CASE REPORT

The First Study Investigating the Clinical Outcomes of Boston Keratoprosthesis Type I Implantation in Indonesia

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ABSTRACT

Introduction and Objective: Boston keratoprosthesis (Boston KPro) is an artificial cornea (collar button design) for a severely damaged cornea that is not suitable for penetrating keratoplasty (PKP). One main advantage of Boston KPro type I is there is no need to perform tarsoraphy. There were no previous studies investigating the clinical outcome of Boston KPro implantation in Indonesia, therefore we aimed to investigate the visual outcomes, device retention, and complications following Boston KPro type 1 keratoprosthesis.
Case Presentation: This study was a case series of 11 patients conducted at Jakarta Eye Center with 18 months follow up period. The inclusion criteria were patients with severe corneal diseases that are not amenable for PKP. We found that VA baseline were LP (±72.72%) and HM (27.27%) (mean VA baseline=2.51±0.14 logMAR or equal to HM – LP VA) which significantly improved to 1.09 ± 0.69 logMAR (equal to 6/60 Snellen, ±36.3% were near normal vision based on WHO criteria), p=0.007. Two cases (±16.7%) were still HM because of implant explantation with corneal melting. There were 80.5% retention rates at final follow-up and other complications were retroprosthetic membrane formation (26.7%), elevated IOP (13.9%), and sterile corneal stromal necrosis (17.8%).There was no endophtalmitis found in this study.
Conclusion: Boston K-Pro type 1 is a recommended option for patients with multiple corneal graft failure. It provides promising visual outcome with good retention rates. The number of Boston K-Pro type 1 implantations should be increased to counterbalance the corneal blindness burden in Indonesia.

Keywords : *Boston keratoprosthesis, severe corneal injury, multiple graft failure, Indonesia*

The first suggestion of using keratoprosthesis (a glass plate held by a silver ring) was proposed by Guillaume Pellier de Quengsy, a French ophthalmologist in 1789. [1] The first surgical case in a human was performed in 1855 with a quartz crystal implant developed by Nussbaum. Keratoprosthesis is a surgical procedure where a severely damaged cornea is replaced with an artificial cornea. There are several design of keratoprosthesis, for instance the Boston Keratoprosthesis (developed by Prof. Claes Dohlman, MD, PhD), the AlphaCor [2], and the osteo-odonto keratoprosthesis also known as the 'OOKP'

(originally described by Strampelli and modified by Falcinelli).[3]

After FDA approval in 1992, application of Boston KPro started increasing throughout the world. The Boston KPro consists of a fixed front plate fitting that is secured into place with a fenestrated back plate and locking titanium c-ring on top of a donor corneal rim. The entire device is then implanted into the host corneal bed in the traditional fashion of penetrating keratoplastic surgery.[4] Boston KPro has 2 designs of similar type: type I and type II. Moreover, type II is reserved for severe end-stage ocular surface disease desiccation and requires a permanent tarsorrhaphy. Boston KPro may offer visual rehabilitation for severe cornea diseases at high risk for failure with penetrating keratoplasty (PKP). One feature of Boston KPro optic is how it is independent to healthy corneal epithelium or precorneal tear film. This feature is particularly beneficial in eyes with chronic ocular surface disorders.[5]

Several publication about Boston KPro with large single-surgeon, single-center, and multicenter series have been published by North American surgeons [6, 7] establishing the indications for and outcomes of Boston keratoprosthesis implantation. However, publication in other countries only report small sample sizes, thus essentially nothing is known about the indications for and outcomes of Boston keratoprosthesis surgery outside of North America.[8, 9] The purpose of this study was to determine the outcome of the Boston KPro type 1 in the rehabilitation of severe ocular trauma.

PATIENTS AND METHODS

This study was a case series of 11 patients conducted at Jakarta Eye Center with 18 months follow up period. All surgical procedures were performed by one surgeon (Johan A. Hutauruk, MD) using Boston KPro type 1. The inclusion criteria were patients with severe corneal diseases that are not amenable for PKP (for instance: multiple graft failure, Stevens-Johnson syndrome (SJS), Ocular cicatrical pemphigoid (OCP) and chemical ocular burns).

All patients were maintained on topical antibiotic prophylaxis after surgery, and most patients were maintained in a bandage soft contact lens indefinitely, unless either contact lens placement or exchange was not possible because of anatomic factors such as the presence of symblepharons or an extensive tarsorrhaphy.

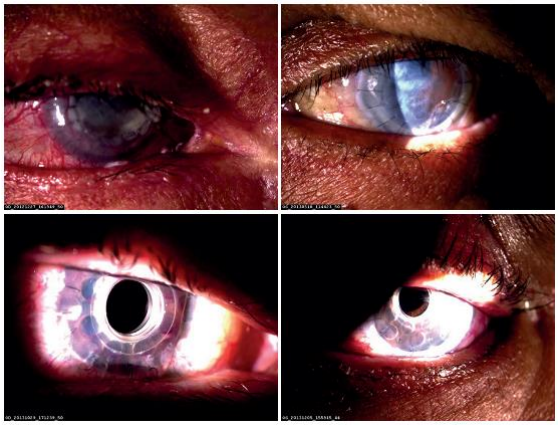

Fig 1. Preoperative and postoperative of Boston K-Pro type 1 procedure

Data were collected for each procedure regarding the preoperative characteristics of each eye, the surgical procedure(s) performed, and the postoperative outcomes. Data from postoperative outcomes consisted of visual acuity (VA) (at baseline and post implantation), retention rates and (if any) other ocular complications (such as: retroprosthetic membrane formation, sterile corneal stromal necrosis, and endophthalmitis). Statistical analysis was performed with *p* values less than 0.05 considered to be statistically significant.

RESULT

Visual Outcome

Visual acuity is calculated in logMAR (logarithm of the minimum angle to resolution). Preoperatively, baseline VA

were light perception (±72.72%) and hand movement (±27.27%) with mean BCVA was 2.51±0.15 logMAR. There was statistically significant improvement in vision throughout the entire postoperative course using Wilcoxon test analysis (**Error! Reference source not found.**).

Table 1. Visual outcome of Boston KPro 1

	Pre	Post	*p* value
Visual acuity (logMAR)	2.51±0.15	1.09±0.69	0.007*

All cases gained at least 1 line except 2 patients. Mean final BCVA significantly improved to 1.09 ± 0.69 logMAR. Fig 2 display the individual data of pre and post VA.

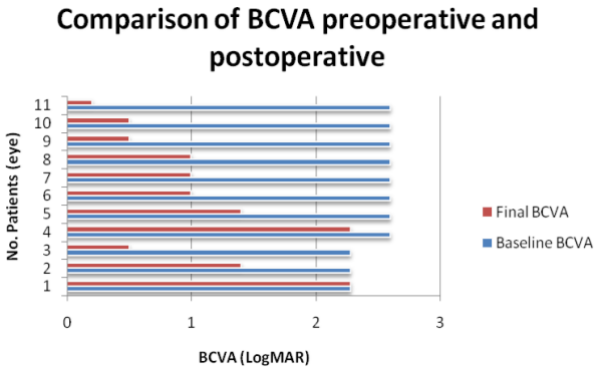

Fig 2. Comparison of BCVA preoperative and postoperative

Complication

A summary of major postoperative KPro-1 complications is provided in Table 2. Overall, 2 eyes had one or more complications. There were 80.5% retention rates at final follow-up and other complications were retroprosthetic membrane formation (26.7%), elevated IOP (13.9%), and sterile corneal stromal necrosis (17.8%). Retroprosthetic membranes occurred in 2 eyes (26.7%). The incidence of retroprosthetic membranes was associated with moderate vision loss. The most devastating complications led to device extrusion which happened in 2 eyes, one after 3 years and one after 4 years. Elevated IOP was found in 2 eyes and 1 eye had simultaneous tube implant with the Boston KPro. No endophthalmitis occurred in this study.

Table 2. Postoperative complication

Complication	Eyes (%)
Implant explantation with corneal melting*	2 (18.18)
Retroprosthetic membrane formation	2(26.7)
Elevated IOP**	2(13.9)
Sterile corneal stromal necrosis	2(17.8)
Endophtalmitis	0(0)

*One after 3 years and 1 after 4 years
**One patient had simultaneous tube implant with the Boston K-Pro

DISCUSSION

The present study provides an opportunity to evaluate visual outcomes, device retention, and complications after Boston KPro-1 implantation in eyes with a severely damaged cornea that is not suitable for penetrating keratoplasty.

Visual Outcome

Previous reports confirm that the Boston KPro 1 procedure provides visual rehabilitation in the early postoperative course that is commensurate with the excellent media clarity provided by the optic.[10] Mean final BCVA of this study was significantly improved from 2.51 ± 0.15 logMAR to 1.09 ± 0.69 logMAR, p=0.007. This result is similar to a multicenter study of 300 eyes with mean final value 0.89 ± 0.64 logMAR.[6] VA outcomes of Boston KPro implantation are quite promising, VA could reach 20/200 or better in more than 40% of patients [9, 11, 12] and being maintained for an average of 2 years.

Complication

Retention rates of Boston KPro are high, previously reported at 94% after 1 year and 89% after 2 years.[13] Outcome of our retention rate was 80.5% at final follow-up (mean 14.2 months), also similar with another study which was 79.2% retained

device at 1 year.[9] On the other hand, UCLA (University of California, Los Angeles) study had higher retention rate which was 91.7 % at 1 year follow up.[9]

Results of our study suggest retroprosthetic membrane complication is similar to other studies. The incidence of retroprosthetic membrane in clinical series is reported to be between 25% and 65% [9, 11, 14-16] (Table 3). It is believed inflammation is the most important factor for retroprosthetic membrane formation. Although retroprosthetic membrane is the most common complication of this procedure, the management of retroprosthetic membranes may require no treatment or are amenable to YAG laser treatment or surgical membranectomy.

Table 3. Comparison between study

	N eyes	Mean follow-up (months)	Retention rate	Complication
Zerbe et al. [11]	141	8.5	95%	RPM (35 eyes) High IOP (21 eyes)
Aldave et al. [14]	50	17	84%	RPM (22 eyes) PED (19 eyes)
Bradley et al. [16]	30	19	83.3%	RPM (13 eyes) High IOP (8 eyes) Endophtalmitis (3 eyes)

RPM= Retroprosthetic membrane formation; PED= Persistent epithelial defect; SCSN= Sterile corneal stromal necrosis

Devastating complications such as implant explantation with corneal melting occurred in this study. However it happened after 3 years and 4 years follow up. Furthermore, previous study also demonstrated the significantly increased risk of developing infectious keratitis, stromal necrosis, or both in the setting of a persistent corneal epithelial defect after keratoprosthesis surgery.[5] In addition, similar result was found in large study which demonstrate persistent epithelial defects affected almost 40% of patients.[14] The development of persistent epithelial defects was found to be a significant risk factor for sterile corneal stromal necrosis and infectious keratitis.[5] Moreover sterile corneal stromal necrosis was found in this study. Since pathogenic organisms were not identified, evidence-based management decisions are difficult to be made. Hence, all keratoprosthesis surgeons should be encouraged to evaluate for and aggressively manage all cases of persistent corneal epithelial defects postoperatively.

We found no endophtalmitis, compared to 9 of 101 eyes (International Study) and 1 of 94 eyes (UCLA).[7, 9] One retrospective consecutive case series of 126 eyes who had Boston KPro type 1 implantation revealed 3 cases (2.4%) who developed infectious endophthalmitis.[17]

CONCLUSION

Boston K-Pro type 1 is a recommended option for patients with multiple corneal graft failure. It provides promising visual outcome with good retention rates, with at least 83% at the mean follow-up after 14 months. All patients undergoing the procedure require close follow-up and ongoing maintenance. The most common complications are retroprosthetic membrane, stromal necrosis, and elevated IOP. Devastating complications of corneal melting were found, however there was no endophthalmitis found in this study. The number of Boston K-Pro type 1 implantations should be increased to counterbalance the corneal blindness burden in Indonesia.

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