Review Article

Indications, Visual Outcomes and Complications of Boston Keratoprosthesis; a Systematic Review

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Abstract

Over many years the development in Boston keratoprosthesis (B-KPro) and its design and post-operative management has much improvement. Recently, the use of Boston has increased signify-cantly. It became a reasonable option for patients with corneal disease and poor prognosis for a traditional penetrating keratoplasty. Immune systems diseases, deep corneal vascularization, compound injuries or limbal stem-cell deficiencies (LSCD), the grafts are more likely to be rejected are the most indications of B-KPro. In this review, systematic literature search about indications, outcomes, complications and the retention rates over a period of 6 years from 2015 to 2021. The studies published in English .The outcomes are good along Intermediate and long-term but the risk of serious complications after B-KPro making frequent lifelong follow up, monitoring and treatment a must.

Keywords: Boston keratoprosthesis, KPro, B-KPro, corneal transplantation, limbal stem cell deficiency

1. Intruduction

Corneal illnesses are the second main source of visual deficiency around the world, cataract being the

most common [1-3]. Corneal transplantation is extremely effective at re-establishing vision, giving positive results in many complicated or severe conditions. However, in certain condition, such as immune system diseases, deep corneal vascularization, compound injuries or limbal stem-cell deficiencies (LSCD), the grafts are more likely to be rejected [1,4]. Keratoprosthesis (KPro) often allows for visual restoration in conditions where transplantation of the cornea fails to offer a good prognosis [5]. The Boston keratoprosthesis or B-KPro graft, in the current ophthalmic trend, has shown extensive utility and is globally acclaimed to be effective. Globally, some 36 million people have been established to be blind. Corneal illness is amongst the leading five causes of blindness, the top four being listed as cataract, refractive errors (uncorrected), glaucoma and AMD (age-related macular degeneration). Also, worldwide, bilateral blindness or visual impairment has been estimated at 4.9 million people and unilaterally, 23 million. The concept of a prosthetic or artificial cornea has gained traction with the populations, bringing in hope of normal or semi-normal vision [6].

In 1974, after examining the first case series of patients who had the type 1 B-KPro implant placed, the FDA approved the design and utilization in further similar circumstances. B-KPro has undergone various changes and improvements since its inception in order to improve the surgeon's confidence as well as the postoperative outcomes. Corneal transplants, i.e. keratoplasty (penetrating, anterior lamellar, or endothelial), is effective in re-establishing visual acuity. Keratoprosthesis implantation entails removing the cornea to its full thickness and replacing it with an artificial cornea. An artificial cornea is a notion that has been around for over 200 years [7]. Many of these impaired patients are found in developing countries where resources are always scarce, leading to a necessity of affordable quality of treatment by keratoprosthesis. Although Nussbaum is proffered to have conducted the first human transplant of KPro in 1855, many contradict this by putting forth that an ophthalmologist, Guillaume Pellier de Quengsy's brother, may have been the first to perform such a procedure in 1789 during the French Revolution.

Experts believe that Nussbaum’s surgery using a quartz crystal implant may have been the first reported human KPro surgery. However, history shows that Keratoprosthesis is a two-century-old notion that was originally fully detailed during the French Revolution, but attention decreased after Eduard Zirm, in 1905, conducted the first full-thickness penetrating keratoplasty in human, successfully [8-10]. For many, corneal transplantation is a blessing that could allow an opportunity for sight. For some, however, this may not be possible owing to the hostile ocular environment, which makes it difficult for the ocular graft to survive. Graft rejection is common in several eye conditions, such as aniridia, severe chemical burns, or even autoimmune illnesses. Keratoprosthesis can provide hope and the prospect of eyesight restoration in such instances [4]. Recent decades have seen the development of several KPros, of which only three are currently in utilization for clinical practice. These are the Osteo Odonto KPro (OOKP), the Boston type 1 KPro, and the Boston type 2 KPro. With Claes Dohlman showering his lifetime supervision on the Boston KPro, this prosthetic has progressed from a simple innovative concept reaching the status of a well-established technology in the last 50 years. The "Nut-and-Bolt"

design, also known as the screw design, has become redundant and no longer used. In the current transplant, a collar button design has been implemented with a snap-on, 2-piece architecture containing the donor corneal transplant sandwiched between two plates. A central opening in the donor cornea is passed by an optic stem on the front plate made of poly-methyl-methacrylate. The porous titanium back plate allows aqueous humor to supply the donor cornea with nutrients and hydration [11]. In the older versions, a second titanium ring was employed to lock the back plate, which is again not needed in the latest design. The device is sutured firmly into eye of the recipient during the corneal trephination, just as a penetrating corneal graft. Short duration topical steroids in addition to lifelong prophylactic antibiotic eye drops are typically given. It is necessary to indefinitely wear a soft contact lens as part of the postoperative treatment. The Boston KPro can be used mainly in eyes with appropriate blinking function (wet eyes) while in dry, non-blinking eyes, the modified OOKP is the alternative [12].

This device was given commercial FDA approval in 1992. From then on, its utility has steadily expanded over the past 20 years, not only in the United States but also worldwide. In Boston, MA, and other locations throughout the world, an active keratoprosthesis research program continues to foster device innovation [13-15]. The most often employed artificial cornea i.e. keratoprosthesis remains at present, the Boston Keratoprosthesis (KPro). It's a procedure for treating corneal disease that doesn't respond to regular penetrating keratoplasty (PKP) or corneal transplantation. The continuous research and subsequent advancements in design along with the insisted upon enhanced postoperative care have delivered improved outcomes. This has catalyzed an exponential increase in the usage of the device in recent years [16-19].

2. Development and Advancement of the Boston KPro Type 1

First introduced in the 1970s by Dr. Dohlman, the Boston Type I Keratoprosthesis is at present, the most commonly employed keratoprosthesis device, both in the US and globally. B-KPro boasts a collar button design, consisting of three parts: a front plate with an optical stem, a corneal allograft button and a back plate. Typically, the front and back plates are shaped using medical-grade PMMA (poly-methyl-methacrylate). These sandwich a corneal graft and are secured with a titanium locking ring. Once the device assembly is complete, a partial-thickness trephination is done on the host cornea and full-thickness resection completed using curved corneal scissors. The keratoprosthesis is then secured to host tissue using interrupted or running sutures [1, 2, 13]. The power of the B-KPro is decided by two elements, namely, the radius of curvature of the optical surface (set at 3.5–3.7 mm central diameter) and the front plate (5mm central diameter).

The B-KPro can be availed in either a single standard pseudo-phakic power or an aphakic power at customized axial lengths (range 16–31 mm in increments of 1 mm). The front edge is refined during the manufacturing process carefully, in order to avoid the sensation of a foreign body ensuring a smooth blend between the poly-methyl-methacrylate and donor cornea. The central stem comprises an intraocular segment and a locking interface. The intraocular segment has a flat interface allowing the passage of light rays without bending. The locking interface secures the back plate. In the original

design, two and a half turn threads were present for screwing the back plate in place. 2003 marked a turning point in the screws when a titanium locking ring was added to secure the back plate in position, thereby preventing later intraocular unscrewing of the plate [3, 4, 9, 12]. In 2007, another revolutionized newer stem having no threads was introduced. This thread less design was anticipated to eliminate corneal graft damage in the process of screwing, show easier application by the ophthalmic surgeons and bring about inexpensive manufacture of the device possible owing to the process of moulding rather than machining. The back plate has shown evolution and progress over the past two decades. Early cycles of the back plate comprised of a strong 8 mm PMMA. In any case, the tall frequency (over 50%) of sterile keratolysis watched with this show was thought to be auxiliary to diminished wholesome bolster from the fluid humor to the giver cornea. This driven perception brought about the improvement of a fenestrated back plate. Sixteen circular gaps (1.17 mm distance across each) in an 8.5 mm measured back plate and eight circular gaps (1.3 mm breadth each) in a 7.0 mm measured back plate were included to the plan permitting fluid to reach the join.

This alteration brought about in a diminish in keratolysis to roughly 10% of cases [20]. Right now, the back plate is accessible in two materials, the initial PMMA and more current titanium demonstrates. PMMA is a dormant and well-tolerated fabric with long-term secure intraocular utilize. Titanium too gives amazing tissue resistance in organic inserts and has numerous extraordinary properties, counting tall resistance to erosion, softness and quality. These characteristics permit the titanium back plate to be more slender (titanium back plate has an edge thickness of 0.25 mm compared to 0.8 mm central and 0.6 mm fringe thickness within the PMMA back plate).

Titanium is non-magnetic; hence patients can be subjected to attractive reverberation imaging. Besides, the titanium back plate can be colored through electrochemical anodization to progress cosmesis. In 2014, the click-on adaptation was presented counting a titanium backplate that clicks onto the stem without the required for a locking ring. At first, the most advantage of the titanium back plate was thought to be a decrease in retroprosthetic film (RPM) arrangement. Todani and colleagues detailed a diminished recurrence in RPM arrangement from 31.2% with the PMMA back plate to 13% with titanium at 6-month follow-up. Be that as it may, a case-matched control think about by Talati and colleagues detailed no statistically noteworthy contrast within the recurrence of outwardly critical RPM in titanium and PMMA back plate bunches at 12 months (35% and 30%, separately). Furthermore, Taniguchi and colleagues as of late detailed that not one or the other the fabric or the measure of the B-KPro back plate had a noteworthy effect on point life structures [21].

A minimal expense simulation of artificial cornea, named the Auro KPro, based on the same design is currently manufactured by Auro-lab in India [22, 23]. Although proof is still generally restricted, results seem similar to those of the B-KPro. The FDA propagated another B-KPro model in 2019: The Lucia keratoprosthesis. This plan decreased assembling expenses and allowed for a solitary titanium back plate 7.75 mm in width. Furthermore, the spiral petaloid shape of the back plate and anodization to earthy coloured shading assist with working on superficial appearance [22, 24].

Generally, patients who have a past filled with numerous bombed PKs are possibility for a keratoprosthesis relocate. Different signs incorporate serious keratitis or visual surface illness coming about because of limbal undifferentiated cell disappointment, for example, aniridia, Stevens-Johnson condition, visual cicatricial pemphigoid and substance injury [7, 20, 25]. The Boston Sort II Keratoprosthesis may be a comparable contraption with a more drawn out optic planning to reach out through an opening made within the upper eyelid. It is appeared for the foremost genuine cicatrizing visual surface malady [18, 26]. Current literature boasts plentiful retrospective studies exploring at the short-term outcomes of Boston KPro surgeries. The general consensus is that the Boston KPro shows good visual outcomes, retention rates, and fewer complications. However, there is less evidence for medium-term (2–5 years) and long-term (>5 years) effects as follow-up rarely extends up to or beyond 5 years. Accordingly, the goal of this study was to comprehensively investigate the Boston type 1 KPro's effectiveness by reporting on visual and retention findings over the years, from short term to long term, as well as to review its postoperative sequelae.

3. Methodology

3.1 Search Strategy

A systematic search strategy to identify and retrieve the relevant literature was developed, the components of the review specifically established as Boston keratoprosthesis, its indications, complications, visual outcomes and retention rate. A review of literature through PubMed, Science direct, and Google scholar databases using relevant medical subject heading terms (MeSH) such as “Boston Keratoprosthesis”, “KPro” and “B-KPro” yielded around 455 results of which only 187 were relevant from 2015 to 2021. (Table 1, Fig 1). The searches were limited to studies published in English.

Of the 455 citations; the creators surveyed the abstracts of these articles and chosen 187 that tended to the B-KPro. Letters, publications, case reports, surveys, histopathology reports, and research facility considers were avoided from these abstracts, and 48 full-text articles were looked into for pertinence. Of these 48 articles, 15 met the consideration criteria based on think about plan and the number of eyes detailed within the think about. Review surveys were constrained to thinks about that included 10 eyes or more. The commentators were not veiled to the names of the distributions or their reviewers.

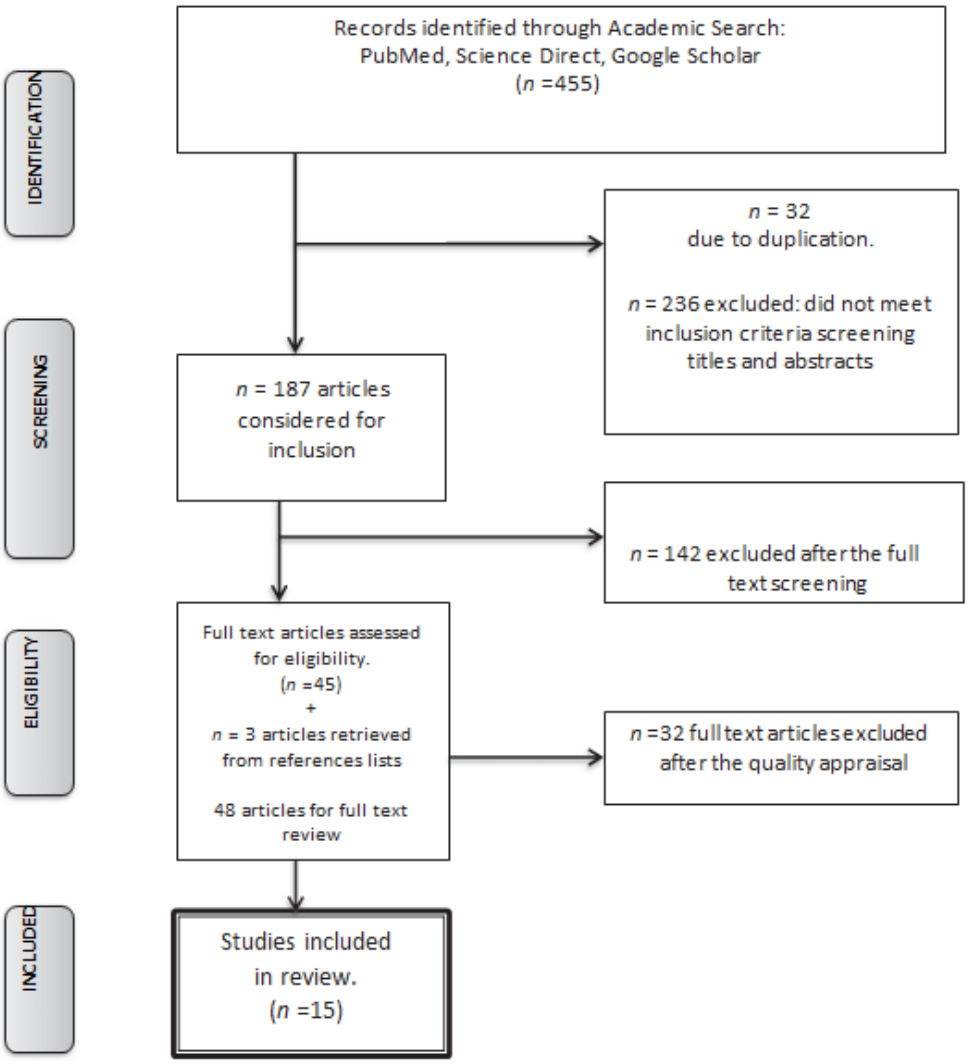

Figure 1: Prisma Review Flow Chart

3.2 Data Analysis and Findings

Data was extracted using a specifically designed data extraction table (Table 1). The data groups analyzed included the objective, settings, and sample, strategy and key findings.

TABLE 1: Summary of Studies Regarding Boston Keratoprosthesis

	AUTHOR/ YEAR/PLACE	OBJECTIVE	SETTINGS	METHODOOLGY	CONCLUSION
1	Touma et al[27] 2021 Canada	To analyse the results of Boston keratoprosthesis (KPro) type I implantation between patients who are legally blind	Single centre	Retrospective comparative case series Boston KPro type I implantation 2008 - 2017 Patients divided into 2 groups based on the preoperative best-	Improvement in vision, with final BCVA being superior in the unilateral blind group

		versus sighted in the contralateral eye.		corrected visual acuity (BCVA) in the contralateral eye: group I (>20/200) and group II (20/200).	
2	Nayman et al [28] 2021 Canada	To analyse long-term outcomes of primary versus secondary (post graft failure) Boston keratoprosthesis type 1 (KPro) implantation	Single centre	Retrospective study using medical records of patients having undergone KPro implantation between 2008 and 2017 with preoperative Snellen BCVA of ≤20/100 and minimum 5 years follow-up	Primary KPro yielded favourable long-term visual outcomes but had more complications and lower retention rates than secondary KPro.
3	Takashi et al [29] 2020 Japan	To analyse retention and visual outcomes of B-KPro vs PKPs in a 5year period, and the complications thereof.	Multi-centre	Retrospective study in Patients who underwent B-KPro or PKP in a five year period	B-KPro implantation is effective and safe for Japanese patients, given the reported improvements in visual acuity and low rates of complications
4	Moshiri et al [30] 2019 USA	To determine the spectrum of retinal complications (RCs)	Single centre	Retrospective Study of All records of patients who received a type 1 B-KPro from Jan 2004 to Dec 201	Long-term visual outcomes in eyes may depend on maintaining a healthy posterior pole.
5	Fung et al [31] 2018 Canada	To report outcomes and complications of Boston type 1 keratoprosthesis (B-KPro) implantation in children.	Multi-centre	Retrospective Records reviewed for Data on preoperative characteristics, surgical procedure(s) performed, and postoperative outcomes. All children 16 years of age or younger who underwent KPro surgery between January 2010 and November 2014.	Substantially greater rate of complications, greater chance of device failure, and worse visual outcomes than in adults and is thus not recommended for use in children
6	Lee et al [32] 2017 USA	To analyse the long-term visual outcomes and complications after Boston keratoprosthesis type II implantation in the largest single-centre case series with the longest average follow-up.	Single centre	Retrospective review of consecutive clinical case series Between January 1992 and April 2015 at the all patients wo had keratoprosthesis type II implanted by 2 surgeons. For each eye, data were collected and analyzed on the preoperative characteristics, intraoperative procedures, and postoperative course.	The Boston keratoprosthesis type II is a viable option to salvage vision in patients with poor prognosis for other corneal procedures.

7	Homayounfar et al 2017 [33] USA	outcomes of Boston type I keratoprosthesis implanted in elderly patients.	Single centre	Retrospective case series on patients 75 years or older between 1 January 2007 and 31 December 2012.	Effective modality in corneal blindness in elderly patients. Failure to restore or maintain ambulatory vision was typically due to non-corneal comorbidities, often unrelated to the keratoprosthesis.
8	Aravena et al [34] 2016 Chile	To analyse the long-term outcomes of the Boston type I keratoprosthesis (KPro) in the management of limbal stem cell deficiency (LSCD).	Single centre	Retrospective review of KPro procedures performed by a single surgeon from May 1, 2004, to January 1, 2015.	Significant improvement in BCVA in the majority of eyes with LSCD through 5 years after surgery, with better visual outcomes than eyes without LSCD.
9	Salvaldor-Culla et al [35] 2016 Dominican Republic	To analyze the long-term results in visual acuity (VA), retention, and complications of patients who had Boston keratoprosthesis type 1 after ocular chemical burns	Single centre	Retrospective review of 42 eyes from 36 patients who had B-Kpro type 1 implantation after severe ocular burn between April 2006 and October 2014,	Strict control of the postoperative complications is necessary for long-term success.
10	Gu et al [36] 2016 China	to analyse clinical outcomes (functional and anatomic) of B-KPro after severe chemical burns	Single centre	Retrospective 19 patients that sustained severe chemical injuries were studied from May 2009 and June 2015.	postoperative VA declined with the development of complications, and ocular surface disorders caused by the chemical burns were associated with a greater incidence of KPro retention failure. The retention rate was comparable in patients using ipsilateral autologous corneal tissue with allograft corneal tissue.
11	Goins et al [37] 2016 USA	To determine the visual outcomes, device retention, and complications after Boston type 1 keratoprosthesis (KPro-1) device implantation.	Single centre	Retrospective Comprehensive review of every case of KPro-1 implantation at a tertiary eye care centre.	Satisfactory visual outcomes and excellent device retention in a majority of cases. However, serious postoperative complications are common and may compromise the final

					visual result.
12	Noel et al [38] 2016 Canada	To analyse the outcomes	Single centre	Retrospective review of all Kpro procedures between June 2008 and July 2013.	Kpro improves VA in a majority of cases, and is a viable option for a poor prognosis in traditional penetrating keratoplasty.
13	Rishi et al [39] 2016 India	To describe the spectrum of vitreoretinal complications in eyes with Boston keratoprosthesis type I and evaluate the treatment outcomes.	Single centre	Retrospective Interventional case series from April 2003 to December 2013 and developed vitreoretinal complications.	Vitreoretinal complications can be managed by appropriate intervention in such eyes with encouraging anatomical and functional results.
14	Lee et al [40] 2015 USA	To review the published literature on safety and outcomes of the Boston type I keratoprosthesis	SLR multicentre	Retrospective; peer-reviewed literature searched in PubMed and the Cochrane Library in December 2012, July 2013, and January 2014	The device improves vision in cases of severe corneal opacification that were not amenable to corneal transplantation using human cadaveric keratoplasty techniques.
15	Duignan et al [41] 2015 Ireland	To evaluate the outcomes of the type-I and type-II Boston keratoprostheses	Single centre	Retrospective; hart review of keratoprosthesis implantations carried out in our institution from November 2002 to March 2014 was performed.	Excellent visual acuity and retention outcomes for the long-term stability of type-I and type-II BKpo for patients in whom a traditional graft is likely to fail.

BCVA = best-corrected visual acuity, RCs = retinal complications, LSCD = limbal stem cell deficiency

These studies were further analyzed in depth in terms of the indications for the keratoprosthesis, the visual outcomes both long term and short term, the safety of the implant, its complications (if any) and also the satisfaction of the patients receiving the treatment.

4. RESULTS

The Boston keratoprosthesis was once thought of as a last resort surgery. Currently, commonly used, with its modified enhancements in design, selection of patients and quality of care postoperatively. The use of B-KPro has been well accepted in the cases of failed PKP; aniridia; as well as ocular trauma including chemical burns, herpes keratitis, corneal dystrophies and so on [32, 42]. Table 2 show the various indications, outcomes and the retention rates of the Keratoprosthesis over a period of 6 years from 2015, to 2021. With more than 1000 eyes analysed over 15 studies, the mean retention rate was found at around 78%. Most studies indicated that the visual acuity improves to 20/200 or better. The single study with pediatric population showed that the outcomes in children were not as in adults. Children have low

outcome with keratoprosthesis and they showed more complications.

TABLE 2: Studies Discussing the Indications, Visual Outcomes and Retention Rates of Keratoprosthesis

	AUTHOR	NUMBER OF EYES	INDICATIONS	FOLLOW UP (months)	VISUAL OUTCOMES	RETENTION RATE
1	Touma et al [27] 2021 Canada	visual acuity (BCVA) in the contra-lateral eye: group I (>20/200) – 56 eyes group II (20/200) – 53 eyes	Aniridia Post infectious scarring Trauma	Na	50/56 eyes (89.3%) in group I achieved a visual acuity 20/200 compared with 37/53 eyes (69.8%) in group II.	73.9% -77.1%
2	Nayman et al [28] 2021 Canada	40 -primary 42 -secondary	Primary- Aniridia (48%) Secondary- Endothelial disease (24%)	59.6±2.3 months	Mean BCVA was similar between groups at 5 years (logarithm of minimal angle resolution 1.3±0.8 in the primary group vs 1.5±0.8 p<0.05)	Primary – 70% Secondary – (91%)
3	Takashi et al [29] 2020 Japan	NA	NA	At 5 years post-op	BCVA ≥ 20/200 with B-KPro than those with PKP (80.0% vs. 17.6%; P = 0.03)	B-KPro (100%) and PKP (26%) at 5 years post-op (P < 0.01)
4	Moshiri et al [30] 2019 USA	36	Aniridic keratopathy, bullous keratopathy, failed corneal grafts, corneal chemical injury, Stevens–Johnson syndrome, corneal melt, graft-versus-host disease, and trauma.	AV 53.8 months	Post op BCVA ≥20/200 in group with RC (20 eyes) - 10% and NRC (16 eyes) - 44% Rest - no LP	NA
5	Fung et al [31] 2018 Canada	11	Prior donor graft failure (45%) (mostly for corneal opacity or aniridia)	Post-op (6.5–85.0 months)	BCVA of 20/400 retained in 2 eyes. 5 lost light perception	36.40%
6	Lee et al [32] 2017 USA	48	Stevens–Johnson syndrome (41.7%) mucus membrane pemphigoid (41.7%)	(6moths to 20years)	Post-op BCVA ≥20/200 (37.5%) and BCVA ≥20/100 (33.3%)	50%

7	Homayounfar et al 2017 [33] USA	44	Corneal graft failure (52.3%) corneal scar (18.2%) limbal stem cell dysfunction (18.2%)	AV 27.5 ± 0 months	82% had immediate Post op BCVA of ≥20/200 45.5% retained at last follow up	88.90%
8	Aravena et al [34] 2016 Chile	54 – LSCD 95 - Non LSCD	Failed corneal transplant LSCD (25.9%) Non LSCD (95.8%) Primary causes LSCD – (74.2%)	AV 37.1 ± 0 months	At 1 year, CDVA ≥ 20/200 achieved by LSCD -	NA
9	Salvaldor-Culla et al [35] 2016 Dominican Republic	42	Chemical burns	AV 40.2± 24.4 months	68.6% Patients had VA of ≥20/200 after 2-years 76.9% of 13 patients had VA of ≥20/200 at 5 years	91.40%
10	Gu et al [36] 2016 China	19	Chemical burns	AV 41.3 ± 5.5 months	89.4% Achieved BCVA 20/200 atleast once 36.8% achieved BCVA 20/200 till last follow up	73.60%
11	Goins et al [37] 2016 USA	75	Primary causes	AV 41.4months	Post op BCVA 20/428	85.30%
12	Noel et al [38] 2016 Canada	44	Failed corneal transplantation (70%)	AV 21 ± 12 months	Post-op BCVA: 20/400 (range 20/30 to NLP)	95.50%
13	Rishi et al [39] 2016 India	45	Silicone-oil induced keratopathy (35%) Chemical injury (31%) Repeat corneal graft failure (22%)	28 months	Mean preoperative visual acuity improved from 1.84 ± 0.89 logMAR to 1.5 ± 0.87 logMAR (P = 0.01)	NA
14	Lee et al [40] 2015 USA	2176	NA	(6-47 months)	Post-op BCVA of 9 articles reported ≥20/400 (45% – 89% eyes) 5 articles reported ≥20/50 (43% – 69% eyes) ≥20/50 (11% – 39% eyes)	65 – 100%

15	Duignan et al [41] 2015 Ireland	34	Primary (67.6%) Previous failed graft (32.4%)	42 ± 31 months	Pre-operative mean VA: 20/1205 (does not include 48% of eyes with HM or LP vision) Final mean VA: 20/150	80.60%

BCVA = best-corrected visual acuity, RC = Retinal complications, NRC = No retinal complications, LP = Light perception, LSCD = limbal stem cell deficiency, AV = Average, NA = Not Available.

Whereas most cases showed a positive long-term outcome with the Boston keratoprosthesis, many cases showed a side effect, with several complications in the long run. As Table 3 show, the most commonly seen anterior segment complications were Retro prosthetic membrane (45.93%), Glaucoma (21.16%), Infectious keratitis (17.31%) and corneal melt/necrosis (20.33%).

TABLE 3: Studies Discussing the Anterior Segment Complications of Boston Keratoprosthesis

AUTHOR	Retroprosthetic membrane	Glaucoma	Infectious keratitis	Corneal melt/necrosis
Touma et al [27]	Group 1- 30.4% Group 2 -47.2 % Total – 38.5%	Group 1- 17.9% Group 2 -17 % Total – 17.4%	Group 1- 21.4% Group 2 - 7.5% Total – 14.6%	Group 1 -12.5% Group 2 -18.9% Total – 15.5%
Nayman et al [28] 2021 Canada	Primary – 45% Secondary – 36%	35% -	- 19%	- -
Takashi et al [29] 2020	88.9%	11.1%	33.3%	-
Moshiri et al [30] 2019	28%	-	-	-
Fung et al [31] 2018	81%	All had preop glaucoma	27.2%	45.5%
Lee et al [32] 2017 USA	60.4%	27.1% (progression) 8.3% (New)	-	-
Homayounfar et al 2017 [33]	45.5%	9.1%	9.1%	9.1%
Salvaldor-Culla et al [35] 2016	11.9%	33.3%	-	31% Extrusion (secondary) – 9.5%
Gu et al [36] 2016	52.6%	31.5%	-	26.3%
Goins et al [37] 2016	33.3%	-	16%	-
Noel et al [38] 2016	52%	23% (new) 7% (progression)	2%	11%

Rishi et al [39] 2016	24%	-	-	-
Lee et al [40] 2015	30±19%	Elevated IOP (27.5±18.1%)	-	-
Duignan et al [41] 2015	52.9%	17.6%	-	14.7%

The commonly seen posterior segment complications with the Boston keratoprosthesis across the fifteen studies were Retinal detachment (15.23%), Endophthalmitis (11.85%), Epiretinal membrane (10%) Cystoid Macula Edema (10%) Sterile vitritis(6.26%) Choroidal detachment (5.43%) Hypotony (22%) and others such as posterior capsule opacification and extrusion of device. See Table 4.

TABLE 4: Studies Discussing the Posterior Segment Complications of Boston Keratoprosthesis

AUTHOR	Retinal detachment	Endophthalmitis	Epiretinal membrane	Cystoid Macula Edema	Sterile vitritis	Choroidal detachment	Vitreous Haemorrhage	Others
Touma et al [27] 2021	Group 1 – 7.1% Group 2 – 20.8% Total – 13.5%	Group 1 – 8.9% Group 2 – 11.3% Total – 10%	Group 1 - 7.1% Group 2 – 5.7% Total – 6.5%	Group 1 – 23.2% Group 2 – 3,8% Total – 13.5%	Group 1 - 7.1% Group 2 - 7.5% Total – 7.4%	-		Hypotony Group 1 – 23.2% Group 2 – 28.3% Total – 25.7% PCO Group 1 - 10.7% Group 2 - 9.4% Total – 10%
Nayman et al [28] 2021 Canada	-	-	-	--	-	-	-	Hypotony Primary – 35% Secondary- 21%
Moshiri et al [30] 2019	31%	19%	11%	14%		6%	6%	Retinal vein occlusion (3%) Macular hole (3%)
Fung et al [31] 2018	45.5%	27.3%	-	-	-	-	-	GDD erosion (18%)
Lee et al [32] 2017	18.8%	6.3%	-	-	-	8.3%	8.3%	Tarsorrhaphy revision (52.1%)

Homayoun far et al 2017 [33]	2.3%	6.8%	-	13.6%	6.8%	-	-	Replacement of kpro (11.4%)
Salvaldor-Culla et al [35] 2016	4.8%	2.4%	4.8%	-	4.8%	-	4.8%	PCO (52.4%) Hypotony (9.5%)
Gu et al [36] 2016	10.5%	-	10.5%	-	-	-	-	Ischemic optic neuropathy (5%)
Goins et al [37] 2016	-	9.3%	-	-	4%	-	-	Device extrusion (14.7%) Maculopathy (34.7%) Progressive optic neuropathy (9.3%)
Noel et al [38] 2016	7%	-	-	-	7%	-	11%	PCO (14%) Hypotony (7%) Others (~50%)
Rishi et al [39] 2016	13%	9%	9%		2%	2%	4%	
Lee et al [40] 2015		4.6±4.6%			5.6±4.7%			
Duignan et al [41] 2015	5.9%	14.7%	14.7%	2.9%	11.8%		2.9%	Neovascular age-related macular degeneration (5.9%) Hypotony (5.9%)

4. Discussion

For several many years, prosthetic keratoplasty become reserved for treatment of eyes that had corneal blindness due to severe corneal opacification, especially case in which patients had poor visual diagnosis. Results of B-KPro surgical treatments have been often seemed with combined perspectives as to protection and viable visual effects. Many researches evaluate brief-term efficacy and safety results but did not look for long term effects. Keeping this in mind, the objective of this assessment was to evaluate the outcomes and complications of the B-KPro for treatment of corneal diseases not suitable for corneal keratoplasty.

Snellen chart measured visual acuity was the mainstay investigation the papers involved and ranged from 20/100 to light perception before surgery. Visions post-operative ranged from 20/20 to no light perception. Five articles found a range of 45-

90% of eyes seeing 20/200 or better [33, 35 37 39, 43]. Seven reported best-corrected visual acuity by Snellen chart of 20/40 or better in 10-40% eyes [28, 31, 33, 35, 37, 39, 43], and four articles [27, 28, 30, 39] reported 20/50 or better vision in 40-70% eyes.

These articles elucidate that the B-KPro device can lead to acceptable restoration of vision in conditions of pre-op corneal opacification. Another finding was that consistency standards with Boston KPro went from 65-100% in thirteen works [18, 23, 41, 43, 25, 27-30, 37-39]. From these a general result proportion of normal maintenance of 88% can be refreshed. Three articles [28, 35, 38] announced degrees of consistency of 90% or better, while just one article [29] revealed a definite maintenance of 100%. Although these numbers seem great, a considerable most of these examinations were found to have generally short subsequent occasions, going from 8.5 to 21 months.

The review with the longest development of 60 months observed a degree of consistency of 100% [29]. Each of the articles evaluated for complications, of which Retroprosthetic membrane was the most well-known. The incidence of Retroprosthetic membrane range from 1% to 65% (mean SD, 30.019.0%) in 16 articles [13, 18, 30-32, 37, 41, 43, 19-21, 23, 25-28]. Glaucoma was the second complication, with a range from 2.4% to 64.0% (mean SD, 27.518.1%), followed by corneal melts and keratitis.

The posterior segment complication was less common than anterior segment. The rate of endophthalmitis range from 0% to 12.5% (mean SD, 4.64.6%) in the 15 articles that detailed its event. Although good visual recovery and low retention rates have been reported for the B-KPro, caution should still be exercised when implanting the device in patients with certain conditions that are prone to keratolysis, because these can lead to an increased risk. In particular, patients with mucous membrane pemphigoid, toxic epidermal necrolysis, Ecto-dermal dysplasia, and Stevens-Johnson syndrome should be monitored very closely after implantation of the B-KPro device [10, 13, 34].

Neurotrophic keratitis, regular epithelial imperfections, herpetic eye infections can be regarded as relative contraindications to the B-KPro. The Type II KPro is probably considered as a superior treatment desire for these conditions. Glaucoma one of the important complications of B-KPro, which is the second most common complications. A number of authors performed B-KPro surgery in conjunction with glaucoma drainage device implantation, either simultaneously or sequentially [15, 22, 24, 28, 29]. As Measuring the IOP in patients who had KPro difficult, Tonometry measurements are challenging.

Digital palpation of the globe still the common method used for measuring IOP. So, all patients with the B-KPro should be followed up for glaucoma, with frequent visual field and optic nerve assessment [15]. Conclusions that B-KPro is an alternative option for patients who corneal disease with poor prognosis to corneal keratoplasty. 89% of patients had a visual acuity of 20/200 or better after B-KPro. Although this visual restoration after B-KPro, it has a side effects like Retroprosthetic membrane which maximum happen in the first 2 years. There are no enough researches about the use and safety of B-KPro in children. Patients with autoimmune conditions such as mucous membrane pemphigoid and Stevens-

Johnson syndrome, as well as conditions associated with neurotrophic corneas and chronic epithelial defects, had higher rates of severe complications resulting from the resulting from the BI-KPro device.

The common anterior segment complications after B-KPro implantation are Retro-prosthetic membrane and glaucoma, and for posteri-or segment are endophthalmitis and vitritis. The potential for complications increases with time after B-KPro surgery and with eyes that are predisposed to inflammatory effects around the backplate of the B-KPro device. This assessment does not take into account either the differences in B-KPro designs or newer modifications in care after surgery, such as the use of therapeutic contact lens and long-term fortified antibiotics.

5. Conclusion

The B-KPro often remains a patient's only chance of visual recovery for cases with severe corneal disease and not suitable for corneal keratoplasty. The advances in its design and techniques have led to continuously improving results. However Complications occur. A high level of suspicion, frequent follow up, aggressive management can help decrease the occurrence of these complications. The ongoing research in B-KPro continues and has the potential to further improve outcomes.

Declaration of conflicting Interest

The authors declare that there is no conflict of interest.

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