

RESULTS OF PENETRATING KERATOPLASTY IN TERTIARY CARE CENTRE

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Abstract:

Blindness due to corneal scarring is one of the leading causes of treatable blindness. Full thickness penetrating keratoplasty is still considered to be the most acceptable surgical method, keeping this in mind and with the Purpose To study visual outcome after penetrating keratoplasty and to evaluate intra and post operative complications and to study the various factors which influences the graft survival. In our study we have operated 32 eyes of 32 patients and they were studied over 24 month's period. Patient with all types of corneal opacity, Keratoconus and Failed corneal transplant were considered for optical keratoplasty. At the end of 24 months we found that Out of 32 patient's male to female ratio was 2.2:1. Mean age was 47 ± 12 years. Most common indication was corneal scar (43.75) most common preoperative risk factor for graft failure was vascularised recipient cornea (28.12%). Good quality graft (2+) had better survival rate (83.33%) and better visual prognosis (81.8%). Small graft size had better survival rate (78.57%) Young donor below 50 years of age, graft survival rate was 87%. Most common intra-operative complication was suture related difficulties (28.12%). Postoperative corneal graft edema was commonest complication (57%) Total 34.36% of patients gained vision $\geq 6/24$. 37.5% patients between 4/60-6/60. Total graft survival rate was 71.87%. Total corneal graft failure rate was 28.13%. **Conclusions:** Full thickness Penetrating Keratoplasty gives satisfactory visual outcome. Pre-operative evaluation of donor corneas & recipient eyes is important. Post operative follow up is recommended.

Keywords: Visual outcome, penetrating keratoplasty, Graft Failure

Introduction

There are approximately 50 million blind populations in the world. In addition, nearly 150 million people suffer from 'low vision'. The fact that there are 200 million people in the world today who are in some

way severely visually disabled is a tragic, unacceptable situation in both social and economic terms blindness prevalence is presumed to increase by nearly 2 million every year due to the rising proportion of ageing population and service deliverance

not keeping in pace with the incidence. Corneal disease remains the second most important cause of blindness today, following cataract which is almost totally reversible in the present era. Around 6 million people in India are suffering from corneal blindness.

On extrapolating Indian data, it is derived that approximately 1.5–2 million people develop corneal ulcer annually in developing countries. The most frequent causes of corneal blindness according to this survey included keratitis in childhood (36.7%), trauma (28.6%), and keratitis during adulthood (17.7%).⁴

Visual rehabilitation in many of these cases is possible with corneal transplantation.

Predominant causes include adherent leucoma and vascularized corneal scar secondary to trachoma, keratitis in childhood, trauma, and keratitis in adults. Improving the outcome of relatively high-risk keratoplasty would require improvement in eye banking standards, high-quality training programs in corneal subspecialty and eye banking, enhanced surgical infrastructure and improvement in postoperative care of corneal grafts. Corneal transplantation is the only option for visual rehabilitation of those currently blind from corneal diseases.

Need for Corneal Graft Registry

A corneal graft registry contains all the valuable information of donor and tissue details and the utilization of cornea. It is maintained by the eye banks.

However, in a country like India with different disease epidemiology, compliance and follow up, it is necessary to have our own registry to audit and evaluate the available transplant services and utilize this information to improve our outcomes.

Donor Tracking Protocol

It is a system that helps in collection and collation of statistical information on the practice of corneal transplantation and helps

in tracking the donor and other tissue details. It is an indirect means of evaluating both immediate and long term outcomes of corneal transplantation and helps to provide feedback to contributing eye banks and operating surgeons for the benefit of their patients.

In 3rd world nations, blindness due to corneal diseases is one of the leading causes. Corneal grafting is done to restore the vision of the patients and is boon for such patients as most of them can be successfully treated by this procedure.

The major hurdle in meeting the vast challenge of corneal blindness is the availability of donor cornea for keratoplasty.

Aims and Objective:

1. To study the visual out-come after penetrating keratoplasty in tertiary care centre.
2. To evaluate various indications for penetrating keratoplasty.
3. To evaluate the intra and post operative complications in penetrating keratoplasty.
4. To study the various factors which influencing graft outcome.

5. Methodology

Type of study

This is a case series of 32 patients, assigned to undergo penetrating keratoplasty at a tertiary care centre.

Plan of study

32 eyes of 32 patients were selected for study that underwent penetrating keratoplasty and followed up for 24 months.

Inclusion criteria

Patient with all type of corneal opacity, Keratoconus and Failed corneal transplant.

Exclusion criteria

Non willing recipient, Posterior segment abnormality, Certain systemic infection (AIDS, viral hepatitis, septicemia etc), Malignancy, leukemia to recipient and Therapeutic keratoplasty

Preoperative assessment

Detailed ocular and medical history was taken. Emphasis was given on the occupation, history of trauma to eye and any previous ocular surgery. In the past history of diabetes mellitus, hypertension, chronic use of any ocular or systemic medication and any other immunocompromised condition which will predispose for corneal infection was asked. Visual acuity uncorrected and with pin hole visual acuity was recorded pre-operatively in both eyes separately. Anterior segment examination done with slit lamp biomicroscopic examination. Presence of any corneal vascularisation was looked for. Associated ocular conditions such as blepharitis, conjunctivitis, dacryocystitis, spheroidal corneal degeneration, tear film deficiency, bullous keratopathy, and pre existing viral keratitis, lid abnormalities, Bell's palsy, lagophthalmos, trichiasis, suture infiltrates and adherent leucoma were noted.

Detailed fundus examination was done if possible. When an adequate view of the retina was not possible, and the integrity of the globe was compromised by a large corneal perforation, B-scan ultrasonography was done.

After the above examination the following investigations were done in all patients pre-operatively, Syringing was done, Conjunctival swab for culture and sensitivity, ECG, Blood sugar random and if necessary fasting and post prandial level were checked, Operative fitness of each patient was obtained from the physician, Pre anesthetic check was done in patients who had large perforated fungal corneal ulcer in whom general anesthesia was given. Preoperatively all the patients were hospitalized.

Locally all patients were started with local broad spectrum antibiotic drops 8 times a day. Before surgery 2 drops of 5% povidine eye drops once. Systemically Oral

acetazolamide 250 mg TDS was started to lower the IOP and prevent perforation of the ulcer. Patients with secondary glaucoma were treated first medically followed by penetrating keratoplasty.

Pre-operative preparation:

Injection TT was given and xylocaine sensitivity was done, The day before surgery eyelashes were cut and patch test was done, In the morning on the day of operation two tablets of acetazolamide 250mg were given to patient, 45 minutes prior to surgery Inj Mannitol 100cc was given, In phakic eyes, the pupil was constricted pre-operatively with 1% pilocarpine so as to protect the clear lens during surgery.

Surgical technique

All cases were performed by single surgeon and observation noted by same surgeon throughout the study.

. Anesthesia: all patients were operated in local peribulbar block except younger children. Which consist of 2% lignocaine with adrenaline in 1: 100,000 with bupivacaine 0.5%.

Preparation of donor cornea:

Donor corneas were obtained from the corneoscleral button preserved in McCarey Kaufman culture medium or from the eyeball preserved in moist chamber. Evaluation of the donor cornea was done under microscope. After assuring the quality of donor cornea, it was trephined with the endothelial side facing up using a sharp disposable trephine kept perpendicular to the donor cornea. The donor tissue trephine was oversized by 0.5mm than the host trephine.

Preparation of the recipient bed:

Involved area was measured using a caliper. A trephine that is at least 1mm larger than the size of the lesion was used to increase the chance of a stable and non infected recipient bed. A guarded entry into the anterior chamber was done using lance tip blade followed by excision of diseased cornea using corneoscleral extension

scissors. Injection of viscoelastics agent beneath the peripheral rim of host cornea done to release any peripheral synechiae and to protect the peripheral corneal endothelium.

Placement of the donor corneal tissue in the host bed:

The tissue so obtained was gently grasped with fine-toothed forceps at the junction of the epithelium and stroma and transferred on to the recipient bed, where it rested on viscoelastic material.

Placement of four interrupted radial 10-0 nylon cardinal sutures:

The first 10-0 nylon interrupted suture was placed in the 12 o'clock position. The donor cornea was grasped with fine-toothed, double-pronged forceps at the epithelial-stromal junction, and the suture was passed directly under the forceps teeth, through the donor and aligned host tissue. Suture depth was approximately 90% to prevent wound gape. The suture was tied snugly using an initial triple loop followed by two additional single loops. Additional viscoelastic was placed in the anterior chamber as needed to help maintain proper graft orientation and anterior chamber depth.

The second suture was placed 180° away at 6 o'clock. Equal amount of tissue distribution on either side was ensured. The 3 o'clock suture was placed and tied, followed by the 9 o'clock suture. After the sutures were tied, the anterior chamber was re-formed and tissue alignment checked once again.

Results

Table 1: Age and gender wise distribution:

Parameter	Result
Age range	12-65yrs
Mean age	47 ±12 yrs
Male	68.75%
Female	31.25%

Complete suturing:

12 additional radial interrupted 10-0 nylon sutures were placed snugly to ensure adequate tissue apposition, but not tightly. The anterior chamber was reformed with balanced salt solution or air as needed. The knots were buried on either the donor side or the host side, facilitated by a quick flicking motion and a tightly formed chamber.

Postoperative management:

Systemic:

- Systemic (oral or intravenous) antibiotics for 7 days and continue if required
- Oral Acetazolamide 250mg BD or TDS.
- Oral Ranitidine 150mg BD
- Oral Diclofenac 50mg BD
- Oral Multivitamin tablets BD

Locally:

- Moxifloxacin 0.5% eye drop 2hrly for 48 hrs followed by QID.
- Atropine 1% eye drop TDS.
- Lubricant eye drops six times per day.
- Chloramphenicol ointment was given at bed time.
- Weak steroid eye drops were given
- Cyclosporine eye drops were started post operatively as needed.

Statistical Methods: This is a hospital based prospective comparative clinical trial study of 32 patients, assigned to undergo penetrating keratoplasty.

Statistical software: The Statistical software namely SPSS 22.00 and 8.0, epienpho 7.1 were used for the analysis of the data and Microsoft word and Excel have been used to generate graphs, tables etc

Average age group in our study was 47 (± 12 years). More number of males was affected than females in our study. Most beneficiary age group in our study was 51-60, almost 47% corneal transplant done in this group, followed by the age group 41-50 (21.87%). 9.37% in age group 11-20, 6.25%

in 21-30, 9.37% in 31-40, 6.25% in age group of 61-70. Table 2 showed us that the gender distribution of in our study. 68.75% patients were male as compared to the female which were only 31.25%. male female ratio was 2.2:1 this.

Table 2: Indications for Keratoplasty

DIAGNOSIS	Result
Adherent Leucoma	6.25%
Corneal Dystrophy	9.37%
Corneal Degeneration	3.12%
Corneal Scar	43.75%
Failed Graft	12.5%
Keratoconus	3.33%
Pseudophakic Bullous Keratopathy	23%
Aphakic Bullous Keratopathy	

Amongst them the corneal scar was found the most common indication for keratoplasty in our study there were total 14 patients (43.75%), out of these this 14 patients, 7 (50%) patients had corneal scar due to the trauma. 7 (50%) patients had corneal scar due to the keratitis. Followed by

pseudophakic bullous keratopathy accounting 5 (16.67%), re-grafting 4 (12.5%), and corneal dystrophies 3 (9.37%), aphakic bullous keratopathy a Adherent leucoma 2(6.25%), keratoconus and corneal degeneration each 1 (3.12%)

Table 3: Failed Graft

	Result
Graft Failure	15.63%
Allograft Graft Rejection	9.37%
Graft Infection	3.12%

There were total 9 (28.13%) failed graft. Primary graft failure occurred in 5(15.63%). Allograft Graft rejection noted in 3 (9.37%).

1 (3.12%) failed due to infection. Total 9 corneal transplants were failed and total failure rate was 28.12%.

Table 4: Visual Acuity

BCVA	Result at the end of the 6 months	
$\geq 6/24$	34.36%	71.87%
4/60-6/60	37.5%	
FAILED	28.13%	

We divide the patients into three groups. **Group 1** who got the vision $\geq 6/24$ **Group 2** vision between 4/60 -6/60 and **Group 3** who failed to improve vision. In our study 11 (34.36%) cases were in **group 1** the best corrected vision $\geq 6/24$ at the end of 6 months, in **group 2**, there were 12(37.5%) cases who got vision between 4/60-6/50, in **group 3**, there were 9(28.13%) cases who failed to get vision. Overall survival rate is 71.87% results were comparable with other studies.

Correlations between the pre-operative recipients associated risk factors and outcome

Most common risk factor we found was the corneal vascularization. Total 9 patients were having the corneal vascularization approaching more than 2 mm of cornea from limbus. Out of this 9 (28.12%) patients, 5 (55%) corneal graft were failed at the end of the 6 month which was statistically significant finding in our study ($P=0.025$).

Correlation between enucleation-transplant time and effect on corneal graft survival

In group 1(<24 hrs) we were able to transplant 14 eyes (43.75%) out of which 11(78.57%) survived, in group 2 (24-48hrs) out of 14 (43.75%) 9 (64.28%) survived, in 3rd group (48-72hrs) out of 4 (12.5%) 3 (75%) survived. Eyes with more than 72 hours were not used for the optical keratoplasty. This comparison was not statistically significant ($P > 0.05$).

Correlation of enucleation-transplant time and quality of vision

We divided all patients into three groups; patient who got the vision $\geq 6/24$, between 4/60 – 6/60 and those failed to get vision or failed graft. 11 (34.37%) patients got vision $\geq 6/24$ out of this 6(54.54%) patients were from the **group 1** (<24 hrs), as compare to the 5 (45.45%) who got vision $\geq 6/24$ were from **group 2** (24-48 hrs) and 0% from

group 3 (48-72 hrs) it clearly showed that quality vision is better in group 1.

Donor cornea quality and the outcome

There were 2 groups according to the endothelial cell count of the donor graft. '1+' in which cell count were between 1500-2000 cell/mm², total 14 (43%) cornea were used and '2+' in which cell count were more than >2000 cell/mm²,¹⁸ (56.25%) cornea were used, in our study cell count below 1500 cell/mm² were not used.

Graft clarity was better 83.33% in group 2 good qualities (2+) of corneas as compared group 1 fair quality (1+) cornea 57.14%.

Graft size versus graft survival

. Graft sizes used in our study were small (7-7.5 mm) 14 (43.75%) with graft clarity 78.57% and failure in 23.1%. Medium size (8 mm) 12 (37.5%) had survival rate of 75% and failed 25%. Large size (≥ 8.5 mm) 6 (18.75%), 50% were survived and 50% were failed at the end of 6 month. We did not find statistically significant difference ($P=408$). Though the failure rate was higher in large sized corneal graft as compared to small and medium sized graft.

Correlation between donors age and graft survival

. We had divided the donor in 4 groups according to their age (age group range 37-63 average ages 54.33 year). they were 31-40 years, 41-50 years, 50-60 years and >60 years, maximum numbers of donated corneal tissue were obtained from age group 51-60 years, total 20 (62.5%) corneas. In first group survival rate was 100%, in second group it was 80%, in third group it was 75% and in last group it was 25%. This difference was statistically not significant ($p=0.385$), but failure rate was more in the in donor age > 50 is (88.89%).

In our study we found that as the donor age increased the failure rate also increased along with it. Donor age had the indirect effect on the graft survival or failure.

Intra operative complications

Most common intra-operative complication in our study was suture related difficulties 28.12%. Which includes while placing 4 cardinal suture, irregular suturing, loose suturing, and difficulties during burying sutures. Vitreous loss is 2nd most common complication we faced in 3 (9.37%) surgeries. 2 patients during the removal anterior chamber IOL and in an aphakic patient. Anterior vitrectomy was done in all such cases before placing the graft. Donor graft related complication occurred in 2(6.5%) cases these were irregular size during the trephination of the graft and graft was cut through in one case. Difficulties during anterior chamber formation occurred in 1(3.12%).

Summary and Conclusion

Corneal transplantation for optical purpose was performed on 32 eyes of 32 patients diagnosed as the corneal opacity.

- 68.75% were male and 31.25% were female male to female ratio was 2.2:1
- Mean age was 47 ±12 years and ranges from 12-65 years of age.
- Most common indication for penetrating keratoplasty was corneal scar (43.75%) secondary to keratitis and trauma, followed by pseudophakic bullous keratopathy (16.67%), regrafting (12.5%), corneal dystrophies (9.37%), ABK and Adherent leucoma (6.25%) and keratoconus, corneal degenerations (3.12%).
- Most common preoperative associated risk factor for graft failure was preoperative vascularised recipient cornea (28.12%) and patients with previous corneal graft failure (10%) others were Anterior chamber IOL, Aphakia and Anterior synechiae.
- Re-grafting and recipient vascularised cornea were most influencing preoperative associated risk factors for

graft failure with total failure rate was 75% and 55.56% respectively.

- Cornea used within 24 hours of enucleation had better survival rate 78.57% and better visual prognosis.
- Good quality corneal graft (2+) had better survival rate (83.33%) and better visual prognosis (81.8%) as compared to the fair quality (1+) which was (57.14%) and (18%) respectively.
- Small graft size had better survival rate (78.57%) over large graft size (50%).
- Young donor patients < 50 year of age corneal graft had better survival prognosis 87%.
- Most common intra-operative complication was suture related difficulties (28.12%). Other was vitreous loss 9.37%, donor graft related complications in 6.35% cases and difficulties to form anterior chamber noted in 3.12%.
- Anterior synchiaolysis (12.5%) was most common procedure done during penetrating keratoplasty followed by removal of anterior chamber IOL and anterior vitrectomy in 9.37% and triple procedure in 3.12%
- Postoperative corneal graft oedema was most common complication noted postoperatively in our study (57%) followed by suture related complications (25%).others were graft failure (15.63%),shallow or irregular anterior chamber (12.5%), allograft rejection and postoperative uveitis (9%), raised IOT and epithelial defects (6.25%) and postoperative wound leak, posterior capsular opacification, cataract in (3.12%).
- Post operative irregular or shallow anterior chamber (75%), uveitis (66.67%) and corneal graft oedema (39%) were

found to be most influencing complications for corneal graft failure.

- Wound leak and postoperative graft infection had 100% failure but these cases were to less to correlate with graft failure.
- Total 34.36% of patients gained vision \geq 6/24. 37.5% patients gained vision between 4/60-6/60. Total cornea graft survival (optically clear) rate was 71.87%.
- Total corneal graft failure (optically opaque cornea) rate was 28.13%.
- Causes of graft failure were graft failure 15.63%, allograft rejection 9.9.37% and graft infection 3.12%.

Conclusion

- Outcomes in our study are comparable to similar studies.
- Penetrating keratoplasty gives satisfactory visual outcome in our tertiary care institute.
- Pre-operative evaluation of donor corneas & recipient eyes is important.
- A meticulous post operative follow up is recommended.
- There is need for increased awareness regarding eye donation.

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