Review Article

Keratoprosthesis: Current global scenario and a broad Indian perspective

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Keratoprosthesis (Kpro) forms the last resort for bilateral end-stage corneal blindness. The Boston Type 1 and 2 Kpros, the modified osteo-odonto Kpro and the osteo-Kpro are the more frequently and commonly performed Kpros, and this review attempts to compile the current data available on these Kpros worldwide from large single-center studies and compare the indications and outcomes with Kpros in the Indian scenario. Although the indications have significantly expanded over the years and the complications have reduced with modifications in design and postoperative regimen, these are procedures that require an exclusive setup, and a commitment toward long-term follow-up and post-Kpro care. The last decade has seen a surge in the number of Kpro procedures performed worldwide as well as in India. There is a growing need in our country among ophthalmologists to be aware of the indications for Kpro to facilitate appropriate referral as well as of the procedure to enable basic evaluation during follow-ups in case the need arises, and among corneal specialists interested to pursue the field of Kpros in understanding the nuances of these surgeries and to make a judicious decision regarding patient and Kpro selection and more importantly deferral.

Key words: Boston keratoprosthesis, keratoprosthesis, ocular surface disorders, osteoodonto keratoprosthesis

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Prosthetic corneas form the last resort for corneal blindness, especially in eyes with end-stage ocular surface disorders and in those at a high risk for conventional penetrating keratoplasty.[1,2] The choice of keratoprosthesis (Kpro) depends on the underlying etiology, the anatomy of the ocular surface and the tear film status. Broadly speaking, keratoprostheses are categorized into the Type 1 and 2 Kpros based on the type of eye they cater to.

Largely, eyes with normal lids, blink and tear film without an underlying immunological etiology are considered as candidates for the Type 1 Kpro, the prototype of which is the Boston Type 1 Kpro. However, in eyes with severely dry or keratinized ocular surface with an underlying immunological disorder, associated with lid abnormalities, Type 2 Kpros are considered as the treatment option of choice. Decision-making, therefore, forms one of the most important aspects of Kpro surgery not only for choosing the appropriate patient for Kpro but also for choosing the correct type of Kpro for the patient, which would go a long way in determining a successful outcome.

Most of the series reported thus far from a single center cater to only one type of Kpro predominantly and its outcomes. The ease of availability, technique, and the lesser need for support from ancillary disciplines has allowed the Boston Type 1 to be performed easily in various centers across the globe. On the other hand, the biological Kpros are currently being performed in a few centers across the world, as is the Boston Type 2 Kpro and are usually mutually exclusive.

At the Sankara Nethralaya Ocular Surface Clinic, Kpro procedures are being performed since 2003, with the initiation of the modified osteo-odonto Kpro (MOOKP) procedure for the 1st time in India under the guidance of the father of OOKP, Professor Giancarlo Falcinelli from Italy. This was followed by initiation of the Type 1 Kpro in January 2008, followed subsequently by the Boston Type 2 Kpro in January 2013 and the osteo-Kpro in January 2014, thus in all probability making it the only center currently that actively performs and offers all types of Kpros.

This review briefly presents the results of the various types of Kpros performed at our institute, comparing the same with the outcomes from large single-center studies of different types of Kpros. Etiology-specific, complication-specific, and multicenter studies have not been included due to a possibility of an overlap with the patients from the single-center studies. Guidelines regarding choice of Kpro and surgical techniques are described. The

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experience with various types of Kpros has provided some insight into understanding the virtues of a particular type of Kpro as well as its shortcomings, helping apply lessons learnt from one type to another.

Types of Keratoprosthesis/Design

The design of a Kpro can be likened to some extent to that of an intraocular lens consisting of an optic and a haptic. The optic, which forms the central part of the Kpro responsible for viewing, in most types is a cylinder made of polymethyl methacrylate (PMMA) – creating an optically clear window. It is the haptic of the Kpro which determines the type of the prosthesis, and this could be divided into:

- Biocompatible – usually a PMMA skirt with the corneal graft as in the Boston Type 1 and 2 Kpro
- Biointegrated – as in the Dacron mesh that forms the skirt around the PMMA optic in the Pintucci Kpro
- Biological – tooth or the bone that forms an autologous biological tissue that supports the optical cylinder in the osteoodonto and the osteo-Kpro, respectively.

The supporting cover tissue adds to the Kpro complex which is the bandage contact lens in the Type 1 Kpro that prevents the carrier graft desiccation. In Type 2 Kpros, the supporting cover is the skin in the Boston Type 2 and the buccal mucosa for the osteo and the osteo-odonto and Pintucci Kpros, respectively.

Indications

Kpros are performed for bilateral corneal blindness not amenable to conventional penetrating keratoplasty.

Indications for Type 1 Keratoprosthesis

With improved outcomes, the indications for Type 1 Kpro have been expanding over the past decade. However, it is best to categorize these based on prognostic hierarchy since eyes with guarded prognosis have an increased risk to develop complications.[2,3]

Good prognosis

1. Multiple failed grafts
2. Aniridia
3. Herpetic keratitis
4. Silicon oil-filled eyes.

Guarded prognosis

1. Pediatric corneal conditions
2. Chemical injuries.

Very guarded prognosis

1. Underlying immune conditions such as Stevens–Johnson syndrome (SJS)/ocular cicatricial pemphigoid (OCP)
2. Severe chemical injuries with severe forniceal shortening and lid abnormalities.

Indications for Type 2 keratoprosthesis

Based on the long-term anatomical and functional outcomes, the choice of Kpro in severe end-stage ocular surface disorders is preferably the MOOKP. In case of the patient being unsuitable for the same, the other Type 2 Kpros are chosen for the following:

1. SJS
2. OCP/mucous membrane pemphigoid
3. Severe chemical injuries
4. Severely keratinized surface.

The exclusion criteria for Kpros are tabulated in Table 1.

Pediatric Kpro forms a separate entity and the Type 1 Kpro is performed in pediatric population to visually rehabilitate children with congenital bilateral corneal disorders not amenable to penetrating keratoplasty. Type 2 Kpros are usually not performed in the pediatric population.

Preoperative Evaluation

1. A detailed history taking to determine etiology, onset (to gauge extent of amblyopia-loss of vision before 5 years of age is considered as a poor indicator for visual recovery), and previous intraocular surgeries is of paramount importance
2. All patients require a detailed ophthalmic evaluation including a B scan with axial length measurement
3. Perception of light and accurate projection of rays is assessed
4. Intraocular pressure is estimated by means of digital tonometry
5. Ultrasound biomicroscopy/anterior segment optical coherence tomography (ASOCT) helps assess the anterior segment details in eyes with scarred opaque corneas
6. Adequacy of blink is confirmed (Type 1)
7. Schirmer's I wetting is determined for adequacy of tears (Type 1)
8. Patency of nasolacrimal duct is confirmed by means of syringing to rule out focus of infection (for Type 1, if puncta open for Type 2)
9. Patients enlisted for the MOOKP should have a detailed dental and oral mucosal evaluation with a spiral computed tomography scan to evaluate the canines preoperatively along with determining fitness for general anesthesia
10. Counseling the patient and family with respect to realistic expectations, the need for compliance with postoperative

Table 1: Exclusion criteria for keratoprosthesis procedures

Exclusion criteria		
	Specific for MOOKP	Specific for Boston Type 2
1. Unrealistic expectations	1. Edentulous	1. Absent eye lids
2. Nil perception of light	2. Poor oral hygiene	
3. Advanced glaucoma/retinal conditions	3. Unfit for general anesthesia	
4. Unwilling or unable to report for regular follow-ups	4. <18 years of age	
5. Unwilling to accept cosmetic outcome		
6. Unwilling to follow postoperative care and restrictions		
7. Dense amblyopia		

MOOKP: Modified osteo-odonto keratoprosthesis

care and follow-ups, the expected cosmetic outcome and the need to report back or to the nearest ophthalmic specialist immediately in case of unexplained drop in vision or pain, forms the most important aspect
11. A detailed check-list is verified before every procedure/stage to ensure a complete preoperative evaluation.

Surgical Technique and Postoperative Care

Boston Type 1 keratoprosthesis

1. Decide on the type of Kpro to be ordered: pseudophakic/aphakic; adult (8.5-mm backplate)/pediatric (7.0-mm backplate)
2. Axial length to be specified for aphakic Kpro
3. Kpro to be ordered for, and an extra Kpro to be ordered as a standby
4. Local or general anesthesia as indicated
5. The recipient cornea is marked with the trephine as required
6. Kpro to be assembled before trephining the recipient. Backplate of the Kpro measures 8.5 mm and hence the minimum donor graft size to be 8.5 mm. The donor cornea is usually oversized by 0.5 mm. The central 3 mm opening in the donor cornea is subsequently trephined
7. Fresh therapeutic grade donor cornea is preferred to assemble the Kpro
8. The optic is placed on the adhesive strip upside down. The donor graft is slid down the stem of the optic into its slot using a wrench. The back-plate is slid in place. The assembly is then locked with the titanium ring and checked for a snug fit
9. The recipient cornea is further trephined and removed. Any intraocular procedure as planned to be performed
10. The assembled Kpro is then sutured like in a penetrating keratoplasty using 16 interrupted 9-0 nylon sutures, preferably buried
11. A bandage contact lens is placed on the Kpro.[4]

Postoperative regimen

1. Fourth generation fluoroquinolone 4 times a day for a month, continued 2/day indefinitely
2. Topical vancomycin (14 mg/ml) 4 times a day for a month, continued 1/day indefinitely, for high-risk eyes
3. Topical steroids tapered to 2/day, indefinitely or discontinued after 6 months
4. Topical lubricants as required
5. BCL to be changed once in 3 months, application of 5% povidone-iodine in clinic at the time of BCL replacement
6. Follow-up every 3 months.[2]

Examination during each follow-up visit

1. Change in refraction. A hyperopic shift could indicate an early leak, a myopic shift could be indicative of raised intraocular pressure
2. Deposits on BCL, if any, to preferably be submitted for microbiological evaluation.
3. To assess for air bubbles under the optic flange as well as immobile bubbles beneath the BCL that could indicate early thinning of the carrier graft
4. The graft around the optic should be inspected for the presence of any infiltration
5. Slit-beam examination to assess for any irregularity in the carrier graft
6. Presence of retroprosthetic membrane (RPM), if any
7. Presence of loose sutures, if any, should be removed
8. Intraocular pressure is monitored by digital tonometry
9. 90D lens examination to document the optic disc and posterior pole findings
10. Following removal of the BCL for replacement, the graft should be stained with sterile fluorescein to look for the presence of any epithelial defect or leak
11. Use of 5% povidone-iodine in the eye is recommended at the time of BCL replacement.
12. Slit-lamp photographic documentation of the eye
13. Humphrey visual field analysis once in 6 months
14. ASOCT to identify early graft thinning, periprosthetic tissue loss, retroprosthetic membrane, and angle details once in 6 months
15. B-scan ultrasonography once in a year.

Boston Type 2 keratoprosthesis

The procedure is largely similar to the Boston Type 1 Kpro in terms of Kpro assembly and suturing.

The differences include:

1. The anterior nub of the Kpro protrudes by 2 mm to accommodate the skin
2. The backplate is titanium and snaps onto lock the Kpro complex. There is no separate titanium ring
3. In the recipient, the entire conjunctival mucosa is removed from lid margin to lid margin
4. Sphincterotomy is done to keep the pupil mid-dilated
5. Following Kpro suturing, pars plana vitrectomy is performed along with Ahmed glaucoma valve implantation in all eyes
6. The lid margins are excised to completely be rid of hair follicles. A meticulous suturing of the lid margins in 2 layers is done around the optic.

Postoperative regimen

1. Systemic and topical steroids to be tapered and stopped over a month
2. Topical antibiotic drops – fourth generation fluoroquinolone for 2 weeks
3. Topical antibiotic ointment at bedtime to be continued indefinitely
4. Meticulous cleaning over the Kpro for the 1st postoperative week to prevent skin overgrowth
5. Lid sutures are removed on day 10
6. Follow-up once every 3 months.

Modified Osteo-Odonto Keratoprosthesis

A three-staged procedure; the MOOKP is performed largely as per the Rome-Vienna Protocol.[5] In the 1st stage, termed Stage 1 A, the eye is prepared for the procedure by removing the iris, doing a cryolens extraction and a limited anterior vitrectomy. A tectonic penetrating keratoplasty at this stage is performed only in case of any corneal thinning noted.

A month later, the Stage 1 B + C is done. This involves harvesting the chosen canine tooth, preferably maxillary and fashioning it into an osteo-odonto alveolar lamina with the optical cylinder fixed. The lamina is placed in the contralateral cheek subcutaneous pouch for it to develop its fibrovascular covering over the next 2–3 months. Simultaneously, the buccal mucosa measuring 3 cm in diameter is harvested and draped over the ocular surface securing it to the 4 recti muscles.

Three months later, the Stage 2 of the procedure is performed. The lamina is removed from the subcutaneous pouch and prepared. The mucosa over the ocular surface is reflected with an inferior hinge. The central cornea is trephined as per the posterior diameter of the optical cylinder and the lamina is placed in the eye. The oral mucosa is reflected back over the lamina and sutured and a central opening is made in the mucosa for the cylinder to protrude through.

Postoperative regimen

1. Systemic and topical steroids and antibiotics are administered after every stage as warranted
2. Topical antibiotic ointment is continued once a day indefinitely
3. Topical lubricants are continued indefinitely
4. Follow-up once every 6 months, in addition, to evaluate the health of the oral mucosa and the lamina.

Osteo-Keratoprosthesis

The procedure is very similar to the MOOKP. The bone is harvested instead of the tooth from the tibia and the same is fashioned into an osteo-lamina, in which the optical cylinder is fixed.

The final appearance of the eyes following each of the Kpros is illustrated in Fig. 1.

Beyond the surgical technique and postoperative care, it is imperative to follow certain general guidelines with regard to Kpros and the same has been highlighted in Table 2.

Keratoprosthesis Setup

Setting up a Kpro unit involves considerable planning and execution. A strong sense of commitment forms the most important prerequisite. The team should constitute glaucoma, vitreoretinal, and oculoplastic colleagues along with anesthetists, and nursing staff.

For Type 2 Kpros, a more elaborate setup is required with the need for general anesthesia. Coordination with oromaxillofacial surgeons and radiologist is crucial. The appropriate instruments have to be procured for the dental or bone graft procedures.

While ordering for Type 1 Kpros, aphakic Kpros require the axial length of the eye to be provided. A second Kpro is always kept as a backup for an inadvertent loss or breakage of the Kpro during surgery.

Table 2: General guidelines and practical pearls regarding keratoprosthesis procedures

1. An important caveat is to recommend Kpro only in cases with bilateral corneal blindness
2. Kpro is not an alternate to penetrating keratoplasty
3. Kpro is not advised for patients with normal vision in one eye. It benefits neither the visual field nor the stereoacuity, and hence, these should not be quoted as reasons for performing Kpro in patients with one normal eye Improving cosmesis is not an indication for performing Kpro
4. All options to attempt visual recovery including PROSE lenses should be exhausted before considering Kpro
5. Multiple prior intraocular procedures can impact the outcome of Kpro, especially with respect to glaucoma, and hence a judicious decision needs to be taken regarding Kpro versus multiple grafts in eyes amenable to penetrating keratoplasty. Conversely, Kpro is usually considered as the last resort, since complications related to Kpro can be globe threatening
6. Patients have to be willing to be compliant with medications that approximately cost up to INR 20000 annually for the Type 1 Kpro, apart from travel and stay to follow-up once every 3 months indefinitely, to avoid exposure to external source of water indefinitely (for Type 1 and Type 2 Kpro), failure to agreeing to abide by any of the above is an exclusion criteria for Kpro
7. With multiple Kpro options available for visual rehabilitation in the chronic stage of severe bilateral chemical injuries, every chemical injury in the acute stage should be managed aggressively with the sole aim of preventing corneal perforation, and salvaging the globe however severe the injury might be. Severe cases in the acute stage should be referred to tertiary centres if required. Any posterior segment complication in the acute stage should be corrected. A simple tarsorrhaphy before referring could reduce the risk of perforation in eyes with exposure and large epithelial defects
8. Type 1 Kpro is a viable alternative in eyes with chronic hypotony with silicon oil in the eye. 5000 centistokes oil is the preferred choice for long-term retention of oil
9. Type 1 Kpro is not primarily recommended in patients with underlying immunological conditions such as SJS or MMP, even if the tear film is adequate
10. Bilateral Kpro is contraindicated
11. Bilateral Kpro is contraindicated, to reemphasize. The other eye is continuously monitored, to be retained as a reserve eye in case of loss of vision in the eye with Kpro secondary to complications

Kpro: Keratoprosthesis, MMP: Matrix metalloproteinases, SJS: Stevens–Johnson Syndrome

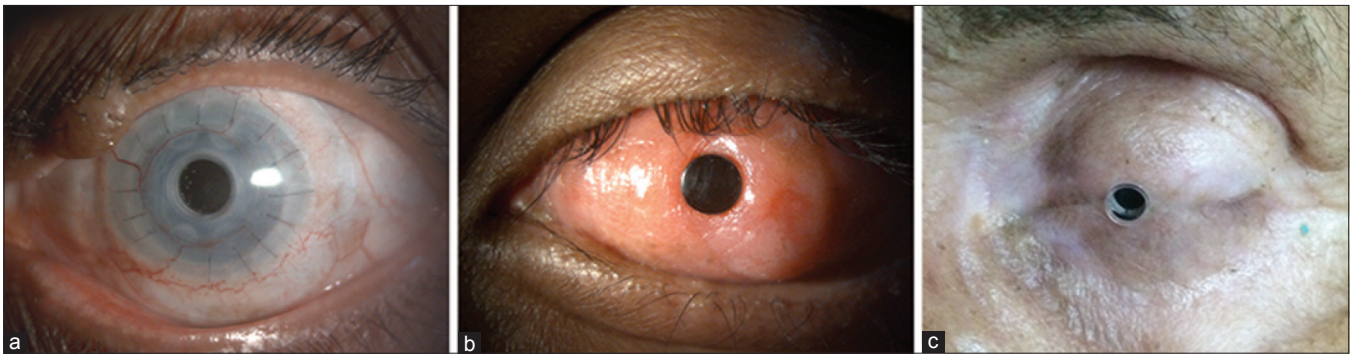

Figure 1: Final appearance of the eye following Boston Type 1 keratoprosthesis (a), modified osteo-odonto keratoprosthesis (b) and Boston Type 2 keratoprosthesis (c) at postoperative 9, 12, and 2 years, respectively

Table 3: A comparison of single-center indications and outcomes of Type 1 and Type 2 keratoprosthesis

Number	Study	Number of eyes (patients)	Mean follow-up (months)	Indications (%)	BCVA ≥20/200 (%)	Complications							Anatomical Retention (%)
						Melt (%)	RPM (%)	Glaucoma			RD (%)	Endophthalmitis (%)	
								Prior (%)	Progression	New (%)			
Boston Type 1													
1	Chan *et al.*,[6] Cincinnati, USA, 2004-2010	128 (110)	29 (3-77)	Chem-20 SJS-12 MMP-2 Others-66	NA	16	NA	NA	NA	NA	NA	NA	NA
2	Bouhout *et al.*,[7] Canada, 2008-2012	110 (96)	31±15 (2-59)	Chem-13 Immune-10 Others-87	NA	14	42	NA	55	NA	NA	11.8 IK-1.8	NA
3	Goins *et al.*,[8] Iowa, USA, 2008-2014	75	41.4 (0.8-82.8)	Chem-12 MFG-53.3 Aniridia-13.3 Viral-12	62.7% (>20/400)	14.7	33.3	89.3	NA	NA	12	9.3	85.3
4	de la Paz *et al.*,[9] Barcelona, Spain, 2006-2011	67	26	Chem-17.9 Immune-23.8	NA	NA	34	NA	NA	NA	NA	NA	78
5	Aravena *et al.*,[10] Los Angeles, USA, 2004-2011	58 (55)	82.8±20.5 (57-145)	Chem-16.2 SJS-10.8 MFG-50	86 - achieved 68.9 - maintained	25.9	51.7	74.1	14	24.1	15.5	0	74.3
6	Patel *et al.*,[11] New York 2006-2010	58 (51)	21.5±11.4 m (3-47)	Chem-5.17 MMP-5.17 MFG-81	43.1%	6	50	75.9	25.9	NA	10.3	1.7	87.9
7	Güell *et al.*,[12] Barcelona, Spain, 2006-2011	54 (53)	20.15±12.7 (1-56)	Chem-1.85 SJS-1.85 MMP-1.85 MFG-90.7	33.3	NA	NA	74	NA	NA	NA	NA	96
8	Lekhanont *et al.*,[13] Bangkok, Thailand, 2006-2013	42 (40)	64.9±15.2 (48-88)	Chem-19.04 SJS-19.04 MFG-59.5	66.7 - achieved 42.9 - maintained	23.8	52.4	NA	42.2	54.2	4.76	11.9 IK 21.4	80.9
9	Greiner *et al.*,[14] California, USA, 2004-2010	40 (35)	33.6 (5-72)	Chem-25 Aniridia-12.3 MFG-47.5	89 (>1 year fu) 59 - maintained	15	55	NA	22.5	27.5	NA	12.5	80

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Table 3: Contd...

Number	Study	Number of eyes (patients)	Mean follow-up (months)	Indications (%)	BCVA ≥20/200 (%)	Complications							Anatomical Retention (%)	
						Melt (%)	RPM (%)	Glaucoma			RD (%)	Endophthalmitis (%)		
								Prior (%)	Progression	New (%)				
10	Chew *et al.*,[15] Philadelphia, USA, 2005-2007	Type 1 36 Type 2 1	16±6 (6-28)	Chem-5 SJS-3 MFG-78	43 (>20/50)	11.1	65	73	13.5	38	NA	11	100 0	
11	de Oliveira *et al.*,[16] Brazil, 2008-2012	30	32 (1-55)	Chem-33.3 SJS-13.3 MFG-53.3	80	NA	26.6	53.3	43	10	6.6	0 IK 3.3	NA	
12	Duignan *et al.*,[17] Ireland, 2002-2014	Type 1 31 Type 2 3	42±31 (2-110)	Chem-8.8 SJS-2.9 MMP-5.9 MFG-11 MMP-2 SJS-1	Achieved - 73.5 Maintained - 47	14.7	52.9	32.4	NA	17.6	5.9	14.7 IK 11.76	82.4	83.9 6.66
13	Shihadeh and Mohidat[18] Jordan, 2007-2010	20 (19)	18.1±9.5 (3-36)	Chem-15 MMP-5	65	10 - extrusion	45	25	20	NA	NA	5	NA	
14	Arfaj and Hantera[19] Saudi Arabia, January–December 2009	4	11 (median) (6-14)	Chem-2 Trachoma-1 MFG-1	100	25	NA							
15	Our study Chennai, India (unpublished data), January 2008-June 2017	65	38.61 (2-116)	Chem-40 SJS-4.6 MMP-1.5 MFG-23.07 Si oil-30.7	69.2	49.2	24.6				26.1	15.4	81.53	
Type 2 Kpros														
1	OOKP Falcinelli *et al.*,[20] Rome, Italy, 1973-1999	181	144 (12-300)	Chem-37.5 SJS-2.5 OCP-21.5	55 (retained BCVA at 18 years)	2	1			7	3	2 14 (8)	85 (18 years)	
	OOKP Liu *et al.*,[21] UK, 1996-2006	36	46.8 (6-108)	Chem-16.7 SJS-44.4 MMP-13.8	78	19.4	16.7	47.2		24	8.6	8.6	72%	

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Table 3: Contd...

Number	Study	Number of eyes (patients)	Mean follow-up (months)	Indications (%)	BCVA ≥20/200 (%)	Complications							Anatomical Retention (%)
						Melt (%)	RPM (%)	Glaucoma			RD (%)	Endophthalmitis (%)	
								Prior (%)	Progression	New (%)			
2	OsteoKpro Charoenrook *et al.*,[22] Barcelona, Spain, 1987-2013	113	4.2 years (1 m-17.4 years)	Chem-25.7 OCP-24.8 SJS-15.9 Thermal-6.2	5 years–33 10 years 19.2 years 15 years–12	27.4	4.4			10.6	10	3.7	69.5-5 years 53.5-10 years 42.8-15 years
3	Boston Type 2, Lee *et al.*,[23] Boston, USA, 1992-2015	48	70.2±61.8 (6 m-19.8 years)	SJS-41.7	37.5	50	60.4	72.9	27.1	8.3	6.3	10.4	50
4	SN Study-OOKP, Chennai, India (unpublished data), 2003-2017	100	60.45 (6-144)	SJS-62 Chem-36	66	23	2			0	5	10	68
5	SN-Study Boston Type 2 Chennai, India (unpublished data), 2013-2017	12	15.9 (2-47)	SJS-75 Chem-16.7 MMP-8.3	83.3	8.3	8.3		0	0	8.3	8.3	91.6

MMP: Mucus membrane pemphigoid, chem: Chemical injury, SJS: Stevens–Johnson Syndrome, MFG: Multiple failed grafts, BCVA: Best-corrected visual acuity, RD: Retinal detachment, RPM: Retroprosthetic membrane, Kpro: Keratoprosthesis, NA: Not available, OOKP: Osteo-odonto keratoprosthesis, MMP: Matrix metalloproteinases, OCP: Ocular cicatricial pemphigoid

An affiliation to an eye bank is required to procure the corneal tissue for Kpros that require a carrier graft and as a backup tissue for the others that might reveal intraoperatively, the need for a tectonic keratoplasty.

Consent forms and checklists have to be elaborate and cross-checked before every stage of surgery. Counseling by a psychologist helps the patient in a smooth transition in the perioperative period. It is essential to have a mentor and be trained in the procedure before initiating Kpro surgeries to understand better the nuances involved in the same.

Outcomes

In recent times, the outcomes of especially the Type 1 Kpro have considerably improved. The visual outcome depends on the indication and is noted to be best among eyes with multiple failed grafts. A comparison of the outcomes of the different types of Kpro from single-center studies have been tabulated and compared with our outcomes (unpublished data) [Table 3].

The only other reported series from India include the International results of the Type 1 Kpro (59% of the 113 eyes belonging to the international arm were from 5 centers across India)[24] and our short-term outcomes of the MOOKP in 50 eyes.[25] This data has been used for comparison along with our current outcomes.

Previous donor graft failure has been the major indication for Type 1 Kpro in most series in comparison to ours that catered primarily to chemical injuries. Silicone oil-filled eyes formed the second common indication in our series for performing type 1 Kpro.[26]

The most common complications encountered are sterile melts, glaucoma, and retroprosthetic membrane and these are discussed further in detail.

Sterile melts

Sterile melts have been noted to occur in up to 26% of eyes in various series [Fig. 2]. It is imperative to pick up early signs described earlier.

In the presence of melt, the general dictum is to assess the extent of associated thinning. In mild cases, cyanoacrylate glue application to the area of thinning would suffice. In moderate cases involving a few or more clock hours, a crescentic or annular lamellar graft [Fig. 2] would be required to address the melt. In the presence of extensive melts, associated with aqueous leak, it would probably be best to replace the Kpro with a new one, unless the area of leak is very small and can be addressed by the above other means. In addition, medical supportive measures could include topical medroxyprogesterone and systemic doxycycline with copious lubrication and a tarsorrhaphy in cases with frequent BCL displacements leading to graft desiccation.

Sterile melts occurred in almost 50% of the cases in our series, primarily in patients with chemical injuries. This increased occurrence of melts in eyes with chemical injuries has been reported by Chan *et al*. with chemical injuries accounting for 35% of melts in their series. Considering that the Type 1 Kpro is performed in a relatively larger number (27% compared to 7%) of patients with chemical injuries in our country, an indication that has been seen to be associated with increased risk of sterile melts, Kpro surgeons in India should be aware of the same and attempt to pick up early signs of melt to salvage the Kpro. This can occur at any time frame following the Kpro.

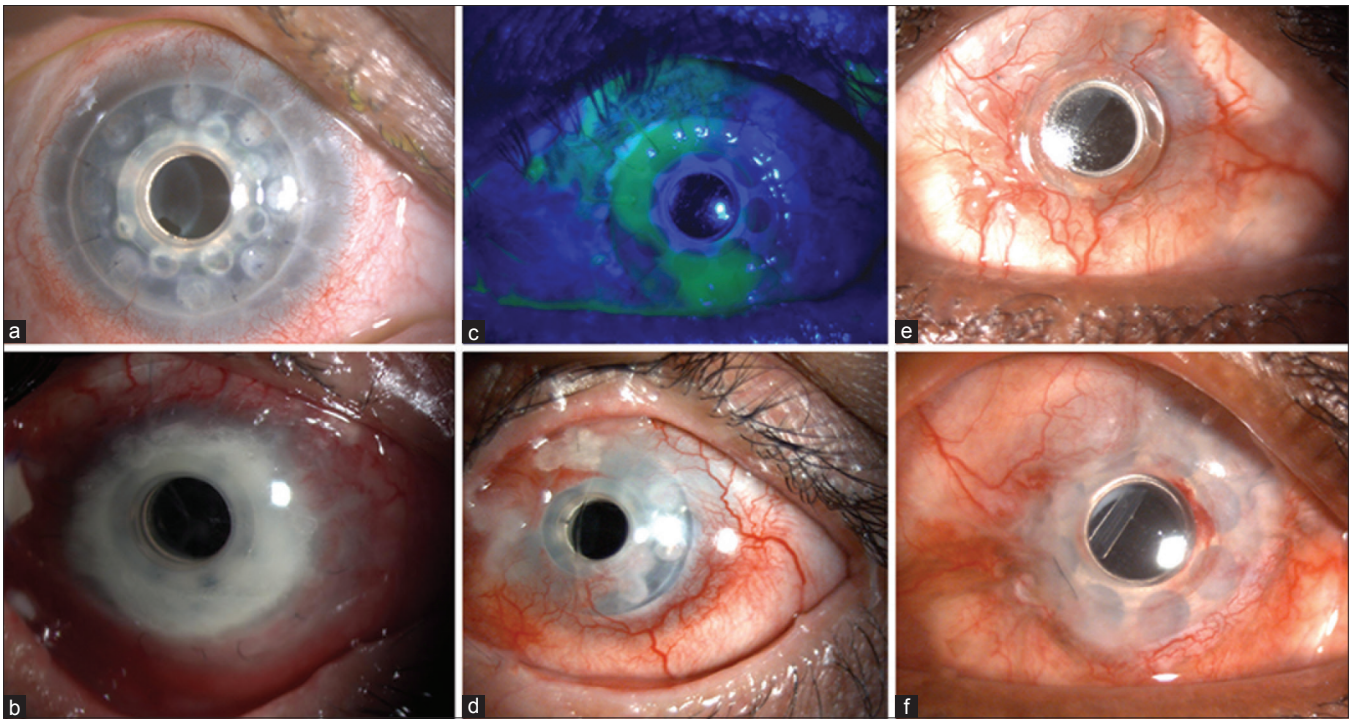

Figure 2: (a) Retroprosthetic membrane in a silicone oil-filled eye after Boston Type 1 keratoprosthesis, not visually significant. (b) Carrier graft infiltration in an eye with vitreous exudates and endophthalmitis 2 years following Boston Type 1 keratoprosthesis. (c) Epithelial defect noted on fluorescein staining after BCL removal, not associated with thinning. (d) Sterile carrier graft melt with edge lift of the keratoprosthesis. (e) Perioptic annular melt with no leak. Note the air bubble in the gap beneath the flange of the optic. (f) Same eye as e following an annular lamellar graft

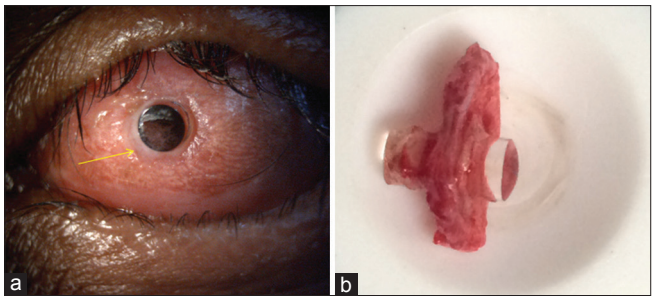

Figure 3: (a) Aqueous leak (indicated by yellow arrow) around the optical cylinder 8 years after modified osteo-odonto keratoprosthesis. (b) Laminar resorption seen following removal of the lamina

Periprosthetic tissue loss has been referred to as one of the possible associations with idiopathic sterile vitritis, and the same terminology can be extended to the melts involving the haptic in other types of Kpro.[27] A similar process in the MOOKP/OKP is termed as laminar resorption[28] [Fig. 3]. A sterile inflammatory process that initiates the keratolysis could by virtue of proximity spill over into the vitreous, especially in single chamber aphakic eyes leading to a sterile vitritis. Sterile vitritis induced decrease in vision was the most common presenting feature of laminar resorption in our MOOKP series that resolved completely in most instances with systemic steroid-antibiotic management.[28]

Retroprosthetic membrane

RPM has been reported as the most common complication in various series published so far with majority of the studies quoting an occurrence in more than 50% of the eyes. However, RPM was seen in our series in only 25% of the eyes, especially in silicone oil-filled eyes. Although RPM was noted to be the most common complication in the group performed outside of North America, it was seen in only 26.7% of the eyes at a mean follow-up of 14.2 months.[23] RPM has also been implicated as one of the causes for sterile corneal melts by virtue of preventing access of aqueous to the carrier graft.[6] A recent study has shown no benefit of titanium backplate over a PMMA backplate in the formation of RPM, with similar rates of RPM noted in both.[29] Performing a total pars plana vitrectomy appears to reduce the rate of RPM formation.[30]

Although details regarding the Kpro being aphakic or pseudophakic were not available for all the series', the international arm of the multicenter study, of which Indian centers formed an important subset had aphakic Kpros implanted in 62% of the eyes. All the Type 1 Kpros in our series were aphakic Kpros.

Whether the eye being aphakic or pseudophakic contributes toward the formation of RPM needs to be studied further. Theoretically, an aphakic eye without the posterior capsule and the iris in certain instances does not provide any scaffold for the RPM to form similar to what is seen in the MOOKP eyes where the rate of primary RPM formation is very low.

Visually insignificant RPM's can be observed and monitored [Fig. 2]. Visually significant RPM's can be addressed by means of neodymium: yttrium-aluminum-garnet laser membranotomy or a surgical membranectomy.

Glaucoma

Glaucoma continues to be the most common comorbid factor with progressive decrease in vision post-Kpro occurring most commonly secondary to continued progression of glaucoma.[2] Interestingly, there was no de novo glaucoma in the MOOKP eyes in our series. In eyes with coexistent glaucoma before Kpro placement, glaucoma needs proactive and aggressive management. It would be prudent to simultaneously place a drainage implant in eyes with the Type 1 Kpro, and the timing of placing a valve in eyes undergoing the MOOKP procedure is based on the stage of surgery.[31]

Endophthalmitis

At 15.4%, endophthalmitis in our series of Type 1 Kpros was noted to be more compared to the other single-center series' over a mean follow-up of 38 months (9% in the international study group at 14.2 months mean follow-up).[24] Endophthalmitis was noted in 10% of eyes with the MOOKP as well as the Boston Type 2 Kpro in our series. Fungal etiology was noted in almost equal number of eyes as those with bacterial endophthalmitis.

Conclusion

Considering the tropical region, in which we live with a primarily agrarian population, the risk of infection is probably bound to be more compared to the results quoted in the Western literature.[32] The indication profile in the developing countries also varies with the guarded and very guarded prognosis categories forming a major proportion of cases that undergo Type 1 Kpro. Hence, direct comparisons with outcomes and complications and applying them to different geographical zones might not be appropriate. Lekhanont *et al*. reported infective keratitis in 21.4% of the eyes and endophthalmitis in 11.9% at a mean follow-up of 64.9 months in a single-center series from Thailand.[13]

Among the MOOKP also, SJS forms a major indication, unlike other studies where chemical injuries predominate.[20,21] Issues specific to eyes with SJS in terms of laminar resorption and its consequences, therefore, have led to outcomes in our country that are suboptimal compared to reported outcomes in the non-SJS category.[28,33] However, the results with the MOOKP appear to be superior to the Boston Type 2 Kpro at a longer follow-up in a similar SJS population, retaining MOOKP as the procedure of choice in these eyes.

Variations and modifications from existing procedures to improvise or simplify techniques and outcomes should be done in a controlled manner, comparing outcomes with the existing gold standards, and should not be attempted by novice Kpro surgeons.

With a holistic understanding of Kpro and its implications, the need to follow strict postoperative compliance with medications, follow-ups and restrictions cannot therefore be overemphasized. Herein, decision-making and counseling plays the most crucial aspect of Kpro surgery, knowing when to operate and when not.

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Conflicts of interest

There are no conflicts of interest.

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