The Aurolab Keratoprosthesis (KPro) versus the Boston Type I Kpro: 5-year Clinical Outcomes in 134 Cases of Bilateral Corneal Blindness

SAYAN BASU, JUAN CARLOS SERNA-OJEDA, SIRISHA SENTHIL, RAJEEV REDDY PAPPURU, BHUPESH BAGGA, AND VIRENDER SANGWAN

• PURPOSE: To compare the clinical outcomes of Boston Type I keratoprosthesis (Boston Kpro) with its low-cost version, the Aurolab Kpro (auroKPro).

• DESIGN: Retrospective comparative case series.

• METHODS: This study included 134 eyes of 130 patients with severe bilateral corneal blindness but with wet ocular surfaces. The patients underwent either Boston Kpro (n = 78) or auroKPro (n = 56) implantation based on the device availability and patient's affordability. The primary outcome measurements were anatomical retention (defined as absence of device extrusion, exchange, or explantation) and functional recovery of 20/200 or better visual acuity at yearly time points until 5-years of follow-up.

• RESULTS: Limbal stem cell deficiency was the most common indication (60.5%) for surgery, followed by multiple failed grafts (35%). Both groups were comparable at baseline with respect to indications for surgery and associated ocular co-morbidities ($P > 0.05$). The overall anatomical retention rates were similar in the Boston Kpro (55 of 78, 70.5%) and auroKPro (35 of 56, 62.5%) groups ($P = 0.11$). Kaplan-Meier survival rates at 5 years of follow-up were greater for the Boston Kpro with respect to both anatomical retention (63 ± 6% vs. 43.4 ± 10%, respectively; $P = 0.057$) and functional recovery (42.4 ± 6% vs. 32.2 ± 7%, respectively; $P = 0.345$), but these differences were not statistically significant. Complications such as intraoperative device breakage (7%) and postoperative extrusions (12.5%) were significantly more common with the auroKPro ($P = 0.023$).

• CONCLUSIONS: Both the auroKPro and the Boston Kpro are effective treatment options for patients with severe bilateral corneal blindness. The auroKPro can be considered an alternative to the Boston Kpro when affordability or availability of the Boston Kpro is a limiting factor. (Am J Ophthalmol 2019;205: 175–183. © 2019 Elsevier Inc. All rights reserved.)

THE BOSTON TYPE I KERATOPROSTHESIS (BOSTON Kpro) is probably the most popular artificial corneal device in use globally.[1] The Boston Kpro, as it is popularly known, is indicated in eyes with blinding corneal pathologies where conventional or compartmental corneal transplantation has repeatedly failed or is very likely to fail if performed. The indications for its use have continued to expand over time, and there are numerous long-term studies that have validated its effectiveness both in and out of North America.[2–6] However, despite its global popularity, a major limiting factor for the use of the Boston Kpro in developing countries is its cost.[7,8] Although the Boston Kpro is distributed internationally at rates corresponding to the gross domestic product (GDP) of each country, even the subsidized cost of the Boston Kpro is often beyond the scope of the economically disadvantaged patients who ironically tend to suffer from the severe kind of corneal blindness that merits its implantation.

To address this problem in India, the design of the Boston Kpro was shared with an Indian manufacturer (Aurolab, Madurai, India) for local production and distribution of the device since 2011. The Indian-made device was renamed the auroKPro and sold for less than US$100.[9] The auroKPro was found to be effective in restoring good vision to eyes with end-stage corneal disease in preliminary noncomparative case series; however, these studies had small numbers with limited duration of follow-up.[9,10] Therefore, before the example of the auroKPro is established as a model of technology transfer that can be replicated across the world, both the efficacy and the safety of the device need to be established beyond reasonable doubt. In addition to sufficient numbers of patients and adequate follow-up, a true comparison between 2 similar devices can only be ensured when personal bias and all other confounding factors that are likely to influence the clinical outcome like indications, surgeon's experience, and postoperative protocols are controlled for. Because the authors had no financial interest in either of

AJO.com Supplemental Material available at AJO.com.
Accepted for publication Mar 10, 2019.

From the Tej Kohli Cornea Institute (S.B., J.C.S.-O., B.B., V.S.), LV Prasad Eye Institute, Hyderabad, Telangana, India; VST Glaucoma Centre (S.S.), LV Prasad Eye Institute, Hyderabad, Telangana, India; and Kannuri Santhamma Centre for Vitreo-Retinal Diseases (R.R.P.), LV Prasad Eye Institute, Hyderabad, Telangana, India.

Inquiries to Sayan Basu, Room 606A, Sixth Floor, Kallam Anji Reddy Campus, LV Prasad Eye Institute, Hyderabad 500034, Telangana, India; e-mail: sayanbasu@lvpei.org

0002-9394/$36.00
https://doi.org/10.1016/j.ajo.2019.03.016

the devices, they had the unique opportunity to study and compare the outcomes of both devices in similar settings and indications. In this study, the authors report the 5-year outcomes in terms of anatomical retention rates, visual improvement, and complications of the auroKPro compared to those of the Boston Kpro in a large cohort of 134 eyes in patients with severe bilateral corneal blindness.

SUBJECTS AND METHODS

• **STUDY DESIGN, SUBJECTS, AND APPROVAL:** This was a retrospective comparative case series of patients who underwent surgical implantation of either the Boston Kpro or the auroKPro device from August 25, 2009, onward, at the LV Prasad Eye Institute, Hyderabad, India. All keratoprosthesis surgeries were performed by 3 ocular surgeons (B.B., S.B., and V.S.S.) or cornea fellows under their supervision. The study was approved by the Institutional Review Board and the Ethics Committee and was conducted in strict adherence to the tenets of the Declaration of Helsinki. All adults and legal guardians of children who underwent the surgical procedure gave informed written consent. Patients who underwent implantation of other keratoprosthesis designs (Boston Type 2 keratoprosthesis, modified osteo-odonto keratoprosthesis, LVP keratoprosthesis, and Lucia Type 2 keratoprosthesis) or modifications of the Boston Type I keratoprosthesis design (Lucia Type 1 Keratoprosthesis versions 1 and 2 and Boston Type I Kpro with "click-on" titanium back plate) were not included in this study.

• **CASE SELECTION:** Only bilaterally blind individuals were eligible for this procedure, and no patient underwent bilateral procedures if the operated first eye was still functional. Eyes with extensive symblepharon, forniceal shortening, and uncorrected eyelid pathologies (including inadequate closure) were excluded. This procedure was also avoided in eyes that were very dry (according to Schirmer test I score of 10 mm or less at 5 minutes) or had doubtful visual potential, which was accessed by checking for a reliable perception of light, normal ultrasonography B-scan test results and in some cases by an endoscopic examination of the posterior segment.[11]

• **ASSIGNMENT, SURGICAL TECHNIQUE, AND POSTOPERATIVE REGIMEN:** The Boston Kpro was ordered and obtained from the Massachusetts Eye and Ear Infirmary (MEEI, Boston, Massachusetts, USA) and the auroKPro from Aurolab (Madurai, India). From August 1, 2011, when the auroKPro became available, both devices were offered to the patients. The auroKPro is based on the snap-on design of the Boston Kpro (Supplemental Figure, A and C auroKPro; B and D Boston Kpro), with a polymethylmethacrylate (PMMA) optical cylinder, 16-holed PMMA backplate, and titanium locking ring.[9,10] The titanium locking ring was obtained from MEEI, and its cost was included in the cost of the auroKPro device. The patients or their guardians chose the device based on the price and the waiting time. The Boston Kpro had an average waiting time of 3–4 weeks, whereas the auroKPro was available on demand. It was also explained that the auroKPro was expected to be equivalent to the Boston Kpro but not the same device. The technique used for the implantation of both devices was the same as previously described.[4,9,12] Briefly, optical power of the device and the size of the carrier corneal graft were selected based on each individual case, considering diverse factors. After excision of the host cornea, extracapsular cataract extraction was performed if the patient was phakic, and a plano posterior chamber intraocular lens was implanted in the capsular bag, or the eye was left aphakic. The implant with a PMMA back plate was assembled on a donor graft and was sutured in place with 16 10-0 nylon interrupted sutures, and a 15- to 16-mm-diameter plano soft bandage contact lens (Kontur Contact Lens Co, Richmond, California, USA; or SilkLens, Bengaluru, Karnataka, India) was placed on the eye on completion of the surgery.[4,12]

All patients underwent comprehensive ophthalmic examinations of both eyes at every follow-up visit. The patients were routinely evaluated on day 1 and at 1 week, 1 month, 3 months, and every 2–3 months thereafter. The postoperative medications included topical administration of prednisolone acetate 1% eye drops in tapering doses, moxifloxacin 0.5% eye drops 4 times daily, and either fortified vancomycin or chloramphenicol 0.5% eye drops once daily. At the 2–3 monthly follow-up visits, the original contact lens was replaced with a SilkLens contact lens, and a drop of 5% povidone-iodine was placed in the conjunctival cul-de-sac.

• **DATA COLLECTION:** Data for every visit were collected in a predesigned spreadsheet; data included patient age and sex, type of keratoprosthesis, cause of the corneal pathology, details of prior ocular procedures, presence or absence of limbal stem cell deficiency (LSCD), symblepharon, severe dry eye disease, Snellen best-corrected visual acuity (BCVA), intraoperative surgical details, postoperative complications, additional surgeries, duration of follow-up, and retention of the device.

• **PRIMARY OUTCOME MEASUREMENTS:** The primary outcome measurements were anatomical retention and functional recovery. Anatomical retention was defined as the duration for which the keratoprosthesis device remained in the eye without being extruded, explanted, or exchanged or the eye being eviscerated or enucleated. Survival was not carried over if the device was exchanged. Functional recovery was defined both as the postoperative duration for which at least a BCVA of 20/200 (limit for

legal blindness) was maintained with the keratoprosthesis in place.

• **SECONDARY OUTCOME MEASUREMENTS:** The secondary outcome measurements were incidence of intraoperative and postoperative complications. New or worsening glaucoma was defined as increased intraocular pressure, as measured by digital palpation, high enough to warrant additional topical or systemic medication or glaucoma surgery, increased cup-to-disc ratio, or visual field loss. Any case with a sudden drop in vision and presence of vitreous cells underwent a 2-port pars-plana vitreous biopsy with automated vitrector, and the biopsied sample was sent for routine microbiological examination. During the procedure pericylinder leakage was checked for once the irrigation cannula had been secured and turned on. If microbiology was negative, the case was labeled as sterile vitritis. When microbiology was positive, these cases were labeled as "endophthalmitis." A cost-benefit analysis was also performed to compare the cost of surgical procedures required per patient in each group.

• **STATISTICAL ANALYSIS:** MedCalc version 11.4.3.0 software (Mariakerke, Belgium) was used for data analysis. Comparisons between Boston Kpro and auroKPro were performed. Continuous parametric data were reported as mean ± standard deviation, and nonparametric data were reported as median with range. The comparisons in the distribution between the Boston Kpro and auroKPro groups were performed with Pearson chi-square test. A Kaplan-Meier survival analysis was used for the anatomical and functional outcomes, and a log-rank test was performed to compare the survival curves of both groups. A 2-tailed *P* value less than 0.05 was considered statistically significant.

RESULTS

• **BASELINE DEMOGRAPHICS:** This study included 134 eyes of 130 patients. The Boston Kpro was implanted in 78 eyes of 75 patients and the auroKPro in 56 eyes of 55 patients. Table 1 summarizes the baseline characteristics of the eyes and compares preoperative characteristics of Boston Kpro with those of the auroKPro group. It is important to note that both groups were comparable at baseline in all aspects.

• **PRIMARY OUTCOMES:** *Anatomical Retention*. Anatomical success was noted in 90 cases (67.2%) of the 134 cases at final follow-up. The overall anatomical retention rates in the Boston Kpro group (55 of 78; 70.5%) were similar to those in the auroKPro group (35 of 56; 62.5%; $P = 0.11$). Figure 1 shows the Kaplan-Meier survival curve demonstrating the cumulative probability of anatomical retention of the implanted keratoprosthesis over a 5-year follow-up period. A log-rank test comparison of the survival curves demonstrated that the Boston Kpro had an overall retention rate of 63 ± 6% compared with 43.4 ± 10% in the auroKPro group at 5 years postimplantation, but this difference was not statistically significant ($P = 0.057$).

Of the 23 failures in the Boston Kpro group, 12 had penetrating keratoplasty and tarsorrhaphy; 9 had their prosthesis exchanged for another Boston Kpro or another type of Type 1 keratoprosthesis; and 2 eyes

TABLE 1. Baseline Demographic Characteristics

Characteristics	Boston Kpro (%)	auroKPro (%)	*P* Value
Females	12 (16)	14 (25.4)	0.332
Males	63 (84)	41 (74.5)	
Socioeconomic status			
Lower class	30 (40)	32 (58.2)	0.132
Middle class	32 (42.6)	18 (32.7)	
Upper class	13 (17.4)	5 (9.1)	
Laterality			
Left	46 (58.9)	23 (41.0)	0.084
Right	32 (41.0)	33 (58.9)	
Age			
Adults	71 (94.6)	49 (89.1)	0.900
Pediatric	4 (5.3)	6 (10.9)	
Previous penetrating corneal procedure			
No	38 (48.7)	34 (60.7)	0.232
Yes	40 (51.2)	22 (39.2)	
Indication for surgery			
Failed corneal graft	32 (41.0)	15 (26.7)	0.126
Multiple ocular surgeries	25 (32)	9 (16.1)	
Trauma or infection	4 (5)	4 (7.1)	
Dystrophies or degenerations	3 (4)	2 (3.5)	
Limbal stem cell deficiency	44 (56.4)	37 (66.0)	
Chemical burns	33 (42.3)	21 (37.5)	
Others	11 (14.1)	16 (28.5)	
KPro exchange	2 (2.5)	4 (7.1)	
Known pre-existing ocular comorbidity			
Prior glaucoma	23 (29.4)	10 (17.8)	0.310
Prior retinal disease	3 (3.8)	2 (3.5)	
BCVA at presentation			
Visual acuity worse than 20/2000	56 (71.7)	46 (82.1)	0.672
Visual acuity 20/200 to 20/2000	22 (28.2)	10 (17.8)	
Axial length			
Mean	23.4	22.7	0.57
± SD	2.9	3.4	

BCVA = best corrected visual acuity; Kpro = keratoprosthesis; SD = standard deviation.

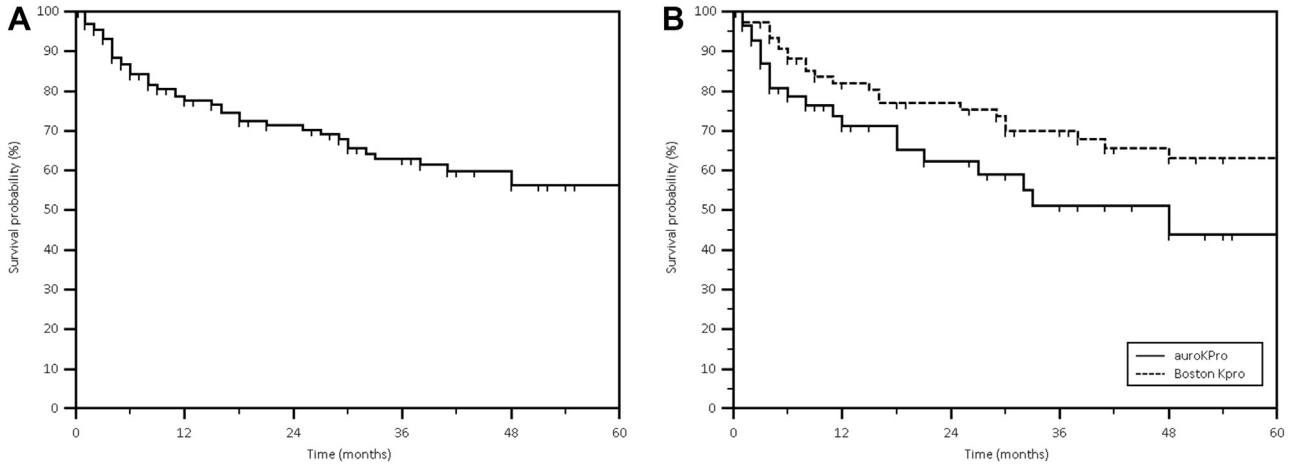

FIGURE 1. Kaplan-Meier survival curves show 5-year cumulative probability of anatomical retention of Boston Type I keratoprosthesis and its low-cost alternative, the auroKPro. Overall survival in 134 cases (A) and comparison between the survival curves of the Boston Type I keratoprosthesis group (B) (n = 78) and the auroKPro group (A) (n = 56).

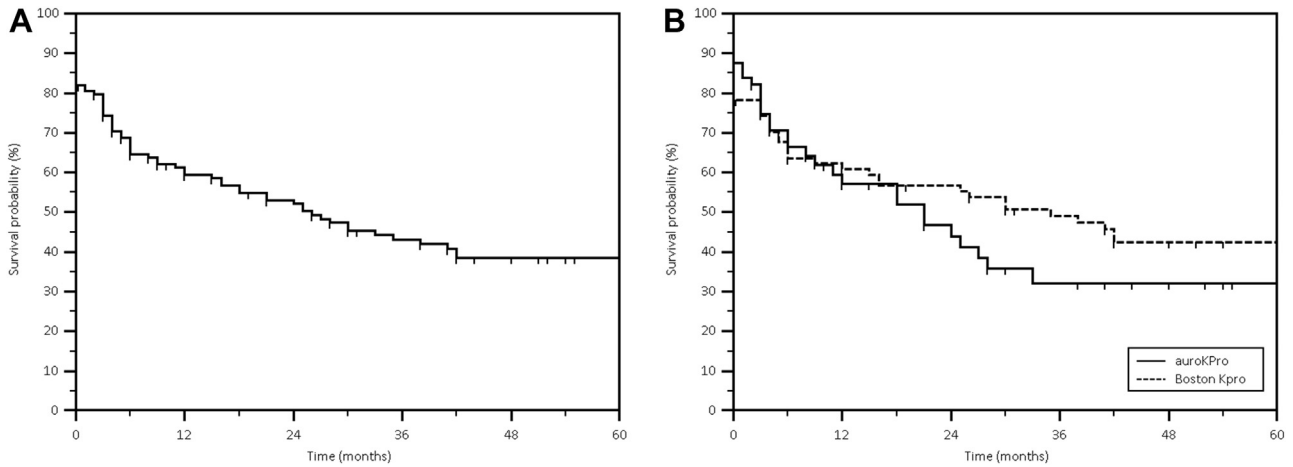

FIGURE 2. Kaplan-Meier survival curves show 5-year cumulative probability of functional recovery of 20/200 or better best corrected visual acuity of the Boston Type I keratoprosthesis and that of its low-cost alternative, the auroKPro device. Overall survival in 134 cases (A) and comparison between the survival curves of the Boston Type I keratoprosthesis group (B) (n = 78) and auroKPro group (A) (n = 56).

had extrusion and required tectonic keratoplasty with tarsorrhaphy. Of the 21 failures in the auroKPro group, 11 had penetrating keratoplasty and tarsorrhaphy; 3 had their prosthesis exchanged for another auroKPro or another type of Type 1 keratoprosthesis; and 7 eyes had extrusion and required tectonic keratoplasty with tarsorrhaphy.

Functional Recovery. Among those cases with a retained keratoprosthesis and still in follow-up, functional recovery was noted in 87.3% (n = 60), 91.1% (n = 49), 86.7% (n = 44), 92.5 % (n = 28), and 100% (n = 21) in the Boston Kpro group and in 90% (n = 40), 77% (n = 35), 75% (n = 29), 100% (n = 17), and 100% (n = 15) in the auroKPro group at 1, 2, 3, 4, and 5 years, respectively. A total of 25 (17 Boston Kpro and 7 auroKPro) eyes never achieved 20/200 or better vision despite a retained keratoprosthesis and clear medium, because of pre-existing undiagnosed optic neuropathy (10), macular scarring or degeneration (9), and amblyopia (6). Figure 2 shows the Kaplan-Meier survival curve demonstrating the cumulative probability of eyes retaining BCVA of 20/200 or better over a 5-year follow-up period. Log-rank test comparison showed that, at 5-years of follow-up, the Boston Kpro group had greater functional recovery than the auroKPro group (42.4 ± 6% vs. 32.2 ± 7%, respectively), however this difference was not statistically significant ($P = 0.345$).

TABLE 2. Postoperative Complications in Patients Undergoing Keratoprosthesis Implantation

Complication	Boston Kpro (%)	auroKPro (%)	*P* Value
New glaucoma	26 (33.3)	12 (21.4)	0.25
Extrusion	2 (2.5)	7 (12.5)	0.023
Sterile corneal necrosis/melt	15 (19.2)	12 (21.4)	0.754
Retroprosthetic membrane	11 (14.1)	14 (25.0)	0.11
Infectious endophthalmitis	5 (6.4)	6 (10.7)	0.446
Retinal detachment	5 (6.4)	4 (7.1)	0.960
Infectious corneal infiltrate/ keratitis	5 (6.4)	4 (7.1)	0.960
Sterile vitritis	1 (1.2)	3 (5.3)	0.199

Kpro = keratoprosthesis.

• **SECONDARY OUTCOMES:** *Intraoperative Complications*. Intraoperative problems with the device assembly were seen exclusively with the auroKPro. In 33 cases (59%) the locking ring did not insert properly at the first try and needed multiple attempts before it snapped onto the appropriate groove in the optical cylinder. In 9 cases (16%) assembly problems caused chipping of the posterior edge of the optical cylinder, and in another 4 cases (7.1%) the PMMA back plate cracked, and the device had to be replaced before implantation.

Postoperative Complications. Table 2 shows the postoperative complications observed during follow-up. The overall incidence of new postoperative glaucoma was 28.4% with similar incidence in both groups ($P = 0.25$). Extrusions were significantly more common with the auroKPro ($P = 0.023$), whereas the incidence of other complications such as retroprosthetic membranes, sterile corneal melting, sterile vitritis, microbial keratitis, and endophthalmitis was similar in both groups ($P > 0.05$) (Figure 3).

Cost-Benefit Analysis. The total cost of surgery was approximately US$1113 and US$326 for the Boston Kpro and the auroKPro, respectively. In the Boston Kpro group, 49 (glaucoma valve implantation = 19; vitreous biopsy + explantation + keratoplasty + tarsorrhaphy = 14, vitreous biopsy + keratoprosthesis exchange = 9; pars plana vitrectomy = 4; membranectomy = 2; tarsorrhaphy = 1) additional surgical procedures were performed at an average additional cost of US$266/patient over the course of the follow-up period. In the auroKPro group, 41 (glaucoma

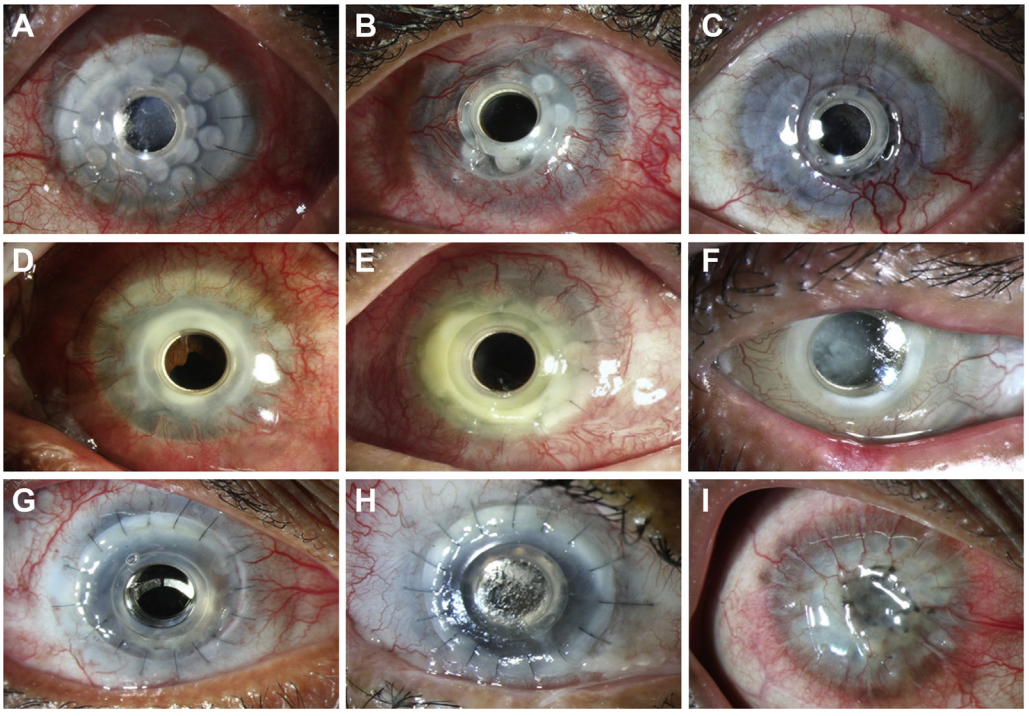

FIGURE 3. Clinical views of different postoperative complications of Boston Type I keratoprosthesis (Boston Kpro) and its low-cost alternative, the auroKPro: (A) retroprosthetic membrane in Boston Kpro; (B) sterile corneal melting without vitritis in the auroKPro device; (C) sterile corneal melting with vitritis in auroKPro; (D) bacterial keratitis in Boston Kpro; (E) fungal keratitis in Boston Kpro; (F) fungal endophthalmitis in Boston Kpro; (G) intraocular dislocation of the locking ring in the auroKPro; (H) contact lens deposits in the auroKPro; and (I) extrusion of the Boston Kpro.

TABLE 3. Outcomes of Different Series with Boston Type I Keratoprosthesis

Study	Year	Details	Number of Eyes	Mean Follow-up	Anatomical Outcome (Retention Rate)	Functional Outcome (Snellen Visual Acuity)
Zerbe et al.[5]	2006	Multicenter study from 17 surgical sites in the United States	141	Mean 8.5 ± 6.1 mo (range, 0.03–24 mo; median, 12 mo)	95%	≥20/200 (57%)
Aldave et al.[4]	2009	Retrospective review, single center in the United States	50	Mean 17 mo (range, 3–49 mo)	84%	≥20/100 1 y (75%) 2 y (69%)
Dunlap et al.[14]	2010	Retrospective case series from 2 centers in the United States	126	6 mo	Not reported	≥20/200 (54%)
Aldave et al.[6]	2012	Retrospective case series from 11 international centers	107	Mean 14.2 mo (range <1–48 mo)	82.2%	≥20/100 1 year (68%) 2 years (59%)
Ciolino et al.[15]	2013	Cohort study from 18 centers	300	Mean 17.1 ± 14.8 mo (range, 1 wk to >6.1 y)	93%	Not reported
Srikumaran et al.[3]	2014	Retrospective case series from 5 centers in the United States	158	Mean 46.7 ± 26 mo (range, 6 wk to 8.7 y)	74.8%	≥20/200, median,6.3 mo (70%)
Rudnisky et al.[16]	2016	Cohort study from 18 centers	300	Mean 17.1 ± 14.8 mo (range 1 wk to >6.1 y)	Not reported	≥20/200 at last reported follow-up (55%)
Goins et al.[17]	2016	Retrospective case series from 1 center in the United States	75	Mean 41.4 mo (range, 0.8–82.8 mo)	85.3%	≥20/400 at last reported follow-up (62.7%)
Shanbhag et al.[18]	2018	Systematic review including patients of 9 centers with LSCD due to chemical burns	106	Mean 24.99 ± 14 mo	88.9%	≥20/200 at last examination (64.1%)
Current study	2018	Boston Type I Kpro group	71 eyes	Mean 36.7 ± 29.3 mo (range 1–99 mo)	70.5%	≥20/200 1 y (87.3%) 2 y (91%)
Current study	2018	auroKPro group	55 eyes	Mean 17.1 ± 16.3 mo (range 1–60 mo)	62.5%	≥20/200 1 y (90%) 2 y (77.3%)

auroKPro = Aurolab Kpro; Kpro = keratoprosthesis; LSCD = limbal stem cell deficiency.

valve implant = 7; vitreous biopsy + explantation + keratoplasty + tarsorrhaphy = 18, vitreous biopsy + keratoprosthesis exchange = 3; pars plana vitrectomy = 7; membranectomy = 3; tarsorrhaphy = 3) additional surgical procedures were performed at an average additional cost of US$346/patient over the course of the follow-up period. The overall cost was US$1,379/patient for the Boston Kpro and US$672/patient for the auroKPro, respectively.

DISCUSSION

THIS STUDY COMPARED THE EFFICACY AND SAFETY OF THE auroKPro with that of the Boston Kpro in identical settings, in the hands of the same surgeons, and in similar indications. The study found that the auroKPro performed reasonably well, both in terms of anatomical survival and visual recovery over a period of 5 years, sufficient to be considered an alternative to the Boston Kpro; particularly in resource limited settings where affordability or availability are the main limiting factors for the use of the Boston Kpro. However, there are some caveats to these observations. Although the comparison of survival rates between the 2 groups did not reach statistical significance, the differences noted were clinically significant. Additionally, despite the fact that the initial cost of the keratoprosthesis implantation procedure was significantly lower, the following long-term maintenance costs were slightly higher in the auroKPro group.

In both groups, eyes with LSCD constituted approximately two-thirds of all cases. This was largely because of chemical burns, which has a higher incidence in developing countries like India than in the Western world.[13] Previous studies have shown that the Boston Kpro has a higher retention failure rate in cases with LSCD than with other common indications like multiple failed grafts.[6,14,15] However, a recent systematic review of Boston Kpro in severe chemical burns reported an anatomical survival of 88.9% and functional recovery of 20/200 vision in 64.1% at last follow-up.[16] Table 3 compares the outcomes of previously published large studies (>50 eyes) of the Boston Kpro with the findings of this current study.[3–6,17–20] The anatomical retention rates in this study are lower by 10 or more percentage points compared to that in other studies. The authors believe that the main reason for this was the lack of cornea specialists trained in keratoprosthesis surgery in India who could provide optimal aftercare. Simple maintenance procedures like replacement of the bandage contact lens, application of cyanoacrylate glue for an early pericylinder melting, or tarsorrhaphy for a persistent epithelial defect were not performed locally where the patient was followed, and patients were referred to the authors' institute. This critical delay resulted in patients presenting late with advance corneal graft melting or infection which then necessitated an explanation or exchange of the keratoprosthesis. This situation is likely to improve in the future as keratoprosthesis surgery becomes a regular part of corneal training in India and more cornea-fellows become competent in managing keratoprosthesis complications. The authors have also started conducting annual workshops to educate corneal surgeons who were not exposed to keratoprosthesis surgery during their fellowship training, to improve the level of post-keratoprosthesis care in the country.

The most common vision-threatening complication noted in this series was the occurrence of new glaucoma and progression in pre-existing glaucoma. Although other authors have recently proven the safety of concurrent Boston Kpro and a glaucoma drainage device implantation,[21,22] the present protocol was to implant glaucoma valves only if there was documented progression despite maximal medical therapy. A major concern that the authors had at the time of initiating the keratoprosthesis program in 2009 was the risk of infectious complications because of the tropical climate and higher prevalence of fungal keratitis in the general population. A lot of emphasis, therefore, was placed on antibiotic prophylaxis and replacement of bandage contact lenses with povidone-iodine lavage. The incidence of infectious endophthalmitis in this series was similar or even lower than those reported from other centers across the world.[23–26] Similarly, the rates of infectious keratitis (7% in both groups) was lower than that reported in other major series.[4,6,27,28]

A major strength of this study was the fact that it was a comparison between 2 similar devices used by the same surgeons in identical settings in a similar group of patients. An ideal study design would have been a prospective randomized controlled noninferiority trial; however, because the choice of the keratoprosthesis was made by the patient and not the surgeon, selection bias might have largely been controlled for as shown from the similarity of the two groups at baseline (which is the main aim of randomization). Because keratoprosthesis designs keep evolving over time, the authors excluded all other Boston Kpro designs that could have confounded the comparison. Therefore, the results of this study cannot be extrapolated to the new titanium "click-on" backplate design of the Boston Kpro or newer refinements in the design of the auroKPro. Because this was a retrospective study without a priori sample size calculation, some of the trends observed, such as lesser survival or poorer patients in the auroKPro group might have shown statistical significance with more cases. The authors acknowledge that, because they did not study the compliance rate in terms of missed clinic visits or discontinuity in medication usage, they are unable to comment on whether the 2 groups where comparable in this aspect or if compliance issues influenced the outcomes.

The auroKPro is a unique example of technology transfer between the United States of America and India, solely for humanitarian purpose of benefiting bilaterally cornea-blind patients. In this study, the authors found that the outcomes of the auroKPro were comparable to those of the Boston Kpro, albeit with some shortcomings. This would be analogous to a biological product that is biologically similar but not exactly biologically equivalent to the original molecule. However, the outcomes of the auroKPro were indeed encouraging, and the authors believe that it may have applicability in situations where affordability or availability of the Boston Kpro is a limiting factor. Based on the authors' experience with the auroKPro, the manufacturers have recently refined their design to match it more closely to that of the Boston Kpro. As the support system for keratoprosthesis surgery continues to improve in India, the authors are hopeful that the newer design of the auroKPro will perform even better in helping more and more affected individuals regain a blindness-free near normal life.

FUNDING/SUPPORT: ALL AUTHORS HAVE COMPLETED AND SUBMITTED THE ICMJE FORM FOR DISCLOSURE OF POTENTIAL CONflicts of Interest and none were reported. This work was funded by the Hyderabad Eye Research Foundation, Hyderabad, India. The funding organization had no role in the design or conduct of this research.

Conflict of Interest: The authors indicate no financial conflict of interest.

The authors thank the Massachusetts Eye and Ear Infirmary for providing the Boston Type I keratoprosthesis to Indian patients at a subsidized rate and creating a novel not-for-profit model of partnership with Indian manufacturers by means of the auroKPro.

REFERENCES

1. Avadhanam VS, Smith HE, Liu C. Keratoprostheses for corneal blindness: a review of contemporary devices. *Clin Ophthalmol* 2015;9:697–720.
2. Traish AS, Chodosh J. Expanding application of the Boston type I keratoprosthesis due to advances in design and improved postoperative therapeutic strategies. *Semin Ophthalmol* 2010;25(5–6):239–243.
3. Srikumaran D, Munoz B, Aldave AJ, Aquavella JV, Hannush SB, Schultze R, et al. Long-term outcomes of Boston type 1 keratoprosthesis implantation: a retrospective multicenter cohort. *Ophthalmology* 2014;121(11):2159–2164.
4. Aldave AJ, Kamal KM, Vo RC, Yu F. The Boston type I keratoprosthesis: improving outcomes and expanding indications. *Ophthalmology* 2009;116(4):640–651.
5. Zerbe BL, Belin MW, Ciolino JB. for the Boston Type 1 Keratoprosthesis Study Group. Results from the multicenter Boston type 1 keratoprosthesis study. *Ophthalmology* 2006;113(10):1779.e1–1779.e17.
6. Aldave AJ, Sangwan VS, Basu S, Basak SK, Hovakimyan A, Gevorgyan O, et al. International results with the Boston type I keratoprosthesis. *Ophthalmology* 2012;119(8):1530–1538.
7. Kim MJ, Bakhtiari P, Aldave AJ. The international use of the Boston type I keratoprosthesis. *Int Ophthalmol Clin* 2013;53(2):79–89.
8. Ament JD, Stryjewski TP, Ciolino JB, Todani A, Chodosh J, Dohlman CH. Cost-effectiveness of the Boston keratoprosthesis. *Am J Ophthalmol* 2010;149(2):221–228.
9. Sharma N, Falera R, Arora T, Agarwal T, Bandivadekar P, Vajpayee RB. Evaluation of a low-cost design keratoprosthesis in end-stage corneal disease: a preliminary study. *Br J Ophthalmol* 2016;100(3):323–327.
10. Venugopal A, Rathi H, Rengappa R, Ravindran M, Raman R. Outcomes after auro keratoprosthesis implantation: a low-cost design based on the Boston keratoprosthesis. *Cornea* 2016;35(10):1285–1288.
11. Reddy Pappuru RR, Tyagi M, Paulose RM, Dave VP, Das T, Chhablani J, et al. Role of diagnostic endoscopy in posterior segment evaluation for definitive prognostication in eyes with corneal opacification. *Am J Ophthalmol* 2017;176:9–14.
12. Basu S, Taneja M, Narayanan R, Senthil S, Sangwan VS. Short-term outcome of Boston Type 1 keratoprosthesis for bilateral limbal stem cell deficiency. *Indian J Ophthalmol* 2012;60(2):151–153.
13. Vazirani J, Nair D, Shanbhag S, Wurity S, Ranjan A, Sangwan V. Limbal stem cell deficiency-demography and underlying causes. *Am J Ophthalmol* 2018;188:99–103.
14. Salvador-Culla B, Kolovou PE, Arzeno L, Martínez S, López MA. Boston keratoprosthesis type I in chemical burns. *Cornea* 2016;35(6):911–916.
15. Sejpal K, Yu F, Aldave AJ. The Boston keratoprosthesis in the management of corneal limbal stem cell deficiency. *Cornea* 2011;30(11):1187–1194.
16. Shanbhag SS, Saeed HN, Paschalis EI, Chodosh J. Boston keratoprosthesis type 1 for limbal stem cell deficiency after severe chemical corneal injury: a systematic review. *Ocul Surf* 2018;16(3):272–281.
17. Dunlap K, Chak G, Aquavella JV, Myrowitz E, Utine CA, Akpek E. Short-term visual outcomes of Boston type 1 keratoprosthesis implantation. *Ophthalmology* 2010;117(4):687–692.
18. Ciolino JB, Belin MW, Todani A, Al-Arfaj K, Rudnisky CJ. for the Boston Keratoprosthesis Type 1 Study Group. Retention of the Boston keratoprosthesis type I: multicenter study results. *Ophthalmology* 2013;120(6):1195–1200.
19. Rudnisky CJ, Belin MW, Guo R, Ciolino JB. for the Boston type 1 Keratoprosthesis Study Group. Visual acuity outcomes of the Boston keratoprosthesis type 1: multicenter study results. *Am J Ophthalmol* 2016;162:89–98.
20. Goins KM, Kitzmann AS, Greiner MA, Kwon YH, Alward WL, Ledolter J, et al. Boston type 1 keratoprosthesis: visual outcomes, device retention, and complications. *Cornea* 2016;35(9):1165–1174.
21. Lenis TL, Chiu SY, Law SK, Yu F, Aldave AJ. Safety of concurrent Boston type I keratoprosthesis and glaucoma drainage device implantation. *Ophthalmology* 2017;124(1):12–19.

22. Netland PA, Terada H, Dohlman CH. Glaucoma associated with keratoprosthesis. *Ophthalmology* 1998;105(4):751–757.
23. Lee WB, Shtein RM, Kaufman SC, Deng SX, Rosenblatt MI. Boston keratoprosthesis: outcomes and complications: a report by the American Academy of Ophthalmology. *Ophthalmology* 2015;122(7):1504–1511.
24. Greiner MA, Li JY, Mannis MJ. Longer-term vision outcomes and complications with the Boston type 1 keratoprosthesis at the University of California, Davis. *Ophthalmology* 2011; 118(8):1543–1550.
25. Rishi P, Rishi E, Koundanya VV, Mathur G, Iyer G, Srinivasan B. Vitreoretinal complications in eyes with Boston keratoprosthesis type I. *Retina* 2016;36(3): 603–610.
26. Chew HF, Ayres BD, Hammersmith KM, Rapuano CJ, Laibson PR, Myers JS, et al. Boston keratoprosthesis outcomes and complications. *Cornea* 2009;28(9):989–996.
27. Wagoner MD, Welder JD, Goins KM, Greiner MA. Microbial keratitis and endophthalmitis after the Boston type 1 keratoprosthesis. *Cornea* 2016;35(4):486–493.
28. Kim MJ, Yu F, Aldave AJ. Microbial keratitis after Boston type I keratoprosthesis implantation: incidence, organisms, risk factors, and outcomes. *Ophthalmology* 2013;120(11): 2209–2216.