Type 1 Boston keratoprosthesis: outcomes at two Canadian centres

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ABSTRACT • RÉSUMÉ

Objectives: To report the outcomes of patients who underwent Boston type 1 keratoprosthesis (Kpro) surgery at the University Health Network (Toronto, Ont.) and the University of Ottawa Eye Institute (Ottawa, Ont.) between June 2008 and July 2013.

Design: Retrospective case series.

Participants: Forty-four eyes of 43 patients who underwent Kpro surgery.

Methods: A retrospective review was conducted of all Kpro procedures performed by 4 attending cornea surgeons. The preoperative characteristics and postoperative course of each patient were analyzed.

Results: In 31 eyes (70%), the primary indication for a Kpro was failed corneal transplantation. The remaining 13 eyes (30%) had Kpro as a primary procedure. In all eyes, preoperative visual acuity (VA) was 20/150 or worse, with 39 eyes (89%) having a VA of counting fingers, hand movement, or light perception. Mean follow-up time was 21 ± 12 months (range 12–57 months). The retention rate at the last follow-up was 95%. Best-achieved median VA was 20/100 (range 20/20 to no light perception [NLP]), with 37% of patients achieving a VA of >20/40 at some point during their postoperative course. At the last follow-up, median VA was 20/400 (range 20/30 to NLP). The 2 most common complications included retroprosthetic membrane formation (23 eyes, 52%) and elevated intraocular pressure (10 eyes, 23%). There were 5 cases (11%) of stromal melt and 1 case (2%) of infective keratitis.

Conclusions: This study demonstrates that Kpro improves VA in a majority of cases, and is a viable option in situations in which there is a poor prognosis for traditional penetrating keratoplasty.

Objet : Présenter les résultats obtenus pour des patients qui ont reçu une kératoprothèse Boston type 1 (KPro) au University Health Network (Toronto, Ontario) et à l'Institut de l'œil de l'Université d'Ottawa (Ottawa, Ontario) entre juin 2008 et juillet 2013.

Nature : Étude de cas rétrospective.

Participants : 44 yeux de 43 patients qui ont subi une chirurgie Kpro.

Méthodes : On a réalisé un examen rétrospectif de toutes les implantations de kératoprothèse Boston pratiquées par quatre chirurgiens traitants spécialistes de la cornée. Les caractéristiques préopératoires et la phase postopératoire de chaque patient ont été analysées.

Résultats : Pour 31 yeux (70 %), l'indication primaire était l'échec d'une greffe de cornée. Pour les 13 yeux (30 %) restants, la Kpro était pratiquée comme procédure primaire. Pour tous les yeux, l'acuité visuelle (VA) préopératoire était de 20/150 ou pire, et pour 39 yeux (89 %) l'AV se limitait au compte de doigts, à la distinction d'un mouvement de la main ou à la perception de la lumière. La durée moyenne du suivi a été de 21 ±12 mois (fourchette de 12 à 57 mois). Le taux de rétention au dernier suivi était de 95 %. La meilleure acuité visuelle médiane obtenue était de 20/100 (portée : 20/20 - aucune perception lumineuse); 37 % des patients ont atteint une AV de >20/40 à un certain moment durant la phase postopératoire. Au dernier suivi, l'AV médiane était de 20/400 (portée : 20/30 - aucune perception lumineuse). Les deux complications les plus courantes étaient la formation d'une membrane rétroprosthétique (23 yeux, 52 %) et l'élévation de la pression intraoculaire (10 yeux, 23 %). Il y a eu 5 cas (11 %) de fonte du stroma et 1 cas (2 %) de kératite infectieuse.

Conclusion : Cette étude démontre que la Kpro améliore l'acuité visuelle dans une majorité de cas et constitue une option viable dans des situations où le pronostic pour la kératoplastie transfixiante classique n'est pas bon.

The Boston keratoprosthesis (Kpro) is a synthetic corneal substitute that serves as a viable treatment option in instances in which a standard penetrating keratoplasty (PK) carries a poor prognosis.[1] It is the most widely used corneal substitute and is a treatment option in patients with repeat graft failure or those who are at risk for graft failure.[2]

Kpro provides a clear visual axis, and compared with a standard PK, it has been demonstrated to accelerate postoperative visual recovery.[3] It is composed of a polymethylmethacrylate (PMMA) optic and a back plate, with donor corneal tissue fastened in between. As in traditional PK, the combined Kpro and donor cornea complex is sutured into a trephined host recipient.

Although the use of Kpro has been quite limited in the past, several advances in the Kpro design have led to its increased use in recent years.[1] Some of these advances include the introduction of holes in the Kpro back plate,

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the addition of a titanium ring, and the development of a threadless assembly design. These modifications have led to a reduction in the incidence of some of the most significant complications associated with the surgery such as corneal melting, extrusion, and endophthalmitis.[1,4–6]

To date, only 1 other Canadian group has published its experience with Kpro.[7] Consequently, we sought to report the outcomes and complications of all Kpro surgeries performed by our institutions between January 2008 and July 2013. To the best of our knowledge, this series is one of the first datasets to describe patients treated exclusively with the newer threadless Kpro technology. It also represents the majority of Kpros implanted within the province of Ontario.

Methods

The study was an interventional case series, with institutional review board approval at both the Ottawa Hospital Research Institute (Ottawa, Ont.) and the University Heath Network (Toronto, Ont.). A retrospective review of all Kpro procedures performed by K.M.B., C.C.C., D.S.R., and A.R.S. between June 2008 and July 2013 was conducted. Patients with previous uncontrolled glaucoma were excluded from the study. Patients with <12 months' follow-up were excluded from the study.

The study included 44 eyes of 43 patients. Medical records were examined to identify patient demographics, indication for Kpro surgery, intraocular pressure (IOP) history, visual potential, and any relevant medical comorbidities. Medical records were also used to evaluate the intraoperative course and to identify postoperative complications.

The Boston type 1 Kpro was purchased from the Massachusetts Eye and Ear Infirmary (Boston, Mass.). Only the threadless design was used. All patients received the PMMA back plate. To determine whether Kpro was indicated, visual acuity (VA), tonometry, slit-lamp examination, and B-scan ultrasound were used. An A-scan was performed to measure axial length. A standard technique was used for implantation.[8] No concomitant limbal tissue was transplanted at the time of Kpro implantation. All patients had a 16-mm bandage contact lens (Kontur Kontact Lens, Hercules, Calif.) applied immediately after surgery. After the treatment, all patients were initially maintained on topical prednisolone acetate (1%), moxifloxacin, and vancomycin (14 mg/mL). There was slight variability in the duration that the specific surgeon maintained patients on vancomycin, though most patients used vancomycin for at least 3 months before switching to either polysporin or moxifloxacin.

Patients were followed postoperatively on day 1, week 1, month 1, and every 1–3 months thereafter. During each follow-up visit, a detailed ophthalmological examination was performed, including measurement of VA, IOP by digital palpation,[9] and slit-lamp biomicroscopy. All patients were followed by the glaucoma service. Glaucoma progression was determined using previously defined criteria by Talajic et al.[10] In brief, definite glaucoma progression was determined based on the presence of one of the following: Goldmann visual field defect widened by more than 15 degrees in any direction in a pattern characteristic for glaucoma; mean defect worsened by more than 10 decibels on a Swedish interactive threshold algorithm (SITA) fast; paracentral scotoma extended centrally with decreased VA and fixation loss; or glaucoma surgery required for high IOP on maximal medical therapy. Individuals who had raised IOPs but did not meet the definite criteria as defined by Talajic were classified as having "elevated IOP."

Descriptive and inferential statistics were performed. VA data were found not to follow a normal distribution, and as such, median values were reported and used in our analysis. All VA data points were converted to logMAR using standard protocols.[11] A logMAR score of 2, 3, 4, or 5 was assigned to patients with counting fingers, hand motion, light perception, and no light perception (NLP) VA, respectively. Pre- and postoperative VA data were compared using the nonparametric Wilcoxon signed-rank test. Kaplan–Meier survival analyses were also performed.

Results

A Boston type 1 KPro was implanted in 44 eyes of 43 patients. Thirty of these surgeries were performed at the University Health Network (Toronto, Ont.) and 14 were performed at the University of Ottawa Eye Institute (Ottawa, Ont.). The median age was 59 years (range 1–91 years) and 49% of the patients were male. The 8.5-mm-diameter back plate was used in 36 eyes, and the remaining 8 eyes (7 adult and 1 paediatric) received the

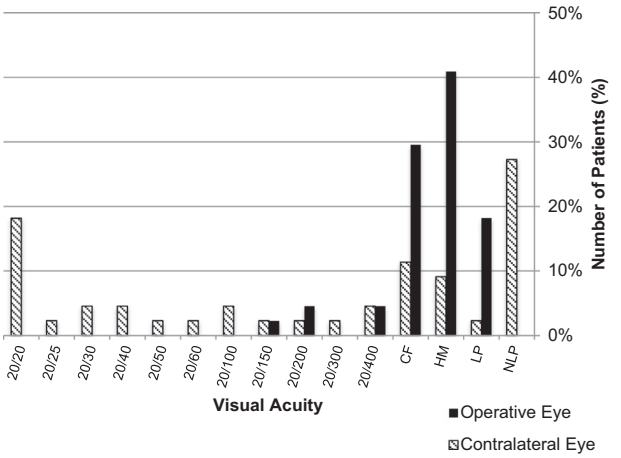

Fig. 1—Preoperative visual acuity of both the operated and contralateral eye of patients undergoing Kpro surgery. CF, counting fingers; HM, hand motion; LP, light perception; NLP, no light perception.

Table 1—Preoperative diagnosis of eyes implanted with a Boston type 1 keratoprosthesis

Preoperative diagnosis	Eyes, n (%)
Failed corneal transplantation	31 (70)
Herpetic keratitis	6 (14)
Herpetic keratitis	6 (14)
Aniridia	3 (7)
Chemical burn	3 (7)
Corneal ulcer	3 (7)
Corneal dystrophy	2 (5)
Other*	7 (16)
No prior corneal transplantation	13 (30)
Chemical burn	4 (9)
Primary LSCD	3 (7)
bacterial keratitis	2 (4)
Aniridia	1 (2)
herpetic keratitis	1 (2)
thermal trauma	1 (2)
SJS	1 (2)

LSCD, limbal stem cell deficiency; SJS, Stevens–Johnson syndrome.

*Other includes aphakic glaucoma, congenital ectodermal dysgenesis, graft-versus-host disease, iridocorneal endothelial syndrome, microcornea and chronic angle closure glaucoma, pseudophakic bullous keratopathy, pseudophakic edema, and thermal injury.

7.0-mm back plate. A smaller back plate was preferred in certain instances because of ease of suturing. Preoperative best-corrected visual acuity (BCVA) ranged from 20/150 to light perception, with 89% of patients having a BCVA of counting fingers, hand motions, or light perception. Median VA in the contralateral eye was counting fingers (range 20/20 to NLP) (Fig. 1).

The primary indication for a Kpro was corneal graft failure in 31 eyes (70%). The remaining 13 eyes (30%) had a Kpro implanted as a primary procedure. In 8 of these eyes (62%), either primary or secondary limbal stem cell deficiency was an underlying etiology. The mean number of prior PKs for the total group was 1.6 ± 1.4, and for the subgroup with a history of failed PK, the average was 2.2 ± 1.2 (range 1–6). The decision to proceed with Kpro rather than a traditional PK was because of the presence of 1 or more comorbid conditions known to increase the risk of graft failure, such as limbal stem cell deficiency or corneal vascularization. A list of preoperative diagnoses for both groups is presented in Table 1. A known history of glaucoma was present in 19 eyes (43%). Nine of the patients had undergone surgical management (6 with glaucoma valve implantation and 3 with trabeculectomy), whereas the remaining 10 were medically managed. In all instances, these patients' pressures were below 22 mm Hg at 1 month before surgery. Six eyes (14%) were hypotonous preoperatively.

Table 2—Concomitant procedures performed during keratoprosthesis surgery

Concomitant procedure	Patients, n (%)
Intraocular lens removal	21 (48)
Anterior vitrectomy	19 (43)
Synechiolysis	12 (27)
Cataract extraction	7 (16)
Iridectomy	3 (7)
Posterior vitrectomy	3 (7)
Intravitreal bevacizumab injection	1 (2)

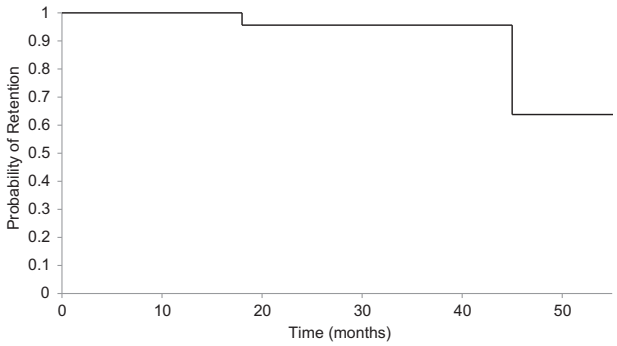

Fig. 2—Kaplan–Meier survival curve demonstrating the cumulative retention rate of eyes with keratoprosthesis implantation.

The implantation of Kpro was uncomplicated in all but 1 case, where the patient suffered a choroidal hemorrhage. The most common concomitant procedures were intraocular lens (IOL) removal (48%), anterior vitrectomy (43%), synechiolysis (27%), and cataract extraction (16%). In total, 64% of participants were pseudophakic, and the IOL was removed in 47% of cases (2 anterior chamber IOL and 2 dislocated posterior chamber IOL). There was 1 case of capsular rupture.

Table 2 contains a summary of all concomitant procedures. Of the 44 Kpros implanted, 29 were aphakic and 15 were pseudophakic. The decision to use either pseudophakic or aphakic was largely a reflection of different practice patterns. Some surgeons preferred to leave an intact posterior chamber IOL as it was believed that it may act as a barrier to the vitreous, whereas others believed that the presence of an IOL may crowd the anterior segment and create an interface for retroprosthetic membrane (RPM) formation. Follow-up at time of analysis ranged from 12.0 to 57 months (mean 21 months, SD 12 months). At the last follow-up, Kpros had been retained in all but 2 of the eyes (42 [95%]). These Kpros were removed postoperatively at 18 and 45 months. Both Kpros were removed secondary to severe corneal melting around the implant (Fig. 2).

During their postoperative course, VA improved in 79% of patients. Not all patients maintained this improvement, however. At the last follow-up, VA improved in 24 (56%) patients, 13 (30%) had their VA remain the same, and 6 (14%) had a decrease in their vision. The youngest patient in the study was 1 year old at the time of Kpro surgery, and as a result, VA data could not be obtained. Kaplan–Meier survival analyses were used to evaluate the visual outcomes. In the first analysis, a postoperative BCVA worse than preoperative BCVA was considered a failure (Fig. 3A). In the second analysis, a postoperative BCVA worse than 20/200 was considered a failure (Fig. 3B). At 24 months, the probability of postoperative BCVA better than preoperative BCVA was 0.80. At 24 months, the probability of post-op BCVA worse than 20/200 was 0.36. Median best-achieved VA was 20/100, with

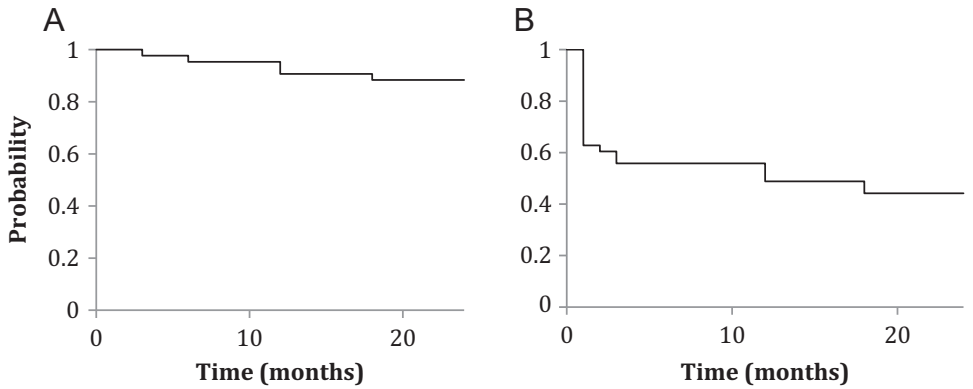

Fig 3—Kaplan–Meier survival analyses. Panel (A) considers failure as postoperative BCVA worse than preoperative BCVA. Panel (B) considers failure as postoperative BCVA worse than 20/200. BCVA, best-corrected visual acuity.

16 (37%) patients achieving a VA of >20/40 and 30 (70%) having a VA of >20/200 at some point in their postoperative course. Median VA was 20/150 (range 20/30 to NLP) at 3 months' follow-up and 20/300 at 6 months (range 20/30 to NLP). At the last follow-up, median VA was 20/400 (range 20/30 to NLP) (Fig. 4). The Snellan VA values were converted to logMAR and plotted over time. Given that the values were non-normally distributed, median values were reported. Preoperatively, the median VA was 3.0 and the greatest improvement was noted at 2 months (0.85). At the last follow-up, the median VA decreased to 1.15. The non-parametric Wilcoxon signed-rank test revealed significant visual improvement at 1, 2, 3, 6, 12, 18, and 24 months postoperatively when compared with preoperative BCVA values (Fig. 5).

A majority of patients (41 [93%]) developed 1 or more postoperative complications. The most common complications were RPM formation (23 [52%]), elevated IOP >25 (10 [23%]), and epithelial defect and glaucoma progression (7 each, 15% each) (Table 3). For the patients with an epithelial defect, 6 were managed with tarsorrhaphy and 1 spontaneously resolved. In 3 instances, the epithelial defect progressed to melt. Unsurprisingly, all 3 of these patients had chemical burns as an underlying etiology. The most commonly performed interventions were YAG membranectomy (30%), tarsorrhaphy (16%), and Nd:YAG (neodymium-doped yttrium aluminium garnet) capsulotomy (14%). A list of all interventions is given in Table 4. For the 5 patients suffering from stromal melts, 2 were treated with amniotic membrane grafting, whereas the other 3 were treated with lamellar corneal grafts. The amniotic membrane grafting was sufficient to control melting and extrusion; however, 2 of the lamellar keratoplasties (LKP) failed. In these cases, repeat LKP was performed with additional coverage using harvested oral buccal mucosa. A detailed description of this surgical technique, as well as a summary of the postoperative course for these patients, has been described elsewhere.[12] Additionally, collagen crosslinking was successfully used in 1 patient to control a microbial keratitis and associated corneal thinning.

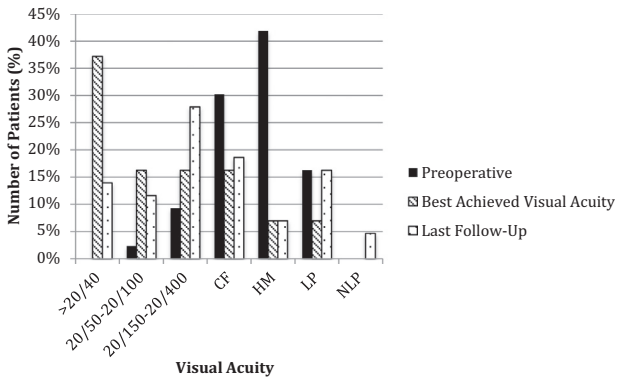

Fig. 4—Visual acuity of eyes preoperatively and postoperatively. CF, counting fingers; HM, hand motion; LP, light perception; NLP, no light perception.

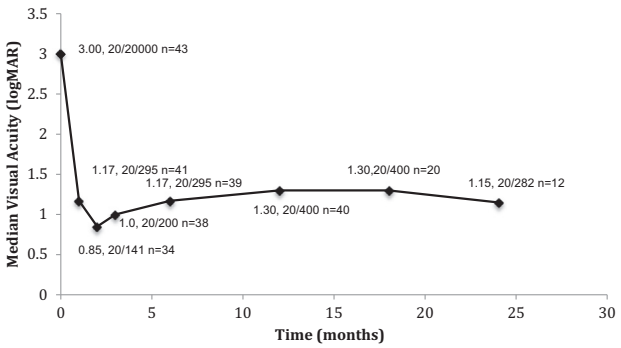

Fig. 5—Median visual acuity (logMAR) over time. The data indicate significant visual improvement at all time points when compared with BCVA preoperatively (1 month, $p < 0.0001$; 2 months, $p < 0.0001$; 3 months, $p < 0.0001$; 6 months, $p = 0.0001$; 12 months, $p = 0.0048$; 18 months, $p = 0.0078$; 24 months, $p = 0.0164$). The 0 time point corresponds to preoperative BCVA. BCVA, best-corrected visual acuity.

Table 3—Summary of all postoperative complications experienced by keratoprosthesis patients

Postoperative complication	Patients, n (%)
Retroprosthetic membrane	23 (52)
Elevated intraocular pressure	10 (23)
Epithelial defect	7 (16)
Glaucoma progression	7 (16)
Posterior capsule opacification	6 (14)
Prolonged conjunctival inflammation	6 (14)
Stromal melt	5 (11)
Vitreous hemorrhage	5 (11)
Corneal infiltrate	4 (9)
Hypotony	3 (7)
Retinal detachment	3 (7)
Sterile vitritis	3 (7)
Uveitis	2 (5)
Other*	10 (23)

*Other includes cystic macular edema, endophthalmitis, infectious keratitis, persistent disc swelling, phthisis, and significant vitreous opacities.

Discussion

The results of this study confirm that good patient outcomes can be achieved with the threadless Kpro design. With an average follow-up time of 20 ± 13 months, our patients experienced an excellent anatomic retention rate of 95%, a value that is comparable to other Kpro case series (83%–100%).[1,3,7,13–16]

Visual acuity

Kpro has been shown to offer enhanced visual rehabilitation compared with standard PK.[3] This is consistent with our data because, of the 34 patients whose VA improved, 22 (65%) obtained their "best achieved visual acuity" within the first 2 months postoperatively.

Despite the initial visual enhancement, in many instances, Kpro failed to provide sustained visual improvement. For instance, although 37% of patients obtained a vision of ≥20/40 during their postoperative course, only 14% of patients retained this quality of vision at the last follow-up. The number of patients with a final vision ≥20/40 is comparable to data collected by Robert et al.,[7] (11%) although it is somewhat lower than the values reported at other centres (18%–23%).[1,3,13–15]

Table 4—Summary of all postoperative procedures completed on keratoprosthesis patients

Postoperative procedure	Patients, n (%)
Nd:YAG membranectomy	13 (30)
Tarsorrhaphy	7 (16)
Nd:YAG capsulotomy	6 (14)
Pars plana vitrectomy	5 (11)
Surgical membranectomy	4 (9)
Lamellar corneal graft	3 (7)
Repair of retinal detachment	3 (7)
Amniotic membrane grafting	2 (5)
Kpro removal	2 (5)
Oral buccal mucous membrane allograft	2 (5)
Pars plana Ahmed glaucoma valve implantation	2 (5)
Vitreous tap	2 (5)
Collagen crosslinking	1 (2)
Drainage of choroidal hemorrhage	1 (2)
Eye examination under anaesthesia	1 (2)

Overall, 79% of patients showed some postoperative visual improvement. Although 18 patients (42%) in our study had a VA at the last follow-up that was either the same or worse than their preoperative vision, it is important to note that many of these patients were identified as having limited visual potential before surgery. Patients 1–3 had prephthisical eyes, 2 of which underwent concurrent Kpro surgery in combination with silicone oil and pars plana vitrectomy. Chan et al[17] have shown that although this therapy is highly successful in maintaining ocular structure and preventing phthisis, in most instances, the visual benefits are modest. Thus, this surgery was performed in an attempt to maintain the minimal vision possessed by these monocular patients (counting fingers and light perception). Patients 4 and 5 had aniridia, and as a result, their visual potential was limited due to the macular and optic nerve hypoplasia that is often associated with this disease. Patient 6 was not expected to make substantial visual improvement as he had silicone oil placed in his eye as a consequence of concomitant retinal disease. Patient 7 had a preoperative history of glaucomatous optic neuropathy and recurrent retinal detachments. Patient 8 had a preoperative history of chronic angle closure glaucoma. Patient 9 failed to show any improvement in VA due to the development of optic neuritis postoperatively. Although it might seem counterintuitive to offer Kpros to patients with limited visual potential, it is important to note that most of these patients were bilaterally legally blind and that Kpro was offered in an effort to provide some functional vision.

Postoperative complications

At the last follow-up, 93% of patients had at least 1 postoperative complication related to Kpro, and 20% required additional surgery. As seen in Table 3, 51% of patients developed an RPM. This was the most common postoperative complication and required intervention in 57% of cases. The rate of RPM formation is consistent with data produced in other series (26%–65%).[1,14,18,19] In a recently published large cohort study, it was determined that patients who had a history of infectious keratitis were twice as likely to develop an RPM, whereas chemical injury was found to be almost protective, with less than 1/3 of patients developing this complication.[18] This was not our experience. Although individuals with chemical injury achieved good visual outcomes at the last follow-up, 4 of 6 developed an RPM. Conversely, only 4 of 10 with a history of infectious keratitis developed this complication. That said, our sample size was too small to draw definitive conclusions.

Glaucoma remains one of the most challenging postoperative complications to address. A history of glaucoma was present in 43% of eyes. Postoperatively, 10 eyes (23%) experienced elevated IOP. Glaucoma progression occurred in 7 eyes (16%). These findings were in line

with previously published glaucoma complication rates (IOP elevation 15%–38%, glaucoma progression 7%–14%).[1,7,13,19] In 1 large published series of 167 eyes, the incidence of preoperative glaucoma was 66%, and 26% went on to develop de novo glaucoma afterwards.[20] Postoperative surgical management for glaucoma was conducted on 3 patients in our series. The remaining patients with high IOP were managed medically and were seen in conjunction with our glaucoma service. Recent literature suggests that aggressive preoperative IOP control may lead to much better outcomes in this demographic.[21] An inability to measure IOP postoperatively by means other than digital palpation makes treatment of this patient population difficult and stresses the importance of rigorous follow-up.[9,22]

Stromal melt occurred in 5 of our patients (11%), a rate that is comparable to what has been reported at other centres (6%–18%).[4,23] Given that stromal melt has been strongly associated with conditions known to induce chronic conjunctival inflammation, it was unsurprising that 4 patients had chemical burn as an underlying etiology.

Collagen crosslinking was used in 1 patient who developed melting of the cornea adjacent to the Kpro optic because of an infectious corneal ulcer. The protocol used was recently described.[24] The epithelial defect resolved, and the melting process stabilized within weeks. To this end, KMB is now crosslinking donor corneal tissue before using it in surgery as part of the Kpro complex. Although still controversial, recent evidence suggests that this technique may potentially benefit patients at high risk of melting.[25]

Given that the VA outcomes and complication rates are both in line with what has been previously reported by groups using older Kpro technologies, the theoretical advantage of threadless design stems largely from the fact that it is easier for the surgeon to assemble and that it does not cause shredding damage to the posterior graft membranes. Consequently, it is unsurprising that we did not notice any relative improvement when compared with other series using the older design.

Conclusions

The outcomes of Kpro surgery at the University Health Network and University of Ottawa Eye Institute are comparable to what has been published by other leading international centres. The retention rates of Kpro were excellent and VA could be improved in the short- to middle-term periods of follow-up. Although postoperative complications were frequent, this was to be expected given the complex preoperative comorbidities that many of our patients faced. Despite these complications, Kpro offers the potential to improve sight in a patient population with no other options.

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