

ORIGINAL ARTICLE

A PROSPECTIVE STUDY ON INDICATIONS AND VISUAL OUTCOME OF PENETRATING KERATOPLASTY

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ABSTRACT

Objective: Purpose of the study is to carry out a prospective study to analyze the utilization of donor corneas for different pathological conditions and the visual outcome after penetrating keratoplasty (PK).

Methods: A prospective investigational analysis of 100 donor corneas used for PK between June 2006 and June 2008 with a follow-up of 12 months, was conducted to analyse the indications and visual outcome in different pathological conditions.

Results: It was recorded that 'Corneal Opacity' was the most common indication for utilisation of donor corneas (43%), followed by Acute Infective Keratitis (AIK) cases (25%) and Pseudophakic Bullous Keratopathy (PBK) cases (14%). Utilisation of donor corneas for 'Regrafts' was in 7% cases and Descemetocoele was the indication in 5%. Acute bullous keratopathy (ABK) (3%) and Keratoconus (3%) were uncommon indications for utilisation of donor corneas in the present study. Patients having "Normal" visual acuity increased from 0% cases preoperatively, in all categories to 20.9% in corneal opacity, 14.3% in Regrafts 7.1% in PBK, 40% in Descemetocoele, 66.6% in Keratoconus, 33.3% in ABK, and 4% in AIK after 1 year.

Conclusion: Indication for utilisation of donor corneas which carry a poorer prognosis for graft survival are relatively more common in India than in the developed world but PK improves the quality of life by causing a significant improvement in visual acuity.

Keywords: Eyebank, donor cornea, penetrating keratoplasty, indications, pathological conditions, visual acuity, developing world.

INTRODUCTION

According to the World Health Organisation nearly two million people have corneal blindness which is a significant cause of visual impairment and blindness in the developing world.^[1] Penetrating Keratoplasty (PK) is the mainstay of surgical treatment of corneal blindness. We depend on the eyebank for the corneas where it is procured and harvested. Hyman L^[2] suggested that eye bank data may be useful in describing and monitoring future indications and trends for PK because they provide a broader base of information than that obtained through a single institution. Many studies have been done on the indications for PK in India^[3-8] and the developed world.⁹⁻¹⁸ The prognosis of the PK to a great extent, depends on the indication which is the pathology responsible for causing the corneal blindness.^[19,20,21] The purpose of this study was to carry out a prospective study to analyze the utilization of donor corneas from our eye bank data for different pathological conditions, and to study the visual outcome after penetrating keratoplasty (PK) done for each indication.

METHODS

A prospective investigational analysis from our Eye bank data of 100 donor corneas used for penetrating keratoplasty between June 2006 and June 2008, with a follow-up of 12 months was conducted to analyze the indication and visual outcome in different pathological conditions for penetrating keratoplasty in our institution. The corneas utilised for the study were from our eye bank. The Institutional Ethical Committee had cleared the project. All the patients had given their informed consent.

Enucleation of the eye was done after noting the details such as age, gender, cause of death, history of surgery done on the eye and past history of any disease. The whole globe was subjected to gross examination and slit lamp biomicroscopy for grading as per established guidelines.^{22,23,24} The tissue blood sample was screened for S.HIV, S.HbsAg, S.VDRL and S.HCV. When found suitable for keratoplasty, the sclero-corneal rim was preserved under strict aseptic condition, appropriately labelled and stored in M-K media at 4°C. Endothelial cell count and morphological analysis of donor cornea was done using Keratoanalyser (Eye bank specular

microscope). Inclusion criteria for donor cornea was corneas of grade 'excellent', 'very good', and 'good' by slit lamp examination and, corneas with endothelial cells >2000 cells/mm² on eye bank keratoanalyser. Exclusion criteria for donor cornea included donor cornea of grade 'Fair' and 'Poor' on slit lamp examination, corneas with endothelial cells <2000 cells/mm² on eye bank keratoanalyser, donor tissue removed more than six hours after death and viable storage period of corneal scleral button more than 3 days.

Pre-operative assessment of recipient included demographic details of patient, chief complaints, presence of any predisposing factors such as ocular surface disorders, trauma, contact lens use, systemic history, past history of ocular surgery and graft infection. Clinical examination included uncorrected visual acuity, best corrected visual acuity, cycloplegic refraction (not done in infective keratitis cases), slit lamp biomicroscopy to determine any ocular pathology, applanation tonometry (not done in infective keratitis cases), and dilated fundus examination to rule out posterior segment pathology and sac syringing. Investigations included tear film status, gonioscopy, routine blood investigations, fasting blood sugar, fasting urine sugar, serology to screen for AIDS (HIV), Hepatitis (HbsAg) and sexually transmitted diseases (VDRL). Blood pressure, ultrasonography of the posterior segment was performed to rule out vitreous exudation suggestive of endophthalmitis and specular microscopy.

The medical records were reviewed for indications for keratoplasty. All penetrating keratoplasties were performed with standard technique under local anaesthesia except in children where general anaesthesia was used. Donor button oversized by 0.5 mm was used, except in cases of keratoconus where the graft of same size as the recipient was used. Anterior vitrectomy was performed when required. Donor cornea was sutured to host with interrupted 10.0 nylon monofilament sutures with adjustable suture technique. All cases received amikacin, cefazolin and dexamethasone subconjunctivally at the end of the operation, except in infective keratitis where dexamethasone was not given. Intraoperative data recording included details of the surgical procedure, the type of surgery, whether combined with cataract surgery, secondary intraocular lens implantation and anterior vitrectomy. Postoperatively, the eyes were patched and topical steroid was administered once the epithelium was intact over the transplant, except in cases of infective keratitis. Gradually steroid was tapered over a period of one year. Topical antibiotics and antifungals were continued till there was no suspicion of infection. Short-acting cycloplegic was instilled till iritis subsided. Topical antiglaucoma medication and lubricants were given in the initial period. The patients were evaluated on first day, first week, first, third and six month and one year post operatively in the same manner as the preoperative assessment mentioned above.

Blindness in an eye was defined using the visual acuity criterion of $<20/400$ recommended by the World Health Organisation. [25] The results were statistically

analyzed using paired and unpaired t Tests. Results were considered as significant with a two-sided *P* value of <0.05 .

OBSERVATIONS

In the present study, the donor's age ranged from 10 years to 83 years. (Table-1) Maximum number of donors was from 51 to 60 years group (32%). Donor corneas from older age groups were predominantly from death due to natural causes, while the younger donor corneas were mostly from accidental deaths. In the present study the Male donors were more (62%) than Female donors (38%). (Table-1)

Table 1: Age and Sex distribution of donors

Age groups (yrs)	Male	Female	Total cases
<10	1	0	01
11-20	2	1	03
21-30	5	1	06
31-40	13	6	19
41-50	18	9	27
51-60	17	15	32
61-70	5	3	08
>71	1	3	04
Total	62	38	100

Table-2: Age and Sex Distribution of Recipient

Age Groups (Yrs.)	Male	Female	No of Cases
<10	0	1	01
11-20	5	8	13
21-30	8	5	13
31-40	8	5	13
41-50	17	9	26
51-60	10	6	16
61-70	9	6	15
>71	3	0	03
TOTAL	60	40	100

Table-3: Indications for Utilisation of Donor Corneas

Indications	% of donor cornea
Acute infective keratitis	25
Corneal opacity (AIK-22 & others 21)	43
Regrafts	07
Pseudophakic bullous keratopathy	14
Aphakic bullous keratopathy	03
Descemetocele	05
Keratoconus	03
Total	100

It was recorded that 'Corneal Opacity' was the most common indication for utilisation of donor corneas (43%), followed by AIK cases (25%) and PBK cases (14%). For 'Regrafts' it was 7% and Descemetocele was the indication in 5%. ABK (3%) and Keratoconus (3%)

were uncommon indications for utilisation of donor corneas in the present study.(Table-5)

before & 1 year after PK in different pathological conditions is tabulated in Table-5.

The findings of visual acuity before & 1 year after PK are tabulated in Table-4. The recordings of visual acuity

Table-4: Visual Acuity after Penetrating Keratoplasty

Best Corrected Visual Acuity (BCVA)	Category of Visual Impairment	PRE OP %of Case	POST OP %of Cases
NO PL	Blind	01	01
PL/PR TO <20/1200	Blind	76	28
20/1200 TO <20/400	Blind	08	04
20/400 TO < 20/200	Severe Visual Impairment	07	07
20/200 TO < 20/60	Visual Impairment	08	41
20/60 TO 20/20	Normal	00	19

Table-5: Visual Acuity (Va) in Different Pathological conditions

Patho-logical Condition	PL/PR to <20/1200		20/1200 to <20/400		20/400 to < 20/200		20/200 to < 20/60		20/60 to <20/20	
	Blind				Severe Visual Impairment		Visual Impairment		Normal	
	Pre	Post	Pre	Post	Pre	Post	Pre	Post	Pre	Post
AIK	22 (88.0)	15 (60.0)	03 (12.0)	01 (04.0)	00 (00.0)	00 (00.0)	00 (00.0)	07 (28.0)	00 (00.0)	02 (08.0)
Corneal opacity	28 (65.1)	06 (14.0)	05 (11.6)	04 (09.3)	07 (16.3)	06 (14.0)	03 (06.9)	18 (41.9)	00 (00.0)	09 (20.9)
Regrafts	06 (85.7)	02 (29.0)	00 (00.0)	00 (00.0)	00 (00.0)	01 (14.3)	01 (14.3)	03 (42.9)	00 (00.0)	01 (14.3)
PBK	11 (78.5)	01 (07.1)	00 (00.0)	00 (00.0)	00 (00.0)	00 (00.0)	03 (21.4)	09 (64.3)	00 (00.0)	04 (28.6)
Descematocele	05 (100.0)	02 (40.0)	00 (00.0)	00 (00.0)	00 (00.0)	00 (00.0)	00 (00.0)	01 (20.0)	00 (00.0)	02 (40.0)
Kerato Conus	01 (33.3)	00 (00.0)	00 (00.0)	00 (00.0)	00 (00.0)	00 (00.0)	02 (66.6)	01 (33.3)	00 (00.0)	02 (66.6)
ABK	03 (100.0)	02 (66.6)	00 (00.0)	00 (00.0)	00 (00.0)	00 (00.0)	00 (00.0)	00 (00.0)	00 (00.0)	01 (33.3)

Figure in parenthesis indicate percentage

DISCUSSION

The purpose of our study was to document the utilisation of donor corneas of our eye bank for PK and the visual outcome of these cases at our institution which is a major referral centre for the treatment of corneal diseases.

Hyman L [2] evaluated the indications and surgical techniques for penetrating keratoplasties (PKs) to determine present trends and suggest future directions for PK. Analyses were based on 3,941 PK cases. He suggested that eye bank data may be useful in describing and monitoring future indications and trends for PK because they provide a broader base of information than that obtained through a single institution. Therefore, eye bank data may be useful in describing and monitoring future indications and trends for PK because they provide a broader base of information than that obtained through a single institution.

We at our institute studied the utilisation of 100 donor corneas graded good and above procured from our eye bank. As searched from literature not much data was available for comparison of our study for utilisation of donor corneas, so we have compared our study with literatures in which PK was performed for different indications (Table-6). In our present study, we found that ‘corneal opacity’ was the most common indication for utilisation of donor corneas (43%). Other studies reporting corneal opacity as commonest indication are Dandona et al [3] (35.6%), Shilpa et al [4] (42.54%), Sony et

al [5] (38.03%), Laxman Dasar et al [8] (60.7%), Varghese et al [6] (12.39 %) reports it to be less common indication. Kanavi et al (18.68%) and Xie et al (16%) report it as the second most common indication in their study. Dobbins et al (11.2%), Mamalis et al (8.2%) report it as a less common cause while Cosar et al, Brady et al and Haaman et al do not even categorize this indication. [9-18] Most [3, 4, 5] studies carried out in India report corneal opacity as the significantly (p<005) commonest indication compared to the other indications. The incidence of commonest indication of corneal opacity in India is also significantly different from the incidence in the developed world.

AIK (25%) was the second most common indication in our study and Xie et al report it as their commonest indication (31%). Saldanha et al (20%), Sony et al (28.38%) and Haamann et al (13.9%) also have reported AIK as their second commonest indication. Literature from western countries reports it to be less common indication for PK. Varghese et al [9] reports it as the commonest indication for PK.

The three groups of corneal scarring due to keratitis (22), AIK (25) and Descemetoccele (5%) together suggest that keratitis of various aetiologies was responsible for about 52.0 % of the PKs in our series. (Table-3) The comparative analysis of the above observation reveals a pattern also suggested by other authors of Indian Subcontinent like Dandona et al, Shilpa et al, Sony et al that the single largest indication for PK in the developing countries

was keratitis and this trend may be indicative of several problems prevalent in the developing countries related to availability, accessibility and affordability of eye care often leading to delayed diagnosis of corneal infections and consequent corneal opacification²¹. As compared with our study, the proportion of PKs done for corneal scarring and AIK has been reported to be less in the developed world.⁹⁻¹⁸

PBK (14%) was reported as third and therefore less common indication in our study while Saldhana et al (50%), Dobbins et al (31.5%), Cosar et al (27.2%), Brady et al (23%), Haaman et al (28.3%) report it as their commonest indication. Mamalis et al (23.0%) document it as a common indication too. This analysis illustrates how PBK has been reported to be the leading or the second most common indication for PK in the developed world.⁹⁻¹⁸

Regraft was a less common indication (7%) in our study, while most Indian studies also report this as a less common cause, Dandona et al (17.1%) and Cosar et al (18.1%) document it as their second common indication. In the developed world regrafts have been reported to make up 6.6% to 18.2% of the indications for PK.³⁻¹²

Descemetocoele was found as a less common cause (5%) in our study while other authors have not categorized this condition in their study.

ABK (3%) is a less common indication in our study and all other authors also report it as a less common indication (6.09-14%). This could be due to the fact that in India and worldwide intracapsular technique has decreased.

Keratoconus (3%) is a less common indication in our study similar to Dandona (6%) and Haamann at al (6.7%) but studies of Kanavi et al (34%) done in Iran reports it as their commonest indication. Mamalis et al (24.2%) and Lindquist (24%) reports it as their commonest indication. Indication for keratoconus may be more in study by Kanavi et al and Mamalis et al (24.2%) as the incidence of keratoconus is more in the Middle East population. With the advent of newer techniques like Deep Anterior Lamellar Keratoplasty, Collagen cross linking, Intacs etc. for management of keratoconus the indication for PK is decreasing which is manifested in it being a less indication for PK.

Corneal Dystrophy was not found as an indication in any case in our study while Dobbins et al (23.2%), Cosar et al (15.2%) and Brady et al (16%) report it as a common indication.

The leading indication for PK in our series was corneal scarring unlike the developed world where pseudophakic bullous keratopathy and keratoconus are the leading indications for PK.⁹⁻¹⁸ Corneal scarring with vascularisation and adherent leucoma has a poor prognosis for graft survival, active infectious keratitis has a very poor prognosis for graft survival,^{19,20,21} Pseudophakic bullous keratopathy have a fair to good prognosis for graft survival while Keratoconus has

an excellent prognosis for graft survival after PK. It appears from our study that indications for PK that have a relatively poorer prognosis for graft survival make up a higher proportion of PKs done in the India than in the developed world.

In our study there was an improvement in visual acuity to "Normal" (20/60 to 20/20) from 0% cases preoperatively to 19% post operatively. The "Blind" (PL/PR to < 20/400) category patients decreased significantly from 85% preoperatively to 33% post operatively, in "Visually impaired" (20/200 to <20/60) group preoperatively from 8% cases to 41% after PK. The cases of worse categories preoperatively, improve significantly to better categories postoperatively.

After 1 year patients having "Normal" VA increased from 0% cases preoperatively, in all categories to 20.9% cases in corneal opacity, 14.3% in regrafts 28.6% in PBK, 40% in descemetocoele, 66.6% in keratoconus, 33.3% in ABK, and 8% in AIK. The gain in VA was more in cases of Optical (keratoconus, PBK, corneal opacity and regrafts, ABK) PK as compared to Therapeutic (AIK and descemetocoele) PK. The 'AIK' patients improved 36%, corneal opacity cases improved 56.2%, 'Regraft' patients 56.7%, in Descemetocoele cases 60%, in keratoconus 33.3% improved, in PBK there were 78.5% cases that improved and in ABK the improvement was in 33% cases.

Lalit Dandona et al²⁶ studied the visual outcome in a large series of corneal transplants in India. His results shows that before corneal transplant 80.2% of the eyes were blind (visual acuity <20/400), whereas at last follow up 41.8% eyes were blind. The odds of having visual acuity >20/60 were higher if the transplant was done for keratoconus or corneal dystrophies moderate for pseudophakic bullous keratopathy and corneal scar other than adherent leucoma; and high for previous transplant failure, aphakic bullous keratopathy, miscellaneous than for the other preoperative diagnoses. According to Varghese et al⁶ the distribution of visual acuity before corneal transplantation and at last follow up showed that, before transplantation 85.37% eyes were blind. The percentage of blind eyes dropped to 48.78% (p=0.001) on last follow up. These findings are nearly similar to our study where the "Blind" category patients decreased significantly from 85% preoperatively to 33% post operatively and keratoconus group benefited the most.

Jost B et al²⁷ evaluated visual outcome after penetrating keratoplasty in 245 patients. Increase in visual acuity and the best-corrected postoperative visual acuity were significantly highest for the patients with keratoconus followed by those with herpetic corneal scars, non-herpetic corneal scars, and finally patients with pseudophakic/aphakic bullous keratopathy. The increase in visual acuity did not vary significantly among the study groups. This is similar to our findings where the best-corrected postoperative visual acuity was significantly highest for the patients with keratoconus followed by those with ABK, corneal scars, and pseudophakic bul-

lous keratopathy. Bertelmann²⁸ in his study of 293 PK patients also reports the best improvement of visual acuity in keratoconus patients.

In our study in re-graft cases VA improved to 20/1200 to <20/400 in 29.0% cases, to 20/200 to <20/60 in 42.9% and 20/60 to <20/20 in 14.3%. Similarly in study by Vanathiet al²⁹ the indications and outcome of repeat penetrating keratoplasty was analyzed, a BCVA of 20/60 or better was seen in five eyes only (17.9%) and less than 20/60 in 23 eyes (82.1%). Similar studies by Patel

NP³⁰ report a visual acuity of 20/40 or better in 41% cases.

When used for therapeutic purpose out of the 25 cases, 15 cases gained VA of PL/PR TO <20/1200 i.e. BLIND category, 1 case gained VA or 20/1200 TO <20/400 i.e. BLIND category, 7 cases gained VA of 20/200 TO <20/60 i.e. Visual Impairment and 2 case gained VA of 20/60 TO <20/20 Normal. Thus by performing therapeutic PK, eyes of few cases could be salvaged and useful vision could be attained.

Table-6: Indications of PK- in Different Studies

Study	Region	Corneal opacity	AIK	PBK	ABK	Re-grafts	Desce metocele	Keratoconus	Corneal dystrophy	Miscell- Aneous
Present study	Western India	43.0	25.0	14.0	3.0	7.0	5.0	3.0	-	-
Dandona et al ³	South India	35.6	12.2	10.6	11.8	17.1	-	6.0	9.6	5.9
Saldanha et al ⁴	South India	12.3	20.0	50.0		13.3	-	-		
Shilpa et al ⁵	Western India	42.54		17.67	12.5	14.36	-	-	4.97	7.39
Sony et al ⁶	North India	38.03	28.38	6.18	7.27	11.5	-	-	3.85	
Varghese et al ⁷	South India	12.39	37.61	18.26		13.04		8.26		10.43
Laxman Dasar et al ⁸	South india	60.7	2.94	8.82		12.7		1.96		12.64
Hyman L ²	USA		12.0	23.0	10.0	17.0	-	13.0		13.0
Dobbins et al ⁹	USA	11.2		31.5	7.5	8.9	-	11.4	23.2	
Cosar et al ¹⁰	UK			27.2		18.1	-	15.4	15.2	
Xie et al ¹¹	China	16.0	31.0	13.0		5.0	-	13.0	4	
Brady et al ¹²	USA			23.0	14.0	10	-	15.0	16	
Mamalis et al ¹³	Middle East	8.2		23.0		13.1	-	24.2		5.8
Haamann et al ¹⁴	Denmark		13.9	28.3	10.0	11.1	-	6.7		
NAI-Yousuf ¹⁵	UK			7.6		40.9	-	15.0		15.6
Lindquist TD ¹⁶	USA			21.2		8.1	-			
Damji KP ¹⁷	Canada	13.5	9.0	22.2		12.2	-	17.1		8.3
Kanavi et al ¹⁸	Iran	18.68		9.19	6.09	5.28	-	34.51	6.47	

(*all Values in %)

Our study has tried to use eye bank donor cornea utilisation which were graded “good” and above for PK. The donor corneas were used for those indications which carry a poorer prognosis for graft survival. The improvement in VA was seen more in optical PK, as compared to therapeutic PK indicating that visual gain was less if PK was performed in inflamed eyes. Our findings stress upon the fact that still in our country either healthcare is not easily accessible to the people or there is less awareness in people for the utilisation of healthcare facilities. It can be concluded that utilisation of donor corneas for pathological conditions which carry a poorer prognosis for graft survival are relatively more common in India than in the developed world but penetrating keratoplasty improves the quality of life by causing a significant improvement in visual acuity.

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