >50 PD^{34,39}
- 2) Postoperative outcomes were defined as follows:
 - a) Post-surgical angle achieved with reference to target angle.
 - b) For patients without target angle measurements, outcomes were measured as follows:
 - Good outcome: Residual deviation of ≤ 10 PD.
 - Borderline outcome: Residual deviation of 11 PD to 20 PD.
 - Poor outcome: Residual deviation >20 PD.
- 3) Post-operative outcomes: Measured at the 2-3 months post-operative visit.
- 4) Re-operations: All those cases where an additional surgery was done to correct for complications in first surgery.
- 5) Second surgery: A case where an additional surgery had to be performed in order to completely correct the deviation.

3.7 Data Management and Statistical Analysis

3.7.1 Data Collection and Storage

- Data was collected retrospectively beginning from June 2008 to June 2013.

- Data was collected from the patients' files; through liaison with records officers working at records office who provided a copy of patients who have undergone strabismus surgery.
- Files were retrieved using theatre and ward records. ICD 49 and ICD 50 codes were used to retrieve all patients diagnosed with strabismus and those having undergone surgery included. ICPM 5-101, ICPM 5-102 and ICPM 5-103 codes were used for retrieving patients having undergone strabismus surgery. Consecutive patients files which meet the inclusion criteria were constituted in the study and a questionnaire used to extract data.
- Data was collected manually by the principal investigator using paper questionnaires in the records department, where entry of only authorised personnel was allowed.
- The data sheets were filed and kept in a secure lockable cabinet.

3.7.2 Data Analysis and Presentation

Information extracted from the questionnaires was entered by the principal investigator into the personal password protected computer using Microsoft Excel 2007 cleaned, verified and transferred to SPSS version 20.0 for analysis. The personal identifiers in the data were de-identified for confidentiality before importation into the statistical package for analysis. Data was backed-up in a password protected flash-drive.

Descriptive statistics were presented as Means with Standard Deviations for normally distributed continuous variables. Count and proportions were used for the tabulation of categorical variables such as gender and categorical test results.

Bivariate associations pre and post operation of relevant outcomes were assessed by parametric tests (chi-square, fishers or paired t-test). All statistical tests with P-value <0.05 were considered statistically significant. Results are presented in form of pie charts, bar charts and tables. All analyses were performed in SPSS version 20.0.

3.7.3 Missing Data

Records with missing data were excluded if they were critical for analysis e.g. age and date of surgery. Missing data that was not critical was reported in results.

Ethical Considerations

During the data collection period files to be assessed were selected one day prior to collecting data. The selection was done after checking clinic and theatre bookings to ensure that none of the selected patient files were for review on that day. A copy of the selected files was also made available to the clinic in order to trace the file in the event that a patient without prior booking came to the clinic.

Approval to perform the study was sought from the ethics, research and standards committee of Kenyatta National Hospital/University of Nairobi. Permission was sought from Kikuyu Eye Unit. All the data obtained was handled confidentially.

Dissemination Plan

Kenyatta National Hospital and Kikuyu Eye Unit will be furnished with a copy of the research findings.

CHAPTER FOUR

RESULTS

One hundred and ninety nine (199) children underwent surgery for strabismus from June 2008 to June 2013.

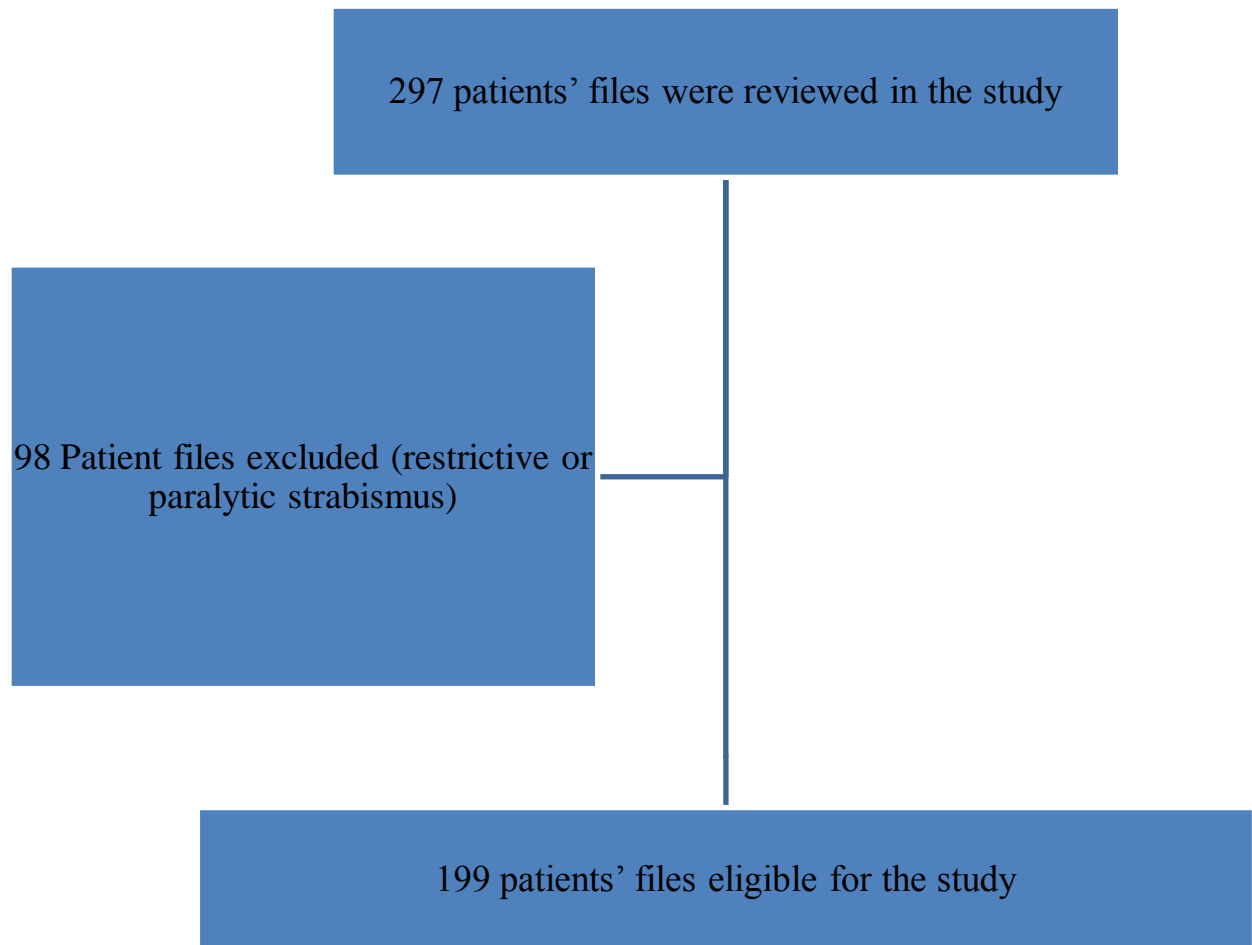


Figure 1: Flow diagram for reviewed records during the study period

5.0 Demographic data

Table 1: Demographic Characteristics

Variables	Number of Patients	Percentage	P Value
Study Center (n = 199)			
KNH	41	20.6	N/A
KEU	158	79.4	
Sex (n = 199)			
Male	94	47.2	0.978
Female	105	52.8	
Age at diagnosis (n = 199)			
<5 yrs	112	56.3	0.076
5 – 15 yrs	87	43.7	
Age at surgery (n = 199)			
<5 yrs	59	29.6	0.00
5 – 15 yrs	140	70.4	

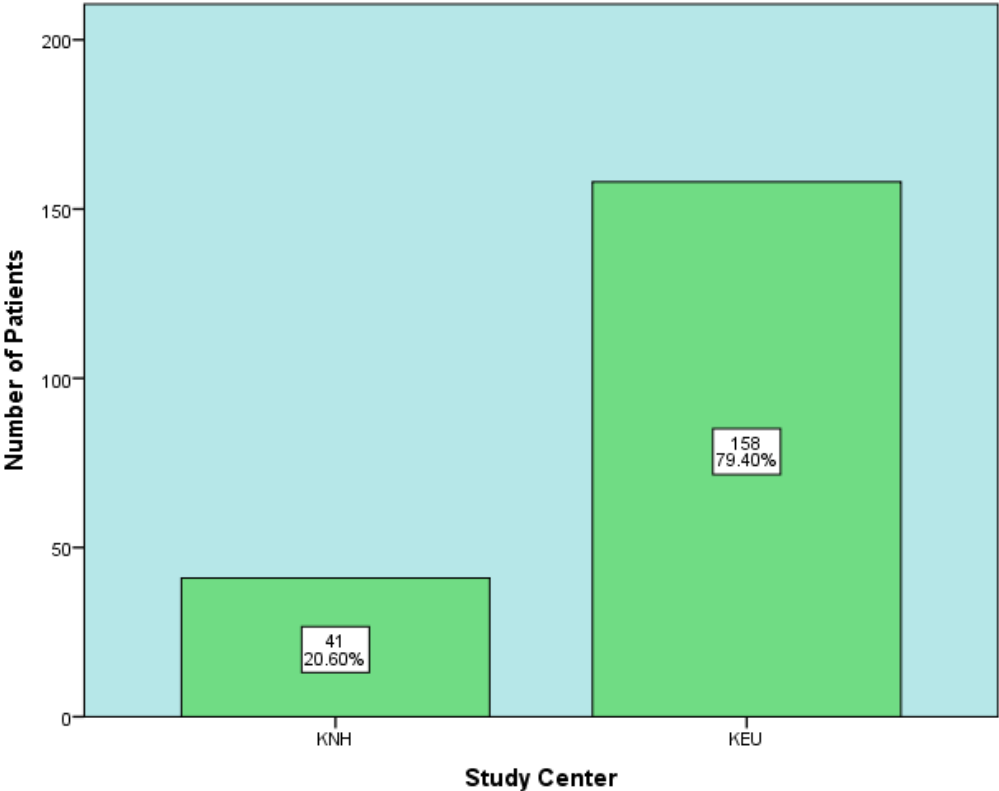
Mean age at Diagnosis was 6.2 yrs (SD=6.889); mean age at surgery was 9.6 yrs (SD=7.708)

Most(44.7%) were diagnosed at age 1-3 yrs; (33.7%) had surgery at 4-6 years

5.1 Study center

Kenyatta National Hospital operated 41/199 (20.6%) patients while 158/199 (79.4%) were operated at Kikuyu Eye Unit.

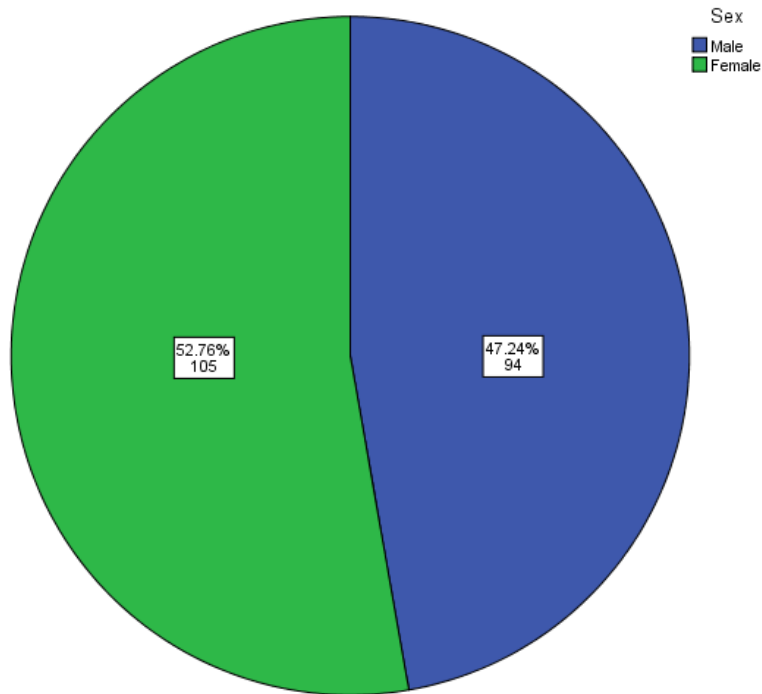
Figure 2: Study Center (n=199)



5.2 Sex Variation

Both male and female patients were nearly equal. 94 (47.2 %) were males and 105 (52.8%) were females with a 1:1 ratio (p=0.978).

Figure 3: Sex of Patients (n=199)



5.3 Age at diagnosis and Age at surgery

The age group was 1 to 15 years. 112/199 (56.3%) were less than 5 years of age and 87/199 (43.7%) were more than 5 years of age at the time of diagnosis. 59/199 (29.6%) were less than 5 years and 140/199 (70.4%) were more than 5 years at the time of surgery. The average age of surgery was 9.6 years, (standard deviation [SD] 7.708) and the average age of diagnosis was 6.2 years (standard deviation 6.889). Most patients were diagnosed between 1 to 3 years (44.7%) and most had surgery between 4 to 6 years (33.7%).

5.4 Refractive Status of Patients

Table 2: Preoperative Refraction

Refraction	No. of Patients	Percentage
Hypermetropia with Astigmatism	65	32.7
Hypermetropia	50	25.1
Myopia with Astigmatism	28	14.0
Astigmatism	21	10.6
Not Assessed	21	10.6
Myopia	10	5.0
Emmetropia	4	2.0
Total	199	100

Most patients (32.7%) were found to have hypermetropia with astigmatism, followed by hypermetropia (25.1%). Some patients did not have any refraction assessed (10.6%) and the reason for not refracting was not recorded.

5.5. Types of Pre-operative Strabismus

Table 3: Types of Strabismus

Age at Diagnosis (years)	Type of Strabismus			P-Value
	n	Esotropia	Exotropia	
<5yrs	112	73	39	0.148
>5 yrs	87	65	22	
Total	199	138	61	

Esotropia was seen in 138/199 (69.3%) and exotropia in 61/199 (30.7%). There is no statistical significant difference between the number of patients with esotropia and exotropia among the under 5yrs and over 5 years.

5.6 Size of Pre-operative Angles

Table 4: Types of Pre-operative Angles and Types of Strabismus

Pre-op Angle	Type of Strabismus (%)			P-value
	Esotropia	Exotropia	Total	
Small (10-≤30)	15 (7.5)	12 (6.0)	27 (13.6)	0.095
Moderate (30-≤50)	70 (35.2)	30 (15.1)	100 (50.3)	0.841
Large (>50)	53 (26.6)	19 (9.5)	72 (36.1)	0.326
Total	138 (69.3)	61 (30.6)	199 (100)	

27/199 (13.6%) had a small angles, 100/199 (50.3%) had moderate angles and 72/199 (36.2%) had large angles. Most of the patients had moderate pre-operative angles.

5.7 Types of surgeries performed

Table 5: Types of Surgery for Esotropia

Type of Pre-op Angle	Type of Surgery	No. of Patients (%)
Small	MR Recession/ LR Resection	9 (6.5)
	Bilateral MR Recession	3 (2.2)
	Unilateral MR Recession	3 (2.2)
Moderate	MR Recess/ LR Resection	46 (33.3)
	Bilateral MR Recession	19 (13.8)
	BMR Splitting Operation	3 (2.2)
	Unilateral MR Recession	1 (0.7)

	Bilateral lever arm reducing	1 (0.7)
Large	MR Recession/ LR Resection	25 (18.1)
	Bilateral MR Recession	28 (20.3)
	Total	138 (100)

Amongst the esotropes surgeries undergone were 80/138 (58.0%) medial rectus recession and lateral rectus resection procedure, 50/138 (36.2%) bilateral medial rectus recession, 4/138 (2.8%) unilateral medial rectus recession, 3/138 (2.2%) bilateral medial rectus splitting operation while 1 (0.7%) bilateral lever arm reducing. The most common surgery was a recession-resection.

Table 6: Types of Surgery for Exotropia

Type of Pre-op Angle	Type of Surgery	No. of Patients (%)
Small	Bilateral LR Recession	8 (13.1)
	LR Recession/ MR Resection	3 (4.9)
	Unilateral LR Recession	1 (1.6)
Moderate	LR Recession/ MR Resection	18 (29.5)
	Bilateral LR Recession	12 (19.7)
Large	LR Recession/ MR Resection	15 (24.6)
	Bilateral LR Recession	4 (6.6)
	Total	61 (100)

Amongst the exotropes surgeries undergone were 36/61 (59.0%) lateral rectus recession and medial rectus recession, 24/61 (39.3%) bilateral lateral rectus recession while 1/61 (1.6%) had unilateral lateral rectus recession.

Table 7: Adjunct Surgeries (n=18)

Type of Adjunct Surgery	Horizontal Strabismus Surgery	Indication	No. of Patients
MR ½ tendon infraplacement	MR Recess/ LR Resect	A pattern	1
MR ½ tendon supraplacement	MR Recess/ LR Resect	V pattern	1
LR ½ tendon infraplacement	BLR Recess	V pattern	1
LR ½ tendon supraplacement	BMR Recess	A pattern	1
Bilateral inferior oblique recession	MR Recess/ LR Resect	IOOA	7
Unilateral inferior oblique recession	MR Recess/ LR Resect	IOOA	1
Bilateral superior oblique recession	LR Recess/ MR Resect	SOOA	1
Bilateral inferior oblique myomectomy	BLR Recess	IOOA	2
SO spacer	BLR Recess	SOOA	1
SO tenotomy	MR Recess/ LR Resect	SOOA	2

Other surgeries were also performed on 18 patients in addition to the horizontal muscle surgeries for A and V pattern and inferior and superior oblique over-action (IOOA/ SOOA).

5.7 Surgical Outcomes

Good outcome (post-operative deviation ≤ 10 PD) was seen in 41/90 (45.6%) patients with esotropia and 19/32 (59.4%) patients with exotropia, borderline outcome (residual deviation 11PD–20PD) in 34/90 (37.8%) patients with esotropia and 11/32 (34.4%) patients with exotropia, and poor outcome (residual deviation > 20 PD) in 15/90 (16.7%) patients with esotropia and 2/32 (6.3%) patients with exotropia.

Table 8: Outcomes for Esotropia

Outcome	Surgery							Total
	MR Recess/ LR Resect			BMR Recess			BMR Splitting op	
	S	M	L	S	M	L	M	
Good (≤ 10)	5	18	4	0	6	6	2	41
Borderline ($>10-\leq 20$)	0	14	3	2	6	8	1	34
Poor (>20)	0	4	5	0	2	4		15
Total	5	36	12	2	14	18	3	90

PD= Prism Diopter , LR= Lateral Rectus, MR= Medial Rectus, BMR= Bilateral Medial Rectus, S= Small, M=Moderate, L= Large.

48/138 patients were lost to follow-up at the 2-3 month post-operative visit. Most patients had moderate angle strabismus of which most had good and borderline outcomes.

Table 9: Overall Outcomes for Esotropia

Outcome	RR	BMR Recess	BMR Splitting	P-Value
Residual Deviation in PD	No. of Patients (%)			
Good	27 (50.9)	12 (35.3)	2 (66.7)	0.272
Borderline	17 (32.1)	16 (47.1)	1 (33.3)	0.367
Poor	9 (17.0)	6 (17.6)		0.731
Total	53 (100)	34 (100)	3 (100)	

PD= Prism Diopter , RR= Recession-Resection, BMR= Bilateral Medial Rectus.

On comparing recess-resect procedures with bilateral medial rectus recessions in esotropia for good, borderline and poor outcomes by chi square test had $p = 0.272, 0.367, 0.731$. However while comparing with percentage, recess-resect did better for good (50.9%) and borderline (32.1%) compared to bilateral medial rectus recessions for good (35.3%) and borderline (47.1%). The outcomes for recess-resect was nearly the same for poor (17.0%) compared to bilateral medial rectus recession for poor (17.6%) outcomes. 3/90 (9.6%) had bimedial rectus splitting operation however the patients were too few to be comparable to the other types of surgeries.

Table 10: Outcomes for Exotropia

Outcome	Surgery					Total
	LR Recess/ MR Resect			BLR Recess		
	S	M	L	S	M	
Good (≤ 10)	1	10	4	1	3	19
Borderline ($>10-\leq 20$)	0	7	0	2	2	11
Poor (>20)	0	0	1	0	1	2
Total	1	17	5	3	6	32

PD= Prism Diopter , LR= Lateral Rectus, MR= Medial Rectus, BLR= Bilateral Lateral Rectus, S= Small, M=Moderate, L= Large.

29/61 patients were lost to follow-up. Most patients had moderate angle strabismus in both surgical procedures. Majority had good outcomes.

Table 11: Overall Outcomes for Exotropia

Outcome	RR	BLR Recess	P-value
Residual Deviation in PD	No. of Patients (%)		
Good	15 (65.2)	4 (44.4)	0.282
Borderline	7 (30.4)	4 (44.4)	0.453
Poor	1 (4.3)	1 (11.1)	0.477
Total	23 (100)	9 (100)	

PD= Prism Diopter , RR= Recession-Resection, BLR= Bilateral Lateral Rectus.

Comparing recess-resect procedures with bilateral lateral rectus recessions in exotropia for good, borderline and poor by chi square test had $p = 0.282, 0.453, 0.477$ respectively. However while comparing with percentage, recess-resect did better for good (65.2%) compared to bilateral rectus recessions for good (44.4%). The outcomes for recess-resect for borderline (30.4%) and poor (4.3%) were lower than bilateral rectus recession for the same (44.4% and 11.1%).

5.8 Complications

Intra-operative complications like slipped or lost muscles were not seen. There were 14/199 (7%) of subconjunctival haemorrhage, 4/199 (2%) of dellen, 3/199 (1.5%) of chronic suture granuloma and 2/199 (1%) cases of ptosis.

Table 12: Complications (post-op complications as a result of surgery)

Complications	Number of Patients	Percentage
Chronic Suture Granuloma	3	1.5
Subconjunctival Haemorrhage	14	7.0
Dellen	4	2.0
Ptosis	2	1.0
None	176	88.4
Total	199	100

5.9 Second surgery and indication

22/199 (11.1%) of patients underwent a second surgery. 15/22 (68.2%) were for residual esotropia, 7/22 (31.8%) were for residual exotropia.

Table 13: Second surgery and indication

Indication of Second Surgery	Number of Patients	Percentage
Residual Esotropia	15	68.2
Residual Exotropia	7	31.8
Total	22	100

CHAPTER FIVE

DISCUSSION

The purpose of this study was to review the outcomes of childhood strabismus surgery in patients operated at KNH and KEU. Strabismus is not in itself a blinding disease however it is a condition which often does not receive as much attention as other blinding diseases like cataract, glaucoma, trauma amongst others. Nevertheless the psychosocial impact and effects on BSV and cosmesis of this condition make it important for us to determine if we are achieving the aims of surgery. With these facts put into consideration it is important to note that in Kenya no other study has previously been done on the outcomes of surgery and this study will lay baseline data on the same.

It was seen in our study that majority of the patients in the study were from KEU (79.4%). More patients operated were female (52.8%) than male, with a ratio of 1:1. From the patients operated, most were more than 5 years of age which was found to be highly statistically significant ($p=0.00$) with most patients being operated between 4-6 years. The mean age of surgery, 9.6 years was similar to that found in the study by Gogate et al where average age was 9 years 8 months³⁷. The age at surgery has been a topic of debate and the advantage to be considered of early surgery is in preventing sensory changes and establishing better post-operative outcomes. The advantage of later surgery is that it allows for better measurements and hence less residual deviations and need for second surgeries. The refractive status of the patients showed majority of children having Hypermetropia with astigmatism (32.7%) followed by Hypermetropia (25.1%). This is an expected finding in children, however the study may have overestimated the number of children having a refractive error since all patients refractions were analyzed without considering the amount of refraction that would cause visual impairment for particular age groups.

Majority patients undergoing surgery had esotropia 138/199 (69.3%). This finding was expected since esotropia is the most common childhood strabismus and has been demonstrated by Mtanda et al in a study on esotropia¹⁰. The more common surgery being performed for both esotropia and exotropia was the recess-resect procedure followed by the bilateral recessions. However there

was no statistical significance seen in the outcomes in both procedures for both esotropia and exotropia ($p=0.272$ and $p=0.282$ for good outcomes in esotropia and exotropia respectively). For esotropia it was seen that there were more good outcomes in the recess-resect (50.9%) procedure compared to bilateral recessions (35.3%), however there was a larger portion of moderate (36/90) to large angles (12/90) in recess-resect procedures compared to the bilateral recession procedure where the moderate angles (14/90) were fewer than large angles (18/90). Similarly in exotropia the recess-resect (65.2%) procedure had better outcomes than the bilateral recession (44.4%) procedures, however again moderate angles (17/32) were more than large angles (5/32) for the recess-resect procedures which most patients underwent (23/32) than the bilateral recession which had less patients (9/32) none of which had large angles. Larger angles tend to require a two-stage surgery and hence the outcomes may have been affected by this. In our study 22/199 (11.1%) patients underwent a second surgery. Majority were for residual esotropia (68.2%) followed by residual exotropia (31.8%). These surgeries would have most probably been done on the large angles that required a two-stage surgery.

In this study surgery for exotropia had better outcomes than esotropia. Similar findings were seen in other studies. The study by Gogate et al evaluating outcome of horizontal strabismus surgery in children had success rates of 44.6% in bilateral recessions and 61.7% in recess-resect procedures for esotropia and 53% in bilateral recessions for exotropia when deviation was within 10 prism diopters. A similar success was seen in Keenan while looking at outcomes of childhood tropia where he saw 85.7% good outcomes in recess-resect procedure for exotropia and 57.5% good outcomes in bilateral recess procedures for esotropia^{36,51}. In Cameroon Mvogo found good outcomes in 61% of recess-resect procedures for exotropia³⁵.

The results were determined using prism measurements recorded in the patient charts. In circumstances where no prism measurements were recorded, Hirschberg measurements were taken with the appropriate prism conversion. This may have influenced the outcome results due to the different methods employed in measuring the anatomical angles. Also different clinicians took post-operative measurements which may have influenced the readings because of variability in technique.

No major complications were seen in this study like scleral perforation, slipped or lost muscle. The most common complication was subconjunctival haemorrhage (7%) followed by dellen (2%) which was higher than a study by Jeong et al on complications of strabismus surgery where he found dellen in 0.5%⁵⁴. Chronic suture granuloma (1.5%) was also seen however this was less than that found by Jeong (2.8%)⁵⁴ and Espinoza (2.1%)⁵⁵ who did a study on conjunctival suture granulomas after strabismus surgery. Ptosis (1%) was the least common complication seen and this was most likely not a direct result of the horizontal muscle surgery but a complication of an adjunct surgery being done.

CONCLUSIONS

1. Most common (58.3%) surgery performed was a recess-resect procedure for all types of tropia.
2. Exotropia had better outcomes than Esotropia as in other studies.
3. No major complications seen (e.g. scleral perforation, lost or slipped muscle). Most frequent complication was subconjunctival haemorrhage (7%).
4. Second surgeries (11.1%) were done for residual deviation.

RECOMMENDATIONS




1. Document all refractions.
2. Prospective study on surgical dosages with control of confounding factors.

LIMITATIONS

1. Variability in results due to many different surgeons.
2. Patients lost to follow-up.
3. Confounders on surgical dosages mm: variable refraction, variable angle, variable age.

APPENDICES

APPENDIX I: APPROVAL LETTER FROM ETHICS AND RESEARCH COMMITTEE



UNIVERSITY OF NAIROBI
COLLEGE OF HEALTH SCIENCES
P O BOX 19676 Code 00202
Telegrams: varsity
(254-020) 2726300 Ext 44355

KNH/UoN-ERC
Email: uonkh_erc@uonbi.ac.ke
Website: www.uonbi.ac.ke

KENYATTA NATIONAL HOSPITAL
P O BOX 20723 Code 00202
Tel: 726300-9
Fax: 725272
Telegrams: MEDSUP, Nairobi

Ref: KNH-ERC/A/385 Link: www.uonbi.ac.ke/activities/KNHUoN 9th December 2014

Dr. Amberin Fatima Fazal
Dept. of Ophthalmology
School of Medicine
University of Nairobi

Dear Dr. Fazal

Research proposal: Review of outcome of childhood strabismus surgery at Kenyatta National Hospital and Kikuyu Eye Unit - A retrospective study (P647/11/2014)

This is to inform you that the KNH/UoN-Ethics & Research Committee (KNH/UoN-ERC) has reviewed and **approved** your above proposal. The approval periods are 9th December 2014 to 8th December 2015.

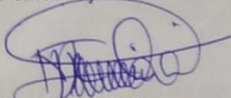
This approval is subject to compliance with the following requirements:

- Only approved documents (informed consents, study instruments, advertising materials etc) will be used.
- All changes (amendments, deviations, violations etc) are submitted for review and approval by KNH/UoN ERC before implementation.
- Death and life threatening problems and severe 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.
- 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.
- 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.*)
- Clearance for export of biological specimens must be obtained from KNH/UoN-Ethics & Research Committee for each batch of shipment.
- 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.

For more details consult the KNH/UoN ERC website www.uonbi.ac.ke/activities/KNHUoN.

"Protect to Discover"

Yours sincerely



PROF. M. L. CHINDIA
SECRETARY, KNH/UON-ERC

c.c. The Principal, College of Health Sciences, UoN
 The Deputy Director CS, KNH
 The Assistant Director, Health Information, KNH
 The Chairperson, KNH/UON-ERC
 The Dean, School of Medicine, UoN
 The Chairman, Dept. of Ophthalmology, UoN
 Supervisors: Dr. Kahaki Kimani, Dr. Joseph Nyamori, Dr. Daniel Mundia

APPENDIX II: APPROVAL LETTER FROM KIKUYU EYE UNIT



P.C.E.A Kikuyu Hospital

P.O. Box 45-00902 Kikuyu, Tel: (020) 2044766-68, (020) 2044769-71
Fax: (020)2044765/772 Mobile:0722-207636 / 0733-606133 / 0736-270192

10th November 2014

Dr. Amberin Fatima Fazal
UON Department of Ophthalmology
NAIROBI

Dear Madam,

RE: STUDY ON STRABISMUS SURGERY

Thank you for choosing KEU to conduct a study on Strabismus Surgery.

We would like to inform you that the hospital's Medical Committee has approved your request. You will work with Dr. Mundia who has been attending to strabismus patients.

At the end of the study you are required to furnish the hospital with copy of the research findings.

Yours faithfully,

A handwritten signature in black ink, appearing to be 'AM' with a flourish, written over a horizontal line.

Dr. Alain N. M'bongo-Zindamoyen
Director of Clinical Services (Eye Unit)

Cc

Dr. Mundia

APPENDIX III: QUESTIONNAIRE

REVIEW OF OUTCOMES OF STRABISMUS SURGERY AT KENYATTA NATIONAL HOSPITAL AND KIKUYU EYE UNIT

Section A: Demographic Information

1. Date of data collection: _____

2. Study Number: _____

3. Study Centre: KNH KEU

4. Sex
 a) Male b) Female

5. Age at diagnosis:
 Years _____ Months _____

6. Age at surgery:
 Years _____ Months _____

7. Refraction (Refractive Error of patient)
 Myopia
 Hypermetropia
 Emmetropia
 Isometropia
 Anisometropia
 Astigmatism
 Other _____

3. a) Date of first hospital visit _____

b) Date of surgery _____

Section B: Clinical records of patient

1) Diagnosis at admission _____

2) Intra-operative diagnosis _____

3) Surgery performed _____

4) Target angle _____

5) **Outcome measures**

I: Visual Acuity (*Smallest letters that can be read on a standardized chart, logmar, including fixating and following objects for very young children*) RE: Right Eye, LE: Left Eye.

		RE				LE			
	Date of Visit	Patient chart reading	Logmar	Fixating and following objects/light		Patient chart reading	Logmar	Fixating and following objects/light	
PRE-OPERATIVE				Yes	No			Yes	No
1 MONTH				Yes	No			Yes	No
1-3MONTHS				Yes	No			Yes	No
3-6MONTHS				Yes	No			Yes	No
6-12 MONTHS				Yes	No			Yes	No

II: Ocular Examination

		RE		LE	
	Date of Visit	Anterior Segment	Posterior Segment	Anterior Segment	Posterior Segment
PRE-OPERATIVE					
1 MONTH					
1-3MONTHS					
3-6MONTHS					
6-12 MONTHS					

III: Angle Measurements Angle measurements taken using Prisms or Hirschberg’s test. H= Hirschberg’s test (A test of alignment using corneal light reflex to determine deviation. 1mm=7°=15 PD.), P= Prism Measurement, U= Upgaze, C= Center, D= Down-gaze, N= Near, F= Far.

Table 1: Without spectacle correction

	Date of Visit	Test Used		RE						LE						
				U		C		D		U		C		D		
				N	F	N	F	N	F	N	F	N	F	N	F	
PRE-OPERATIVE		H	P													
1 MONTH		H	P													
1-3 MONTHS		H	P													

3-6 MONTHS		H	P											
6-12 MONTHS		H	P											

Table 2: With spectacle correction (includes spectacle correction for refractive errors with or without prisms)

	Date of Visit	Test Used		RE						LE					
				U		C		D		U		C		D	
				N	F	N	F	N	F	N	F	N	F	N	F
PRE-OPERATIVE		H	P												
1 MONTH		H	P												
1-3 MONTHS		H	P												
3-6 MONTHS		H	P												
6-12 MONTHS		H	P												

IV: Binocular Vision Grade 1, 2, 3 being simultaneous perception, fusion and stereopsis respectively. P= Present, A= Absent and NA= Not Assessed. Tick as appropriate.

	Date of Visit	Grade 1			Grade 2			Grade 3					
		Test Used	P	A	NA	Test Used	P	A	NA	Test Used	P	A	NA
PRE-OPERATIVE													
1 MONTH													
1-3 MONTHS													

3-6 MONTHS													
6-12 MONTHS													

V: Complications (Any post-op complications as a result of surgery, Mark all that apply)

<input type="checkbox"/> Loss of vision <input type="checkbox"/> Post-op Nausea and vomiting <input type="checkbox"/> Acute allergic suture reaction <input type="checkbox"/> Chronic suture granuloma <input type="checkbox"/> Reaction to synthetic absorbable suture <input type="checkbox"/> Subconjunctival cysts <input type="checkbox"/> Subconj haematoma <input type="checkbox"/> Prolapse of tenon's capsule <input type="checkbox"/> Suture abscess	<input type="checkbox"/> Delle <input type="checkbox"/> Lid fissure anomalies <input type="checkbox"/> Ptosis <input type="checkbox"/> Scleral perforation <input type="checkbox"/> Slipped or lost muscle <input type="checkbox"/> Anterior segment ischemia <input type="checkbox"/> Hyphema <input type="checkbox"/> Posterior chamber haemorrhage <input type="checkbox"/> Symblepharon	<input type="checkbox"/> Orbital haemorrhage <input type="checkbox"/> Orbital cellulitis <input type="checkbox"/> Endophthalmitis <input type="checkbox"/> Operation on the wrong muscle <input type="checkbox"/> Diplopia <input type="checkbox"/> Other (specify) _____ _____ _____ _____
--	---	---

6) Additional Therapies

Pre-operative	Post-operative
<input type="checkbox"/> Spectacle correction <input type="checkbox"/> Amblyopia therapy <input type="checkbox"/> Prisms <input type="checkbox"/> Orthoptic exercises <input type="checkbox"/> Other _____	<input type="checkbox"/> Spectacle correction <input type="checkbox"/> Amblyopia therapy <input type="checkbox"/> Prisms <input type="checkbox"/> Orthoptic exercises <input type="checkbox"/> Other _____

7) Re-operation

a) Yes b) No

Indication for re-operation _____

8) Second surgery

a) Yes b) No

Indication for second surgery _____

APPENDIX IV: VISUAL ACUITY CONVERSION CHART

Letter Size	3/Meter	10/Foot	Decimal	6/Meter	20/Foot	LogMAR
30M	3/30	10/100	.10	6/60	20/200	1.0
24M	3/24	10/80	.12	6/48	20/160	0.9
19M	3/19	10/83	.16	6/38	20/125	0.8
15M	3/15	10/50	.20	6/30	20/100	0.7
12M	3/12	10/40	.25	6/24	20/80	0.6
9.5M	3/9.5	10/32	.32	6/19	20/63	0.5
7.5M	3/7.5	10/25	.40	6/15	20/50	0.4
6M	3/6	10/25	.50	6/12	20/40	0.3
4.8M	3/4.8	10/16	.63	6/9.5	20/32	0.2
3.8M	3/3.8	10/12.5	.80	6/7.5	20/25	0.1
3M	3/3	10/10	1.00	6/6	20/20	0.0
2.4M	3/2.4	10/8	1.25	6/4.8	20/16	-0.1
1.9M	3/1.9	10/6.3	1.60	6/3.8	20/12.5	-0.2
1.5M	3/1.5	10/5	2.00	6/3	20/10	-0.3

APPENDIX V: BUDGET (KENYA SHILLINGS)

Item	Quantity	Unit cost) (Kshs)	Total kshs
Printing and Packing	70 pages	10	700
Photocopy of Proposal	80 pages	3	240
Binding Proposal	3 copies	120	360
Proposal Printing 2 nd draft	40 pages	10	400
Photocopy of proposal 2 nd draft	80 pages	3	240
Binding of proposal 2 nd draft	3 copies	150	450
Ethics			3,000
Sub-total			5,390
Contracted services			
Statistician	1	50,000	55,0000
Research assistants	3	40,000	40,000
Sub-totals			90,000
Communication			
Telephone			4,000
Transport			8,000
Miscellaneous			1,500
Subtotal			13,500
Results			
Printing of questionnaire	2pages	10	20
Photocopy of questionnaire	3*200 pages	3	1,800
Printing of results (black & white)	3*70 pages	10	2,100
Printing of results (color)	10*20 pages	20	4,000
Copy of final book			
Black and white	70*8 copies	3	1,680
Color copies	20*80	20	3,200
Binding of final paper	8 copies	200	1,680
Grand total			128,370

APPENDIX VI: STUDY TIME FRAME

	2014												2015		
Activities	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Jan	Feb	Mar
Proposal development															
Research and Ethical Committee approval															
Data Collection															
Data Analysis															
Report writing															
Thesis Defence															
Dissemination of findings forums															

REFERENCES

1. Yanoff M., Duker J, Wilkinson CP. Ophthalmology. *PAEDIATRIC AND ADULT STRABISMUS*. 2008;11(3).
2. Maconachie GD, Gottlob I, McLean RJ. Risk factors and genetics in common comitant strabismus: a systematic review of the literature. *JAMA ophthalmology*. 2013;131(9):1179-86. Epub 2013/07/13.
3. World Health Organization. Preventing blindness in children: Report of a WHO/IAPB Scientific Meeting, 2000.
4. Taylor J. A dissertation on the art of restoring the healthful position of the eye. *Milan* 1756.
5. Remy C, Aracil P. [History of strabismus surgery]. *Journal francais d'ophtalmologie*. 1983;7(6-7):493-8.
6. Friedman Z, Neumann E, Hyams W, & Peleg B. Ophthalmic screening of 38,000 children, age 1 to 2 1/2 years, in child welfare clinics. *Journal of pediatric ophthalmology and strabismus*. 1979;17(4):261-267.
7. Frandsen D. Occurrence of squint: a clinical-statistical study on the prevalence of squint and associated signs in different groups and ages of the Danish population. Bogtrykkeriet Forum 1960.
8. Graham PA. Epidemiology of strabismus. *Br J Ophthalmol*. 1974;58(3):224-231.
9. Ebana, C, Bella-Hiag L, Epesse M. [Strabismus in Cameroon]. *Journal français d'ophtalmologie*. 1995;19(11):705-709.
10. Mtanda, A. T. Cyclic esotropia – A case report and review of the literature. *East Africa Journal of Ophth*. 1986;45-47.

-
11. Onsomu EMa. Strabismus as seen in children aged 3 to 5 years attending Nairobi city council day nursery schools in Nairobi province, Kenya: University of Nairobi; 2003.
 12. Karimurio, J. Comitant esotropia in a Kenyan African population at Kenyatta National Hospital. Dissertation, University of Nairobi, 1990, unpublished data.
 13. Kanski, Jack J. "Clinical ophthalmology." *A systematic approach. 7th ed. Boston, Massachusetts: Butterworth-Heinemann (2011).*
 14. Mein J, Trimble R. Diagnosis and management of ocular motility disorders. 2nd ed. Oxford: Blackwell Scientific. 1991:227.
 15. Kanski, Jack J. "Clinical ophthalmology." *A systematic approach. 2nd ed. Boston, Massachusetts: Butterworth-Heinemann (2007): 629.*
 16. Chernysheva SG. [Clinical classification of incomitant strabismus]. *Vestnik oftalmologii.* 2012;128(3):33-6. Epub 2012/11/06.
 17. Popova NA. [Nonconcomitant strabismus. Proposals on its clinical classification]. *Vestnik oftalmologii.* 2008;124(5):59-61. Epub 2008/12/10.
 18. Basic and Clinical Science Course, Section 6: Pediatric Ophthalmology and Strabismus, 2012-2013.
 19. CEMAS Working Group. A National Eye Institute sponsored workshop and publication on the classification of eye movement abnormalities and strabismus (CEMAS). *The National Eye Institute Publications* 2001.

-
20. Von Noorden K. Theory and Management of Strabismus. In Binocular vision and ocular motility, Morsby, 1996; Chapter 10-16.
 21. Worth CA. Squint: its causes, pathology, and treatment: P. Blakiston's Son and Company; 1915.
 22. Donders F. Strabismus convergens, the result of hypermetropia. On the Anomalies of Accommodation and Refraction of the Eye. 1864:291-309.
 23. Amitava AK, Kewlani D, Khan Z, Razzak A. Assessment of a modification of Bruckner's test as a screening modality for anisometropia and strabismus. Oman journal of ophthalmology. 2011;4(2):102. Epub 2011/09/08.
 24. Pratt-Johnson JA, Tillson G. Management of strabismus and amblyopia: a practical guide: Thieme; 2001.
 25. Khumbo Kalua. Strabismus as seen in children at the University of Nairobi. Dissertation, University of Nairobi 2002, unpublished data.
 26. Model D, Eizenman M, Sturm V. Fixation-free assessment of the Hirschberg ratio. Investigative ophthalmology & visual science. 2010;51(8):4035-9.
 27. Wheeler MC. Objective strabismometry in young children. Archives of ophthalmology. 1943;29(5):720-NP.
 28. Brodie SE. Photographic calibration of the Hirschberg test. Invest Ophthalmol Vis Sci. 1987; 28:736-42.
 29. DeRespinis PA, Naidu E, Brodie SE. Calibration of Hirschberg test photographs under clinical conditions. Ophthalmology. 1989;96:944-9.

-
30. Eskridge JB, Perrigin DM, Leach NE. The Hirschberg test: correlation with corneal radius and axial length. *Optom Vis Sci.* 1990; 67:243-7.
31. Eskridge JB, Wick B, Perrigin D. The Hirschberg test: a double-masked clinical evaluation. *Am J Optom Physiol Opt.* 1988;65:745-50.
32. Jethani, JN. Hirschberg's Corneal Reflex Test: Theoretical and Experimental Observations. 69th AIOC Proceedings, Ahmedabad 2011.
33. Riddell PM, Hainline L, Abramov I. Calibration of the Hirschberg test in human infants. *Investigative ophthalmology & visual science.* 1994;35(2):538-543.
34. Thomas S, Guha S. Large-angle strabismus: can a single surgical procedure achieve a successful outcome? *Strabismus.* 2010;18(4):129-136.
35. Mvogo CE, Bella AL, Ellong A, Didier O, Eballe AO, Tambi FT. Surgical management of primary exotropia in Cameroon. *Clinical ophthalmology (Auckland, NZ).* 2007;1(4):471.
36. Keenan JM, Willshaw HE. The outcome of strabismus surgery in childhood exotropia. *Eye.* 1994;8(6):632-637.
37. Gogate PM, Rishikeshi N, Taras S, Aghor M, Deshpande MD. Clinical Audit of Horizontal Strabismus Surgery in Children in Maharashtra, India. *Strabismus.* 2010;18(1):13-17.
38. Berland JE, Wilson ME, Saunders RA. Results of large (8–9mm) bilateral lateral rectus recession for exotropia. *Binocular Vis Strabismus Q.* 1998;13:97–104.

-
39. Lau FHS, Fan DSP, Yip WWK, Yu CBO, Lam DSC. Surgical outcome of single-staged three horizontal muscles squint surgery for extra-large angle exotropia. *Eye*. 2010;24(7):1171-1176.
40. Wright, K. W., Edelman, P. M., McVey, J. H., Terry, A. P., & Lin, M. High-grade stereo acuity after early surgery for congenital esotropia. *Archives of ophthalmology*.1994;112(7):913-919.
41. Rosenbaum Al. The goal of adult strabismus surgery is not cosmetic. *Arch Ophthalmol* 1999;117:250.
42. Kushner BJ, Morton GV. Postoperative binocularity in adults with longstanding strabismus. *Ophthalmology*. 1992;99:316-319.
43. Morris RJ, Scott WE, Dickie, CF. Fusion after surgical alignment of longstanding strabismus in adults. *Ophthalmology*. 1993;100:135-138.
44. Scott WE, Kutschke PJ, Lee WR. 20th Annual Frank Costenbader Lecture—Adult strabismus. *J Pediatr Ophthalmol Strabismus*. 1995;32:348-352.
45. Bau V. [Correcting refraction and amblyopia therapy--conservative management of strabismus in childhood]. *Klinische Monatsblätter für Augenheilkunde*. 2008;225(3):R37-48; quiz R9-53. Epub 2008/03/21. Refraktionsausgleich und amblyopietherapie - konservative schielbehandlung im kindesalter.
46. Paysse EA. Adult strabismus: goals of realignment surgery. *Binocular vision & strabismus quarterly*. 2001;16(1):9-10. Epub 2001/03/10.
47. Revel C, Cypres C, Bourron-Madignier M. [Experience in the early detection of strabismus in child day care centers. Value in the prevention of amblyopia in young children]. *Pediatric*.

1988;43(3):241-3. Epub 1988/01/01. Experience de dépistage précoce du strabisme dans les crèches. Intérêt dans la prévention de l'amblyopie chez le jeune enfant.

48. Shen YD, Chen CY, Wu CH, Cherng YG, Tam KW. Dexamethasone, ondansetron, and their combination and postoperative nausea and vomiting in children undergoing strabismus surgery: a meta-analysis of randomized controlled trials. *Pediatric Anesthesia*. 2014;24(5):490-8.

49. Hertle RW, National Eye Institute Sponsored Classification of Eye Movement A, Strabismus Working G. A next step in naming and classification of eye movement disorders and strabismus. *Journal of AAPOS : the official publication of the American Association for Pediatric Ophthalmology and Strabismus / American Association for Pediatric Ophthalmology and Strabismus*. 2002;6(4):201-2. Epub 2002/08/20.

50. Von Noorden G K. Principles of surgical treatment. *In Binocular vision and ocular motility: theory and management of strabismus, 4th ed*. St Louis: Mosby. 1990; Pg 479-536.

51. Keenan JM, Willshaw HE. Outcome of strabismus surgery in congenital esotropia. *British journal of ophthalmology*. 1992;76(6):342-345.

52. Mehta VJ, Utz VM, Traboulsi EI, & Rychwalski PJ. Outcomes of Strabismus Surgery with or without Trainee Participation as Surgeon. *Ophthalmology*. 2014;121(10):2066-2069.

53. Waqar S, Jones D, Gibbon C, & Sleep T. Outcomes of horizontal strabismus surgery in newly appointed UK trained strabismologists. *Eye*. 2013;27(4):572.

54. Jeong G, Roh YB. Complications on Strabismus Surgery. *Journal of Korean Ophthalmological Society*. 1988;29(4):619-623.

55. Espinoza GM & Lueder GT. Conjunctival pyogenic granulomas after strabismus surgery. *Ophthalmology*. 2005;112(7):1283-1286.

56 . T R Grin. L B Nelson Large unilateral medial rectus recession for the treatment of esotropia. *British Journal of Ophthalmology*. 1987; 71(5): 377–379.