

## Short-term outcome of Boston Type 1 keratoprosthesis for bilateral limbal stem cell deficiency

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This study reports the short-term functional and anatomical outcome of Boston Type 1 keratoprosthesis (Boston Kpro) implantation for bilateral limbal stem cell deficiency (LSCD). Retrospective analysis was done on eight eyes of eight patients who underwent Boston Kpro implantation between July 2009 and October 2009. The best corrected visual acuity (BCVA) and slit-lamp biomicroscopy findings were assessed at 1, 3 and 6 months postoperatively. All eight eyes retained the prosthesis. BCVA of 20/40 or better was achieved in 8, 6, and 5 eyes at 1, 3, and 6 months, respectively, postoperatively. One patient each developed epithelial defect, sterile stromal melt and fungal keratitis in the late postoperative period associated with antecedent loss of the soft contact lens from the eye. Boston Kpro has good short-term visual and anatomical outcome in patients with bilateral LSCD, provided compliance with postoperative care can be ensured.

**Key words:** Boston keratoprosthesis, limbal stem cell deficiency

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The Boston Type 1 keratoprosthesis (Boston Kpro) was developed to treat patients with blindness due to end-stage corneal disease and poor prognosis for penetrating keratoplasty, like in eyes with repeated graft failure, severe corneal neovascularization and limbal stem cell deficiency (LSCD) as a result of chemical and thermal burns, provided the ocular surface is still wet.<sup>[1,2]</sup> With the evolution of the design and the postoperative care regimen of the Boston Kpro, outcomes have improved significantly and its popularity is on the rise all over the world.<sup>[3,4]</sup> The aim of this study was to review the short-term visual and anatomical outcome of this procedure in our initial few cases.

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## Materials and Methods

This was a retrospective, interventional case series of eight eyes of eight patients in whom Boston Kpro was implanted between July 2009 and October 2009 for bilateral LSCD with a minimum postoperative follow-up of 6 months duration. Informed written consent was obtained from all the study patients before they underwent this procedure.

All patients underwent a complete preoperative ophthalmological work up (study and fellow eye) including best corrected visual acuity (BCVA) measurement, slit-lamp biomicroscopy, intra-ocular pressure measurement, posterior segment evaluation by ultrasound B scan and axial length measurement for both eyes.

All patients were operated under general anesthesia with endotracheal intubation. The Boston Kpro was ordered and obtained from the Massachusetts Eye and Ear Infirmary (Boston, MA, USA) and the standard technique of implantation as described previously was performed.<sup>[1,2]</sup> Briefly, the recipient cornea was trephined with a 8.5-mm disposable trephine; extracapsular cataract extraction (ECCE) was performed if the patient was phakic and a plano posterior chamber intra-ocular lens (PCIOL) was implanted in the capsular bag or the eye was left aphakic. The implant with a backplate diameter of 8.5 mm was assembled on a 9-mm donor lenticule and was sutured in place with 16, 10-0 nylon interrupted sutures. A 16-mm diameter Kontur (Kontur Contact Lens Co., Richmond, CA, USA) plano contact lens (CL) was placed on the eye on completion of the surgery.

Postoperatively, the patients were routinely evaluated on day 1, 1 week, 1 month, 3 months, and every 3 months thereafter. The postoperative medication included topical administration of prednisolone acetate 1% eye drops in tapering doses, moxifloxacin 0.5% eye drops four times daily, and fortified vancomycin 0.5% eye drops once daily. The patients underwent routine ophthalmic examination at each follow-up visit.

The medical records were reviewed and the following data were retrieved: demographic characteristics (age, gender, and laterality), initial diagnosis, previous surgeries (including type, date, and visual outcome) and duration of follow-up (in months), BCVA and slit-lamp findings at each follow-up visit. The incidence and type of complications intraoperatively and postoperatively were also noted.

## Results

The demographic data of the eight patients are provided in Table 1. The data on initial diagnosis and previous surgical

**Table 1: Demographic and baseline data of the patients**

Age in years (mean ± SD, range)	30.12 ± 11.9, 18–47
Duration of disease prior to surgery in years (mean ± SD, range)	4.6 ± 5.7, 0.5–16
Duration of follow-up in months (mean ± SD, range)	8.75 ± 1.48, 7–10
Laterality (right eye:left eye)	3:5
Gender (male:female)	7:1

**Table 2: Initial diagnosis, previous surgical procedures and their outcomes**

Patient	Age (years)	Sex	Initial diagnosis	Previous surgery	Outcome
1	41	M	Bilateral acid burn	AMG (thrice), ECCE with PCIOL	Vascularized scar
2	34	M	Bilateral alkali burn	AMG, Cu LSCT	Vascularized scar
3	19	F	Bilateral acid injury	AMG	Vascularized scar
4	47	M	Mooren's ulcer	CR with TA (four times), PK (twice)	Failed graft
5	20	M	VKC	Lr LSCT (thrice), LK	Failed graft
6	21	M	Cracker injury	COMET, PK	Failed graft
7	18	M	Bilateral alkali burn	PK, Cu LSCT	Failed graft
8	41	M	Bilateral alkali burn	AMG	Vascularized scar

AMG = amniotic membrane grafting, ECCE = extracapsular cataract extraction, PCIOL = posterior chamber intra-ocular lens, CuLSCT = cultivated autologous limbal stem cell transplantation, CR with TA = conjunctival resection with tissue adhesive, VKC = vernal keratoconjunctivitis, PK = penetrating keratoplasty, Lr LSCT = live related limbal stem cell transplantation, COMET = cultivated oral mucosal epithelial transplantation, LK = lamellar keratoplasty, M = male, F = female

procedures are provided in Table 2. No patient had evidence of any ocular inflammation, as assessed clinically, at the time of surgery [Fig. 1]. Six of the eight eyes had an aphakic and two eyes had a pseudophakic Boston Kpro implantation.

The preoperative and postoperative BCVA of each patient at each follow-up visit is given in Table 3. The number of eyes with BCVA of 20/40 or better was 4, 7, 8, 6 and 5 at day 1, 1 week, 1 month, 3 months, and 6 months, respectively, postoperatively. The mean spherical refractive error was  $-0.375 \pm 1.2$  D (range  $-2.5$  D to  $+1.25$  D) at 3 months postoperatively. Two of the eight eyes that had 20/40 or better vision at 1 month postoperatively developed a visually significant posterior capsular opacification (PCO) at 3 months and 1 eye developed the same at 6 months. All five patients who completed 9 months of follow-up maintained the same BCVA as at the 6 month follow-up visit.

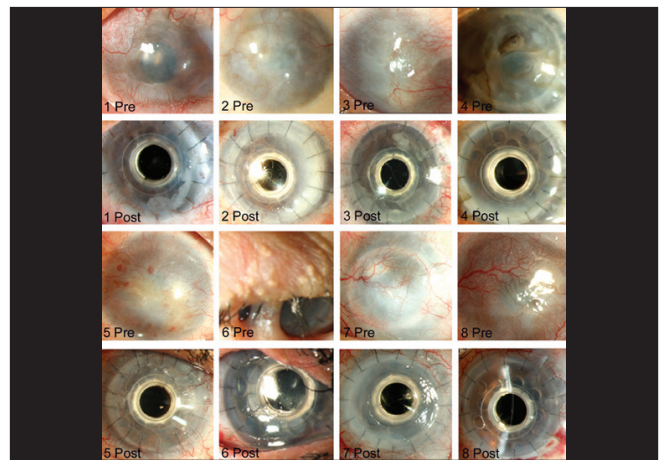
The details of the postoperative complications, their management and outcomes are provided in Table 4.

## Discussion

In our series of eight eyes of eight patients with bilateral LSCD, we noted encouraging short-term visual and anatomical outcomes with the Boston Kpro. We had attempted multiple alternative surgical modalities [Table 2] in almost all the eyes with limited success before we resorted to using the Boston Kpro. All patients retained the prosthesis with remarkable improvement in BCVA and most patients retained their best vision at last follow-up.

Boston Kpro implantation has been shown to have excellent visual outcomes in eyes with bilateral LSCD, provided the posterior segment of the eye is normal and the optic nerve is healthy and our experience has been similar.<sup>[5,6]</sup> The surgical technique is single-staged and simple and there were no serious intraoperative complications. Postoperatively, we encountered one case each of sterile graft melt and fungal keratitis, both of which were managed conservatively [Table 4] and the prosthesis could be retained. The soft CL is necessary in these eyes to stabilize the surface and its loss could have led to surface breakdown and secondary fungal infection (patient 8), for which use of vancomycin is considered a risk factor.<sup>[4,7]</sup>

We chose to implant Boston Kpro in these cases with poor functional vision in both eyes on the basis of our disappointing



**Figure 1:** Slit-lamp photographs of patients before and after Boston Kpro implantation. Top row: preoperative photographs of patients 1–4 (left to right); second row: 1 month postoperative photographs of patients 1–4 (left to right); third row: preoperative photographs of patients 5–8 (left to right); bottom row: 1 month postoperative photographs of patients 5–8 (left to right)

clinical experience with live related stem cell transplantation or cultivated oral mucosal epithelial transplantation (COMET) along with lamellar or penetrating keratoplasty for visual rehabilitation. Previous studies have shown that these modalities either fail despite long-term immunosuppression or have disappointing visual outcomes even when being successful anatomically.<sup>[8,9]</sup>

The drawbacks of this study are the short follow-up and small sample size; however, to our knowledge, this is the first report of the successful use of this prosthesis in the Indian subcontinent and this is where the relevance and value of our outcomes lie. We are also initiating a large, long-term prospective study to validate our results. In this study, we found that the Boston Kpro has good short-term visual and anatomical outcome in patients with bilateral LSCD, provided compliance with postoperative care can be ensured.

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**Table 3: Pre-operative and post-operative best spectacle corrected visual acuity at day 1, 1 week, 1 month, 3 months, 6 months and 9 months in Snellen equivalents**

Patient	Preoperative	Postoperative					
		Day 1	1 week	1 month	3 months	6 months	9 months
1	<1/60	20/50	20/40	20/30	20/30	20/40	
2	<1/60	20/25	20/25	20/25	20/20	20/50	
3	<1/60	20/40	20/25	20/20	20/30	20/25	20/25
4	<1/60	20/100	20/60	20/40	20/50	20/50	20/50
5	<1/60	20/25	20/20	20/20	20/25	20/30	20/30
6	<1/60	20/60	20/40	20/40	20/40	20/40	20/40
7	<1/60	20/50	20/30	20/30	20/20	20/20	20/25
8	<1/60	20/25	20/30	20/30	20/80	20/200	

**Table 4: Intraoperative, early (<6 weeks) postoperative and late (>6 weeks) postoperative complications of Boston Kpro**

Complication (Patient #)	Predisposing factor	Treatment	Outcome
Early postoperative period (<6 weeks)			
Raised IOP (Patient 1)	None	Topical and oral anti-glaucoma medications for 1 week	IOP normalized within 1 week
Late postoperative (>6 weeks)			
Epithelial defect around optical stem (Patient 3)	Loss of CL for 1 week	CL replaced	Resolved without sequelae
Epithelial defect with stromal melt around optical stem (Patient 1)	Multiple episodes of loss of CL	TA application and paramedian tarsorrhaphy	Melt arrested, no perforation, no infection
Epithelial defect with fungal keratitis, stromal melt and perforation (Patient 8)	Loss of CL for 2 weeks	Topical and systemic antifungals for 1 month, TA application and paramedian tarsorrhaphy	Infection cured, melt arrested, RCM formation

IOP = intra-ocular pressure; CL = contact lens; TA = tissue adhesive; RCM = retrocorneal membrane

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