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A study to assess the outcome of optical penetrating keratoplasty in a tertiary health care centre in north India

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Abstract

Blindness is one of the major problems in the world and more so in developing countries which opacity results in significant morbidity both in terms of loss of vision and socio-economic reasons corneal blindness is one of the major causes of visual deficiency. The solution to this problem is keratoplasty. The main purpose of this study is to analyze the indications, visual outcome, postoperative complications, and follow-up of corneal transplants done for optical purposes. 20 patients posted for optical penetrating keratoplasty in the Department of Ophthalmology, Guru Gobind Singh Medical College & Hospital, Faridkot were taken for the study. In our study, the final vision at the end of six months was more than 6/60 in 1 case, in the range of 4/60 to 6/60 in 7 cases. So, overall, 40% of patients achieved the vision of 4/60 or more. Vision is 3/60 or less in 12 (60%) cases. Complications like a recurrence of host disease occurred in 2 cases (10%), aphakic retinal detachment in one case, 6 (30%) cases developed postoperative glaucoma, 7 cases (35%) had epithelial defects, allograft rejection in 3 cases (15%), endophthalmitis in one case, graft infection in 2 (10%) cases. The results of this study show that penetrating keratoplasty helps patients regain vision which makes them able to move independently.

Keywords: Blindness, visual deficiency, visual outcome, cataracts and corneal diseases

Introduction

Cataracts and corneal diseases are the two most common causes of blindness in countries with less-developed economies [1]. In India, Corneal opacities have emerged as the second leading cause of blindness. It has been reported that nearly 90% of the global cases of ocular trauma and corneal ulceration leading to corneal blindness occur in developing countries like ours [2]. The prevalence of blindness in India has come down by around 47 percent since 2007, according to the National Blindness and Visually Impaired Survey (2019), indicating that the country is close to achieving the WHO's goal of reducing it to 0.3 percent of the total population by 2020. The prevalence of blindness in all age groups was 0.36%. The prevalence of blindness in the population aged ≥ 50 years was 1.99%. Major Causes of Blindness in the population aged 0-49 years was corneal opacity contributing 37.5% [3].

International Classification of Diseases 11 (2018) classifies Vision impairment into two groups [4].

1. Distance vision impairment

1. Mild – presenting visual acuity worse than 6/12,
2. Moderate – presenting visual acuity worse than 6/18,
3. Severe – presenting visual acuity worse than 6/60,
4. Blindness – presenting visual acuity worse than 3/60

Near vision impairment

Presenting near visual acuity worse than N6 or M.08 with existing correction. The current definition of blindness adopted under the National Program for control of blindness (NPCB) is presenting distance Visual acuity less than 20/200 in the better eye. A limitation of the field of vision to under 20° from the central point of fixation in the better eye is also considered blindness [5]. Corneal blindness is one of the major causes of reversible blindness, which can be managed with the transplantation of a healthy donor cornea. Penetrating keratoplasty is defined as the full-thickness replacement of host corneal tissue with full-thickness donor corneal tissue.

Keratoplasty can be done for various purposes and is classified as optical, therapeutic, tectonic, and cosmetic. Common indications of penetrating keratoplasty in different regions of the world are Pseudophakic Bullous Keratopathy, Fuch's dystrophy, Keratoconus, Corneal scars, Ulcerative keratitis, failed graft, and in children are Congenital corneal opacities [6-7].

Complications of penetrating keratoplasty are Wound leak, Persistent epithelial defect, Postoperative inflammation, Suture related infiltrates, Suture induced vascularization, Raised intraocular pressure, Pupillary block, Anterior synechiae formation, Choroidal detachment /hemorrhage, Primary graft failure, Post PK astigmatism, Post PK glaucoma- Graft infection, Graft rejection, graft failure [8]. In this study we have evaluated various indications, visual outcomes, and complications related to keratoplasty

Aims and Objective

- To study the visual outcome of optical penetrating keratoplasty.
- To study the post-operative complications of optical penetrating keratoplasty.

Materials and Methods

Study was conducted in the Department of Ophthalmology, Guru Gobind Singh Medical College & Hospital, Faridkot in 20 eyes of 20 patients. Donor grafts were taken from eyes that had been enucleated within six hours of the death of the deceased after proper consent from the relatives and preserved under MK Media.

Donor Selection Criteria [9]

All eyes retrieved within six hours of death and after clinical assessment of donor's corneal endothelium were graded based on donor corneal clarity into

- **Grade A:** Donor cornea with healthy epithelium and no stromal edema and corneal thickness of nearly adult corneal thickness.
- **Grade B+:** Healthy epithelium, stromal edema less than one-third of the total cornea and corneal thickness 10 to 25% above normal adult corneal thickness.
- **Grade B:** Normal epithelium or sloughed epithelium, stromal edema one-third to one-half of a related cornea, and corneal thickness 25 to 33% above normal adult corneal thickness.
- **Grade B:** Sloughed epithelium, stromal edema one-third to one half of cornea, and corneal thickness 33% to 50% above normal adult corneal thickness.
- **Grade C:** Sloughed epithelium, stromal edema from one-half to a two-third, and corneal thickness more than 50% above normal adult corneal thickness.
- **Grade D:** Sloughed epithelium, stromal edema more than two-thirds of the cornea, and corneal thickness more than 50% above normal adult corneal thickness.

Corneas of Grade A and B+ were used for optical purposes.

Donor Exclusion Criteria Death from an unknown cause, CNS diseases, such as Creutzfeldt-Jakob disease, subacute sclerosing panencephalitis, Rubella, Reye's syndrome, rabies, and infectious encephalitis, Infections such as HIV, hepatitis, septicemia, syphilis, and endocarditis, Eye

diseases such as Retinoblastoma, Malignant tumor of the anterior segment, and Active ocular inflammation, Prior ocular surgery (Exception: pseudophakic eyes were used), Congenital or acquired anterior segment abnormalities such as keratoconus and Fuchs' endothelial dystrophy [10].

Recipient Inclusion Criteria

All patients with unilateral or bilateral healed corneal opacity were eligible for corneal transplant, except those mentioned in the exclusion criteria.

Recipient Exclusion Criteria

Stevens-Johnson syndrome, Ocular mucous membrane pemphigoid, Severe dry eye, Chemical burns, Pediatric cases, Therapeutic, tectonic, lamellar grafts, Cases with no perception of light, Active ocular and periocular infection, Systemic diseases like Diabetes mellitus and Hypertension.

Preoperative preparation of recipient: An informed consent of all patients was taken and patients who signed consent were evaluated preoperatively for keratoplasty. Preoperative visual assessment, slit-lamp examination, and B scan of patients were done, intraocular pressure was recorded and hyper-osmotic agents were given to the patients to lower the intraocular pressure if not otherwise contraindicated.

Surgical Technique: Surgery was performed under local anesthesia. Full-thickness donor corneal tissue was used for transplantation. With the help of corneal trephine, excision of the recipient and the donor corneal button was done. Circular trephine blades ranging from 7.5 mm to 8.5 mm in diameter were used to punch the donor lenticule. The host graft disparity was kept at 0.5 mm with the donor graft being larger than the host, the donor lenticule was placed over the recipient bed with 16 interrupted 10-0 monofilament nylon sutures.

Postoperative care: The patient received an eye drop of 0.5% moxifloxacin and an eye drop of 1% prednisolone four times a day depending upon the response. Cycloplegics and preservative-free artificial tears were given depending on the patient's condition on follow-up and subsequently tapered over six months. Immunosuppressants i.e. oral prednisolone were given in all cases after ruling out contraindications, Anti-glaucoma drugs were also given in cases where raised IOP (glaucoma) was present.

Follow up: Patients were followed up on day 1, day 7, after 15 days, after one month, after 3 months, and after 6 months. All patients underwent a complete ophthalmological examination on follow-up visits. Data so collected was analyzed statistically

Observations and Results

Demographic data: Patients in this study belonged up to 80 years of age. One case (5%) belonged to the 20-40 years age group, 2 cases (10%) belonged to the 41-60 years age group, and 17 cases (85%) belonged to the 61-80 years age group. Out of 20 cases, 15 (75%) were males and 5 (25%) were females.

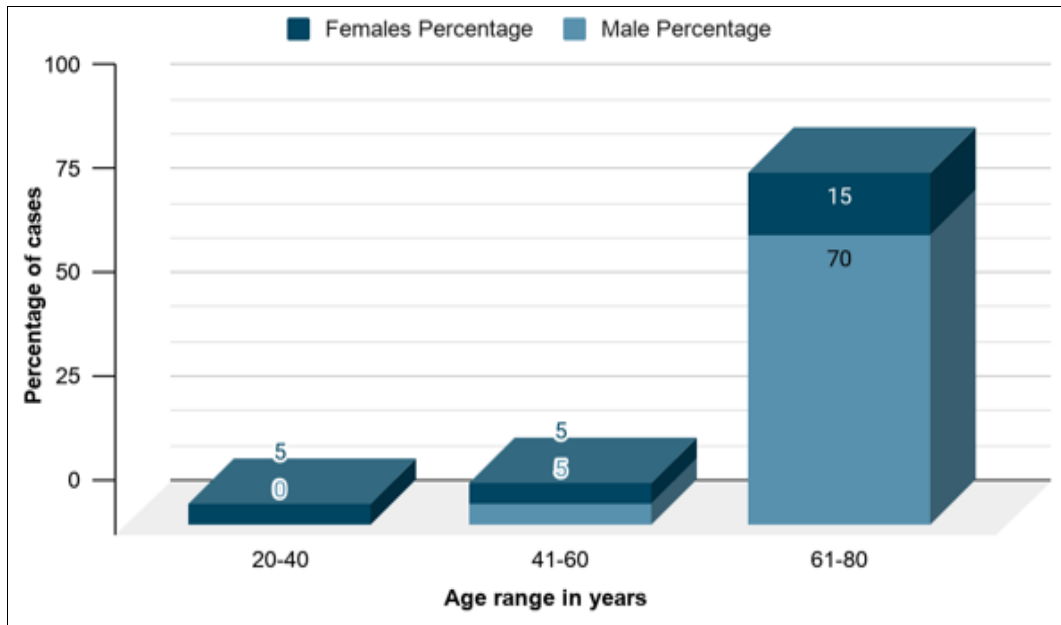


Fig 1: Demographic data

Preoperative Indications of Keratoplasty in All Cases

Figure 2 shows preoperative indications of optical penetrating keratoplasty in all cases, Out of 20 cases 6 cases (30%) had Corneal scarring due to trauma. 4 cases (20%)

were due to healed infective keratitis, 3 cases (15%) due to Corneal degeneration, 3 cases (15%) due to Graft failure, 3 cases (15%) due to Pseudophakic bullous keratopathy, and 1 case (5%) had Aphakic bullous keratopathy.

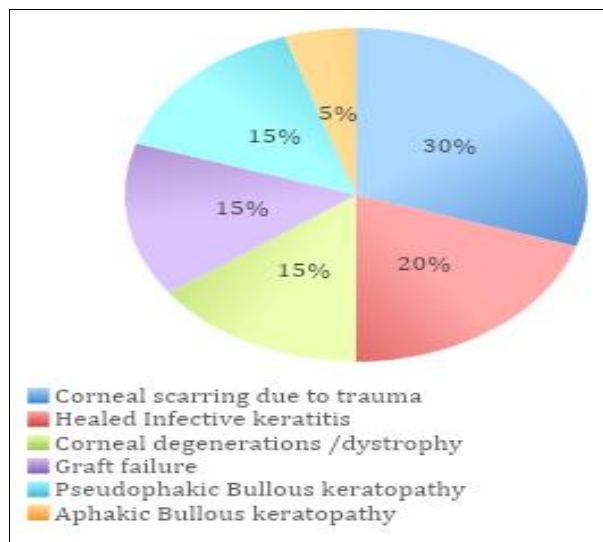


Fig 2: Preoperative Diagnosis of Corneal Pathology

Preoperative observations

Figure 3 shows Preoperative observations in all 20 cases. Anterior synechiae were present in 11 cases (55%); vascularisation was present in 13 cases (65%). In 10 cases (50%) the lens had already been removed; 4 cases (20%) were aphakic while 5 cases (25%) patients were having cataracts and in 1 case (5%) the lens was normal. Intraocular pressure was found raised preoperatively in 6 cases (30%), low in none, and normal in 14 cases (70%). Preoperative vision in the index eye was PL+PR+ in 2 cases (10%), while in 8 cases (40%) hand movements were present and in 10 cases (50%) patients it was finger counting at 1 meter, In 4 cases (20%) fellow eye was having a cataract, PL-VE in 5 cases (25%) while in 5 cases (25%) similar pathology was found and the other eye was normal in 4 cases (20%).

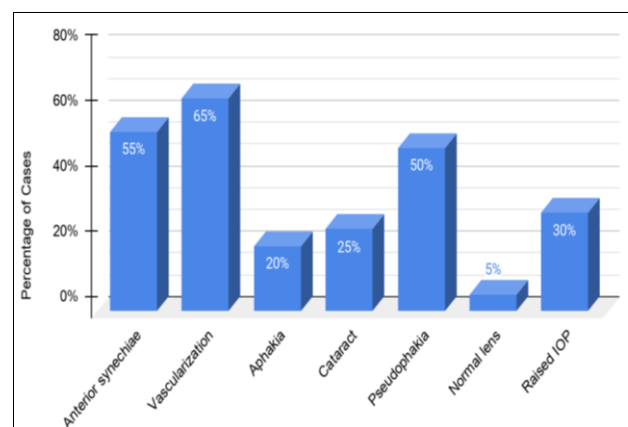


Fig 3: Preoperative Observations

Complications

Figure 4 shows various complications in the postoperative period which were Early clouding of the graft, Graft

infection, Epithelial abnormality, Postoperative glaucoma, Allograft reaction, Recurrence of host disease, Endophthalmitis and Retinal detachment.

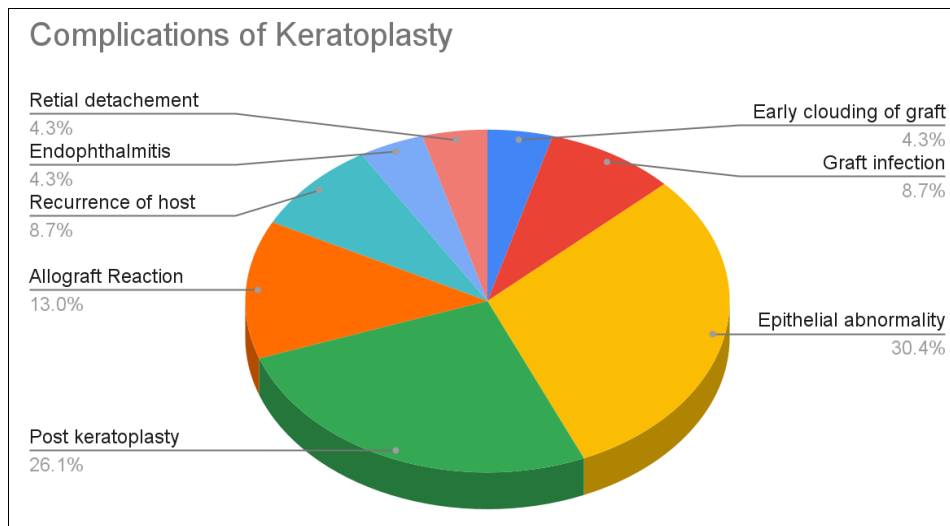


Fig 4: Complications of keratoplasty

Table 1: Visual outcome in cases with triple procedure

Total No. of cases	Type of Cataract		Postoperative
	Mature cataract	Immature cataract	Visual outcome >6/60
2	1(5%)	1(5%)	none

Table 1 shows visual outcomes in cases with the triple procedures, 2 cases out of 20 (5%) were operated for cataract extraction & intraocular lens implantation along with penetrating keratoplasty. one had a mature cataract and one had an immature cataract They did not attain the vision of >6/60.

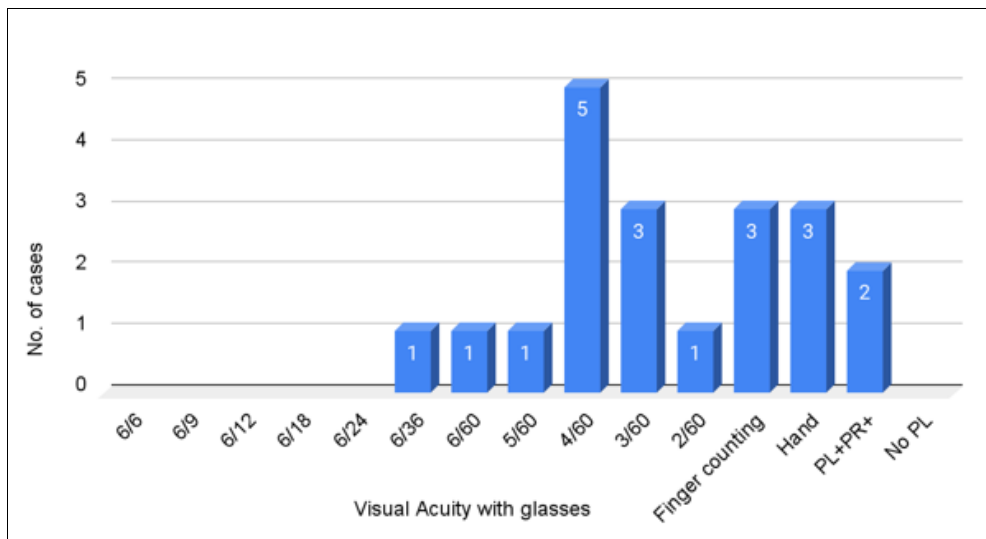


Fig 5: Postoperative visual acuity at 6 months

Figure 5 shows postoperative visual acuity at 6 months, Visual acuity of 6/36 was seen in 1 case, 6/60 in 1 case, 5/60 in 1 case, 4/60 in 5 cases, 3/60 in 3 cases, 2/60 in 1 case, counting finger at 1 m in 3 cases, Hand movements in 3 cases, PL+PR+ in 2 cases and no perception of light in none.

Final improvement in vision

Figure 6 shows the final improvement in vision, which shows that the final vision at 6 months of follow-up was >6/60 in one, 7 cases (35.00%) had vision between 6/60-4/60. 12 cases (60.00%) had a vision of 3/60 or less. While none of the cases had nil vision, the end of follow up.

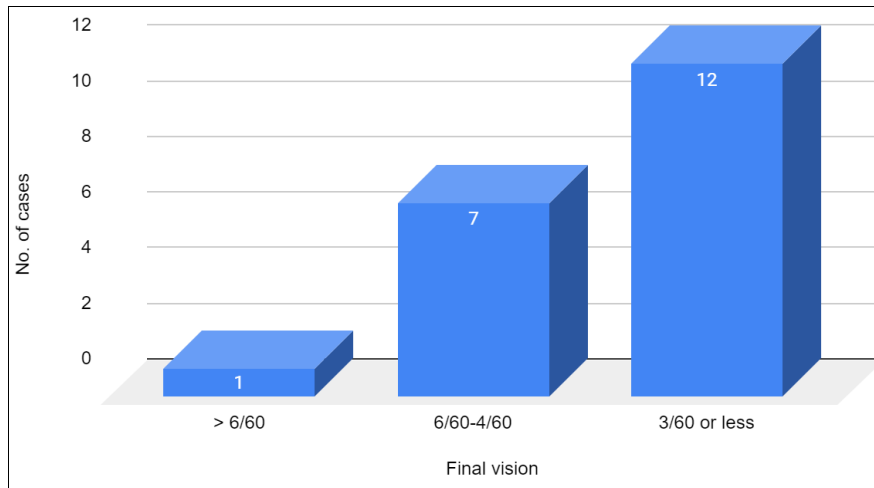


Fig 6: Final Improvement in Vision

Discussion

Corneal blindness is the second leading cause of blindness in India in population aged ≥ 50 years contributing 8.2% of cases and the most common cause of blindness in the population aged 0-49 years contributing 37.5% of cases, according to the National Blindness and Visually Impaired Survey (2019), the prevalence of blindness in all age groups was 0.36% [3]. Corneal transplant is the only available treatment in most government setups to visually rehabilitate the patient with corneal opacity. The present study on visual outcome after penetrating keratoplasty consisted of 20 postoperative cases from the department of ophthalmology of G.G.S. Medical College, Faridkot. In our study, the age of the patients ranged from 40-80 years. 15 (75.00%) patients were males and 05 (25.00%) patients were females. Donor material used was cadaver eyes stored in MK Media and all eyes were used within 24 hours. All patients were followed for six months. Visual outcomes and complications were noted and analyzed which have been discussed below.

Indications for penetrating keratoplasty: In this study, the most common indication for penetrating keratoplasty was found to be corneal scarring due to trauma 6 (30%) cases followed by healed infective keratitis 4 (20%) cases, corneal degeneration /dystrophy 3 (15%) cases, graft failure 3 (15%) cases, pseudophakic bullous keratopathy 3 (15%) cases, aphakic bullous keratopathy 1 (5%) case. Dasar L *et al.* (2013), did a retrospective study in which 102 penetrating keratoplasties were performed in south India. The leading indications for penetrating keratoplasty were corneal scarring (60.7%), followed by re-grafting (12.7%), spheroidal degeneration (9.8%), aphakic bullous keratopathy (5.88%), pseudophakic bullous keratopathy (2.94%), acute infectious keratitis (2.94%), corneal dystrophy and keratoconus (4.9%) (11). Raj A *et al.* (2016) reviewed the medical records of 145 PK, the common indications were Bullous keratopathy both aphakic and pseudophakic (26.89%), Active infective keratitis (20.68%), Corneal scarring (33.10%), graft failure (11.72%), Anterior staphyloma (2.75%), corneal dystrophy (2.75%), Keratoconus (0.68%), Others (1.37%). (12) Common indications in this study correspond with the mentioned studies

Complications: Following major complications were seen in our patients:

Infection: This complication was present in 2 (10%) cases in our study, one had viral keratitis and the other had bacterial keratitis; both cases presented after 4-6 weeks of follow-up. In both cases visual prognosis was bad. Prabhakar S (2018) conducted an interventional prospective study in 34 patients who underwent PKP, Six (17.64%) patients developed postoperative infections [13]. The infection rate in the above-mentioned study corresponds to our study and it has been found that suture-related infections are a common cause of corneal infections in patients of keratoplasty.

Endophthalmitis: In our study endophthalmitis occurred in 1 (5%) case. Intravitreal antibiotic injections were given. The final vision did not improve. According to a study conducted by Chen JY *et al.* (2015) in (n = 11320), the overall incidence of endophthalmitis occurring after primary PK in this study was 0.67%. The incidence of endophthalmitis occurring within 6 weeks of surgery was 0.16%. [14]. The incidence does not correlate with our study because the number of patients in our study was very less and also our study is a prospective study.

Allograft Reaction: Incidence of allograft reaction increases in cases of pre-existing vascularisation, stromal keratitis, and re-grafting. In our study 3 (15%) cases developed this complication. These cases had pre-existing anterior synechiae, pre-existing vascularisation. Two of the cases had repeat grafts. Hoffmann F *et al.* (1989) evaluated records of 357 patients and found the incidence of allograft reaction as 20% [15]. Jirásková N *et al.* (1999) reviewed 100 consensual penetrating keratoplasties found the incidence of allograft rejection as 23%. [16] Out of 7 cases of allograft rejection only 1 (14.28%) case responded to treatment with corticosteroids and showed final improvement in visual acuity.

Epithelial abnormalities: In our study 7 cases (35%) had epithelial defects which correspond to the done by Chou L *et al.* (1994) who prospectively studied 84 consecutive patients undergoing penetrating keratoplasty over a 6-month interval to identify risk factors for postoperative epithelial defects. 31% (26 of 84) of the patients had epithelial defects on the first postoperative day [17] Kim T *et al.* (1996) reviewed the records of 39 patients undergoing 40 consecutive penetrating keratoplasties to identify donor factors that might correlate with the presence of an epithelial

defect on the first postoperative day in which 18 (45%) cases out of 40 had epithelial defects^[18]. In a study done by Raj A *et al.* (2018) out of 91 eyes studied 33 (36.26%) had epithelial defects involving >1/2 of the graft at first POD.^[12] In our study Out of a total of 7 cases of epithelial defects, 3 cases (42.85%) had final improvement in vision. The incidence in our study correlates with the above-mentioned studies.

Glaucoma: In our study, 6 (30.00%) cases developed postoperative glaucoma. Out of 6 cases, 3 (50.00%) cases had a pre-existing rise in IOP, 3 (50.00%) cases had anterior synechiae and 4 (66.66%) cases had pre-existing vascularisation. Foulks GN *et al.* (1987) found that out of 502 penetrating keratoplasty cases performed, the occurrence of chronic postoperative glaucoma was 18%.^[19] França ET *et al.* (2002) did a retrospective study in 228 patients who underwent penetrating keratoplasty and 49 (21.5%) developed glaucoma.^[20] Yildirim N *et al.* (2011), reported the incidence and risk factors for post keratoplasty glaucoma (PKG) in 122 eyes, The rate of PKG development was 34% within 39 months of follow-up. PABK, corneal perforations, keratitis, and previous high intraocular pressure were high-risk factors for PKG^[21]. The high incidence of glaucoma is due to preoperative raised tension, vascularisation, and the presence of anterior synechiae. Patients were treated with topical antiglaucoma drugs and oral acetazolamide. Final visual improvement occurred in 3 (50%) out of the total 6 cases of glaucoma. The incidence in our study correlates with the above-mentioned studies.

Retinal Detachment: One case had post penetrating keratoplasty Aphakic Retinal detachment. Forstot SL *et al.* (1975) studied 610 penetrating keratoplasties, 5.4% incidence of retinal detachment occurred after keratoplasty that involved vitrectomy. The resultant detachments had a poor prognosis probably because of delayed diagnosis and difficulties in visualization. Vitreous manipulation, therefore, may be essential to graft clarity but it is hazardous.^[22] In our study one case developed postoperative aphakic retinal detachment, this patient had anterior chamber intraocular lens preoperatively and the indication for keratoplasty was Pseudophakic bullous keratopathy, the lens was removed intraoperatively and vitreous prolapse had occurred and the patient was kept Aphakic, postoperative Retinal detachment had occurred on the 90th postoperative day and the final vision did not improve.

Recurrence of host disease: In our study recurrence of host disease occurred in 2 cases (10%) both cases had herpes simplex keratitis in donor graft both were given oral and topical antiviral drugs, final vision improved in one case, in other case vision did not improve due to presence of cataract. Strek *et al.* (1995) retrospectively studied 49 consecutive penetrating keratoplasties for herpes simplex keratitis. Recurrence of HSV infection occurred in 18 (39%) eyes at an average of 12.6 months after surgery (range 0.3–46)^[23]. In a retrospective study conducted by Gong *et al.* (2019) on patients with recurrent fungal keratitis after initial lamellar keratoplasty (LK) or penetrating keratoplasty (PK) for fungal keratitis, Fungal keratitis recurred in 112 of 1448 patients (7.7%) treated initially with PK or LK (24). In our study 2 cases had developed recurrence of host disease in one on 27th postoperative day and the other on 25th

postoperative day in both cases oral and topical steroids were withheld for some time until complete recovery occurred.

Postoperative visual acuity at 6 months and Final Visual Improvement: In our study, Visual acuity of 6/36 was seen in 1 case, 6/60 in 1 case, 5/60 in 1 case, 4/60 in 5 cases, 3/60 in 3 cases, 2/60 in 1 case, counting finger at 1 m in 3 cases, Hand movements in 3 cases, PL+PR+ in 2 cases and no perception of light in none. The final vision at the end of six months with a pinhole was more than 6/60 in 1 (5.00%) cases, in the range of 4/60 to 6/60 in 7 (35.00%) cases. So, overall, 40% of patients achieved the vision of 4/60 or more. Vision is 3/60 or less in 12 (60%) cases. The negative perception of light was none. In a study on penetrating keratoplasty after ocular trauma, Doren GS *et al.* (1990) studied 41 patients who underwent penetrating keratoplasty for a corneal opacity caused by trauma, of the 39 patients who were on follow up for one year, 20 (51%) patients achieved visual acuity of 6/60 or more^[25]. Another study done by Rao SK *et al.* (1999) was a retrospective review of the case records of 38 patients who underwent bilateral PK and had at least 6 months of follow-up after corneal transplantation in the second eye. He concluded that 50% of patients had visual acuity of >6/60^[26]. Insler MS *et al.* (1986) found that, out of 11 cases of multiple grafts, only 1 (9.09%) case had visual acuity of 6/30.^[27] Vanathi M *et al.* (2005) did a retrospective study to analyze the indications and outcome of repeat penetrating keratoplasty in a tertiary care center in India. Three (18.6%) of the 16 eyes with multiple corneal re-grafts achieved a BCVA of 6/60. Overall, only five eyes (all with a single re-graft) achieved a BCVA of 6/18 or better at the end of follow-up^[28]. Patients with re-grafting have poor visual outcomes due to increased risk of allograft rejection and increased incidence of secondary glaucoma. In our study, 3 patients were of re-grafting, out of which only 1 case (33.33%) case had achieved visual acuity of 4/60 and 1 case (33.33%) had visual acuity of HM, and one case had visual acuity of PLPR. Decreased visual outcome in our study is because 6 patients had cataracts 3 had graft reactions one had retinal detachment and one had endophthalmitis.

Visual outcome in patients with the triple procedure

In our study, out of patients who underwent the triple procedure, none of the cases had achieved a final visual outcome of 6/6. One patient had 4/60 vision and the other had 3/60. Studies done by Lindstrom RL *et al.* (1981) and Hunkeler JD *et al.* (1983) found that final visual acuity in cases of triple procedure was 6/15 in 61% cases and 6/12 in 89% cases^[29-30]. In our study, the final Snellen's visual acuity was 6/36 in one case, 6/60 in one case.

Following conclusions have been drawn from the study

After assessing the demographic profile of patients undergoing penetrating keratoplasty, it was found that most of the patients were males and were involved in active work like agriculture, construction, and industrial work. Most of the patients came from rural areas. The age and sex of the patients did not affect the final visual outcome, The presence of preoperative vascularised corneas, preoperative high intraocular pressure, presence of anterior synechiae, patients with re-grafts have poor graft survival rates, Patients with re-graft for the second time are even more prone to graft rejection than first-time re-graft cases. Intraoperative

complications like iris prolapse and Hyphema were uncommon in our study because of better instrumentation, Postoperative complication like wound dehiscence was also not present in our study because of better operative techniques. As most of the cases had preoperative vascularised corneas, results were not that good and thus resulted in around 15.00% cases of allograft reaction, As patients came from rural backgrounds with less hygienic conditions complications like graft infection and endophthalmitis also occurred in our study, Most of the patients in our study were old, from rural backgrounds, and in very poor states of the cornea with dense cataracts so visual outcome was not good in most of our cases.

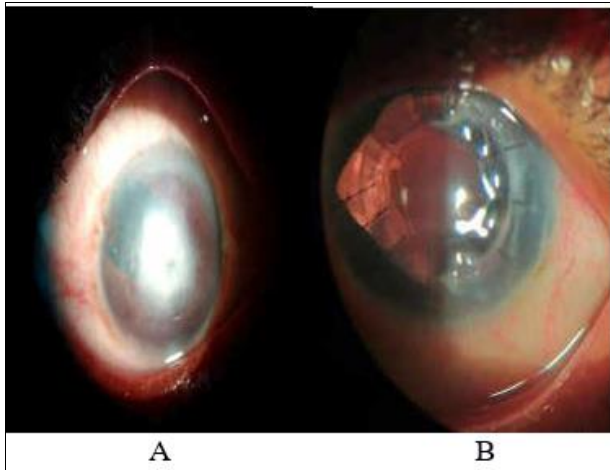


Fig 7: (A) Healed infectious keratitis (B) Postop picture of a patient with clear graft

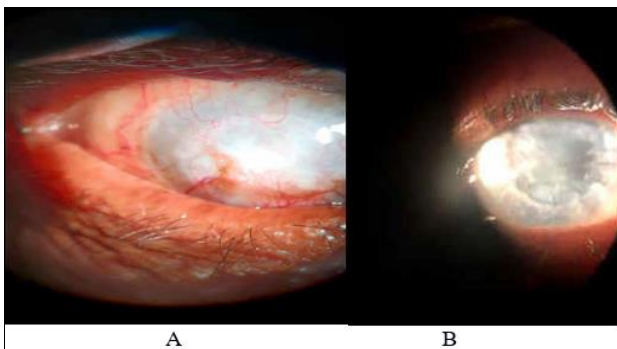


Fig 8: (A) Corneal opacity due to graft failure (B) Allograft Reaction

Conclusion

In our study visual outcome of more than 3/60 was present in 40% of cases. This can improve further if the complication rate decreases. But as in our study, it was not possible as most cases in our study were old and associated with many perioperative complications (like vascularisation, anterior synechiae, raised intraocular pressure) and delayed medical consultation, also most of these cases belonged to the rural background, poor socio-economic strata and with both eyes blind. Patients were counseled regarding realistic expectations from keratoplasty surgery. Patients were told that strong glasses, a contact lens, or further refractive surgery may be necessary, and, in some cases, stable vision will not occur for many months, often close to a year after corneal transplant surgery. Due to lack of awareness about transplant surgery patients often come very late with many complications and with dense cataracts and also patients from rural background lives in less hygienic conditions and

are often noncompliant these all factors also affect the outcome of the procedure so these can be decreased by spreading more and more awareness about the corneal transplantation, especially in rural setups so that the patients come in the right time and better surgical results may be obtained.

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