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Long-term Outcomes of Boston Type 1 Keratoprosthesis Implantation

A Retrospective Multicenter Cohort

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Purpose: To study the long-term outcomes of Boston type 1 keratoprosthesis (KPro) surgery.

Design: Retrospective, multicenter case series.

Participants: A total of 158 eyes of 150 patients underwent KPro implantation at 5 participating tertiary centers in the United States between January 2003 and December 2006. Of those, 139 eyes of 133 patients were included in the analyses.

Methods: The medical records of consecutive adult patients who received KPro surgery were reviewed. All patients with at least 1 postoperative visit were retained in the outcomes analyses. In eyes in which a repeat KPro procedure was performed, only the outcomes of the initial surgery were analyzed.

Main Outcome Measures: Visual acuity (VA) outcomes, postoperative complications, and device retention.

Results: The mean follow-up was 46.7±26 months with all but 4 eyes having at least 6 months of follow-up. Preoperatively, only 10.8% of the eyes had VA of ≥20/200. Postoperatively, the VA in 70% of eyes improved to ≥20/200. The probability of maintaining VA of ≥20/200 at 7 years was 50%. The device retention rate was estimated at 67% at 7 years. The 7-year cumulative incidence of complications was 49.7% for retroprosthetic membrane formation, 21.6% for glaucoma surgery, 18.6% for retinal detachment, and 15.5% for endophthalmitis.

Conclusions: Although the risk for complications with longer follow-up seemed to increase, this large multicenter cohort demonstrates favorable outcomes with KPro, with a large number of patients achieving and retaining useful vision over a 7-year period. *Ophthalmology 2014;121:2159-2164 © 2014 by the American Academy of Ophthalmology.*

Over the past decade, the Boston type 1 keratoprosthesis (KPro) has emerged as a viable treatment option for eyes at high risk of failure with traditional donor penetrating keratoplasty. Since the US Food and Drug Administration granted marketing clearance in 1992, the KPro has undergone multiple design revisions to maximize the outcomes.[1] Although once considered a procedure of last resort, there has been a renewed interest in KPro implantation after the publication of multiple studies that have reported favorable outcomes.[2–7] As of August 2013, 8140 KPros have been implanted in patients worldwide: 5406 in the United States and 2734 abroad (Gelfand L, personal communication, 2013).

Thus far, the majority of the KPro studies reporting results have had a limited number of eyes or limited follow-up. Although short-term results suggest excellent visual outcomes with acceptable complication rates,[2–10] studies reporting long-term outcomes after this procedure are few,[5,7,10] and the follow-up periods are highly variable in these studies. It is currently unknown whether the complication rates will stabilize with time or significantly worsen after a certain length of time after surgery. To that end, we report the visual acuity (VA) outcomes, complications, and retention rates in the longest longitudinal cohort of patients after KPro surgery.

Methods

This is a retrospective, multicenter review of patients who underwent KPro implantation surgery between January 2003 and December 2006 by experienced surgeons at 5 tertiary referral centers in the United States (A.J.A., J.V.A., S.B.H., M.B., E.K.A.). The study was reviewed and approved by the institutional review board at each site in accordance with the Declaration of Helsinki and was Health Insurance Portability and Accountability Act compliant. Information from each eye/patient was collected retrospectively between May 2011 and April 2012 and entered in a uniform Microsoft Excel spreadsheet (Microsoft Corp, Redmond, WA) at each site. De-identified data were then reviewed by 2 of the authors (D.S. and B.M.) for completeness and consistency. Patients aged younger than 18 years of age at the time of surgery or without at least 1 postoperative follow-up visit were excluded from the analyses. Eyes that underwent KPro removal and subsequent repeat KPro implantation in the same eye (n = 19) during the specified time period were included only once

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in the study. For the retention analyses, these eyes were counted as failures. The VA was analyzed in 2 ways. In 1 analysis, all eyes regardless of KPro retention status were included, and the vision at the last visit was defined as the final vision. In a separate analysis, only the VA of the eyes that retained the initial KPro device were assessed. Demographic, clinical, and VA data were collected. One eye belonged to a patient with severe mental retardation such that VA could not be assessed and was excluded from the VA analysis but included in other outcomes assessments.

In regard to device retention analyses, eyes were divided into 5 categories based on the indication for KPro implantation and comorbid conditions: (1) ocular surface disease (OSD), which included eyes with severe keratoconjunctivitis sicca, cicatrizing conjunctivitis from chemical or thermal trauma, or autoimmune cause such as mucous membrane pemphigoid, Stevens–Johnson syndrome, or atopic disease; (2) congenital corneal abnormalities, including eyes with Peters' anomaly, aniridia, and congenital glaucoma; (3) infectious keratitis, including eyes with known or presumed viral, bacterial, fungal, or parasitic keratitis; (4) bullous keratopathy/corneal dystrophy, including isolated stromal or endothelial disorders such as Fuchs' endothelial corneal dystrophy, pseudophakic or aphakic bullous keratopathy, and keratoconus; and (5) unknown, including eyes with a diagnosis other than those listed or for which the original indication for keratoplasty was unknown. A subgroup analysis with respect to device retention was performed on the basis of these diagnostic categories.

The VA information was collected preoperatively, best ever, at 6 months after surgery and yearly thereafter. The VA was measured using the Snellen chart with manifest refraction. The VA was recorded as no light perception if the eye was enucleated during the follow-up. The final VA was the level of best-corrected vision measured at the last follow-up visit. The achievement and maintenance of a $\geq$20/200 VA and postoperative complication rates were estimated with Kaplan–Meier survival curves for the entire cohort. Eyes with a repeat KPro were censored from the Kaplan–Meier survival curves at the time of removal of the first KPro. Statistical analyses were performed using SAS software version 9.3 (SAS Inc, Cary, NC).

Table 1. Baseline Characteristics (n = 139 Eyes)*

Characteristic	
Mean age at the time of surgery (SD)	63.9 yrs (18.3)
Female (%)	54.7
Indication for surgery (%)	
Prior failed graft	72.6
Primary keratoprosthesis	27.3
Initial corneal diagnosis (%)	
OSD	23.0
Congenital corneal abnormalities	12.9
Known/presumed infectious keratitis	12.2
Bullous keratopathy/dystrophy†	35.3
Unknown	16.5
Lens status (%)	
Phakic	17.3
Aphakic	22.3
Pseudophakic	60.4
Glaucoma status (%)	
Known history of glaucoma	58.3
Previous glaucoma surgery (tube shunt, trabeculectomy, diode)	30.4
Retina status (%)	
History of retinal detachment	13.7
Other retinal disease (macular degeneration, epiretinal membrane, diabetic retinopathy)	19.4
Other associated conditions (%)	
Uveitis	5.8
Chronic hypotony	2.2
Length of postoperative follow-up (SD)	46.2 mos (26)
Median (IQR)	48.7 mos (23.8–66.1)
% Eyes with >4 yrs of postoperative follow-up	52.5

IQR = interquartile range; OSD = ocular surface disease; SD = standard deviation.
*The study group included 133 patients (139 eyes). Six patients had bilateral keratoprosthesis implantation surgery.
†Corneal dystrophy group included patients with Fuchs' endothelial dystrophy, keratoconus, and other stromal dystrophies.

Results

All included eyes in this study received a KPro device with a 7- or 8.5-mm fenestrated back plate. A total of 158 eyes of 150 patients underwent KPro implantation surgery for the first time between January 2003 and December 2006 at the mentioned sites. Of these, 13 patients (15 eyes) were aged younger than 18 years of age at the time of surgery, and 4 patients (4 eyes) had no postoperative follow-up data and thus were excluded from the analysis, leaving 139 eyes of 133 patients. The mean follow-up for all eyes included was 46.7±26 months (range, 6 weeks to 8.7 years) with more than half of the eyes (52.5%) having more than 4 years of follow-up. Fifteen eyes had 7 years of follow-up. All but 4 included eyes had a postoperative follow-up of at least 6 months. Two patients were lost to follow-up within 6 months after surgery, and 1 patient died of unrelated causes 2 months after surgery. One patient with severe OSD underwent explantation of the device because of sterile corneal necrosis 6 weeks after the implantation. These 4 eyes were still included in all of the analyses.

The baseline characteristics of the included eyes are summarized in Table 1. The mean age of the patients at the time of surgery was 63.9 years, with nearly equal men and women in the cohort. The indication for KPro surgery was prior donor graft failure in the majority of eyes (73%); 27% of the eyes underwent a primary KPro procedure without having received a previous donor keratoplasty. Approximately one-fourth (23.0%) of the eyes had OSD. More than half (58.3%) of the eyes had a known history of glaucoma. Approximately one-third of the eyes (30.4%) had received prior glaucoma surgery. One-third of the eyes had preexisting retinal disease, with 13.7% having a history of retinal detachment.

Seventy percent (97/139) of the eyes had at least 1 concomitant procedure at the time of the KPro procedure. Twenty-five percent of the eyes required an anterior vitrectomy, and more than one-fifth of the eyes (21%) underwent simultaneous glaucoma surgery.

Postoperative Outcomes

Visual Acuity. The distribution of vision preoperatively, best-ever postoperatively, and at last visit in all patients regardless of whether or not they were able to retain the initial KPro device is shown in Figure 1. The group included 138 eyes for the preoperative and best-ever postoperative VA. One mentally retarded patient who could not have vision measured accurately was excluded completely from vision analysis. Eight eyes with device removal with no post-removal acuity recorded were excluded from VA assessment at the last visit. Figure 2 shows the distribution of VA information in the 103 eyes in which the initial KPro device was retained. Preoperatively, 10.8% of the eyes had a best-corrected VA of $\geq$20/200. Postoperatively, 70% of the eyes