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Review Article

Boston keratoprosthesis – Clinical outcomes with wider geographic use and expanding indications – A systematic review

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Abstract

Over 2 decades of research, several design modifications, and improvements in post-operative management have made Boston keratoprosthesis (B-KPro) a viable option for patients with corneal blindness for whom traditional keratoplasty procedure has a very low probability of success. In this systematic review, we examined the indications, visual outcomes, complications and retention rate of the literature published in the past 10 years (2005–2014). While most of the studies report smaller datasets (typically <50 eyes), some of the recent multicenter studies have reported large datasets (up to 300 eyes). Most of the literature is published from the US; however, last few years have witnessed some papers reporting the successful use of B-Kpro from developing countries or arid climatic conditions (such as the Kingdom of Saudi Arabia). Due to differences in the causes of corneal blindness in different geographic regions, newer indications for B-Kpro are emerging (e.g. trachoma). Additionally, improving clinical outcomes and increasing surgeon confidence have also expanded indications to include cases of unilateral visual impairment and paediatric age. We observed that there is growing body of evidence of successful clinical use of B-KPro; however, financial challenges, lack of trained surgeons, shortage of donor corneas must be overcome to improve accessibility of B-KPro.

Keywords: Boston keratoprosthesis, KPro, B-KPro, Keratoprosthesis implantation, Corneal transplantation

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Introduction

Corneal diseases are the leading cause of blindness worldwide, second only to cataract.[1–3] While corneal transplantation is highly successful in restoring sight,[2] severely diseased eyes with deep corneal vascularization, limbal stem cell deficiency (LSCD), autoimmune diseases and chemical injury etc. are prone to graft rejection.[1,4] Keratoprosthesis (KPro) seems to offer visual rehabilitation in such situations where corneal transplantation has an extremely poor prognosis.[1,4] As of today, Boston keratoprosthesis (B-KPro) is the most commonly used KPro device worldwide. First case series of patients who had undergone type 1 B-KPro was reported in 1974, and the device was approved by the FDA in 1992.[5] Since its introduction, B-KPro has undergone several design modifications, improving postoperative outcomes and surgeon confidence.

A review of literature reveals that most of the papers have been published from the US and reported smaller datasets (typically <50 eyes).[6–12] Recently, some of the papers from the US have reported large multicenter data set of up to 300 eyes.[13,14] With increasing accessibility of training programmes, last 4 years have witnessed several papers studying B-KPro implantation indications, complications and outcomes being published from regions across the world, particularly those from harsher climatic conditions (e.g. Jordan and Saudi Arabia in the Middle East) and from the developing countries (e.g. India, Nepal, Indonesia etc.).[5,12,15–17] Since the causes of corneal blindness necessitating B-KPro implantation vary with different geographical loca-

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tions and climatic conditions newer indications for B-KPro implantation (e.g. trachoma) are emerging. Similarly, the rate of post-operative complications and their management may vary with different geographical locations and climatic conditions.

At this time point, it is worthwhile to conduct a review of recent publications to examine the indications, visual outcomes, complications and retention rate of the B-Kpro literature published in the past 10 years, particularly of those from harsher climatic conditions (such as Saudi Arabia).

Systematic review – methodology

We searched the PUBMED on December 18, 2014 (no time limits) using relevant search terms such as *Boston keratoprosthesis, Boston KPro, B KPro* etc. and found 230 related publications. Additionally, Google search engine was searched for relevant literature. English language studies (reviews, case series and case reports) were included in the study. Results of English language publications published between 2005 and 2014 and reporting outcomes of 4 or more patients were reviewed and compared in Table 1. In this review, we discuss about common indications, postoperative outcomes including visual acuity, retention rate, complications of B-KPro and their management.

Keratoprosthesis: development history

The idea of replacing severely opacified cornea with artificial cornea (KPro) was first introduced by the French ophthalmologist, Guillaume Pellier de Quengsy way back in 1789. After the first report of successful implantation of a quartz crystal into the cornea was published in 1853,[4,18] attempts were made to refine KPro; however, high rate of failure with tissue necrosis, leakage, infection and extrusion of the device limited further developments. In the mean time, the first successful human to human corneal graft by Zirm in 1906 shifted the focus to keratoplasty and interest in KPro development decreased.[4] Gradually as the limitations of corneal transplantation came to fore, there was a renewed interest to develop KPro. KPro development received a major fillip after the high bio-compatibility of polymethylmethacrylate (PMMA) was learnt during World War II.[4]

Several different materials and designs have been proposed for KPro; some of the KPros are totally synthetic [e.g., B-KPro (also known as 'Dohlman–Doane' KPro) or AlphaCor] and the others are totally biological (e.g., tissue engineered cornea). Combined devices consisting of synthetic as well as biological material (e.g., Osteo-odonto KPro) are also available.[19] Of these, US Food and Drug Administration (FDA) approved KPros include B-KPro and AlphaCor.[20] With almost 200 peer-reviewed publications to date and with >6000 implantations performed worldwide until 2011, B-KPro is the most commonly used KPro in the United States and the rest of the world.[16,19,21,22]

B-KPro – description

B-KPro is a double-plated PMMA device with a central rigid optic that perforates the cornea. There are 2 variants of the device. Type 1, the more common variant, is a collar button-shaped device with front plate (diameter 5.5–7.0 mm),[20] a central optical stem, and a back plate (available in 8.5 mm diameter adult size and 7.0 mm diameter paediatric size),[23] with 8/16 holes that facilitate the nutrition and hydration of the corneal graft.[24,25] The back plate of the KPro is either screwed on to the stem to allow firm apposition with the donor tissue or snapped onto the stem with no rotating movement. A titanium locking ring is snapped in place behind the back plate to prevent loosening of the back plate. The graft prosthesis combination is then sutured to the recipient's trephined corneal opening as in penetrating keratoplasty. Type 1 B-KPro is available in a single standard pseudophakic power or customized aphakic optic allowing a maximum visual field of 60°.[20]

Type 2 B-KPro has a through-the-lid design with a 2 mm anterior nub designed to penetrate through a tarsorrhaphy and allow a visual field of 40°.[26] Type 2 is used in rare cases of symblepharon, extreme dry eyes, and other clinical sequelae associated with the autoimmune and inflammatory disease category that includes Stevens Johnson Syndrome (SJS) and Ocular Cicatricial Pemphigoid (OCP).

B-KPro – introduction and improvements over time

B-KPro was originally developed at the Massachusetts Eye and Ear Infirmary in the 1970s by Claes Dohlman as a collar button design made of PMMA consisting of a front plate, a stem, and a back plate.[20,22,27] Since the FDA approval in 1992 for marketing the device, several design changes and improvements in the post-operative management have helped reduce the postoperative complications and enhance the overall efficacy and safety of the procedure.[19,22,27,28]

The first significant improvement included replacement of the solid back plate with a back plate with holes. Addition of 16 round holes (1.17 mm diameter each) in the adult 8.5 mm sized back plate and 8 (1.3 mm diameter each) in the paediatric 7.0 mm sized back plate facilitated endothelial and keratocyte nutrition.[23,27,28] In addition, holes are also hypothesized to play a role in allowing the aqueous to replenish the fluid that has evaporated from the corneal surface, thus keeping the cornea hydrated and preventing dellen formation and dryness that could have lead to shrinkage, with subsequent leakage.[8]

In 2003, titanium locking ring was introduced to prevent any later intraocular unscrewing of the plates due to inadequate manual screwing.[19,27,28] However, this system still had several downfalls as manual screwing of the plates required rotation of the back plate which caused extensive damage to the posterior graft layers.[23] In order to prevent the carrier corneal graft from such damage and make the device easy to use, a newer design with threadless stem was introduced in 2007.[19,23] Incidentally, it also decreased the cost of manufacturing of the device as machining was replaced by moulding.[19]

The latest attempt to improve B-KPro outcomes has focused on exploring alternative materials. While PMMA is a transparent, biologically inert material with long history of safe intra-ocular use, several post-operative complications have been linked to the thick PMMA back plate.[28] Due to titanium's high resistance to corrosion, bio-inertness, ductility, lightness and strength[29] it can be easily machined