Gamma-Irradiated Corneas as Carriers for the Boston Type 1 Keratoprosthesis: Advantages and Outcomes in a Surgical Mission Setting

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Purpose: The Boston keratoprosthesis (KPro) is the most commonly used KPro worldwide. There are limited data on the outcomes when irradiated corneas are used as KPro carriers. We report a retrospective analysis of corneal transplantations performed in a regular surgical mission setting in Beirut, Lebanon, using the Boston KPro type 1 and gamma-irradiated carrier corneas, and we describe visual outcomes, complications, and retention percentage.

Methods: We conducted a retrospective analysis of 17 consecutive eyes from 16 patients who underwent Boston KPro type 1 implantation at the Beirut Eye Specialist Hospital between December 2010 and July 2012. Patient medical records were reviewed for preoperative, intraoperative, and postoperative details.

Results: Postoperatively, 9 (52.9%), 5 (29.4%), and 2 (11.7%) eyes had a corrected visual acuity of 20/400 or better, 20/100 or better, and 20/40 or better, respectively, at the most recent follow-up visit. A total of 16 eyes (94.1%) improved in corrected visual acuity over the course of follow-up. Overall, 13 eyes (76.4%) developed at least 1 complication after surgery. Retroprosthetic membrane formation was the most common complication, occurring in 10 eyes (58.8%). Neither infectious keratitis nor corneal stromal necrosis was noted during the follow-up period. The retention percentage was 94.1%.

Conclusions: The visual acuity outcomes, incidence of complications, and retention percentage of the KPro using gamma-irradiated carrier corneas are comparable with the outcomes of KPro implantation reported in the literature using fresh grafts as carriers. KPro with irradiated corneal carrier grafts seems to be an effective option to increase the supply of transplantation suitable corneas in remote areas, where fresh corneal grafts may be scarce.

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The Boston keratoprosthesis (KPro) is the most commonly used KPro worldwide, with >6000 devices implanted to date.[1] The basic design of the Boston KPro is a donor cornea placed between 2 plates.[2] The majority of corneas used for this purpose have been freshly donated grafts. The primary obstacle in expanding KPro access outside major cities and into developing countries is the shortage in cornea supply and a relatively low recruitment of donated corneas for transplant.[3,4] The limited supply of fresh corneas is further challenged with a rising demand for corneal transplantation as the population ages.[5] The need to identify alternative sources for grafts, such as frozen or irradiated corneas, has become a crucial issue.[6,7]

Gamma-irradiated corneal tissue [VisionGraft Sterile Cornea; Tissue Banks International (TBI), Baltimore, MD] has several advantages that make it a carrier of choice in Boston Kpro procedures for international surgical missions. Unfortunately, there are limited data on the outcomes of irradiated corneas used as KPro carriers.[8] We report a retrospective study of the Boston KPro type 1 corneal transplantation performed using the VisionGraft irradiated cornea and describe visual outcomes, complications, and retention percentage in a surgical mission setting.

MATERIALS AND METHODS

We conducted a retrospective analysis of 17 eyes in 16 patients (7 female and 9 male; age range, 4–76 years) who underwent a Boston KPro type 1 implantation at the Beirut Eye Specialist Hospital in Lebanon, performed by a single surgeon (S.M.). Consecutive surgeries performed from December 2010 to July 2012 were considered for inclusion in this study.

All patient medical records were reviewed for preoperative and postoperative characteristics. Visual acuity was recorded using the Snellen chart; other techniques reported included counting fingers (CF), hand motion (HM), and light perception (LP). Preoperative intraocular pressure (IOP) was measured using Goldmann applanation tonometry or a pneumatonometer (Reichert Model 30, Depew, NY) depending on the status of corneal disease.

Patients were considered for KPro implantation if they were deemed to have adequate visual potential and if they had

a low chance of success with penetrating keratoplasty (PKP). Exclusion criteria included the following: no LP, no recognition of nasal light projection, minimal chance of recovering meaningful vision (eg, chronic retinal detachment or near end-stage glaucoma), and the presence of comorbid ocular conditions associated with an unacceptably high risk of developing postoperative complications (eg, inadequate eyelid function, severe ocular surface desiccation, ocular surface keratinization, and recalcitrant intraocular inflammation).

Surgical Technique

The Boston KPro type 1 was obtained from the Massachusetts Eye and Ear Infirmary (Boston, MA). Gamma-irradiated carrier corneas were obtained from Tissue Bank International [VisionGraft Sterile Cornea; Tissue Banks International (TBI), Baltimore, MD].

The standard implantation technique was performed as described by Dohlman and Barnes.[2] The VisionGraft was supplied either as a KPro ring consisting of a precut donor button of a 8.5- or 9.0-mm diameter with a central 2.8-mm hole, or as a cornea with a rim, in which case the cornea was trephined by the surgeon in the operating theater. The recipient cornea was prepared as is typically done for a traditional PKP (the usual host trephine being 0.50 mm smaller than the donor). If the patient was pseudophakic (noted in 4 eyes), the intraocular lens was explanted intraoperatively. In our experience, it was difficult to assess the intraocular lens stability preoperatively. Because the KPro was preassembled, we preferred to avoid having to disassemble it or implant a pseudophakic KPro in an unexpectedly aphakic patient. An anterior vitrectomy was conducted in 8 eyes. In phakic patients (5 eyes), a lensectomy was performed. No intraocular lens was placed after the lensectomy, as is routine practice. There were no intraoperative posterior capsular ruptures in the cases requiring a lensectomy. An Ahmed valve (New World Medical, Rancho Cucamonga, CA) was placed in 1 patient because of a refractory high IOP, despite the administration of topical medications. All carrier grafts were sutured in place with 12 interrupted 9-0 nylon sutures. At surgical completion, a subconjunctival injection of gentamicin (20 mg) and dexamethasone (2 mg) was administered, and a 16-mm diameter soft KontourTM contact lens (Kontour Contact Lens, Richmond, CA) was placed and maintained throughout the entire follow-up period.

Data Analysis

Statistical analysis was performed with a Fisher exact test using the Statistical Program for Social Sciences version 13.0 (SPSS v13.0, SPSS Inc, Chicago, IL).

RESULTS

Patient Characteristics

Seventeen eyes from 16 patients were included (Table 1). Among the patients, 9 (56.2%) were male, and 7 (43.8%) were female. Their mean age was 49.8 ± 21.1 years (range, 4–76 years). The mean follow-up period was 15.2 ± 3.3 months (range, 12–22 months). The most common preoperative diagnoses were bullous keratopathy (8 eyes; 47.1%) and chemical injury (2 eyes; 11.8%). Preoperative comorbidities included glaucoma (7 eyes; 41.2%), limbal stem cell deficiency (8 eyes; 47.1%), and previous retinal detachment repair (1 eye; 5.9%). Five (71.42%) of the 7 eyes with a history of glaucoma were on >1 pressure-lowering topical medication. Among these, 2 eyes had a prior trabeculectomy. Another eye had a prior trabeculectomy but was not receiving any pressure-lowering medication. Preoperative visual acuity ranged from LP (5 eyes; 29.4%) to CF at 1.5 m (1 eye; 5.9%).

The most common indication for KPro implantation was a prior failed corneal transplantation (10 eyes; 58.8%). The number of prior transplantations varied from 1 to 3. The mean number of prior transplants among these eyes was 1.5 ± 0.7. Six patients had undergone 1 prior corneal transplant; the decision was made to proceed with a KPro implant rather than to repeat transplantation because of the presence of ≥1 comorbid conditions that increased the risk of experiencing repeat transplant failure, such as extensive corneal vascularization. The indication for KPro implantation in the 7 eyes that did not previously receive a corneal transplantation was limbal stem cell deficiency with corneal vascularization and opacification.

Intraoperative Variables

Of the 17 KPro implants, all were found to be aphakic. Fifteen eyes (88.2%) had at least 1 concomitant procedure performed with KPro implantation. These concurrent procedures included anterior vitrectomy (8 eyes; 47.1%), cataract extraction (5 eyes; 29.4%), conjunctivoplasty (1 eye; 5.9%), and Ahmed valve placement (1 eye; 5.9%). No intraoperative complications occurred during the KPro implantation.

Visual Acuity Outcomes

Postoperatively, none of the patients had a corrected visual acuity (CDVA) better than 20/25 or worse than HM. Postoperatively at the most recent follow-up visit, 9 (52.9%), 5 (29.4%), and 2 (11.7%) eyes had a CDVA of 20/400 or better, 20/100 or better, and 20/40 or better, respectively. Visual deterioration occurred in 5 eyes (29.4%) because of postoperative complications. In these cases, the worsened CDVA was secondary to retinal detachment in 2 eyes (CF2m to HM and CF5m to CF0.5m), vitritis in 1 eye (20/200–20/400), vitreous hemorrhage in 1 eye (CF2m to HM), and extrusion in 1 eye (20/400 to HM).

We also assessed postoperative visual acuity at 3-month intervals (Table 2). The percentage of eyes that exhibited an improvement (compared with preoperative vision) at 3, 6, 9, and 12 months was 82.4% (14 eyes), 88.2% (15 eyes), 76.5% (13 eyes), and 94.1% (16 eyes), respectively. We also reviewed the visual acuity at the last follow-up examination and compared it with the preoperative visual acuity (Table 3). Overall, 16 eyes (94.1%) had an improved CDVA over the course of the follow-up.

Postoperative Variables

Overall, 13 eyes (76.4%) developed at least 1 complication after surgery. Retroprosthetic membrane (RPM)

TABLE 1. Patient Data (Online)

Patient Number	Age (yrs)	Follow-up (mos)	Prior PKP	KPro Indication	Initial Corneal Diagnosis	Concomitant Procedures	Preoperative BCVA	Postoperative BCVA at Last Visit	Postoperative Complications	Postoperative Procedures
1	43	18	0	Vascularized cornea	BK	AV	HM	CF2m	RPM	YAG
	43	18	0	Vascularized cornea	BK	AV	CFNF	20/200	RPM	YAG ×2
2	50	12	0	Vascularized cornea	BK	AV	CF1m	20/100	None	None
3	47	22	1	Failed PKP	Acanthamoeba keratitis	AV	HM	CF0.5m	None	None
4	46	21	0	Vascularized cornea	Chemical injury	ECCE, CP	HM	20/400	Sterile vitritis low IOP	CP, PPV
5	36	12	1	Failed PKP	GVHD	AV, IE, AhV	HM	20/40	RPM	YAG ×2
6	75	17	2	Failed PKP	Chemical injury	IE	HM	20/400	RPM	YAG
7	67	13	0	Vascularized cornea	SJS	ECCE	LP	CF0.5m	RPM	YAG
8	68	18	2	Failed PKP	BK	IE	HM	20/80	RPM	YAG
9	76	15	3	Failed PKP	BK	AV	HM	20/400	None	None
10	43	15	1	Failed PKP	Gelatinous dystrophy	ECCE	CF1.5m	20/25	RPM	YAG
11	67	13	1	Failed PKP	OCP	ECCE	HM	HM	Extrusion	Tarsorrhaphy
12	62	15	1	Failed PKP	BK	AV	HM	20/60	None	None
13	4	12	1	Failed PKP	Unknown	ECCE	LP	CF0.5m	RPM	None
14	76	14	0	Vascularized cornea	BK	AV	LP	CF0.5m	RPM RD	YAG
15	19	12	0	Vascularized cornea	BK	IE	LP	HM	RPM RD	None
16	25	12	2	Failed PKP	MVA	None	LP	HM	VH	None

AhV, Ahmed valve; AV, anterior vitrectomy; BCVA, best-corrected visual acuity; BK, bullous keratopathy; CFNF, counting fingers near the face; CP, conjunctivoplasty; ECCE, extracapsular cataract extraction; GVHD, graft versus host disease; IE, IOL exchange; MVA, motor vehicle accident; OCP, ocular cicatricial pemphigoid; PED, persistant epithelial defect; PPV, pars plana vitrectomy; RD, retinal detachment; SJS, Stevens–Johnson syndrome; VH, vitreous hemorrhage; YAG, Yttrium-aluminum-garnet membranotomy.

formation was the most common complication occurring in 10 eyes (58.8%). Eight eyes were treated with yttrium–aluminum garnet (YAG) membranotomy. Two eyes required a second YAG laser treatment. Increased IOP, as determined by tactile tension, occurred in 5 eyes (29.4%), primarily in eyes with a history of glaucoma. All the cases of increased IOP were managed with topical glaucoma medication. Persistent epithelial defects were not specifically monitored, unless there was a suspicion of infectious keratitis or corneal stromal necrosis. We did not document the presence of infectious keratitis or corneal stromal necrosis during the follow-up period.

Retention

Retention percentage was 94.1% at 1 year postoperatively. Extrusion occurred in 1 eye at 3 months postoperatively. The indication for KPro implantation in this patient was ocular cicatricial pemphigoid. The exact reason for the

TABLE 2. Preoperative and Postoperative Best-Corrected Visual Acuity at Various Follow-up Points (Online)

	Baseline	3 mos	6 mos	9 mos	12 mos	15 mos	18 mos
Number of eyes	17	17	17	17	17	9	5
20/20–20/50	0 (0%)	1 (5.9%)	2 (11.8%)	2 (11.8%)	2 (11.8%)	1 (11.1%)	0 (0%)
20/60–20/100	0 (0%)	1 (5.9%)	3 (17.6%)	3 (17.6%)	3 (17.6%)	2 (22.2%)	1 (20%)
20/200	0 (0%)	1 (5.9%)	1 (5.9%)	2 (11.8%)	1 (5.9%)	1 (11.1%)	1 (20%)
20/400	0 (0%)	2 (11.7%)	3 (17.6%)	2 (11.8%)	3 (17.6%)	3 (33.4%)	1 (20%)
CF	3 (17.7%)	6 (35.3%)	6 (35.3%)	6 (35.3%)	5 (29.5%)	2 (22.2%)	2 (40%)
HM	9 (52.9%)	6 (35.3%)	2 (11.8%)	2 (11.8%)	3 (17.6%)	0 (0%)	0 (0%)
LP	5 (29.4%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)

NLP, no light perception.

TABLE 3. Comparison of Preoperative Visual Acuity With Visual Acuity at the Last Follow-up

	Preoperative BCVA		
Postoperative BCVA	**LP (n = 5)**	**HM (n = 9)**	**CF (n = 3)**
LP	0	0	0
HM	2	1	0
CF	3	2	0
20/400	0	3	0
20/200	0	0	1
20/100–20/50	0	2	1
>20/50	0	1	1

Eyes below the weighted line represent improved visual acuity.
BCVA, best-corrected visual acuity.

extrusion could not be determined because the patient was lost to immediate follow-up examination before presenting with the extrusion. Trauma was excluded as an etiology through history gathering.

DISCUSSION

Gamma irradiation is a validated technique for sterilizing many donor tissues, including bone and sclera, against bacteria, fungal spores, and viruses.[9] The use of gamma-irradiated tissue has several advantages over the use of freshly donated and host cornea. Gamma-irradiated tissue has a shelf life of at least 1 year and a theoretically lower risk of infectious disease transmission.[7] Another advantage of gamma-irradiated tissue is that it costs approximately 20% less than does fresh donor tissue at most surgical centers, which was also the case at our institution.[8]

We reviewed the outcomes of patients implanted with the Boston KPro using gamma-irradiated tissue in a surgical mission setting. Akpek et al[8] published a similar study using precut gamma-irradiated lenticules in Boston KPro type 1 implantations performed on 11 eyes at a US university setting and reported favorable clinical results over an average follow-up period of 16.5 months. The vast majority of patients in this particular study had experienced a failed PKP before their procedure (72.7%), compared with 58.8% in our study. One of their patients (9.1%) belonged to a high-risk category (Stevens–Johnson syndrome/toxic epidermal necrolysis), whereas 2 (11.7%) eyes in our study belonged to a high-risk group (1 with Stevens–Johnson syndrome and 1 with ocular cicatricial pemphigoid). One of these patients, who was diagnosed with ocular cicatricial pemphigoid, experienced KPro extrusion, and the overall retention percentage of KPro in our study was 94.1% at 1 year. This is similar to previously published retention percentages of 87.9% and 92.9% at 1 year.[10,11] The most common postoperative complication in our study was RPM formation (58.8%), which required removal using a YAG laser. The incidence of this complication is similar to that reported in previous studies and does not seem to be related to the use of gamma-irradiated tissue.[10–12]

Daoud et al[7] reported 4 cases of corneal stromal necrosis using gamma-irradiated corneas in corneal and glaucoma surgeries and related these findings to the patients' histories of corneal melting, rather than to the use of irradiated corneas as carriers. Other investigators did not encounter cases of infectious keratitis or corneal stromal necrosis using gamma-irradiated corneas in KPro,[7,8] which is consistent with our findings.

Significant improvements in visual acuity were noted in 16 eyes (94.1%) in our study. In the data published by Aldave et al,[13] 75% and 71% of the eyes had a CDVA of 20/400 or better at 6 and 12 months, respectively, after KPro implantation. In our study, 52.9% of the eyes had a CDVA of 20/400 or better at 6 and 12 months after KPro implantation (Table 2). It is difficult to compare visual acuity outcomes across studies, because this may be affected by several factors that are independent of ocular surface diagnoses, such as preoperative retinal and optic nerve status. Glaucoma was present preoperatively in 41.2% of the eyes of our study compared with 76%, 75.9%, 60.0%, and 40.0% in previous studies.[10–13] A history of glaucoma surgery was present in 17.6% of the eyes of our study compared with 58.0%, 63.8%, 38.9%, and 19.0%, respectively, in the same studies.[10–13]

One drawback of our study was the follow-up period; the frequency of postoperative complications increases with time after KPro implantation. Accordingly, we may not have captured the complete incidence of postoperative events, because the mean follow-up time in this study was 15.2 ± 3.3 months. Further, visual acuity outcomes may worsen postoperatively with time. Trends toward the development of late complications and declining visual acuity highlight the need for long-term studies.[11]

We have described visual acuity outcomes, complication rates, and retention percentages for the Boston KPro type 1 using an irradiated graft as a carrier. KPro implantation using an irradiated corneal graft as a carrier seems to offer a convenient and effective solution to use in corneal transplants, especially in settings wherein access to fresh corneal grafts is difficult.

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