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Keratoprotheses in End-Stage Ocular Surface Diseases: Comparative Review of Current Concepts and Clinical Outcomes

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Abstract

Introduction and Purpose

Keratoprotheses remain a treatment of last resort for patients with severe corneal blindness and end-stage ocular surface disease when conventional therapeutic options, including corneal transplantation and limbal epithelial stem cell transplantation are ineffective or contraindicated. This review summarizes currently available keratoprotheses models according to the tear status of the ocular surface and compares their clinical outcomes, retention rates, complications, and surgical technique.

The State of Knowledge

Boston keratoprosthesis type I remains the most commonly used device for eyes with a wet-ocular surface, demonstrating favorable retention rate and visual rehabilitation. In contrast, Boston keratoprosthesis type II and modified osteo-odonto keratoprosthesis are primarily indicated in severe dry eye disease and cicatrizing ocular surface disorders. Novel devices, including Lucia keratoprosthesis, CorNeat keratoprosthesis, Moscow eye microsurgery complex in Russia, Lux keratoprosthesis and Pintucci keratoprosthesis aim to improve affordability, biointegration, and long-term retention.

Conclusions

Despite ongoing advances in device design and surgical techniques, complications such as glaucoma, retroprosthetic membrane formation and extrusion remain significant challenges. Further long-term studies using standardized outcome measures are required to determine the optimal keratoprosthesis for specific clinical indications.

Key words

Dry Eye Disease; Limbal Stem Cell Deficiency; Polymethyl Methacrylate; Corneal Injury

Introduction

Keratoprosthesis (Kpro) is a reserved option for patients with severe corneal blindness in case any accessible treatment leading to vision restoration was excluded or has failed. With the widespread availability of corneal transplantation and advances in limbal epithelial stem cells (LESCs) transplantation techniques, the use of keratoprostheses (Kpros) has declined. Nevertheless, in complex cases Kpros often remains the last therapeutical option for vision preservation. Examples include patients with a high risk of corneal graft failure following severe ocular trauma, insufficient limbal stem cells reserve and autoimmune diseases such as Stevens-Johnson syndrome (SJS), Sjögren's disease or ocular mucous membrane pemphigoid (MMP) [1-4]. A significant advantage of Kpros is relatively early visual rehabilitation. The patient must be aware of the limited field of view, aesthetic result, and sometimes a multi-stage surgical process regarding the type of Kpro and the importance of frequent and long-lasting follow-up [5]. As various diseases may lead to end-stage ocular surface diseases, each patient must be assessed regarding underlying aetiology, tear status, ocular surface anatomy and concomitant adnexal involvement. Table 1 summarizes Kpro models according to ocular-surface status indication. The most commonly used Kpro is Boston Kpro type I (BKpro-I), dedicated to eyes with a wet ocular surface and preferably with a nonautoimmune underlying aetiology of corneal blindness. Thanks to the advancement of new techniques, alternative Kpros have been developed, such as Aurolab Kpro (AuroKpro) [7], CorNeat Kpro [8] or AlphaCor [9,10], whereas Lucia Kpro [11] or Ophthalmic Research Centre Kpro (ORC-Kpro) [12] represent a modification of BKpro-I. Concerning dry eye diseases, especially with severe keratinisation of the ocular surface, there are indications for Boston Kpro type II (BKpro-II), modified osteo-odonto Kpro (MOOKP) or alternative Kpros such as Lux Kpro, LVP Kpro, Pintucci Kpro, Moscow eye microsurgery complex in Russia (MICOF) and tibial osteo-Kpro. Each Kpro consists of an optic and a haptic part. The centrally located optic part provides vision and is usually made of polymethyl methacrylate (PMMA). The haptic part supporting the PMMA stem defines the type of Kpro and is often stated as a 'skirt' according to its composition. Regarding the origin, the skirt was divided by Iyer et al. into biocompatible, biointegrated or biological composition [13-16]. Despite significant advances in Kpros design and surgical techniques, the optimal selection of devices for specific ocular surface conditions remains challenging, particularly due to the increasing availability of novel Kpro models and modifications. Therefore, we aim to present currently available Kpros according to the tear status of the ocular surface, together with a comparison of their clinical outcomes. To complete the review, brief descriptions of the application techniques used for the most common types of Kpro were included.

Wet-ocular Surface	Dry-ocular Surface
Boston Kpro type I	Boston type Kpro type II
Aurolab Kpro	Modified osteo-odonto Kpro
CorNeat Kpro	Lux Kpro
AlphaCor	LVP Kpro
Lucia Kpro	Pintucci Kpro
Ophthalmic Research Centre Kpro	Moscow eye microsurgery complex in Russia
	Tibial osteo-Kpro

Table 1. Summary of Kpro models according to ocular-surface status indication.

Methods

This narrative review presents evidence from 36 studies published between 1995 and 2026, identified and selected using databases such as PubMed, Scopus and Embase. Priority was given to meta-analyses, systematic reviews and clinical studies to ensure inclusion of high-quality evidence and minimize the risk of bias.

Wet-ocular Surface

The first introduced BKpro-I precursor was composed of a corneal allograft button, a PMMA optical stem combined with a PMMA frontplate and a backplate. PMMA is considered to provide biocompatibility, however, subsequent studies using the titanium backplate model or surface modifications of PMMA showed a lower incidence of complications such as retroprosthetic membrane (RPM). Additionally, titanium composition enhanced LESC's proliferation and decreased cell death as an adhesion surface. Therefore, the most commonly used BKpro-I design consists of a PMMA optical stem and frontplate with a sixteen-hole titanium backplate secured by a posteriorly placed titanium ring [5,17-19].

Prior to the surgical procedure, a typically 8.5-mm-diameter corneal allograft is harvested, and usually a 3-mm-diameter opening is trephined for the PMMA optical stem. If necessary, peripheral iridotomy

or extracapsular lens extraction may be performed. The prepared corneal button, titanium plate, and supporting ring are placed on the optical stem and are tightly fitted between the layers. The donor cornea should be 0.5-mm-diameter wider than the host cornea trephination, consequently an 8-mm-diameter recipient cornea trephine is performed and followed by securing the Kpro by sutures into the cornea wound.

Since pre-existing glaucoma or developing de novo as a complication is a significant issue, the procedure may be extended to include implantation of a drainage device to lower intraocular pressure. After the procedure, typically soft contact lenses, antibiotics and corticosteroids are advised [20-22].

A meta-analysis conducted by Priddy et al. in 2019 evaluated the medium- and long-term outcomes of the BKPro-I across 30 studies. The reported retention rate was 88% at 2 years and 74% at 5 years of follow-up. The most frequent long-term complications were glaucoma, followed by RPM formation. The mean preoperative best-corrected visual acuity (BCVA) was reported as counting fingers or worse, whereas at the 2-year follow-up, 62% of eyes achieved a BCVA of $\geq 20/200$. However, data at the 5-year follow-up were inconsistent due to variability and limitations in the reporting of poor visual outcomes [23].

Concerning the cost of the BKpro-I device, it was a considerable limiting factor, particularly in developing countries, in 2011, when AuroKpro was designed. Basu et al. comparison of BKpro-I and AuroKpro in a 5-year follow-up showed similar results in terms of overall anatomical retention rate (BKpro-I 70.5% vs AuroKpro 62.5%; $p=0.11$). The BCVA of $\geq 20/200$ at 2-year follow-up was 91% in the BKpro-I group and 77% in the AuroKpro group. Functional recovery was assessed ($42.4 \pm 6\%$ vs. $32.2 \pm 7\%$ respectively; $p=0.345$) with de novo glaucoma and RPM remained the most prevalent complications in both groups. The intraoperative breakage and postoperative extrusion frequency were statistically significantly higher in the AuroKpro group [24]. Another comparison between BKpro-I and AuroKpro conducted by Shanbhag et al. supported the earlier conclusion regarding overall anatomical retention rate (BKpro-I 68% vs AuroKpro 63%; $p=0.89$). Functional recovery was similar to Basu et al. study (BKpro-I $42.6 \pm 8\%$ vs AuroKpro $35.03 \pm 10\%$; $p=0.9$). The most common complication was de novo glaucoma, and no statistical difference in any complication was reported between the two groups [25].

The Boston Kpro team developed Lucia Kpro, achieving better affordability and appearance due to backplate modifications. The round holes were changed to radial, and anodization of the backplate enabled brown or blue colour of the Kpro [11]. Results of Lucia Kpro implantation were presented by Ortiz-Morales et al. with a mean follow-up of 20.5 ± 8.83 months. The retention of the device was sustained in 96% of recipients (44/46) over the follow-up period. The most frequent complication was the RPM formation, followed by de novo glaucoma. The study shows 62.5% of functional success and

BCVA $\geq 20/40$ was achieved by 23%, but further studies are necessary to evaluate the long-term outcomes and compare to other Kpro [26].

Further research enhancing the availability or biointegration of the Kpro has led to the development of novel devices. Ophthalmic Research Centre introduced the more affordable ORC-Kpro, resulting in anatomical success and limited functional improvement due to advanced glaucoma in short-term follow-up [12]. Artificial corneas such as AlphaCor consist of both an optical part and skirt made from poly (2-hydroxyethyl methacrylate) with peripheral interconnecting pores allowing better biointegration. Hicks et al. reported results of 322 AlphaCor implantations with a mean follow-up of 15.5 months and a 62% retention probability at 2-year follow-up ($p=0.01$). Similarly, Jiraskova et al. observed a 58% retention rate at 2-year follow-up among 15 eyes with AlphaCor. In both studies, stromal melting was the most notable complication [9,10]. In 2023, Bahar et al. described the first-in-human implantation of the CorNeat Kpro, an innovative device characterized by subconjunctival integration and microporous matrix stimulating cellular growth [8].

Additionally, novel techniques enabling the coating of Kpro with diverse substances are used to enhance biointegration. Nanohydroxyapatite, calcium phosphate, and L-3,4-dihydroxyphenylalanine have demonstrated substantial improvements regarding Kpro biointegration, but further studies need to be performed [5,27].

Dry-ocular Surface

Severe, chronic and bilateral dry eye disease (DED) leading to end-stage blindness, particularly associated with autoimmune etiology such as Stevens-Johnson syndrome, mucous membrane pemphigoid, or extensive ocular burns, may constitute an indication for an alternative group of Kpros. It is typically manifested by corneal blindness accompanied by significant keratinization, eyelid abnormalities and desiccation of the ocular surface. The devices dedicated to DED generally comprise a central optical part, usually fabricated from PMMA, and a hard haptic part, as well as Kpro, recommended for wet ocular surface. However, a distinguishing feature regards the covering of the noncentral part of the eye, which compensates for impaired blinking function. In BKpro-II, tarsorrhaphy preserves the ocular surface from desiccation. In contrast, other biocompatible models such as MICOE, LVP and Lux Kpro are covered by buccal or labial mucosal grafts. Moreover, mucosal grafts are also commonly used to cover biological models such as MOODK and its alternative using tibial bone block [1,5-7,13,15].

Overall, the main difference concerning BKpro-I and BKpro-II is the length of the anterior extension of the device, which allows for the eyelid layer in BKpro-II [14]. Regarding surgical procedure, all ocular surface mucosa should be removed through sharp dissection, including bulbar, forniceal and

tarsal conjunctiva. The anterior eyelid margin should be excised with all eyelash follicles. Moreover, the eye is preferred to be aphakic. Further procedure is similar to BKpro-I implantation, including excision of the recipient cornea, trephination of the donor cornea and implantation of the device with corneal graft, preceded by glaucoma drainage valve if it is required. Subsequently, the upper eyelid is fashioned to the anterior extension of the Kpro, and complete tarsorrhaphy is performed, leaving only the optical part exposed. Postoperatively, the patient receives topical antibiotics and short-term topical corticosteroids [13,28,29].

In 2022, Saini et al. reported outcomes of 56 BKpro-II implantations in 53 patients, with a mean follow-up of 45.8 months. The most common indication was SJS or toxic epidermal necrolysis (TEN). Postoperatively, 89% of eyes achieved BCVA \geq 20/200 at some point during follow-up. However, at a final follow-up of more than 5 years, 50% of eyes retained BCVA \geq 20/200. In univariate analysis of patients who experienced irreversible loss of \geq 20/200 BCVA, several factors were significantly more frequent compared to those who retained the mentioned BCVA ($p=0.4$). These included previous implantation of an older design of BKpro-II, absence of preoperative systemic immunosuppression and lack of concurrent glaucoma tube implantation. The most prevalent complications were de novo glaucoma or progression of preexisting glaucoma, followed by choroidal effusions [28]. Previously, Pujari et al. in a study evaluating 29 implantations of BKpro-II in 26 patients acknowledged the results concerning functional success in long-term observation. At the final follow-up of more than 5 years, 46% had BCVA \geq 20/200. Additionally, the analysis of cumulative functional success, defined as the ratio of cumulative years with BCVA \geq 20/200 to total duration of time since surgery, was higher in patients with SJS/TEN (0.91) compared to those with MMP (0.64) or other indications (0.45). However, the differences did not reach statistical significance. In contrast, the RPM was the most common complication and retention rate was 58% during a total follow-up time [29].

Tarsorrhaphy may limit the use of BKpro-II, particularly in patients with extensive ocular trauma, including adnexa. Given that favourable biointegration and biocompatibility of the device influence both anatomical and functional success, the biological Kpros have presented superior long-term outcomes [13-15]. Osteo-odonto Kpro (OOKP), originally introduced by Strampelli and modified by Falcinelli (known as MOOKP), has emerged as a successful but technically demanding, multistage procedure. It involves the harvesting of a canine or other monoradicular tooth together with the surrounding alveolar bone and periosteum, along with the optical stem collectively referred to as osteo-odonto-acrylic-lamina (OOAL). Compared to BKpro-II, in the MOOKP technique the ocular surface is covered with buccal mucosal graft [30]. The procedure is performed unilaterally, preserving the contralateral eye in the event of Kpro failure. Patients must be aware of the cosmetic outcome and prepared for long-lasting and close follow-up [13].

The first stage of MOOKP involves anterior segment preparation, which includes keratoplasty, removal of all ocular surface epithelia, and securing a buccal mucosal graft covering the entire ocular surface. The OOAL is prepared in collaboration with a maxillofacial surgeon. Previously selected tooth is harvested with the surrounding alveolar bone and its periosteum. Subsequently, the dental lamina is drilled at the widest part, allowing for placing an optical cylinder. The OOAL thus prepared is typically inserted in the subcutaneous pouch formed in the contralateral orbito-zygomatic area. The second stage is performed 2-4 months later to allow for fibrovascular tissue formation around the OOAL and proper integration of the buccal mucosal graft. At this stage, the buccal mucosal graft is incised, and a central corneal trephination is performed to accommodate the optical cylinder. Total iridodialysis and lensectomy are subsequently carried out. The OOAL is then inserted into the corneal opening, sutured and covered with a mucosal flap, exposing only the anterior part of the optical stem through the mucosal layer. Several modifications of the procedure have been described [13,15,30,31].

In an analytical review by Ortiz-Morales et al. involving 958 patients who underwent MOOKP implantation, 78% achieved BCVA $\geq 20/400$ at the end of the follow-up period, ranging from one to 364 months (median: 36.7 months). Additionally, 91% of patients improved visual acuity at some point during the follow-up, while anatomical success at the final follow-up was reported in 88% of cases. The most common indications for the procedure were autoimmune diseases, followed by chemical injuries. Intraoperative complications occurred in 22% of patients, with maxillofacial structures being the most frequently affected. Among postoperative complications, the largest group was related to the lamina [31].

In patients with inadequate dental status, osteo-Kpro (OKP) utilizing a tibial bone block instead of a tooth-base lamina represents a viable alternative to MOOKP. Hille et al. compared long-term outcomes between 59 patients with OOKP and 34 patients with OKP (mean follow-up: 90 months and 54 months, respectively). The Kaplan-Meier survival analysis showed a slightly higher retention rate for OOKP, with survival rates of 95% vs. 89% at 2 years, 92% vs. 81% at 5 years of follow-up. Even 20 years after OOKP implantation, the retention rate was estimated at 56%, representing a more favourable outcome compared to other types of Kpros [32].

Patients with DED of autoimmune etiology are particularly predisposed to Kpro extrusion. While BKpro-II can be replaced, failure of the MOOK, especially among patients with poor dental status, significantly limits the possibility of visual rehabilitation [33]. In response to this clinical need, alternative biocompatible devices have been developed. LVP Kpro was designed for patients with dry-surface of the eye and contraindications to MOOKP. Based on the BKpro-I design, the device features an elongated optical stem and requirement of corneal graft, covered by mucosal transplant. In a study conducted by Basu et al., implantation outcomes of LVP Kpro in 58 eyes with mean follow-up of 2.5 ± 1.1 years were reported. Kaplan-Meier analysis showed BCVA $\geq 20/400$ in 62% of eyes at 1 year,

40% at 2 years and 33% at 5-years of follow-up. At the final follow-up, 78% of patients had improved BCVA by at least two lines. RPM formation was the most frequent complication. Although the retention rate remains favorable for MOOKP, the LVP Kpro presents a viable alternative when MOOKP is contraindicated or unfeasible [34].

The Lux Kpro was designed to combine the beneficial features of BKpro-II and MOOKP, offering potential treatment option for complex cases. The mucosal graft securing eye surface is performed before Kpro implantation in order to protect the ocular surface. Upon successful mucosal integration, the Lux Kpro comprising a cone-shaped PMMA optical cylinder, titanium sleeve, backplate and corneal graft can be implanted. The mean length of follow-up conducted by Bakshi et al. among 9 patients was 18.7 months. All patients achieved a BCVA $\geq 20/200$, and the retention rate was 100% at the final examination. Although further studies with larger cohorts and longer follow-up are required, the short-term outcomes appear promising [33].

Wang et al. presented results of MICOF Kpro implantation with at least 5 years of follow-up in Chinese patients who presented indications typically advised to undergo MOOKP surgery. The first surgical stage involves creating a central lamellar corneal pocket. In cases involving thin corneas, a titanium frame is inserted into the pocket. After 3 months, a second stage is performed, including pars planar irrigation, 2.5 mm trephination in the central overlying corneal tissue, lensectomy and anterior vitrectomy. The PMMA optical cylinder is then screwed into the titanium frame. Moreover, auricular cartilage has been innovatively utilized to support the PMMA cylinder. The ocular surface is typically covered with mucosal graft. In a cohort of 91 eyes, with mean follow-up of 8.38 ± 3.22 years, final examination revealed that BCVA $\geq 20/200$ was achieved in 45% and BCVA $\geq 20/100$ in 35% of cases. The most common postoperative complication was mucosal overgrowth observed in 32%. The anatomical retention rate was 85%, representing a comparatively favorable outcome in relation to BKpro-II. Nevertheless, the procedure's complexity and the loss of functional vision in over half of the patients underscore its limitations [35].

To improve biointegration, the Pintucci Kpro was developed with a Dacron mesh skirt facilitating connective tissue colonization. Pintucci et al. subsequently developed a technique involving subcutaneous implantation of the Dacron skirt for 40 days, followed by mucosal grafting of the ocular surface. The second stage consists of the Pintucci Kpro insertion [13,36]. Maskati et al. conducted Pintucci Kpro implantations in 31 eyes with a mean follow-up of 3.2 years. No cases of infection or RPM were observed. Glaucoma was the most frequent complication. Only 13% achieved BCVA $\geq 20/200$, while 77% of patients improved to greater than finger counting at 1.5 meters. Despite limited visual outcomes and the need for additional surgical interventions due to high complication rate, no Kpro failures were reported during the follow-up period [37]. The Table 2 provides an overview of

selected Kpro models according to their material composition, ocular surface coverage and supporting tissue characteristics.

Keratoprosthesis	Composition	Covering Tissue / Surface Support
BKpro-I	PMMA optical stem and frontplate with titanium backplate	Corneal graft
AuroKpro	Modified BKpro-I design	Corneal graft
ORC-Kpro	Modified BKpro-I design	Corneal graft
Lucia Kpro	Modified BKpro-I design with radial holes and anodized backplate	Corneal graft
AlphaCor	Poly (2-hydroxyethyl methacrylate) with interconnecting pores	Artificial cornea
CorNeat Kpro	Microporous matrix stimulating cellular growth	Subconjunctival integration
BKpro-II	PMMA optical part with elongated anterior extension	Corneal graft and complete tarsorrhaphy
MOOKP	Tooth-bone lamina with PMMA optical cylinder	Mucosal graft
Tibial OKP	Tibial bone block with PMMA cylinder	Tibial bone lamina implantation
Lux Kpro	Cone-shaped PMMA cylinder, titanium backplate	Prior mucosal grafting
LVP Kpro	Elongated PMMA optical stem	Mucosal graft covering corneal graft
MICOF	PMMA cylinder fixed into titanium frame with auricular cartilage support	Two-stage implantation with lamellar corneal pocket
Pintucci Kpro	PMMA optical part with Dacron mesh skirt and mucosal graft	Two-stage implantation with subcutaneous skirt

Keratoprosthesis	Composition	Covering Tissue / Surface Support
		colonization

Table 2. Overview of selected Kpro models, including their material composition and methods of ocular surface coverage and where applicable, supporting tissue characteristics.

Conclusions

Kpros represent the treatment of last resort and should only be considered when no other therapeutic options are available. Each Kpro must be individually selected based on the patient’s specific profile, the underlying cause of ocular surface disease, and both anatomical and functional status of the eye. A wide range of Kpro models is currently available. Among devices indicated for a wet-ocular surface, the BKpro-I demonstrates the most favourable outcomes in the largest patient group, whereas for a dry-ocular surface, the MOOKP remains the option with the highest anatomical and functional success. The search for ‘ideal’ Kpro continues, and emerging alternatives or device modifications require further investigation in large patient cohorts with long-term follow-up. Reporting results of any given Kpro should be based on standardized outcome measures and comparable follow-up periods to ensure reliable comparisons between different devices.

Disclosure Section

Author Contributions

Conceptualization, M.B., G.L. and O.G.; methodology, M.B.; software, G.L.; validation, M.B., O.G., and G.L.; formal analysis, O.G.; investigation, M.M.; resources, G.L.; data curation, O.G.; writing—original draft preparation, M.B.; writing—review and editing, O.G. and G.L.; visualization, M.B.; supervision, G.L.; project administration, O.G.; funding acquisition, M.B. All authors have read and agreed to the published version of the manuscript.

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During the preparation of this work, the authors used ChatGPT (GPT-5.5 model) for the purpose of improving language, readability and verification of bibliographic styles. After using this tool, the authors reviewed and edited the content as needed and take full responsibility for the substantive content of the publication.

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