

Utilization rate of corneal tissue obtained from donors over 75 years of age in Western India for keratoplasty

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Purpose: To examine the utilization patterns of cornea procured from diseased individuals ≥ 75 years of age at an eye bank in western India. **Methods:** In this retrospective study, data from 1,217 eyes of 653 donors with age ≥ 75 years were reviewed from October 2008 to December 2019. Donor age, lens status, endothelial cell count (ECD), utilization of the tissue for transplantation or non-clinical purposes (e.g., research, training/discarded), and causes of non-utilization were noted. **Results:** The mean age of the donors was 80.9 ± 4.6 years and the tissue utilization rate was 36.5% (445 out of 1,217 eyes). The eyes used for keratoplasty procedures had a lower donor age (79.6 ± 5.7 vs. 81.5 ± 5.1 ; $P < 0.001$), a higher endothelial cell count (2493 ± 531 vs. 2034 ± 581 ; $P < 0.001$), and were more often phakic (61% vs. 36.6%) compared to the unused group. A multivariable logistic regression analysis showed that the likelihood of tissue utilization for keratoplasty was 13% higher with every 100-cell increment in donor ECD (odds ratio [OR] = 1.13, 95% CI = 1.10–1.16, $P < 0.001$) and 33% lower with having a pseudophakic status in the donor eye (OR = 0.67, 95% CI = 0.52–0.87, $P = 0.03$). Age was not a significant determinant of tissue utilization when used in the same multivariable model. **Conclusion:** More than one-third of the eyes (36.5%) can be utilized even when the donors are above 75 years of age. Eyes that were more likely to be utilized for keratoplasty were phakic and had a significantly higher ECD; age was not a determinant in tissue utilization.

Key words: Cornea transplant, donor cornea, eye banking, old age, lens status-phakic/pseudophakic/aphakic

Corneal blindness is a leading cause of preventable blindness in India and a major public health problem.^[1] Currently, an estimated 1.2 million people are blind due to corneal diseases in India and 25,000–30,000 patients with corneal blindness are added every year.^[2,3] Nearly 50% of corneal blindness is potentially treatable.^[2,3] With increasing awareness regarding eye donation in the general population and improved infrastructure of the eye banks, corneal collections have shown a steady increase from 38,646 corneas collected in 2007–2008 to 63,256 in 2016–2017 as per the National Program for Control of Blindness (NPCB).^[4,5] Based on the present availability of safe donor eyes and utilization rates, it is estimated that 2,70,000 donor eyes are required to perform 1,00,000 corneal transplants per year in India, an approximately four-fold increase from the present availability of donor's eyes.^[6] With the wide disparity in demand and supply of donor human eyes, it is imperative to focus on the precise and efficient utilization of the donated corneas. Currently, the utilization rate ranges between 25 and 60%.^[4,5,7]

Tissue utilization at an eye bank (EB) can reflect various causes of tissue exclusion which can be improved further to control corneal blindness in developing countries. Donor age is considered to be an important factor influencing tissue utilization, with many cornea surgeons often demanding tissue from younger individuals. With increased life expectancy, a majority of the donations are from older diseased

people (age > 60 years)—this demand may not be satisfied by EBs. However, tissues from donors ≥ 75 years are often underutilized simply because of the surgeon's preference for a younger tissue. We performed a retrospective study to evaluate the quality and utilization rate of corneal tissues from donors > 75 years old received by our EB in western Maharashtra, India. The aim of this study was to study the utilization of the cornea procured at our EB from this very elderly cohort, evaluate various donor factors affecting its utilization, and determine the reasons why the corneas could not be used, and to identify the areas for potential improvement in the utilization rate of the corneas from this cohort.

Methods

This was a retrospective study conducted at a large EB, a not-for-profit organization established in October 2008 at Thane, Maharashtra, India. The study was conducted in accordance with the tenets set forth in the Declaration of Helsinki. An ethics committee approval was obtained for the study with an exemption from full review.

All donor eyes received and processed at our EB from October 2008 to December 2019 were identified and the utilization rates from the donors ≥ 75 years of age were

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analyzed retrospectively. Our EB receives donor tissues from homes and hospitals in the city and adjacent areas through voluntary organizations and eye collection centers. All the tissues offered to our EB are accepted, with no upper cut-off for age. The relatives were counseled if the serological status or medical or ocular history had a contraindication for transplantation and asked for willingness to donate for research/training. The procured cornea was transported in the McCarey–Kaufman (MK) medium. The donors were screened for human immunodeficiency virus (HIV), hepatitis B virus (HBV), hepatitis C virus (HCV), and syphilis (venereal disease research laboratory [VDRL]), before the utilization of the retrieved corneas. The eyeballs from the donors with positive ocular or medical history or positive serology were excluded from the transplantation.^[8]

A slit-lamp examination of the donor eye was done for epithelial defects or edema, exposure keratitis, corneal scars, stromal edema, or opacification, Descemet's membrane folds, the presence of "snail tracks" (linear ruptures of endothelial cells), condition of the anterior chamber, iris, pupil, and lens status and examined for any iatrogenic perforation of the anterior chamber.^[9] When found suitable for keratoplasty, the sclerocorneal rim was preserved under strict aseptic condition, appropriately labeled, and stored in the McCarey–Kaufman media at 4°C. The endothelial morphology was then assessed by specular microscopy. The corneas with specular count ≥ 2000 cells/mm² were labeled and marked for optical keratoplasties. The eyeballs not utilized clinically because of the donor's medical history or poor quality (endothelial guttata/striae, low endothelial count, arcus senilis, epithelial defects, stromal edema, collapsed anterior chamber, corneal scar/infiltrate) were utilized for training or research purposes depending on the requirement. The reasons for non-utilized or discarded tissues were noted.

Donor age, gender, lens status of the donor tissue, death-to-enucleation time interval, storage time in the eye bank, utilization of the tissue for optical transplantation, therapeutic transplantation, discarded or non-clinical purpose (e.g., research, training/discarded), and causes of using tissues for the non-clinical purpose were noted. Keratoplasties are performed according to the state waiting list, where recipients are categorized according to the need for transplantation. Preference is given to children <12 years and one-eyed subjects.

The utilization rate of the donated corneas refers to the proportion of the corneas from the retrieved eyes that were actually used for transplantation. The reasons for non-use of donated corneas were classified mainly into failed serology (i.e. confirmed positive, repeatedly reactive samples, poor blood sample quality, or missing serological test results), other medical contraindications, microbial contamination during 14 days of storage of corneas in the cornisol medium, poor tissue quality (e.g., endothelial cell density <1000 cells per mm², central corneal opacity) and others. The donor parameters associated with the utilization were evaluated which included donor age, sex, endothelial cell count (ECD), and lens status.

Statistical analysis

All the continuous variables were described as means with standard deviation or median with interquartile range (IQR) while the categorical variables were presented as proportions (*n*, %). The comparison between the continuous variables across two groups was done using the Student's *t*-test or the Wilcoxon's rank-sum test for non-parametric distribution while the analysis of variance (ANOVA) was used when comparing across more than three groups. The group

differences between the categorical variables were done using the Chi-square or Fischer's exact test.

All data were collected using Microsoft Excel and analyzed using STATA 12.1 I/C (Stata Corp, Fort Worth, Texas, USA). All the *P*- values <0.05 were considered statistically significant.

Results

We included data from 1,217 eyes of 653 subjects with age ≥ 75 years who donated their corneas during the 11-year study period and had documented endothelial cell counts. The mean age of the donors was 80.9 ± 4.6 years (median = 80 years, IQR = 77–84 years, range = 75–98 years), 366 (56%) were men and 648 eyes (53.2%) were pseudophakic.

The donor tissue was utilized for various keratoplasty procedures in 445 eyes (36.5%). A comparison between the demographic and endothelial cell densities of the eyes that were used for keratoplasty versus those that remained unused is shown in Table 1. The eyes that were used were harvested from significantly younger patients, had higher endothelial cell counts [Fig. 1], and were more often phakic as opposed to the unused group that were more often pseudophakic, had lower counts, and were from older donors.

The rate of tissue utilization varied significantly over the 11-year study period from 24 to 51% and is shown in Fig. 2. Of the 445 eyes used for keratoplasty, therapeutic keratoplasty was the commonest indication (*n* = 242, 54%), followed by optical penetrating keratoplasty (PK) (*n* = 163, 37%), endothelial keratoplasty (DSEK/DMEK, *n* = 31, 7%), and DALK (*n* = 9, 2%). Of these utilized eyes, 70 (16%) had ECD below 2,000 cells and all were used for therapeutic keratoplasty. Of the remaining 772 eyes that were unused, 530 (69%) were used for research and training purposes while the remaining 242 (31%) were discarded due to the poor quality of the tissue. The most common cause of tissue exclusion was the poor quality of the cornea (*n* = 303; 39%), followed by the donor's medical history (*n* = 242, 31%, including sepsis, pneumonia, and communicable disease), and failed serology (*n* = 190, 24.6%).

The eyes used for optical PK and endothelial keratoplasty were harvested from significantly younger donors, had higher ECD, and were more often phakic compared to those used for therapeutic keratoplasty [Table 2]. A comparison of the ECD in the eyes utilized for various indications as well as those not utilized is shown in Fig. 3. A multivariable logistic regression

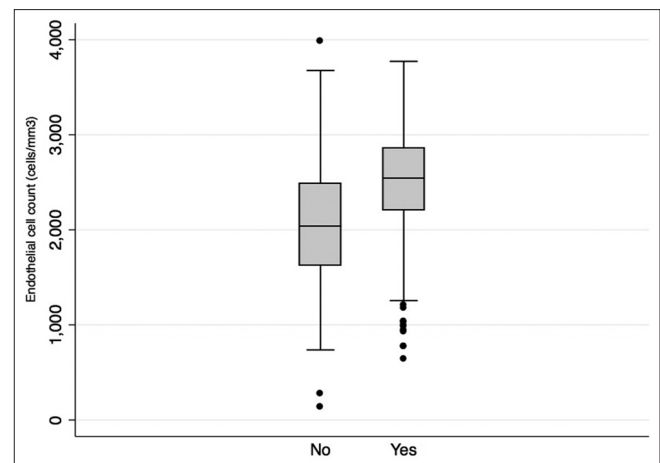


Figure 1: Box and whisker plot showing the endothelial cell density in the eyes that were used for keratoplasty vs. those that remained unused

analysis showed that the likelihood of tissue utilization for keratoplasty was 13% higher with every 100-cell increment in donor ECD (odds ratio = 1.13, 95% CI = 1.10–1.16, $P < 0.001$) and 33% lower with having a pseudophakic status in the donor eye (odds ratio = 0.67, 95% CI = 0.52–0.87, $P = 0.03$). Age was not a significant determinant of tissue utilization when used in the same multivariable model including ECD and lens status.

Discussion

In this retrospective analysis of the quality and utility of donor corneal tissue received at our EB in western India, we found that more than a third of the eyes (36.5%) can be utilized even when the donors are above 75 years of age. The eyes that were more likely to be utilized for keratoplasty were phakic and had a significantly higher ECD; age was not a determinant in tissue utilization.

Using donor age to determine the suitability of a cornea for transplantation has been an area of considerable controversy among corneal surgeons worldwide. As the elderly population continues to increase, the availability of older donor tissue will expand by as much as 20–35%.^[10] Surgeons often seek the youngest corneal tissue available and defining an upper age limit cut-off for donor corneas is an important decision for most eye banks. In our study, the

donors were above 75 years of age, with the average age being 81 years. Our study has demonstrated that increased donor age is not a deterrent for transplantation if the quality of the donor cornea is good. Similar results have been reported by different studies. The Cornea Donor Study Group evaluated the effect of donor age on cornea graft survival in 1,090 corneal transplants with a moderate risk of failure (principally for Fuchs’ dystrophy and pseudophakic corneal edema).^[10] They found a similar overall 5-year graft survival rate of 86% for the grafts using corneas (with an endothelial cell density of 2,300–3,300 cells/mm²) from donors ≤65 years old and from donors ≥66 years of age. They further reported that irrespective of donor age, the endothelial cell loss is substantial over the first 5 years after the transplant even when the graft has been successful.^[10] Wakefield *et al.*^[11] reported no significant effect of the donor age, up to 90 years, and preoperative donor ECD above the lower limit of 2,200 cells/mm², on endothelial failure at 5 years following PK. Using data from over 16,000 PKs with up to 21 years of follow-up, the Australian Corneal Graft Registry (ACGR), in 2012, published the median duration of graft survival for donor age groups 1–20, 21–40, 41–60, 61–80, and >80 years of 15.35, 15.71, 13.54, 11.80, and 12.94 years, respectively.^[12] Armitage and Eastly reported a 45% utility rate in the donors of 80 years.^[13] Raj *et al.*^[14] reported a utility rate of 35.5% wherein nearly 80% of the donor corneas belonged to the age group of >65 years. Mannis *et al.*^[15] found no significant difference in the 10-year success rates of the PK comparing the donor ages 12–65 and 66–75 years.

In our study, the harvested eyes that were used had higher endothelial cell counts and were more often phakic (61%) as opposed to the unused group. Multivariable logistic regression analysis showed that the likelihood of tissue utilization for keratoplasty was 13% higher with every 100-cell increment in the donor ECD and 33% lower with having a pseudophakic status in the donor eye. Our results are in agreement with the studies that demonstrated that a thorough endothelial cell assessment during banking ensures that large numbers of corneas from donors more than 65 years of age can be used successfully.^[16–18] The quality of the tissue received by any EB is dependent on the demographics and level of awareness regarding eye donation among the population which it is covering. With the increasing life expectancy and trend of relatively early cataract extraction in the urban population, the number of elderly and pseudophakic

Table 1: Comparison between the demographics and endothelial cell counts of the eyes that were used for transplantation vs. those not used

Variable	Used eyes (n=445)	Unused eyes (n=772)	P
Age (years)	79.6±5.7	81.5±5.1	<0.001
Gender (% men)	253 (55%)	426 (57%)	0.56
Eye (% right eye)	214 (48%)	380 (49%)	0.70
ECD (mean±SD)	2493±531	2034±581	<0.001
ECD (median with IQR)	2544 (650)	2040 (859)	
ECD (95% CI)	2444-2543	1994-2076	
Lens status: Phakic lens	272 (61%)	283 (36%)	<0.001
Pseudophakic lens	173 (39%)	475 (61%)	
Aphakia	0	8 (1%)	
Undetermined	0	6 (<1%)	

ECD=Endothelial cell density

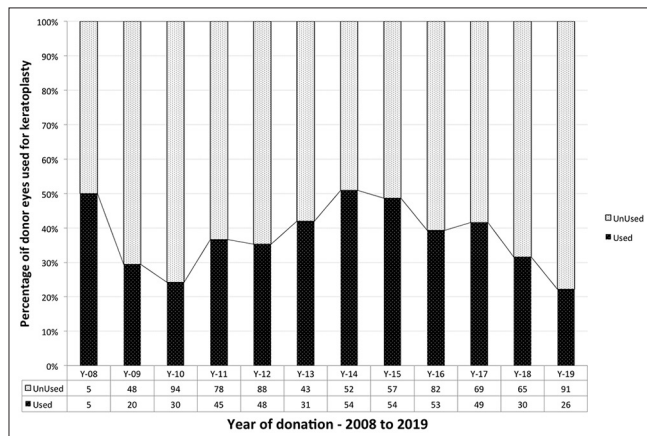


Figure 2: Year-wise distribution of the utilization rates of the corneas procured from the donors >75 years of age over the 11-year study period

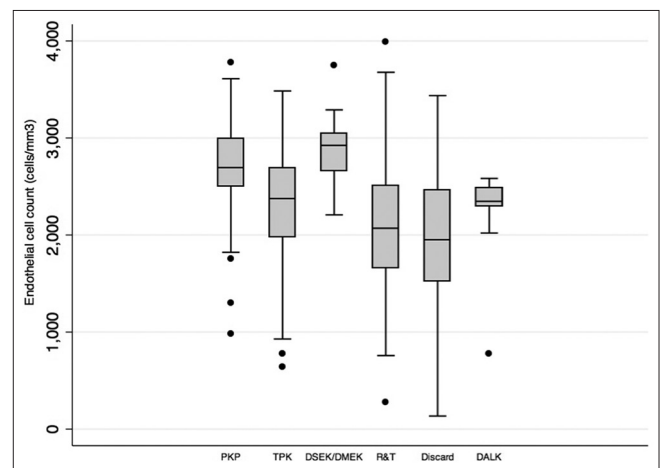


Figure 3: Box and whisker plot showing the comparison between the endothelial cell density of the donor corneas used for various procedures as well as used for research and training purposes and discarded

Table 2: Comparison between the eyes used for different indications

Variable	Optical PK (n=163)	Therapeutic PK (n=242)	Endothelial keratoplasty (n=31)	DALK (n=9)	P
Age (years)	78.3±7.1	80.8±4.6	77.6±2.4	79±4.3	<0.001
Gender (%Men)	96 (59%)	135 (56%)	16 (52%)	6 (66%)	0.88
Eye (% right eye)	78 (48%)	118 (49%)	14 (45%)	4 (44%)	0.99
ECD (mean±SD)	2706±418	2312±542	2874±212	2191±557	<0.001
Lens status:Phakic	117 (72%)	122 (50%)	27 (87%)	6	<0.001
Pseudophakic lens	46 (28%)	120 (50%)	4 (13%)	3	
Aphakia	0	0	0	0	
Undetermined	0	0	0	0	

PK=Penetrating keratoplasty, ECD=Endothelial cell density

donors is increasing. In our study, more than half of the donor eyes were pseudophakic which may have resulted in a lesser availability of the optical grade corneas. The eye donation awareness programs targeting multispecialty hospitals or trauma centers for accident victims can be more rewarding to receive the increased number of optical grade corneas.

In our study, therapeutic keratoplasty was the most commonly performed keratoplasty (54%), followed by optical PK (37%), endothelial keratoplasty (Descemet Stripping Endothelial Keratoplasty/Descemet's membrane endothelial keratoplasty, DSEK/DMEK 7%), and deep anterior lamellar keratoplasty (DALK 2%). The eyes with ECD below 2,000 cells were all used for therapeutic keratoplasty. The eyes used for optical PK and endothelial keratoplasty were harvested from significantly younger donors, had higher ECD, and were more often phakic compared to those used for therapeutic keratoplasty. A high proportion of therapeutic surgeries being performed reflects a greater incidence of acute infectious and corneal melting disorders in contrast to the reports from developed countries.^[19] Based on the reports from previous studies in India, the leading indication for PK was corneal scarring due to healed keratitis and acute infectious keratitis.^[20,21] A similar high incidence of therapeutic keratoplasty is also reported from other Southeast Asian countries.^[22,23] The high rate of therapeutic keratoplasty performed for active infection may be due to a delay in the initiation of treatment and late referral to the tertiary eye care centers.

Worldwide, there is a procedural shift from full-thickness corneal transplant to anterior lamellar transplants for the selective removal of diseased anterior corneal layers, and endothelial keratoplasty for the replacement of deep stromal and endothelial layers. We did observe an encouraging trend of the increased utilization rate of donor corneas for endothelial keratoplasty and DALK. In a study of trends in corneal transplantation in New Zealand, Cunningham *et al.*^[24] reported that while PK was the commonest type of surgery in 90.7% of the recipients, a shift in transplantation type was noted in the final year of their study period, with deep anterior lamellar keratoplasty and Descemet's stripping endothelial keratoplasty accounting for 32.3% of all the transplants. In contrast, Gogia *et al.*,^[25] on reviewing the changing pattern of corneal utilization in an EB in North India, found the increase in donor corneal utilization was reflected only in the usage of non-optical grade corneas for therapeutic transplantations and anterior lamellar transplantations and not for the optical grade corneas. This indicated that despite increased tissue procurement over the years, the quality of the tissue was average. They also did not observe any significant increase in the incidence of usage of a single donor cornea for multiple recipients.^[25]

The mean age of the donors in our study was 81 years (range = 75–98 years) and 56% were men. This is similar to many studies which also reported a male preponderance.^[20,26] The rate of tissue utilization was 36.5% in our study and varied significantly over time from 24 to 51%. Studies from other parts of India have mostly reported rates ranging from 25 to 60%.^[4,7,14,16,20] A higher tissue utilization rate of 75% was reported by Ranjan *et al.*^[27] from a community EB in eastern India. The mean age of the donors was 52 ± 21 years, and the majority of the donors were motivated (86%) under the hospital cornea retrieval program (HCRP). The higher utility rate in their study can be attributed to the relatively younger donor age and exclusion of non-eligible harvesting tissues through the HCRP. The rates from the Indian studies are much lower as compared to the other international EBs, which varied from 66% in the US in 2013^[28] to 71% in the UK in 2010.^[29] The New Zealand EB study reported 90% donor corneas suitable for transplantation with a high utilization rate of 88%.^[26] A thorough pre-screening of the potential donors to exclude non-eligible ones could be the reason for the higher tissue utility rate in their study. Also, the most commonly used storage media in developing countries is the MK media (as in our study), which allows preservation only for up to 4 days and suffices for the commonly performed therapeutic keratoplasties or emergency surgeries. In contrast, elective procedures are more common in Europe and the USA, where long-term storage media like organ culture and Optisol, respectively, are used. Although the NPCB guidelines allow the use of intermediate storage media like OptisolGS and Eusol, the cost and availability are the major limitations to their widespread use. This could be a possible reason for the low utilization rates in developing countries.

The main causes of tissue exclusion in our study were sub-optimal tissue quality (infiltrate on slit-lamp examination, low ECD, or poor quality on specular microscopy) accounting for nearly 40% (n = 351) of the total tissues, followed by medical contraindications of the donor and failed serology tests. The lesser availability of the optical grade tissues in the elderly and pseudophakic groups could have led to a relatively lower corneal tissue utility rate in our study. Similar results were reported by Singh *et al.*^[30] who found that the most common cause of non-utilization was poor quality (37.3%), followed by the medical history of the donor (15.4%). They further noted that 49.5% of the tissues were pseudophakic in their cohort and the corneal utility rate was the lowest when they received the maximum number of pseudophakic and elderly (>70 years) donor eyes.^[30] Hopefully, increasing the uptake of the lamellar keratoplasty techniques may have a positive impact on the utilization rates of the donated corneas in the future. A large proportion of the tissue exclusion due to medical contraindications in the donor in our study was due to

a history of septicemia and malignancy preceding donor death. The thorough scrutiny by the counselor/medical practitioner to assess their suitability prior to the removal can avoid the rejection of unusable tissue. If all these potentially modifiable factors are addressed in our study, the utilization rate could potentially be improved. A failed serological test accounted for the third most common cause for non-utilization. The rates reported in our study are roughly in the same range as reported by Jadeja *et al.*^[16] and Viegas *et al.*^[31] who discarded 19 and 33.4% of the corneas in their studies, respectively, due to the positive or inconclusive serological tests.

The limitation of this study is that the final outcomes after keratoplasty were not available. As these data are from an EB, we could only gather data on what procedure was finally done on the recipient using the donor tissue supplied to them. However, this study provides good evidence that increased donor age need not be a limiting factor for the procurement of cornea for the EBs, and good qualitative and quantitative endothelial analysis of the corneal tissue can optimize the uptake in the recipient eyes.

Conclusion

In summary, this study demonstrates that more than a third of the eyes (36.5%) can be utilized even when the donors are above 75 years of age. The eyes that were more likely to be utilized for keratoplasty were phakic and had a significantly higher ECD; age was not a determinant in tissue utilization.

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Conflicts of interest

There are no conflicts of interest.

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