International Journal of Research in Medical Sciences
Raina K et al. Int J Res Med Sci. 2017 May;5(5):1903-1907
www.msjonline.org
pISSN 2320-6071 | eISSN 2320-6012
DOI: http://dx.doi.org/10.18203/2320-6012.ijrms20171815

Original Research Article

Boston keratoprosthesis type 1 - indication, complication and visual outcomes

Kritika Raina*, Alka Gupta

Department of Ophthalmology, LLRM Medical College, Meerut, Uttar Pradesh, India

Received: 20 February 2017
Accepted: 24 March 2017

***Correspondence:**
Dr. Kritika Raina,
E-mail: kritikaraina1@gmail.com

ABSTRACT

Background: Diseases affecting the cornea are a major cause of blindness all over the world, second only to cataract in overall importance. In India, there are approximately 6.8 million people who have corneal blindness with vision less than 6/60 in at least one eye, and of these, about 1 million have bilateral corneal blindness.
Methods: The study was conducted in upgraded department of ophthalmology, L.L.R.M. Medical College, Meerut, India from January 2014 to June 2015. It was prospective interventional study. Included those patients who have Failed corneal graft with poor prognosis for further grafting, multiple corneal graft failure, having nearly total corneal neovascularization, vision less than 6/60 with associated other complications in better eye and no vision in opposite eye and Healed Chemical burn and those patients who has end stage glaucoma or RD (retinal detachment), defective perceptions and projection of light and not willing for the procedure.
Results: A total of 20 patients were enrolled for the study which were followed up and assessed over 12 months. It was observed that maximum number of patients were in the age group of 41-60 years (45%) and in the >60 years group are minimum (20%). Among these 14 cases (70%) were male and 6 cases (30%) were female.
Conclusions: The Boston type 1 keratoprosthesis provides visual recovery for eyes with multiple PK failures or with poor prognosis for primary PK, showing excellent retention rates. Most of the cases had a significant improvement in vision after Boston type I KPro implantation.

Keywords: Boston keratoprosthesis, Blindness, Cornea

INTRODUCTION

Diseases affecting the cornea are a major cause of blindness all over the world, second only to cataract in overall importance.[1] In India, there are approximately 6.8 million people who have corneal blindness with vision less than 6/60 in at least one eye, and of these, about 1 million have bilateral corneal blindness.[2] If the present trend continues, it is expected that the number of corneal blind individuals in India will increase to 8.4 million in 2010 and 10.6 million by 2020.[3] Standard corneal transplantation or penetrating keratoplasty (pk) is a well-established treatment for some form of corneal blindness. In some high-risk group however, the results are often poor. Thus, the need for a new strategy for patients with poor PK prognosis has resulted in the emergence of the artificial cornea or keratoprosthesis.[5,6]

The idea of replacing a severely opacified cornea with artificial material was first proposed by the French ophthalmologist Quengsy GP, and it has evolved over the last 2 centuries.[7,8]

KPros can be grouped into three basic categories based on their fixation method in the eye: 1) a collarstud device sandwiches cornea between the two skirt plates (e.g.,

Boston KPro), 2) an intracorneal device secures the skirt inside the corneal stromal layers (e.g., AlphaCor), and 3) an epicorneal device is held on the surface of the cornea and sclera (e.g., osteoodontoKPro [OOKP], Pintucci KPro). In general, these devices have a central core that is a transparent optical portion that transmits the light to the retina. Although only two prostheses, the Boston type 1 KPro (Boston KPro) and OOKP, have proven successful.

Boston keratoprosthesis type 1 is a collar button design keratoprosthesis. It consists of three components: a front plate (diameter 5.5-7.0mm) with central optical stem, a back plate and titanium locking c-ring. It is available in either a single standard pseudophakic plano power or customized aphakic powers (based on axial length) with adult (8.5 mm diameter) and pediatric (7.0 mm diameter) sized back plates. The device is currently machined from medical grade polymethylmethacrylate (PMMA) by a small, family owned and operated precision machine shop (J.G. Machine Co., Inc.) in Woburn, Massachusetts.

Recent advances in design have addition of holes (at present 16 holes) in the back plate allows diffusion of nutritive aqueous to support donor graft stroma and keratocytes.[9,10] Second, in 2004, a titanium locking c-ring was added to prevent intraocular disassembly of the device. Third, in 2007, the design was changed from a threaded (screw-type) assembly to a threadless design which simplified assembly and produced less damage to the donor endothelium.[11]

It is indicated for patients with refractory corneal blindness and poor prognosis for penetrating keratoplasty. It is usually reserved for patients with multiple graft failure and those with ocular surface disease in which conventional corneal transplantation is considered of high risk.[12] The surgery is reversible at any time.

Closely monitored, long-term follow-up is a necessity with the device. Typical regimes include a topical fourth generation fluoroquinolone with or without topical vancomycin 14mg/ml. Another postoperative management intervention is the indefinite placement of a bandage contact lens (BCL).[13] It is needed to maintain adequate ocular surface hydration and prevent stromal melt, dellen formation and necrosis and also provide comfort and protecting from possible exposed sutures. Life-long topical steroids is necessary in all KPro eyes to prevent inflammation.[10,14] Also, the addition of 5% povidone iodine washes were added in each checkup with patients having high risk of endophthalmitis as well as those with a single eye, self-immune diseases or previous endophthalmitis history.

The three most commonly reported postoperative complications are retroprosthetic membrane (RPM), elevated intraocular pressure/glaucoma and infectious endophthalmitis(IE).[15,17] Other less frequent complications include sterile vitritis, stromal melt, retinal detachment and vitreous hemorrhage. The aim of our study was Discuss various indication for Keratoprosthesis, critically analyse the complication in post-operative period and to evaluate the visual outcomes in patients of Keratoprosthesis.

METHODS

The study was conducted in upgraded department of ophthalmology, L.L.R.M. Medical College, Meerut, India from January 2014 to June 2015. It was prospective interventional study. Included those patients who have Failed corneal graft with poor prognosis for further grafting, multiple corneal graft failure, having nearly total corneal neovascularization, vision less than 6/60 with associated other complications in better eye and no vision in opposite eye and Healed Chemical burn and those patients who has end stage glaucoma or RD (retinal detachment), defective perceptions and projection of light and not willing for the procedure. Patients were selected from the OPD and waiting list of Meerut eye bank society recipient record. Preoperative work up includes detailed general and ocular history, visual acuity, Slit lamp examination of anterior segment, Fundus (if is not possible B-Scan done) and Axial length measurement to decide diopteric power of the KPro. Written informed consent was taken from every patient before undergoing surgery.

Technique: Intravenous mannitol was given half an hour before surgery to ensure a low intraocular pressure and Regional peribulbar anesthesia given. The patient‘s part was painted and draped. First of all, a corneal donor button was prepared (8.5 - 9.0 mm) and a central 3 mm hole is trephined. The central trephination performed before the outer diameter punch was used. The donor button was then placed over the stem of the front plate, and the back plate was placed on top of this complex. A titanium locking ring was then snapped into place. The recipient cornea was prepared as for traditional penetrating keratoplasty, with a usual host trephine measuring 0.5 mm less in diameter than the donor graft. In phakic patients, lens extraction was performed at the time of BKPro implantation. If pseudophakic, the intraocular lens (IOL) was left in place or explanted, depending on the IOL stability. If aphakic, a core anterior vitrectomy was performed. The KPro/donor carrier was then sutured with multiple interrupted 10-0 nylon stitches. The first suture (10-0 monofilament nylon) was passed through the donor corneal button at 90% depth at 12 O‘clock, and passed through the host cornea at the same depth. The second suture is placed at 6 O‘clock. A third and fourth suture was then placed at 3 and 9 O‘clock position. A total of 12 interrupted sutures were generally required. All suture knots were buried on the donor side. Subconjunctival gentamicin (40 mg in 1 ml) and dexamethasone (4mg in 1 ml) was injected. An antibiotic drop instilled and pad and bandage applied for 24 hours. At the conclusion of the case, a bandage contact lens was placed. Postoperatively systemic antibiotic for

5days and topical antibiotic Gatifloxacin 0.3% eye drop 6 times/day, Preservative free carboxymethylcellulose 6 times/day, low dose steroid 2times/day given. Patients with raised IOP were given antiglaucoma treatment accordingly. patients followed by day 1,1st week,3rd week,1st month and bimontholy for 1 year. After the implantation at every visit the patient will be subjected to Snellen's Visual Acuity-BCVA, slit lamp biomicroscopy, ocular digital pressure, graft status, retention of device, posterior pole assessment, any complication and Pre-and postoperative Digital color photographs of the patient was taken.

RESULTS

A total of 20 patients were enrolled for the study which were followed up and assessed over 12 months. It was observed that maximum number of patients were in the age group of 41-60 years (45%) and in the >60 years group are minimum (20%). Among these 14 cases (70%) were male and 6 cases (30%) were female.

Table 1: Indication.

Indication	Number of eyes (%)
Failed PK	9 (45)
Leucomatous CO with vascularisation	6 (30)
Surface corneal dystrophy	2 (10)
Healed chemical burn	2 (10)
Bullous keratopathy with vascularisation	1 (5)
Total	20 (100)

It was observed that failed PK (Figure 1) (9 of 20 eyes; 45%) was the most common primary indication, followed by leucomatous corneal opacity with severe vascularization (20%), surface corneal dystrophy (10%), healed chemical burn (fig 2) (20%) and bullous keratopathy with vascularisation (5%) cases. The majority of patients had pre-operative visual acuity of ≤ FCCF (13 patients equivalent to 65% of total) followed by those with visual acuity > FCCF (7 patient equivalent to 35% of total).

Table 2: Complications encountered post operatively.

Complications	Number of patients	%Age
Retro-prosthetic membrane	4	20
Increased IOP	3	15
Endophalmitis	1	5
Total	8	40

The common complications encountered were RPM (20%), increased IOP (15%), and endophalmitis (5%). 0% patients required vitrectomy in aphakic keratoprosthesis, 50% patients required YAG LASER. It was observed that retention of device in 19 patients (95%) and one patient (5%) was eviscerated.

Table 3: Visual acuity at different follow up.

Follow up	Visual	Acuity	
Time	**<6/60 (%)**	**6/60-6/24 (%)**	**≥6/18 (%)**
Day 1	18 (90)	2 (10)	0
Day 7	17 (85)	3 (15)	0
Day 21	13 (68)	6 (32)	0
1 Month	9 (47)	10 (53)	0
3 Month	8 (42)	11 (58)	0
1 Year	8 (42)	10 (53)	1(5)

DISCUSSION

Corneal blindness is a significant public health problem in India. When the cornea becomes severely diseased and vision is compromised, cornea transplantation may be necessary. Many people with corneal disease can benefit from corneal transplantation involving tissue from human donors. This is the most common treatment for severe corneal opacity. However, in many cases, this treatment rapidly fails. An alternate treatment for patients with severe corneal opacity is the Keratoprosthesis, which is an "artificial cornea. The Boston Keratoprosthesis (KPro) is the most widely used artificial cornea. The Boston Keratoprothesis can be used after standard corneal transplant has failed or when such a transplant would be unlikely to succeed9. Thus, keratoprosthesis implantation is a procedure designed to help patients whose conditions are the most difficult to treat.[5,10,11]

The prognosis of KPro procedures depends on the preoperative diagnosis. The difference between the best and the worst group differed markedly and has been documented to correlate well with the degree of the preoperative inflammation. According to the degree of the vision achieved and retention rate, Yaghouti and Dohlman12 classified the prognosis ranking (best to worst) as follows: 1) Graft failure in the eyes without past inflammation (corneal edema, etc.); 2)Graft failure in eyes with past inflammation (past herpes simplex or zoster, uveitis, etc.); 3) Pemphigiod (susceptible to retroprosthetic membrane formation); 4)Chemical burns (susceptible to glaucoma and retinal detachment), 5) Stevens-Johnsons syndrome (poor prognosis, high risk of endophthalmitis). Zerbe et al have also reported good outcomes for patients with chemical burns.[13]

In our study, 09 patients with no pre-operative inflammation, the post-operative results were good.

Of the two eyes with h/o chemical burn, which was expected to be of the worst prognosis of the 20 cases, one achieved BCVA of 4/60, was quiet and had a good control of glaucoma till the last follow up of 12 months. While we had to perform evisceration in the other eye d/t continued inflammation.

In consistent with the previous reports from other parts of the world, of all the 20 eyes,[19] had a significant increase in vision after Boston type I keratoprosthesis implantation

Results from the first multicenter study, including 136 eyes with kpro device, demonstrated improvements in the retention rate (95% in 8.5 months of follow-up) and in the visual prognosis.[11] The main postoperative complication observed was RPM formation (25%), followed by an increase of IOP (15%). There were no reported cases of endophthalmitis after surgery.

Aldave et al [4] found similar results with type I BKPro regarding anatomical retention and visual acuity improvement in 50 eyes of 49 patients. The most common complications were RPM (44%) and persistent epithelial defects (38%). In this study, with an average follow-up of 17 months, there were no cases of endophthalmitis.

In our study also, the retention rate was as high as 95% in a follow up period of 12 months. The main post-operative complication was RPM (20%), followed by raised IOP (15%). However, one case of endophthalmitis (5%) was encountered in our study which was most probably d/t preoperative inflamed eye which persisted post- operatively.

In our study with the Boston type 1 keratoprosthesis, most of the patients (95%) attained a improved visual acuity, comparable to the 57% reported in the multicentre Boston keratoprosthesis study18. 53% achieved 6/60 or better at their last visit following keratoprosthesis implantation. In addition, compared with standard PK, the Boston keratoprosthesis provided relatively rapid visual recovery, with 32% of our patients attaining their BCVA by the 1 week postoperative visit, 42% by 1 months and 26% by 1 year. Dunlap et al also demonstrated rapid visual improvement with 56% of their patients achieving their BCVA at month 1.[26] Several recent keratoprosthesis series report visual outcomes by time points. Our percentage of patients who achieved 6/60 vision or better at 1 year was 58% while it was 75% in Bradley et al23, 82% in Aldave et al [24], and 77% in Chew et al[25] which might be d/t a smaller sample size in our study and a poor pre-operative vision status.

The main indication of keratoprosthesis implantation remains prior failed corneal transplant (45% in our study). Because keratoprosthesis patients are specifically chosen because of the belief that repeat PK would result in graft failure, it could be inferred that repeat keratoplasty in this high-risk group would have worse results. Our survival rate was 100% in a follow up of 12 months in failed PK patients compared to the rates in recent keratoprosthesis series (91.6% with an average follow¬ up of 13 months in the multicentre Boston type 1 keratoprosthesis study,[27] 83.3% at an average follow-up of 19 months in Bradley et al,23 84% at an average follow-up of 17 months in Aldave et al.[24] However, we require to follow patients for even a longer period, to assess whether the superior survival function compared with repeat PK will be maintained.

One barrier to keratoprosthesis implantation remains the concern over the high risk of postoperative complications. In our study, the most common post-operative complication was RPM which occurred in 20% of the patients. Despite the high prevalence of RPM, most were successfully treated with yttrium aluminium garnet membranotomy echoing the need for early detection and treatment. Todani et al[30] in a multicentre study reported that eyes with titanium backplates had a statistically significant less chance of inducing RPMs than its PMMA counterparts. Since our study had only PMMA plates, so we cannot comment on this observation.

A commonly reported challenge after keratoprosthesis implantation is accurate assessment of IOP, a particular concern as glaucoma is a common comorbidity in these patients. The percentage of patients who developed elevated IOP following keratoprosthesis in our study was 15%, within the range from other series (14% in multicentre Boston keratoprosthesis study,[18] 18% in Aldave et al,[24] and 38% in Chew et al.[25] Most were successfully managed with medication. Retinal detachment occurred in 10.3% of eyes (3.5% in multicenter Boston type I keratoprosthesis study,18 7% in Aldave et al, [24] and 4.8% in Dunlap et al.[26] However, no such complication was reported in our study.

CONCLUSION

The Boston type 1 keratoprosthesis provides visual recovery for eyes with multiple PK failures or with poor prognosis for primary PK, showing excellent retention rates. Most of the cases had a significant improvement in vision after Boston type I KPro implantation. Aphakic KPro holds a higher success rate than pseudophakic kpro I in terms of complication like RPM. However, patients require close lifelong follow-up to manage any complications. However, several challenges unique to the keratoprosthesis remain, including the accurate assessment of glaucoma status, maintenance of the optic–cornea interface, and the formation of RPM.

Funding: No funding sources
Conflict of interest: None declared
Ethical approval: The study was approved by the Institutional Ethics Committee

REFERENCES

1. Prevention of blindness: report of a WHO Study Group. Geneva, World Health Organization. 1973: 10-11 (WHO Technical Report Series, No. 518). Available at http://apps.who.int/ iris/ bitstream/ 10665/ 38222/ 1/ WHO_TRS_518_eng.pdf

2. Sinha S. Corneal Grafting Surgery- Historical Aspects Vajpayee R.B. Corneal Transplantation. Cornea. 2001;1:2-4.
3. Kanpolat A, Ciftci OU. The use of rigid gas permeable contact lenses in scarred corneas. CLAO J 1995;21:64-66.
4. Eye Bank Association of America. Cornea donation andtransplantation statistics Available at http://www.restoresight.org/donation/statistics.htm. Accessed, 2009.
5. Barber JC. Keratoprosthesis: past and present. Int Ophthalmol Clin. 1988;28:103-109.
6. Hicks CR, Fotton JH, Chirila TV, Crawford GJ, Constable IJ. Keratoprosthesis: advancing toward a true artificial cornea. SurvOphthalmol. 1997;42:175-89.
7. Pellier de Quengsy G. PrZcis au coursd'operationsur la chirurgie des yeux. Paris: Didot; 1789.
8. Chirila TV, Hicks CR. The origins of the artificial cornea: Pellier de Quengsy and his contribution to the modern concept of keratoprosthesis. Gesnerus. 1999;56(1-2):96-106.
9. Khan BF, Harissi-Dagher M, Khan DM, Dohlman CH. Advances in Boston keratoprosthesis: enhancing retention and prevention of infection and inflammation. Int ophthalmol clinics. 2007;47(2):61-71.
10. Harissi-Dagher M, Khan BF, Schaumberg DA, Dohlman CH. Importance of nutrition to corneal grafts when used as a carrier of the Boston keratoprosthesis. Cornea. 2007;26(5):564-8.
11. Dohlman CH, Harissi-Dagher M, Graney J. The Boston keratoprosthesis: a new threadless design. Digit J Ophthalmol. 2007;13(3).
12. Zerbe BL, Belin MW, Ciolino JB. Results from the multicenter Boston Type 1 Kerato prosthesis Study. Ophthalmology. 2006;113(10):1779-84.
13. Harissi-Dagher M, Beyer J, Dohlman CH, The role of soft contact lenses as an adjunct to the Boston keratoprosthesis. Int Ophthalmol Clin, 2008;48(2):43-51.
14. Dohlman CH, Harissi-Dagher M, Khan BF, Sippel K, Aquavella JV, Graney JM. Introduction to the use of the Boston keratoprosthesis. Expert Review of Ophthalmology. 2006;1(1):41-8.
15. Chew HF, Ayres BD, Hammersmith KM, Rapuano CJ, Laibson PR, Myers JS, Jin YP, Cohen EJ. Boston keratoprosthesis outcomes and complications. Cornea. 2009;28(9):989-6.
16. Bradley JC, Hernandez EG, Schwab IR, Mannis MJ. Boston type 1 keratoprosthesis: the University of California Davis experience. Cornea. 2009;28(3):321-7.
17. Aldave AJ, Kamal KM, Vo RC, Yu F. The Boston type I keratoprosthesis: improving outcomes and expanding indications. Ophthalmology. 2009;116(4):640-51.

Cite this article as: Raina K, Gupta A. Boston keratoprosthesis type 1 - indication complication and visual outcomes. Int J Res Med Sci 2017;5:1903-7.