Donor corneal tissue utilization and factors responsible for rejection in tertiary eye care hospital in North India

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Abstract
Purpose: To evaluate the donated cornea and find out the pattern & factors influencing the utilization of corneal tissue.

Study design: Retrospective, non-comparative observational study.

Material and Methods: Data of 1273 donor eyes collected from all over the Haryana under Hospital Cornea Retrieval Programme (HRCP) and those collected from voluntary donors at their residence from April 2011 to March 2020 were analyzed including the cause of death, gender, age, place of tissue procurement, Death to Enucleation time, grades of tissue and various utilization parameters.

Results: A total number of 1273 of eyes were procured out of which 774 (60.8%) were fit for corneal transplantation while 499 (39.19%) were not fit.

Conclusion: Utility of the donor cornea depends upon various factors like age, death enucleation time, cause of death, maintenance of cold chain and technique of tissue procurement.

Keywords: Eye bank, eye donation, donor cornea, corneal transplantation, rejection, utilization

Introduction
Corneal transplantation or keratoplasty is the most commonly performed and also the most successful all organic transplant worldwide [1]. 68,419 eyes were donated in year 2018-19 against the set target of 50,000 [2]. A significant proportion of corneas harvested are found unsuitable for transplantation. Procurement of eyes by trained personnel, proper storage and evaluation of donated cornea is critical for the success of corneal transplantation. Around 270,000 donor corneas are required for performing 100,000 corneal transplant surgeries in India [3].

Blindness continues to be one of the major public health problems in developing countries. Cataract and corneal diseases are major causes of blindness in countries with less-developed economies [4]. According to the World Health Organization, corneal diseases are among the major causes of vision loss and blindness in the world today, after cataract and glaucoma [5]. In India, it is estimated that there are approximately 6.8 million people who have vision less than 6/60 in at least one eye due to corneal diseases; of these, about a million have bilateral involvement [6, 7]. It is expected that the number of individuals with unilateral corneal blindness in India will increase to 10.6 million by 2020 [7]. According to the National Programme for Control of Blindness (NPCB) estimates, there are currently 120,000 corneal blind persons in the country. According to this estimate there is addition of 25,000-30,000 corneal blindness cases every year in the country [8].

Material and Methods
This is a retrospective observational study conducted in the Regional Institute of Ophthalmology, PGIMS, Rohtak, India. The patient’s record was assessed from the institutional eye bank from April 2011-March 2020. A total number of 1273 of eyes were donated during the period collected in the hospital, from voluntary donors at their residence and from other Eye Donation centres. Detailed medical history and cause of death was noted for all the donors. All the eyes were collected irrespective of the cause of death or any contraindication for Corneal Transplantation surgery after taking consent from family members in cases where the cornea can only be used for training or research purpose. If not willingness, eyes were not procured. Serological testing was performed from the blood collected
during eye donation and testing was done for HIV (Human Immunodeficiency Virus), Hepatitis B (HBsAg-Hepatitis B Surface Antigen), HCV (Hepatitis C Virus) & Syphilis. If the sample was found to be reactive for any of the above it was not used for corneal transplantation and discarded properly. Team involved in that particular eye donation was intimated and needful was done. All donor eyes were graded after slit-lamp examination. If the cornea was found to be healthy for corneal transplantation, the corneoscleral rim was excised, preserved and specular microscopy was performed. Cornea with specular count ≥2000 cells/mm² is utilized for optical transplantations and with suboptimal specular count for therapeutic transplantations. Donor eyes not used clinically because of donor’s past medical history or poor quality (endothelial guttate/striae, low endothelial count, arcus senilis, epithelial defects, stromal edema, collapsed anterior chamber, corneal scar/infiltrate) were utilized for training or research purpose depending on the requirement.

**Results**
A retrospective analysis of 1273 donor eyes were done over a period of 9 years from April 2011 – March 2020. Among 672 donors, two eyes each were collected from 607 donors and one donor eye each from 71 donors. 774 donor eyes (60.8%) were used for corneal transplantation and 499 donor eyes (39.19%) were rejected from using for transplantation. 774 donor eyes (60.8%) were utilized in different types of keratoplasty procedures, therapeutic, optical, corneal patch graft etc. The rejected donor eyes were used for training purpose or discarded if serology tested positive for HIV (Human Immunodeficiency Virus), HBsAg (Hepatitis B Surface Antigen), HCV (Hepatitis C) or Syphilis.

![Fig 1: Donor Eyes](https://www.ophthalmoljournal.com/)

Details of 499 rejected donor eyes (39.19%) were assessed and various factors responsible for rejection were analyzed. Most common cause of tissue rejection was Poor Tissue Quality- (n=330, 66.13%) followed by Corneal opacity- (n = 54, 10.82%), HIV- (n = 28, 5.61%), Corneal degeneration-(n = 24, 4.81%), Exposure Keratopathy- (n = 16, 3.20%), HCV- (n = 8, 1.60%), Inadequate Blood Sample- (n = 8, 1.60%), Poor MK medium or Tissue collection- (n = 8, 1.60%), Hepatitis B- (n = 12, 1.3%), Malignancies- (n = 5, 1%), Septicemia- (n = 4, 1.3%) & Microcornea- (n = 2, 0.40%). Poor tissue quality (n = 330, 66.13%) was the most common cause for tissue rejection for corneal transplantation.

![Fig 2: Causes of Donor Eye Rejection](https://www.ophthalmoljournal.com/)

Poor tissue quality was due to epithelial defects, Hazy graft, Epithelial edema, Stromal edema, Descemet’s folds, Improper donor tissue collection or Iatrogenic scissor cuts/abrasions while making buttons. Corneal opacities were graded as Nebular, Macular, Leucomatous and endothelial dusting due to adherent leukemia or other ocular pathology. Donor eyes collected from donors who tested positive for HIV (Human Immunodeficiency Virus), HBs Ag (Hepatitis-B), HCV (Hepatitis-C) or Syphilis were discarded as it is an absolute contraindication for transplantation due to risk of disease transmission to the host. Failure to extract adequate blood sample for serological testing due to lack of training of staff in peripheral centres.
Table 1: Cause of rejection Number of eyes (499)

<table>
<thead>
<tr>
<th>Cause of rejection</th>
<th>Number of eyes (499)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Poor Tissue Quality</td>
<td>330</td>
</tr>
<tr>
<td>Corneal Opacity</td>
<td>54</td>
</tr>
<tr>
<td>HIV</td>
<td>28</td>
</tr>
<tr>
<td>Corneal Degeneration</td>
<td>24</td>
</tr>
<tr>
<td>Exposure Keratopathy</td>
<td>16</td>
</tr>
<tr>
<td>Hepatitis B</td>
<td>12</td>
</tr>
<tr>
<td>Inadequate Blood Sample</td>
<td>08</td>
</tr>
<tr>
<td>HCV</td>
<td>08</td>
</tr>
<tr>
<td>Poor MK Media</td>
<td>08</td>
</tr>
<tr>
<td>Malignancy</td>
<td>05</td>
</tr>
<tr>
<td>Septicaemia</td>
<td>04</td>
</tr>
<tr>
<td>Microcornea</td>
<td>02</td>
</tr>
</tbody>
</table>

1.6% of the donor eyes were not used for transplantation due to poor MK media (Contaminated media or failure to maintain the cold chain) or improper tissue collection.

Death-to-enucleation time was analysed and found that the majority of the tissues were retrieved within 6 hrs of death. Corneal buttons were collected and preserved directly in the McCarey-Kaufman (MK) medium at the site of excision and kept in the tissue-carrying boxes.

Death-Enucleation time was divided into following groups- Group I- < 2 hours, Group II- 2-4 hours, Group III- 4-6 hours, Group IV- > 6 hours. Above groups were classified according to the total no of eyes and donor eyes rejected for transplantation.

Fig 3: Death Enucleation Time

Percentage of rejected donor eyes in different groups was Group I- 34.0%, Group II- 41.4%, Group III- 41.5%, Group IV- 34%.

Out of 672 donors (n = 1273) there were 398 Males (59.2%, n = 744) and 274 Females (40.8%, n = 529). Rejection rate in males was 44.3% (343/744 donor eyes) and in females was 29.4% (156/529 donor eyes). Rejection rate was higher in males as compared to females.

Fig 4: Gender Distribution

Donor eyes that were not fit for transplantation were divided into following 10 groups according to the age of the donor.
Table 2: Age Group of donor number of donor eyes and percentage

<table>
<thead>
<tr>
<th>Age Group of Donor</th>
<th>Number of Donor Eyes</th>
<th>Percentage (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt; 10 years</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>11-20 years</td>
<td>2</td>
<td>0.40</td>
</tr>
<tr>
<td>21-30 years</td>
<td>7</td>
<td>1.4</td>
</tr>
<tr>
<td>31-40 years</td>
<td>38</td>
<td>7.61</td>
</tr>
<tr>
<td>41-50 years</td>
<td>63</td>
<td>12.62</td>
</tr>
<tr>
<td>51-60 years</td>
<td>88</td>
<td>17.63</td>
</tr>
<tr>
<td>61-70 years</td>
<td>158</td>
<td>31.66</td>
</tr>
<tr>
<td>71-80 years</td>
<td>89</td>
<td>17.83</td>
</tr>
<tr>
<td>81-90 years</td>
<td>34</td>
<td>6.81</td>
</tr>
<tr>
<td>91 years &amp; Above</td>
<td>20</td>
<td>4.0</td>
</tr>
<tr>
<td>Total</td>
<td>499</td>
<td></td>
</tr>
</tbody>
</table>

Maximum number of donor eyes that were not fit for transplantation were from 51-80 years of age accounting for 67% (n = 335) of the total rejected eyes.

Poor tissue quality might have been due to:
- Poor handling,
- Iatrogenic damage while removal,
- Prolonged transportation
- Exposure keratitis,
- Increase death enucleation time
- Poor public awareness.

Discussion
- Most if the eyes rejected were from higher age group (60 and above).
- Death enucleation time was more than 4 hours in majority of the cases.
- Poor public awareness.
- Lack of training of ophthalmic staff in handling of donated eyes at peripheral eye collection centres.
- Poor cold chain maintenance during transportation of tissue from the peripheral centres to the eye banks

Conclusion
- Awareness regarding importance of eye donation.
- Need of properly trained grief counsellors who can motivate the deceased family to encourage eye donation in younger age groups.
- Prompt intimation to eye collection centres by the deceased family members so as to reduce the death enucleation time.
- Proper training of Medical and para-medical personnel for careful handling of donor tissue.

References

Fig 5: Number of Donor Eyes
of National Programme for Control of Blindness, India and World Health Organization 1986-89.


