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Long-term Visual Outcomes and Complications of Boston Keratoprosthesis Type II Implantation

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Purpose: To report the long-term visual outcomes and complications after Boston keratoprosthesis type II implantation in the largest single-center case series with the longest average follow-up.

Design: Retrospective review of consecutive clinical case series.

Participants: Between January 1992 and April 2015 at the Massachusetts Eye and Ear Infirmary, 48 eyes of 44 patients had keratoprosthesis type II implanted by 2 surgeons (C.H.D. and J.C.).

Methods: For each eye, data were collected and analyzed on the preoperative characteristics, intraoperative procedures, and postoperative course.

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

Results: The most common indications for surgery were Stevens–Johnson syndrome in 41.7% (20 of 48 eyes) and mucous membrane pemphigoid in 41.7% (20 of 48 eyes). Mean follow-up duration was 70.2 months (standard deviation, 61.8 months; median, 52 months; range, 6 months to 19.8 years). Almost all patients (95.8%, 46 of 48 eyes) had a preoperative visual acuity of 20/200 or worse. Postoperative visual acuity improved to 20/200 or better in 37.5% (18 of 48 eyes) and to 20/100 or better in 33.3% (16 of 48 eyes) at the last follow-up visit. The most common postoperative complication was retroprosthetic membrane formation in over half (60.4%, 29 of 48 eyes). The most pressing postoperative complication was glaucoma onset or progression in about a third. Pre-existing glaucoma was present in 72.9% (35 of 48 eyes). Glaucoma progressed in 27.1% (13 of 48 eyes) and was newly diagnosed in 8.3% (4 of 48 eyes) after surgery. Other postoperative complications were tarsorrhaphy revision in 52.1% (25 of 48 eyes), retinal detachment in 18.8% (9 of 48 eyes), infectious endophthalmitis in 6.3% (3 of 48 eyes), and choroidal detachment or hemorrhage in 8.3% (4 of 48 eyes). Half of eyes retained their initial keratoprosthesis at the last follow-up (50.0%, 24 of 48 eyes).

Conclusions: The Boston keratoprosthesis type II is a viable option to salvage vision in patients with poor prognosis for other corneal procedures. Retroprosthetic membranes, keratoprosthesis retention, and glaucoma are major challenges in the postoperative period; however, the keratoprosthesis can still provide improved vision in a select group of patients. *Ophthalmology 2016;■:1–9 © 2016 by the American Academy of Ophthalmology.*

Keratoprosthesis development and utilization have grown considerably in the past 2 decades. Currently, the Boston keratoprosthesis has become the most widely used artificial cornea in the world. This device first received United States Food and Drug Administration approval for marketing for both type I and type II designs in 1992. The device has undergone several modifications since its development, most recently with a new click-on design that uses an integrated locking ring function in addition to the introduction of a titanium back plate, which received United States Food and Drug Administration approval in 2013.[1,2] With improvements in the design, as well as postoperative management with prophylactic topical antibiotics,[3] the Boston keratoprosthesis has gained popularity, with over 11 000 type I implantations and about 200 type II implantations worldwide as of December 2015 (Gelfand L, personal communication, 2015).

The Boston keratoprosthesis type II implantation is reserved for cornea patients with severe dry ocular surface disease who are poor candidates for traditional penetrating keratoplasty or for keratoprosthesis type I procedures. Cell-based management such as keratolimbal allograft and cultivated oral mucosal transplantation are other options for these patients; however, these options have little utility for advanced-stage ocular surface diseases. The Boston keratoprosthesis comprises 3 main components: a front plate, an optical stem, and a polymethyl methacrylate (PMMA) or titanium back plate. The Boston keratoprosthesis type II is a modified version of the Boston keratoprosthesis type I and has an additional anterior nub that is designed for implantation through surgically closed eyelids (Fig 1). Patients usually have severe chronic inflammation of the ocular surface, which reduces the quantity and quality of tear film. Specific indications for this implant include Stevens–Johnson syndrome (SJS), mucous membrane pemphigoid (MMP), and severe chemical burns.[4] The Boston keratoprosthesis type II is considered

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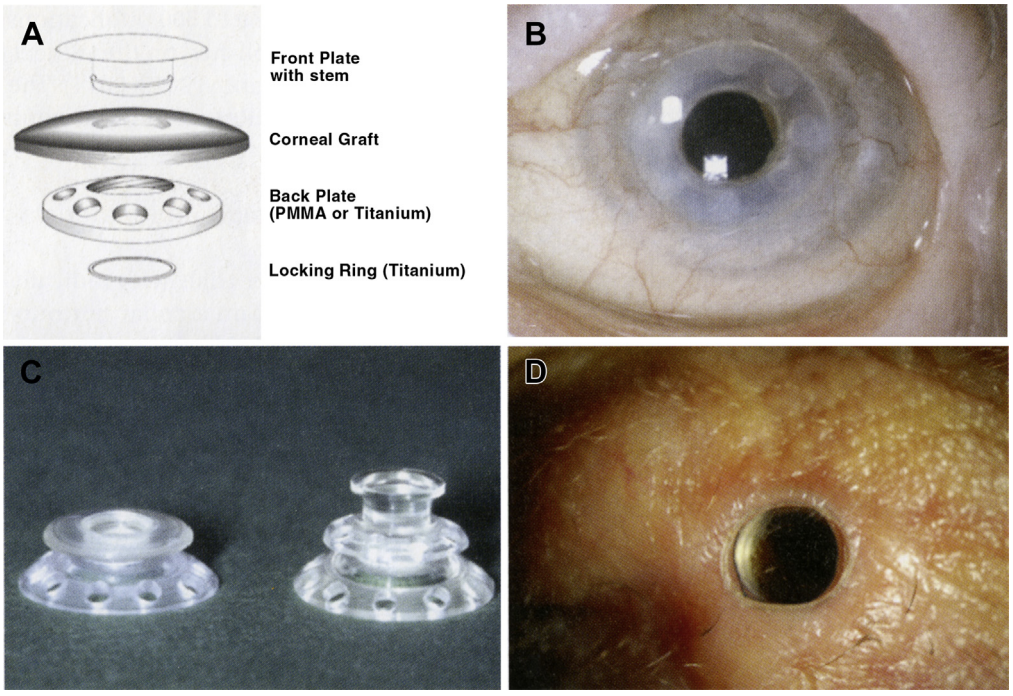

Figure 1. **A**, Components of assembly of a Boston keratoprosthesis type I implant. **B**, Slit-lamp photograph of a Boston keratoprosthesis type I implant with a polymethyl methacrylate (PMMA) black plate. **C**, Boston keratoprosthesis type I (left) and type II (right) devices with PMMA black plates. **D**, Slit-lamp photograph of a Boston keratoprosthesis type II implant with the optic extending through a surgically closed eyelid.

a last-resort intervention to salvage functional vision in these patients.

Thus far, the majority of keratoprosthesis studies have been limited to the type I design or do not distinguish results between the type I and type II implants.[5–10] Only 1 study has reported on the type II design but with fewer patients (i.e., 29 eyes, some of which are likely included in this study) and a shorter follow-up time. The study did not report the mean follow-up time for the entire study population but only reported the mean follow-up time for a subgroup of 21 eyes that were followed for at least 1 year, with a mean of 3.7±2.8 years.[11] Therefore, it can be inferred that the mean follow-up time of the total study population was less than 3.7±2.8 years. This is compared with our current study of 48 eyes with mean follow-up of 5.9±5.2 years.

In this study, we report visual acuity outcomes, postoperative complications, glaucoma status, and proportions of device retention in the largest cohort with the longest follow-up period of patients who had Boston keratoprosthesis type II implantation.

Methods

Surgical Technique

The Boston keratoprosthesis type II was developed at the Massachusetts Eye and Ear Infirmary (Boston, MA). The technique for implanting the Boston keratoprosthesis type II is similar to that for the type I, except that all conjunctival epithelium must be removed, and the keratoprosthesis type II optic extends through surgically closed eyelids (Fig 1). The detailed technique of Boston keratoprosthesis implantation has been described elsewhere.[11–13]

Data Collection and Analysis

The study was reviewed and approved by the institutional review board of the Massachusetts Eye and Ear Infirmary. The study was conducted under Health Insurance Portability and Accountability Act compliance and adhered to the tenets of the Declaration of Helsinki. Data were collected and analyzed by a retrospective chart review. All Boston keratoprosthesis type II surgeries were performed by 2 surgeons (C.H.D. and J.C.) at the Massachusetts Eye and Ear Infirmary between January 1992 and April 2015. Patients who underwent primary Boston keratoprosthesis type II implantation either had failed prior corneal surgery or were poor candidates for penetrating keratoplasty or Boston keratoprosthesis type I surgery. Patients with less than 6 months of follow-up were excluded.[14] Visual acuity, intraocular pressure (IOP), medication use, visual field testing, and postoperative complications were tracked at each follow-up visit. Statistical analyses were performed using SPSS software (IBM, Armonk, NY). All results are described as a mean ± standard deviation, unless otherwise stated.

Definition of Glaucoma

Patients were deemed to have preexisting glaucoma if before keratoprosthesis surgery there was a documented history of glaucoma with elevated IOP and chronic glaucoma medication use or prior glaucoma surgery such as glaucoma drainage device (GDD) implantation, trabeculectomy, or cyclophotocoagulation. Preoperative disc photography and visual field testing were usually not possible because of advanced corneal opacification in these

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