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Ophthalmic Technology Assessment

Boston Keratoprosthesis: Outcomes and Complications

A Report by the American Academy of Ophthalmology

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Objective: To review the published literature on safety and outcomes of the Boston type I keratoprosthesis (BI-KPro) for the surgical treatment of corneal opacification not amenable to human cadaveric corneal transplantation.

Methods: Searches of peer-reviewed literature were conducted in PubMed and the Cochrane Library in December 2012, July 2013, and January 2014 without date restrictions. The searches were limited to studies published in English and yielded 587 citations. The abstracts of these articles were reviewed, 48 articles were selected for possible clinical relevance, and 22 were determined to be relevant for the assessment objectives. Nine studies were rated as level II evidence and 13 studies were rated as level III evidence. Excluded were level III evidence, case reports, review articles, letters, editorials, and case series with fewer than 25 eyes.

Results: In 9 articles, a best-corrected Snellen visual acuity (BCSVA) of 20/200 or better occurred in 45% to 89% of eyes. Five articles described a BCSVA of 20/50 or better in 43% to 69% of eyes, and 4 articles found a BCSVA of 20/40 or better in 11% to 39% of eyes. Retention rates of the BI-KPro ranged from 65% to 100%. Reasons for loss of vision after BI-KPro implantation most commonly included corneal melts resulting from exposure keratopathy, endophthalmitis, and infectious keratitis or corneal ulceration. The 2 most common complications after surgery were retroprosthetic membrane formation (range, 1.0%–65.0%; mean ± standard deviation [SD], 30.0±19.0%) and elevated intraocular pressure (range, 2.4%–64.0%; mean ± SD, 27.5±18.1%). The 2 most common posterior segment complications were endophthalmitis (range, 0%–12.5%; mean ± SD, 4.6±4.6%) and vitritis (range, 0%–14.5%; mean ± SD, 5.6±4.7%).

Conclusions: The reviewed articles on BI-KPro use suggest that the device improves vision in cases of severe corneal opacification that were not amenable to corneal transplantation using human cadaveric keratoplasty techniques. A number of severe anterior and posterior segment complications can develop as follow-up continues, making ongoing close observation paramount for patients undergoing this surgery. These complications include infection, device extrusion, and permanent vision loss. *Ophthalmology 2015;122:1504-1511 © 2015 by the American Academy of Ophthalmology.*

The American Academy of Ophthalmology prepares Ophthalmic Technology Assessments to evaluate new and existing procedures, drugs, and diagnostic and screening tests. The goal of an Ophthalmic Technology Assessment is to evaluate the peer-reviewed scientific literature, to distill what is well established about the technology, and to help refine the important questions to be answered by future investigations. After appropriate review by all contributors, including legal counsel, assessments are submitted to the Academy's Board of Trustees for consideration as official Academy statements. The purpose of this study by the Ophthalmic Technology Assessment Committee Cornea and Anterior Segment Disorders Panel is to review the published literature on safety and outcomes of the Boston type I keratoprosthesis (BI-KPro) for the surgical treatment of corneal opacification not amenable to human cadaveric corneal transplantation.

Background

Prosthokeratoplasty is a form of artificial corneal transplantation reserved for the treatment of severe corneal opacification in situations where cadaveric corneal transplants have failed or have a very low likelihood of success. Keratoprosthesis (KPro) surgery often is considered a procedure of last resort for patients with bilateral severe corneal opacification after multiple unsuccessful cadaveric corneal transplants. However, indications have broadened to unilateral or bilateral corneal opacification after repeated

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graft failure, ocular trauma, herpetic keratitis, limbal stem cell deficiency, aniridia, Stevens-Johnson syndrome, silicone oil keratopathy, and congenital corneal opacification. Although various devices are used for KPro surgery throughout the world, 2 have received 510(k) clearance by the United States Food and Drug Administration. One device is the Boston type I KPro (BI-KPro), also referred to as the Dohlman-Doane KPro, which gained Food and Drug Administration clearance in 1992. The second device is the Alphacor (Argus Biomedical Pty Ltd., Perth, Australia), previously referred to as the Chirila KPro, which gained Food and Drug Administration clearance in 2002. At the time of this assessment, the Alphacor device has been used rarely in the United States. The BI-KPro is the device most commonly used for prosthokeratoplasty in the United States. Its use rapidly increased from 2002, when fewer than 50 devices were implanted, to 1161 devices implanted in 2009 and more than 9000 implanted throughout the world as of the summer of 2014.[1] This report focuses on the literature assessing outcomes and complications of the BI-KPro.

History

The concept of an artificial corneal transplant is not a new idea. In 1789, Guillaume Pellier de Quengsy, a French ophthalmologist, proposed introducing glass into the cornea in an attempt to create a clear window in opacified corneas.[2] Keratoprosthesis studies continued in the 19th century using glass, crystal, various plastics, polymers, and hydrogel implants.[3,4] Additional artificial cornea transplant devices, including the BI-KPro,[5–9] were described in the mid to late 20th century.

The BI-KPro is a collar button design developed by Dohlman et al[10] in 1974. There is an older snap-on version and a newer click-on version. The snap-on version consists of 3 components: a front plate with optical stem, a back plate, and a titanium locking C-ring. The optical stem and back plate are made of polymethyl methacrylate (Fig 1). The polymethyl methacrylate plates are inserted through a central 3.0-mm hole created in cadaveric donor corneal tissue. The device is locked posteriorly with a titanium locking ring. The donor cornea is sutured to the recipient corneal tissue in a manner similar to that used in regular penetrating keratoplasty (Fig 2).

The newer click-on version consists of 2 pieces in which the back plate serves as its own locking washer (Fig 3). It is available in type I and type II formats. The type II format is reserved for patients with severe end-stage ocular surface disease desiccation. It is similar to the type I device, but it requires a permanent tarsorrhaphy to be performed through which a small anterior nub of the type II model protrudes. Because of a lack of adequate data on this device in the peer-reviewed literature, this assessment focuses on the more commonly used type I device. The BI-KPro is available in either a single standard pseudophakic plano power or customized aphakic powers (based on axial length) with adult-sized (8.5-mm diameter) and pediatric-sized (7.0-mm diameter) back plates.

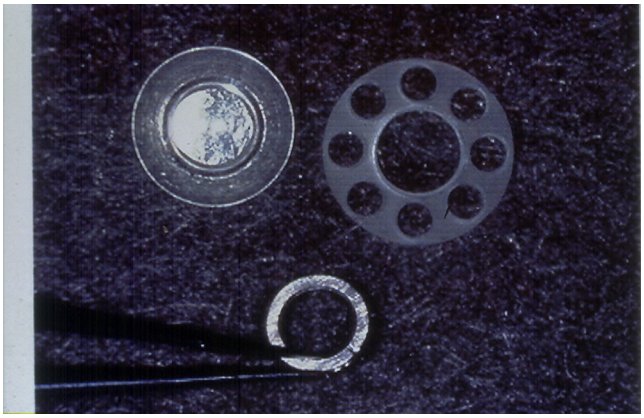

Figure 1. The various pieces that make up the Boston type I keratoprosthesis: top left, collar button; top right, back plate; bottom with forceps, titanium locking ring. (Courtesy of W. Barry Lee, MD.)

The BI-KPro design has been modified since its initial design.[11] First, 8 holes were added into the back plate in 1996 to allow diffusion of nutritive aqueous to support the donor graft stroma and keratocytes (Fig 1). Devices with either 8 or 16 holes are available in the current 8.5-mm back plate model (Fig 3).[11] In 2004, a titanium locking C-ring was added to prevent intraocular disassembly of the device. In 2007, the design was changed from a threaded (screw-type) assembly to a threadless design, which simplified assembly and produced less damage to the donor endothelium. The most recent advance in design is the implementation of a titanium back plate, which likely improves biocompatibility and retention to reduce the risk of retroprosthetic membranes (RPM) and keratolysis.[12] The newest back-plate model became available in 2012.[12,13]

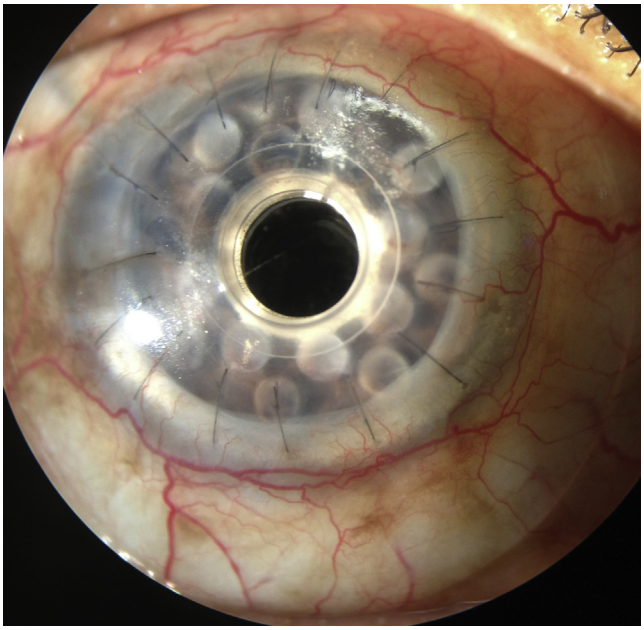

Figure 2. Slit-lamp photograph showing the Boston type I keratoprosthesis several months after implantation. (Courtesy of W. Barry Lee, MD.)