## HOSPITAL CORNEA RETRIEVAL PROGRAMME – A WAY FORWARD

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## ABSTRACT AND KEYWORDS

Background/Purpose:

To study the clinical indications, visual outcome, complications of penetrating keratoplasty and to compare the effect of hospital corneal retrieval vs home retrieval with the visual outcome and complications post keratoplasty. In addition, the study aims to highlight the effectiveness of the hospital donor cornea retrieval program. Methods:

A 2 year prospective study was conducted with 52 patients who underwent penetrating keratoplasty for optical indications with regular follow up on post-operative day 1 (POD),  $1^{st}$ ,  $3^{rd}$  month and  $6^{th}$  month. The various indications for keratoplasty, early and late complications and factors causing them , Death to enucleation, preservation time and the mode of cornea retrieval were also noted. The results were compared with the post-operative visual acuity and the incidence of developing graft failure post operatively. Results:

The most common indication was bullous keratopathy (38.4 %). Overall improvement in vision was seen in 69.2 % of patients compared to pre-operative vision. Most common early post operative complication was epithelial defect (30.7 %) and late complications were secondary glaucoma leading to graft failure. Donor factors such as lesser death to enucleation and preservation time was associated with better visual outcome (p<0.001). Hospital retrieved corneas had better visual outcome (p=0.20) and lesser rate of graft failure (p=0.004). Conclusion:

We conclude that lesser rates of graft failure are associated with hospital retrieved corneas and the need for adequate systems for hospital cornea retrieval are required to increase effective cornea retrieval and to optimise the results post optical penetrating keratoplasty. Keywords:

Cornea-retrieval, Enucleation. Keratoplasty.

## 1. INTRODUCTION

Corneal diseases are one of the major causes of blindness and visual impairment in developing countries. In 2010, the World Health Organization identified that globally 4.9 million people were bilaterally corneal blind, which accounted for 12% of the total burden of global blindness (39 million).<sup>[1]</sup> Most of the corneal blindness is preventable and the value of keratoplasty in these conditions cannot be emphasized enough. <sup>[2]</sup> Although newer modalities of keratoplasty have come into the picture, penetrating keratoplasty (PK) still remains the gold standard for conditions that involve full thickness of the cornea. Various host and donor related factors influence the visual outcome post penetrating keratoplasty. Optimizing conditions that help in obtaining good quality donor cornea and reducing complications post keratoplasty due to host factors and iatrogenic factors result in better visual outcomes post-surgery.

To get more number of corneas, Eye Bank Association of India have started Hospital Corneal Retrieval Programme (HCRP), where attempts are being made to motivate and counsel the relatives of a deceased person in the hospital for eye donation by sensitizing them regarding corneal blindness and benefits of corneal transplantation, and organizing for quick, convenient enucleation or corneoscleral button excision.<sup>[3]</sup> In a tertiary center with multi-disciplinary intensive care units (ICUs) and other machinery, it is essential to develop adequate systems that can help in the early and proper retrieval of donor corneas. This requires a system to be in a place that comprises eye bank technicians, trained assistants, and eye donation councilors headed by an ophthalmologist. Lesser death to enucleation and preservation time has been associated with better postoperative visual outcome and clearer grafts. An effective hospital cornea retrieval orucement of the enucleation time and preservation time thereby improving visual outcome post keratoplasty.

Various factors contribute to donor cornea quality, early and late complications post keratoplasty, and their effect on visual outcome. Hence, we aim to study the clinical indications, visual outcomes, complications of penetrating keratoplasty, and the factors affecting them like, the effect of hospital versus home corneal button retrieval and death to enucleation time. We also aim to highlight the effectiveness of the hospital cornea retrieval program that exists in our institution that has aided in obtaining excellent outcomes post keratoplasty.

## 2. MATERIALS AND METHODS

This is a prospective study conducted in a university teaching hospital in South India with an established eye bank facility done over a period of 2 years. The study was conducted following the guidelines of the declaration of Helsinki and after institutional ethical committee approval. With reference to the article by Manu et al (year) where the sample was taken as 30, the sample size for our study was calculated to be 52, with an alpha error of 5% and a confidence interval of 95%. A total of 52 patients (24 males and 28 females) who underwent penetrating keratoplasty were included in the study after obtaining informed consent for the same. All-optical penetrating keratoplasties that were included in this study were performed by a single surgeon. All patients

had a minimum follow-up period of 6 months. Data pertaining to the indications for keratoplasty, evaluation of cornea prior to the surgery, visual acuity pre-operatively, complication of surgery, and visual acuity at the end of postoperative day 1 (POD), 1<sup>st</sup> month 3<sup>rd</sup> month, and 6<sup>th</sup> month were also noted. Mode of retrieval of donor cornea either the hospital or home retrieval, death to enucleation time, mode of preservation, and pre-operative corneal status was taken. The effect of death to enucleation time and the mode of donor cornea retrieval were compared to the final visual acuity of the patient post-surgery and the incidence of developing graft failure.

## 2.1 Patient selection

All patients who underwent keratoplasty from the year 2018- 2020 in a university teaching hospital in South India were included in the study. All patients requiring therapeutic keratoplasty or tectonic grafts and patients who were lost to follow up or had a follow-up period of <6 months were excluded from the study.

## 2.2.Donor cornea Grading:

Whole globe retrieval is practiced in our center and the entire globe is preserved in a McCarey Kauffman (MK) media. The corneal button is harvested. The whole globe corneas and all buttons used for performing keratoplasty were deemed fit after slit-lamp examination and evaluation under specular microscopy. The grading was performed by a single trained cornea specialist and was used to evaluate the donor cornea quality and is described in detail in the image (Figure 5,6). A specular microscopy count of fewer than 1500 cells/cm<sup>3</sup> was deemed unfit and those corneas are not used for keratoplasty.

## 2.3. Surgical Technique:

Donor cornea was preserved in MK medium. Under sterile aseptic precaution, appropriate sized donor cornea (7 to 8.5mm) was trephined using Iowa punch. Following trephination, donor graft is placed on recipient bed and secured using 16 interrupted 10/0 nylon sutures. Additional procedures like cataract extraction, intraocular lens implantation, anterior vitrectomy, synechiolysis, iridectomy, pupilloplasty were performed as and when required. All-optical PKs included in this study were performed by a single surgeon.

## 2.4. Post-operative evaluation:

Routine post-operative medication consisted of topical prednisolone 1% combined with topical antibiotic four times daily. Following discharge, the patient was seen on 1<sup>st</sup> postoperative day and subsequently after 1<sup>st</sup> month, 3<sup>rd</sup> month, and 6<sup>th</sup> month. Steroid drops were asked to continue at once-daily dosage lifelong. At every visit, intraocular pressure was measured and symptoms of graft rejection (RSVP: R-redness, S-sensitivity to light, V-vision loss, P-pain) were explained to the patient.

Graft rejection was defined as the presence of one or more of the following signs: mild if there were 1-5 keratic precipitates (KP), sub-epithelial infiltrates and increased corneal thickness without an increase in aqueous cells, and severe rejection if >5 KPs inflammatory cells seen in

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the stroma (not due to infection), endothelial rejection line or increased thickness with aqueous cells. Graft clarity was graded as grade 4 if grafts were optically clear with an excellent view of iris details, grade 2-3 (borderline) if there was moderate to significant corneal haze with or without a good view of iris details, and grade 1 (failed) for opaque grafts with a poor view of iris and anterior segment details<sup>[4]</sup>

#### 2.5. Statistical analysis:

Statistical analyses were performed with SPSS for Windows version 14.0 (SPSS, Inc., Chicago, IL, USA). The results were represented in percentage. A p-value <0.05 was considered statistically significant.

Within each group, we evaluated factors that might affect postoperative best-corrected visual acuity (BCVA) and compared the preoperative and postoperative variables between the groups. The student's *t*-test was conducted for quantitative traits, and the  $\chi^2$  test was used to compare proportions of qualitative traits between groups.

### **3. RESULTS**

In our study, we found that the commonest indication for keratoplasty was pseudophakic/aphakic bullous keratopathy followed by corneal injury secondary to trauma (Figure 1). The commonest complication in the immediate postoperative period was an epithelial defect (Figure 2) and the late postoperative complication at the end of 6 months was graft failure followed by secondary glaucoma (Figure 3). The visual acuity pre-operatively ranged from the perception of light (PL) present to 6/60 and post-operatively from hand movements close to face (HMCF) to 6/12 (Table 1, Figure 4). The improvement in visual acuity to 6/60 or better was seen in 26 patients and an overall improvement in visual acuity was 69.2%. The improvement better than cf@1m (counting fingers) was seen in 36 out of 52 patients. Overall 69.2% of patients showed improvement in visual acuity over 6 months. Also, comparing the death to enucleation and preservation time and its outcome on post-operative visual acuity, we found that when the death to enucleation time was less than 4 hours there was a significant improvement in visual acuity postoperatively (p<0.001) (Table 2& 3).

The effect of mode of retrieval of cornea either home or hospital was also analyzed and compared to the post-operative visual acuity and a relation was established. We found the 46 out of the 52 patients had undergone keratoplasty with hospital retrieved donor corneas. When we compared this data with the post-operative visual acuity we found that the improvement in vision was found to better than counting fingers at 3 meters (cf@3 m) as statistically significant (p=0.02) (Table 4). The comparison was also made between mode of corneal retrieval with the incidence of post-operative graft failure and found that hospital derived corneas had a lesser incidence of graft failure and this result was statistically significant (p=0.004) (Table 5).

#### **4. DISCUSSION**

In our study, we found that bullous keratopathy is the commonest indication (38.4 %) [Figure 1] and our results have been comparable to a study done by Thomas et al<sup>[5]</sup> where they looked at 30

patients who underwent penetrating keratoplasty and found pseudophakic bullous keratopathy (PBK) to be the commonest indication. A study by Kalpana et al. where they have looked at 113 eyes that underwent PK concluded that bullous keratopathy was the most common indication for PK 50.4 % and corneal opacities were 36.8% <sup>[6]</sup>. These results were also very similar to our study. This may be since many of the patients in our study sample much like the other two studies in comparison had undergone eventful cataract surgeries in our institution and were followed up for post-operative corneal complications like aphakic and pseudophakic bullous keratopathy

We found that the commonest complication in the immediate post-operative period was epithelial defects in 30.7% of cases and these were iatrogenically induced intra-operatively or due to suture-related complications [Figure 2]. Many of these patients were treated with bandage contact lenses and the protruding sutures were trimmed. It has been postulated that epithelial defects and suture-related complications may result in graft rejection and subsequent failure <sup>[7]</sup>. The commonest indication for PK in our study was bullous keratopathy and 7 out of 20 patients who underwent PK for bullous keratopathy developed secondary glaucoma. The commonest late post-operative complication after 6 months was secondary glaucoma. In a study by Franca et al, 18 out of 48 patients who had bullous keratopathy developed high intraocular pressure and secondary glaucoma.<sup>[8]</sup> [Figure3]

There was an overall improvement in visual outcome in our cohort from PL+ to 6/12. We considered a vision of counting fingers at 1 meter (CF @1 m) or better as an overall improvement in visual acuity and found that there was an overall improvement in vision in 69.2% of patients. The results were comparable to Thomas et al. who found an overall improvement of 76.2% in their study<sup>[5]</sup> [Table 1, Figure 4].

The hospital retrieval of donor cornea (46/52), lesser death to enucleation (< 4 hours = 23), and preservation time (< 6 hours = 30) is associated with better quality donor grafts, and hence producing better visual recovery and lesser rate of complications in those patients where p-value is found to be < 0.05 [Table 2, 3 & 4]. The mode of cornea retrieval becomes paramount in determining the rate of complications and the overall visual acuity of the patient post-operatively. In a study by Raj et al, 91 PK patients were evaluated and those with death to enucleation time (DET) of <4 hours and death to preservation time (DPT) of < 6 hours have a better visual prognosis <sup>[9]</sup>. We also found similar results in our study and the majority of the patients the DPT and DET were <4 hours contributing significantly to the clarity of the graft. However, we did not analyze the age of the donors.

Halliday et al. reported that there was no significant correlation between the time taken to reach a postoperative acuity of 6/12 and either storage time of donor corneas or age of the donor <sup>[10]</sup> Feizi et al. investigated the influence of donor and eye bank factors, including age, sex, cause of death, DPT, graft quality, storage time, and type of storage media on post-PK complications and outcomes. <sup>[11]</sup> Donor and eye bank variables affected the quality of donor corneas in the early postoperative course which is also proved in the current study. The results demonstrated that DPT was correlated significantly with epithelium-related problems after PK <sup>[9]</sup> Lesser death to enucleation and preservation time has also been studied by Van et al. and reported that the rate of

complications increased with the increasing interval that existed between death and preservation of donor cornea  $^{[12]}$ .

Dora et al <sup>[13]</sup> talk on the hospital cornea retrieval program and reported that there is a need for retrieval of the cornea from eligible and willing donors in a multidisciplinary set up with an organizational structure including a team of Eve bank technicians and grief councillors. It also aims at establishing an organizational structure that includes a team that comprises who form the pillars of this machinery and their role in obtaining corneas from hospitals cannot be stressed enough. It also involves training the nursing staff about the methods to protect the corneas of patients who are on the end of life care and they also speak to the next of kin of patients and educate them about the importance of prompt eye donation and also arrange and facilitate the early collection of donor corneas. We follow a similar kind of organizational set up in our centre to optimize the retrieval of donor corneas and ensure their efficient utilization. Bhavna et al. studied eye donation awareness and conversion rate in HRCP and established that the role of grief councillors in increasing the number of corneal retrievals in a tertiary care centre in motivating donors and families thereby increasing the conversion rate. In our setup, we have dedicated grief councillors who when informed about the possibility of the end of life of care in ICU patients will contact the next of kin and brief them about the importance of eye donation and the need for early cornea retrievals.<sup>[14</sup> In our organizational set up we have a dedicated team of grief councillors who are spread across multidisciplinary ICUs and work closely with the nursing staff and are also trained to discuss with the next of kin of patients who are receiving end-of-life care. This efficient system has enabled us to promptly retrieve good quality donor corneas from hospital ICUs which have been primed with adequate measures to protect the quality of corneas. <sup>1</sup> Yew et al. concluded that imparting proper knowledge about eye donation can increase corneal retrieval. Subjects who had been a witness to prior eye donation in family or neighbourhood could be easily motivated for donation.<sup>[15]</sup>

In our study, we correlated the rate of graft failure to the mode of donor cornea retrieval and found that there was a strong correlation between the hospital derived corneas and the possibility of obtaining a clear graft (p=0.004) [Table 5]. This is probably because of the efficient and timely retrieval of corneas from young donors. This has been made possible due to the effective hospital corneal retrieval program that exists in our set up. The reduced DET and DPT are also strong contributors to the better quality grafts and reduced complications that have been noted in our study. It is difficult however to comment on the lack of effectiveness of home retrieved corneas as we do not have adequate data to extrapolate the result. But, the fact that the majority of hospital retrieved corneas have had good results in our study emphasizes the need for effective machinery to be in place especially in multidisciplinary setups to harvest good quality donor corneas.

## **5.LIMITATIONS**

The sample size in our study is very small and there needs to be a larger sample to establish our claims. Also, the data regarding hospital and home retrieval corneas are skewed in favour of

hospital retrieval corneas. Though the overall rate of graft clarity and visual improvement can be attributed to the effective hospital corneal retrieval program that exists, it is difficult to establish its superiority as compared to home retrieved corneas as only 6/52 patients had home retrieved corneas. However, this could be a future direction in which research can be carried out and various outcomes can be investigated.

## **6.CONCLUSION**

Various donor and host factors influence the post-operative visual recovery after keratoplasty. The donor factors such as lesser death due to enucleation, preservation time, and hospital donor cornea retrieval are contributory to better visual prognosis. With our results, we conclude that lesser rates of graft failure are associated with hospital-derived corneas and the need for adequate systems according to the hospital cornea retrieval program are required to be initiated to increase hospital donor cornea retrieval.

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#### TABLES

Pre-operative	Post-operative
(n)	(6 months)
10	0
15	14
11	2
11	2
10	3
2	4
2	2
2	3
2	8
	-
0	10
0	8
52	50
52	52
	(n) 10 15 11 10 2 2 2 0

Table 1: Pre-operative and Post-operative visual acuity, n = no. of patients PL+, HMCF, CFCF, CF@1, CF@2, CF@3

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## TABLE 2: COMPARISON OF DEATH TO ENUCLEATION TIME TO POST OPERATIVE VISUAL ACUITY(n=52)

DEATH TO	POST OP VA	POST OP VA	P-Value*
ENUCLEATION	>CF@3(n=29)	<cf@3(23)< td=""><td></td></cf@3(23)<>	
TIME			
<4 HOURS <u>n</u> (%)	23(79.3)	0	0.001
>4 HOURS n(%)	6(20.7)	23(100)	

\*P-Value<0.05 considered as significant using Chi-square test

# TABLE 3: COMPARISON OF DEATH TO PRESERVATION TIME TO POST OPERATIVE VISUAL ACUITY(n=52)

DEATH TO	POST OP VA	POST OP VA	P-Value*
PRESERVATION	>CF@3(n=29)	<cf@3(n=23)< td=""><td></td></cf@3(n=23)<>	
TIME			
<6 HOURS n(%)	27(93.1)	3(13.0)	0.001
>6 HOURS n(%)	2(6.9)	20(87.0)	

\*P-Value<0.05 considered as significant using Chi-square test

## TABLE 4: COMPARISON OF MODE OF DONOR CORNEA RETRIEVAL TO POST OPERATIVE VISUAL ACUITY(n=52)

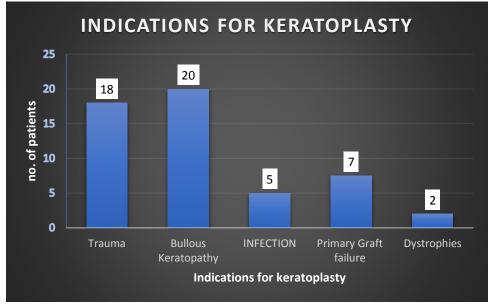
MODE OF	POST OP VA	POST OP VA	P-Value*
RETRIEVAL	>CF@3 (n=23)	<cf@3(n=29)< td=""><td></td></cf@3(n=29)<>	
HOSPITAL n(%)	17(74.0)	29(100)	P=0.020
HOME n(%)	6(26.0)	0	

\*P-Value<0.05 was tested by using Chi-square test

# TABLE 5: COMPARISON OF MODE OF DONOR CORNEA RETRIEVAL TO OCCURRENCE OF GRAFT FAILURE(n=52)

MODE OF	Graft failure(n=17)	Clear graft(n=35)	P-Value*
RETRIEVAL			
HOSPITAL n(%)	12(71.0)	34(97.1)	0.004
HOME n(%)	5(29.0)	1(2.9)	

\*P-Value<0.05 considered as significant using Chi-square test



## FIGURES

Figure 1: Indications for keratoplasty

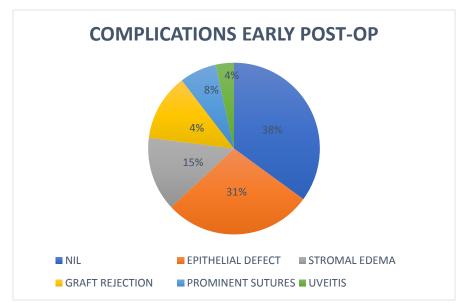


Figure 2: Early post-operative complications of keratoplasty

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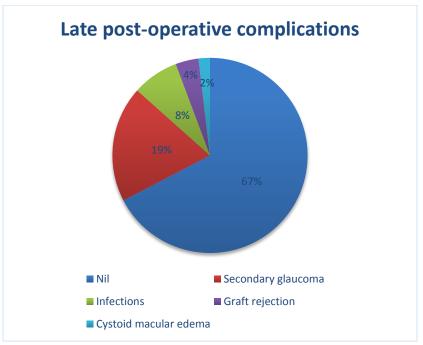
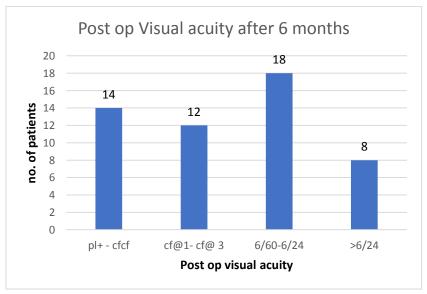
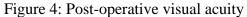


Figure 3 : Late post-operative complications of keratoplasty





Qualified visual improvement better that cf@1m was seen in 36 out of 52 patients. Overall 69.2% patients showed improvement in visual acuity over 6 months

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Figure 5 : Donor cornea evaluation sheet

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SREB No. :\_\_\_/\_\_ Date :

/\_\_\_\_

Time

**Cornea Evaluation Sheet** 

Technician

Cornea Size mm RE	Cornea Size mm LE
PITHELIUM         . Intact surface ? Yes / No         Haze ?         Degree : light / moderate / heavy         3. Exposure Keratitis ? Yes / No         Amount :      % (of surface)         Degree : light / moderate / heavy         Location : Central / periphery / mid-periphery         Type : diffused/band         4. Sloughing ? Yes / No         Amount :      % (of surface)         Degree : light / moderate / heavy         Location : Central / periphery / mid-periphery         Location : Central / periphery / mid-periphery         5. Other defects ? Yes / No         Location : Central / periphery / mid-periphery         Dimension :      mm	EPITHELIUM 1. Intact surface ? Yes / No 2. Haze ? Degree : light / moderate / heavy 3. Exposure Keratitis ? Yes / No Amount :% (of surface) Degree : light / moderate / heavy Location : Central / periphery / mid-periphery Type : diffused/band 4. Sloughing ? Yes / No Amount :% (of surface) Degree : light / moderate / heavy Location : Central / periphery / mid-periphery 5. Other defects ? Yes / No Location : Central / periphery / mid-periphery Dimension :mm
STROMA         1. Clear ?       Yes / No         2. Cloudiness ?       Yes / No         Degree : light / moderate / heavy         3. Arcus Senilis ?       Yes / No         Amount :       mm (from limbus)         Degree : light / moderate / heavy         4. Opacities ?       Yes / No         Comments :	STROMA         1. Clear ?       Yes / No         2. Cloudiness ?       Yes / No         Degree : light / moderate / heavy         3. Arcus Senilis ?       Yes / No         Amount :       mm (from limbus)         Degree : light / moderate / heavy         4. Opacities ?       Yes / No         Comments :       Yes / No
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Medical Director

Administrator

Technician

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	SRI RAN	Porur, Chenn		OSPITAL	
		EYE	BANK		
	1	lissue Distri	ibution For	m	
ye Bank Number : S	REB No. /	1	1		
Donor Name :			Age :	Sex:	M F
Date of Death :	1 1		Time :	/ h	irs
Date of Enucleation	: 1	1	Time :	/ h	irs
Cause of Death :					
Medical History :					
Ocular History :					
Death to preservati	on time : RE	hrs. mins			LE
Tissue Type :	Whole Globe	Cornea		Whole Globe	Cornea
Storage :	мк	Optiso		мк	Optisol
Lot No :				·	
		Status			Status
Corneal :	Excellent	Very G	Good 🗌	Excellent	Very Goo
Corneal :	Excellent Good	_		Excellent Good	Very Goo
				-	
Rating :	Good Intact Surface		s	Good	Fair NSFS
Rating :	Good Intact Surface	Fair NSF e Haze ratitis Sloug	s	Good	Fair NSFS
Rating :	Good I f Intact Surfac Exposure Ke	Fair NSF e Haze ratitis Sloug	s	Good [ Intact Surface Exposure Ker	Fair NSFS
Rating :	Good I f Intact Surface Exposure Ke Other Defect	Fair NSF e Haze ratitis Sloug is Cloud	s	Good [ Intact Surface Exposure Ker Other Defects	Fair NSFS
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Figure 6 : Eye bank donor cornea grading form

Abbreviations :

- PK Penetrating keratoplasty
- DET Death to enucleation time
- DPT Death to preservation time
- VA- Visual acuity
- PL Perception of light
- CF Counting fingers
- BCVA Best corrected visual acuity
- POD Post operative day