PREVALENCE AND PATTERN OF CORNEAL DISEASES IN PAEDIATRIC PATIENTS AT KENYATTA NATIONAL HOSPITAL EYE CLINIC AND THE UNIVERSITY OF NAIROBI EYE CENTRE

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DECLARATION

This proposal is my original work, and it has never been submitted for a degree or award at any other university.

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ABBREVIATIONS

AKC	Atopic Keratoconjunctivitis
CCO	Congenital Corneal Opacities
IOL	Intraocular lens
KNH	Kenyatta National Hospital
LCSD	Limbal Stem Cell Deficiency
WHO	World Health Organisation

OPERATIONAL DEFINITION OF TERMS

Adolescent	Child from 13 to less than 18 years of age
Child	Any human being under the age of 18 years
Corneal disease	Clouding, disruption or scarring of the cornea from structural or functional anomaly, infection, inflammation, injury, degeneration or dystrophy.
Infant	Child up to 1 year of age
Neonate	Child in first 28 days of life
Paediatric	Relating to persons who are younger than 18 years.
Postverbal children	Children who are old enough to communicate with words.
Preschooler	Child from 3 up to less than 6 years of age
Preverbal children	Children who are yet to communicate with words either due to young age or neurodevelopmental delay.
School age	Child from 6 to less than 13 years of age
Supportive Management	Medical treatment defined by the avoidance of invasive measures such as surgery or other invasive procedures. This may include ocular medications that improve patient comfort but not treating the primary condition.
Toddler	Child from 1 to less than 3 years of age

ABSTRACT

The World Health Organisation's (WHO) 2030 in sight initiative aims to elevate, integrate and activate strategies with the goal of ending avoidable sight loss. This includes childhood blindness, which often results from corneal pathologies leading to corneal scarring. However, the prevalence and pattern of corneal diseases vary between countries.

Broad Objective: To determine the prevalence and pattern of corneal diseases in paediatric patients at Kenyatta National Hospital eye clinic and the University of Nairobi Eye Centre (Uni-Eye).

Study Design: Retrospective case series.

Study Site(s): Kenyatta National Hospital eye clinic and the University of Nairobi Eye Centre (Uni-Eye).

Methods: All files of paediatric patients seen at Kenyatta National Hospital (KNH), eye clinic and the University of Nairobi Eye Centre (Uni-Eye) in the year 2019 and diagnosed to have corneal diseases were selected and enrolled. The information collected included; age, sex, residence, diagnosis, presenting visual acuity, presenting best corrected visual acuity, management and final visual acuity.

Results: From a total of 776 files of paediatric patients seen at the two eye clinics in the year 2019, 95 files had a diagnosis of corneal disease which represented a prevalence of 12.2%. Corneal injury and allergic corneal disease were the most frequent categories, accounting for 36.8% and 29.5% respectively. Males accounted for 61% of cases. Corneal injury and congenital corneal diseases were the most frequent causes of blindness at 58.3% and 16.7% respectively. Seven patients were referred for specialized services.

Conclusion: Corneal injury is a major cause of monocular blindness. These findings provide insights into the burden of corneal diseases in Kenyan paediatric patients and highlight the need for targeted interventions with appropriate follow-up to prevent childhood blindness.

1 CHAPTER ONE: INTRODUCTION

1.1 Background Information

Corneal diseases encompass a wide variety of disorders which frequently lead to corneal scarring and monocular or binocular blindness.(1) The epidemiology of corneal diseases is diverse and varies across different regions and populations.(2) In the developing world, corneal scars are a common cause of visual impairment in the paediatric age group.

In developed countries, the leading aetiologies of paediatric corneal blindness include congenital opacities of the cornea, inherited corneal disorders and corneal ectasias.(3) In less developed countries the major causes of corneal scarring are vitamin A deficiency causing xerophthalmia, measles, neonatal conjunctivitis and the deleterious effects of traditional ocular remedies.(4) In the case of developing countries that are deficient in eye care specialists, surgical infrastructure and eye bank facilities, prevention of corneal diseases is key.(2)

There have been relatively few studies done on the prevalence and pattern of corneal diseases in children. Locally no study has been done to the best of our knowledge to elucidate on the prevalence and pattern of corneal diseases in the paediatric age group.

A study by Ajaiyeboa et al showed corneal diseases to be the major cause of blindness and visual impairment among students in Nigeria.(5) In Gambia, a study by Onabolu et al showed that paediatric corneal diseases were majorly caused by corneal trauma.(6) This was also the case in a study by Bella et al in Cameroon where corneal trauma contributed to 48.2 % of paediatric corneal diseases.(7) In Nepal however, a study by Panjiyar et al showed keratitis and corneal ulcers to be the most frequent corneal pathology in paediatric-age patients.(8)

It is notable that the few studies done did not describe the treatment modalities prescribed for the various corneal diseases. The purpose of this study was to describe the prevailing prevalence and pattern of paediatric corneal disorders in the Kenyan setting, their management modalities as well as their visual prognoses.

2 CHAPTER TWO: LITERATURE REVIEW

2.1 Corneal diseases

Corneal diseases may be classified based on aetiology into congenital and acquired. Under acquired corneal diseases, further categorisation may be done based on the aetiology and/or pathophysiology of the disease into infectious corneal diseases, corneal dystrophies, corneal degenerations, ectatic corneal diseases, allergic corneal diseases, ocular surface diseases and traumatic injuries to the cornea.

2.2 Congenital corneal diseases

Congenital corneal diseases are morphological or physiological abnormalities of the cornea that occur during intrauterine development. Congenital corneal disorders are generally categorised into two, namely; congenital corneal opacities and anomalies of the corneal size and shape. The causes of congenital corneal opacities are multifactorial ranging from genetic to prenatal and postnatal environmental factors. (9) Congenital corneal anomalies of size and shape are mostly ectasias which are characterised by abnormal corneal dimensions and/or curvature.

2.3 Acquired corneal diseases

2.3.1 Infectious corneal diseases

Infectious corneal diseases are caused by bacteria, fungi, viruses, protozoa and parasites. Infectious keratitis which is characterised by corneal inflammation, corneal ulceration and stromal infiltration can progress rapidly with corneal destruction and blindness. It is considered an ophthalmic emergency. Corneal involvement and resultant corneal scarring in ophthalmia neonatorum is a major aetiology of visual impairment in less developed nations. (1) Trachoma caused by infection with chlamydia trachomatis is currently the world's most common infectious cause of blindness and visual disability. (10)

2.3.2 Corneal dystrophies

Corneal dystrophies are a set of heritable corneal illnesses characterised by the accrual of aberrant material in the cornea, resulting in varying degrees of visual impairment. Corneal dystrophies are often bilateral and are slow to progress.

2.3.3 Ectatic corneal diseases

Keratoconus is defined by increased corneal protrusion and thinning, resulting in uneven astigmatism and impaired vision.(11) It is a markedly asymmetrical bilateral disease linked with atopy, down syndrome, leber congenital amaurosis, retinitis pigmentosa, marfan's syndrome, and mitral valve prolapse.(12) Keratoglobus is a corneal ectasia distinguished by bilateral and symmetric corneal thinning and anterior bulging.(13) The disease's congenital form has been linked to leber congenital amaurosis and blue sclera syndrome.(14)

2.3.4 Allergic corneal diseases

Atopic keratoconjunctivitis is a chronic inflammatory illness that affects both eyes and causes recurring bouts of significant conjunctival and eyelid inflammation, as well as corneal damage. (15) Corneal epithelial defects, keratitis, corneal scarring, and keratoconus are all serious and vision-threatening complications. Vernal keratoconjunctivitis is a chronic, bilateral, asymmetrical, and seasonally worsened ocular surface allergic inflammation affecting the tarsal and/or bulbar conjunctiva.(16) The corneal abnormalities in children with VKC may result in a permanent reduction or loss of eyesight.(17)

2.3.5 Ocular Surface Diseases

Dry eye syndrome refers to a set of disorders characterised by a raised osmolality of the tear film and ocular surface inflammation, as well as associated ocular discomfort. (18) Dry eye is uncommon in paediatric age groups, and its pathophysiology is poorly understood. As a result, it is frequently ignored.(18) Neurotrophic keratitis (NK) is an uncommon degenerative corneal disorder caused by a partial or entire loss of trigeminal innervations, culminating in a reduced (hypoesthesia) or loss (anaesthesia) of corneal sensitivity. (19) Reduced corneal sensitivity eventually leads to decreased lacrimation reflex, corneal epithelial alterations, corneal ulceration, stromal scars, and neovascularisation. (19)

Exposure keratitis is an inflammation of the cornea resulting from the drying of the ocular surface, epithelial sloughing, and secondary infection when the cornea loses its protection from the eyelid and is exposed to air.(20) In children, eyelid defects predisposing patients to exposure keratitis include congenital lagophthalmos, congenital lid coloboma and eyelid defects from trauma.(21) Limbal stem cell deficiency (LCSD) results in epithelial breakdown and persistent inflammation.

Conjunctival ingrowth, vascularisation, and corneal scarring are all possible outcomes. (22) Aniridia, ectodermal dysplasia, chemical burns, stevens–johnson syndrome, severe contact lens overwear, many ocular operations (particularly when mitomycin c is used) and drug toxicity are prominent causes of LCSD.(18)

Xerophthalmia resulting from Vitamin A deficiency is a major cause of preventable childhood blindness in underdeveloped nations and its ocular manifestations may include corneal xerosis, keratomalacia and sterile corneal perforation.(23)

2.3.6 **Corneal injury**

Corneal injuries account for the greater majority of ocular cases encountered in emergency rooms, both among children and adults. (24) Corneal injuries can be divided into two types: traumatic and exposure-related. Corneal abrasion, corneal foreign body, corneal laceration and corneal perforation are all examples of traumatic injuries. (25)

Trauma can induce irreversible changes to the cornea's normal structure and physiology, which can lead to corneal fibrosis and visual impairment. (26) Chemical, thermal and radiation burns to the eye are examples of exposure-related injuries. Corneal damage in youngsters can lead to persistent amblyopia if it is not treated early. (27)

Table 1: Categories of corneal diseases

Corneal Disease Category	**Diagnosis**
Congenital corneal diseases	• Congenital corneal dystrophies • Epibulbar choristomas • Sclerocornea • CYPB1 mutation • Peters anomaly • Primary congenital glaucoma • Axenfeld-Rieger Syndrome • Congenital metabolic disorders of the cornea • Congenital toxoplasmosis infection • Congenital rubella infection • Congenital cytomegalovirus infection • Congenital herpes simplex infection • Congenital syphilis infection • Microcornea • Megalocornea • Cornea plana
Corneal dystrophies	• Epithelial basement membrane dystrophy • Epithelial recurrent erosion dystrophies • Franceschetti corneal dystrophy • Dystrophia smolandiensis • Dystrophia helsinglandica • Subepithelial mucinous corneal dystrophy • Meesmann corneal dystrophy • Lisch epithelial corneal dystrophy • Gelatinous drop-like corneal dystrophy • Reis-Bücklers corneal dystrophy • Thiel-Behnke corneal dystrophy • Lattice corneal dystrophy, type 1 • Granular corneal dystrophy, type 1

	• Granular corneal dystrophy, type 2 • Macular corneal dystrophy • Schnyder corneal dystrophy • Fleck corneal dystrophy • Posterior amorphous corneal dystrophy • Central cloudy dystrophy of François • Pre-Descemet corneal dystrophy • Fuchs endothelial corneal dystrophy
Ectatic corneal diseases	• Keratoconus • Keratoglobus
Allergic corneal diseases	• Atopic keratoconjunctivitis • Vernal keratoconjunctivitis
Infectious Corneal Diseases	• Infectious Keratitis • Unspecified microbial keratitis • Bacterial keratitis • Viral keratitis • Fungal keratitis • Ophthalmia neonatorum • Trachoma • Measles
Ocular surface diseases	• Dry eye • Exposure keratitis and eyelid disorders • Limbal stem cell deficiency (LCSD) • Vitamin A deficiency, Xerophthalmia
Corneal Injury	• Corneal abrasions • Corneal foreign body • Corneal laceration • Corneal perforation • Chemical injury • Thermal injury • Radiation injury

2.4 Prevalence and pattern of corneal diseases

Data on the prevalence and/or pattern of corneal disorders in children is scarce as only a handful of studies have been done to describe this. This could be due to the relatively lower prevalence of corneal diseases when compared to other eye diseases.(28)

Corneal illnesses were the leading cause of blindness and visual impairment in a study conducted by Ajaiyeoba et al on the frequency and causation of eye disorders among students in southwestern Nigeria. These were complications of vernal ulcers caused by keratoconus and bilateral corneal opacities.(5)

Onabolu et al did a study on corneal diseases in children in the Gambia from 2005 to 2006. This was a six-month prospective hospital-based research to determine the influence of the expanded vaccination and human resource development program on the causes and patterns of corneal eye disorders in children in The Gambia. From the study the most frequent corneal disease in children was corneal trauma at 32.4% of all cases, this was followed by vernal kerato-conjunctivitis at 22.54% of the cases. The third most prevalent corneal disease in children was congenital eye disease contributing to 16.9% of all cases. This was matched by corneal infections, also at 16.9%. Corneal scarring from unknown causes and corneal dystrophy/degenerations contributed to 7.04% and 0.02% of corneal diseases respectively. The major cause of monocular and binocular blindness were congenital diseases and trauma. The research concluded that congenital ocular deformity was the leading cause of bilateral corneal blindness in children in The Gambia, and that avoidable causes such as measles, ophthalmia neonatorum, and keratomalacia were no longer the leading causes of bilateral corneal blindness. In addition, the study found that adequate primary health care, as well as eye care, can mitigate the risk of corneal blindness in children. (6)

In 2014, Panjiyar et al. published research in Nepal that found the major cause of unilateral childhood blindness to be corneal disease. The study was a retrospective case series undertaken at an eastern tertiary eye hospital with the primary goal of studying the patterns of corneal illnesses in the pediatric outpatient department. (8) The frequency of isolated corneal illness was found to be 9.4% in the research. Keratitis and corneal ulcers were the most common diseases seen in patients with corneal pathology, accounting for 47.8% of the cases. Corneal trauma was found in 5.6% of patients while vitamin A insufficiency resulting in corneal opacity and keratomalacia was seen in 0.06% of cases. There was no evidence of trachoma or congenital corneal illness. The study

concluded that the majority of childhood corneal blindness was caused by avoidable and treatable causes.

Bella et al did a study in Cameroon where they examined the pattern of corneal diseases in children reviewed at Yaoundé Gynaeco-Obstetric and Paediatric Hospital. The study was conducted between 2002 and 2010 and showed the prevalence of cornel pathology to be 2.1%. Males were more impacted than females. The leading etiology of corneal disease was trauma at 48.2%. This was followed by infection at 28.0% of the cases. Visual impairment and blindness occurred in 50% of the cases with known follow-up data, with one instance being bilateral. The Bella et al study concluded that, despite the low frequency of corneal disease in children, the pathologies detected frequently resulted in poor visual prognosis. Major causes were identified as preventable and it was recommended that parents, paediatric health care providers, teachers and children be educated on ocular injury prevention. (7)

3 CHAPTER THREE: STUDY RATIONALE AND OBJECTIVES

3.1 Study rationale

The control of childhood blindness is a priority due to the high number of blind years it is associated with. Corneal diseases represent an important cause of childhood blindness in the developing world and their prevalence and pattern have been noted to be highly variable.

Kenyatta National Hospital eye clinic and the University of Nairobi Eye Centre receive a large number of paediatric age patients all year round. Understanding the prevalence and pattern of corneal diseases in these two centres will be instrumental in developing effective prevention and treatment modalities for paediatric corneal diseases.

The information gained from this study may also help to gauge the success of various preventative strategies for paediatric corneal diseases such as Vitamin A supplementation, measles vaccination and newborn eye care. The study may also provide guidance on appropriate resource mobilization and allocation to novel or neglected corneal diseases afflicting children.

3.2 Objectives

3.2.1 Broad objective

1. To determine the prevalence and pattern of corneal diseases in paediatric patients at Kenyatta National Hospital eye clinic and the University of Nairobi Eye Centre (Uni-Eye)

3.2.2 Specific objectives

1. To determine the prevalence of corneal disease in paediatric patients at Kenyatta National Hospital eye clinic and the University of Nairobi Eye Centre (Uni-Eye)
2. To describe the pattern of corneal diseases among paediatric patients at Kenyatta National Hospital eye clinic and The University of Nairobi Eye Centre (Uni-Eye).
3. To evaluate the effect of corneal diseases on visual acuity in paediatric patients at Kenyatta National Hospital eye clinic and the University of Nairobi Eye Centre (Uni-Eye)

4 CHAPTER FOUR: RESEARCH METHODS

4.1 Study design

The study was a retrospective case series involving the review of records at Kenyatta National Hospital eye clinic and the University of Nairobi Eye Centre (Uni-Eye) in the period between the 1st of January 2019 and the 31st of December 2019.

4.2 Study area

The study was conducted at two locations, the Kenyatta National Hospital eye clinic and the University of Nairobi Eye Centre (Uni-Eye), which were selected because of their close proximity, common pool of staff and the cross referral of patients between the two locations.

Kenyatta National Hospital is a national teaching and referral hospital which is about four kilometres from the Nairobi city centre. It facilitates research and medical education at the University of Nairobi, Kenya. (KNH Strategic plan, 2019-2023). The KNH eye clinic (Clinic 35) provides comprehensive eye care services from Monday to Friday. The University of Nairobi Eye Centre (Uni-Eye) is located at the University of Nairobi School of Dental Sciences compound along Arwings Kodhek Road, Nairobi. The centre was established by the Department of Ophthalmology, University of Nairobi and provides comprehensive eye care services from Monday to Friday.

4.3 Target population

The target population included paediatric patients managed for corneal diseases at Kenyatta National Hospital eye clinic and the University of Nairobi Eye Centre (Uni-Eye) in the period between the 1st of January 2019 and the 31st of December 2019. From this population, all the files of patients with corneal disease were extracted and subjected to the inclusion and exclusion criteria. The target population has been limited to 2019 since the COVID 19 pandemic could potentially create selection bias due to the possible altered health seeking behavior in 2020 and 2021.

4.4 Inclusion and exclusion criteria

4.4.1 Inclusion criteria

- All patients below 18 years of age and diagnosed with corneal diseases at KNH eye clinic and Uni-Eye in the year 2019.

4.4.2 Exclusion criteria

- Patients missing critical data such as age, sex and presenting visual acuity.
- Patients whose information is recorded on cards only.

4.5 Sample size determination

Fischer's formula was used to calculate the minimum required sample size.

Based on hospital records, a total of 2292 paediatric-age patients attended the KNH eye clinic in the year 2019.

A study done at a pediatric outpatient department of a hospital in the eastern region of Nepal to study the patterns of corneal diseases showed that isolated corneal diseases accounted for 9.4% of all cases seen.

$$n = \frac{z^2\ P(1-P)}{d^2}$$

$$n = \frac{1.96^2\ 0.094(1-0.094)}{0.047^2}$$

n = sample size

d = degree of precision 4.7%

z = z score 1.96 (95% confidence interval)

P = proportion = 0.094

The calculation gave a sample size of 148.1059404 rounded off to 148

Corrected for population size less than 10000

$$nf = \frac{n}{1 + (n/N)}$$

Where N = estimated population size =9.4 % of 2292 paediatric age patients seen at the KNH eye clinic in the year 2019= 215

nf= desired sample size of the target population less than 10,000

n = sample size

$$n_f = \frac{148}{1 + (148/2292)}$$

nf =87.6584022

nf = 88 children diagnosed with corneal diseases

Based on the sample size calculation above, a census of all patients seen in the year 2019 was projected to be able to achieve the minimal sample size of 88 children with corneal disease.

4.6 Study materials

A predesigned file abstraction tool was used to collect the data.

4.7 Sampling and recruitment

All files of paediatric patients seen at KNH eye clinic and the University of Nairobi Eye Centre (Uni-Eye) in the period between 1st of January 2019 and 31st of December 2019 and diagnosed to have corneal diseases were selected and exclusion was done appropriately.

4.8 Data collection procedure

Attendance records at KNH eye clinic and Uni-Eye were used to obtain file numbers of patients in the paediatric age range reviewed within the study period. This information was then used to retrieve the medical records of all pediatric patients who attended the two clinics with a diagnosis

of corneal disease using the ICD 10/11 codes. The exclusion criteria were applied at this stage and a list of all medical records meeting the inclusion criteria was created.

The medical records of the patients were used to obtain information on age, sex, residence, diagnosis, presenting visual acuity, presenting best corrected visual acuity, management and final best corrected visual acuity. The final best corrected visual acuity was presumed to be the findings recorded after 3 months from the date of presentation. All collected information relevant to the study was recorded in a predesigned file abstraction tool.

For the analysis of visual impairment, the International Classification of Diseases 11 (2018) classification system was used as described below.

Distance vision impairment:

- **Mild** –visual acuity worse than 6/12 to 6/18
- **Moderate** –visual acuity worse than 6/18 to 6/60
- **Severe** –visual acuity worse than 6/60 to 3/60
- **Blindness** –visual acuity worse than 3/60

For pre-school age and non–verbal children, the recorded visual acuity and best corrected visual acuity was compared to the normal age-appropriate visual acuity and graded by the principal investigator as either ‘no visual impairment’, or ‘with visual impairment’.
The diagnosis was grouped into the categories listed in appendix B.

4.9 Data management and analysis

4.9.1 Data cleaning and uploading

The data was uploaded into a spreadsheet software Excel 2019©. Data cleaning was thereafter done visually and statistically checking for missing data, outliers, inappropriate duplication and misclassification. The data collected was then coded and analysed using R software version 4.1.0.

4.9.2 Data Analysis

Descriptive analysis was done on the data as appropriate. Continuous variables were examined for normality in distribution using QQ plots and the Shapiro-Wilk Test. Measures of central tendency and dispersion were calculated depending on the normality of distribution. Categorical data was described using proportions after which the information was presented as summary statistics, tables and graphs. Sub-group descriptive analysis was done where applicable.

Inferential analysis was done to investigate the effect of corneal diseases on visual acuity in paediatric patients. Odds ratio was iteratively calculated for change in visual acuity (Improvement/ No improvement) against different diagnoses and management types. Simple logistic regression was done with visual acuity as the binary dependent variable against select independent variables like age, sex and type of management.

4.9.3 Data management and storage

The information was stored both as hard copies in the form of filled questionnaires as well as soft copies in a hard drive. The data was retained for the duration of the study period and will be retained for a further 5 years from the date of successful publication of the results.

4.9.4 Ethics Consideration

The Kenyatta National Hospital-University of Nairobi Ethics and Research Committee provided approval to conduct the study. Permission to use the patient's files was sought from the deputy director of clinical services and deputy director of health information, KNH.

The patient's file identity and details were kept anonymous at all times by the use of coded questionnaires.

No photographs of patients' files were taken. Data was stored in one computer and protected with a password to facilitate confidentiality.

5 RESULTS

5.1 Demographic characteristics

A total of 95 records were abstracted from the clinic records which totalled 776.The mean age was 7.5 years with a standard deviation of 5.6 years. The youngest patient was 1 week old while the oldest was 18 years old. The majority of patients (54.7%) were between 6 and 18 years old, with equal proportions of patients in the 6-13 and 13-18 age groups.

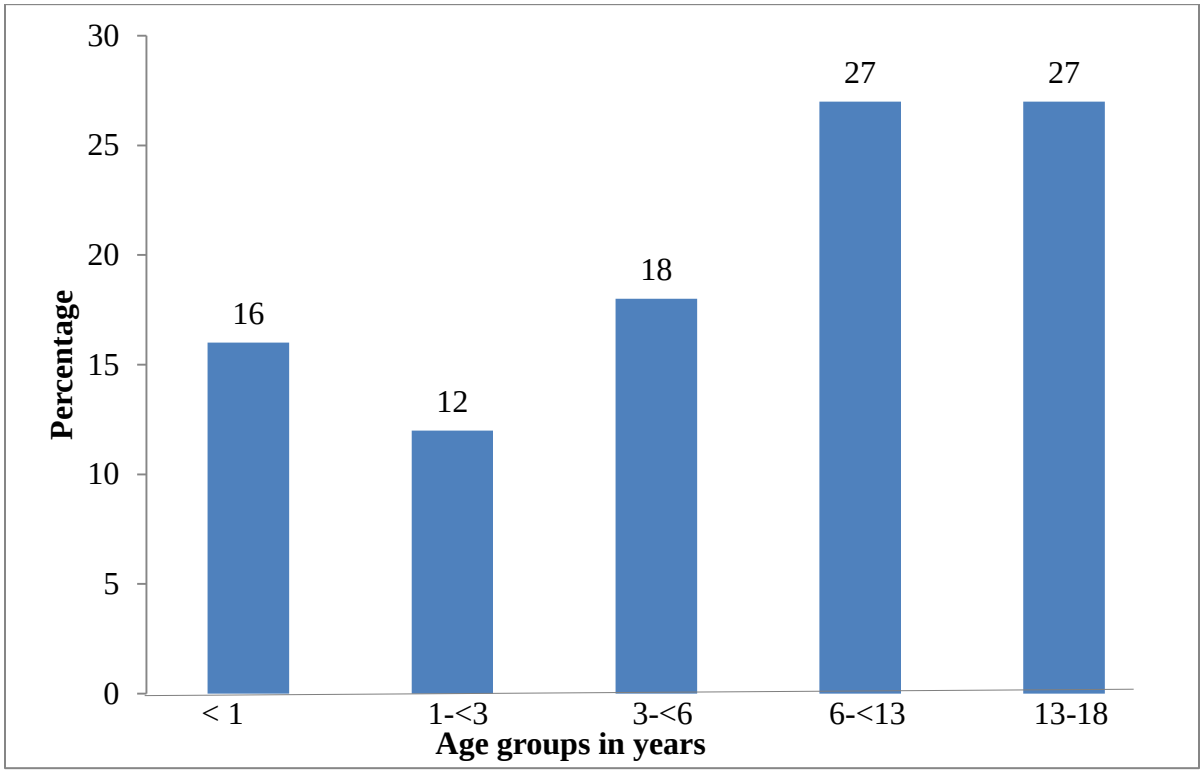


Figure 1 Bar chart: Distribution of paediatric patients with corneal disease by age (n=95)

In terms of sex, there were more male patients than female patients, with males comprising 61.1% of the sample. This difference was found to be statistically significant with a P-value of 0.03.

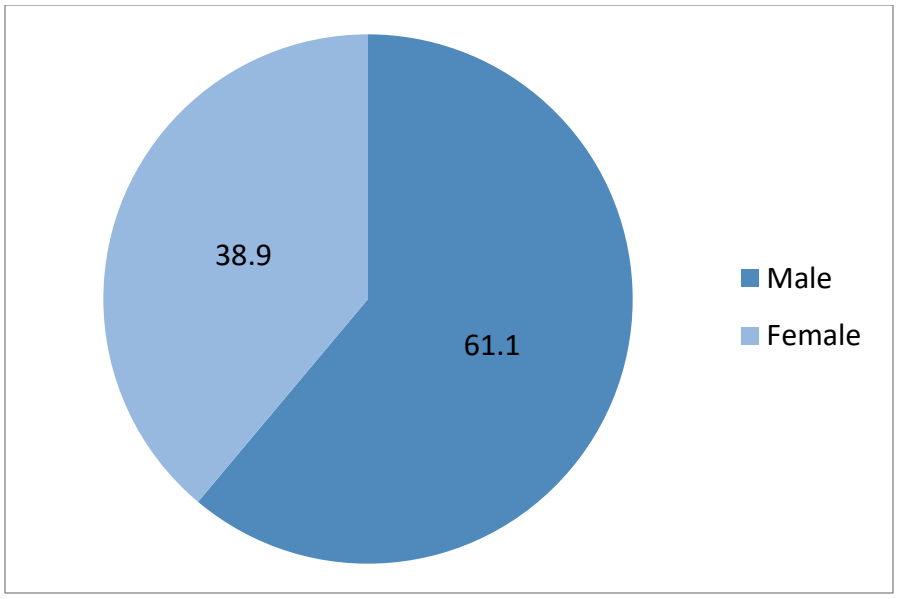


Figure 2 Pie Chart: Distribution of paediatric patients with corneal disease by sex (n=95)

The majority of patients (47.4%) seeking treatment for eye conditions were from Nairobi county, followed by Kiambu county (14.7%) and Kajiado county (12.6%). The remaining counties, including Kitui, Makueni, Machakos, Murang'a, Nakuru, Kirinyaga, Mandera, Nyeri and Homabay had less than 5% each. The proportion of patients with no recorded county was 8.4%

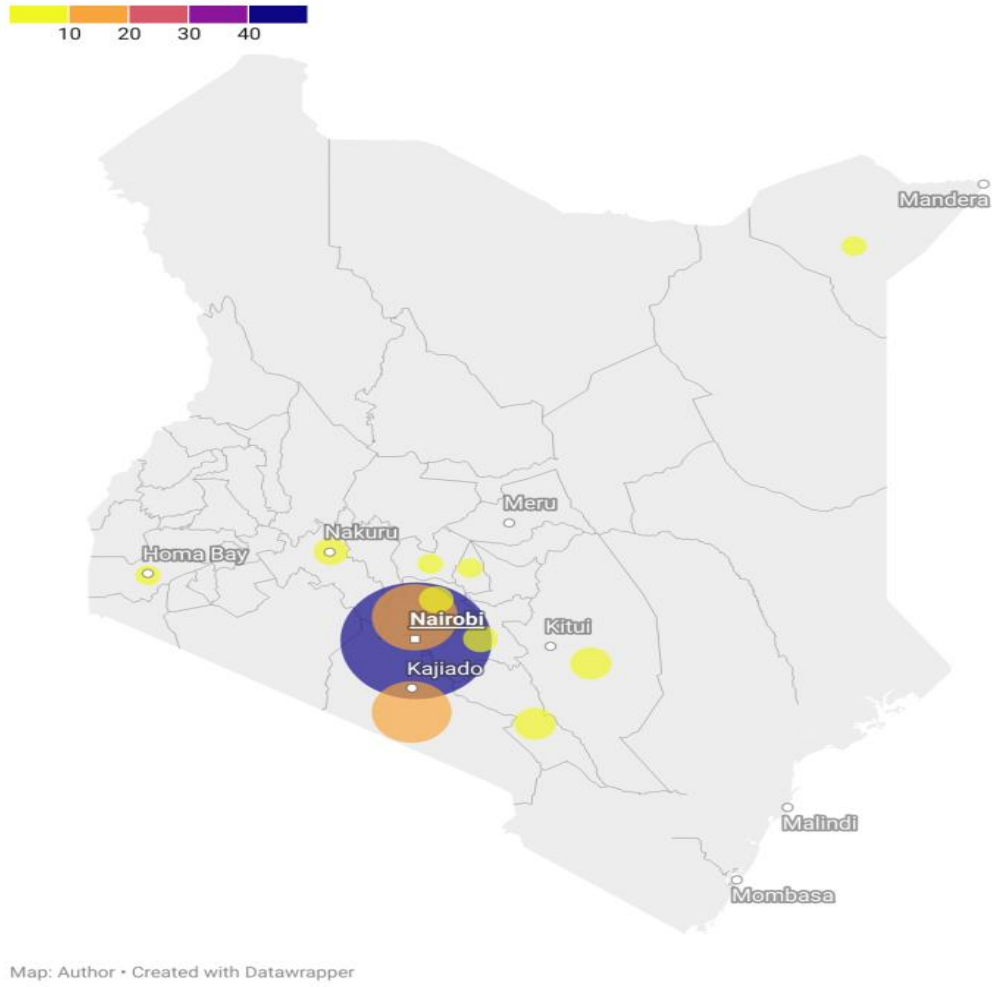


Figure 3 Distribution of paediatric patients with corneal disease by county of residence

5.2 Analysis of Corneal diseases- Spectrum

The analysis of the types of corneal diseases revealed 18 different types of corneal pathologies which were categorised into 6 aetiological classes as illustrated in the branch diagram below.

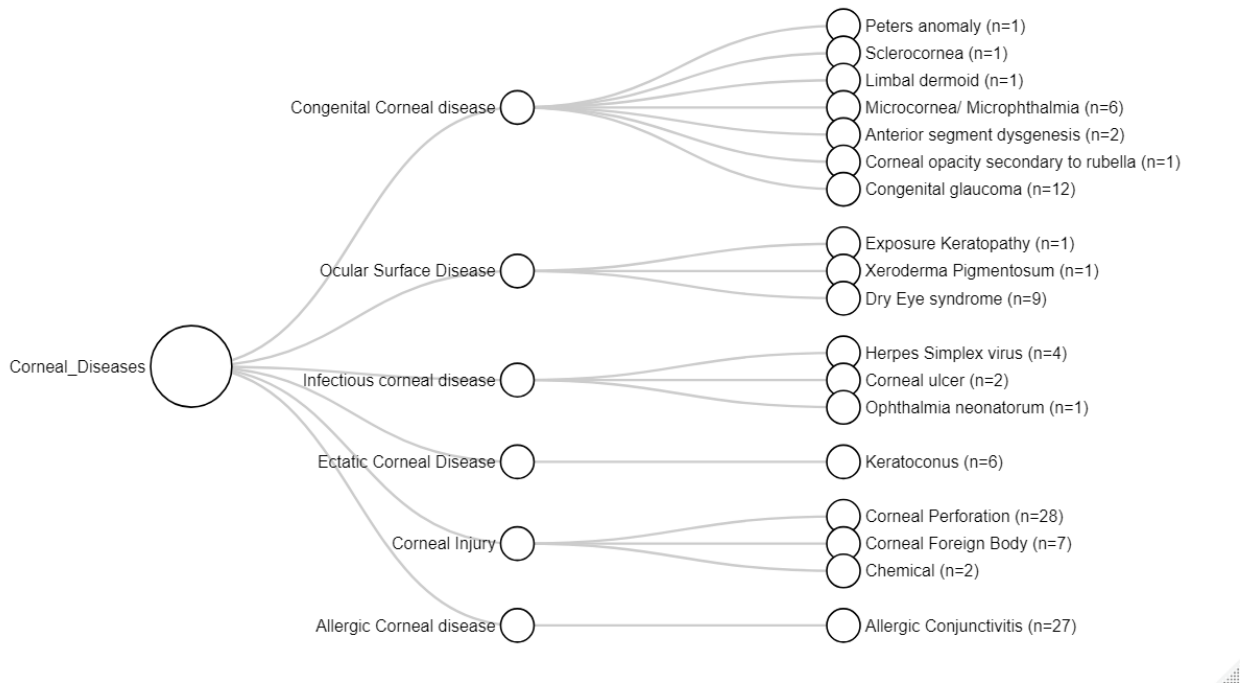


Figure 4 Dendrogram of the spectrum of corneal diseases

Congenital corneal diseases found in the study included congenital glaucoma, microcornea/ microphthalmia, anterior segment dysgenesis, sclerocornea, limbal dermoid, corneal opacity secondary to rubella, and Peters anomaly. Ocular surface disease found were dry eye syndrome, exposure keratopathy, and xeroderma pigmentosum. Infectious corneal diseases consisted of herpes keratitis, corneal ulcer, and ophthalmia neonatorum. Corneal injury found in the subjects was corneal perforation, corneal foreign body and chemical injury. The ectatic corneal disease seen was keratoconus while the allergic corneal disease encountered was allergic keratoconjunctivitis.

5.3 Analysis of Corneal diseases- Prevalence

The 3 most common disease classes were corneal injury (32 %), allergic corneal diseases (25%) and congenital corneal disease (19%) respectively. Ectatic corneal diseases accounted for the least proportion of patients with corneal disease at 5%.

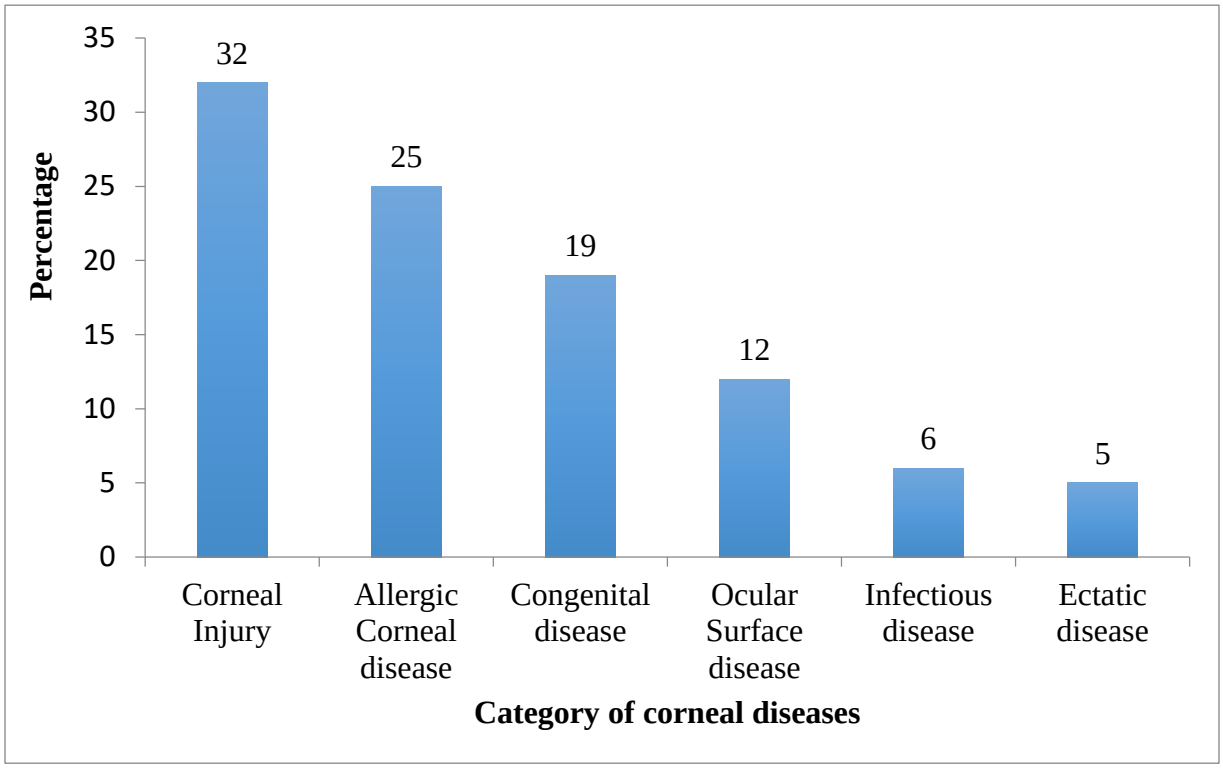


Figure 5 Bar chart: Corneal disease categories of paediatric patients with corneal disease

The prevalence of corneal diseases (total and specific) was obtained using the formula below:

$$Period\ prevalence\ of\ corneal\ diseases\ in\ peaditric\ population\ at\ UON/KNH\ in\ 2019$$

$$= \frac{No.of\ records\ with\ corneal\ disease\ at\ UON/KNH\ from\ Jan\ 2019 - Dec\ 2019 (n = 95)}{No.of\ paaediatric\ patients\ with\ inclusion\ criteria\ at\ UON/KNH\ \ from\ Jan\ 2019 - Dec\ 2019 (n = 776)}$$

Diseases with a prevalence above 30 cases per 1,000 population include congenital glaucoma, corneal perforation, and allergic keratoconjunctivitis. Corneal perforation (36.1/1000) had the highest prevalence followed by allergic conjunctivitis (34.8/1000) and then congenital glaucoma (15.5/1000). Diseases with a prevalence of 10-20 cases per 1,000 population included microcornea/microphthalmia, dry eye syndrome, herpes keratitis, and keratoconus.

Diseases with a prevalence of less than 10 cases per 1,000 population included anterior segment dysgenesis, sclerocornea, limbal dermoid, corneal opacity secondary to rubella, exposure keratopathy, xeroderma pigmentosum, and ophthalmia neonatorum.

Table 2 Prevalence of specific corneal diseases in paediatric patients. (n=776)

Category	Diagnosis	Number	Prevalence per 1000 cases
Congenital Corneal disease	Congenital glaucoma	12	15.5
	Microcornea/ Microphthalmia	6	7.7
	Anterior segment dysgenesis	2	2.6
	Sclerocornea	1	1.3
	Limbal dermoid	1	1.3
	Corneal opacity secondary to rubella	1	1.3
	Peters anomaly	1	1.3
Ocular Surface Disease	Dry Eye syndrome	9	11.6
	Exposure Keratopathy	1	1.3
	Xeroderma Pigmentosum	1	1.3
Infectious corneal disease	Herpes Keratitis	4	5.2
	Corneal ulcer	2	2.6
	Ophthalmia neonatorum	1	1.3
Ectatic Corneal Disease	Keratoconus	6	7.7
Corneal Injury	Corneal Perforation	28	36.1
	Corneal Foreign Body	7	9
	Chemical injury	2	2.6
Allergic Corneal disease	Allergic Keratoconjunctivitis	27	34.8

5.4 Analysis of Corneal diseases- Gender distribution

The study analysed the gender distribution of various diagnoses for corneal diseases. Among the analysed diagnoses, congenital glaucoma, corneal perforation, dry eye syndrome, keratoconus, and allergic keratoconjunctivitis had a higher prevalence in males. Congenital glaucoma had the

highest male prevalence, with 11 cases in males and only 1 case in females, resulting in an M:F ratio of 11:1.

Microcornea/microphthalmia, anterior segment dysgenesis, corneal ulcer, and corneal foreign body had similar prevalence in males and females. Herpes simplex virus had a higher prevalence in females, with 3 cases in females and only 1 case in males, resulting in an M:F ratio of 1:3. Chemical injury, corneal opacity secondary to rubella, exposure keratopathy, Peters anomaly, sclerocornea, and ophthalmia neonatorum had either all male or all female cases.

Table 3 Distribution by sex of specific corneal diseases in paediatric patients (n=113)

Diagnosis	Males	Females	M:F ratio
Congenital glaucoma	11	1	11:1
Corneal Perforation	19	9	2.1:1
Dry Eye syndrome	6	3	2:1
Keratoconus	4	2	2:1
Corneal Foreign Body	4	3	1.3:1
Anterior segment dysgenesis	1	1	1:1
Corneal ulcer	1	1	1:1
Allergic kerato-conjunctivitis	13	14	1:1.1
Microcornea/ Microphthalmia	3	4	1:1.3
Herpes Simplex virus	1	3	1:3
Chemical injury	2	0	m*
Corneal opacity secondary to rubella	0	1	f*
Exposure Keratopathy	1	0	m*
Peters anomaly	1	0	m*
Limbal dermoid	0	1	f*
Sclerocornea	1	0	m*

Ophthalmia neonatorum	1	0	m*
Xeroderma pigmentosum	0	1	f*
Total	69	44	1.6:1
m* - all male f* - all female			

5.5 Analysis of Corneal diseases- Laterality

The majority of corneal conditions were bilateral at 54% while unilateral corneal diseases accounted for 46%. The difference was not statistically significant with a p-value 0.44.

Corneal opacity secondary to rubella, exposure keratopathy, Peters anomaly, sclerocornea, ophthalmia neonatorum, xeroderma pigmentosum, keratoconus, and dry eye syndrome were 100% bilateral. Allergic keratoconjunctivitis had 96% bilateral cases and 4% unilateral cases. Congenital glaucoma had 83.3% bilateral cases and 16.7% unilateral cases. Microcornea/microphthalmia had 57.1% bilateral cases and 42.9% unilateral cases. Chemical injury had a 50% bilateral and 50% unilateral cases. Herpes simplex keratitis, corneal ulcer, corneal perforation, corneal foreign body, and limbal dermoid were 100% unilateral.

Table 4 Distribution by laterality of specific corneal diseases in paediatric patients (n=113)

Corneal disease	Percentage Bilateral	Percentage Unilateral
Corneal opacity secondary to rubella*, Exposure Keratopathy*, Peters anomaly*, Sclerocornea*, Ophthalmia neonatorum*, Xeroderma pigmentosum*, Keratoconus, Dry Eye syndrome	100	0
Allergic Keratoconjunctivitis	96	4
Congenital glaucoma	83.3	16.7
Microcornea/ Microphthalmia	57.1	42.9
Chemical injury	50	50
Herpes Simplex keratitis, Corneal ulcer, Corneal Perforation, Corneal Foreign Body, Limbal dermoid*	0	100
* Conditions with 1 patient		

5.6 Analysis of Corneal diseases- Comorbidities and complications

Traumatic cataract had the highest number with 14 cases, representing 14.7% of the cases analyzed. Phthisis had 6 cases, representing 6.3% of the cases analyzed. Uveal prolapse had 5

cases, representing 5.3% of the cases analyzed. Endophthalmitis had 2 cases, representing 2.1% of the cases analyzed. Scleral laceration, angle closure glaucoma, anophthalmic socket, hyphema, hypopyon, painful blind eye, trichiasis, uveitis, and vitreous hemorrhage had 1 case each, representing 1.1% of the cases analyzed. It is important to note that trauma-related conditions, including traumatic cataract, phthisis, uveal prolapse, and endophthalmitis, accounted for the majority of the comorbidities/complications observed in the analyzed cases.

Table 5 Prevalence of comorbidities/ complications in paediatric patients (n=95)

Diagnosis	Number	Percentage
Traumatic Cataract*	14	14.7
Phthisis*	6	6.3
Uveal prolapse*	5	5.3
Endophthalmitis*	2	2.1
Scleral Laceration*, Angle Closure Glaucoma*, Anophthalmic socket**, Hyphaema*, Hypopyon*, Painful blind eye, Trichiasis, Uveitis*, Vitreous Haemorrhage*	1	1.1
* Trauma related ** Contralateral eye		

5.7 Analysis of Corneal diseases- Visual impairment preverbal children at presentation and 3 months

Visual impairment in preverbal children was analysed at presentation and at 3 months. There was a paradoxical increase in the level of visual impairment in some of the categories. This may be attributed to selection bias where those with improved visual acuity would miss the 3-month follow-up due to self-discharge and other factors while those with persistent visual impairment would remain in the clinic.

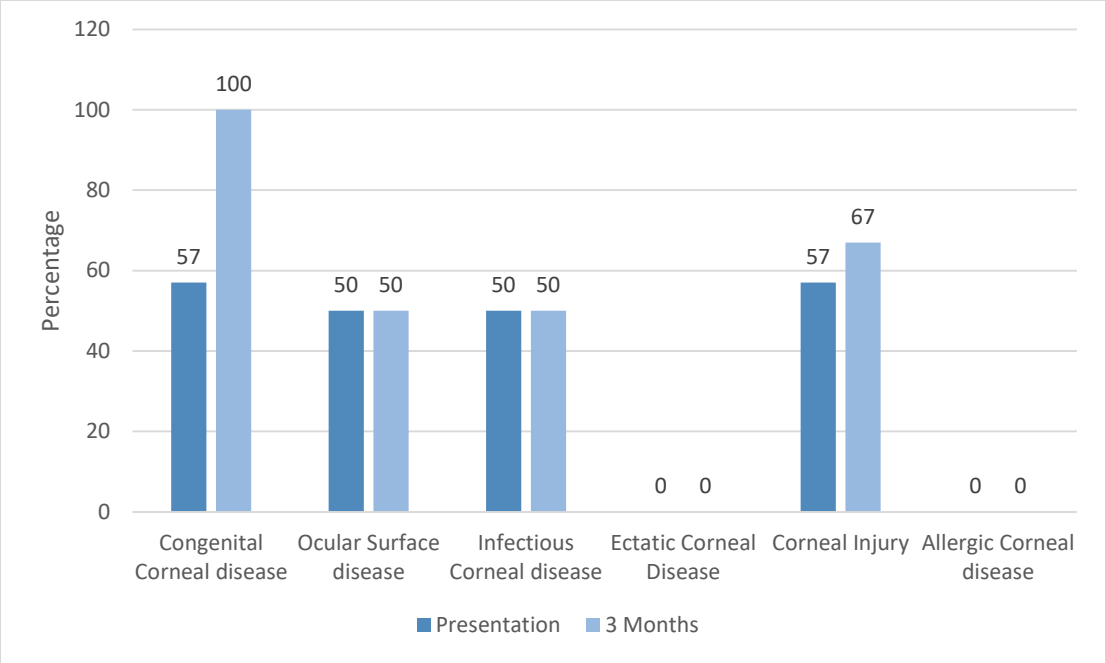


Figure 6 Percentage of visual impairment in preverbal children at presentation and at 3 months

At presentation, 57% of patients with Congenital Corneal disease had visual impairment, while at 3 months, this percentage increased to 100%. For Ocular Surface disease and Infectious Corneal disease, the percentage of visual impairment was 50% at both presentation and 3 months. Patients with Ectatic Corneal Disease had 0% visual impairment both at presentation and 3 months. The percentage of visual impairment in patients with Corneal Injury increased from 57% at presentation to 67% at 3 months. There was no visual impairment reported in patients with Allergic Corneal disease at both presentation and 3 months.

5.8 Analysis of Corneal diseases- Visual impairment postverbal children at presentation and 3 months

This analysis examined the percentage of visual impairment (normal, mild, moderate, severe, and blind) at presentation and at 3 months for different types of corneal diseases in post-verbal children based on ICD11 classification.

Table 6 Percentage of post verbal children with visual impairment at presentation and 3 months

	Post Verbal- ICD11 Classification									
		No VI		Mild VI		Moderate VI		Severe VI		Blind	
		Presentation	3 Months	Presentation	3 Months	Presentation	3 Months	Presentation	3 Months	Presentation	3 Months
Congenital Corneal disease (%		25	17	12.5	17	12.5	33	0	0	50	33
Ocular Surface disease(%)		59	100	18	0	14	0	0	0	9	0
Infectious Corneal disease(%)		33	50	33	25	0	0	0	0	33	25
Ectatic Corneal Disease(%)		0	67	31	0	54	17	0	0	15	17
Corneal Injury(%)		18	19	14	38	5	10	0	0	64	33
Allergic Corneal disease(%)		57	95	25	0	17	5	0	0	2	0

At presentation, 25% of children with congenital corneal disease had no visual impairment, which decreased to 17% at 3 months, while the percentage of children who were blind decreased from 50% to 33%. For ocular surface disease, 59% of children had no visual impairment at presentation, which increased to 100% at 3 months, and there was overall reduction in mild, moderate, severe, or blind categories.

In infectious corneal disease, the percentage of children with mild visual impairment decreased from 33% at presentation to 25% at 3 months, and the percentage of those who were blind increased from 33% to 25%. For ectatic corneal disease, there was a significant improvement in visual impairment, with the percentage of children with no visual impairment increasing from 0% at presentation to 67% at 3 months. The percentage of children who were blind increased slightly from 15% to 17%.

For corneal injury, there was a slight improvement in the percentage of children with no visual impairment, from 18% at presentation to 19% at 3 months. The percentage of children who were blind decreased from 64% to 33%. Finally, for allergic corneal disease, the percentage of children with no visual impairment increased from 57% at presentation to 95% at 3 months, and there was overall reduction in mild, moderate, severe, or blind categories.

5.9 Analysis of Corneal diseases- Association between visual impairment and diseases types

Odds ratios were calculated to test for the association between visual impairment and the different types of corneal diseases in preverbal children using quantitative methods of visual acuity and post-verbal children classified according to ICD 11(2018). The odds ratio for congenital corneal disease was 2.7 (95% CI: 0.9 - 8.1, p=0.07) for preverbal children and 3.04 (95% CI: 0.59-15.59, p=0.18) for post-verbal children.

For ocular surface disease, the odds ratio was 1.3 (95% CI: 0.17-9.9, p=0.80) for preverbal children and 0.62 (95% CI: 0.25-1.56, p=0.30) for post-verbal children. For infectious corneal disease, the odds ratio was 0.38 (95% CI: 0.07-2.1, p=0.26) for preverbal children and 0.47 (95% CI: 0.08-2.63, p=0.39) for post-verbal children.

The odds ratio for ectatic corneal disease was not applicable (NA) as there were no cases in the quantitative methods group. For corneal injury, the odds ratio was 0.57 (95% CI: 0.15-2.17, p=0.41) for preverbal children and 0.83 (95% CI: 0.41-1.67, p=0.60) for post-verbal children. The odds ratio was not applicable (NA) for allergic corneal disease in preverbal children and 0.66 (95% CI: 0.33-1.29, p=0.23) in post-verbal children.

Table 7 Odds ratio of visual impairment in the different categories of corneal disease

	Preverbal children- Quantitative methods of visual acuity			**Post verbal children ICD 11(2018) Classification**		
	Odds ratio	95% CI	P-value	Odds ratio	95% CI	P-value

Congenital Corneal disease	2.7	0.9 - 8.1	0.07	3.04	0.59-15.59	0.18
Ocular Surface disease	1.3	0.17-9.9	0.80	0.62	0.25-1.56	0.30
Infectious Corneal disease	0.38	0.07-2.1	0.26	0.47	0.08-2.63	0.39
Ectatic Corneal Disease	NA			NA		
Corneal Injury	0.57	0.15-2.17	0.41	0.83	0.41-1.67	0.60
Allergic Corneal disease	NA			0.66	0.33-1.29	0.23

5.10 Analysis of Corneal diseases- Blindness at presentation and 3 months

Descriptive analysis was done on the number and percentage of blind eyes at presentation and at 3 months follow-up for different types of corneal diseases. At presentation, the highest percentage of blind eyes was observed in cases of corneal injury (58.3%), followed by congenital corneal disease (16.7%), and ocular surface disease (8.3%).

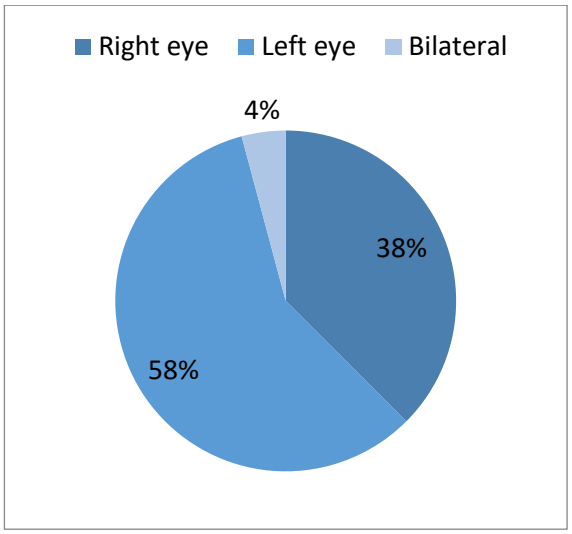
At 3 months follow-up, the highest percentage of blind eyes was observed in cases of corneal injury (63.6%), followed by congenital corneal disease (18.2%), ectatic corneal disease (9.1%), and infectious corneal disease (9.1%). Allergic corneal disease had only one blind eye at presentation and no blind eyes at 3 months follow-up. Overall, the total number of blind eyes decreased from 24 at presentation to 11 at 3 months follow-up.

Table 8 Causes of blindness by corneal disease category at presentation and at 3 months

	At presentation (n=24 blind eyes)		At 3 months (n=11 blind eyes)	
	Number	Percentage	Number	Percentage
Corneal Injury	14	58.3	7	63.6
Congenital Corneal disease	4	16.7	2	18.2
Ocular Surface disease	2	8.3	0	0
Ectatic Corneal Disease	2	8.3	1	9.1
Infectious Corneal disease	1	4.2	1	9.1
Allergic Corneal disease	1	4.2	0	0
Total	24	100	11	100

At presentation, the majority of blind cases were unilateral at 96% with 58% involving the right eye and 38% involving the left eye. Only 4% of the blind cases were binocular. At 3 months, 100% of blind eyes were unilateral with no case recorded of binocular blindness.

Presentation



3 Months

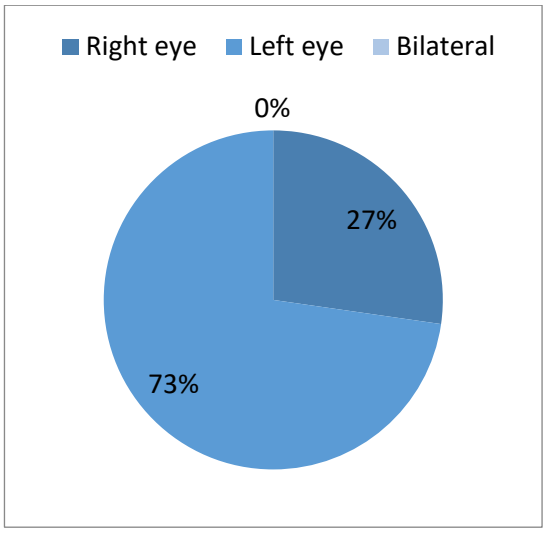


Figure 7 Pie chart showing laterality of blindness at presentation and at 3 months in paediatric patients

Analysis was done to check for the association between corneal disease types and blindness in post-verbal children based on ICD 11(2018) classification. Congenital corneal disease had an odds ratio of 5.04 (95% CI: 1.17-21.57, p=0.03) for blindness compared to no blindness. Corneal injury had an odds ratio of 4.07 (95% CI: 1.64-10.06, p=0.002) for blindness compared to no blindness. Infectious corneal disease, ectatic corneal disease, and ocular surface disease did not have significant odds ratios for blindness. Allergic corneal disease had a low odds ratio of 0.06 (95% CI: 0.01-0.45, p=0.006) for blindness compared to no blindness, indicating a lower likelihood of blindness in this condition.

Table 9 Odds ratio of blindness at presentation in the different categories of corneal disease

	Post verbal children ICD 11(2018) Classification

	Blind	No blindness	Odds ratio	95% CI	P value
Congenital Corneal disease	4	4	5.04	1.17-21.57	0.03
Corneal Injury	14	32	4.07	1.64-10.06	0.002
Infectious Corneal disease	1	5	1.04	0.12-9.35	0.97
Ectatic Corneal Disease	2	11	0.94	0.19-4.55	0.94
Ocular Surface disease	2	20	0.47	0.11-2.19	0.34
Allergic Corneal disease	1	53	0.06	0.01-0.45	0.006

Odds ratios were calculated to test for any association between uniocular blindness and the different types of corneal diseases. Patients with congenital corneal disease had the highest odds ratio for blindness at presentation (5.04) and this was statistically significant with a p value of 0.03.

Patients diagnosed with corneal injury at presentation had an odds ratio of 4.07 for uniocular blindness and this was also statistically significant with a p value of 0.002.

5.11 Analysis of Corneal diseases- Management modalities

There was significant overlap in the management modalities with the majority of patients being treated medically at 86.3 % followed by surgical management at 47.4%. Protective eyewear accounted the least in management modalities.

There were 7 referrals of whom 3 were referred for corneal crosslinking, 3 for low vision rehabilitation and 1 for scleral fixated intraocular lens (IOL).

Table 10 Management of corneal diseases in paediatric patients (n= 95)

Management	Count	Percentage
Medical	82	86.3
Surgical	45	47.4
Spectacle correction	9	9.5
Referral	7	7.37
Supportive management	2	2.13
Protective eyewear	1	1.1

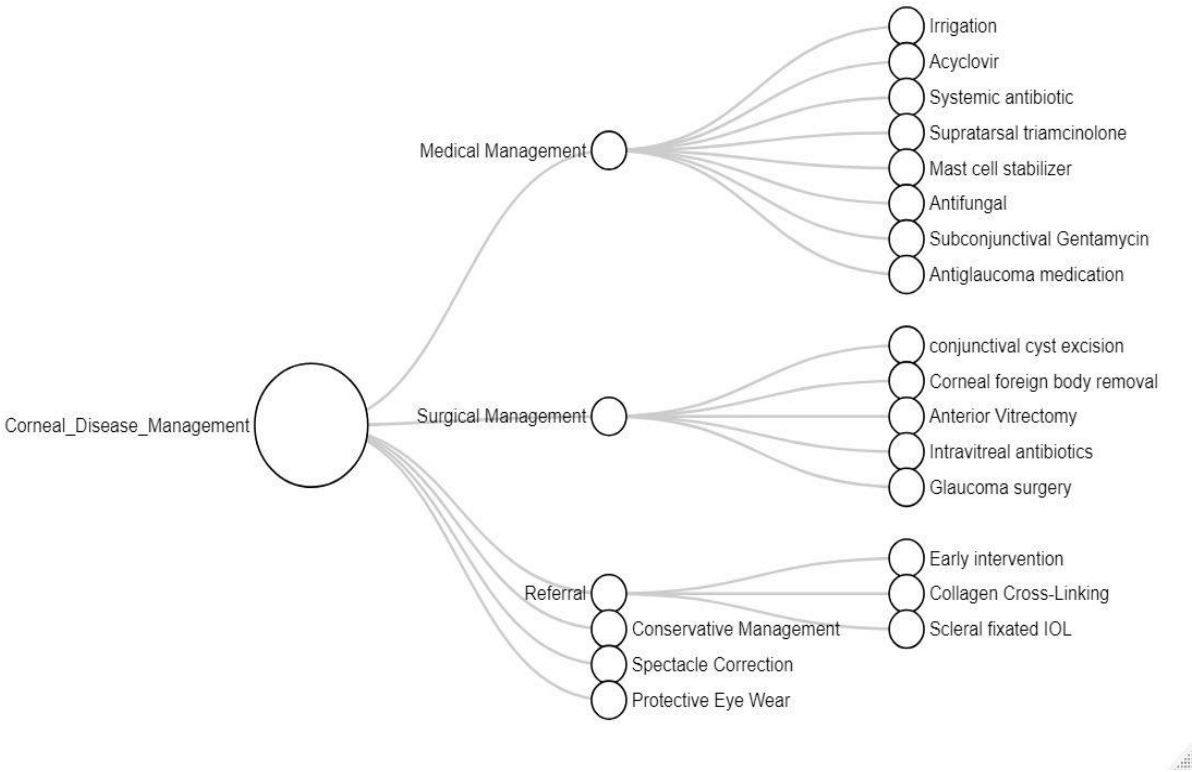


Figure 8 Dendrogram of the management of paediatric patients with corneal diseases

6 DISCUSSION

The prevalence of corneal diseases amongst paediatric patients at KNH eye clinic and Uni-eye centre in 2019 was 12.2 %. This figure is approximate to the study by Panjiyar et al where the prevalence of corneal diseases amongst paediatric patients in a tertiary eye hospital in Nepal was 9.4% (8). This was however in contrast to the study by Bella et al in Cameroon and the study by Onabolu et al in The Gambia which showed a prevalence of 2.1% and 42% respectively. (29) (6) This marked variation could be the result of differences in the inclusion criteria applied. In addition, the role of regional variations in the prevalence of corneal disease cannot be ruled out.

The mean age of the patients in our study was 7.5 years which was comparable to the study by Bella et al in Cameroon which had a mean age of 7.1 years. (7) School-going children and adolescents bore the majority of corneal diseases with the two age groups each accounting for 27.4% of the cases. This is in contrast to the study by Bella et al in Cameroon where the age groups 0-5 years and 6-10 years were the most represented at 38.7% each.

With regard to distribution by sex, a larger proportion of paediatric patients with corneal disease were male at 61%. This finding is consistent with studies by Panjiyar et al, Bella et al and Onabolu et al. (8)(4)(6) This finding can be explained by the high frequency of corneal injury recorded at 32 % and the fact that boys accounted for the larger proportion of these cases at 67.9%. Male children are likely at a higher risk for corneal injury as a direct consequence of a more aggressive style of play.

With respect to the residence of the patients, the majority of patients from any single county were from Nairobi County at 47.4%. A comparable proportion of patients (44.2%) however hailed from counties outside Nairobi which underpins the role of Kenyatta National Hospital and by extension the KNH eye clinic as a national referral centre.

In terms of the pattern of corneal disease categories, this study found corneal injury and allergic corneal diseases to be the most frequent at 32% and 25% respectively. This is in keeping with the study by Onabolu et al in the Gambia where corneal trauma and vernal keratoconjunctivitis accounted for 32.4% and 22.54% of the corneal diseases in children respectively. (6)

The high proportion of patients with corneal injury may be due to the fact that Kenyatta National Hospital receives a large number of corneal trauma cases with 45.7 % of the cases being referrals from outside Nairobi County. This finding may be indicative of the lack of adequate ophthalmic surgical services in other counties outside Nairobi. Inadequate surgical consumables and/or ophthalmic surgical equipment could also play a role.

Compared to other studies, the prevalence of infectious corneal diseases was relatively low at 6% of the cases. In a study by Ajayi et al on the pattern of corneal disorders in Nigeria, infectious disorders accounted for 27.7% of corneal disorders in children while in the study by Panjiyar et al in Nepal, keratitis and corneal ulcer accounted for 47.8 % of the cases. (30)(31)
Infectious corneal diseases and in particular fungal keratitis have been shown to be more frequent in areas with hot and humid climates as well as in agrarian communities.(32) (33) The paucity of these cases in our study could stem from the fact that the catchment area of Nairobi has a subtropical temperate climate and is largely urban.

For specific diagnoses, corneal perforation was noted to be the most prevalent followed by allergic keratoconjunctivitis and congenital glaucoma. The preponderance of corneal perforation is in keeping with the studies by Bella et al in Cameroon and Onabolu et al in the Gambia which both found corneal trauma to be the predominant cause of corneal pathology. (7)(6)

It is notable from this study that no cases of vitamin A deficiency causing xerophthalmia were recorded. This is in contrast to the study by Panjiyar et al in Nepal where 11 cases of corneal opacity secondary to xerophthalmia were identified in the year 2014. The absence of this condition in our study could be indicative of the relative success of the Kenya Expanded Programme on Immunization and the Malezi Bora campaign in increasing the coverage of measles immunization and Vitamin A supplementation in children. (34)Moreover, only one case of ophthalmia neonatorum and congenital opacity secondary to rubella was recorded in the two centres in 2019. This low prevalence could be evidence of increased coverage of maternal and child health services compared to previous years. (35)

Congenital glaucoma was the most common diagnosis in infants (under 1 year) which is comparable to the study by Onabolu et al in The Gambia which found congenital glaucoma and anterior segment dysgenesis to be the most prevalent conditions in children with congenital corneal

disease. (6) The fact that Uni-Eye centre has a regular glaucoma speciality clinic that receives referrals could explain the high proportion of congenital glaucoma cases in this age group.

In the study by Bella et al in Cameroon, the highest prevalence of corneal trauma was amongst children aged 6-10 years while infection was more frequently seen in those aged 0-5years. (7) This is in contrast to our study where corneal perforation afflicted the majority of toddlers (1-< 3 years) and preschoolers (3-< 6 years) at 58.3 % and 46.1 % respectively. The high prevalence of corneal perforation in toddlers and preschoolers could be a result of increased outdoor activity and unsupervised play.

Among school-going children and adolescents, the most frequent diagnosis was allergic keratoconjunctivitis which is consistent with a study by Behera et al which examined the prevalence of allergic conjunctivitis and associated comorbidities among school-going children in Western Odisha, India. (36)

For specific corneal diseases, congenital glaucoma had a notable male preponderance with a male-to-female ratio of 11:1. A study by Sitoula et al on primary congenital glaucoma in a tertiary care hospital in Nepal found the male-to-female ratio to be 2:1. (37) The significantly higher male-to-female ratio in our study may portend a variance in health seeking behaviour amongst caregivers of male and female children.

In terms of laterality, 54% of the corneal diseases were bilateral while 46% were unilateral, this is in contrast to the study by Bella et al in Cameroon where corneal pathology was found to be unilateral in 86.3% of cases and bilateral in 13.7%. For specific corneal diseases, this study found herpes simplex keratitis, corneal ulcer, corneal perforation, limbal dermoid and corneal foreign body to be largely unilateral conditions while dry eye syndrome, keratoconus, corneal opacity secondary to rubella, sclerocornea, peters anomaly and xeroderma pigmentosum all had bilateral involvement. This had an impact on the degree of visual impairment with the patients having peters anomaly, sclerocornea and corneal opacity secondary to rubella all having significant binocular visual impairment and the one patient with xeroderma pigmentosum having binocular blindness.

The pattern of comorbidities or complications reflected the high frequency of corneal injury with the majority of them being trauma related. Traumatic cataract was the major comorbidity noted

amongst patients with corneal perforation which explains why cataract surgery was the most common intervention in this subset of patients.

With regard to visual impairment, 59% of patients who had their visual acuity recorded had some degree of visual impairment at presentation compared to 48% at 3 months. The majority of patients with visual impairment both at presentation and at 3 months were in the postverbal age group.
From the calculated odds ratios, congenital corneal disease and ocular surface disease were more likely to cause visual impairment compared with other corneal diseases. The relationship was however not statistically significant relationship based on a 95% confidence level.
It is likely that late presentation in the case of congenital glaucoma as well as the bilateral involvement of peters anomaly, sclerocornea and corneal opacity secondary to rubella may have played a role in their poor visual prognoses.

Corneal injury and congenital corneal disease were the most frequent aetiologies of blindness both at presentation and at 3 months. The two corneal disease categories also had the highest odds ratio for blindness at presentation. This is in contrast to a study by Wang et al on the prevalence and causes of corneal blindness in a rural northern Chinese population which found keratitis to be the most blinding corneal pathology in childhood. (38) Our findings are however consistent with the study by Onabolu et al in the Gambia which found congenital corneal disease and corneal trauma to be the major causes of bilateral and unilateral blindness respectively. (6)

In terms of laterality, the majority of blind cases were uniocular both at presentation and at 3 months. In the study by Onabolu et al in the Gambia, the majority of blind eyes were also unilateral at 30.98% of the children compared to 14.08% for bilateral cases. (6) The significance of this finding is that the majority of patients with blind eyes were not functionally impaired when the better eye was considered. Monocular blindness is however associated with a limited visual field, reduced stereopsis and an overall lower quality of life score compared to visually unimpaired persons. (39) Patients with monocular blindness may also be at a higher risk of ocular injuries in the contralateral eye.

In terms of management, the most frequent management modality was medical management followed by surgical management and spectacle correction. The least prescribed management modality was protective eyewear with only 1 patient being recommended this treatment.

This may have been an omission considering the large proportion of patients with monocular blindness.

It was notable that 7 patients were referred, 3 for corneal cross-linking, 3 for low vision rehabilitation and 1 for scleral fixated IOL. The lack of these services and in the case of scleral fixated IOL, the unavailability of the IOL in both centres could have resulted in this.

7 STUDY LIMITATIONS

As this was a review of records, there was as expected missing data especially on visual acuity. The proportion of missed data was more than 75% in some study variables and hence analysis could not be done without introducing a form of bias. This was seen with best corrected visual acuity and as a result the effect of refractive error could not be assessed.

The reduced number of 3-month visual acuity evaluation had the potential of introducing bias in either direction. There was no clear outcome for the missing records.

The type of visual acuity testing was also in many instances not age-appropriate especially in toddlers and preschoolers which complicated the grading of visual impairment.

8 CONCLUSION

1. The prevalence of corneal diseases in KNH eye clinic and Uni Eye centre in 2019 was 12.2 % with a male preponderance.
2. Corneal injury was the most prevalent corneal disease category.

3. In terms of specific diagnosis, corneal perforation was the most prevalent corneal diagnosis and represented the most common diagnosis amongst toddlers and preschoolers while allergic keratoconjunctivitis was most prevalent among school-age children and adolescents
4. Congenital corneal diseases had the highest positive association with any degree of visual impairment but this was not statistically significant and corneal injury was the most frequent cause of monocular blindness
5. A small proportion of patients (7.3%) were referred for either corneal cross-linking, low vision rehabilitation or scleral fixated intraocular lens.

9 RECOMMENDATIONS

1. County hospitals should endeavour to provide adequate ophthalmic surgical services in order to reduce the high referral rate of corneal trauma cases.
2. Further studies needed to investigate the contributory causes of the corneal diseases with high prevalence.
3. Age-appropriate visual acuity testing methods should be emphasized among clinicians and allied staff.
4. Better record-taking and documentation should be practiced among clinicians with better outcomes documentation for those lost to follow up at 3 months.
5. Steps should be made to avail corneal cross-linking, corneal transplant and low vision rehabilitation services at Kenyatta National Hospital.

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11 APPENDIX

11.1 Budget

Item	Unit price	Quantity		Total cost (ksh)
Proposal/Ethical approval				
Proposal printing (Before ERC Corrections)	10	33 pages (3 copies)		990
Binding of first proposal	100	3 copies		300

Ethics proposal cost				2000
Proposal Printing (After ERC Corrections)	10	33 pages (3 copies)		990
Binding of second proposal	100	3 copies		300
Internet Costs				10000
			Subtotal	**14,580**
Collection of data				
HP Laptop	1	45000		45000
Questionnaire printing	10	2 pages (88)		1,760
Stationery (Pens)	10	20		400
Box file for questionnaires	400	1		400
Flash disc (16gb)	2000	1		2000
KNH research permission letter				1500
KNH records -Access to files fee				1500
			Subtotal	**52,560**
Contracted services				
Records retrieval (Records clerk-KNH)	20	2292 files		45,840
Statistician				40,000
Data entry clerk (Excel)				20,000
			Subtotal	**105,840**
Dissemination				
Printing of final book	10	(Approximately 60 pages) 3 copies		1,800
Binding of finished book	500	7 copies		3,500
			Subtotal	**5,300**
			Total	**178,280**

11.2 Data abstraction tool

Biodata

CODE…… Age.…… Sex: Male ☐ Female ☐ Residence…….....

Diagnosis

Diagnosis	**Category**	**Laterality (BE, RE, LE)**

1.	Congenital corneal diseases	
2.	Infectious corneal diseases	
3.	Corneal dystrophies	
4.	Corneal degenerations	
5.	Ectatic corneal diseases	
6.	Allergic corneal diseases	
7.	Ocular surface diseases	
8.	Corneal Injuries	
9.	Others	

Visual Acuity

	RE	**LE**	**Degree of visual impairment**
Presenting visual acuity			

Presenting best corrected visual acuity			
Final best corrected visual acuity (At 3 months)			

Management

Management modality	**Tick as appropriate**	**Description**
Supportive management		
Spectacle correction		
Medical management		
Surgical management		
Referral		

Comments-

Collected by- **Date**

11.3 Classification of corneal diseases

1. Congenital corneal diseases

- Congenital corneal dystrophies
- Epibulbar choristomas
- Sclerocornea

- CYPB1 mutation
- Peters anomaly
- Primary congenital glaucoma
- Axenfeld-Rieger Syndrome
- Congenital metabolic disorders of the cornea
- Congenital Toxoplasmosis infection
- Congenital Rubella infection
- Congenital cytomegalovirus infection
- Congenital herpes simplex infection
- Congenital syphilis infection
- Microcornea
- Megalocornea
- Cornea plana

2. Infectious corneal diseases

- Infectious Keratitis
- Unspecified microbial keratitis
- Bacterial Keratitis
- Viral keratitis
- Fungal keratitis
- Ophthalmia neonatorum
- Trachoma
- Measles

3. Corneal dystrophies

- Epithelial basement membrane dystrophy
- Epithelial recurrent erosion dystrophies
- Franceschetti corneal dystrophy
- Dystrophia smolandiensis
- Dystrophia helsinglandica
- Subepithelial mucinous corneal dystrophy
- Meesmann corneal dystrophy
- Lisch epithelial corneal dystrophy
- Gelatinous drop-like corneal dystrophy
- Reis-Bücklers corneal dystrophy
- Thiel-Behnke corneal dystrophy

- Lattice corneal dystrophy, type 1
- Granular corneal dystrophy, type 1
- Granular corneal dystrophy, type 2
- Macular corneal dystrophy
- Schnyder corneal dystrophy
- Fleck corneal dystrophy
- Posterior amorphous corneal dystrophy
- Central cloudy dystrophy of François
- Pre-Descemet corneal dystrophy
- Fuchs endothelial corneal dystrophy

4. Ectatic corneal diseases

- Keratoconus
- Keratoglobus

5. Allergic corneal diseases

- Atopic keratoconjunctivitis
- Vernal keratoconjunctivitis

6. Ocular surface diseases

- Dry eye
- Neurotrophic Keratitis
- Exposure Keratitis and Eyelid Disorders
- Limbal Stem Cell Deficiency (LCSD)
- Vitamin A deficiency, Xerophthalmia

7. Corneal Injury

- Corneal abrasions
- Corneal foreign body
- Corneal laceration
- Corneal perforation
- Chemical injury
- Thermal injury
- Radiation injury

8. Others

This category will include all other unspecified corneal disorders as well as conditions that are rare in children such as corneal degenerations.

For the avoidance of interobserver variation the principal investigator to will conduct the data collection.

11.4 ERC & NACOSTI letters

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Ref: KNH-ERC/A/140

6th April, 2022

KENYATTA NATIONAL HOSPITAL APPROVED 06 APR 2022 P.O. Box 20723 - 00202, NAIROBI QUALITY HEALTH CARE KNH/UoN-ERC

Dr. Paul Gathuku Irari
Reg. No. H58/33930/2019
Dept. of Ophthalmology
Faculty of Health Science
University of Nairobi

Dear Dr. Irari

RESEARCH PROPOSAL PREVALENCE AND PATTERN OF CORNEAL DISEASES IN PAEDIATRIC PATIENTS AT KENYATTA NATIONAL HOSPITAL EYE CLINIC AND THE UNIVERSITY OF NAIROBI EYE CENTRE (P11/01/2022)

This is to inform you that KNH-UoN ERC has reviewed and approved your above research proposal. Your application approval number is **P11/01/2022.** The approval period is 6th April 2022– 5th April 2023.

This approval is subject to compliance with the following requirements;

i. Only approved documents including (informed consents, study instruments, MTA) will be used.
ii. All changes including (amendments, deviations, and violations) are submitted for review and approval by KNH-UoN ERC.
iii. Death and life threatening problems and serious adverse events or unexpected adverse events whether related or unrelated to the study must be reported to KNH-UoN ERC 72 hours of notification.
iv. Any changes, anticipated or otherwise that may increase the risks or affected 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.
v. Clearance for export of biological specimens must be obtained from relevant institutions.
vi. 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.
vii. Submission of an executive summary report within 90 days upon completion of the study to KNH-UoN ERC.

Prior to commencing your study, you will be expected to obtain a research license from National Commission for Science, Technology and Innovation (NACOSTI) https://research-portal.nacosti.go.ke and also obtain other clearances needed.

Yours sincerely,

DR. BEATRICE K.M. AMUGUNE
SECRETARY, KNH-UoN ERC

c.c. The Dean, Faculty of Health Sciences, UoN
The Senior Director, CS, KNH
The Chairperson, KNH- UoN ERC
The Assistant Director, Health Information, KNH
The Chair, Dept. of Ophthalmology, UoN
Supervisors: Dr. Mukiri Mukuria, Dept. of Ophthalmology, UoN
Dr. Lucy Njambi, Dept. of Ophthalmology, UoN

KNH/R&P/FORM/01

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Research & Programs: Ext. 44705
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Study Registration Certificate

1. Name of the Principal Investigator/Researcher
   DR. PAUL GATHUKU IRARI
2. Email address: gathukuirari@gmail.com Tel No. 0713582443
3. Contact person (if different from PI).....
4. Email address: ..... Tel No. .....
5. Study Title
   PREVALENCE AND PATTERN OF CORNEAL DISEASES IN PAEDIATRIC PATIENTS AT KENYATTA NATIONAL HOSPITAL EYE CLINIC AND THE UNIVERSITY OF NAIROBI EYE CENTRE
6. Department where the study will be conducted OPHTHALMOLOGY
   (Please attach copy of Abstract)
7. Endorsed by KNH Head of Department where study will be conducted.
   Name: DR JOSEPH UWAKWA Signature ..... Date 30/05/22
   DEPARTMENT OF OPHTHALMOLOGY
8. KNH UoN Ethics Research Committee approved study number P11/01/2022
   (Please attach copy of ERC approval)
9. I DR. PAUL GATHUKU IRARI commit to submit a report of my study findings to the Department where the study will be conducted and to the Department of Medical Research.
   Signature..... Date 27/5/22
10. Study Registration number (Dept/Number/Year) Ophthalmology /22/2022
    (To be completed by Medical Research Department)
11. Research and Program Stamp KENYATTA NATIONAL HOSPITAL 31 MAY 2022

All studies conducted at Kenyatta National Hospital **must** be registered with the Department of Medical Research and investigators **must commit** to share results with the hospital.

REPUBLIC OF KENYA

NATIONAL COMMISSION FOR SCIENCE,TECHNOLOGY & INNOVATION

Ref No: **537116**

Date of Issue: **22/June/2022**

RESEARCH LICENSE

This is to Certify that Dr.. Paul Gathuku Irari of University of Nairobi, has been licensed to conduct research in Nairobi on the topic: PREVALENCE AND PATTERN OF CORNEAL DISEASES IN PAEDIATRIC PATIENTS AT KENYATTA NATIONAL HOSPITAL EYE CLINIC AND THE UNIVERSITY OF NAIROBI EYE CENTRE for the period ending : 22/June/2023.

License No: **NACOSTI/P/22/18017**

537116

Applicant Identification Number

Director General
NATIONAL COMMISSION FOR SCIENCE,TECHNOLOGY & INNOVATION

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