THE PREVALENCE AND OCULAR FINDINGS OF PSEUDOEXFOLIATION SYNDROME AMONG SOMALI PATIENTS AT GARISSA COUNTY REFERRAL HOSPITAL EYE CLINIC

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2022

DECLARATION

I certify that the work described in this dissertation is mine and has never been submitted to another institution for credit.

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LIST OF ABBREVIATIONS

IOP- Intraocular pressure

KNH- Kenyatta National Hospital

LOXL 1- Lysyl oxidase-like 1 gene

P- Probability value

PXG- Pseudo exfoliation glaucoma

PXF- Pseudoexfoliative material

PXFS-Pseudo exfoliation syndrome

SNP-Single nucleotide pleomorphism

SPSS-Statistical package for the social sciences.

PSC-Posterior subcapsular cataract

>- Greater than

< - Less than

OPERATIONAL DEFINITIONS

1. **Angle-closure**-Shaffer grade 0
2. **Glaucoma**- IOP > 21 mmHg in individuals with glaucomatous optic nerve head damage or typical visual field deficits, anti-glaucoma medication users, or glaucoma surgery patients**.**
3. **Increased posterior trabecular meshwork pigmentation**- Spaeth grade 3+ and 4+.
   Spaeth posterior trabecular pigmentation grading:
   0: Absence of any pigmentation
   1+: hardly any pigment
   2+: Mild pigmentation
   3+: Moderate dense
   4+: A lot of pigment
4. **Narrow-angle** -Shaffer grade 2 and 1.
5. **Open-angle**- Shaffer angle grade 4 and 3.
6. **Poor pupillary dilation**- pupillary dilation less than 5mm,40 minutes after instillation of 1 drop of tropicamide 1% and phenylephrine 2.5%, 3 times five minutes apart.
7. **Pseudoexfoliation syndrome** is a disorder characterized by the deposition of white flakes on the corneal endothelium, iris, trabecular meshwork, pupillary borders and anterior lens capsule or IOL.
8. **Shaffer grading of the angle of the chamber.**

Grade 4 (35–45°) is the broadest angle at which the ciliary body can be easily seen.

Grade 3 (25–35°) is an open angle where at least the scleral spur can be seen.

Grade 2 (20°) is a relatively small angle where just the trabecular can be seen.

Grade 1 (10°) is a very narrow-angle where only the Schwalbe line may be seen.

Grade 0 (0°) is a closed angle caused by iridocorneal contact and is identified by the inability to locate the apex of the corneal wedge.

9. **Blindness**-Best corrected visual acuity in the better eye is less than 3/60.
10. **Visual impairment-** Best visual acuity in better eye <6/18 but > 6/60.

11. **Somali**-Any person who belongs to Somali ethnic descent and identifies himself/herself as Somali, and speaks the Somali language.

ABSTRACT

Background: Pseudoexfoliation syndrome is a multisystemic disorder characterized by the accumulation of fibrillar materials in the eye. Pseudoexfoliation syndrome is attributed to the most prevalent secondary open-angle glaucoma in the world and increases the risk of cataracts and complications during cataract surgery. The purpose of this study was to determine the prevalence and ocular features of pseudoexfoliation syndrome among Somali patients at Garissa County Referral Hospital.

Objective: To determine the prevalence and ocular findings of pseudoexfoliation syndrome among Somali patients at the Garissa referral hospital eye clinic.

Design of the study: A cross-sectional descriptive study.

Study Area: Garissa County Referral Hospital eye clinic.

Methods: A systematic random sampling method was employed to select patients for the study. The recruited patients were administered informed consent, and a complete history and physical examination were carried out. The data obtained was recorded in a structured questionnaire and analyzed using statistical package for social sciences version 20. The results were presented in frequencies, charts, and percentage distribution tables for categorical variables.

Results: The prevalence of the pseudoexfoliation syndrome was 28.1% (95%CI: 20.1 % - 37.3%). The majority of the patients had bilateral pseudoexfoliation syndrome contributing to 59.4% of the cases. The mean age of the patients with pseudoexfoliation syndrome was higher than mean of patients without pseudoexfoliation syndrome (65.7+/-12.2 vs 60.32+/-11.81). The prevalence of pseudoexfoliation syndrome increased significantly with age. The Prevalence of pseudoexfoliation syndrome among patients aged 40-50 was 18.8% and 34.4 % in patients aged > 70 years. The majority of pseudo-exfoliative material deposits were found on the pupillary margin at 74.5%. Cataract was more common in the pseudo-exfoliation group with a prevalence of 82.4% and nuclear cataract was the most common cataract. The prevalence of glaucoma among patients with Pseudoexfoliation syndrome was 15.7%. There was a positive correlation between age, type of cataract, glaucoma, and pseudoexfoliation syndrome.

Recommendations: In-depth assessment of patients with pseudoexfoliation syndrome to identify ocular morbidities earlier and institute proper management. Follow up study in the community should be done to determine the prevalence of pseudoexfoliation in the Somali community.

1.0.CHAPTER ONE: INTRODUCTION

In 1917, Lindberg JG published the first description of pseudoexfoliation syndrome (1)**.** It was later identified as a systemic disorder with ocular manifestation characterized by the deposition of white, fluffy proteinaceous material in the eye. The pseudoexfoliative materials are deposited in the anterior chamber and its angle, the trabecular meshwork, the anterior surface of the iris, the anterior capsule of the lens, and occasionally on the corneal endothelium (2).

The appearance of white dandruff-like materials associated with iris transillumination defect, inadequate pupil dilation, lens instability, and corneal endothelial abnormalities are well-recognized clinical features of PXFS. The most significant clinical implications of the condition are the high risks of developing pseudoexfoliation glaucoma (PXG) and the increased risk of complications from cataract surgery. Studies have revealed a close association between PXFS and glaucoma. Patients with pseudoexfoliation syndrome have higher IOP but the relationship between PXFS and glaucoma is independent of IOP (3).

The prevalence studies on pseudoexfoliation syndrome show significant regional, ethnic, and racial variation. In nations like India, the prevalence is low (6% in individuals older than 70 years), whereas, in Finland and Saudi Arabia, the prevalence is higher (> 15%) (4).

1.2 Pathogenesis of pseudoexfoliation syndrome

Pseudoexfoliation syndrome is a multisystemic disorder affecting numerous organs such as the eye, heart, kidney, and brain. In the eye, the PXF deposits are found on the zonules, anterior lens capsule, pupillary edge of the iris, cornea, and iridocorneal angle (5).

The cause of pseudoexfoliation syndrome is not well understood, however, it is hypothesized that the combination of genetics, environmental, and biological factors contribute to the pathogenesis of the syndrome.

1.2.1 Genetic predisposition

1.2.1.1 Lysyl oxidase-like 1 gene

This is an enzyme that catalyzes the crosslinking of elastic polymers and is encoded by the LOXL1 gene on chromosome 15q24.1. Recent studies have demonstrated a substantial correlation between LOXL1, PXFS, and PXG. Lysyl oxidase-like 1 (LOXL1) gene exon 1 single nucleotide polymorphisms (SNPs) have recently been discovered to be a significant genetic risk factor for PXF syndrome and PXF glaucoma. LOXL1 is a pivotal cross-linking enzyme in extracellular matrix metabolism and seems to be specifically required for elastic fiber formation and stabilization (6).

The aberrant activity of the gene is linked to abnormalities in the metabolism of elastin fibers and the distribution of extracellular matrix on the ocular surfaces (protein sink model). The pathophysiology of PXG may be influenced by modifications to the biochemical characteristic of elastic in tissues such as the lamina cribrosa and the trabecular meshwork (7).

Numerous studies have employed immunostaining and proteolysis to find out the composition of PXF materials from the anterior lens capsules of lenses removed during cataract surgery from individuals with PXFS and PXG. These studies have shown the PXF materials consist of the following;

1. elastic fiber
2. basement membrane
3. blood-derived components

The presence of elastotic end products including tropoelastin, fibrillin, and elastin in several human tissues including the eye provides evidence that PXF is an elastotic process.

The presence of blood-derived product such as complement proteins in PXF deposits might point out the role of inflammation in the pathogenesis of PXFS (8)(9).

1.2.1.2 Clusterin

This is a disulfide-linked heterodimeric protein that is expressed by the CLU gene on chromosome 8 and is associated with cellular debris removal and apoptosis.

Clusterin functions as a protein chaperone that inhibits misfolded proteins from precipitating and aggregating.

Clusterin is significantly downregulated in the anterior segment tissues and aqueous humor of eyes with pseudoexfoliation syndrome (10).

Pseudoexfoliative deposits are produced when protein aggregates around the center of PXF elastic microfibrils when clusterin levels are low (11).

1.2.2 Environmental and Epidemiological Factors

1.2.2.1 Geographical location

Geographical location is an important risk factor for PXFS. Different regions and populations have varying prevalences of PXFS globally. People living at higher altitudes have higher pseudoexfoliation syndrome than those living at lower altitudes (12)**.**

1.2.2.2 Solar exposure

Longer sun exposure is linked to a higher chance of developing pseudoexfoliation syndrome. People with greater early-life solar exposure have a higher lifetime risk of developing pseudoexfoliation syndrome than people with less early-life solar exposure (13).

1.2.2.3 Diet

PXG and pseudoexfoliation syndrome are more likely to develop in non-vegetarians and people who drink more than three cups of coffee every day.

1.2.3 **Biological factors**

1.2.3.1 Age

Age is the major risk factor for the development of pseudoexfoliation syndrome. According to studies, PXG and pseudoexfoliation syndrome are more common in the older population (14). The reason for this is not clearly understood but older age might be contributing to elastotic degeneration of elastic fibers as suggested to be one of the mechanisms resulting in PXFS and PXG.

1.3 Pseudo exfoliation Glaucoma

Pseudoexfoliation syndrome is the most frequent cause of secondary open-angle glaucoma in the world. The intraocular pressures are six times more likely to be higher in patients with pseudoexfoliation syndrome than in patients without PXFS. These patients have a 15% chance

of developing ocular hypertension, and their chances of developing glaucoma range from 0-93% (15).

The Blue Mountain study found that persons with PXFS in either eye had a two- to three-fold increased chance of developing open-angle glaucoma, while those with PXFS in both eyes have a five-fold increased risk. PXF deposits and/or iris pigments accumulate on the trabecular meshwork, resulting in PXG. It might also be caused by trabecular meshwork congestion (16).

Pseudoexfoliative glaucoma is mostly asymptomatic and bilateral. At the time of presentation, the majority of patients already have significant optic nerve head injury and a visual field defect in the affected eye which is linked to a worse prognosis. PXG has a higher fluctuation of IOP and a poor response to treatment as compared to other secondary glaucomas (17)(18).

Like PXFS, Pseudo-exfoliative glaucoma is more common in older people. Men are more frequently affected than women and usually occurs between the ages of 60 and 70 years (19).

1.4 Clinical Presentation

1.4.1 Symptoms

PXF syndrome is usually an asymptomatic condition and can present in one or both eyes. The blue mountain study has demonstrated that most unilateral disorders progress to bilateral conditions later in life.

1.4.2 Signs

Pseudoefoliative materials are deposited on all anterior segment structures that are submerged in the aqueous humour. On the anterior lens capsule, the PXF materials form a concentric double-ring pattern where the peripheral ring is located more peripherally and only visible with a slit lamp exam at full pupillary dilation. The central ring is situated on the iris sphincter as shown below in Figure 1 (20).

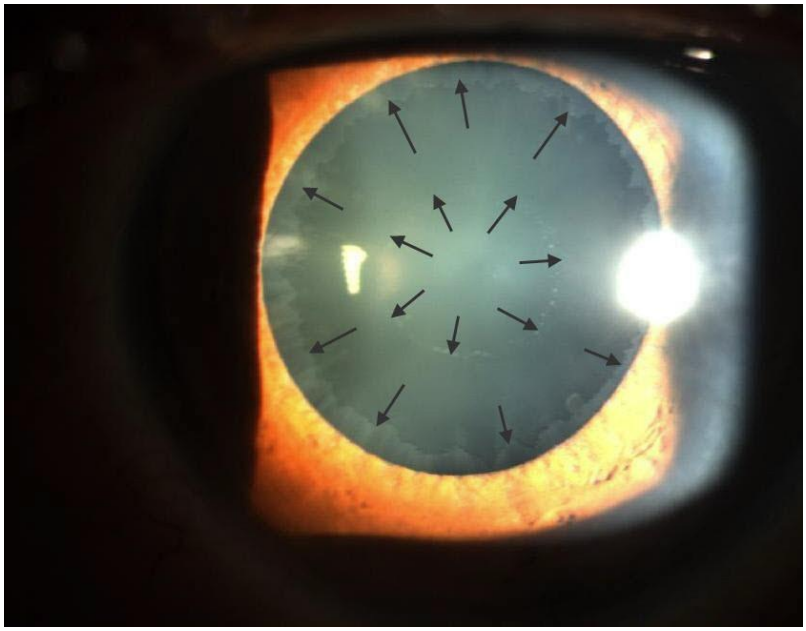

Figure 1: A Photograph of the anterior segment demonstrating PXF materials on the lens capsule. The arrows show a double-ring pattern.

Pseudoexfoliative materials are found on the iris sphincter and the pupillary ruff.

Defects are seen on the pupillary iris on transillumination.

The exfoliation materials and pigment deposits are also seen on the trabecular meshwork. The deposits are more on the inferior than the superior quadrants of the trabecular meshwork (21).

PXFS often predisposes individuals to secondary open-angle glaucoma. Signs of glaucoma that are seen among these individuals include optic nerve cupping, glaucomatous visual defects, narrower anterior chamber angles, trabecular meshwork pigmentation, and higher IOP. Phacodenesis and poor pupillary dilatation are seen in patients with PXFS (22).

The PXF materials can be deposited on the ciliary process and zonules resulting in the weakening of the zonules, zonular dialysis, and spontaneous lens subluxation or dislocation (23).

2.0 CHAPTER TWO: LITERATURE REVIEW

2.1 Epidemiology

Pseudoexfoliation syndrome is a multisystemic disorder of public health concern affecting over 60-70 million individuals globally. The prevalence of the disease differs in different parts of the world and is affected by geographical location and ethnicity (24).

A study by Kovac B et al at the Belgrade military medical academy in Serbia discovered that 17.5% of patients scheduled for cataract surgery had pseudoexfoliation syndrome. The patients with pseudoexfoliation syndrome were significantly older than those without pseudoexfoliation syndrome (79.7 +/- 6.1 years vs 73.5 +/- 9.1 years), ($p<0.000$). The prevalence of PXF syndrome was found to increase with age, arising from 7.3% among those in the seventh decade of life to 27% in patients older than 80 years, ($p< 0.001$) (25).

Yildirim N et al. reported a prevalence of pseudoexfoliation syndrome of 5% in Turkey. The prevalence of glaucoma was 26% among the participants with pseudoexfoliation syndrome. In comparison to the normal population, subjects with pseudoexfoliation syndrome had a higher incidence of cataracts, cardiac disorders, hypertension, and psychiatric disorders. (26).

A population-based multicentered study in India by Atul Kamath et al found a variation of the prevalence of pseudoexfoliation syndrome in the North and south of India. The prevalence was 10% in South India and 6% in North India. The South Indian population were farmers spending more time in sunlight than the North Indian population. This could clarify that environmental factors contribute to the pathophysiology of pseudoexfoliation syndrome (27).

A hospital-based retrospective study in upper Egypt by Shazley et al found that pseudoexfoliation syndrome is a common problem in upper Egypt. The prevalence of pseudoexfoliation was 4.14% and the subjects' average age was 68.25 years. The majority of the patients had bilateral PXFS, which was strongly linked to hearing loss, glaucoma, and cataracts (28).

A hospital-based cross-sectional study in Gondar University Comprehensive Specialized Hospital in Ethiopia by Yibekat BT et al found that Ethiopians had a high prevalence of

pseudoexfoliation syndrome of 34.6% and a significantly higher proportion of PXFS in males compared to females (39%vs 25.3%) unlike other parts of the world that show female disease predominance.

Patients with PXFS had greater intraocular pressures than healthy patients of the same age. The participants with PXFS had significantly higher rates of glaucoma than those with no PXFS.

Pseudoexfoliation syndrome was more common among rural residents (47.6%) than urban residents (17.3%). Subjects with more outdoor activity time had a higher proportion of PXFS (48.3%) than those with indoor activity (20.9%) (29).

A community-based cross-sectional study by Sherief et al in Ethiopia found a prevalence of pseudoexfoliation syndrome of 12% (9.7-14.3%, CI 95%). The average age of patients with PXFS was 63.9. (SD 9.96). Men were more commonly affected than females (12.4%vs vs. 11.6%) nevertheless, this wasn't statistically significant (p=0.738). The proportion of patients having PXFS increased with age, reaching 26.9% in those over 60 years. The mean IOP was higher in the PXFS group than those with no PXFS (20.65+/-5.15 vs 15.0 +/-2.3 mmHG) (30).

In Kenya, a hospital-based survey at the Kikuyu Eye unit by Musonda Lillian C. et al found a prevalence of PXFS of 21.9% among the patients attending the eye unit. The prevalence of PXFS was not the same among the different ethnic groups. The Somali patients had a higher proportion (70%) of PXFS among the cases. The patients with pseudoexfoliation syndrome had cataracts(77%) and glaucoma(28.3%).Other ocular associations were zonular dehiscence(10.6%) and branched retinal vein occlusion(1.8%) (17).

2.2 Ocular presentation of pseudoexfoliation syndrome

The most common sign of pseudoexfoliation syndrome is the presence of whitish deposits on the anterior lens capsule. Three different zones of material deposition are frequently seen on the anterior lens capsule surface. The iris excursion scraping the PXF material off the lens capsule causes a clear intermediate zone. The intermediate zone is surrounded by a peripheral zone of PXF material deposit. In 20% of Pseudoexfoliation syndromes, the central zone may not be seen and the peripheral granular zone can only be seen after pupillary dilatation (31).

Pseudoexfoliative materials were found on the ciliary process, the zonules, or both in the eyes of individuals with unilateral involvement in 77% of the eyes that were examined (32).

When the zonular weakening is severe enough, phacodonesis can be seen with a detailed slit examination (33).

Pseudoexfoliative material is frequently more discernible at the inferior angle of the anterior chamber and angle pigmentation is frequently intense yet irregular (34).

Increased pigmentation has been linked to an increase in IOP, and it is seen along the Schwalbe line and in the angle (35).

When PXFS is present, the angle is frequently narrow or occludable. A study by Wishart PK et al. found that up to 18% of the individuals with PXFS had occludable angles. The posterior trabecular meshwork had more pigmentation in all cases of pseudoexfoliation syndrome. Increased pigmentation of the trabecular meshwork could be an initial sign of exfoliation syndrome (36).

Pseudoexfoliative materials deposition on the surface of the iris result in iris sphincter atrophy and fibrotic changes which could be the reason why eyes with PXFS have inadequate dilation. The pupillary edge of the iris is additionally impacted, which eventually results in the disappearance of the pupillary ruff (21)(37).

A study by Mirza et al in Pakistan found 16% of patients with PXFS had glaucoma. Angle-closure glaucoma affected 4% of the glaucoma patients, while open-angle glaucoma affected 12% of them. Ocular hypertension was seen in 9% of the participants who underwent the examination. PXG was common among patients aged > 50 years and ocular hypertension was common among those aged < 40 years (38).

A study in Saudi Arabia by Al-Saleh SA et al found high IOP and cataracts were common complications among patients with pseudoexfoliation syndrome with 45% of the patients having high IOP and 26% presenting with cataracts. Poor pupillary dilatation was more common among patients with pseudo-exfoliation than those with no pseudo-exfoliation syndrome. Some patients (9.5%) had occludable angles on gonioscopy (39).

A population-based study in Saudi Arabia Summanen P et al discovered that people with PXFS have higher rates of cataracts compared to normal populations. PXFS has been associated with

a higher prevalence of nuclear opacities. The patients with uniocular PXFS had more advanced cataracts in the affected eye (40).

2.3 Systemic association of pseudoexfoliation syndrome

Systemic signs have been found in patients with pseudoexfoliation syndrome. Streeten BW et al. found aggregates comparable with pseudoexfoliative materials in the lung, heart, liver, and gallbladder in addition to the conventional ophthalmic signs in patients with PXG and bilateral PXFS. Elastic and oxytalan fiber aggregates were the most frequently observed materials in the autopsies (41).

Pseudoexfoliation syndrome has been associated with diseases such as cardiovascular disease, sensory-neural hearing loss, and Alzheimer's type dementia (42)(43).

Studies have linked arterial hypertension to PXFS syndrome. The Australian blue mountains eye study found a strong correlation between pseudoexfoliation syndrome and a history of hypertension, angina, or both (44).

Patients with PXF syndrome have high rates of abdominal aortic aneurysms. A study by Schumacher et al found that 44 percent of patients who had surgery for abdominal aneurysms had signs of PXFS in their eyes (45).

3.0 CHAPTER THREE: JUSTIFICATION OF STUDY AND OBJECTIVES

3.1 Justification of the Study

A study on pseudoexfoliation syndrome among Kenyan communities (17) has shown that pseudoexfoliation syndrome is a common eye problem among the Somali community. However, it is not known whether there are distinct risk factors, presentations, or trends of the syndrome in the Somali community.

There have been no studies on pseudoexfoliation syndrome among the Somali community in Kenya.

3.2 Objectives

3.2.1 Broad objective

To determine the prevalence and ocular findings of pseudoexfoliation syndrome among the Somali patients at Garissa County Referral Hospital eye clinic.

3.2.2 Specific objectives

1. To determine the prevalence of pseudoexfoliation syndrome among the Somali patients at Garissa County Referral Hospital eye clinic.
2. To describe the ocular findings of pseudoexfoliation syndrome among the Somali patients at Garissa County Referral Hospital eye clinic.

4.0 CHAPTER FOUR: STUDY METHODS

4.1 Study Area Description

The study was conducted at Garissa County referral hospital which is located at Garissa town. Garissa County has a population of 841,353 and a population density of 19/km^2 with a land area of 44753 km$^{2.}$ The town lies at a longitude of 39.6460, a latitude of -0.4532, and an elevation of 147m/482 feet.

The eye clinic is run by an ophthalmologist, ophthalmic clinic officers, and ophthalmic nurses. The clinic serves patients from Garissa County, Wajir, Mandera, Tana River, and Kitui County. An average of 40 patients attends the clinic per day.

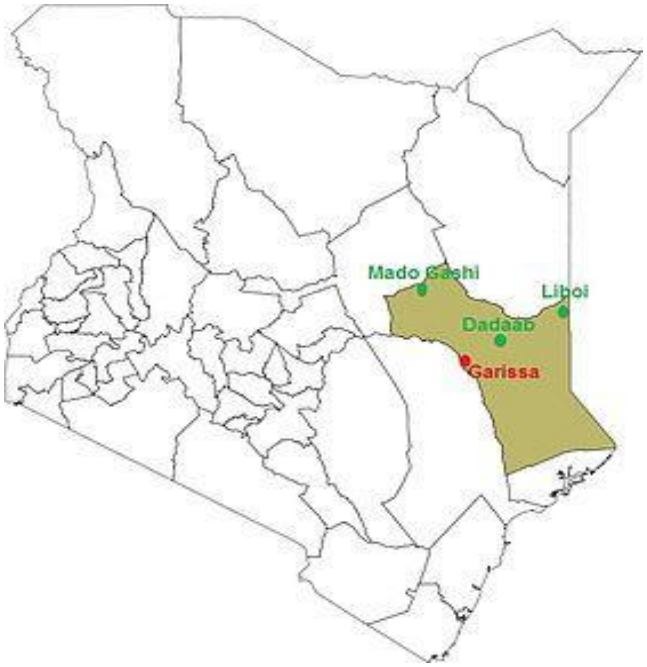

Figure 2: The Kenya map showing the location of Garissa town.

4.2 Study design

A cross-sectional descriptive study

The study involved the examination of the participants during the specific study period and describing the ocular findings as seen during the clinical examinations of the participants. The exposure and outcome variables were measured at the same time. No intervention or follow-up of the participants was done. Due to the limited time and resources, this design was

employed to get the required data in the shortest time possible with the least cost, however, the study sample was not entirely representative and generalization of the result was not possible. The study evaluated prevalence rather than incidence and was not providing a temporal relationship between the exposure and outcome**.**

4.3 Target Population

Patients aged 40 years and above attending Garissa County referral hospital eye clinic during the study period.

4.4 Inclusion and exclusion criteria

4.4.1 Inclusion criteria

The Somali patients aged 40 years and above who attended the Garissa County Referral Hospital eye clinic during the study period.

4.4.2 Exclusion criteria

Eyes with the following were excluded.

1) Uveitis
2) Traumatic cataract
3) Corneal opacities that interfered with anterior segment examination

4.5 Sample size determination

Fisher's formula was used to estimate the expected minimal sample size for this study (equation 1).

A prevalence of 21.9% was used in the estimation of the minimum sample size of this study as reported in a study by Musonda et al, 2005.

$n = (Z\text{^}2 \text{ x } p \text{ x } (100 - p))/d\text{^}2$ ……equation 1

Where;

n - Minimum sample size

Z - Standard normal deviation which was set at 1.96 and corresponds to a 95% confidence level

P - The proportion of patients with pseudoexfoliation syndrome (21.9%) from a previous study by Musonda et al, 2005(31)

d - Margin of error at 8% (0.08)

Calculations;

$= (〚1.96〛\text{ ^2 x } 0.219\ (1 - 0.219))/0.08\text{x}0.08$

n= 103 patients

Adjusting for non-response rate;

$n = n\text{x}1/0.9$ ……. equation 2

=114 patients

The estimated sample size for the study was therefore 114 patients**.**

4.6 Prevalence calculation

In this study, the prevalence was the number of patients in the sample with pseudoexfoliation syndrome divided by the total number of patients in the sample.

Prevalence = $\frac{\text{Number of patients in the sample with pseudoexfoliation syndrome X 100.}}{\text{Total number of patients recruited and examined}}$

4.7 Sampling, Recruiting, and consenting procedure

Systematic random sampling was employed in the selection of participants who were recruited in the study. Every 4th adult Somali patient age 40 and above on the everyday list of patients visiting the eye clinic was randomly selected for inclusion in the study. The sampling procedure was conducted five days per week for the months of March and April in 2023. Consent for participation in the study was sought from all the selected patients before administering questionnaires.

4.8 Data collection procedures

All participants' biodata was taken. A complete history and ophthalmic examination were carried out on each participant. The required data was gathered from participants using a structured questionnaire. The questionnaire comprised closed and open-ended questions in three sections. Section A constituted personal details including age, sex, place of residence, and nationality. Sections B and C captured the patient's ophthalmic history and clinical examination findings including the best corrected VA acuity taken using E-chart, and IOP that was taken using I-Care tonometry. Anterior segment examination was carried out using a Slit lamp, Gonioscopy was done using 3-mirror geniolens. The Pupils were dilated using tropicamide 1% and phenylephrine 2.5% eye drops and a fundoscopy was done for each participant. A pre-test was carried out to assess the reliability of the questionnaire before starting the actual data collection**.**

4.9 Study materials

1. Snellen chart, E-chart
2. Slit lamp biomicroscope
3. 3-Mirror Geniolens
4. Indirect ophthalmoscope
5. Tropicamide 1 % and phenylephrine 2.5%
6. Tetracaine
7. I-care tonometer
8. Torch
9. 90D lens
10. 20D lens.

4.10 Variables

4.10.1 Dependent variable

The outcome variable of the study was pseudoexfoliation syndrome which is a systemic disorder with ocular manifestations characterized by the deposition of fibrillar materials on the structures of the anterior segment of the eye**.**

4.10.2 Independent Variables

Sociodemographic factors include; age, sex, and place of residence.

4.11 Data Management

The questionnaire was coded, checked for completion, and entered into the Statistical Package for Social Sciences (SPSS) Version 20. Data cleaning was done before analysis. Data were analyzed and results were presented in frequencies, charts, and percentage distribution tables for categorical variables. Mean and standard deviation was used to present results for continuous variables. In a univariate analysis, the Chi-square test was employed to look for any potential associations between the dependent and independent variables, and a categorical variable with low counts was subjected to Fisher's exact test of independent variables (less than 5 counts in a cell of contingency table).

Using a probability value ($P \leq 0.05$), Significant relationships between variables were identified. Using an odds ratio and a 95% confidence interval, potential relationships were evaluated for statistical significance.

4.12 Quality assurance

The recruitment of the participants into the study was done by the principal investigator. The data was collected in pre-designed questionnaires to avoid inaccuracies. The same instruments were used to examine all the participants. The examination of the participants was done by the principal investigator who then recorded the examination findings in the pre-designed questionnaire**.**

4.13 Ethical consideration

4.13.1 Approval by the Ethics and Research Committee

The study approval was obtained from the Kenyatta National Hospital/University of Nairobi ethics and research committee. Further approvals were requested and obtained from Garissa County referral hospital's administration, and the National Commission for Science, Technology, and Innovation (NACOSTI).

Written consent for participation in the study was obtained from all the participants before the examination.

4.13.2 Confidentiality

The patient's identity and information were kept anonymous at all times using coded questionnaires. Files were not photographed and no file was taken out of the record department during data collection. The data was stored in a password-secured computer only accessible to the investigator.

4.14 Result dissemination

The result of the study was presented in the ophthalmology department. Submissions will also be made to ophthalmology scientific journals for publishing. A copy of the dissertation will be submitted to the Garissa County referral hospital's CEO office.

CHAPTER 5: RESULTS

5.1 Introduction

The study sought to determine the prevalence and ocular findings of pseudoexfoliation syndrome among Somali patients at the Garissa County Referral Hospital eye clinic.114 patients aged 40 years and above were enrolled into the study. All the questionnaires were filled and analyzed giving the study a 100% response rate.

5.1.1 Patient flow diagram

Registration of patients

↓

Patient selection (138 patients)

↓

Included (114) ⇔ excluded (24 patients) →

- 6 Corneal scars
- 4 Uveitis
- 2 Traumatic cataracts
- 4 Pseudophakia bullous keratopathy
- 3 Keratitis
- 5 Dense senile cataracts

5.2 Socio-demographic characteristics of patients.

The majority of the patients were aged between 61 to 70 years contributing to 29.8% of the participants. The mean age of the participants was 61.8+/-11.8. The youngest patient was 40 years and the oldest patient was 90 years old.

5.2.1 Distribution of participants by age

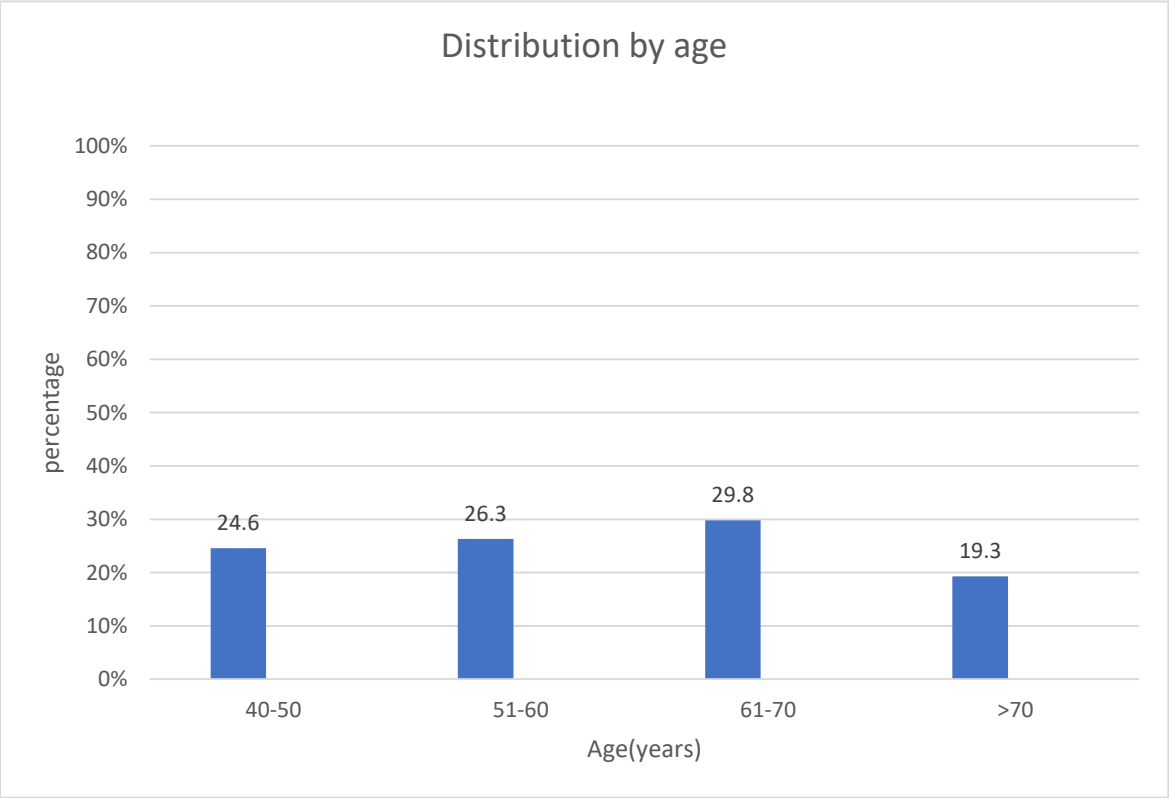

Figure 3: Distribution of participants by age(n=114).

5.2.2. Distribution of participants by sex, clan, and location

There were more females (57%) than males (43%) contributing F: M ratio of 1.3:1.

The majority of the respondents (98.2%) were of Kenyan origin and most of the patients (78.9%) belong to the Ogaden clan.

Overall,57% of the patients were residing in urban areas.

Table 1: Distribution of the participants by sex, clan, and location (n=114)

Sociodemographic Characteristics	Number of patients	Percent (%)
Gender		
Female	65	57.0
Male	49	43.0
Clan		
Ogaden	90	78.9
Ajuran	6	5.3
Dagodia	7	6.1
Wardey	5	4.4
Others (Merahan, Gare)	6	5.3
Residence		
Rural	49	43.0
Urban	65	57.0

5.3 Clinical Presentation of the Participants

The commonest chief complain among the participants was poor vision which accounted for 67.5%.

The majority of the patients (58.8%) were on follow and the duration of illness was within 12 months in most of the patients (71.1%).

5.3.1 Distribution of chief complains of the participants

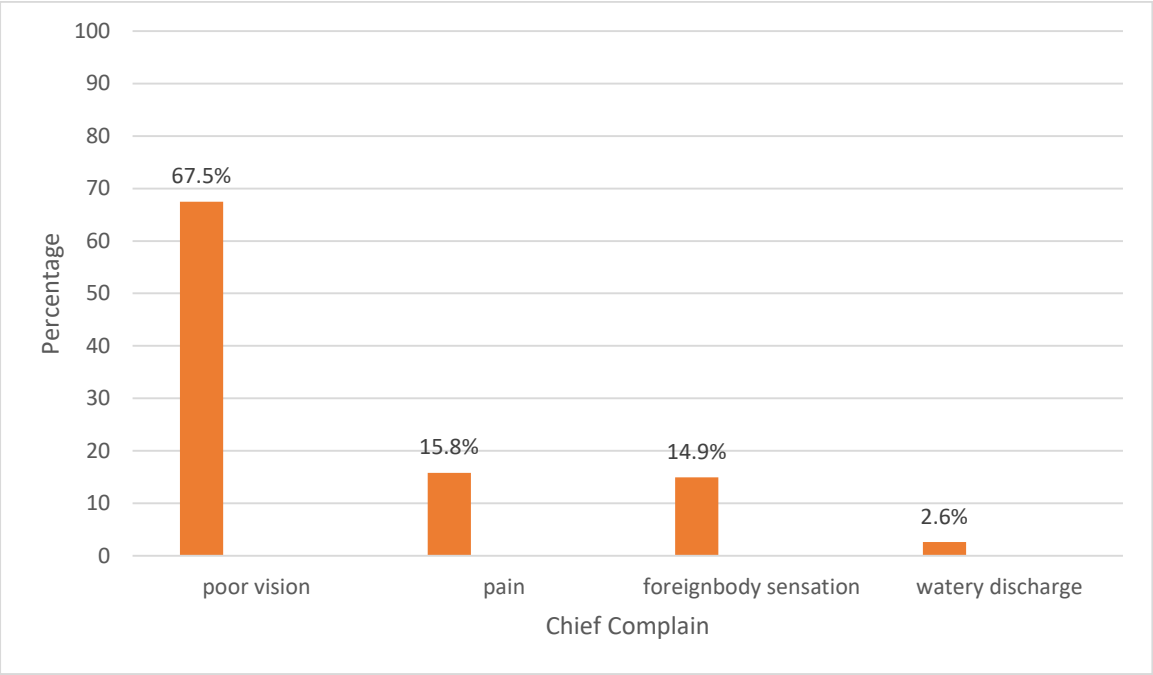

Figure 4. Distribution of chief complain of the participants(n=114)

5.3.2 Duration of illness of the participants(months)

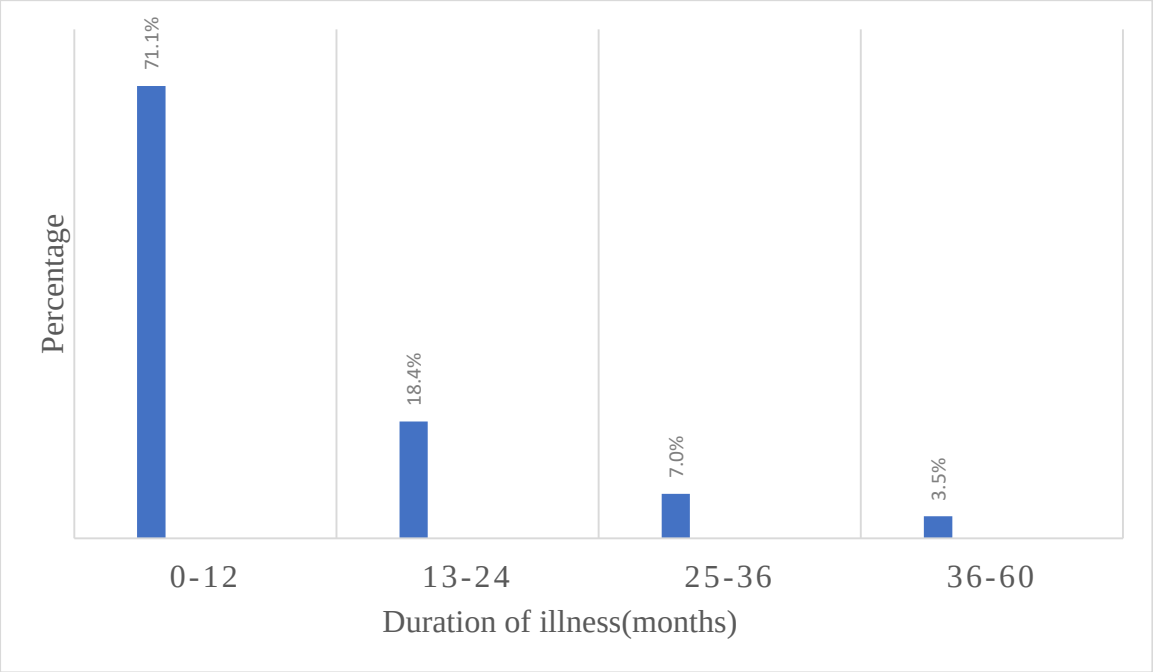

Figure 5: Duration of illness of participants in months(n=114)

5.3.3 Nature of Visit of the Participants

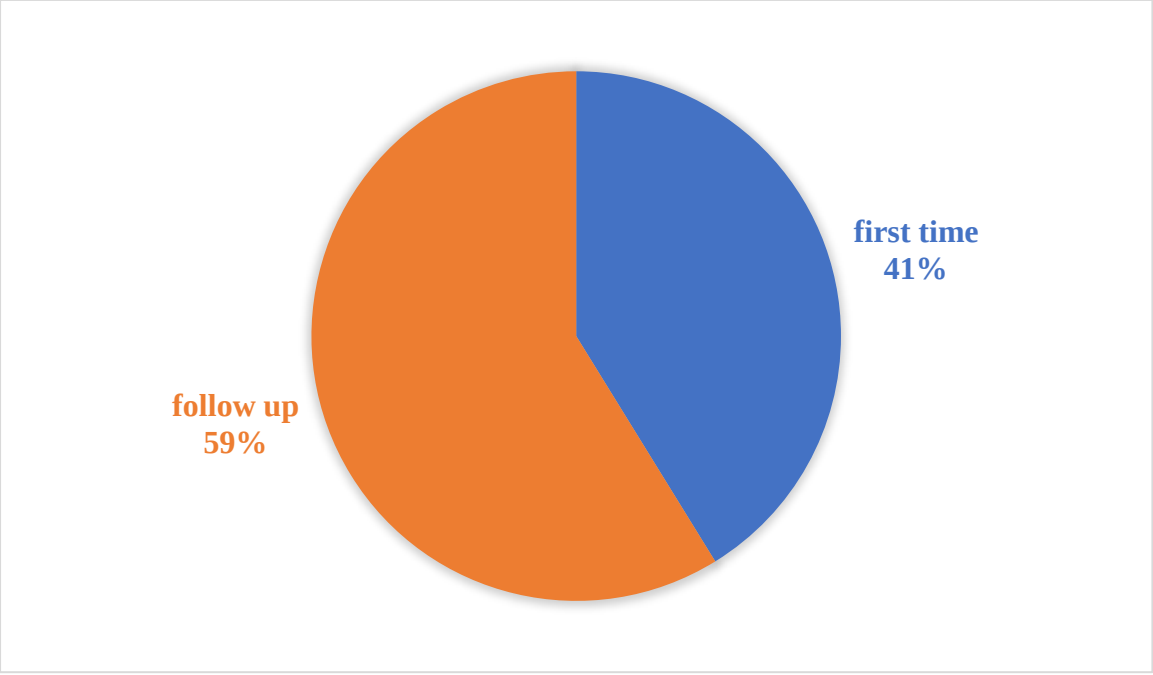

Figure 6: Nature of visit of the participants(n=114)

5.4 The prevalence of pseudoexfoliation syndrome

Thirty-two (32) patients had pseudoexfoliation syndrome giving a prevalence of pseudoexfoliation syndrome of 28.1% (95%CI: 20.1 % - 37.3%) as shown in Figure 3.

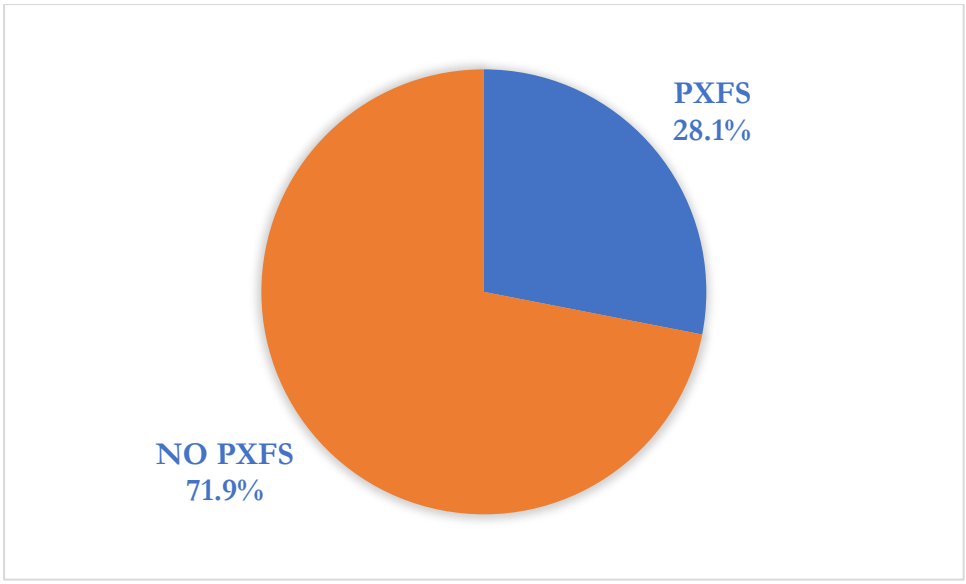

Figure 7: The prevalence of pseudoexfoliation syndrome among Somali patients(n=114)

5.5 Patient factors associated with pseudoexfoliation syndrome

Pearson chi-square and Fischer's exact test were conducted to investigate the existence of an association between patient characteristics and the presence of pseudoexfoliation syndrome among the patients. There was significant association between age and pseudoexfoliation syndrome among Somali patients (p=0.032). The proportion of pseudoexfoliation syndrome was increasing with increasing age. Other factors investigated were nationality, clan, chief complain, duration of illness, and nature of visit but were not statistically significant at a 95% level of confidence (p<0.05). Patients with pseudoexfoliation syndrome were significantly older than patients with no pseudoexfoliation syndrome(p<0.029).

The trend of pseudoexfoliation syndrome with age

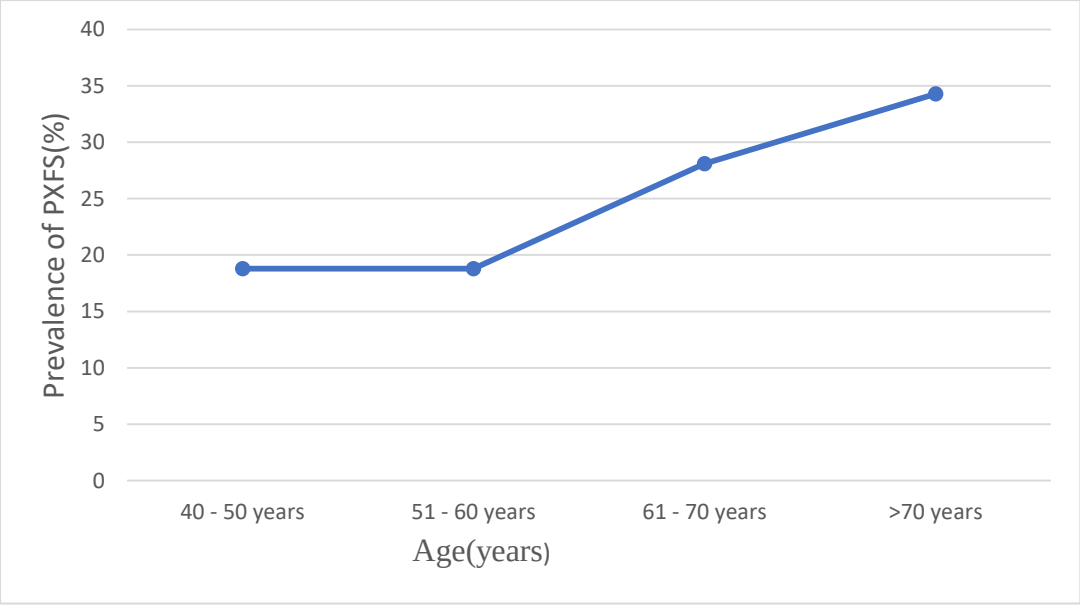

Figure 8: The trend of pseudoexfoliation syndrome with age(n=32)

Table 2: Patient factors associated with pseudoexfoliation syndrome

Patient factors	**Pseudoexfoliation**		**P-value**
	Present n(%) n=32 patients	**Absent n(%) n=82 patients**	
Age (mean, SD)	**65.7±12.42**	**60.32±11.81**	<0.029***
40 – 50	6(18.8)	22(26.8)	<0.032*
51 – 60	6(18.8)	24(29.3)	
61 – 70	9(28.1)	25(30.5)	
>70	11(34.4)	11(13.4)	
Gender			
Female	16(50)	49(59.8)	0.402*
Male	16(50)	33(40.2)	
Location			
Rural	17(53.1)	32(39.0)	0.208*
Urban	15(46.9)	50(61.0)	

* Pearson Chi-square, ** Fischer's exact test, ***independent t test

5.6 Laterality of pseudoexfoliation syndrome among the participants.

The majority of the patients (59.4%) had bilateral pseudoexfoliation syndrome.

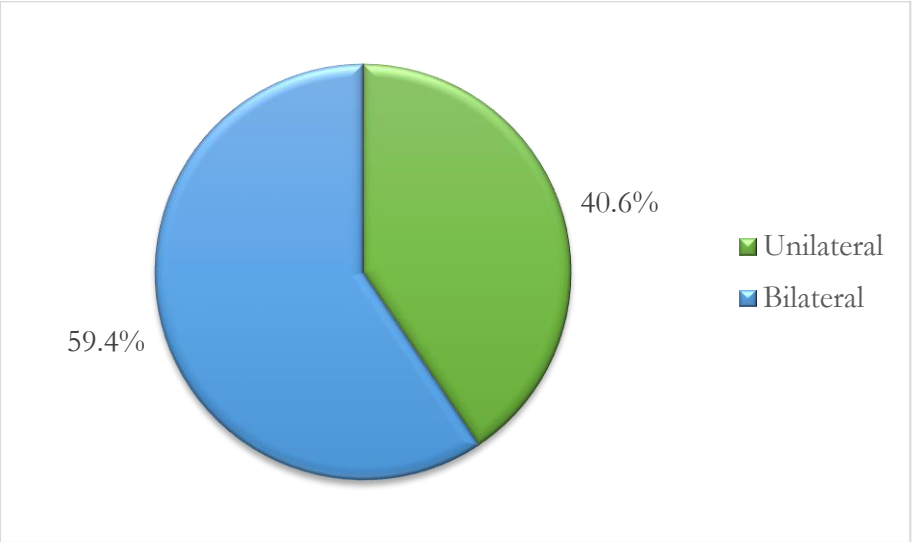

Figure 9: Laterality of pseudoexfoliation syndrome (n=32 patients)

5.7 Distribution of Pseudoexfoliative materials in the eyes of the participants

The majority of the eyes (74.5%) had pseudoexfoliation materials deposited on the pupillary margin while 17.7% of eyes had PXF materials deposited on both the anterior lens capsule and pupillary margin as shown in Figure 10.

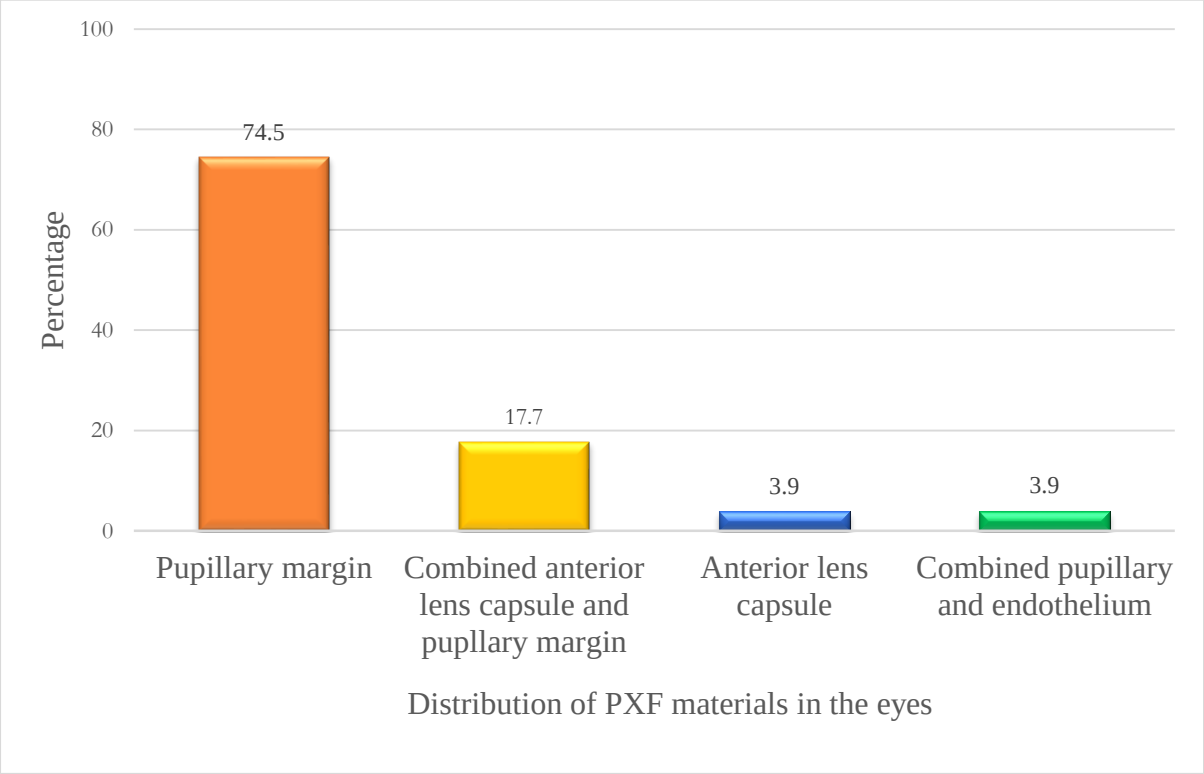

Figure 10: Distribution of Pseudoexfoliative materials in the eyes of the participants (n=51 eyes)

5.8 Specific anterior and posterior segment findings of eyes with pseudoexfoliation syndrome

Ocular findings based on the number of eyes were compared between patients with pseudoexfoliation syndrome and those without pseudoexfoliation syndrome. Pseudoexfoliation syndrome was significantly associated with the following; Optic nerve head changes, the presence of cataract, nuclear cataract, anterior chamber angle pigmentation and the presence of glaucoma($p<0.001$).

Table 3: The findings on the visual acuity and intraocular pressure (IOP).

Ocular finding	Number of eyes with PXFS, n (%) (n =51 eyes)	Number of eyes without PXFS, n (%) (n =159 eyes)	P-value
Visual acuity			
<6/18	16(31.4)	52(34.0)	0.345*
6/24-6/36	9(17.6)	38(24.8)	
6/60-3/60	9(17.6)	35(22.9)	
<3/60	17(33.4)	34(18.3)	
IOP (mmHg)			
Mean IOP, SD	16.4 ±9.06	14.58±4.05	0.146***

* Pearson Chi-square, ** Fischer's exact test*** independent t-test

Table 4: The anterior segment findings of eyes with pseudoexfoliation syndrome.

Ocular finding	Number of eyes with PXFS, n (%) (n =51 eyes)	Number of eyes without PXFS, n (%) (n =159 eyes)	P-value
Grade of the Angle			
0	0	0	
1	2(3.9)	0	
2	7(13.7)	20(12.6)	
3	29(56.9)	82(51.6)	
4	13(25.5)	57(35.8)	
Increased pigmentation in the trabecular meshwork			
Yes	32(62.7)	11(6.9)	**<0.001***
No	19(37.3)	148(93.1)	
Pupillary dilation adequacy			
Yes(>5mm)	46(90.2)	141(88.7)	0.607*
No(<5mm)	5(9.8)	18(11.3)	
Lens findings			
Presence of cataracts			
Yes	42(82.4)	98(61.6)	**<0.006***
No	9(17.6)	61(38.4)	
Cataract type present			
Cortical	14(33.3)	68(69.4)	**<0.001****
Mixed	9(21.4)	19(19.4)	
Nuclear	19(45.3)	9(9.2)	
PSC	0	2(2.0)	
Phacodenesis			
Yes	6(11.8)	0	
No	45(88.2)	159(100)	
Location of lens/IOL			
Central	48(94.1)	157(98.7)	
Subluxation	3(5.9)	2(1.3)	
Dislocation	0	0	

* Pearson Chi-square, ** Fischer's exact test*** independent t test

Table 5: The posterior segment findings of the eyes with pseudoexfoliation syndrome

Ocular finding	Number of eyes with PXFS, n (%) (n =51 eyes	Number of eyes without PXFS, n (%) (n =159 eyes)	P-value
Optic nerve head changes (VCDR)			
<0.5	31(60.8)	114(71.7)	**<0.001****
0.5 - 0.65	12(23.5)	30(18.9)	
0.7 - 0.85	4(7.8)	11(6.9)	
>0.9	4(7.8)	4(2.5)	
Glaucoma			
Yes	8(15.7)	19(11.5)	**<0.001***
No	43(84.3)	140(88.5)	

* Pearson Chi-square, ** Fischer's exact test*** independent t test

CHAPTER 6: DISCUSSION

6.0 Sociodemographic characteristics of the participants

A total of 114 patients were recruited for the study, giving the study a 100% response rate. The majority of the participants were Kenyans (98.2%) and two patients were from Somalia (1.8%). Even though the hospital serves the refugee camps with Somalia residents, in this study only 2 patients were from the refugee camps. This was because of a free eye camp that the hospital together with partners conducted before the start of the study.

Overall,57% of the patients were from urban areas and only 43% were from rural areas. The rural residents are farmers who keep animals. During the study, there was a drought that forced the rural residents to move away from the towns with their animals to search for pasture.

Most of the participants were females (57%). This may be because Somali men are away from their homes during the day to work or look after their animals while Somali women stay at home to look after the homestead.

The majority of the participants (78%) were from the Ogaden clan. The Ogaden clan accounts for the majority of the Somali community in Garissa. Other clans include; Dagodia Ajuran and Balcade.

6.1 The Prevalence of pseudoexfoliation syndrome

In our study, we found a prevalence of pseudoexfoliation syndrome of 28.1% (CI 95% 20.1-37.3).

This is consistent with the finding in a study by Andrikopoulos GK et al Greece that reported a prevalence of pseudoexfoliation syndrome of 27.9% among the participants (46).

This is slightly higher than the prevalence found by Musonda et al at the Kikuyu eye unit (17) which showed a prevalence of 21.9%. The difference could be attributed to the differences in the setting of the study and the ages of the participants. However, the Musonda study reported that most patients with pseudoexfoliation syndrome were Somali. We found that

pseudoexfoliation syndrome is a common condition among the Somali patients attending the Garissa County referral hospital.

The mean age of patients with PXFS (65.7+/- 12.42) was higher than the mean age of those with no PXFS (60.32+/-11.82) (p=0.032).

A similar finding was found in the study by Sherief et al in Ethiopia and Bahja Abdulhamid et al in Libya (47). There was significant increase of the prevalence of pseudoexfoliation syndrome with age. The prevalence was 18.8% among patients aged 40-50 and 34.4% among patients aged> 70 years (p=0.032). Similar findings were found by Kovac B et al at the Belgrade military medical academy in Serbia (25) and Bahja Abdulhamid et al in Libya (47). This shows that pseudoexfoliation is more common in older age since it is an elastotic process of the extracellular matrix that occurs with ageing. The study affirms that older age is a risk factor for pseudoexfoliation syndrome as reported in previous studies.

Variations in the prevalence of pseudoexfoliation syndrome by sex were reported in different parts of the world. In our study, we found no difference in the prevalence of pseudoexfoliation between men and females (50% vs 50%). The finding is consistent with findings by Bahja Abdulhamid et al in Libya (47) and Lee sang yoon MD et al in Korea (48) who found no statistically significant difference in the prevalence of pseudoexfoliation syndrome between males and females. Similar findings were reported by Kalaci M et al in Mogadishu, Somalia (49). This might be due to differences in sociodemographic, genetic and environmental factors.

The prevalence of pseudoexfoliation was higher in patients from rural areas (53.1%) compared to patients from urban areas (46.9%). The difference was however not statistically significant. Our finding differs from what was found by Yebikat BT et al in Ethiopia who found that pseudo-exfoliation syndrome was more common among rural residents (47.6%) than urban residents (17.3%) (29). The difference could be due to the fewer number of rural residents in our study. The setting of the study and environmental factors may also play a role. People living in rural areas have higher sunlight exposure than those living in urban areas and that may predispose them to pseudoexfoliation syndrome. UV radiation is a known risk factor for pseudoexfoliation syndrome as reported in many studies.

6.2 Ocular findings of patients pseudoexfoliation syndrome

We studied 51 eyes of 32 patients with Pseudoexfoliation syndrome.

Thirteen (13) patients had unilateral disease while nineteen (19) had bilateral disease. This corresponds to a prevalence of 59.4% bilateral and 40.6% unilateral pseudoexfoliation syndrome. This finding is consistent with the study by Abeid AM et al in Iraq that found that 58% of the patients had bilateral PXFS and P Lamba et al in India found bilateral pseudoexfoliation syndrome in 56.8 % of the patients and unilateral PXFS in 43.2% of the patients (50). Although pseudoexfoliation syndrome can present as a unilateral disorder, clinically the unilateral involvement is often a precursor of bilateral disease. The progression of unilateral disease to bilateral disorder was reported in the blue mountain study.

The PXF materials were found on the pupillary margins in 74.5% of the eyes, the lens capsule and pupillary margin in 17.7%, and the anterior lens capsule in 3.9%. This is consistent with the finding in the study by Yebikel BT et al in Ethiopia who found that 77.5% of the eyes had PXF materials on the pupillary margin, 14.70% on the pupillary margin and lens capsule, and 7.8% anterior lens capsule alone (29). The Pupillary margin involvement of pseudoexfoliation syndrome results in loss of pigment frill and pupil atrophy. These changes in pupil contribute to poor pupillary dilation seen in patients with pseudoexfoliation syndrome.

Blindness was more common in eyes with Pseudoexfoliation syndrome(33.4%) compared to eye without pseudoexfoliation syndrome (18.3%) but the difference was not statistically significant (p= 0.345).kk

Rao A et al in India found that among the participants with Pseudoexfoliation syndrome,30% had visual impairment across all stages and 28% had absolu3iite blindness (51). Thomas R et al in India also found significant association between PXFS and blindness (adjusted OR, 2.19; 95% CI: 1.16-4.13) (52). The difference could be attributed to differences in the setting of the study, environmental and genetic factors.

The mean intraocular pressure was high in eyes with PXFS than those without PXFS (16.4+/-9.06 vs 14.58 +/-4.05). This is consistent with findings in the study by Sherief et al in Ethiopia who found higher the mean intraocular pressure in the PXFS group than the non-PXFS group (20.65+/-5.15 vs 15.0 +/-2.3 mmHG) (30). The higher intraocular pressure in these patients predisposes them to pseudoexfoliation glaucoma.

Increased trabecular pigmentation was found in 62.7% of the patients with pseudoexfoliation syndrome compared to 6.9% of the non-pseudoexfoliation syndrome ($p<0.001$). Similar findings were reported by Wishart PK et al.(36) who noted increased pigmentation of the posterior trabecular meshwork (PTM) in all cases in his study. Increased trabecular pigmentation was also reported by Sampaolesi R et al.(34). The increased pigmentation of the posterior trabecular meshwork may be the earliest detectable sign of the exfoliation syndrome.

The majority of the eyes with pseudoexfoliation had open angles with angle grade 3 accounting for 56.9% of the cases. However, there was no statistically significant difference in the width of the angles between the two groups($P=0.219$). This finding is consistent with M. Iwanejko, et al in Poland study that showed no statistical difference in the width of angles of patients with pseudoexfoliation syndrome and those without pseudoexfoliation syndrome (53). Even though Pseudoexfoliation is the commonest cause of secondary open-angle glaucoma, some studies have reported that several patients with pseudoexfoliation syndrome have occludable angles. This emphasizes the importance of gonioscopy examination in patients with pseudoexfoliation syndrome.

In our study, we found that the mean optic nerve head changes were higher in the pseudoexfoliation syndrome group than in the non-pseudoexfoliation group ($p<0.001$). This is consistent with findings of the blue mountain study that showed higher glaucomatous optic nerve head changes in the patients with pseudoexfoliation than in the non-pseudoexfoliation group (3). Pseudoexfoliation glaucoma is an asymptomatic disease, and when present, its often detected at the advanced stage. This has adverse impact on patient management and visual prognosis.

Most of the eyes (90.1%) of patients with PXFS had good pupillary dilatation. This is consistent with the finding by Philip SS et al in India who found good pupillary dilation in most (90.5%) of eyes with early PXFS $\geq$ 7 mm. The adequacy of the pupillary dilation depends on the severity of the disease suggesting that not all eyes with PXFS eyes have poor pupillary dilatation and related complications however, the challenges caused by poor pupillary dilation in cataract surgery among patients with pseudoexfoliation syndrome can't be under-emphasized (3).

In our study, we found cataracts in 82.4 % of patients with pseudoexfoliation syndrome. Nuclear cataract was the commonest type of cataract accounting for 45.3% of cataracts in patients with pseudoexfoliation syndrome. There was a positive correlation between the presence of cataracts, nuclear cataracts and PXFS($p<0.001$). This is consistent with the study by Musonda et al.(17) who found cataracts in 77% of patients with pseudoexfoliation syndrome and Prachee H at al in India who found that nuclear cataract was the most common type of cataract in patients with PXFS accounting for 62% of cataracts (54). Even though multiple factors may contribute to visual impairment and blindness in patients with pseudoexfoliation syndrome, the impact of cataracts can't be underscored.

In our study, we found a remarkable number of lens/IOL subluxations (5.9%) and phacodenosis (11.8 %) in patients with pseudoexfoliation syndrome. Similar findings were reported by Musonda et al in Kenya who found lens subluxation in 6.2% of patients with PXFS (17). Kuchle M et al also found that the prevalence of lens subluxation and/or phacodenosis in patients with PXFS varies between 8.4% and 10.6% (55). This is due to Zonular dialysis which is common in patients with pseudoexfoliation syndrome. The patients with PXFS are predisposed to difficulty lens delivery and IOL instability during cataract surgery.

The prevalence of glaucoma was higher eyes with PXFS compared to eye non-PXFS (15.7 VS 11.5%, $p< 0.001$). This finding is consistent the blue mountain study that found the prevalence of glaucoma in the PXFS group at 14.2% among all ages compared to 1.7% in the non-PXFS group (3). These finds suggest that glaucoma often coexists with pseudoexfoliation syndrome and may be diagnosed at an advanced stage.

6.3 CONCLUSION

1. The prevalence of pseudoexfoliation syndrome is high among the Somali patients attending the Garissa County referral eye unit.
2. The majority of the patients have bilateral pseudoexfoliation syndrome.
3. Pupillary margin deposition of pseudoexfoliation material is the most common presentation.
4. The prevalence of cataracts among patients with pseudoexfoliation syndrome is high and nuclear cataract is the commonest type of cataract in patients with pseudoexfoliation syndrome.
5. Advanced glaucomatous optic nerve head (VCDR) changes are seen in patients with pseudoexfoliation syndrome and the majority of them have increased posterior trabecular meshwork pigmentation.
6. There is a positive correlation between glaucoma and pseudoexfoliation syndrome

6.4 RECOMMENDATIONS

1. In-depth assessment of patients with pseudoexfoliation syndrome to identify ocular morbidities earlier and institute proper management.
2. A follow-up study in the community to determine the true prevalence of pseudoexfoliation in the Somali community.

6.5 LIMITATIONS OF THE STUDY

The study was hospital-based therefore; the results cannot be generalized to represent the prevalence of pseudoexfoliation in the community.

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APPENDICES

Appendix 1: Questionnaire

Serial NO: _____

QUESTIONNAIRE

The prevalence and ocular findings of pseudoexfoliation syndrome among Somali patients at Garissa County referral hospital eye clinic

A. PERSONAL DETAILS

Date **(Tarehe):** _____

Hosp No (**Nambari ya hospitali):** _____

Age **(Umri):** _____

Sex (**Jinsia):** _____

Clan and Nationality (**Kabila na utaifa):** _____

Place of Residence(urban/rural)

Mahala pa kuishi(vijiji/mji): _____

B. OPHTHALMIC HISTORY

i. Chief Complain **(Malalamiko mkuu):** _____

ii. Duration (in month) (**Muda kwa mwezi):** _____

iii. First-time visit / Follow up

(**Mara ya kwanza/ziara ya kufatilia):** _____

iv. On glaucoma medications (**Utumiaji ya dawa wa Glaucoma)** (Yes/NO)

RE: _____LE: _____

v. Had Glaucoma Surgery (**Upasuaji wa glaucoma)** (Yes/NO)

RE ☐ LE ☐

C. EXAMINATION FINDINGS

I. Visual acuity: RE: _____ BCVA_____

LE _____ BCVA_____

II. IOP: RE: _____LE: _____

III. Presence of white, flaky materials on corneal endothelium (Yes/N0)

RE ☐ LE ☐

IV. Presence of white flaky materials on pupillary margin (Yes/N0)

RE ☐ LE ☐

V. Gonioscopy finding:

a) Grade

RE _____ LE _____

b) increased pigmentation of posterior trabecular meshwork (Yes/NO)

RE ☐ LE ☐

VI. LENS

a) The presence of white, Flaky deposits on the anterior lens capsule/IOL (Yes/NO)

RE ☐ LE ☐

b) Presence of Cataract (Yes/NO)

RE ☐ LE ☐

If yes, indicate the type (Nuclear/ Cortical/PSC/Mixed)

RE: _____ LE: _____

c) Presence of phacodenesis (Yes/NO)

RE ☐ LE ☐

d) Location of lens/IOL

Central (Yes/NO)

RE ☐ LE ☐

Subluxated (Yes/NO)

RE ☐ LE ☐

Dislocated (Yes/NO)

RE ☐ LE ☐

VII) Fundoscopy findings

VCDR: RE:_____ LE: _____

Appendix 2: Study Budget

Item	Unit price	Quantity		Total cost (ksh)
Proposal/Ethical approval				
Proposal printing (50 pages) (Before ERC Corrections)	10	3 copies(150pages)		1500
Binding of first proposal	100	3 copies		300
Ethics proposal cost				2000
Proposal Printing (After ERC Corrections)	10	3 copies(150pages)		1500
Binding of second proposal	100	3 copies		300
Internet Costs				12000
			Subtotal	**17,300**
Traveling and Collection of data				
Printing of Questionnaires	10	5 pages (144)		7200
Stationery (Pens)	10	20		400
Box file for questionnaires	400	2		800
Dilating drops (tropicamide with phenylephrine)	350	10		3500
Proparacaine	300	10		3000
Viscoelastic device	400	24		9600
Flash disc (16gb)	2000	1		2000
GRH research permission letter				1500
Travelling cost	182	124		22,568
Miscellaneous cost				10,000
			Subtotal	**60,568**
Contracted services				
Statistician				40,000
Data entry clerk (Excel)				20,000
			Subtotal	**60000**
Dissemination				
Printing of final book	10	(Approximately 100 pages) 3 copies		3000
Binding of finished book	500	7 copies		3,500
			Subtotal	**6500**
			Total	**144,368**

Appendix 3: Study time frame

Task/Time	Mar-22	Apr.	May	Jun.	Jul.	Aug.	Sept.	Oct.	Nov.	Dec.	Jan-23	Feb.	Mar.	Apr.	May	Jun.
Concept development																
Proposal development																
Proposal presentation at department																
Ethical approval																
Data collection																
Data analysis And presentation																
Result dissemination and close-out																

Appendix 4: Participant Information and Consent Form

Serial number: _____

Title of the project: The prevalence and ocular presentation of pseudoexfoliation syndrome among Somali patients at Garissa County referral hospital eye unit

Principal Investigator\and institutional affiliation: Dr Moulid Omar Abdi, resident of ophthalmology, university of Nairobi.

Co-Investigators and institutional affiliation: Dr Emmanuel NYENZE (University of Nairobi), Dr Sheila MARCO(University of Nairobi) and Dr Amal Ahmed(Garissa County Referral Hospital).

Participant information

The above study will be conducted at Garissa County Referral Hospital by the researcher listed above. The purpose of the study is to determine the prevalence and ocular presentation of pseudoexfoliation syndrome among Somali patients attending the hospital during the study period (January to April 2023). The study will provide information that will assist in the management of patients with pseudo-exfoliation syndrome.

Participation in this study is entirely voluntary and participants may withdraw from the study at any time without necessarily giving a reason for their withdrawal. Refusal to participate in the research will not affect the services participants are entitled to in this health facility or other facilities. Participants are free to ask questions and there is no money for participation in the study.

For the participants who agree to participate in the study eye drops will be instilled into their eyes to dilate their pupils to examine the posterior segment of their eyes.

The side effect of the eye drops includes dilating the eye and making your vision blurred temporarily for a short duration of up to 6 hours. During this time participants will feel increased sensitivity to light and will be advised not to drive.

The participants' eyes will then be examined by the researcher and Information obtained from the participants will be kept confidential. A copy of this form will be given to the participants for their records.

CONSENT FORM (STATEMENT OF CONSENT)

Participant's statement

I have read this consent form or had the information read to me. I have had my questions answered in a language that I understand. The risks and benefits have been explained to me. I understand that my participation in this study is voluntary and that I may choose to withdraw at any time. I freely agree to participate in this research study. I understand that all efforts will be made to keep information regarding my identity confidential.

By signing this consent form, I have not given up any of the legal rights that I have as a participant in a research study.

I agree to participate in this research study (Tick). Yes ( ) No ( )

Participant printed name: _____

Participant signature / Thumb stamp _____ Date _____

Researcher's statement

I, the undersigned, have fully explained the relevant details of this research study to the participant named above and believe that the participant has understood and has willingly and freely given his/her consent.

Researcher's name: _____ **Date: _____**

Signature _____

Witness Printed Name (If a witness is necessary, A witness is a person mutually acceptable to both the researcher and participant)

Name _____ Contact information _____

Signature/Thumb: _____ Date; _____

For more information contact _____ at _____ from _____ to _____

Appendix 3: FOMU YA TAARIFA NA RIDHAA YA MSHIRIKI

Nambari ya mfululizo: _____

Kichwa cha mradi: Kuenea na uwasilishaji wa macho wa ugonjwa wa pseudoexfoliation miongoni mwa wagonjwa wa Kisomali katika kitengo cha macho cha hospitali ya rufaa ya Kaunti ya Garissa.

Mpelelezi Mkuu\na uhusiano wa kitaasisi: Dkt.Moulid Omar Abdi, mwanafunzi mkazi,idara wa macho,chou kikuu cha Nairobi.

Wachunguzi-wenza na uhusiano wa kitaasisi: Dr. Emmanuel NYENZE (Chou kikuu cha Nairobi),Dr.Sheila MARCO(Chuo kikuu cha Nairobi) and Dr.Amal Ahmed(Hospitali ya rufaa ya kaunti ya Garissa).

Taarifa za mshiriki

Utafiti hapo juu utafanywa katika hospitali ya rufaa ya kaunti ya Garissa na mtafiti aliyeorodheshwa hapo juu. Madhumuni ya utafiti ni kubainisha kuenea na uwasilishaji wa macho wa ugonjwa wa pseudoexfoliation miongoni mwa wagonjwa wa Kisomali wanaohudhuria hospitali wakati wa kipindi cha utafiti (Januari hadi Aprili 2023). Utafiti utatoa maelezo ambayo yatasaidia katika udhibiti wa wagonjwa wenye ugonjwa wa pseudoexfoliation.

Ushiriki wa utafiti huu ni wa hiari kabisa na mshiriki anaweza kujiondoa kwenye utafiti wakati wowote bila kutoa sababu ya kujiondoa. Kukataa kushiriki katika utafiti hakutaathiri huduma wanazostahiki washiriki katika kituo hiki cha afya au vituo vingine. Washiriki wako huru kuuliza swali na hakuna pesa kwa ajili ya kushiriki katika utafiti.

Kwa washiriki wanaokubali kushiriki katika utafiti matone ya macho yatawekwa kwenye macho yao ili kutanua mboni zao ili kuchunguza sehemu ya nyuma ya macho yao.

Madhara ya matone ya jicho ni pamoja na kupanua jicho na kufanya macho yako kuwa na ukungu kwa muda mfupi wa hadi saa sita. Wakati huu mshiriki atahisi kuongezeka kwa unyeti kwa mwanga na atashauriwa kutoendesha gari.

Kisha macho ya washiriki yatachunguzwa na mtafiti na Taarifa zitakazopatikana kutoka kwa washiriki zitawekwa siri. Nakala ya fomu hii itatolewa kwa washiriki kwa rekodi zao.

FOMU YA RIDHAA (TAARIFA YA RIDHAA)

Kauli ya mshiriki

Nimesoma fomu hii ya idhini au nimesomewa maelezo. Nimejibiwa maswali yangu kwa lugha ninayoielewa. Hatari na faida za utafiti zimeelezewa kwangu. Ninaelewa kuwa ushiriki wangu katika utafiti huu ni wa hiari na kwamba ninaweza kuchagua kujiondoa wakati wowote. Ninakubali kwa uhuru kushiriki katika utafiti huu. Ninaelewa kuwa juhudi zote zitafanywa ili kuweka maelezo kuhusu utambulisho wangu wa kibinafsi kuwa siri.

Kwa kutia saini fomu hii ya idhini, sijaacha haki zozote za kisheria nilizo nazo kama mshiriki katika utafiti.

Ninakubali kushiriki katika utafiti huu (Weka Jibu). Ndio ( ) La ( )

Jina lililochapishwa la mshiriki: _____

Sahihi ya mshiriki / mhuri ya kidole gumba _____Tarehe _____

Kauli ya mtafiti

Mimi, aliyetia sahihi hapa chini, nimeeleza kikamilifu maelezo muhimu ya utafiti huu kwa mshiriki aliyetajwa hapo juu na ninaamini kuwa mshiriki ameelewa na ametoa ridhaa yake kwa hiari na kwa uhuru.

Jina la Mtafiti: _____ Tarehe: _____

Sahihi _____

Jina Lililochapishwa na Shahidi (Ikiwa shahidi ni muhimu, Shahidi ni mtu anayekubalika kwa pande zote mbili kwa mtafiti na mshiriki)

Jina _____Maelezo ya mawasiliano _____

Sahihi/Muhuri wa kidole gumba:_____ Tarehe; _____

Foomka Oggolaanshaha iyo Macluumakdka Ka qayb qaataha

Magaca mashruuca: Baahinta iyo soo bandhigida cudurka 'pseudoexfoliation syndrome' ee indhaha kudhaca bukaannada Soomaaliyeed ee jooga qaybta isha ee isbitaalka ween ee ismaamulka dowlada Gaarisa

Agaasimaga cilmi barista iyo hay'ad la xiriirta: Dr. Moulid Omar Abdi, degane cilmiga indhaha, Jaamacadda Nairobi

Kal kaaliyaha cilmi barista iyo hay'adaha la xiriiro: Dr. Emmanuel NYENZE (Jaamacadda Nairobi), Dr.Sheila MARCO (Jaamacadda Nairobi) iyo Dr.Amal Ahmed (Cisbataalka ween ee Garissa).

Macluumaadka ka qaybqaataha

Daraasada sare kuxusan waxaa lagu samayn doonaa cisbitaalka ween ee ismaamulka dowlada Gaarisa oo uu fulinayo cilmi-baadhaha kor ku xusan. Ujeedada daraasadda ama cilmi barista ayaa ah in la go'aamiyo baahsanaanta iyo soo bandhigida cudurka 'pseudoexfoliation syndrome' ee indhaha ay bukaannada Soomaaliyeed ee tagaya ama booqanaayo cisbitaalka ween muddada daraasadda dhexdeeda (Janaayo ilaa Abriil 2023) . Daraasadan ama cilmi baaristan waxaa ay kacaawinaysaa sidii loo maamuli lahaa bukaanka qabo cudurka pseudoexfoliation syndrome.

Ka-qaybgalka daraasaddan/cilmi baaristan gabi ahaanba waa ikhtiyaarka ka qabygalaha, ka-qaybgalayaashuna way ka bixi karaan daraasadda wakhti kasta iyada oo aan loo baahnayn inay dhiibaan sababta ay uga baxaayaan. Diidmada ka qaybgalka cilmi baarista ma saameyn doonto adeegyada kaqeybgalayaashu ay xaqa u leeyihiin inay ka helaan xaruntan caafimaadka ama xarumaha kaleba. Ka qaybgalayaasha waa u madax bannaan inay su'aalo weydiiyaan mana jirto lacag loogu talagalay ka qaybgalka daraasadda.

Ka-qaybgalayaasha oggolaaday inay ka qaybqaataan daraasaadka indhaha ayaa lagu shubi doonaa indhahooda si ay u kala furfuraan bucda indhaha, si ay u baadhaan qaybta dambe ee indhahooda.

Waxyeellada ay leedahay daawada waxaa ka mid ah inad dareento inn isha balaarato iyo ka dhigista araggaaga mid madow oo ku meel gaar ah muddo gaaban oo ilaa 6 saacadood ah. Inta lagu jiro wakhtigan ka qaybqaataha wuxuu dareemi doonaa kororka dareenka iftiinka waxaana lagula talin doonaa inuusan gaari wadin.

Ka qaybgalayaasha indhahooda ayaa markaas kadib baari doona cilmi-baaraha. Dhamaan xogta laga helo ama laga qaado ka-qaybgalayaashuna waxay ahaan doonaan kuwo sir ah. Nuqul ama qayb ka mid ah foomkan ayaa la siin doonaa ka qaybgalayaasha.

Foomka Oggolaanshaha (Oraada oggalaanshaha)

Hadalka ka qaybqaataha

Waan akhriyay foomkan ogolaanshaha ama macluumaadka waa la ii akhriyay. Waxaan fursad u helay inaan kala shoowroo cilmi-baarista la-taliyahadaraasada/cilmi barista. Su'aalahayga waxaa lagaga jawaabay luqad aan fahmayo. Khatarta iyo faa'iidooyinka waa la ii sharaxay. Waxaan fahamsanahay in ka-qaybgalkayga daraasaddan ay tahay mid ikhtiyaari ah oo aan dooran karo inaan ka noqdo wakhti kasta. Waxaan si xor ah u aqbalay inaan ka qaybqaato daraasaddan cilmi-baarista. Waxaan fahamsanahay inn dadaal buuxa la samayn doono si loo ilaaliyo macluumaadka ku saabsan arimahayga shakhsiga ah.

Saxeexa foomkan oggolaanshaha, kama turjumayso inaan katanaasulay mid ka mid ah xuquuqayha sharciga ah oo aan qayb qaadanaayo daraasaddan ama cilmi-baaristan.

Waxaan aqbalay inaan ka qaybqaato daraasaddan cilmi-baarista

Sax mid. Haa ( ) Maya ( )

Magaca buuxa ee ka qaybqaataha:

_____

Saxeexa ka qaybqaataha / shaambada suulka _____

Taariikhda _____

Hadalka cilmi-baaraha

Anigoo ah midka hoos ku saxeexan, ayaa si buuxda ugu sharaxay ka qaybqaataha kor ku magacaaban faahfaahinta la xidhiidha daraasaddan ama cilmi baadhista waxaanan aaminsanahay inn uu ka qaybqaataha fahmay oo si bareer ah oo xor ah u bixiyay ogolaansho.

Magaca Cilmi-baaraha: _____

Saxeexa _____ Taariikhda: _____

Doorkaga daraasadda: _____ [i.e. shaqaalaha daraasadda oo sharaxay foomka oggolaanshaha la wargeliyey.]

Macluumaad intaas ka badan kala xidhiidh _____ ah_____

laga bilaabo _____ ilaa _____

Magaca Markhaati galaha (Haddii markhaati loo baahdo. Markhaatigu waa qof ay wada aqbali karaan cilmi-baadhaha iyo ka qaybqaataha labadaba)

Magaca buuxa_____

Halka lagaa heli karo _____

Saxiixa / Shaabadda Suulka: _____

Taariikhda:_____

Appendix 5: Ethical approvals

UNIVERSITY OF NAIROBI

FACULTY OF HEALTH SCIENCES

P O BOX 19676 Code 00202

Telegrams: vanity

Tel. 2726300 Ext 44355

KNH.UON ENC

Email: uonknh_erc@uonbi.ac.ke

Website: http://www.erc.uonbi.ac.ke

Facebook: https://%%.facebook.com/uonknh.erc

Twiter•. ONKNH_ERC https://twitter.com/UONKNH_ERC

KENYATTA NATIONAL HOSPITAL

P O BOX 20723 Code 00202

Tel: 726300-9

Fax: 725272

Telegrams: MEDSUP, Nairobi

Ref: KNH-ERC/A/94

3rd March, 2023

Dr. Moulid Omar Abdi

Reg.No.H58/38031/2020

Dept. of Ophthalmology

Faculty of Health Sciences

University of Nairobi

Dear Dr. Abdi,

RESEARCH PROPOSAL: THE PREVALENCE AND OCULAR FINDINGS OF PSEUDOEXFOLIATION SYNDROME AMONG SOMALI PATIENTS AT CARISSA COUNTY REFERRAL HOSPITAL EYE CLINIC (P816/10/2022)

This is to inform you that KNH-UoN ERC has reviewed and approved your above research proposal. Your application approval number is P816/10/2022.The approval period is 3rd March 2023 - 2nd March 2024.

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 KNHIJoN 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.U0N ERC

c.c. The Dean, Faculty of Health Sciences, UoN

The Senior Director, CS, KNH

The Assistant Director, Health Information Dept., KNH
The Chairperson, KNH- I-JoN ERC
The Chair, Dept. of Ophthalmology, IJoN

Supervisors: Dr. Emmanuel Muindi, Dept. of Ophthalmology, UoN Dr. Sheila Marco, Dept. of Ophthalmology, IJoN

Dr. Amal Ahmed Saeed , Consultant Ophthalmologist, Garissa County Referral Hospital

INSTITUTIONAL CONSENT FORM

Title of the project: The prevalence and ocular findings of pseudoexfoliation syndrome among Somali patients at Garissa County referral hospital eye clinic

Researcher: Dr. Moulid Omar Abdi, resident of ophthalmology, University of Nairobi.

I confirm that;

1. I read the above research's material (abstract), and I also had the opportunity to ask about the study.
2. I am aware that my institution's involvement in the study is voluntary but necessary for its completion, and that some of the patients who will visit my facility will have pertinent information collected from them and be examined by the researchers.
3. I hereby give permission for these personnel to gather pertinent data and conduct
4. necessary examinations of patients at my facility in order to conduct this research.
5. I thus fully accept that my institution will participate in the aforementioned study, having understood the significance of the study and being provided with pertinent information.

Name ..DR HAWA BAKARI BOL.....

Title.....C.E.O G.C.R.H.....

Signature.....

GARISSA COUNTY REFERAL HOSPITAL
CHIEF EXECUTIVE OFFICER
P. O. Box 29-70100, GARISSA

Date.....3/3/2023.....

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APPROVED
03 MAR 2023

REPUBLIC OF KENYA

NATIONAL COMMISSION FOR
SCIENCE,TECHNOLOGY & INNOVATION

Ref No: **472024**

Date of Issue: **05/April/ 2023**

RESEARCH LICENSE

This is to Certify that Dr.. Moulid Omar Abdi of University of Nairobi, has been licensed to conduct research as per the provision of the Science, Technology and Innovation Act, 2013 (Rev.2014) in Garissa on the topic: the prevalence and ocular findings of pseudoexfoliation syndrome among Somali patients at Garissa County Referral hospital eye clinic for the period ending : 05/April/ 2024.

License No: **NACOSTI/P/23/24472**

472024

Applicant Identification Number

Director General
NATIONAL COMMISSION FOR
SCIENCE,TECHNOLOGY &
INNOVATION

Verification QR Code

NOTE: This is a computer generated License. To verify the authenticity of this document,
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See overleaf for conditions

THE SCIENCE, TECHNOLOGY AND INNOVATION ACT, 2013 (Rev. 2014)

Legal Notice No. 108: The Science, Technology and Innovation (Research Licensing) Regulations, 2014

The National Commission for Science, Technology and Innovation, hereafter referred to as the Commission, was the established under the Science, Technology and Innovation Act 2013 (Revised 2014) herein after referred to as the Act. The objective of the Commission shall be to regulate and assure quality in the science, technology and innovation sector and advise the Government in matters related thereto.

CONDITIONS OF THE RESEARCH LICENSE

1. The License is granted subject to provisions of the Constitution of Kenya, the Science, Technology and Innovation Act, and other relevant laws, policies and regulations. Accordingly, the licensee shall adhere to such procedures, standards, code of ethics and guidelines as may be prescribed by regulations made under the Act, or prescribed by provisions of International treaties of which Kenya is a signatory to
2. The research and its related activities as well as outcomes shall be beneficial to the country and shall not in any way; i. Endanger national security
    ii. Adversely affect the lives of Kenyans
    iii. Be in contravention of Kenya's international obligations including Biological Weapons Convention (BWC), Comprehensive Nuclear-Test-Ban Treaty Organization (CTBTO), Chemical, Biological, Radiological and Nuclear (CBRN).
    iv. Result in exploitation of intellectual property rights of communities in Kenya
    v. Adversely affect the environment
    vi. Adversely affect the rights of communities
    vii. Endanger public safety and national cohesion
    viii. Plagiarize someone else's work
3. The License is valid for the proposed research, location and specified period.
4. The license any rights thereunder are non-transferable
5. The Commission reserves the right to cancel the research at any time during the research period if in the opinion of the Commission the research is not implemented in conformity with the provisions of the Act or any other written law.
6. The Licensee shall inform the relevant County Director of Education, County Commissioner and County Governor before commencement of the research.
7. Excavation, filming, movement, and collection of specimens are subject to further necessary clearance from relevant Government Agencies.
8. The License does not give authority to transfer research materials.
9. The Commission may monitor and evaluate the licensed research project for the purpose of assessing and evaluating compliance with the conditions of the License.
10. The Licensee shall submit one hard copy, and upload a soft copy of their final report (thesis) onto a platform designated by the Commission within one year of completion of the research.
11. The Commission reserves the right to modify the conditions of the License including cancellation without prior notice.

12. Research, findings and information regarding research systems shall be stored or disseminated, utilized or applied in such a manner as may be prescribed by the Commission from time to time.
13. The Licensee shall disclose to the Commission, the relevant Institutional Scientific and Ethical Review Committee, and the relevant national agencies any inventions and discoveries that are of National strategic importance.
14. The Commission shall have powers to acquire from any person the right in, or to, any scientific innovation, invention or patent of strategic importance to the country.
15. Relevant Institutional Scientific and Ethical Review Committee shall monitor and evaluate the research periodically, and make a report of its findings to the Commission for necessary action.

National Commission for Science, Technology and
Innovation(NACOSTI),
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