STUDY OF THE ANATOMICAL AND VISUAL RESULTS OF THERAPEUTIC PENETRATING KERATOPLASTY

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ABSTRACT

BACKGROUND

Therapeutic penetrating keratoplasty for corneal infections restores anatomical integrity. Improvement in instrumentation and surgical techniques, better postoperative management have improved corneal transplant outcome. Purpose of the study was to know what are the anatomical and visual results after therapeutic keratoplasty and to judge what could be the factors affecting the results.

MATERIALS AND METHODS

Prospective, non-comparative, observational cohort study was done in 56 patient (56 eyes) operated for therapeutic penetrating keratoplasty at tertiary care institute .Patients were reviewed for demographic data, postoperative best-corrected visual acuity, graft clarity, and complications. Pre-operative treatment in bacterial infections included Cefazolin 50 mg/ml and Tobramycin 1.4 % or gentamicin 1.4% half hourly, 1% atropine drops. Fungal infections were treated with Natamycin 5% suspension. Debridement was done. Amphotericin B was used against yeasts. Voriconazole (1%) eye drops were given in Aspergillus species. With full aseptic precautions penetrating keratoplasty was carried out. The graft was 0.5 mm larger than the lesion. Keratoplasties were evaluated for (1) Graft clarity at 1 month and 1 year postoperative. (2) Cure of the infectious disease after surgery. (3) Anatomical success rate and visual results.

RESULTS

At the end of one year clear graft with bacterial keratitis was seen in 23 eyes (74.19%) out of 31 eyes. In fungal keratitis clear graft was seen in 10 eyes (45.45%) out of 22 eyes. 48.22% patients had vision of FC 1m-6/60 compared to preoperative vision at the end of one year. At the end of one year anatomical integrity was maintained in 53 (94.64%) cases and it was lost in 5.36% patients.

CONCLUSION

Patients who underwent keratoplasty with 7.5 mm graft size had maximum graft clarity at the end of one year. Graft was clear in 36 patients (64.29%) out of total 56 patients. At the end of 1 year vision improved to FC 1 mt - 6/60 in 48.22% patients.

KEYWORDS

Therapeutic Keratoplasty, Bacterial Infections, Fungal Keratitis, Graft Clarity, Anatomical Integrity.

HOW TO CITE THIS ARTICLE: Shinde CA, Ghorpade PS. Study of the anatomical and visual results of therapeutic penetrating keratoplasty. J. Evid. Based Med. Healthc. 2017; 4 (25), 1436-1443. DOI: 10.18410/jebmh/2017/279

BACKGROUND

Therapeutic penetrating keratoplasty for corneal infections is successful in restoring anatomic integrity in most eyes.[1-3] Ever since the first successful human full-thickness corneal transplant, or penetrating keratoplasty, by Eduard Zirm in 1906,[4] it has been regarded as one of the most frequently performed tissue transplantations in humans.[5] Improvement in instrumentation and surgical techniques, systematic and efficient tissue banking, and better postoperative management that includes anti-inflammatory and immunosuppressive drugs.[6-9] have collectively improved corneal transplant outcome.[10]

Therapeutic keratoplasty has a definitive role in the management of progressive microbial keratitis refractory to medical therapy.

Virulent and resistant forms of infectious bacteria, fungi, and Acanthamoeba spp. can cause keratitis to progress, even with maximum medical therapy.

Purpose of the study was to know what the anatomical and visual results are after therapeutic keratoplasty and to judge what could be the factors affecting the results.

Aims and Objectives

1. To determine anatomical and visual results of therapeutic penetrating keratoplasty
2. To determine the factors that affect the success or failure in therapeutic keratoplasty.

Financial or Other, Competing Interest: None.
Submission 28-02-2017, Peer Review 06-03-2017,
Acceptance 20-03-2017, Published 24-03-2017.
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DOI: 10.18410/jebmh/2017/279

MATERIALS AND METHODS

Study Design- Prospective, non comparative, observational cohort study.

Study Population- 56 patient (56 eyes) operated for therapeutic penetrating keratoplasty at our tertiary care institute between August 2013 to July 2014 and those who completed 1 year follow up were included for analysis and were reviewed for demographic data, postoperative best-corrected visual acuity, graft clarity, and complications.

Sample Size- 56 patients (56 eyes).

Inclusion Criteria

All patients between the age of 11 to 70 years who were diagnosed with infective keratitis clinically and with corneal scraping for microbial cultures and who underwent therapeutic penetrating keratoplasty.

Exclusion Criteria

- Patients with age less than 11 years and more than 70 years.
- Patients who underwent regraft.
- Patients with less than 1 year of follow-up.

The study was approved by the ethics committee for research on human subjects at the institute. Written informed valid consent was taken.

Evaluation of the Patients and Data Collection

1. **History**

- Time and mode of onset of symptoms of infection (diminution of vision, redness, pain, watering, discharge, swelling), progress and duration of disease.
- History of local trauma, viz. foreign body entering into the eye, or injury with vegetable matter.
- History of treatment taken, local and systemic with detail of the ongoing medications and their dosage, any ocular surgery, steroids, any other surgery, systemic disease.

2. **Examination-** Visual acuity on Snellen's chart.

Local Examination

Torch and slit lamp examination with diffuse and focal illumination was done. Following points were noted: Lids, conjunctiva, cornea, anterior chamber, iris, pupils, lens, intraocular tension– digital, lacrimal sac syringing, staining of the corneal ulcer with fluorescein. Direct and indirect ophthalmoscopy was done in possible cases.

Systemic Examination was done.

3. **Local Investigations**

a) Corneal scraping from the edge of ulcer (Gram's stain), culture (McConkey's and blood agar), antibiotic sensitivity, KOH mount for hyphae in the wet preparation, fungal culture was done in Sabouraud medium.

Routine systemic investigations and ENT, dental, medicine and gynaecological reference were done.

Medical Treatment of the Infective Keratitis/Corneal ulcers (Pre-operative)

a) Bacterial Infections

Fortified antibiotics (cefazolin 50 mg/ml) and (tobramycin 1.4 % or gentamicin 1.4%) half hourly, 1% atropine drops 2 to 3 times a day were given.

Capsule Amoxicillin, systemic analgesic/ anti-inflammatory treatment, oral acetazolamide were given.

b) Fungal Infections

Natamycin 5% suspension was used for filamentous fungal keratitis, every half to one hourly initially and slowly tapered to two hourly, four hourly every two days. Surface debridement was done. Amphotericin B was used against yeasts. Voriconazole (1%) eye drops were given in Aspergillus species, Fusarium species and Candida species keratitis.

Tablet Itraconazole 100 mg twice daily orally or Tablet ketoconazole 200 mg twice daily orally was added in patients refractory to medical therapy.

Acanthamoeba Ulcer

Eye drops Chlorhexidine (0.2%) were added.

Principles of Surgical Technique for Therapeutic Penetrating Keratoplasty-

- The donor tissue was brought to room temperature.
- With full aseptic precautions penetrating keratoplasty was carried out.
- The criteria of taking graft size were: The graft size was 0.5 mm larger than the lesion. The pupil was placed in center of graft and care was taken so that graft did not appear optically eccentric.
- Peripheral buttonhole iridectomy was done superiorly.
- Donor graft was secured on host bed with 16 interrupted 10-0 monofilament nylon sutures and the knots were buried.

Post-operative Management

- Tab Diclofenac was given in a dose of 50 mg twice a day for 5 days.
- Injection Cefotaxime was given 1 gm intravenous twice a day in adults and in children 500 mg intravenous twice a day for 5 days.
- Oral Acetazolamide was continued and Eye drops moxifloxacin (0.5%) were given hourly.

Systemic and local antibiotics/antifungals were continued and modified depending upon the microbiological smear and culture and antibiotic sensitivity reports.

When the smear/culture report of the corneal button showed fungal hyphae,

Tablet Ketoconazole was given systemically 200 mg twice a day for 21 days and Natamycin eye drops (5%) were instilled locally 5 times a day.

Eye drops Chlorhexidine (0.2%) were given in acanthamoeba cases.

Follow-up- After discharge, patients were followed up weekly for a month, then every 15 days for 1 month and then monthly for 1 year.

Keratoplasties were evaluated for three major criteria of success-

1. Graft clarity at 1 month and 1 year postoperative.
2. Cure of the infectious disease after surgery.
3. Anatomical success rate and visual results.

Visual acuity was assessed. Patients were examined on slit lamp daily during their stay in the ward and at each follow up visit. Graft clarity, suture status, secondary infection, anterior chamber exudates, were looked for. Intraocular pressure was checked digitally.

Anatomical success was considered if the integrity of the eye was restored and maintained in perforated or non-perforated corneas at the end of one year.

RESULTS

	Number	Percentage
Male	35	62.5
Female	21	37.5
Total	**56**	**100**

Table 1. Gender wise Distribution of Cases (n=56)

Age Group (Years)	Male		Female		Total	
	Number	Percentage	Number	Percentage	Number	Percentage
0-10	0	0.0	0	0.0	0	0.0
11-20	1	2.9	0	0.0	1	1.8
21-30	3	8.6	1	4.8	4	7.1
31-40	7	20.0	7	33.3	14	25.0
41-50	13	37.1	8	38.1	21	37.5
51-60	8	22.9	4	19.0	12	21.4
61-70	3	8.6	1	4.8	4	7.1
Total	**35**	**62.5**	**21**	**37.5**	**56**	**100**

Table 2. Age wise Distribution of Cases (n=56)

Causative Agent	Male		Female		Total	
	Number	Percentage	Number	Percentage	Number	Percentage
Staph. Aureus*	12	34.3	9	42.8	21	37.5
Pseudomonas	5	14.3	1	4.8	6	10.7
E. coli†	3	8.6	1	4.8	4	7.1
Fungal	13	37.1	9	42.8	22	39.3
Acanthamoeba	2	5.7	1	4.8	3	5.4
Total	**35**	**100**	**21**	**100**	**56**	**100**

Table 3. Causative Agents for Corneal Infection (n=56)

*Staph. Aureus: Staphylococcus aureus, †E. coli: Escherichia coli.

Vision	Number	Percentage
HMCF*	27	49
†PL, PR	29	51
Total	**56**	**100**

Table 4. Pre-operative Vision of Cases (n=56)

*HMCF- Hand movements close to face, †PLPR- Perception of light, Projection of Rays.

Groups	Indication	Male		Female		Total	
		Number	Percentage	Number	Percentage	Number	Percentage
Group 1	Refractory Corneal Ulcer with Hypopyon	16	45.7	8	38.1	24	42.9
Group 2	Perforated corneal ulcer	11	31.4	8	38.1	19	33.9
Group 3	Total corneal abscess	8	22.9	5	23.8	13	23.2
Total		**35**	**100**	**21**	**100**	**56**	**100**

Table 5. Indications for Penetrating Therapeutic keratoplasty (n=56)

Sl. No.	Complications	Male		Female		Total	
		Number	Percentage	Number	Percentage	Number	Percentage
1	Corneal graft Epithelial defect	13	37.1	9	42.9	22	39.3
2	Shallow AC*	9	25.7	6	28.6	15	26.8
3	Weak wound	2	5.7	1	4.8	3	5.4
4	Vascularisation of graft	12	34.3	5	23.8	17	30.4
5	Sec. glaucoma†	5	14.3	3	14.3	8	14.3
6	Reinfection in the graft	6	17.1	2	9.5	8	14.3
7	Complicated cataract	7	20.0	5	23.8	12	21.4
8	Graft ectasia	2	5.7	1	4.8	3	5.4
9	Phthisis bulbi	2	5.7	1	4.8	3	5.4

Table 6. Complications of Penetrating Therapeutic Keratoplasty (n=56)

*AC: Anterior chamber, †Sec. glaucoma: Secondary glaucoma.

Graft Size (mm)	Clear Graft	Hazy Graft	Opaque Graft	Total
7.5	27 (48.2%)	5 (8.9%)	1 (1.7%)	33 (58.8%)
8	3 (5.3%)	0 (0%)	4 (7.1%)	7 (12.4%)
8.5	4 (7.1)	1 (1.7%)	4 (7.1%)	9 (15.9%)
9	2 (3.5%)	3 (5.3%)	0 (0%)	5 (8.8%)
9.5	0 (0%)	1 (1.7%)	0 (0%)	1 (1.7%)
10	0 (0%)	1 (1.7%)	0 (0%)	1 (1.7%)
Total	**36 (64.3)**	**11 (19.6%)**	**9 (16.1%)**	**56 (100%)**

Table 7. Graft Size and Clarity of Graft at the end of one Year

Age Group in Years	Number of Patients	Clear Graft	Hazy Graft	Opaque Graft
11-20	1	1 (100%)	0	0
21-30	4	1 (25%)	3 (75%)	0
31-40	14	11 (78%)	2 (14%)	1 (8%)
41-50	21	15 (71%)	4 (19%)	2 (10%)
51-60	12	6 (50%)	2 (16.67%)	4 (33.33%)
61-70	4	2 (50%)	0	2 (50%)
Total	**56**	**36 (64%)**	**11 (19.5%)**	**9 (16.5%)**

Table 8. Age wise Distribution and Graft Clarity

Group of Patients	Graft Clarity				Anatomical Integrity Lost	Visual Acuity at One Year			
	Clear	Hazy	Opaque	Total	Phthisis Bulbi	No PL*	PL*,PR†	‡HMCF	§Fc 1m-6/60
Total corneal abscess	11 (85%)	1 (7.5%)	1 (7.5%)	13 (23.2%)	1	1 (7%)	0	4 (32%)	8 (61%)
Hypopyon with corneal ulcer	14 (58%)	5 (21%)	5 (21%)	24 (42.8%)	1	1 (4%)	2 (8%)	10 (43%)	11 (45%)
Corneal Perforation	11 (57%)	5 (27%)	3 (16%)	19 (34%)	1	1 (5%)	4 (21%)	6 (31.5%)	8 (42.5%)
Total	**36 (64.29%)**	**11 (19.6%)**	**9 (16.07%)**	**56**	**3 (5.36%)**	**3 (5.36%)**	**6 (10.71%)**	**20 (35.71%)**	**27 (48.22%)**

Table 9. Graft Clarity, Anatomical Integrity and Visual Outcome at the End of One Year

*PL: Perception of light, †PR: Projection of rays, ‡HMCF: Hand movements close to face, §Fc: Finger counting.

	Clear Graft		Hazy Graft		Opaque Graft	
	Number	**Percentage**	**Number**	**Percentage**	**Number**	**Percentage**
Staph. aureus*	19	33.9	0	0.0	2	3.6
Pseudomonas aeruginosa	0	0.0	4	7.1	2	3.6
E.coli†	4	7.1	0	0.0	0	0.0
Fungal	10	17.9	7	12.5	5	8.9
Acanthamoeba	3	5.4	0	0.0	0	0.0
Total	**36**	**64.3**	**11**	**19.6**	**9**	**16.1**

Table 10. Clarity of graft with respect to causative agent. (n=56)

*Staph Aureus- Staphylococcus aureus. †E. coli- Escherichia coli.

At the end of one year clear graft with bacterial keratitis was seen in 23 eyes (74.19%) out of 31 eyes.
In fungal keratitis clear graft was seen in 10 eyes (45.45%) out of 22 eyes.
Opaque graft was seen 5 eyes (22%) out of 22 eyes.
All 3 (100%) cases of Acanthaoemeba had clear graft.
Out of 21 patients infected with staphylococcus infection, 19 (90.4%) patients had clear graft.

Visual acuity	Male		Female		Total	
	Number	**Percentage**	**Number**	**Percentage**	**Number**	**Percentage**
No PL*	2	5.7	1	4.8	3	5.36
PL*, PR†	5	14.3	1	4.8	6	10.71
HM – FCCF‡	10	28.6	10	47.6	20	35.71
§Fc 1m- 6/60	18	51.4	9	42.8	27	48.22
>6/60	0	0.0	0	0.0	0	0.0
Total	**35**	**100**	**21**	**100**	**56**	**100**

Table 11. Post-operative Visual acuity (n=56)

*PL: Perception of light,
†PR: Projection of rays,
‡HM-FCCF: Hand movements to finger counting close to face.
§Fc: Finger counting.

Number of Patients (%)	Before Surgery	After surgery at the End of One Year
Vision Hand movements close to face (HMCF)/PLPR/No PL	56 (100%)	29 (51.78%)
vision FC 1 mt – 6/60	0	27 (48.22%)

Table 12. Preoperative Vision and Post Operative Vision at the end of One Year

*FC: Finger counting

After therapeutic penetrating keratoplasty 48.2% patients had vision of FC 1 mtr-6/60 compared to preoperative vision at the end of one year.

At the end of one year anatomical integrity was maintained in 53 (94.64%) cases. Out of which, 36 patients (64.3%) had clear graft, 11 patients (19.6%) had hazy graft, 9 patients (16.1%) had opaque graft. 3 patients (5.36%) had phthisis bulbi at the end of one year.

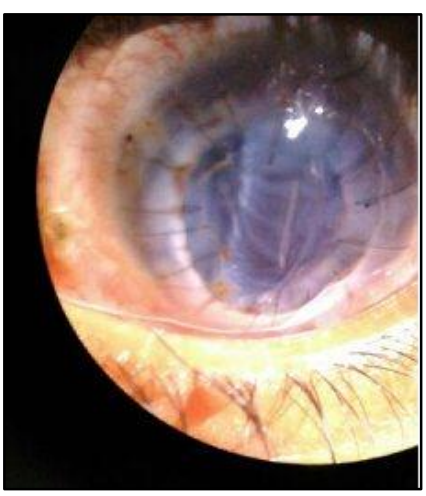

Figure 1. Hazy corneal Graft

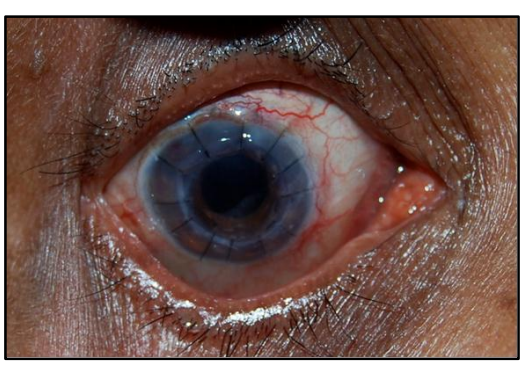

Figure 2. Clear Corneal Graft

DISCUSSION

Success of the therapeutic graft depends upon several factors.[11]

1. Age of the patient.
2. Interval between death and enucleation and the interval between the enucleation and keratoplasty.
3. Condition of recipient cornea at the time of presentation.
4. Type and Virulence of organisms.
5. Graft size.
6. Systemic immunity of the host.
7. Operative technique.
8. Postoperative complications.

1. Age of the Patient

In our study the most common age group affected was between 41-50 years (37.5%) (Table 2)

In our study 1 (100%) patient was there in the age group of 11-20 who had clear graft. (Table 8).

Patients in a young age group of 21-30 years 25% had clear graft.

Age group between 31-40 years had clear graft in 11 out of 14 (78%).

In the age group 51-60 years maximum patients had failed graft.

In 2000 Aasuri MK.[12] et al studied the analysis of 154 penetrating keratoplasties performed in 140 children, aged 14 years or younger. Grafts remained clear in 102 (66.2%) of 154 eyes. Most grafts failed because of allograft rejection (42.3%), infectious keratitis (26.9%), or secondary glaucoma (13.4%).

2. Time Interval between death and enucleation and between the enucleation and keratoplasty.

All the enucleations were done within 2 to 6 hours of death. There was no time lapse between availability of corneo-scleral donor button and keratoplasty surgery.

So in our study, postoperative failure of graft was not related to the time interval between enucleation and keratoplasty surgery.

3. Slit Lamp and Specular Microscopy Examination

Corneo-scleral donor button used for all 56 cases were of good to fair quality. All had endothelial count between 1500 to 1700 cells/mm^2. As keratoplasty was needed in the patients on an emergency basis, the available corneas were used. 64.3% of the patients had clear graft at the end of one year. So, the quality of corneo-scleral button could be the factor for poor outcome in some patients.

4. Condition of Recipient cornea at the Time of Presentation

In India, poverty and ignorance still prevail. The patients with corneal ulcers came late to the hospital to seek medical advice. By that time, the disease had already progressed and in some cases there was impending perforation, or the ulcers had already perforated. The corneal ulcers with impending perforation did not have successful outcome following surgery.

In our study, most of the cases (Group 1) presented with non-healing corneal ulcer with hypopyon (42.9%), (Group 2) perforated corneal ulcer (33.9%), and (Group 3) total corneal abscess (23.2%).

This is similar to the study done by Palaksha D et al[13] for 25 cases, the most common indication for keratoplasty in their study was non-healing corneal ulcer (56%) followed by perforated corneal ulcer (28%).

In our study patients, the group with total corneal abscess had a better prognosis with respect to graft clarity (85% cases had clear graft) and vision (61% cases had vision between FC 1 metre to 6/60) out of the three groups in the study.

5. Type and Virulence of Organism

In our study the most common cause of corneal infections was bacterial keratitis (55.36%). followed by fungal cause (39.3%). (Table 3) Acanthamoeba was present in (5.4%) patients. The most common bacterial cause was Staphylococcus aureus (37.5%) followed by Pseudomonas aeruginosa and E.Coli.

At the end of one year graft clarity was high in cases with bacterial infection which was 23 (41%) patients out of 56 (Table 10). At the end of 1 year, out of the 31 cases of bacterial infection, clear graft was seen in 23 patients (74.19) cases. Out of the bacterial infection, 21 patients infected with staphylococcus aureus, 19 patients (90.4%) had clear graft. None of the patients with pseudomonas infection had clear graft. Out of 22 cases of fungal infection, clear graft was seen in 10 patients (45.45%), all the 3 cases (100%) of acanthamoeba had clear graft.

Compared to Chen WL.[14] study in cases of bacterial keratitis they reported 68.75% clear graft as compared to our study in which 74 % of the bacterial keratitis had clear graft. In study by Chen WL.[14] at 1 year post-operative period, the grafts remained clear as follows: In 22/32 (68.75%) of grafts of bacterial keratitis, 20/39 (51%) of fungal keratitis, and 11/14 (78%) of acanthamoebic keratitis.

So in our study bacterial keratitis had a better prognosis with respect to graft clarity. 74 % cases of bacterial keratitis had a clear graft.

6. Graft Size

33 patients (58.8%) undergoing keratoplasty had graft size of 7.5 mm. (Table 7)

27 (48.2%) out of 56 patients with a 7.5 mm graft size had a clear graft.

All patients with more than 9.5 mm graft had hazy graft.

The larger the graft size, the more the chances of graft opacity, because of the increased chances of immunological graft rejection, vascularisation, peripheral anterior synechiae as well as secondary glaucoma.

Chen WL et al[14] stated that higher percentage of graft clarity at 1 year postoperatively was achieved when grafts were 8.5 mm or less compared with larger grafts.

7. Systemic Immunity of the Host

In our study, all the patients had normal systemic examination. Diabetics are more prone to wound infection. HIV positive patients, Koch's patients and those on immunosuppressants are more prone to reinfection.

8. Operative Technique

All the patients underwent full thickness penetrating keratoplasty. Donor graft was secured on host bed with 16 interrupted 10-0 monofilament nylon sutures and the knots were buried. So in our study, postoperative failure of graft was not related to operative technique.

9. Postoperative Complications

- **Epithelial Defect**.[15,16,17,18] In our study, most common early postoperative complication was epithelial defect which was present in 39.3% cases.
  Palaksha D et al[13] showed similar result, epithelial defect was present in 10 eyes (40%) of the cases.
  Thomas M et al[19] did a study on 22 eyes which showed 3.3% cases had epithelial defect.
- **Vascularisation and Rejection**
  Second most common complication was vascularisation of graft. In our study 30.4% of the patients had vascularization.
  Mittal et al[20] noted such rejection in up to 50% of the grafts with severe vascularisation.
- **Secondary Glaucoma**
  In our study, out of 56 cases, 8 eyes (14.3%) developed secondary glaucoma.
  In Arentsen's study.[21] uncontrolled glaucoma was the cause of failure in 20% of failed grafts.
- **Reinfection**
  In our study out of 56 cases, 8 (14.3%) developed re-infection in the graft. Exposed, broken, or loose sutures, epithelial defects caused due to microbial keratitis are suggestive of reinfection.
- **Cataract**
  In our present study the lens was not visible preoperatively in 32 cases. In 8 cases cataractous changes were seen intraoperatively. At the end of 1 year 12 (21.4%) cases showed cataractous changes.

The main aim of therapeutic keratoplasty in our study was to restore the anatomical integrity of eyeball. Anatomical integrity was maintained in 53 (94.64%) cases. Out of total 56 cases in our study, 36 (64.3%) cases had clear graft, 11 (19.6%) cases had hazy graft, 9 (16.1%) cases had opaque graft. 3 (5.36 %) cases had phthisis bulbi at the end of one year.

In our study, acquiring useful visual acuity was the secondary goal. In our study 27 (48.22%) cases had postoperative vision better than preoperative vision and in 20 (35.71%) cases vision remained the same. In 9 (16.07%) cases vision worsened.

At the end of one year following surgery 27 (48.22%) cases had vision FC 1m-6|60. 20 (35.71%) cases had vision hand movement close to face. 6 (10.71%) cases had vision perception of light and projection of rays. 3 (5.36%) cases had no perception of light.

CONCLUSION

Most common postoperative complication was epithelial defect in the graft seen in 39.3% patients followed by graft vascularization in 30.4% patients. Secondary glaucoma was seen in 14.3% of the patients. Clear graft was seen in 64.3% patients. Hazy graft was seen in 19.6% patients. Opaque graft was seen in 16.1% patients.

Patients who underwent keratoplasty with 7.5 mm graft size had maximum graft clarity at the end of one year. Graft clarity was less in the patients of more than 8 mm graft size.

Post-operatively, at the end of 1 year vision improved to FC 1mt - 6/60 in 48.22% patients while 35.71% patients had vision hand movements close to face. In 10.71% patients visual acuity was perception of light and projection of rays. 5.36% patients had no perception of light (Table 11).

Anatomical integrity was maintained in 94.64% patients and it was lost in 5.36% patients (Table 9)

Fungal keratitis had poor postoperative results.

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