# A clinical study on indications and demography for penetrating keratoplasty in northwest Rajasthan

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# ABSTRACT

**Background:** Penetrating keratoplasty (PK) is a surgical procedure where a diseased cornea is replaced by donated corneal tissue which has been removed from a recently deceased individual having no known diseases. **Objectives:** The objectives of the study were to assess the indications and demographic profile of patients undergoing PK. **Materials and Methods:** In this retrospective cross-sectional non-interventional hospital-based clinical analysis study, hospital records of patients who had undergone for PK surgery at PBM Eye Hospital, S.P. Medical College, Bikaner, Rajasthan, from 1991 to 2020 were reviewed for demographic data (age, sex, age at presentation, etc.), indications for PK, treatment history and comorbid conditions. A total of 387 patients were included in this study. **Results:** The most common age group for PK was 61–70 years (22.23%) followed by 51–60 years (21.05%) and 41–50 years (15.48%). About 65.96% patients were male, 30.87% patients were female, and 3.17% patients were children (<14 year). In the literature, Aphakic bullous keratopathy and pseudophakic bullous keratopathy are usually considered to be the most common indications for PK but in our study corneal opacity is the most common indication (67.10%), followed by Pseudophakic bullous keratopathy (13.20%). PK was done for optical purpose in 94.50% and therapeutic in 5.5% cases. **Conclusion:** Corneal opacity is the most common indication age group for PK in northwest Rajasthan.

KEY WORDS: Penetrating Keratoplasty; Corneal Opacity; Pseudophakic Bullous Keratopathy

#### INTRODUCTION

Blindness from corneal diseases accounts for major cause of visual impairment in developing countries.<sup>[1]</sup> The diseased cornea can be replaced by donor tissue partially or totally by transplantation, by the procedure known as corneal grafting or penetrating keratoplasty (PK). The first keratoplasty was performed by Edward Zirm in 1905, with several changes and newer techniques have evolved in the past decades. Keratoplasty is being increasingly performed in large number with better eye

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banking facilities. The prognosis has improved remarkably with the advent of new techniques and postoperative management. The current choice of corneal surgeons is component keratoplasty, due to which the rate of PK has gone down significantly but PK still remains the gold standard in corneal conditions involving full thickness of the cornea.<sup>[11]</sup> The two main types of Corneal transplantation are, PK and lamellar keratoplasty (LK). The term PK commonly refers to surgical replacement of full thickness of the cornea with that of a donor eye. On the other hand, LK consists of replacing partial thickness donor corneal graft in the diseased cornea.

Indications for PK are

1. Optical keratoplasty which is done to restore vision. Important indications include bullous keratopathy, keratoconus, dystrophies, degenerations, and opacities of the cornea

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- 2. Tectonic grafting is done to restore or preserve corneal integrity in eyes with severe damage for maintaining the integrity of the ocular tissues
- 3. Therapeutic corneal transplantation is done to remove of infected corneal tissue to reduce the microbial load and aid in healing process.<sup>[2]</sup>

The eyeball or cornea is harvested within 6 h of death for best results. Pre-operative evaluations of donor corneal tissue include specular microscopy and slit lamp examination. Contraindications for harvesting donor cornea are death from unknown cause, infectious diseases of the central nervous system (e.g., progressive multifocal leukoencephalopathy), certain systemic infections such as Hepatitis B and C, AIDS, and syphilis.<sup>[3]</sup> In the current scenario of COVID-19 pandemic, voluntary donations are not encouraged, so the number of keratoplasties has declined significantly in dearth of donor corneas and stringent regulations from Eye bank society of India.

There are several factors which may adversely affect the prognosis of a corneal graft and must be addressed before surgery for successful surgical outcomes. Any abnormalities of eyelids and adnexa such as blepharitis, ectropion, entropion, and trichiasis should be corrected before surgery. Ocular surface disorders, uncontrolled glaucoma, and uveitis may affect the visual prognosis of the patients adversely.<sup>[2]</sup>

The PubMed search showed numerous reports published from different countries in the world with regard to demographics and indications for PK. Therefore, we decided to carry out a retrospective study to determine the leading indications for PK at a tertiary care center for northwest Rajasthan (S.P. Medical College, Bikaner).

# MATERIALS AND METHODS

#### **Study Site**

This study was conducted at S.P. Medical College, Bikaner, Rajasthan.

# **Study Design**

This study was a retrospective non-interventional series from hospital database.

#### Method

Available records of a total of 387 patients from 1991 to 2020, who underwent PK were included in our study. The details taken for analysis included demographic details including age, gender, occupation, and residence. Comprehensive eye examination including best corrected visual acuity, lid abnormalities, anterior and posterior segment evaluation, indication for surgery, timing and nature of surgery and post-operative follow-up was recorded. Permission from Institutional Review Board and Ethical committee was taken before the study.

## **Preoperative Preparation of Patients**

Operations were done using the standard protocol; details of the surgical procedure were obtained from Operation Theater register and Cornea Clinic records. Eyelashes were trimmed and painted with betadine 10% solution and lid margins were thoroughly cleaned with Povidone iodine. Xylocaine sensitivity test was done. Gatifloxacin eye drops were instilled hourly in the eye to be operated. Injection Mannitol 200 mL intravenously stat when IOP was to be brought under control. Tablet Acetazolamide 250 mg 2 tablets were given 1 h before surgery for making the eye soft and to counter the positive pressure during surgery. Injection Cefotaxime 1 g IV twice daily was started in all patients after sensitivity test and 1 h before surgery. 0.8% Tropicamide and 5% phenylephrine eye drops were instilled 1 drop every 10 min for 1 h, before surgery for pupillary dilatation in cases where cataract extraction was planned.

## **Surgical Technique**

Fresh Donor cornea was used in all the cases. Appropriately sized corneal donor button (6.5–8.5 mm) was trephined under aseptic precautions, and placed in a Petri dish in saline. After this, trephination in recipient was carried out (6.0–8.0 mm) and donor graft placed on recipient bed. Four primary sutures were placed to anchor the graft and further secured using 16 interrupted 10/0 nylon sutures. Care was taken to bury the sutures to prevent postoperative irritation and suture related complications. Cataract extraction with intra ocular lens implantation was done as a dual procedure in the same sitting. Anterior vitrectomy, synechiolysis, and iridectomy were done when indicated.

#### **Post-operative Management**

Injection Diclofenac 1 ampule IM stat. Injection Cefotaxime 1 gm IV BD was given for 5 days. Oral prednisolone was started in all cases in a dose of 1 mg/kg/day and tapered over 6 weeks oral Acetazolamide 250 mg TID for 3 days. Oral analgesics were given for first 5 days. Combination of Gatifloxacin-Prednisolone eye drops instilled hourly initially and then tapered gradually over 8 weeks. Homatropine eye drops were instilled BD. Lubricant eye drops were given 3 times a day. All patients were examined under slit lamp biomicroscope daily and were discharged after a week depending on the condition of the graft.

#### Follow-up

All patients were followed up at 1<sup>st</sup> week, 1<sup>st</sup> month, 3<sup>rd</sup> month, and 6<sup>th</sup> month and were instructed to use antibioticsteroid eye drops regularly up to 8 weeks. Lubricant eye drops and gel were also continued. Patients were advised to report immediately if pain, redness, blurring of vision or photophobia present. At each follow-up symptoms were noted, vision was recorded and slit lamp examination of the graft was done.

#### Suture Removal

Suture infiltrate, tight sutures, loose sutures, and vascularization at suture site were common indications for immediate removal. Otherwise, postoperatively suture removal was initiated at 4-6 months.

## RESULTS

In our study, 65.96% patients were male, 30.87% patients were female and 3.17% patients were children [Table 1]. The most common age group for PK was 61-70 years (22.23%) followed by 51–60 years (21.05%) and 41–50 years (15.48%) [Table 2]. About 84.75% patients were from rural area and 15.25% patients were from urban area [Table 3]. In our study, corneal opacity was the most common indication (67.10%), followed by pseudophakic bullous keratopathy (13.20%) [Table 4]. PK was done for optical purpose in 94.50% and therapeutic in 5.5% cases [Table 5]. Pre-operative vision was equal or less then finger count close to face in 80.10% patients [Table 6].

## DISCUSSION

Visual rehabilitation by PK is a viable option in patients with visual loss due to corneal diseases. Almost all corneal diseases can be addressed by some or the other form of keratoplasty, thereby improving the quality of life of the patient. However, the prognosis depends on the pathology responsible for causing corneal blindness which, in turn, affects the surgical outcome.

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Gender	n (%)
Male	258 (65.96)
Female	117 (30.10)
Children	12 (3.17)

Table 2: Age distribution	of study population
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Age group	n (%)
0-10	2 (0.51)
11–20	10 (2.58)
21–30	28 (7.32)
31-40	45 (11.62)
41–50	60 (15.48)
51-60	82 (21.05)
61–70	86 (22.23)
71-80	61 (15.76)
>80	14 (3.61)

Table 3: Area distribution of study population	
Area	n (%)
Rural	328 (84.75)
Urban	59 (15.25)

The purpose of this study was to document the demographics and indications for PK at our hospital which is a major referral center for the treatment of corneal diseases in the northwest Rajasthan. In our study, most of the patients (87.24%) belonged to rural areas which are because our institute is a major referral center of northwest Rajasthan and about 80% population hail from rural areas. We observed that 65.96% patients were male, 30.87% patients were female and 3.17% patients were children (<14 year) which indicate that in rural areas of Rajasthan male population involved more commonly in outdoor activities and in agriculture are more prone to corneal pathologies.

The most common age group for PK was 51-70 years (43.28%) which is because incidence of corneal pathologies such as corneal degeneration increases with age. Corneal endothelial cells count also decrease with increasing age and this age group involved more commonly in agriculture related activities in rural areas.

In our study, corneal opacity was the most common indication (67.10%), followed by Pseudophakic bullous keratopathy (13.20%). However, in the literature, Aphakic bullous keratopathy and Pseudophakic bullous keratopathy are usually considered to be the most common indications for PK.

On analysis of other studies, it was found that corneal scarring due to keratitis accounted for 52.5%, trauma accounted for 21.5% of corneal opacity and etiology was undetermined in 26% of cases. Unspecified etiology for corneal scarring is thought to be due to untreated keratitis in maximum

Table 4: Indications of PK	
Indications	n (%)
Corneal opacity	260 (67.10)
Pseudophakic bullos keratopathy	52 (13.20)
Infective keratitis	23 (5.90)
Regrafting	19 (4.9)
Others	33 (8.52)
Total	387

PK: Penetrating keratoplasty

Table 5: Purpose of PK		
Purpose of PK	n (%)	
Optical	366 (94.50)	
Therapeutic	21 (5.5)	

PK: Penetrating keratoplasty

Table 6: Pre-operative vision

PRE-OP Vision acuity	n (%)
PL +	130 (33.59)
HM	99 (25.58)
CFCF	81 (20.93)
CF<1 m	50 (12.91)
CF>1 m	27 (6.97)

number of cases. Adherent leukoma made up 26.7% of the cases of corneal scarring. Another important feature of this series was that 5.90% of the total PKs were done for active infectious keratitis. Corneal scarring and active infectious keratitis together from various etiologies was the single largest indication for PK in the developing world. This factor indicates the manifold problems prevalent in the developing countries related to availability, accessibility and affordability of eye care facilities available at the periphery, often leading to delayed diagnosis of corneal infections and consequent corneal opacification.

In comparison with our study, the ratio of PKs performed for corneal scarring has been reported to be less in the developed world.<sup>[4]</sup> Pseudophakia bullous keratopathy made up 13.20% of all cases of PK done at our institution. Pseudophakic bullous keratopathy was reported to be one of the most common indication for PK in the developed world, accounting for 17.0–38.6% of the PKs with a median value of 23.0% in the recent reports.<sup>[5]</sup>

Regrafts made up 4.9% of all PKs done at our institution and regrafting was required mainly in cases of viral keratitis. Regrafts have been reported to make up 6.6–18.2% of the indications for PK in the developed world.<sup>[6]</sup> This difference could be attributed to the difference in indication of PK done in our part of India.

Fuchs' dystrophy accounted for only 2.2% of the cases undergoing PK in our institution. In the developed world, Fuchs' dystrophy being more prevalent in the it thereby, makes up a higher proportion of the indications for PK, ranging for about 10.4% as quoted in recent reports. The other corneal dystrophies, comprising 3.2% of the PKs in our study, which is comparable with that reported from the developed world.<sup>[7]</sup>

From our study, it was concluded that the most common indication for PK in our series was corneal opacity, unlike the developed world where Pseudophakic bullous keratopathy and keratoconus are most common indications for PK.<sup>[8]</sup> Regarding prognosis, it is seen that Keratoconus has an excellent prognosis for graft survival after PK, although no PK was done for keratoconus in our series so a comparison cannot be made; Pseudophakic bullous keratopathy accounted for 13.20% of cases and were associated with good prognosis.<sup>[9]</sup> Adherent leukoma and Corneal scarring with vascularization have a poor prognosis for graft survival, and active infectious keratitis has a very poor prognosis for graft survival.

# Limitations of the Study

The results of our study apply for northwest Rajasthan and may not be applicable in other geographic locations. Data from larger sample size would be more conclusive. Since this was a demographic study, visual outcome and long-term follow-up were not included.

# CONCLUSION

After analyzing the demographic profile of patients undergoing PK, it was concluded that majority of the patients were males and involved in active work such as construction, agriculture, and industrial work. Most of the patients were of older age group coming from rural areas.

The most common indication for PK in our series of 387 patients was corneal opacity followed by bullous keratopathy. Bullous keratopathy, Fuchs endothelial dystrophy, corneal opacity, and keratoconus had favorable prognosis in the present study. Vascularized corneal opacity has high probability of graft rejection. In case of non-healing corneal ulcers patients, therapeutic success was achieved as PK could eradicate infection and save the eye. Since the therapeutic PK grafts are known to go into failure, an optical keratoplasty can be done once the eye is quiet.

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