

The Boston Keratoprosthesis

An update on recent advances.

BY MICHAEL A. KLUFAS, ScB, AND CHRISTOPHER E. STARR, MD

Standard corneal transplantation or penetrating keratoplasty (PKP) is a well-established treatment for some forms of corneal blindness, as evidenced by the 41,652 corneal transplants performed in the United States in 2008.¹ The procedure typically is well tolerated, and it successfully restores vision to many patients. In some high-risk groups, however, the results are often poor. The low success rate of PKP in patients with repeat graft failures,² cicatrizing diseases such as Stevens-Johnson syndrome (SJS), ocular cicatricial pemphigoid (OCP)³ and other autoimmune diseases, alkali burns,⁴ herpetic neurotrophic keratopathy,⁵ and some pediatric corneal opacities⁶ has led to the development of artificial corneas or keratoprostheses.^{3,7}

The idea of replacing a severely opacified cornea with artificial material was first proposed by the French ophthalmologist Guillaume Pellier de Quengsy^{8,9} in 1789, and it has evolved over the last 2 centuries. Today, many keratoprostheses and synthetic corneas are in development, but only three are commonly used in practice: the Boston Keratoprosthesis (types I and II) or KPro (Massachusetts Eye and Ear Infirmary, Boston, MA), the AlphaCor artificial cornea (Addition Technology Inc., Des Plaines, IL), and the osteo-odonto keratoprosthesis (originally described by Strampelli, modified by Falcinelli, optic available from Osteo-Odonto Keratoprosthesis Optics [Sussex Eye Hospital, Brighton, United Kingdom]). Of these, the Boston type 1 KPro has become the most popular during the past decade, with more than 900 cases performed worldwide in 2008 compared to fewer than 50 cases in 2002 (C. Dohlman, oral communication, April 2009). Since gaining FDA approval in 1992, the Boston KPro—under the guidance of Claes Dohlman, MD, PhD, at the Massachusetts Eye & Ear Infirmary in Boston—has undergone many refinements in design and procedure that have greatly improved outcomes and expanded its indications.

Traditionally, many ophthalmologists have considered keratoprosthetic surgery a procedure of last resort or have not offered it at all. Recent data merit reconsideration.¹⁰⁻¹²

ACHIEVING IMPROVED OUTCOMES

The Boston type 1 KPro is a polymethylmethacrylate collar-button design composed of a front plate with a stem, which houses a central optical cylinder (aphakic and pseudophakic powers available), and a threadless, snap-on back plate (available in adult and pediatric sizes). Cadaveric corneal tissue is sandwiched between the front and back plates and is used for suturing to the eye. The remainder of the surgical procedure is quite similar to PKP and employs 16 interrupted sutures but without the worry of astigmatism.

Ongoing modifications to the Boston KPro's design and postoperative management have improved outcomes.¹¹ The addition of multiple holes to the back plate¹³ allows nutritive aqueous greater access to the corneal tissue, thereby lengthening the viability of the stroma and keratocytes.¹⁴ The addition of a snap-on versus threaded titanium locking ring prevents intraocular unscrewing and extrusion of the KPro/cornea complex, facilitates easier intraoperative assembly, and produces less damage to the posterior layers of the corneal graft.^{2,13} Procedurally, placing a large-diameter soft contact lens after Boston KPro surgery has reduced the incidence of dellen formation, ocular surface dessication, and stromal necrosis.^{15,16} Endophthalmitis by gram-positive cocci, which plagued many early cases, is now seen far less frequently, owing to the use of long-term, daily topical antibiotic prophylaxis with vancomycin and a fourth-generation fluoroquinolone.¹⁷

CLINICAL OUTCOMES

The literature on the Boston KPro is expansive and growing rapidly.¹⁰⁻¹² The 2006 Multicenter Boston Type I Keratoprosthesis Study Group is the largest to date and is compil-

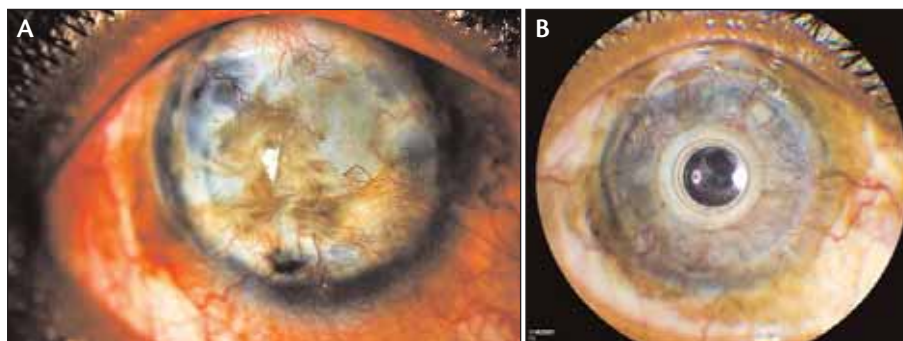


Figure 1. Preoperative photograph of an eye with hand motions vision after multiple failed grafts for keratoconus. The patient also had a history of advanced glaucoma requiring multiple filtration surgeries (A). Seven months after the implantation of a pseudophakic Boston type 1 KPro, the vision in this eye was 20/30 despite an early RPM (B).

ing data from 141 KPro procedures by 39 surgeons at 17 sites.¹⁰ Although graft rejection (73 eyes or 54%) was the most common indication, patients with SJS, OCP, and chemical injury were also included, but they typically fared more poorly in terms of retention and postoperative visual acuity.⁷

At an average follow-up of 8.5 months, postoperative vision improved to better than 20/200 in 57% of eyes and to better than 20/40 in 19% (preoperatively, 96% of patients saw worse than 20/200). The retention rate was 95% at the time of publication, but with a longer average follow-up of 13 months, retention dropped slightly to 92%.¹⁸ Retroprosthetic membrane (RPM) was the most common postoperative complication and occurred in 25% of eyes. Of the eyes with RPM, 63% were successfully treated with a single YAG membranectomy, 11% necessitated surgical membranectomy, and 26% did not require treatment. Elevated IOP was noted as a complication in 15% of eyes, but many of them (52%) had glaucoma preoperatively. Vitritis was reported in seven eyes (5%) and likely represented an immune-mediated phenomenon¹⁹; there were no reports of bacterial endophthalmitis in this large series.

A recent single-center series from the University of California, Davis, of 30 Boston type I KPro procedures had an average follow-up of 19 months.¹² Of the patients observed for 1 year, 75% had improved vision of at least 20/200, and 25% saw better than 20/40. Occurring in 43% of eyes, RPM was again the most common complication. Corneal melt was encountered in 17% of eyes in this series, and high IOP was noted in 27% of eyes. The incidence of endophthalmitis was 10% and was postulated to be a result of longer follow-up. Retention was 83.3% at an average follow-up of 19 months, and in this series, like others, SJS patients fared worse.

Aldave and colleagues recently published the largest single-surgeon series to date of 57 modern Boston type I KPro procedures with an average follow-up of 17 months.¹¹

The percentage of eyes with vision better than 20/100 was 67% at 6 months (n = 45), 75% at 1 year (n = 28), and 100% at 3 years (n = 7). Of note, in a subset of patients with good vision in their fellow eye, 47% had 20/50 or better vision in their KPro eye postoperatively. The overall retention rate was 84%; however, in a subset of eight patients who had no prior corneal surgery, there was 100% retention, and two of these patients had SJS. As in

the other studies, RPM, occurring in 44% of eyes, was the most common postoperative complication, and elevated IOP occurred as a complication in 18% of eyes. Corneal stromal necrosis occurred in 16% of patients, but there were no cases of spontaneous extrusion or endophthalmitis.

Our unpublished series of Boston type I KPro procedures at Weill Cornell Medical Center (n = 8, multiple surgeons) produced similarly promising results (Figure 1). Preoperative vision was worse than 20/400 in all patients. At a mean follow-up period of 9 months, all but one patient with end-stage glaucoma had improved visual acuity, and 50% saw 20/80 or better. To date, we have a 100% retention rate, one case of RPM (12.5%), and no cases of endophthalmitis or stromal melting.

FUTURE DIRECTIONS AND CONCLUSIONS

With its enhanced design, improved outcomes, and expanded indications, the modern Boston KPro type I is quickly becoming the first artificial cornea to warrant mainstream status. Nevertheless, it remains a work in progress, and future directions may include newer materials such as a titanium backplate,²⁰ the optimization of interventions for common comorbidities such as glaucoma,^{21,22} and improved outcomes in high-risk groups such as SJS²³ and OCP.^{24,25} Although treated eyes are complex and require close lifetime follow-up, the KPro procedure itself is fairly straightforward and should be easily adopted by any surgeon familiar with PKP. Unlike other areas of medicine that are rife with unrealistically high expectations, we have found that KPro patients are among the most grateful and satisfied. ■

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