

# Eight-years Egyptian experience of Boston type I keratoprosthesis following failed penetrating keratoplasty or ocular surface disease

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## Abstract:

**PURPOSE:** To evaluate the outcome and complications after implantation of the Boston type I keratoprosthesis (Kpro) in two groups of eyes.

**METHODS:** We retrospectively reviewed records of 28 eyes with failed Penetrating keratoplasty (PKP) (Group A) and 31 eyes with severe ocular surface diseases who implanted Kpro. Follow-up was performed for a mean 37 months. Primary outcomes were Kpro retention and visual improvement, secondary outcomes included the occurrence of complications as endophthalmitis, retro-prosthesis membrane (RPM), intraocular pressure (IOP) abnormalities, posterior capsule opacification (PCO), graft thinning and extrusion.

**RESULTS:** Visual improvement was achieved in 20 eyes in Group A, and in 19 eyes in Group B. In group A, the prosthesis was retained in 25 eyes, while prosthesis retention in Group B was in 26 eyes. Group A had higher rates of PCO, high IOP, soft IOP, and graft thinning. Group B had higher risk of RPM, and endophthalmitis. Two eyes in Group A, and Five eyes in Group B required redo procedure.

**CONCLUSION:** The Boston Kpro type I is an effective procedure in eyes with high risk of keratoplasty failure and in severe ocular surface diseases, it has a high retention rate, higher in cases following failed PKP.

## Keywords:

Boston keratoprosthesis, extruded prosthesis, ocular surface disease, penetrating keratoplasty

## INTRODUCTION

The Boston keratoprosthesis (Kpro) (Woburn, Massachusetts eye and ear infirmary, United States) is a treatment option for eyes with repeated keratoplasty failure,<sup>[1]</sup> herpetic keratitis,<sup>[2]</sup> aniridia,<sup>[3]</sup> congenital corneal opacities as Peter's anomaly<sup>[4]</sup> as well as cicatrizing conditions as Stevens–Johnson syndrome,<sup>[5]</sup> ocular cicatricial pemphigoid (OCP), and ocular burns.<sup>[6]</sup>

The KPro Type I consists of three components: a front plate made of clear polymethyl methacrylate plastic, an 8.5 mm titanium back plate, and a locking ring of titanium. When assembled, it has the shape of a collar-button.<sup>[7]</sup> During implantation,

the device is assembled with a donor corneal graft positioned between the front and back plate which is then sutured in place in a similar technique to penetrating keratoplasty (PKP).<sup>[7]</sup>

A recent design is threadless; during assembly the front and back plates are snapped together with corneal tissue sandwiched in-between, which is used to suture the device to the eye.<sup>[8]</sup> Many studies demonstrated that the results of the procedure are encouraging as regards visual improvement and retention rate.<sup>[9]</sup> In the multicenter Boston type 1 Kpro study, 57% of eyes had final best corrected visual acuity (BCVA) better than 20/200 with 93% retention rate.<sup>[10]</sup>

In patients with refractory corneal diseases and multiple PKP failures, a repeat PKP will always

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have a poor prognosis because of the high rate of complications as graft rejection, concurrent infection, and residual leukoma, so these cases were good candidates for Kpro implantation.<sup>[1]</sup>

This study aims to study the results Kpro implantation in eyes with failed keratoplasty and in eyes with severe ocular surface diseases from patient records.

## METHODS

This retrospective study included the records of 59 eyes of 56 patients with high risk of keratoplasty failure, for whom Kpro type 1 had been implanted. These were performed at the Eye World hospital between December 2010 and July 2019. The study adhered to the tenets of the declaration of Helsinki. These were divided into two groups:

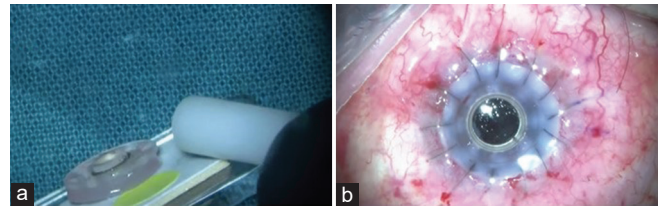
Group A: 28 eyes with single or multiple previously failed PKP, with no significant ocular surface diseases.

Group B: 31 eyes with severe ocular surface diseases as OCP, chemical burn, limbal stem cell deficiency, healed herpetic keratitis, and pediatric corneal opacities with no history of corneal surgeries.

Preoperative assessment: visual acuity measurement by Snellen's chart, intraocular pressure (IOP) measurement using Goldmann applanation tonometer or digital technique, anterior segment slit lamp examination, fundus examination. B-scan ultrasound and anterior segment optical coherence tomography (OCT) were performed for eyes with hazy fundus view. Visual evoked potential and electroretinogram were performed in patients with acuity Perception of light or less to assess retinal and optic nerve functions.

Consent for the intervention was obtained. Patients were advised about the importance of regular follow up and the possibility of other interventions. An information brochure was given for the patients, including the indications, technique, possible complications and the prognosis of the procedure.

All surgeries were done by a single experienced surgeon (I.O.). Surgical technique included initial assembly of the prosthesis with a fresh human donor corneal graft placed between the front and back plates. Subsequently, the recipient cornea is cut by a vacuum trephine. The KPro is applied at the site of trephined recipient cornea, followed by suturing with 10-0 nylon sutures to the recipient's bed [Figure 1]. Combined with the procedure, six eyes had cataract extraction, six eyes had removal of a displaced intraocular lens, ten eyes had pars plana vitrectomy and silicone oil injection, and one eye had silicone oil removal. Postoperatively, a special 18 mm bandage contact lens (HW70, H and W Co., Egypt) was applied. Postoperative medications included topical moxifloxacin/four hours for one month, and topical prednisolone 1%/20 h, then slowly tapered, with long-term artificial tear drops for eyes with dryness. Topical antibiotics and steroids were given twice daily maintenance. Fortified vancomycin eye drops (50 mg/ml) were prescribed for high



**Figure 1:** Keratoprosthesis view intraoperatively. (a) Keratoprosthesis applied to corneal graft and posterior locking ring is secured in place, (b) Keratoprosthesis sutured by 10.0 Nylon interrupted sutures at end of surgery

risk cases including eyes with severe active ocular surface disease and eyes with significant corneal thinning. Moreover, following intravitreal injection for endophthalmitis, topical vancomycin (50 mg/ml), ceftazidime (50 mg/ml) and in some cases, fluconazole (2 mg/ml) were prescribed.

Postoperative follow-up was performed on first postoperative day, 1<sup>st</sup> week, 2<sup>nd</sup> week, 1<sup>st</sup> month, 3<sup>rd</sup> month, and every 3 months for a mean of 37 months (10–96 months). During follow-up, assessment of visual acuity by Snellen's acuity chart, slit lamp examination of the prosthesis and the anterior segment, digital IOP assessment and fundus examination were performed. When necessary, anterior segment OCT, fundus photography, ultrasonography, OCT retinal and optic nerve examination were performed. The contact lens was exchanged, and the conjunctival sac was cleaned using 5% povidone iodine drops.

Statistical analysis was performed using IBM SPSS Statistical Package for Social Sciences, version 22 (SPSS, Inc., Chicago, IL, USA). Descriptive data were done as frequency. Comparison between groups was done as cross tabs- fisher exact test where independent *t*-test significance was set to be  $\leq 0.05$ . Spearman rho correlation test was used to test correlation between incidences between groups. Correlation was significant at 0.01 level.

Consent was obtained from seven patients to obtain and publish photographs of their eyes.

## RESULTS

Demographic characters of eyes in both groups are shown in Table 1. Figure 3a shows Perfectly centered kpro.

### Retention rate of the keratoprosthesis

The prosthesis was retained in 51 eyes (86.4%) and extruded in eight eyes (13.6%) over a mean 37 months (10–96 months) follow up. In Group A, the prosthesis was retained in 25 (89.3%) eyes, while prosthesis retention in Group B was in 26 (83.9%) eyes ( $P=0.709$ ). Table 2 shows the number of eyes with rejected grafts in both groups. Rejected prosthesis were managed by implantation of half-moon grafts in three eyes in Group A, while 4 eyes in Group B required the implantation of another Kpro 1.5 – 3 years after the first Kpro, one eye required Kpro redo twice, the first redo was 5 years following the primary procedure, and the second redo was 1.5 years later.

**Table 1: Demographic characters**

	Group A	Group B, mean±SD (range)	P
Age, mean±SD (range)	51.4±22.3 (9-79)	52.6±22.5 (5-86)	<0.832
Male gender (%)	15 (53.6)	19 (61.3)	0.605
Laterality (right eye) (%)	21 (75)	20 (64.5)	0.412
Preoperative VA	PL-0.01	PL-0.2	
Postoperative VA	No PL-0.6	No PL-0.6	

SD: Standard deviation, VA: Visual acuity

**Table 2: Graft rejections**

	Group 1	Group 2	P <sup>+</sup>
Graft rejection (%)	3 (10.7)	5 (16.1)	0.709
		4 eyes with OCP*	
		1 eye with stem cell deficiency	

\*OCP: Ocular cicatricial pemphigoid, +: Significant when  $P < 0.05$

### Visual outcome

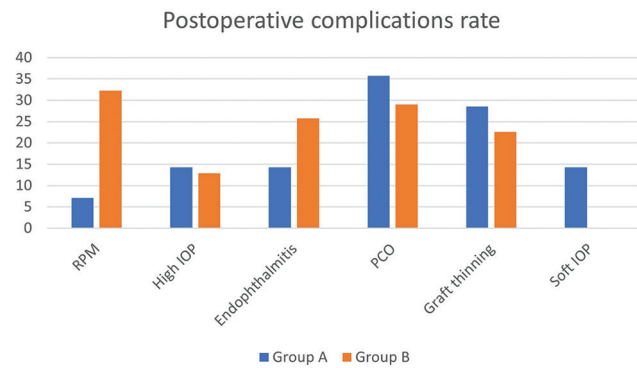
In Group A, 20 eyes had improvement of visual acuity (71.4%), ten eyes (35.7%) had a final visual acuity 6/60 or better. In Group B, final visual acuity was better in 19 eyes (61.3%), thirteen eyes (41.9%) had a final visual acuity 6/60 or better [Table 3]. The difference between different groups was not significant ( $P = 0.411$ ).

### Complications

Figure 2 shows the incidence of complications among both groups. Posterior capsule opacification (PCO) had occurred in 10 (35.7%) eyes in group A, and in 9 (29%) eyes in Group B ( $P = 0.781$ ). These cases underwent successful yttrium aluminium garnet (YAG) laser posterior capsulotomy, only one case required additional surgical capsulotomy 2 years following the YAG procedure [Figure 3b].

Retro-prosthesis membrane (RPM) is a dense membrane forming behind the Kpro, which is different from the faint PCO forming at the posterior lens capsule [Figure 3c]. Twelve eyes developed RPM, 2 (7.1%) eyes in Group A, and 10 (32.3%) eyes in Group B ( $P = 0.023$ ). Among these 12 eyes, four eyes had PCO ( $r = 0.102$ ,  $P = 0.441$ ), in three eyes both PCO and RPM happened coincidentally, only one eye had PCO one year before RPM. Moreover, eight of those 12 eyes had endophthalmitis ( $r = 0.477$ ,  $P < 0.001$ ), in five eyes RPM had developed within one month following endophthalmitis, the remaining three eyes had the development of RPM earlier before endophthalmitis. In three eyes YAG laser was successful to create a sufficient hole in the membrane without further intervention. The other nine eyes required surgical membranectomy, among these; one eye had the surgical membranectomy twice.

In group A, postoperative IOP rise had occurred in 4 (14.3%) eyes, similarly, 4 (12.9%) eyes in Group B had IOP rise ( $P = 0.844$ ). Among these eight eyes, four eyes had preoperative glaucoma, one eye had preoperative large leucoma adherent with associated peripheral anterior synechia (PAS). In two eyes the glaucoma happened following endophthalmitis.



**Figure 2:** Postoperative complications of keratoprosthesis implantation. RPM: retroprosthesis membrane, IOP: Intraocular pressure, PCO: Posterior capsular opacification. Group A has higher rates of high IOP, soft IOP, graft thinning, and PCO, where Group B has higher rates of graft thinning and endophthalmitis

Anti-glaucoma eyes drops were sufficient to control IOP in one eye, three eyes had undergone diode laser cyclophotocoagulation, two eyes required trabeculectomy and two eyes had Ahmed valve implantation.

On the other hand, postoperative hypotony (IOP < five mmHg) had occurred in 4 (14.3%) eyes in Group A, while no eyes in Group B had hypotony ( $P = 0.029$ ).

Postoperative endophthalmitis happened in 4 (14.3%) eyes in Group A, and in 8 (25.8%) eyes in Group B ( $P = 0.272$ ).

Endophthalmitis was treated by intravitreal injection of empirical vancomycin and ceftazidime in eight eyes with vitreous tap and culture. Four eyes required pars plana vitrectomy. Among these, five cases had no growth on culture results, which indicate sterile endophthalmitis. Seven cases had vision improvement, one eye had the same as initial acuity (HM), four eyes had final visual acuity no light perception [Figure 3d].

Eight (28.6%) eyes in Group A had graft thinning, while 7 (22.6%) eyes in Group B had graft thinning ( $P = 0.598$ ). These eyes required implantation of partial thickness half-moon grafts. Some eyes had eventual extrusion of the grafts, this involved two eyes in Group A, and two eyes in Group B [Figure 3e], for which Kpro redo was required.

### DISCUSSION

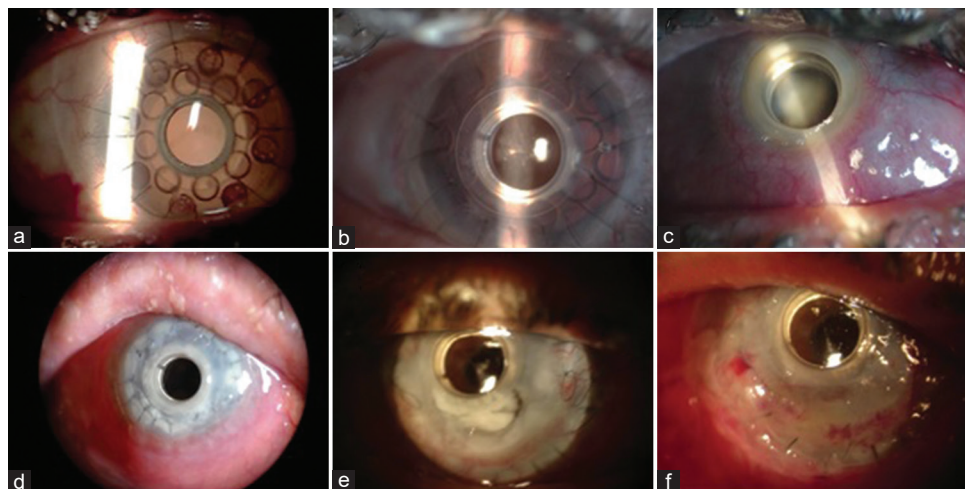
The Boston Kpro type I is a good choice for eyes with corneal opacities not fit for PKP. This study included 59 eyes, we compared the outcome of the procedure in two groups of eyes with different corneal pathology, this included eyes with failed PKP, in comparison with eyes having severe ocular surface diseases. We studied the visual outcome and the prosthesis retention, in addition to recording the postoperative complications.

The prosthesis was retained in 86.4% of eyes over a mean of 37 months follow up period, which indicates good

**Table 3: Visual outcome of the Kpro**

	Group A	Group B	P <sup>‡</sup>
VA improvement (%)	20 eyes (71.4)	19 eyes (61.3)	0.411
VA stable (%)	2 eyes (7.1)	5 eyes (16.1)	0.702
VA deterioration (%)	6 eyes (21.4)	7 eyes (22.6)	0.915
Causes of visual deterioration	Endophthalmitis (2 eye) Graft rejection (2 eye) Soft IOP (2 eye)	Graft rejection (4 eyes) Endophthalmitis (2 eyes) Glaucoma (1 eye)	

VA: Visual acuity, IOP: Intraocular pressure, <sup>‡</sup>Significant when  $P < 0.05$



**Figure 3:** Keratoprosthesis and some of postoperative complications. (a) Perfectly centered keratoprosthesis with good red reflex, (b) Keratoprosthesis with posterior capsular opacification, (c) Thick retroprosthesis membrane, (d) Graft infection, (e) Corneal graft melt, (f) Same patient with partial thickness half-moon grafts put in position

prosthesis retention. The retention rate was higher in eyes following failed PKP (89.3%) than in eyes with ocular surface diseases (83.9%); although the difference was not significant. This may be attributed to the autoimmune nature of these ocular surface diseases in addition to the associated dry eye. These eyes required topical treatment including preservative free prednisolone acetate 1%, sodium hyaluronate eye drops, and for five eyes cyclosporine 0.05% eye drops were added due to severe dry eye, in addition to systemic immunosuppressive therapy as cyclophosphamide and azathioprine. The patients were advised about the need for long term immunosuppressive therapy in addition to regular follow up.

In the Multicenter Boston KPro study<sup>[10]</sup> the retention rate was 95%. Bradley *et al.*<sup>[12]</sup> had retention rate of 83%. Santos *et al.*<sup>[13]</sup> described the long-term retention of the prosthesis in three eyes of patients who had the prosthesis implanted after acanthamoeba keratitis. The prosthesis was retained in the three eyes (100%).

Ciolino *et al.*<sup>[14]</sup> found that ocular surface disease secondary to an autoimmune cause had the lowest prosthesis retention (29% failure rate).

Kpro visual outcome was encouraging, where final visual acuity was better than the preoperative levels in about two thirds of eyes. Again, eyes of Group A had higher percentage of visual improvement (71.4%) than Group B (61.3%). This

is because Group B eyes had higher risk of sight threatening complications as endophthalmitis and RPM.

In their study, Samarawickrama *et al.*<sup>[15]</sup> found that only 46% of eyes had their vision improved, 31% maintained their preoperative BCVA and 23% had removal of their K-Pro or deteriorated in BCVA.

20.3% of our study eyes had developed RPM. It is a dense membrane forming at the back of the Kpro which obscures vision. Although many studies considered it as the most common complication, our patients had lower incidence of membrane formation. The incidence of membrane was significantly higher in Group B, which may be attributed to the chronic inflammatory nature of these diseases. In five eyes (41.7%), the development of the membrane had happened within one month following the onset of endophthalmitis, which was also more common in Group B. Previous studies had membrane risk ranging from 25% to 43%.<sup>[11,13]</sup> It is important to differentiate the RPM from the less dense PCO which happens at the posterior lens capsule.

In our study, eight eyes (13.6%) had postoperative glaucoma. This glaucoma was refractory as it required an intervention in seven eyes, topical antiglaucoma drops were sufficient for control in only one eye. The incidence of glaucoma in the current study is less than its incidence in previous studies. Fifty percent of these eyes had glaucoma prior to the implantation

of Kpro, one eye had a large leucoma adherent associated with PAS. Two eyes had developed glaucoma following endophthalmitis. Also, steroid responsiveness may have contributed to glaucoma development. In the multicenter Boston KPro study<sup>[10]</sup> 15% of eyes had developed postoperative glaucoma, while Bradley *et al.*<sup>[12]</sup> had 27% of eyes with postoperative glaucoma.

20.3% had endophthalmitis, in five eyes the inflammation was sterile. The incidence was higher in eyes with ocular surface diseases than Group A. Again, the chronic inflammatory nature of these diseases may account for the increased risk of endophthalmitis. Bradley *et al.*<sup>[12]</sup> have found that endophthalmitis incidence was 10%, while Chew *et al.*<sup>[16]</sup> have found that endophthalmitis incidence was 11%. In the multicenter Boston KPro study,<sup>[10]</sup> sterile vitritis had occurred in 5% of eyes. Robert *et al.*<sup>[17]</sup> showed that the incidence of endophthalmitis was 5.4%, the presence of pre-operative cicatricial disease was a risk factor for which. Abou Shousha *et al.* reported 31.2% incidence of endophthalmitis in Kpro eyes.<sup>[18]</sup>

In Group B, 8 eyes had developed endophthalmitis. Among these, five eyes had OCP, 2 eyes had corneal scarring secondary to herpetic keratitis, and 1 eye had Stevens-Johnson syndrome. Endophthalmitis followed bacterial pneumonia in one patient with herpetic corneal scarring. All of Group B eyes had severe dry eye, moreover, patients with OCP and Stevens-Johnson syndrome were on systemic immunosuppressive therapy, both could lead to poor wound healing which may raise the incidence of endophthalmitis. Following Kpro implantation in these eyes, fortified vancomycin eye drops (50 mg/ml) were included in the postoperative treatment. Due to the high rate of endophthalmitis in Group B eyes, further preventive measures could include the use of more broad spectrum topical antibiotics to provide wider range of protection against other possible organisms, frequently assessing the compliance of patients to postoperative drops, addition of frequent artificial tears drops and if needed topical cyclosporine, in addition to joint management of these patients with the immunologists who could advice to modify their immunosuppressive therapy for better control of their disease activity.

Ostheimer *et al.* reported graft thinning in 30% of cases following KPro implantation, 60% of these cases had extrusion of the KPro which required secondary KPro implantation.<sup>[19]</sup> In our study 15 eyes (25.4%) had graft thinning, half-moon grafts had been implanted to these eyes. Unexpectedly, Group A eyes had higher incidence of graft thinning than in Group B. Of these eyes four eyes had eventual graft extrusion.

## CONCLUSION

Kpro represent a good solution for eyes with high risk of Keratoplasty failure. It leads to visual improvement in 64%, and it has high retention (86%), both are slightly less in eyes with ocular surface disease. Has risk of some complications, such as PCO, RPM, endophthalmitis, graft thinning, high or soft IOP.

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Nil.

## Conflicts of interest

There are no conflicts of interest.

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