



**St. Paul's Hospital
Millennium Medical College**
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**PENETRATING KERATOPLASTY AT SAINT PAUL HOSPITAL MILLENNUM
MEDICAL COLLEGE, ADDIS ABABA ETHIOPIA INDICATIONS AND OUTCOMES**

**RESEARCH PROPOSAL SUBMITTED IN PARTIAL FULLFILLMENT FOR
SPECIALITY CERTIFICATE IN OPHTHALMOLOGY**

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ACRONYMS

ACGR	Australian Corneal Graft Registry
ABK.....	Aphakic bullous keratopathy
BK	Bullous keratopathy
HSK	Herpes simplex keratitis
IOP	Intraocular pressure
KCN.....	keratoconus
PBK	Pseudophakic bullous keratopathy
PKP	Penetrating keratoplasty
SPHMMC.....	Saint Paul's hospital millennium medical college
SPSS.....	Statistical Package for Social Science
VA.....	visual acuity
WHO	World Health Organization

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1. ABSTRACT

Background: blindness is among the major public health problems in the world, acquired corneal blindness is the third leading cause of visual loss. The large proportion of blindness, mainly found in developing world, is either preventable or treatable.

Penetrating keratoplasty is one of the most successful and most frequently performed solid organ transplants world-wide, which can alleviate selected cases of corneal blindness. However there are few centers that offer penetrating keratoplasty in developing countries especially in sub-Saharan Africa like Ethiopia despite the huge burden imposed by corneal blindness. In addition to these there are limited number of researches done so far that assess the common indications and outcome of PKP in such areas.

Objective: To assess the indications and outcomes of penetrating keratoplasty at Saint Paul's hospital millennium medical college, Addis Ababa; Ethiopia.

Methods: This study is a retrospective cohort of patients for whom PKP was done. The medical records of patients who underwent PKP at Saint Paul's hospital millennium medical college between September 2011 and September 2018 were retrospectively reviewed. The outcome measures were graft survival, visual acuity, and complication rates

Results: A total of 56 patients underwent PKP during the study period and were included in the analysis. The most common indications for PKP surgery were post infectious corneal opacity or leucoma (44.6%) and previous graft failure (19.6%), corneal dystrophy in (10.7%), bullous keratopathy (8.9%), keratoconus (7.1%), and corneal ulcer (5.4%). The overall graft survival at 2 years follow up was 76.8%. Most of the patients present with visual acuity of severe visual impairment or being blind (78.6%). At one year patients with normal uncorrected VA 6/6-6/18 (26.8%) and those with 6/24-6/60 were (34.1%). The common complications were loose stitches (41.8%) and epithelial defect (25.5%).

Conclusion: Leukoma / post infectious corneal opacity is the commonest indication for PKP in our setting.

Ethical review: Ethical approval will be obtained from the SPHMMC, Ethics and Research Committee.

2. INTRODUCTION

2.1 Background

Visual impairment and blindness are among the major public health problem globally. The World Health Organization estimates that globally about 314 million people are visually impaired, of whom 45 million are blind. It has been estimated that over 80% of global visual impairment is preventable or treatable.(1) Globally, acquired corneal blindness is the third leading cause of visual loss after cataract and glaucoma respectively, accounting for 8 million blind, including 1.5 million blind children.(2,3)

In some parts of Africa, 25% to 90% of all causes of blindness are of corneal origin and corneal blindness ranks second only to cataracts as the leading cause of blindness.(4–8) The World Health Organization estimates that corneal blindness is the second leading cause of blindness among all age groups in Ethiopia and the leading cause of visual impairment among children and adolescents in that country.(9)

Ever since the first successful human full-thickness corneal transplant, or penetrating keratoplasty (PKP), by Eduard Zirm in 1906.(10) it has been regarded as one of the most frequently performed tissue transplantations in humans.(11) Improvement in instrumentation and surgical techniques, systematic and efficient tissue banking, and better postoperative management have collectively improved corneal transplant outcome and a relatively high success rate.(12) The eye bank of Ethiopia has been operating in the country since 2003, one of the few eye banks in Africa and the only in Ethiopia, sourcing donor cornea throughout the country.

2.2 Statement of the problem

Although most causes of corneal blindness in less developed nations are either treatable or preventable but in most of such countries the access to sight-restoring corneal transplantation remains challenging.(3) This is because there is limited number of trained corneal surgeons and eye centers that provide corneal transplantation services exacerbated by lack of trained supporting stuffs and inadequate operating room equipment's. There is also few eye banks available sourcing for donor cornea and limited access for corrective lenses for visual rehabilitation.(13,14)

In Ethiopia, Menelik II hospital, a tertiary referral center located in the capital city Addis Ababa, has been the first & the only center with few surgeons providing corneal transplantation for many years. Currently the number of corneal surgeons and the eye centers in the country that provide corneal transplant service (both governmental & private) increase in number. St. Paul's hospital millennium medical college eye center is the second governmental institution in the capital giving corneal transplant service for the past few years.

The assessment of indications and outcome of PKP in Africa especially in sub Saharan Africa is limited. In Ethiopia there are only few such studies done in already established corneal

transplant centers, the one that done at Menellik II tertiary referral hospital was more than five years back.

In recent years, as the number of corneal surgeon's and corneal transplant centers start to increase in number and their allocation away from the capital city makes it possible more patients to get corneal transplantation service. Therefore it is important to describe and document the recent data regarding the main indications and outcomes of patents that undergo PKP in such centers like SPHMMC and also to compare with the previous data done locally and globally.

2.3 Literature review

2.3.1 Indications of Penetrating keratoplasty

The leading indications for corneal transplantation differ from one region to another across the world, primarily due to geographic, socioeconomic factors influencing the etiology or causes of corneal blindness and also depends on the availability and the standard of eye care in the given region.

The general indication of PKP includes: Optical (for improvement of vision and visual rehabilitation);therapeutic (for tissue substitution in refractory corneal infections; Tectonic (for reinforcing altered corneal structure e.g. corneal melting);Cosmetic (rarely, a graft may be performed to improve cosmesis)(15,16)

The common specific indications for PKP includes: keratoconus (KCN); aphakic or pseudophakic bullous keratopathy; corneal scarring of various causes like post inflammatory, post infectious or post traumatic; failed corneal graft; congenital corneal opacities; corneal dystrophies; chemical burns; and select cases of corneal ulcers with good visual potential, etc. (17,18)

A literature review on articles published from January 1980 to May 2014 on indications of PKP with a total of 141 publications from 37 countries and about 180,865 PK cases showed; Post cataract surgery edema (bullous keratopathy) was the predominant indication in North America (28.0%) and ranked second in Europe (20.6%), Australia (21.1%), the Middle East (13.6%), Asia (15.5%), and South America (18.6%). Keratoconus was the leading indication in Europe (24.2%), Australia (33.2%), the Middle East (32.8%), Africa (32.4%), and South America (22.8%). It ranked third in North America (14.2%). Keratitis was the primary indication in Asia (32.3%). Fuchs endothelial corneal dystrophy was the fourth most common indication in North America (12.9%) and Europe (10.2%) and fifth in South America (3.8%).it also revealed there is individual regional changes over time on the indication of PKP. For example in some of the developing world in the past two to three decades there has been a gradual change in profile of keratoplasty indications as a result of improvements in sanitation ,infection control and advancements in the medical and surgical ophthalmology that decrease complications.(19)

A retrospective case note review on 203 post PKP patents at the Corneoplastic Unit and Eye Bank, UK, a tertiary referral centre, over a 10 year period (1990 -1999), showed Regrafting was the most common indication (40.9%), Keratoconus was the second most common indication (15%), followed by Fuchs' endothelial dystrophy (9.3%), PBK (7.6%), and viral keratitis (5.9%).(20)

Retrospective analysis on 94 eyes that underwent PKP from January 1, 2015 to January 1, 2017 in Punjab, India showed; the most common indication for PKP was corneal opacity in 43 (42.15%) cases, post infectious cause was the most common subcategory in the corneal opacity group followed by post -trauma and post chemical burns. The other indications were active infectious keratitis in 16 (15.69%), adherent leucoma in 12 (11.76%), bullous keratopathy in 10 (9.8%), failed graft in 9 (8.82%), staphyloma in 6 (5.88%), KCN in 1 (0.98%), and miscellaneous causes in 5 (4.9%) cases. (21) In another study in India with a review of 1725 grafts, bullous keratopathy (both ABK & PBK) found to be the leading indication making up 25.5% of the cases while KCN in only 6.8% of indication for overall. This high bullous keratopathy as an indication is thought to be due to high rate of cataract surgery done in the country yearly .(22)

In the Kingdom of Saudi Arabia, a large series looked at 1721 grafts; KCN was indicated in (50.9%), corneal oedema in (20.7%), stromal corneal scarring (19.2%) and 9.1% was due to stromal corneal dystrophy.(18) Trachoma was responsible for the corneal scars.

A study among 50 patients who underwent PKP at National Eye Center Hospital, Cairo, Egypt found; the leading indication of PKP was keratoconus (36%), corneal scar due to trauma (20%), corneal scar due to infection (18%) Corneal dystrophy (14%), Bullous keratopathy (6%), corneal abscess (4%) and regrant (2%).(23) Another study from east Africa reviewed 216 corneal grafts at the Kikuyu Eye Hospital in Kenya also found that KCN the most common indication 108(50%), Corneal scar 24(11.0%), Herpes simplex keratitis 17(7.9%), Corneal dystrophy 16 (7.4%), Opaque corneal graft 14 (6.5%), Trachoma 7 (3.2%), Measles 4 (1.9%), Bacterial keratitis 4(1.9%), Other diagnoses 8 (3.7%).(14)

In Ethiopia setting Ayalew Mennen et al in a retrospective study of 312 PKP done from 2000 to 2013Gc at Menelik II tertiary Hospital Addis Ababa, Ethiopia, showed; most corneal transplants were performed for optical rather than therapeutic indications (N = 330; 99%) and the most common indication found to be trachoma or leukoma in 141(44%), followed by corneal dystrophy in 46 (14%), keratoconus in 45 (14%), PBK or ABK in 28(9%), trauma in 27 (8%), previous graft failure in 18 (6%), active ulcer, burn or perforation in 9 (3%), and others in 7 (2%).(24) Another study ,outcome of corneal transplantation versus indications in a tertiary eye care center in Ethiopia, also showed infections were the most predominant indications in Ethiopia.(13)

2.3.2 Outcome of PKP surgery

After PKP surgery, outcome measures can be analyzed under short-term and long-term time periods. Invariably, these would be determined by either visual outcome or corneal graft survival. A number of studies had looked at these two main endpoints as outcome measures in PKP series.(19)

The Australian Corneal Graft Registry (ACGR) study reviewed grafts at 1 year, 5 years and at 7 years and found that corneal grafts achieved survivals of 91%, 72% and 69% respectively over the stated periods.(25)

In outcome study of PKP in Saudi Arabia, the overall graft survival time was 88.9 months $\pm$ 4.9 months while the 3-year and 5-year cumulative survival rates were 90.7% and 84.3% respectively. At last visit following PKP 34 (40%) eyes had best Spectacle-corrected visual acuity of 20/40 or better, and 51 (60.0%) eyes had 20/80 or better, best spectacle-corrected visual acuity was worse than 20/400 in 15 (17.6%) eyes.(18) Another Asian Study from South India by Dandona et al found the graft survival (clear corneal graft) of 69% at two years after PKP surgery. (22)

In East Africa by Yorston et al found 87% of grafts for KCN were clear at two years and 65% for other causes. However, graft clarity does not always guarantee good vision. In the follow-up period, coexisting ocular problems that can reduce vision must be identified and managed appropriately. In both Yorston et al and Mboni visual outcomes were better for grafts for KCN than for other indications.(14,26) Nassar et al in Egypt Cairo the overall graft survival was 86%. Excluding failed grafts, final best-corrected visual acuity achieved was 0.5 or better in 4% patients, 0.3–0.16 in 54% patients, 0.1–0.016 in 28% patients, and less than counting fingers (CF) in 14% patients. Keratoconus had most favorable outcome with graft survival of 94.4% and final visual acuity of 0.16 or better in 83.3% patients. (23)

In Ethiopia, Ayalew Mennen et al. found graft survival rate was 80% overall at 2 years but varied considerably depending on the indication for surgery. Study participants who underwent PKP for KCN had a mean follow-up time of 46 months (SD 21), Their 2-year graft survival rate was 100% with follow-up data available for 89% of study participants (N = 40). Compared with KCN, all other indications had statistically significantly decreased 2-year graft survival including Uncorrected visual acuity improved from baseline mean logarithm of the minimum angle of resolution 2.09 (SD 0.67) to mean logarithm of the minimum angle of resolution of 1.53 (SD 1.03) at 2 years. A number of factors affected the visual acuity outcomes. Patients were not routinely refracted, and only 18% (N = 60) of patients had access to corrective spectacles or contact lenses postoperatively.(24)

2.3.3 Complications of PKP

A Clinical Study on Visual Outcome and Complications of Penetrating Keratoplasty in India by Dr. Manu Thomas et al. among 30 cases with follow period of 6 months found that most common indication was corneal opacity (36.7%) followed by bullous keratopathy (33.3%and

BCVA improved in 76.7 % cases. There was no improvement in 23.3% cases and the causes were rejection due to ocular inflammation, graft infection, glaucoma and retinal pathology detected after surgery. Complications were AC reaction, persistent epithelial defect, filamentary keratitis, suture infiltrate, fistula, vascularization, graft infection, glaucoma, cystoid macular edema and rejection. Surgical success was achieved in 83.3% cases and therapeutic success in 100% cases. (28)

Report data from the Australian Corneal Graft Registry 1990–199240 stated that the common reasons for failure of penetrating corneal graft were rejection (33%), glaucoma (11%), non-viral infections (10%), endothelial cell failure (8%), and herpetic infection (7%). (25)

In Saudi Arabia outcome study, the median follow-up period was 24 months and there was no graft failure occurring less than 6 months after surgery. Graft failure was encountered in eleven (12.9%) of 85 eyes and rate of infection was 9.4% (eight eyes). The causes of corneal graft failure in the study were immune rejection in eight of eleven (72.72%) eyes, raised IOP in two (18.18%) eyes, and infection in one (9.09%) eye. (18)

In the Yorston et al series, 5.1% of grafts failed permanently due to rejections.(14) In Mboni's review, 14.3% grafts failed due to rejection.(26)

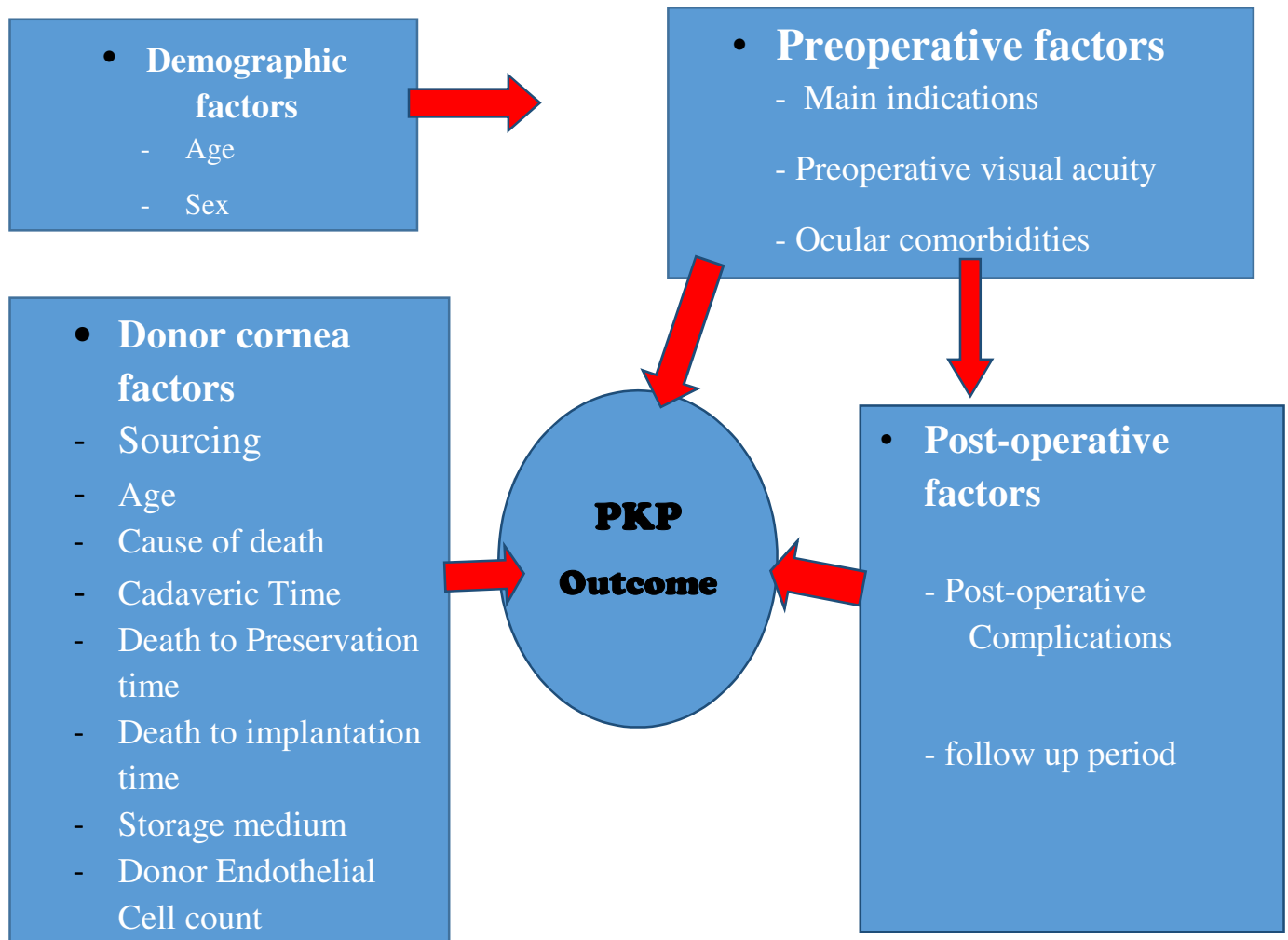
In Egypt, Nassar et al(23)after PKP Complications encountered in patients were persistent epithelial defect in five (10%), graft failure in three (6%), graft rejection in two (4%), endophthalmitis in two (4%), and recurrence of postherpetic corneal opacity in one (2%).

In Ethiopia study by ayalew Mennen et al. (24) The most common postoperative complications included infectious keratitis in 32% (N = 101), secondary glaucoma in 30% (N = 95), endothelial rejection in 26% (N = 83), and endophthalmitis in 7% (N = 21). Patients who had an episode of endothelial rejection had a 3.84-fold increase in the subsequent graft failure rate (95% confidence interval [CI] 2.44–6.04; P, 0.001). There was no observed increased risk of graft failure among study participants who developed secondary glaucoma (hazard ratio 1.06, 95% CI 0.66–1.71, P = 0.8). Compared with imported tissue, those receiving Ethiopian prepared tissue had 0.62 decreased odds of graft failure, but this was not a statistically significant difference (95% CI 0.26–1.45; P = 0.27). Complications varied somewhat by the indication for keratoplasty. As expected, previous graft failure conferred a greater risk of endothelial rejection compared with KCN (P, 0.001). Active ulcer, perforation, or corneal burn conferred a higher risk of infectious keratitis (P = 0.04) and endophthalmitis (P, 0.001) compared with study participants undergoing corneal transplant for KCN. All indications for surgery had similar rates of secondary glaucoma.

The New Zealand National Eye Bank study that looked at PKP survival and visual outcome at one year found the leading cause of failure to be irreversible rejection from one or more episodes of reversible rejection. It also found no statistically significant difference in the association between donor factors (such as age, donor source, and cause of death, death-to-preservation interval, endothelial cell density, donor lens status, and storage duration) and decreased graft survival.(29)

2.3.4 Conceptual framework

(The Conceptual framework of the study was developed after reviewing earlier similar studies to conceptualize the whole research process and to support as guide for tool development and analysis.)



3. RATIONALE OF THE STUDY

The assessment of PKP indications and outcome in Africa especially in sub Saharan Africa is limited. In Ethiopia there are only few such researches done in already established corneal transplant centers. The one that was done at the Menellik II tertiary referral hospital is more than five years back. In addition to this SPHMMC is located at a different sub city with also separate catchment area compared to the Menellik II hospital although both are found in the capital city Addis Ababa...

In recent years, as the number of corneal surgeon's and corneal transplant centers start to increase in number and their allocation away from the capital city makes it possible more patients to underwent corneal transplantation service. Therefore it is important to assess and document the recent data regarding PKP in such centers and also to compare it with the previous data done locally and globally.

SPHMMC ophthalmology clinic, the second governmental corneal transplant center located in the capital city, has been giving PKP service since 2011 but there is no available data regarding the indication and outcome of corneal transplant surgeries done so far. I hope the results of such a review will help to serve as a guide for clinicians in making best case selection, decisions as well as use the evidence in patient counseling in order to maximize the best outcomes and to help decrease complications associated with PKP surgeries.

4. OBJECTIVES

4.1 General objective

- To assess the indication and outcome of PKP over 5 years period (September 2013-september 2017), at SPHMMC ophthalmology clinic Addis Ababa, Ethiopia.

4.2 Specific objectives

- To document the main indications for PKP at SPHMMC
- To determine the outcomes of PKP at SPHMMC (in terms of visual acuity, graft survival and complication rate)
- To determine the factors that influence poor outcome following PKP at SPHMMC

5. METHODS AND MATERIALS

5.1 Study design

A retrospective (Medical Record Review) facility based cross sectional study were conducted

5.2 Study period

The study were conducted by retrospective medical record review of patients who underwent PKP from September 2011 to September 2018 at SPHMMC department of ophthalmology.

5.3 Study area

St Paul's hospital was built by Haile selasse I and with the help of the German Evangelical church in 1969G.c with main intention being helping the poor citizen. It is now a governmental tertiary referral hospital and the second largest hospital in Ethiopia which is located in Gullele sub city, in the capital city, Addis Ababa.

The hospital initially started nursing school and later the medical school (SPHMMC) was opened in 2007, the new millennium era of Ethiopian calendar, which is 7years behind the Gregorian calendar. Currently SPHMMC has 19 departments giving 14 specialty and 16 sub specialty trainings.

Ophthalmology department including optometry unit gives service for more than 16000 patients per year and started recently post graduate training in general ophthalmology having a total of 11 residents. According to the registration log book more than 2000 major and minor surgeries performed per year. There are 12 ophthalmologists giving both clinical service and teaching, of which 7 ophthalmologists and 1 anterior segment & corneal sub specialist which are full time and 2 glaucoma sub specialists and 1 vitro retinal surgeon working as part time. Although the SPHMMC eye clinic has been functioning for many years, corneal transplantation service started a few years back by one experienced Ethiopian anterior segment & corneal surgeon, who performed all of the PKP surgeries in this study.

5.4 Study populations

All patients who underwent PKP surgery during the study period

5.5 Inclusion criteria and exclusion criteria

5.5.1 Inclusion criteria

- Recorded cases of PKP performed between and inclusive of the period from September 2013to September 2018 in the study locations will be included.
-

5.5.2 Exclusion criteria

- Keratoprosthesis
- Non-optical and non-therapeutic indications: tectonic or cosmetic.
- Non-penetrating forms of keratoplasty:
 - Descemet Stripping Endothelial Keratoplasty (DSEK),
 - Descemet Stripping Automated Endothelial Keratoplasty (DSAEK)
 - Deep Lamellar Endothelial Keratoplasty (DLEK)
 - Deep Anterior Lamellar Keratoplasty (DALK)
- The triple procedure (combined corneal graft, cataract extraction and intraocular lens implantation).

5.6 Sample size determination and sampling procedure

The sample size were calculated using single population proportion formula by taking the proportion of patents who are expected to have survived corneal graft of 80 % (taken from a previous study at Menellik II tertiary referral hospital), the 95% confidence interval, precision of 5%

$$\text{Sample size (n)} = \frac{(Z_{\alpha/2})^2 P (1 - P)}{d^2}$$

Where P = proportion of patents who are expected to have survived corneal graft = 80 % (taken from a previous study at Menellik II tertiary referral hospital)(24)

d = absolute precision required

Z = $\alpha/2$ at 95% confidence interval from Z table =1.96

$$\begin{aligned}\text{Thus } n &= \frac{(1.96)^2 \times 0.8(1-0.8)}{(0.05)^2} \\ &= 245.86 \sim n = 246\end{aligned}$$

A convenient sampling method was used and all consecutive patients for whom PKP surgery was done that met the inclusion criteria in the study period were included. A total of 56 cases were included in the final analysis.

A convenient sampling method was used and all consecutive patients for whom PKP surgery was done in the study period were included. A total of 56 cases were included in the final analysis.

5.7 Variables of the study

5.7.1 Dependent variable

- Penetrating keratoplasty (PKP)

5.7.2 Independent variables

Socio demographic factors:

- Age
- Sex

Preoperative factors

- Preoperative(baseline) uncorrected visual acuity
- Preoperative diagnoses / Indications for PKP
- Preoperative ocular co-morbidity in the operated eye

Donor cornea factors

- Donor cornea Sourcing
- Donor Age
- Cause of death
- Death to preservation time
- Death to implantation time
- Storage medium
- Donor Endothelial Cell counts/Density as measured by specular microscope

Intra operative / surgical technical factors

- Corneal button size/graft diameter
- Suturing techniques
- Intra operative complications

Post-operative factors

- Complications rate
- Post-operative visual acuity improvement
- Graft survival

- Follow-up time

5.8 Operational definitions

- PKP done on both eyes of the same patient will be studied independently.
- **Graft Survival:** is when there is clear central corneal graft documented at a specific follow-up period.
- **Graft Failure:** Is when there is irreversible loss of corneal graft clarity and documented as failed graft
- **Primary Graft Failure:** Corneal graft opacity noted on the first postoperative day – synonym is **Early Endothelial Failure**.
- **Secondary Graft Failure:** An irreversible change in a graft preventing recovery of useful vision after the graft had been initially clear 2 weeks after PKP – synonym is Late Endothelial Failure.
- **Time of Graft Failure:** the first postoperative examination of which the patient was seen with a failed graft. This also marks the end-point for the inclusion of such an eye in the outcome analysis; it will be censored in the survival analysis
- **Primary Outcome** measure is the proportion of corneal grafts that remained clear at the end of the 24-month follow-up period.(24)
- **Secondary Outcome:** Measures are(24):
 - (a) **Final visual acuity:** uncorrected visual acuity at the end of the 24-month follow-up or last visit, if this was < 24 months;
 - (b) **Complications of PKP:** These can be: “early postoperative period” (events occurring within the first 2 months postoperatively); and “late postoperative period” (events continuing from or occurring after the “early” and up to the end of the 24-month follow-up period).
- **Lost to Follow-up:** when the patient had not been examined for more than one year from the first missed postoperative examination period or follow up note is not available.
- **Ocular hypertention or glaucoma:** As either a measured IOP >25mmhg or an observed increase in the cup to disc ratio.
- **Visual Acuity:** Ideally, this would refer to the recorded best corrected visual acuity for the graft recipient eye. Visual acuity will be classified according to the WHO categories of visual impairment. See Appendix II. In this review VA will be uncorrected.

5.9 Data collection procedure

Medical record numbers of patients was retrieved from the OR log book. Charts of patients were reviewed thoroughly. Sociodemographic and clinical data of the patients were retrieved. A pre-prepared data collection template was used to collect the data.

5.10. Data processing and analysis

The Data were entered and cleaned by using EPI INFO 3.5.1 and exported to SPSS version 20 for analysis. Results were summarized by using frequency with percentage for categorical variables, mean or median was used to summarize continuous variables with their respective SD and IQR. Descriptive statistic were used to describe demographic characteristics such as age, sex, and preoperative diagnosis or indications into means and percentages for categorical variables. Associations were done by using chi-square test and logistic regression. Associations were considered statistically significant when the p-value is <0.05 , and 95%CI of 95%. Visual acuity were analyzed by using snelles acuity measure for different categories, and log MAR was also used to calculate the means visual improvement. Graft Survival trend was analyzed by using Kaplan-Meier survival function.

6. RESULTS

A total of 56 patients underwent PKP between September of 2011 and September of 2018 were included in this study. There were 29 males (51.8%) and 27 females (48.2%). The median age of the patients was 26 years, with inter-quartile range of 20; minimum and maximum ages were 7 years and 70 years, respectively. The address where most patients came was from Addis Ababa (66.1%) and the rest were from other areas (33.9%). All had baseline uncorrected visual acuity of 6/60 and below at presentation. About 44 (78.6%) of the eyes were blind at presentation (visual acuity of <3/60 - LP). Most (48.2%) had visual acuity limited to counting finger in front, hand motion and light perception, and 30.4% had visual acuity in the range of 2/60 to 1/60.

Table 1. Background characteristics of the patients			
		Frequency	%
Sex	Male	29	51.8%
	Female	27	48.2%
Address	Addis Ababa	37	66.1%
	other area	19	33.9%
Presenting uncorrected Visual acuity	6/6-6/18	-	-
	6/24-6/60	8	14.3
	5/60-3/60	4	7.1%
	2/60-1/60	17	30.4%
	CFI/HM/LP	27	48.2%

Note: CFI = counting finger in front, HM =hand motion, LP = light perception

PKP surgery were done for optical reason for most of the patients (94.6%) and only three patients underwent PKP for therapeutic reasons (5.4%). The most common indications for PKP surgery were post infectious corneal opacity or leucoma (44.6%) and previous graft failure (19.6%). The other indications were corneal dystrophy in (10.7%), bullous keratopathy (8.9%), keratoconus (7.1%), and corneal ulcer (5.4%).

Different types of ocular comorbidities were identified among 42.9% of the patients. The most common comorbidity which accounted for 37.5% of the total comorbidity was vascularized cornea. The next most common comorbidity was keratitis or uveitis accounting for 33.3% of the total comorbidity.

Table 2. Preoperative diagnoses/indications for PKP			
		Frequency	%
Reason for transplant	Optical	53	94.6%
	Therapeutic	3	5.4 %
Main indication	Leucoma or post infectious corneal opacity	25	44.6%
	previous graft failure	11	19.6%
	corneal dystrophy	6	10.7%
	bullous keratopathy(Pseudophakic / aphakic)	5	8.9%
	Keratoconus	4	7.1%
	active ulcer / corneal perforation	3	5.4%
	traumatic CO	1	1.8%
	Others	1	1.8%
Ocular comorbidity	no comorbidity	32	57.1%
	vascularized cornea	9	16.1%
	keratitis or uveitis	8	14.3%
	advanced glaucoma	1	1.8%
	congenital anomaly / nystagmus	1	1.8%
	retinal problem	1	1.8%
	sever vernalkerato conjunctivities/ VKC	1	1.8%
	corneal styphloma	1	1.8%
	Amblyopia	2	3.6%

Donor tissue for transplantation came from the Ethiopian eye bank in 92.9% of cases. The remaining donor tissue was donated from other country, United States. The male proportion of the donors was 64.3%. The median age was 25 years with IQR of 15, minimum and maximum ages of the donors were 2 years and 65 years, respectively. Most donors were black (92.9%), while 5.4% were Caucasians, and one patient was an Indian. The commonest cause of death in the donors was trauma (92.9%) and the cause of death for all source from other country were due to cardiovascular diseases (7.1%).

Optisol was the only storage media used for all donor cornea (100%). The median time from death of the donor to preservation was 5.1 hours with IQR of 3.3, while the mean duration from death of the donor to transplant was 8.2 days (SD of 3, 95% CI 7.3-9). The mean endothelial cell count was 3433 (SD 711.9, and 95% CI 3242-3623)

Table 3. Background characteristics of the donors			
		Frequency	%
Donor source	Ethiopian eye bank	52	92.9%
	Other country	4	7.1%
Donor sex	Male	36	64.3%
	Female	20	35.7%
Donor race	Black	52	92.9%
	Caucasian	3	5.4%
	Indian	1	1.8%
Donor cause of death	Trauma	52	92.9%
	Cardiovascular disease	4	7.1%
Storage medium	Optisol	56	100 %

With regard to the operated eye, PKP performed 48.2% for the right eye, and 51.8% for the left eye. The type of anesthesia used was local retro bulbar anesthesia for all of the operations (98%) except for one seven years old patient who undergo surgery under general anesthesia. The average donor graft diameter was 8 mm (range 7–8.75 mm), and all grafts were performed with an interrupted suture technique (100%), intra operative complications were observed in only three (1.8%) of patients; one vitreous loss, one iris injury, and one sub conjunctival hemorrhage.

The most common post-operative complication was loose stiches which occurred in 41.8% of the transplants, followed by epithelial defect which was observed in 25.5% of the transplants. The other common complications were high IOP (18.2%), infectious keratitis (18.2%), and corneal abscess and Endophthalmitis in 12.9%. Graft rejection occurred in 11.1%, three patients had wound incarceration and one had graft revascularization.

In this study, the overall graft survival at 2 years follow up was 76.8%.The overall incidence of graft failure was 23.2%. Among the cases of failed grafts 7.1% were primary failure and 16.1% were secondary graft failures. Among the cases with secondary graft failure, 5/9 (55.6%) detected at 6th month, 3/9 (30%) at one year, and 1/9 (11%) at 2nd year. Overall, 85.6% of the graft failures occurred by one year after transplant. The most common causes of failed graft were graft rejection and infectious complications. Graft rejection accounted for 31.6% of the failed grafts, while infectious complications accounted for 26.3% of the failed grafts. Other causes of graft failure were; epithelial defect 21%, high IOP 10.5%, and revascularization and wound incarceration 5.3%, each.

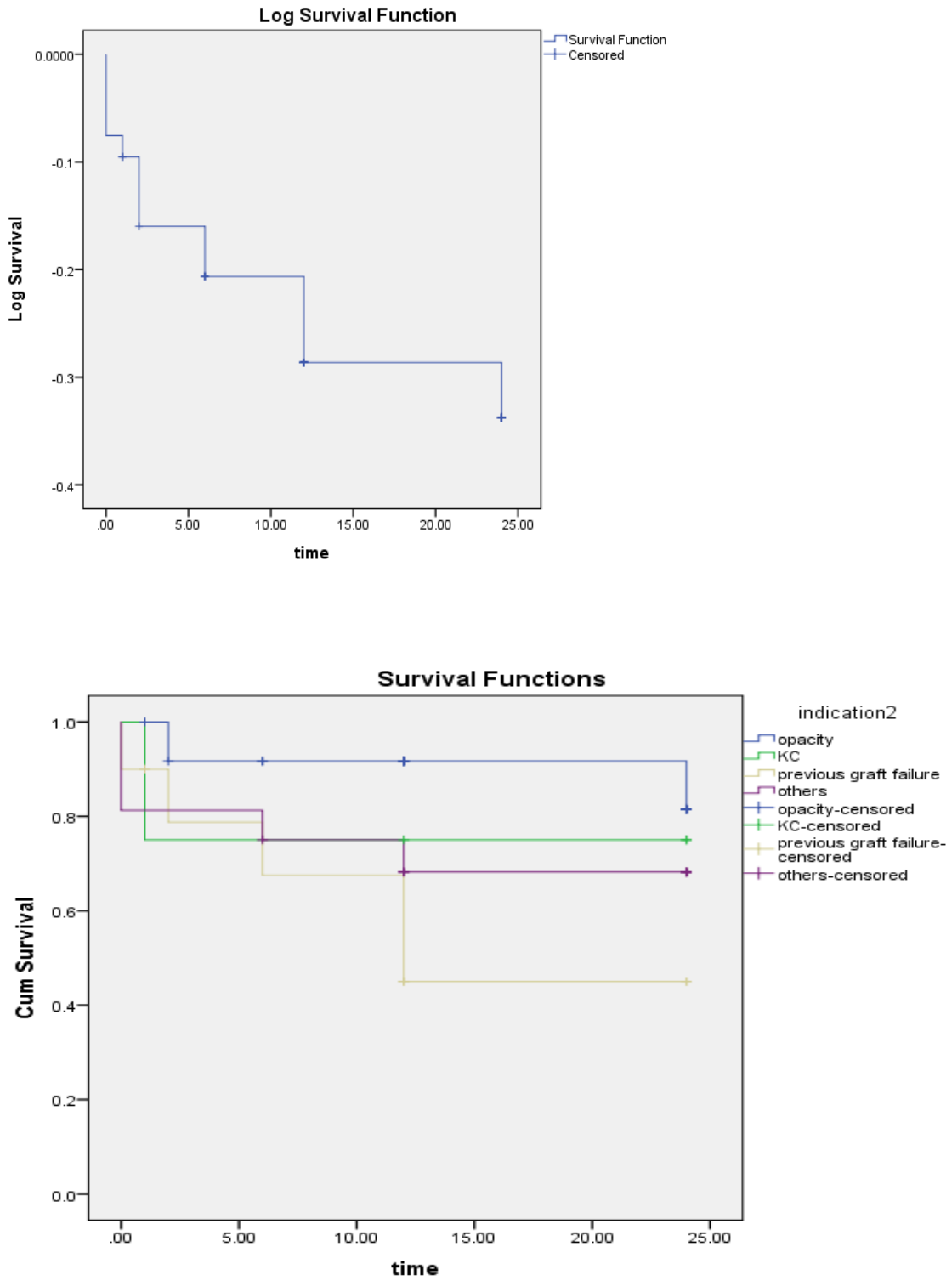


Figure 2 graft survival

There was no statistically significant difference on the mean distribution of the patient's and donor's age, corneal size, and endothelial cell count when compared in those with graft failure versus those who did not have graft failure. The mean, SD and their statistical significance value of these variables is given in the table below.

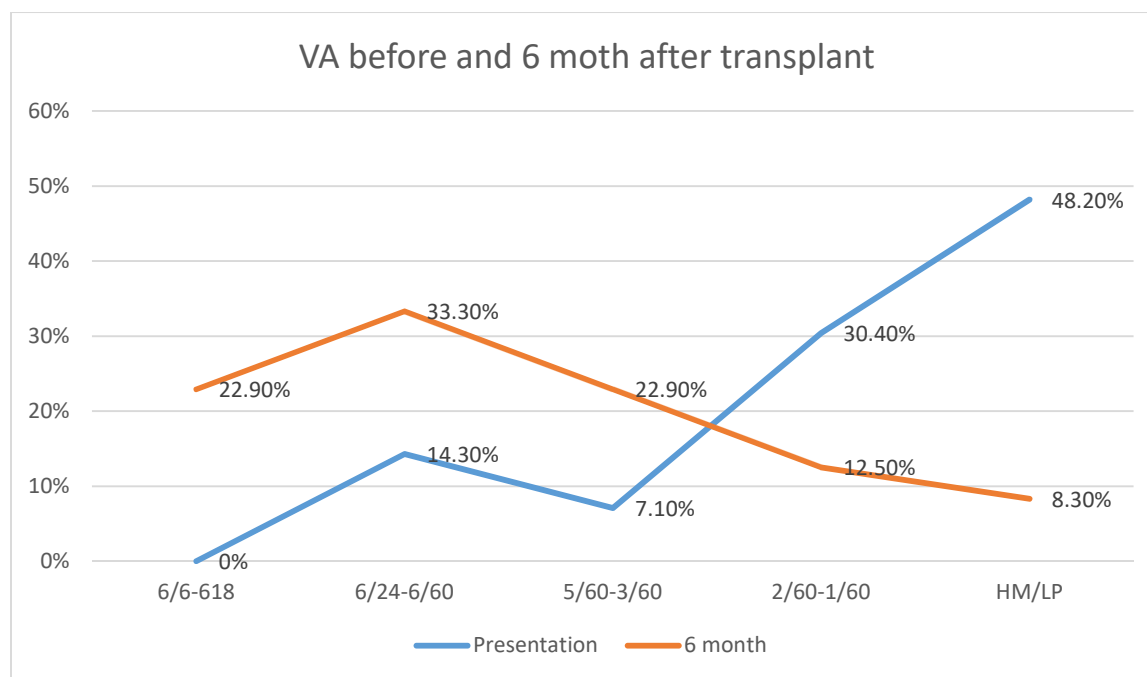
The risk of graft failure was higher in patients for whom PKP was done for previous graft failure and in patients with post infectious corneal opacity. Among patients who had previous graft failure, 5/9 (55.6%) of the PKP have failed, and 30.4% of transplant have failed in those PKP was done for post infectious corneal opacity. Of note, among 6 cases of transplant rejection. 5/6 (84%) occurred in transplants done for post infectious corneal opacity, and the other one case in transplant done for keratoconus. Transplant rejection did not occur in none of the transplants done for previous graft failure, and in none of the other indication for transplant, except the ones mentioned above.

Table.4 Comparison of transplant outcome and indications of transplant					
			Graft failure		Total
			Yes	No	
Main indication for PKP	leucoma/post infectious corneal opacity	Count	7	16	23
		%	30.4%	69.6%	100.0%
	corneal dystrophy	Count	0	6	6
		%	0.0%	100.0%	100.0%
	Keratoconus	Count	1	3	4
		%	25.0%	75.0%	100.0%
	Bullous keratopathy	Count	2	3	5
		%	40.0%	60.0%	100.0%
	previous graft failure	Count	5	4	9
		%	55.6%	44.4%	100.0%
	traumatic CO	Count	1	0	1
		%	100.0%	0.0%	100.0%
	active ulcer / corneal perforation	Count	2	0	2
		%	100.0%	0.0%	100.0%

Table 5 Graft rejection and indications					
			Graft rejection		Total
			Yes	No	
Main indication for PKP	leucoma/post infectious corneal opacity	Count	5	19	24
		%	20.8%	79.2%	100.0 %
	Keratoconus	Count	1	3	4
		%	25.0%	75.0%	100.0 %
	previous graft failure	Count	0	10	10
		%	0.0%	100.0 %	100.0 %
	corneal dystrophy	Count	0	6	6
		%	0.0%	100.0 %	100.0 %
	Others	Count	0	10	10
		%	0.0%	100.0 %	100.0 %
Total		Count	6	48	54
		%	11.1%	88.9%	100.0 %

On the analysis of visual outcome of the patients. Most of the patients showed significant improvement of visual acuity after the PKP surgery. At one month post PKP, only 9.1% had visual acuity limited to perception of hand motion and light compared to 48.2% before transplant. Those patient who had their visual acuity in the range of hand and light perception at one month after transplant, further improvement thereafter was less likely. However, improvement of visual acuity continued to occur up to six months for the rest of visual acuity ranges

Table 6. Visual acuity at presentation and at follow up					
Visual acuity	6/6-6/18	6/24-6/60	5/60-3/60	2/60-1/60	CF infront – LP
Admission	-	8 (14.3%)	4 (7.1%)	17 (30.4%)	27 (48.2%)
1 Month	8 (14.5%)	16,(29.1%)	12 (21.8%)	14 (25.5%)	5 (9.1%)
2 Month	6 (11.8%)	19 (37.3%)	10 (19.6%)	13 (25.5%)	3 (5.9%)
6 Month	11 (22.9%)	16 (33.3%)	11 (22.9%)	6 (12.5%)	4 (8.3%)
1 Year	11 (26.8%)	14 (34.1%)	8 (19.5%)	5 (12.2%)	3 (7.3%)
2 Year	8 (38.1%)	10 (47.6%)	2 (9.5%)	-	1 (4.8%)



7. DISCUSSION

A total of 56 patients underwent PKP between September of 2011 and September of 2018 were included in this study. The number of participant as compared to other locally done study is lower but this is due to the shorter study period and the study area being a newly established eye center. There were 29 males (51.8%) and 27 females (48.2%) and the median age of the patients was 26 years in our study which is similar finding with the previous study in Ethiopia, that showed men (52%) and women (48%) and had a mean age of 33. The review by Mboni et al found a lower female/male ratio of 1:1.2.

When we see the base line uncorrected visual acuity in our study, those with 6/24- 6/60 (14.3%), 5/60-3/60(7.1%), 2/60-1/60(30.4%) and those with count finger in front, hand motion and light perception comprises (48.2%). Thus most of the patients present with visual acuity of severe visual impairment or being blind (78.6%). Similarly Mboni et al found 13.22% at presentation with severe visual impairment and (64.4%) were blind together giving (77.6%). A previous study in Ethiopia setting found a mean baseline uncorrected visual acuity of approximately 6/640 at presentation(13) but the extent of visual impairment or blindness not stated.

The indications for corneal transplant varies greatly across different geographic areas. Many of the studies in most regions of the world so far showed KCN is the leading indication for PKP. The same is true when we see the data on some east Africa countries, for example, a study among 50 patients who underwent PKP at National Eye Center Hospital, Cairo, Egypt found; the leading indication of PKP was keratoconus (36%), corneal scar due to trauma (20%). Another study reviewed 216 corneal grafts at the Kikuyu Eye Hospital in Kenya also found that KCN the most common indication 108(50%), Corneal scar 24(11.0%), However some studies showed post inflammatory as a leading indication. Retrospective analysis on 94 eyes that underwent PKP from January 1, 2015 to January 1, 2017 in Punjab, India showed; the most common indication for PKP was corneal opacity in 43 (42.15%) cases, post infectious cause was the most common subcategory in the corneal opacity group.

In our study, all PKP were done for optical reason. The most common indications for PKP were post infectious corneal opacities (47.2%). The other indications were previous graft failure (19.6%), corneal dystrophy in (10.7%), bullous keratopathy (8.9%), keratoconus (7.1%), and corneal ulcer (5.4%). A similar observation to our study was reported about the main indication in another previous study in Ethiopia which showed 99% of transplants were done for optical reasons and the most common indication found to be trachoma or Leukoma in 44%, followed by corneal dystrophy 14%, keratoconus in 14%. In this study previous graft failure accounted for 6% of corneal transplants(13). The lower proportion of previous graft failure in this study compared to ours may be due to the smaller sample size in our study which may exaggerate relative percentages. There are also studies showed regraft as a main indications, a retrospective case note review on 203 post PKP patents at the Corneoplastic Unit and Eye Bank, UK, a tertiary referral centre, over a 10 year period (1990 -1999), showed Regrafting was the most common indication (40.9%). Therefore, the finding of post infectious corneal opacities as most common cause for transplant in our study is supported by other studies in this setup. Moreover, this is an

expected finding since infectious associated morbidities are very common in developing countries like Ethiopia.

The improvement in prevention and early treatment of infectious causes of corneal opacity, the increased number of patients diagnosed with KCN and the increases in the number of cataract surgery may change the pattern of the indication PKP in the future.

The outcome of PKP, that can be measured in terms of graft survival, visual acuity improvement and complication rate, varies considerably in different reports. The type of indication for the transplant is among the most common factors that can affect PKP outcome. PKP outcome also depends on the duration of follow up after transplant

In our study mean follow-up time for all study participants was 15 months. There was at least 6-month follow-up available for (85.7%), at one year data were available for (73.2%) and at second year follow up period data available only for (37.5%) of the participants. In this study, the overall graft survival at 2 years follow up was 76.8%. A study done in India (22) has showed overall graft survival of 69% at two years, which is comparable to the finding of our study. In our study 22.9%, 26.8% and 38.1% of the patients achieved normal vision at 6 months one year and two years follow up period respectively.

Graft survival after transplant also depends on the type of indication for the transplant. A study from east Africa showed overall graft survival of 65%, but transplant done for KCN was 87% at two years. Similarly, a study in Ethiopia showed 2 years overall graft survival of 80%, but 100% when KCN is analyzed alone. The study also indicated that, graft survival for indications other than KCN was significantly low. The graft survival of 68.2% in our study is low compared to the findings of previous study in Ethiopia and other studies. This is probably due to the difference in the relative proportions of indications for transplant in different studies. In patients included in our study, the most common indications were post infectious corneal opacity and previous graft failure cases. Both of this alone accounted for 64.2% of the transplants. There were only 4 cases of KCN. Therefore, the lower graft survival rate found in our study is reasonable when considering the low frequency of cases known to have best outcome and the small sample size in our study.

Different factors can affect outcome after corneal transplant. A study from Australia (25) reported that, the commonest cause of graft failure was graft rejection which accounted for 33% of graft failures. Other causes of graft failure were; glaucoma (11%), non-viral infections (10%), endothelial cell failure (8%), and herpetic infection (7%). In a study from Saudi Arabia (22), causes of corneal graft failure were immune rejection in eight of eleven (72.72%) eyes, raised IOP in two (18.18%) eyes, and infection in one (9.09%) eye. In our study, the most common causes of failed graft were graft rejection and infectious complications. Graft rejection accounted for 31.6% of the failed grafts, while infectious complications accounted for 26.3% of the failed grafts. Other causes of graft failure were; epithelial defect 21%, high IOP 10.5%, and revascularization and wound incarceration 5.3%, each. Our study showed that graft rejection is most common cause of graft failure which is in agreement with the results of other studies, but infectious complications directly or indirectly contributed for significant proportions of graft

failure. The result of our study also showed that graft failure was not affected by the characteristics of the donor source which was also supported by other studies.

8. CONCLUSIONS AND RECOMMENDATIONS

CONCLUSIONS

The most common indications were post infectious corneal opacities and previous graft failure.

The overall graft survival was 76.8%.

The risk of graft failure was higher in patients for whom PKP was done for previous graft failure

The most common post-OP complication was loose stiches and epithelial defect

Donor characteristics did not affect the incidence of graft failure.

RECOMMENDATIONS

To prepare follow up chart that includes peri operative conditions and follow up of patients that undergo PKP surgery

a review is recommended to look at all forms of corneal grafts (lamellar and combined procedures) in order to evaluate if the outcomes in those cases would yield any new information

To make refraction routine and provide the patient access to spectacles

It is important to prevent and early diagnosis of cause of graft failure

9. LIMITATIONS OF THE STUDY

Getting the medical cards, some of them are lost or difficult to retrieve

Incomplete or absent documentation on the medical card during follow up especially IOP measurement, post OP medications, complications.

Smaller sample size

Absence of refraction or corrected visual acuity for almost all patients

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11. ANNEXES

Annex 1: Data collection format

Title; Penetrating keratoplasty at St. Paul's hospital medical millennium college Addis Ababa
Ethiopia: indication and outcome

Full name/code _____

Medical record number _____

Part 1: Demographic data

1. Age (in years) _____
2. Sex A. Male B. Female
3. Address A. Addis Ababa B. other areas

Part 2: Patients preoperative data

4. Eye to be operated A. Right eye B. Left eye
5. Presenting Visual Acuity -----

S.N		Cont...	
6.	Preoperative diagnosis or Main Indication for surgery	General indications : A. Optical B. Therapeutic	Specific indications : A. Leukoma/trachoma or post infectious corneal opacity B. Corneal dystrophy C. Keratoconus (KCN) D. Pseudophakic bullous keratopathy E. aphakic bullous keratopathy F. Trauma G. Previous graft failure H. Active ulcer /burn /perforation I. Others (specify)-----

8.	Preoperative ocular co-morbidity (In the operated eye)	A. Normal /no significant comorbidity B. Advanced glaucoma C. Cataract D. Retinal pathology E. Dry eye F. Keratitis /uveitis G. Entropion H. Ectropion I. Aphakic J. Pseudophakic K. Failed graft L. Amblyopia M. Congenital anomaly N. Others (specify.....)
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Part 3: Donor tissue characteristics

(Extracted From the eye bank donor tissue form)

S.N		
10.	Donor Corneal Source	A. Local eye bank /Ethiopia eye bank B. Another country specify
11.	Donor age (in years)	
12.	Donor Cause of death	A. Trauma B. Cardiovascular disease C. Others (specify.....)
13.	Death to preservation time (in hours)	-----
14.	Death to implantation time (in days)	-----

15.	Storage media	A. Optisol B. Other (specify)
16.	Endothelial cell count in number (by spectrometry)	A. cells/mm ²

Part 4: Intraoperative Data

S.N		
17.	Eye operated	A. Right eye B. Left eye
18.	Anesthesia used	A. General anesthesia (GA) B. Local anesthesia: a) Retrobulbar (RBA) b) Sub tenones (STA) C. Other (specify.....)
19.	Donor corneal size	mm
20.	Recipient corneal size	-----mm
21.	Suturing technique	A. continuous B. interrupted C. Other (specify.....)
22.	Intraoperative complication	A. No complication B. Complication (Specify..... -----)

23.	Additional procedure	1. Specify.....)
24.	Others finding	

Part 5: Post-operative period -

Section 1- Post-operative Complications (First 2 weeks, 1month, 3 months, 6 months, 12 months and 24 months)

S.N	Section 1- Post-operative Complications	
	Complications	Timing
25.	A. No complication	
	B. Wound leak	
	C. Hyphema	
	D. Loose sutures	
	E. Epithelial defect	
	F. Suture related	
	G. Uveitis	
	H. infectious keratitis	
	I. Endophthalmitis	
	J. Recurrent HSK	
	K. High IOP / secondary Glaucoma	
	L. Graft edema or opacification	
	M. Others (specify)	

Section 2. Post-operative period – graft survival

(1 month, 3 months,6 months 12 months and 24 months)

S.N	Post-operative period – graft survival				
26.	Graft state	Complications	Visual acuity (un corrected)	Visual acuity (Corrected)	Timing
					1 month
					3 months
					6 months
					12 months
					24 months

Section 3: Graft failure

S.N	Graft failure		
27.	Graft failure	Timing when recognize	Possible clinical cause
	A. Primary graft failure		
	B. Secondary graft failure		