Predictors of Visual Outcomes Following Boston Type 1 Keratoprosthesis Implantation

SUMAYYA AHMAD, ESEN K. AKPEK, PETER L. GEHLBACH, KAREN DUNLAP, AND PRADEEP Y. RAMULU

• PURPOSE: To identify predictors of visual outcomes following Boston type 1 Keratoprosthesis (KPro) implantation.
• DESIGN: Retrospective chart review.
• METHODS: Data regarding preoperative clinical and demographic characteristics and postoperative course were collected. PATIENTS: Fifty-nine eyes of 59 adult patients who underwent KPro implantation between January 2006 and March 2012 at a single tertiary care center. MAIN OUTCOME MEASURES: Preoperative factors associated with all-cause and glaucoma-related loss of visual acuity from the best postoperative visual acuity noted.
• RESULTS: Fifty-two of 59 eyes (88%) achieved improved vision post implantation, with 7 eyes failing to gain vision as a result of pre-existing glaucoma (n = 4) or retino-choroidal disease (n = 3). Twenty-one eyes (21/52, 40%) maintained their best-ever visual acuity at last visit (mean follow-up period was 37.8 months). The likelihood of maintaining best-ever vision was 71% at 1 year, 59% at 2 years, and 48% at 3 years. Primary KPro implantation was associated with a higher likelihood of losing best-ever vision as compared to KPro implantation as a repeat corneal procedure (hazard ratio [HR] = 3.06; P = 006). The main reasons for postimplantation vision loss was glaucoma (12/31, 39%), and the risk of glaucomatous visual acuity loss was 15% at 2 years and 27% at 3 years. Prior trabeculectomy was associated with a higher rate of vision loss from glaucoma (HR = 3.25, P = .04).
• CONCLUSION: Glaucoma is the primary reason for loss of visual acuity after KPro implantation. Conditions necessitating primary KPro surgery are associated with more frequent all-cause vision loss. Prospective trials are necessary to better determine which clinical features best predict KPro success. (Am J Ophthalmol 2015;159:739–747. © 2015 by Elsevier Inc. All rights reserved.)

THE BOSTON KERATOPROSTHESIS TYPE 1 (KPRO) IMplantation is an increasingly frequent surgical procedure owing to the favorable outcomes reported by recently published series.[1–8] The US Food and Drug Administration cleared the device for use in 1992, and prior to 2004 fewer than 100 devices had been implanted. As of August 2013, there were 8140 devices implanted worldwide, including 5406 in the United States and 2734 abroad (L. Gelfand, Business Manager, Boston Keratoprosthesis, Massachusetts Eye and Ear Infirmary, written communication, September 28, 2013). Once considered a last resort, the KPro is now a viable alternative for many eyes following failure of traditional donor penetrating keratoplasty. Furthermore, there has been interest in expanding indications for KPro implantation as a primary procedure in patients with select corneal conditions.[3,9–11] Therefore, it is becoming increasingly important to understand the preoperative factors that predict favorable outcomes in order to optimize patient selection for this surgery.

Long-term visual outcomes and complication rates of KPro implantation were recently reported in large, retrospective, multicenter cohorts.[3,8,12] However, these studies did not assess preoperative clinical features that might predict favorable visual outcomes. As such, the ideal patients and disease conditions likely to benefit from KPro implantation have not been fully described.

Various complications are known to contribute to vision loss after KPro implantation. Owing to the changes in the design and postoperative care, device-related complications such as sterile corneal necrosis with extrusion of the KPro or endophthalmitis are less common issues, while glaucoma remains a serious concern for postoperative vision loss.[2,5,13] Although several prior reports have identified glaucoma as a cause of permanent vision loss post KPro implantation, preoperative features that might predispose eyes to glaucoma-related vision loss have not been studied.

Here, we analyze a single-institution cohort of patients who received KPro to identify preoperative factors predicting failure to gain vision postoperatively. Additionally, rates and predictors of all-cause and glaucoma-related postoperative vision loss are determined using survival analysis models run after several years of follow-up.

PATIENTS AND METHODS

THIS IS A RETROSPECTIVE REVIEW OF PATIENTS WHO underwent KPro implantation surgery between January 1,

Accepted for publication Dec 23, 2014.
From The Wilmer Eye Institute, Johns Hopkins University School of Medicine, Baltimore, Maryland
Inquiries to Dr Pradeep Y. Ramulu, The Wilmer Eye Institute, Johns Hopkins University School of Medicine, 600 N Wolfe Street, Maumenee B-110, Baltimore, MD 21287-9238; e-mail: pramulu@jhmi.edu

0002-9394/$36.00
http://dx.doi.org/10.1016/j.ajo.2014.12.024

2006 and March 1, 2012 at the Johns Hopkins Wilmer Eye Institute in Baltimore, Maryland. The study was reviewed and approved by the Johns Hopkins University Institutional Review Board in accordance with the Declaration of Helsinki and was Health Insurance Portability and Accountability Act compliant. A list of patients who underwent KPro procedures was created electronically using current procedural terminology (CPT) code 65770. The medical records were then reviewed to collect information regarding demographics, clinical features, and visual acuity. Patients under the age of 18 years at the time of surgery were excluded. Temporary keratoprosthesis procedures or permanent keratoprosthesis using devices other than Boston type 1 KPro were also excluded.

• **DATA COLLECTION AND ANALYSIS:** Data collection was completed as of February 28, 2014 to allow for maximum follow-up post implantation. Preoperative patient demographics and clinical characteristics including age, sex, ethnicity/race, indication for KPro implantation, etiology of corneal disease, number of prior corneal transplants, pre-existing retinal conditions, best spectacle-corrected visual acuity, details of topical glaucoma medications, history of prior glaucoma surgery, cup-to-disc (C:D) ratio, and intraocular pressure measurements were recorded. Concurrent procedures, intraoperative complications, and lens status were also documented. Visual acuity was measured with manifest refraction using a Snellen chart at every visit by a single technician. Slit-lamp examination was performed at each postoperative visit along with tactile intraocular pressure assessment and dilation. Complications were documented at month 1, month 6, year 1, and yearly up to year 6 (or last follow-up visit). The best-ever visual acuity recorded at any visit post implantation was used as the set point for determination of future vision loss.

Preoperative intraocular pressure was determined by Goldmann applanation tonometry. Preoperative C:D ratio was determined by examination at the slit-lamp examination using a 78-diopter hand-held lens. If the view of the optic nerve was poor, a 20-diopter lens and indirect ophthalmoscope were used. If no view was obtainable, than either the last C:D ratio documented preoperatively or the first postoperative documented C:D ratio was used.

Patient outcomes were categorized into 1 of 3 groups: (1) those who did not have any improvement in vision post implantation; (2) those who had a postoperative improvement in vision and remained within 3 lines (<0.3 logMAR) of their best-ever recorded visual acuity as of their last visit; and (3) those who had a postoperative improvement in vision and then suffered an irreversible loss of ≥3 lines of vision from their best-ever recorded visual acuity throughout the remainder of their follow-up. Three lines was used as the cut-off for worsening because of the variability of visual acuity measurements post KPro (often from reversible causes such as deposits on the optic of the device or contact lens). Counting fingers (CF), hand motion (HM)/light perception (LP), and no light perception (NLP) visual acuity were converted to logMAR 1.8, 2.3, and 2.6, respectively.[14] Acuity, rather than visual field, had to be used to capture glaucoma-related vision loss, as many patients did not perform well with visual field testing after surgery owing to limitations in vision (ie, inability to properly fixate or diffuse depression obscuring pattern defects). Additionally, many patients had sufficiently poor vision that testing with a size V stimulus was used, though there is no clear standard of progression available for this test.

Eyes with an irreversible 3-or-more-line drop from their best-ever visual acuity as of the last visit were then further characterized to determine the cause of this decrease in vision. Glaucoma was presumed to be the cause of visual acuity loss after other ocular issues, including retinal detachment, endophthalmitis, device-related pathology, macular disease, retinal vascular disease, nonglaucomatous optic neuropathy, or retroprosthetic membrane were excluded.

KPro retention was also considered an outcome, and eyes that underwent enucleation or tectonic penetrating corneal transplantation were counted as failures in these analyses. Eyes with KPro removal and repeat KPro, however, were not considered as failures in the retention analysis as long as the device was in situ as of last visit.

• **STATISTICAL ANALYSIS:** Statistical analysis was performed using Stata software version 13.1 (Stata Corp, College Station, Texas, USA). Logistic regression analyses were employed to identify features associated with failure to improve vision at any point post KPro implantation.

Kaplan-Meier survival analyses were subsequently used to identify factors associated with a higher rate of all-cause failure among eyes with initial gain in vision. Failure was first defined as an irreversible loss (owing to any etiology) of ≥0.3 logMAR from the best-ever vision. Cox proportional hazards models were used to determine the impact of preoperative characteristics on visual survival. Additional survival analyses were performed to identify risk factors associated with vision loss secondary to presumed glaucoma. Patients lost to follow-up and eyes failing secondary to other reasons, such as endophthalmitis or retinal conditions, were both administratively censored at the time of last follow-up or failure date, for analysis, when assessing glaucoma-related failure. The need for additional surgery (glaucoma procedure, vitrectomy, yttrium-aluminum-garnet (YAG) laser to retroprosthetic membrane, explantation of KPro when combined with repeat KPro implantation) was not considered an endpoint for failure unless accompanied by irreversible vision loss. Eyes that had removal of the device and reimplantation (n = 5) were included in the study during the concatenated time the device was in place.

Additional analyses were performed to evaluate visual outcomes at the last patient follow-up. In enucleated eyes and eyes that received a tectonic donor keratoplasty, the last follow-up was taken as the last visit in which the KPro was in place.