Indications, Complications and Management Associated with Keratoplasty

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By

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Dedicated to the Almighty, my parents, my beloved better half, my Institute, my teachers, my patients, and my students

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FOREWORD

That's the thing about books, they let you travel without moving your feet.
—Jhumpa Lahiri

I am delighted to introduce a well-thought-off book on Ophthalmology "**Indications, Complications, and Management Associated with Keratoplasty**" authored by Dr Anuradha Raj, Professor & Head, Department of Ophthalmology, All India Institute of Medical Sciences, Bathinda, Punjab, India.

All India Institute of Medical Sciences, Bathinda is an Institute recently established in 2019 with a mission to create an intellectual, academic, and research environment in addition to world-class patient care in the region of Punjab.

Corneal transplantation is the most successful tissue transplant as compared to other transplants and is done to eradicate a major chunk of corneal blindness. With the changing trends and technologies, this surgical procedure witnessed an evolution and a huge paradigm shift in the last few decades.

This book has touched on all the vital aspects of penetrating keratoplasty very precisely. The lucid representations of concepts of penetrating keratoplasty will be of immense use for the postgraduate students in Ophthalmology and will prove instrumental for the Cornea fellows too. I would like to congratulate the author for bringing up this book. I wish the

author the best of luck for this new venture and a more successful way forward.

Prof (Dr.) Dinesh Kumar Singh
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LIST OF ABBREVIATIONS

AC	Anterior chamber
AM	Amniotic membrane
AMT	Amniotic membrane transplant
APCs	Antigen-presenting cells
AS-OCT	Anterior segment optical coherence tomography
BCL	Bandage contact lens
BCVA	Best-corrected visual acuity
BKPro	Boston Keratoprosthesis
CCT	Central corneal thickness
CCTS	Collaborative Corneal Transplant Study
CHED	Congenital hereditary endothelial dystrophy
CJD	Creutzfeldt-Jakob disease
CsA	Cyclosporin A
COVID	Coronavirus disease
DALK	Deep anterior lamellar keratoplasty
DCT	Dynamic contour tonometer
DLEK	Deep lamellar endothelial keratoplasty
DM	Descemet's membrane
DMEK	Descemet's membrane endothelial keratoplasty
DSEK	Descemet's stripping endothelial keratoplasty
DSAEK	Descemet's stripping automated endothelial keratoplasty
EB	Eye bank
EBAA	Eye Bank Association of America
EBAI	Eye Bank Association of India
EBTC	Eye Bank Training Centre
ECCE	Extracapsular cataract surgery
EDC	Eye Donation Centre
ELISA	Enzyme-linked immunoassay
EUA	Examination under anesthesia
GAT	Goldmann applanation tonometer
GDD	Glaucoma Drainage Devices
GHJ	Graft host junction

GR	Graft rejection
HBsAg	Hepatitis B Australia antigen
HBV	Hepatitis B virus
HCV	Hepatitis C virus
HCRP	Hospital Corneal Retrieval Programme
HIV	Human immunodeficiency virus
HLA	Human leucocyte antigen
IOL	Intraocular lens
IOP	Intraocular pressure
KP's	Keratic precipitates
LogMAR	Logarithm of the minimum angle of resolution
LRI	Limbal relaxing incisions
LSCD	Limbal stem cell deficiency
MGD	Meibomian gland dysfunction
M-K	Mc-Karey Kaufman
MPS	Mucopolysaccharidoses
NAT	Nucleic acid testing
Nd:YAG	Neodymium yttrium aluminium garnet
NGO	Non-governmental organizations
NOTTO	National Organ and Tissue Transplant Organization
NPCB	National Programme for Control of Blindness
OCT	Optical coherence tomography
OOKP	Osteo-odonto-keratoprosthesis
OPK	Optical PK
PAS	Peripheral anterior synechiae
PC-IOL	Posterior chamber intraocular lens
PED	Persistent epithelial defect
PH	Potential of hydrogen
PK	Penetrating keratoplasty
PKG	Post keratoplasty glaucoma
PL	Perception of light
PMMA	Polymethyl methacrylate
PR	Projection of rays
SICS	Small incision cataract surgery
SKP	Sclero-keratoplasty
SLET	Simple Limbal Epithelial Transplantation

THOTA	Transplantation of Human Organs and Tissue Act
TMA	Tear meniscus area
TMH	Tear meniscus height
TPK	Therapeutic penetrating keratoplasty
UBM	Ultrasound bio-microscopy
VDRL	Venereal Disease Research Laboratory
VEP	Visually evoked potential

CHAPTER 1

PENETRATING KERATOPLASTY AND ITS INDICATIONS AND OUTCOMES

Corneal transplantation is a surgical procedure where a damaged or diseased cornea is replaced by donated corneal tissue (the graft). Corneal blindness occurs as a result of scarring or clouding of the normally transparent cornea. Keratoplasty or corneal transplantation is a surgical procedure done for sight restoration in various conditions leading to corneal blindness. This procedure is also known as corneal grafting. When the entire full-thickness cornea is replaced by the donor cornea is known as penetrating keratoplasty (PK). The first successful cornea transplant with long-term survival was attempted in 1905 by Edward Zirm. (Zirm 1989, 258-261)

In 1936, Castroviejo did the first transplantation in an advanced case of keratoconus, which significantly improved the patient's vision. (Castroviejo 1948, 127–153)

The new idea of removing the diseased portion of the cornea and leaving behind the normal anatomical corneal layers evolved by the early 1990s, which is known as lamellar keratoplasty. If the corneal stroma is scarred or the endothelium fails, lamellar keratoplasty aims at removing the diseased part of the cornea which leads to minimalization of the risks. In the first half of the 20th century, PK used to be the procedure of choice. According to statistics from the Eye Bank Association of America (EBAA), PK accounted for 51.5% of corneal transplants in America in 2010. (Eye Bank Association of America, 2010. Eye Banking Statistical Report. Washington, DC5-13)

PK remains the gold standard and the most commonly performed transplant procedure. PK is done for the treatment of all full-thickness corneal pathologies despite the newer advancements in this arena.

Indications of PK

PK is required in corneal diseases involving the corneal stroma and endothelium or both.

Optical PK

Optical PK is done to improve visual acuity which cannot be improved by any other procedure. In this procedure, the opaque or distorted host cornea is replaced by clear and healthy donor corneal tissue. Visual gain is the main aim of optical PK. It is the most common form of PK and covers more than 90% of total PKs performed in the majority of countries. A corneal pathology causing a reduction in the best-corrected visual acuity (BCVA) of <6/18 is an accepted norm for optical PK. Common indications include bullous keratopathy, keratoconus, corneal dystrophies, degenerations, and diffuse corneal scarring or large central corneal opacities or adherent leucoma. (Fig 1a, b) Various indications of optical PK are pseudophakic bullous keratopathy, scarring due to keratitis, trauma, keratoconus, corneal degeneration, keratoglobus, and corneal dystrophies. In Western countries, keratoconus is the major indication for PK, but an Indian study involving North India showed corneal opacity due to scarring as the commonest indication for optical PK in 33.10% of cases. (Rahman and Carley 2009, 1288–1294) (Raj and Gupta 2016, NC01-NC4)

Various other studies showed corneal scarring as a major indication of optical PK in different parts of India. (Dandona and Ragu 1997, 163–168) (Sony and Sharma 2005, 989–991) (Dasar and Pujar 2013, 2505–2507)

Tectonic/reconstructive

This type of PK is done to preserve the anatomical integrity of the cornea in patients with descemetoceles, stromal thinning, and impending perforations. The main aim of PK is to reconstruct the anatomy of the globe and to maintain its integrity which otherwise can be lost.

Therapeutic

In India a large proportion of eyes with microbial keratitis progress to corneal perforations, which result in severe ocular morbidities and even lead to the disaster of irreversible loss of globe. (Titiyal and Negi 2006, 686–689) (Ibanga and Asana. 2013, 355–360) Therapeutic PK is done to remove the inflamed and infected corneal tissue and it is mainly indicated in cases of recalcitrant infective keratitis to eliminate the infectious load as these cases are unresponsive to the treatment by antibiotics or antivirals. (Fig 2 a, b) This is an emergency surgical intervention and can be termed therapeutic penetrating keratoplasty (TPK). TPK helps to save many eyes structurally and functionally which otherwise may be lost. It is the most vital treatment strategy for infectious and non-infectious perforated corneal ulcers to salvage the globe. (Fig 3a, b) Visual rehabilitation is of secondary importance for TPK and the primary goals of TPK are to maintain the anatomical integrity of the globe and eradication of infective organisms. Significantly successful outcomes of TPK for perforated infectious corneal ulcers have been reported in the available literature from developing countries. (Bajracharya and Gurung 2015, 2299–2304) High anatomical, therapeutic, and functional success have been reported after TPK and it has a definitive role in the management of refractory infective keratitis. (Raj and Bahadur 2018, 315–320)

Cosmetic

Cosmetic PK is done to improve the appearance of patients with corneal scars which give a whitish or opaque hue to the cornea and patients want to get rid of the corneal scars for their cosmesis.

The outcome of optical PK

Depending upon the indications of PK, the outcome of PK varies relatively. The optical PK is done for visual rehabilitation and the graft outcome includes the final BCVA achieved. Rahman et al. reported that 48% of patients achieved BCVA of 6/12 or better 5 years postoperatively, compared with 9% with the same visual acuity preoperatively. They reported an overall 5-year survival rate of up to 82%. (Rahman and Carley

2009, 1288–1294) Similarly, Raj et al. reported that 32.43% of cases got BCVA of >20/60 after one year of follow up and all cases of corneal dystrophy and keratoconus got BCVA of >20/60 at the last, follow-up except one case where graft failed. (Raj and Gupta 2016, NC01-NC4) Brahma et al. evaluated visual function in a series of keratoconus patients and found improvement in the logarithm of the minimum angle of resolution (LogMAR) visual acuity, decreased glare, and better contrast sensitivity following successful PK. (Brahma and Ennis 2000, 60–66) In cases of optical PK, the donor variables also show an impact on the visual outcome only for the short post-operative follow-ups till nine months. Even the complications of PK are also influenced by both donor and eye bank variables. (Raj and Dhasmana 2016, 56-61) In the available literature graft survival rate varied from 36-to 93%. (Dandona and Naduvilath 1997, 726–731) Some specific indications such as keratoconus and corneal dystrophies show a higher survival rate. The 5-year survival of 82% is considered favorable and may reflect the 'center effect' explained by Vail et al. which shows that centers with regular corneal grafting show more favourable results. (Vail and Gore 1994, 120–127) Peleyer et al. demonstrated that rejection episodes occur in the first three years following keratoplasty with the most frequent episodes in the first year after PK up to the extent of 43%. (Peleyer and Steuh 1992, 2034–2037)

Graft failure is defined as the loss of graft transparency immediately or late after surgery. Graft failure leads to loss of graft clarity and is capable of compromising vision.

There is a pandora box for the risk factors that can lead to graft failure eventually. (Fig.4) It is difficult to isolate each factor as an individual risk for failure but can be divided into the recipient, graft, or surgical procedure-related factors.

Raj et al. reported secondary graft failure in 13.51% of eyes after PK (Raj and Gupta 2016, NC01-NC4). Rahman et al. reported graft failure in 7.4% following an episode of rejection. (Rahman and Carley 2009, 1288–1294) The episode of rejection should be promptly managed to avoid eventual graft failure.

Post-keratoplasty glaucoma (PKG) is one of the most common causes of irreversible visual loss and the second leading cause of graft failure due to significant endothelial cell loss, especially in patients who already have low endothelial reserve. (Foulks 1987, 871-874) The amount of cell loss appears to correlate with the duration of the increased intraocular pressure (IOP). IOP monitoring in the early postoperative period especially one month after PK is mandatory to avoid graft failure due to PKG which is difficult to diagnose otherwise.

The incidence of PKG differs significantly from 0%–12% to 75%. (Kirkness & Moshegov 1988, S19-26) Raj et al. concluded that the incidence of PKG after PK was 32.25% and the subjects within the age group >40 years, corneal opacity, increased recipient size, and increased central corneal thickness (CCT) served as risk factors for PKG. (Raj and Dhasmana 2018, 220-266) Rahman et al. reported the incidence of glaucoma after PK to the tune of 18%. A significantly higher rate of graft failure was observed in patients with PKG. (Rahman and Carley 2009, 1288–1294)

Various factors responsible for IOP elevation in both the early and late postoperative periods are shown in Fig 5.

Outcome of TPK

In cases of refractory microbial keratitis, if conventional medical therapy fails, TPK is the final option to prevent corneal perforation. TPK shows a higher risk of recurrence of infection, graft rejection, PKG, and, graft failure as compared to optical PK. (Reis and Birnbaum 2007,373–380) With the use of better donor tissue quality and surgical techniques, TPK is showing a better outcome as compared to the past in cases of large corneal perforations and refractory corneal inflammation. The primary outcome of TPK is eradication or reduction of the load of the infective organisms and maintenance of anatomical integrity of the globe which is at risk, whereas visual rehabilitation is of secondary importance. The outcome of TPK can be observed in terms of the anatomical, therapeutic, and functional outcomes as their respective success and failure. (Raj and Bahadur 2018,

315–320) Various pre- and post-operative factors show their influence on the outcome of TPK. (Fig 6)

Restoration of the tectonic and anatomical integrity of the globe can be considered an anatomical success and the development of phthisis bulbi or anophthalmos as a result of infective keratitis can be considered an anatomic failure. It is considered a therapeutic success when there is a complete eradication of the micro-organisms with empirical therapy after TPK. (Ti Seng and Scott 2007, 755–762) The functional success of TPK is considered as the restoration of visual function with BCVA ranging from the perception of light (PL), an accurate projection of rays (PR) to 20/40, and its failure can be taken in terms of lack of perception of light or inaccurate projection of rays. (Sharma and Jain 2014, 114–118) Indications and complications significantly affect the anatomical, therapeutic, and functional outcomes. A perforated corneal ulcer is a major indication of TPK. Therapeutic, functional, and anatomical success has been reported by Raj et al. in 91.22%, 70.17%, and 85.96% of cases respectively. (Raj and Bahadur 2018, 315–320) (Sharma and Jain 2014,114–118)

Sukhija et al. concluded therapeutic success in 90% of the cases. The BCVA <6/60 is considered ambulatory vision and Sharma et al. reported ambulatory vision achievement in 35.96% of cases which shows that despite vision achievement being the secondary importance, TPK can help achieve that to a good extent (Sukhija and Jain 2005, 303–309). The type of microorganism present at the time of PK also decides the challenges of the post-operative course of PK and its outcome. Bacterial ulcers have resulted in better outcomes in comparison to fungal ulcers. (Daigavane and Prasad 2019, 143-146) Mundra et al. concluded that the outcomes of TPK in fungal keratitis differ from bacterial infections in their clinical course and management. Recalcitrant fungal keratitis cases need early surgical intervention. They reported good anatomical restoration in 96.4% of cases after TPK but visual rehabilitation was limited. Suppression of postoperative inflammation with steroids can improve graft survival and subsequent visual recovery. (Mundra and Dhakal 2019,1599-1605) Topical steroids can be switched after two weeks of TPK in cases of fungal keratitis to reduce inflammation, but in the meanwhile, they lead to peripheral anterior

synechiae formation, pupillary block, PKG, graft edema, and even graft rejection.

The recurrence of the infection is another hurdle to tackle within these cases especially if the large-sized, deep perforated corneal ulcers and ulcers involving the limbus or adjoining sclera. The persistent epithelial defect and cataracts are the other more common complications that show their impact on the outcome of TPK in perforated ulcers and larger-sized grafts. (Raj and Bahadur 2018, 315–320)

In conclusion, depending on the aim and outcome, there are various types of indications of PK. The outcome of PK depends upon various factors which should always be taken into account to avoid graft failure eventually. The indications of PK immensely affect the prognosis and outcome of PK. Various donor graft variables such as the grade, size of the graft, and eye banking procedures show their impact on the outcome of PK.

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CHAPTER 2

EYE BANKING

History and its milestones

In 1944, Dr R. Townley Paton established the first eye bank in New York City with the help of his colleagues and Lion Club members for Sight restoration. Dr Paton's efforts established the existing principles of eye banking. (Ehlers 2002, 572-578) Eye Bank Association of America (EBAA) was established in 1961 as a non-profit organization for the standardization of eye banking practices for the facilitation of restoration of sight through the promotion and advancement of eye banking. (Mian and Kamyar 2005, 607-624) Mc-Karey and Kaufman 1974 developed a Mc-Karey Kaufman (M-K) medium for the preservation of the excised corneoscleral rim for up to 4 days at 4°C. (Ehlers 2002, 572-578)

The global initiative of Vision 2020 primarily targeted corneal blindness. Visual rehabilitation in corneal blindness is possible only with corneal transplantation and eye banking forms its prominent pillar of foundation. All activities of eye banking including infrastructure, human resources, logistics, and service delivery need to be at par with international standards.

Objective and functions of eye bank

An eye bank is a non-profit organization, managed by a Board of Directors, to increase the quantity by collection (harvesting) of Corneas / Eyeballs from Cadaveric or Brain-Dead persons and the quality of eye tissue through their storage, processing, and distribution to Corneal surgeons in a timely and efficiently coordinated manner. An eye bank is a link between the donor family and a cornea recipient and it assures the safe quality of the donor's eyes for therapeutic and research use. A three-tier organization structure has been recommended for an efficient eye

banking system with the Eye Bank Training Centre (EBTC) at the top of the pyramid followed by Eye Banks and Eye Donation Centre (EDC) at the base. (Fig 1) Tissue harvesting, processing, distribution, creating public awareness as well as training and skill up-gradation of eye banking personnel is the responsibility of EBTC. Eye banks need to comply with regulations formulated by the Eye Bank Association of India (EBAI). The functions of EDC are public and professional awareness of eye donation, coordination with donor families and hospitals to motivate eye donation, corneal tissue harvesting, blood collection for serology, and, safe transportation of tissue to the parent eye bank. Eye banks need to maintain the standards concerning various domains such as donor screening, corneal extraction, processing, preservation, tissue evaluation, and, distribution as per National Organ and Tissue Transplant Organization (NOTTO) guidelines. (Standards of eye banking in India manual 2020) [Table 1]

Table 2-1: Demonstrating various functions of eye bank

1	Co-ordination with donor families and hospitals to motivate eye donation/through the Hospital Cornea Retrieval Programme – (HCRP)
2	Round-the-clock public response system provision over the telephone and conduct public awareness on eye donation
3	Promote retrieval of donor tissue from the hospital setting and develop professional in-service programs in order to maximize identification of suitable donors and referral to the eye bank
4	Procurement of high-quality tissue
5	Ensure safe transportation of tissue
6	Proper evaluation of the procured tissue
7	Screening of eyes as per standards
8	Serological testing for HIV, Hepatitis B, C, Syphilis of cadaveric blood sample
9	Processing of corneal tissue for research or teaching as needed.
10	To distribute high quality tissue for Keratoplasty
11	To eliminate waiting list

Manpower for eye banks

The manpower required for eye banks includes medical staff, executive directors, eye bank managers, technicians, and eye donation counsellors.

According to the National Programme for Control of Blindness and Visual Impairment (NPCB-VI), there are 435 functional eye banks and EDCs in the country involved in the collection and distribution of donated eyes which amounts to nearly 1 eye bank/EDC per 3 million population. (Functional Eye Banks, India. National Programme for Control of Blindness). The Indian government guidelines emphasize that EBAI needs to provide infrastructure, equipment, and facilities to all EDCs and eye banks to ensure their smooth functioning. (Standards of Eye Banking in India 2009) Trends in cornea collections are showing a steady rise from 38646 corneas collected in 2007–08. (Cornea collection during 11th Five-Year Plan). The demand for good quality donor corneas is also on the rise despite limited supply, showing an increasing trend of its utilization rate ranging between 25% and 60%. (Raychaudhuri and Raychaudhuri 2004, 99–101)

Tissue procurement, processing, and evaluation

After obtaining the consent of the family and an elaborate medical interview with the next of kin or a review of the donor's medical records, the safety, and suitability of the tissue are to be determined first. The eye bank must arrange the recovery of tissue and its laboratory processing. In the absence of a death certificate, a Medical Practitioner must ensure that there is no life before recovery. (Fig 2)

Various pre-removal measures should be followed for tissue procurement. The eye banks are notified by the voluntary donor's relative at the time of demise for eye donation. Hospitals also refer these donors to nearby eye banks or may be notified by the EDCs. Consent for eye donation is a must, which is usually given by the donor's relative or next of kin. The eye bank staff needs to tell the relatives to keep the head end elevated to avoid post-mortem damage to the corneas. It also decreases the periorbital edema which helps in the reconstruction of the globe or socket after enucleation

or corneoscleral rim excision. The donor's eyes should be kept cool to avoid dryness with the help of placing the ice packs over the eyes.

A physical assessment of the donor is done to rule out the unnatural cause of death. The eye bank technician should examine the body of the donor for any evidence of intravenous drug abuse, tattoos, and other body piercings.

Blood sampling

About 10 ml of blood sample is drawn for human immune deficiency virus (HIV), Hepatitis B virus (HBV), Hepatitis C virus (HCV), Syphilis, and Coronavirus disease-19 (COVID-19). The Cadaveric blood sampling should not be done more than 10 hours after death, as the serum quality deteriorates after a long time and the chances of false-positive tests increase (Challine and Roudot 2006, 788-793) If post-mortem samples are taken less than 10 hours after death, that can improve the safety and utility of the donor cornea. (Raj and Mittal, 2018, 61-65)

Safety and viability of the donor cornea are essential prerequisites and it depends on the age of the donor, the time between death and enucleation, and the cause of death. Donor testing includes the donor's microbial culture data (e.g., blood, urine, sputum), serologic assay results (e.g., antibodies against various viruses including HIV, HBV, and HCV), and increasingly, nucleic acid testing (NAT) results, including assays for HIV, HBV, HCV or COVID-19 antibodies.

Post-mortem donor's blood samples as soon as possible after death or pre-mortem samples within seven days drawn before death are acceptable. If for any reason, screening has not been done or viral markers are reactive then the tissue is labeled as "potentially hazardous biological material" and can be discarded. (Fig 3) Due to the COVID-19 pandemic, the nasopharyngeal swab should be taken from the cadaveric body to rule out COVID-19 infection. However, no proper guidelines are framed yet regarding the swab and whether should be taken or not.

Donor screening

Various diseases such as systemic infections, neoplasms, and corneal disorders have transmission potential by corneal transplantation. As per EBAA guidelines cause of death of the donor is the first and foremost mandatory information that forms the basis for disqualification of the donor or the donated tissue. Donors are screened based on various risk factors elaborated in Table 2. (Eye Bank Association of America, Medical Standards Manual 1993)

Table 2-2: Showing Donor's risk factors

1.	***Potentially hazardous donor tissue for eye bank personnel and should be strictly avoided.***
	Active Viral Hepatitis Acquired immunodeficiency syndrome (AIDS) of HIV Active viral encephalitis or encephalitis of unknown origin Creutzfeldt-Jakob disease Suspected rabies and persons who, within the past six months, were bitten by an animal suspected to be infected with rabies
2	***Conditions with potential risk of transmission of local or systemic communicable disease from donor to recipient*** 1. Death of unknown cause and likelihood of exclusionary criteria as outlined in this list 2. Death with progressive neurodegenerative disease of unknown etiology, including but not limited to the following: a. Chronic idiopathic demyelinating polyneuropathy b. Amyotrophic lateral sclerosis c. Multiple sclerosis d. Huntington's chorea e. Alzheimer's disease f. Dementia (except due to CVA, brain tumor, head trauma or drug-induced) g. Myasthenia gravis h. Parkinson's syndrome i. Parkinson's like disease j. Creutzfeldt-Jakob disease 3. Active meningitis (viremia, bacteremia, tubercular)