



## ARTICLE

# Boston type I keratoprosthesis versus penetrating keratoplasty following a single failed corneal graft

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**BACKGROUND/OBJECTIVES:** To compare long-term outcomes of the Boston type 1 keratoprosthesis (KPro) with penetrating keratoplasty (PKP) in patients with a failed first PKP.

**SUBJECTS/METHODS:** In this retrospective comparative case series, 48 eyes of 48 patients who underwent a second corneal replacement procedure after a first failed PKP at the Centre Hospitalier de l'Université de Montréal from 2008 to 2020 were included. Minimum follow-up duration was 5 years, and patients with keratoconus were excluded since such subjects are not candidates for KPro. Main outcome measures included best-corrected visual acuity (BCVA), postoperative complications, graft survival and subsequent interventions.

**RESULTS:** Mean follow-up was 6.4 years for PKP and 9.6 years for KPro ( $p < 0.001$ ). Preoperative BCVA was better in PKP patients (means 1.67 vs 2.13,  $p = 0.041$ ). Visual outcomes were similar between groups. KPro patients developed 0.263 complication per patient-year (ppy) compared to 0.245 ppy for PKP. The most common complications for PKP were corneal complications (0.088 ppy) and glaucoma worsening (0.041 ppy). In KPro, glaucoma worsening (0.046 ppy), vitreoretinal complications (0.042 ppy) and retroprosthetic membrane (0.042 ppy) were the most frequent. Graft failure (69.6 vs 20.0%,  $p < 0.001$ ) and reoperation rates (56.5 vs 12.0%,  $p = 0.001$ ) were significantly higher for PKP. Failure mainly resulted from decompensation or rejection in PKP, while all five failures in KPro were caused by melt and/or extrusion.

**CONCLUSIONS:** Both interventions showed similar visual outcomes. Complication profiles were different, with more posterior segment complications in the KPro group, and more corneal complications in the PKP group, often necessitating regraft.

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## INTRODUCTION

The Boston type 1 keratoprosthesis (KPro) is indicated in patients with poor vision because of corneal blindness in whom the chance of success of penetrating keratoplasty (PKP) is low, often due to a history of multiple failed grafts, limbal stem cell deficiency, severe neurotrophic corneal conditions or corneal vascularization [1]. KPro implantation clears the visual axis, providing a potential for visual recovery. Sight-threatening complications such as glaucoma, vitreoretinal complications, melt, and endophthalmitis are frequent and may have limited KPro implantation [2, 3].

Usually, patients receive a PKP as a first corneal intervention, unless the preoperative diagnosis portends a poor prognosis. When a first PKP fails, KPro or PKP can then be performed to reverse corneal blindness. Historically, patients would receive several PKPs before a KPro is considered, with each subsequent PKP holding higher risks of failure [4, 5]. To this day, there is no consensus on which of the two interventions is optimal following a single failed PKP.

As such, the purpose of this study is to compare long-term visual outcomes of KPro and PKP in patients having one previously failed PKP as well as postoperative complications, retention rates and reoperation rates.

## MATERIALS AND METHODS

### Study design and patient selection

This is a single-center, retrospective chart review of patients undergoing PKP or KPro implantation after a first failed PKP at the Centre Hospitalier de l'Université de Montréal (CHUM) from October 2008 to October 2020. All the KPros were performed by a single surgeon (M.H.D) and the PKPs were performed by one of two surgeons (P.T. and L.R.). Surgical techniques and postoperative regimens for KPro have been previously described [6, 7]. PKP was performed with the usual technique, and postoperative regimen included prednisolone acetate (Sandoz, Boucherville, Mississauga, Ontario, Canada) four times daily for the first 3 months, then tapered down progressively thereafter. Moxifloxacin (Alcon Canada, Mississauga, Ontario, Canada) was prescribed four times daily for one week and was extended in case of persistent epithelial defect. No patient from any of the groups received systemic immunosuppression. Patients were considered for KPro when the indication for the initial graft included neovascularization, scarring, and limbal stem cell deficiency. Inclusion criteria were defined as having undergone a PKP or KPro after a single failed PKP at the CHUM by one of the three surgeons of this study. Exclusion criteria included a follow-up duration of less than 5 years and a preoperative diagnosis of keratoconus, since such patients are not candidates for KPro. The study was approved by the CHUM Institutional Review Board and adhered to the tenets of the Declaration of Helsinki.

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## Data collection and analysis

Data collection included patient demographics (age and gender), indication for the initial PKP, and concurrent ocular disorders. These included glaucoma, vitreoretinal disease and previous ocular surgeries. Patients were considered to have preoperative glaucoma if they had a clear history of documented glaucoma, were on IOP-lowering medications and/or had undergone glaucoma surgery.

Best-corrected visual acuity (BCVA), the primary outcome, was recorded pre-operatively, at 3 months, 6 months, and every 6 months thereafter. Snellen visual acuity measurements were converted to logMAR values. The following values for counting fingers, hand motion, light perception and no light perception were used, respectively: 1.86, 2.28, 3.30 and 3.48 [8]. Secondary outcomes included the development of postoperative events such as new-onset glaucoma, worsening glaucoma, immune rejection, vitreoretinal complications, corneal melt, infectious keratitis, endophthalmitis, retroprosthetic membrane, and phtthisis bulbi. Postoperative new-onset glaucoma was diagnosed in patients who had an increased cup-to-disc ratio with a glaucomatous-looking optic nerve, a need for IOP-lowering medications or the presence of visual field (VF) defects characteristic of glaucoma. Glaucoma was considered to have worsened if there was an increase in glaucoma medications, an increase in cup-to-disc ratio of more than 0.1, worsening of glaucomatous VF defects or glaucoma surgery on maximal medical therapy. Graft or device retention rates, reasons for failure, and the number and type of subsequent interventions after the second corneal procedure were recorded.

## Statistical analysis

Data was analyzed using IBM SPSS Statistics, Version 25 (IBM Corporation, Armonk, USA). Statistical analysis was performed using the chi-squared test and independent student *t*-test. Kaplan–Meier curves were used to display BCVA progression between the two groups and the log-rank test was performed to compare survival curves between groups. Statistical significance was defined at  $p < 0.05$ .

## RESULTS

### Baseline characteristics

We reviewed the charts of 141 eyes of 135 patients who underwent a PKP or a KPro after a single failed PKP. Ninety-three eyes were excluded because the patients had a follow up of less than 5 years and/or had keratoconus as the preoperative diagnosis. The remaining 48 eyes from 48 patients were analyzed, from which 23 underwent PKP and 25 underwent KPro as a second corneal replacement procedure. Table 1 presents the baseline characteristics of our patient population. Follow-up data was available at 1 year, 3 years, 5 years and 7 years for 44 eyes (91.7%), 40 eyes (83.3%), 39 eyes (81.3%) and 20 eyes (41.7%), respectively. Two (8.7%) PKP patients and no KPro patient were lost to follow-up. PKP patients had significantly less visits than KPro patients (9.8 vs 15 visits,  $p < 0.001$ ).

### Visual outcomes

BCVA collection was continued even after patients underwent subsequent grafts. Visual outcomes are presented in Table 2. Best achieved logMAR BCVA represented similar visual gains of 1.02 and 1.32 for PKP and KPro patients ( $p = 0.24$ ), which corresponds to 5.2 lines and 5.3 lines of improvement on the Snellen chart, respectively ( $p = 0.94$ ). Best postoperative BCVA was maintained for an average of 4.8 years for PKP and 6.7 years for KPro (Kaplan–Meier estimate, log-rank test  $p = 0.28$ , non-significant). Six (26.1%) PKP patients and 10 (40.0%) KPro patients lost visual potential irreversibly ( $p = 0.31$ , non-significant), of which 3 PKP and 9 KPro eyes had terminal glaucoma.

Kaplan–Meier survival analyses were performed to evaluate maintenance of 20/200 BCVA throughout the follow-up duration (Fig. 1). On average, PKP patients maintained 20/200 vision for 4.3 (95% CI 3.0–5.6) years and KPro patients, for 5.9 (95% CI 4.0–7.8) years. This was non-significant at  $p = 0.83$  (log-rank test).

Further and third corneal procedures in the KPro group included 2 patients who had a second KPro and one who had PKP. In the PKP group, 10 had PKP and 3 had DSAEK as the third

**Table 1.** Baseline characteristics of Study Population ( $N = 48$ ).

Category	PKP	KPro	Significance <sup>a</sup>
Number of eyes	23	25	
Age at second intervention, mean (SD), yrs	69.5 (13.4)	62.2 (13.9)	0.07
Gender, No. (%), Male	16 (69.6)	16 (64.0)	0.68
Follow-up duration, mean (SD), yrs	6.4 (1.3)	9.6 (2.0)	<b>&lt;0.001</b>
Indication for surgery, No. (%)			<b>0.007</b>
Endothelial disease	11 (47.8)	4 (16.0)	
Keratitis	3 (13.0)	4 (16.0)	
Trauma	3 (13.0)	6 (24.0)	
Aniridic LSCD	0	6 (24.0)	
Stromal dystrophy	0	2 (8.0)	
Chemical burn	1 (4.3)	1 (4.0)	
Other	0	2 (8.0)	
Unknown	5 (21.7)	0	
Preoperative BCVA, mean (SD), logMAR	1.67 (0.87)	2.13 (0.61)	<b>0.041</b>
20/200 or better vision preoperatively <sup>b</sup> No. (%)	7 (33.3)	0	<b>0.002</b>
Preoperative glaucoma <sup>c</sup> No. (%)	10 (45.5)	16 (64.0)	0.20
History of glaucoma surgery, No. (%)	1 (4.3)	3 (12.0)	0.34
History of retinal disease, No. (%)	5 (21.7)	6 (24.0)	0.85
History of retinal surgery, No. (%)	0	5 (20.0)	<b>0.023</b>

PKP penetrating keratoplasty, KPro Boston type I keratoprosthesis, BCVA best-corrected visual acuity, LSCD limbal stem cell deficiency, SD standard deviation.

Statistically significant  $p < 0.05$  values are in bold.

<sup>a</sup>The Pearson chi-square (asymptotic 2-sided significance) was used for gender, indications for surgery, number of patients with 20/200 vision preoperatively, preoperative glaucoma, history of glaucoma surgery, history of retinal disease and history of retinal surgery. The independent *t*-test was used for age, follow-up duration, preoperative BCVA and number of glaucoma medications.

<sup>b</sup>Preoperative glaucoma status was unknown in one patient.

<sup>c</sup>Preoperative vision was unavailable for 2 patients in the PKP group.

intervention. After the third intervention, patients maintained 20/200 vision for 17 months on average for the PKP group ( $n = 13$ ) and zero months for the KPro group ( $n = 3$ ). This vision was maintained for 7 months after the fourth intervention (PKP,  $n = 5$ ), and was not reached afterward by the eye in the PKP group who underwent five grafts.

### Complications and graft failures

Table 3 presents the cumulative complication rate of the second corneal procedure for all patients in the study. The most frequent overall complication was worsening of glaucoma. Seventeen PKP patients (73.9%) versus 23 KPro patients (92.0%) had at least one complication in the postoperative period, which was non-significant at  $p = 0.09$ . Given that the follow-up duration between groups was significantly different, the complication rate per patient-year was calculated (Fig. 2). PKP patients developed 0.245 complications per patient-year compared with 0.263 complications per patient-year for KPro. 60% (6 eyes) of PKP patients compared to 68.8% (11 eyes) of KPro patients with preoperative

**Table 2.** Visual outcomes of study population.

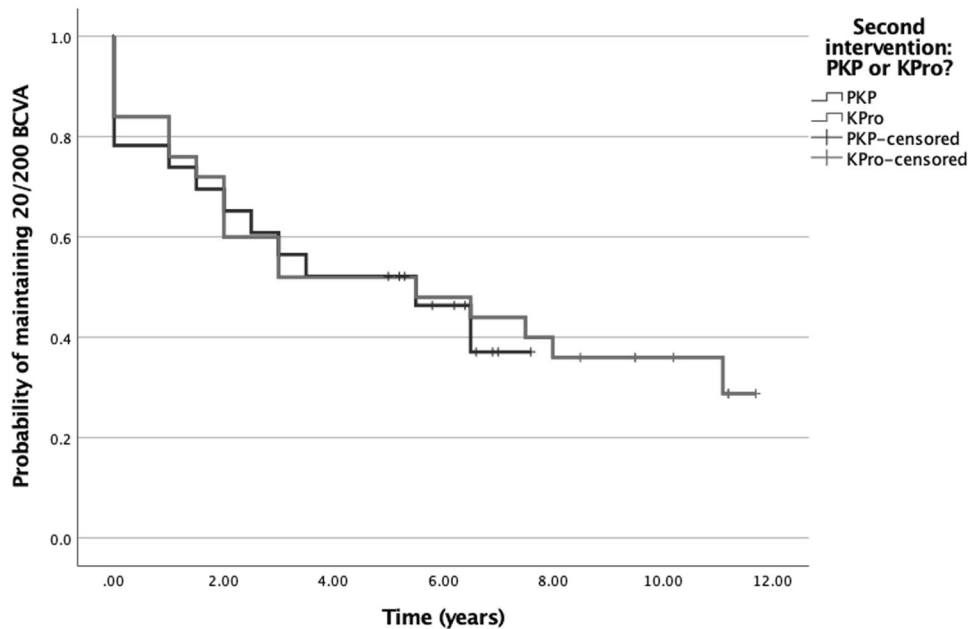
	BCVA, mean (SD), logMAR			Improvement from baseline, mean (SD), logMAR			20/200 VA or better, No. (%)		
	PKP	KPro	Significance <sup>a</sup>	PKP	KPro	Significance <sup>a</sup>	PKP	KPro	Significance <sup>b</sup>
6 months (N = 43)	1.00 (0.62)	1.09 (0.64)	0.64	0.73 (0.89)	1.04 (0.72)	0.24	12 (66.7)	15 (60.0)	0.66
1 year (N = 44)	1.17 (0.66)	1.03 (0.79)	0.55	0.75 (1.00)	1.10 (0.96)	0.26	11 (57.9)	18 (72.0)	0.33
2 years (N = 40)	1.21 (0.80)	1.39 (0.99)	0.54	0.53 (1.29)	0.74 (1.10)	0.60	8 (44.4)	12 (54.5)	0.53
3 years (N = 40)	1.14 (0.94)	1.75 (1.28)	0.10	0.54 (1.20)	0.37 (1.45)	0.68	10 (55.6)	11 (50.0)	0.73
5 years (N = 39)	1.48 (1.13)	1.82 (1.30)	0.39	-0.01 (1.31)	0.31 (1.40)	0.49	8 (44.4)	10 (47.6)	0.84
7 years (N = 20) <sup>c</sup>	1.45 (1.08)	1.62 (1.10)	0.73	0.23 (1.05)	0.50 (1.32)	0.63	3 (33.3)	5 (45.5)	0.58
Best achieved (N = 48)	0.65 (0.62)	0.81 (0.64)	0.40	1.02 (0.91)	1.32 (0.81)	0.24	18 (78.3)	21 (84.0)	0.61

BCVA best-corrected visual acuity, SD standard deviation, PKP penetrating keratoplasty, KPro Boston type I keratoprosthesis.

<sup>a</sup>The independent t-test was used.

<sup>b</sup>The Pearson chi-square (asymptotic 2-sided significance) was used.

<sup>c</sup>VAs after the 7-year follow-ups were not included in this table because N < 9 in each group.



**Fig. 1** Kaplan–Meier estimate of the probability of maintaining 20/200 BCVA throughout follow-up duration. While 73.9%, 56.5%, 52.2% and 37.1% of PKP patients maintained 20/200 vision at 1 year, 3 years, 5 years and 7 years postoperative, 76.0%, 52.0%, 52.0% and 44.0% of KPro retained this VA at the same time points.

glaucoma had glaucoma worsening ( $p = 0.65$ , non-significant). In the subset of patients without preoperative glaucoma, 25.0% ( $n = 3$ ) of PKP subjects compared to 66.7% ( $n = 6$ ) of KPro subjects developed new-onset glaucoma, which bordered on significance ( $p = 0.06$ ). Seven PKP patients (30.4%) had graft neovascularization at any time during follow-up duration, from which two (8.7%) had vessels obstructing the visual axis in the center of the cornea. At the last follow up, neovascularization persisted in six of those patients (26.1%), since one patient received a subsequent graft right before data collection. In addition, the PKP patient who went on to receive KPro had corneal neovascularization on the KPro. In the KPro group, 6 patients (24.0%) had neovascularization on the donor cornea. The KPro patient who later received PKP suffered from complete conjunctivalization of the graft.

Three KPro patients underwent a pars plana vitrectomy after developing retinal detachment. Two patients necessitated

concomitant endolaser and silicone oil implant, and one endolaser with a scleral buckle. Nine KPro patients underwent an intervention for their RPM, 7 patients were treated with a Nd:YAG laser membranectomy and two underwent surgical excision followed by Nd:YAG membranectomy after recurrence. Other complications that necessitated intervention included an epiretinal membrane that was peeled in a KPro patient, cystoid macular edema treated with intravitreal aflibercept in one PKP patient with wet macular degeneration, a descemetocoele that was sealed with glue (PKP) and a corneal ulcer with persistent epithelial defect treated by amniotic membrane graft in a PKP patient. Taking into account all subsequent procedures (including glaucoma surgeries and subsequent corneal replacement procedures), 17 KPro patients (68.0%) underwent intervention for postoperative complications compared to 13 PKP patients (56.5%), which was not statistically significant ( $p = 0.41$ ). Five KPro patients developed melt, extrusion,

**Table 3.** Complication, graft failure and regrant rates of study population ( $N = 48$ ).

Category	PKP ( $N = 23$ )	KPro ( $N = 25$ )	Significance <sup>a</sup>
Rejection, No. (%)	3 (13.0)	0	
New-onset glaucoma, No. (%)	3 (13.0)	6 (24.0)	0.37
Glaucoma worsening, No. (%)	6 (26.1)	11 (44.0)	0.19
Glaucoma surgery, No. (%)	1 (4.3)	9 (36.0) <sup>b</sup>	<b>0.007</b>
Corneal complications, No. (%)	13 (56.5)	7 (28.0)	<b>0.045</b>
Endothelial decompensation, No. (%)	12 (52.2)	0	
Keratitis, No. (%)	2 (8.7)	4 (16.0)	
Corneal melt, No. (%)	0	1 (4.0)	
Extrusion, No. (%)	0	4 (16.0)	
Descemetocele, No. (%)	1 (4.3)	0	
Vitreoretinal complications, No. (%)	4 (17.4)	10 (40.0)	0.09
Retinal detachment, No. (%)	1 (4.3)	4 (16.0)	
Cystoid macular edema, No. (%)	3 (13.0)	3 (12.0)	
Epiretinal membrane, No. (%)	1 (4.3)	3 (12.0)	
Choroidal detachment, No. (%)	0	2 (8.0)	
Vitreous hemorrhage, No. (%)	0	1 (4.0)	
Phthisis, No. (%)	2 (8.7)	4 (16.0)	0.45
Hypotony, No. (%)	1 (4.3)	5 (20.0)	0.10
Endophthalmitis, No. (%)	3 (13.0)	1 (4.0)	0.26
Retroprosthetic membrane, No. (%)	0	10 (40.0)	
Failed second intervention, No. (%)	16 (69.6)	5 (20.0)	<b>&lt;0.001</b>
Patients having additional grafts after second procedure <sup>c</sup> , No. (%)	13 (56.5)	3 (12.0)	<b>0.001</b>
Penetrating keratoplasty	14	1	
DSAEK	4	0	
KPro	1	2	

PKP penetrating keratoplasty, DSAEK Descemet-stripping automated endothelial keratoplasty, KPro Boston type I keratoprosthesis

Statistically significant  $p < 0.05$  values are in bold.

<sup>a</sup>The Pearson chi-square (asymptotic 2-sided significance) was used.

<sup>b</sup>Glaucoma surgery was indicated in one additional KPro patient, but the patient refused it.

<sup>c</sup>2 patients had 2 PKPs, 1 patient had 3 PKPs, 1 patient had a KPro and a PKP, and 1 patient had a PKP and a DSAEK.

or both. These subjects had worse vision at the final follow-up on average (1.88 or CF for patients without melt/extrusion vs 3.01 or LP for patients with melt and/or extrusion). However, this difference was non-significant ( $p = 0.07$ ). Furthermore, three of these five patients developed posterior segment complications (three had retinal detachment, two had choroidal detachment and one had cystoid macular edema). Two of them had their KPro replaced (one of which experienced loss of the eye), one had it removed and received a subsequent PKP before developing phthisis, one underwent evisceration, and the remaining patient developed phthisis shortly after KPro extrusion.

Patients with glaucoma took similar numbers of glaucoma medications preoperatively at  $2.3 \pm 1.2$  and  $2.7 \pm 1.3$  for PKP and KPro, respectively ( $p = 0.55$ ). Postoperatively, PKP patients took  $2.3 \pm 1.5$  glaucoma medications while KPro subjects took  $2.1 \pm 1.5$  drops, which was once again non-significant ( $p = 0.68$ ). On average, cup-to-disc ratio similarly increased by 0.11 for PKP patients and 0.17 for KPro patients throughout follow-up duration ( $p = 0.39$ ). Of the 17 patients that had VF data, 3 (50.0%) had VF progression in the PKP group compared to 2 (18.2%) in the KPro group ( $p = 0.17$ , non-significant).

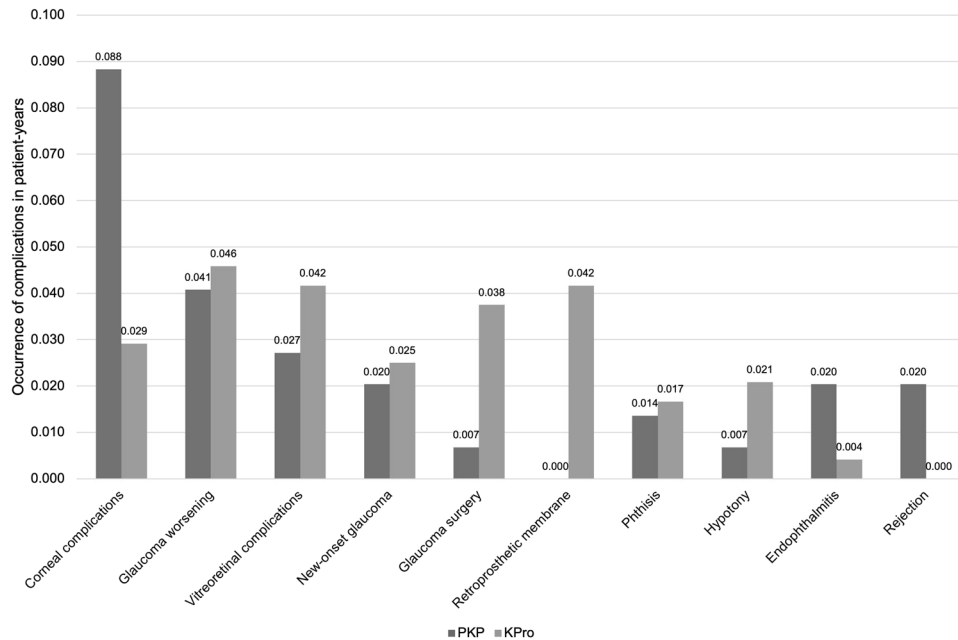
Failure rates of the second intervention (PKP or KPro) were significantly higher in the PKP group ( $N = 16$ , 69.6% vs  $N = 5$ , 20.0%;  $p < 0.006$ ) and significantly more PKP patients underwent additional corneal grafts ( $p = 0.001$ ). The causes of PKP failure included decompensation ( $n = 10$ , 43.5%), rejection ( $n = 3$ , 13.1%), keratitis ( $n = 1$ , 4.3%) and phthisis ( $n = 1$ , 4.3%). The one

remaining case of failure was unknown. KPro failed due to corneal melt ( $n = 1$ , 4.0%) and device extrusion ( $n = 4$ , 16.0%). KPro survived significantly longer than PKP (10.7 [95% CI 9.8–11.6] years vs 4.5 [95% CI 3.4–5.5] years, log rank test  $p < 0.001$ ).

## DISCUSSION

To our knowledge, no study compares long-term outcomes of PKP and KPro as the second intervention and there is no consensus on which of the two interventions is a better option after a single failed PKP [9].

Akpek et al. report a single-center study comparing KPro and PKP in 80 patients with previous graft failures with a mean follow-up duration of 19.5 months for the PKP group and 16.5 months for the KPro group [10]. This study showed better visual outcomes for KPro with similar risks of severe complications. However, these results must be considered with caution given the short follow-up duration. This may overestimate KPro visual outcomes in relation with PKP, since KPro generally achieve visual potential much earlier than PKP [11]. Furthermore, some late complications may not have been taken into account. Another important study on the matter is a meta-analysis which compares outcomes of secondary PKP in the current literature with a single KPro cohort ( $N = 104$ ) [12]. Similar conclusions were drawn, with a follow-up of 2–5 years in the PKP literature review and a mean of 3.7 years for their KPro cohort. KPro provided better visual outcomes, with comparable complication risks. Only one study has specifically



**Fig. 2** Complication rates of study population. Complication rates per patient-years for patients in the PKP (blue) and KPro (orange) groups.

compared outcomes in PKP and KPro patients who previously failed a single graft ( $N = 42$ ) [13]. Although this paper reported better visual outcomes in KPro, they had a relatively short follow-up duration (2 years). Furthermore, their preoperative characteristics were markedly different from most other studies, with lower baseline vision for PKP, lower prevalence of preoperative glaucoma, and preoperative diagnoses heavily weighted towards infectious ulcers in both groups [14–18]. A recent study had shown significantly better final visual acuity in patients who underwent primary KPro or KPro after fewer failed grafts when compared with patients who previously underwent multiple grafts [19]. This study had a minimal follow-up duration of 5 years and included 68 eyes. Currently there is no consensus on which intervention is best after a failed PKP, but KPro seems to fare better at least in the early postoperative period.

We report a primary study which includes 48 carefully selected patients who failed one graft with long follow-up durations (mean 8.1 years). Mean follow-up duration was significantly longer in KPro patients (9.6 years vs 6.4 years). In fact, KPro necessitates more commitment from patient and surgeon. Therefore KPro subjects in this study were followed up for longer and more regularly than for PKP. Preoperative diagnoses were comparable to previous studies, except for keratoconus patients which were excluded since they are not candidates for KPro [14–18]. 24% of KPro patients had aniridia compared to none in the PKP group. Treating aniridia with PKP is associated with poor outcomes due to the associated limbal stem cell deficiency and a KPro is often favored in such situations [20].

Long-term visual outcomes were similar between groups in this study. Preoperative BCVA, however, was significantly worse in the KPro group. This is expected since KPros are usually implanted on more advanced corneal disease with worse visual acuity who have a high risk of rejection with traditional corneal replacement surgeries. However, to render the groups comparable, BCVA improvement from baseline was analyzed, and was similar between the two interventions.

Complication profiles were different between groups, each posing its own set of challenges. KPro had more complications than PKP, although this was non-significant (92.0 vs 73.9%,  $p = 0.09$ ). KPro also had slightly more complications when adjusting for follow-up duration (0.263 vs 0.245 complication per patient-

year). While PKP had significantly more graft-related complications (endothelial decompensation and rejection), KPro patients tended to have more complications that decrease visual potential, such as glaucoma-related complications and vitreoretinal disease, although these differences were non-significant. Also, KPro subjects who developed melt and/or extrusion had particularly complicated postoperative courses. In fact, most of these patients developed posterior segment complications, and all of them either had their KPro removed/replaced or developed phthisis. Both groups underwent similar numbers of interventions for postoperative complications, with KPro subjects undergoing more surgeries for posterior segment complications, while PKP patients received more re-grafts. The high prevalence of glaucoma and vitreoretinal disease in KPro is expected [2, 15, 16, 21–23]. In PKP, each additional graft decreases chances of success, as was shown in this study [5, 24–27]. Failure rate of the second intervention was higher in PKP subjects (69.6% vs 20.0%). These rates are consistent with current and past literature [12, 21–24, 26, 27]. The two studies comparing repeat PKP and KPro after failed grafts also reported 2-year success rates much higher for KPro than PKP (86–94% vs 44–67%) [10, 12]. Therefore, PKP and KPro have different complication profiles, with PKP having more graft-related complications and KPro suffering from more posterior segment complications.

Limitations of this study include the difference in follow-up duration and baseline BCVAs between groups. We minimized the former by excluding all patients with less than 5 years of follow-up, as well as comparing visual outcomes at each time point. We also calculated complication rates per patient-years to minimize the effect of follow-up duration. Difference in baseline BCVAs between groups was taken into account by evaluating BCVA improvement from baseline. Other limitations include its retrospective design and the potential for error in this large chart review.

In conclusion, this long-term study highlights important findings. It shows similar visual outcomes between patients who underwent PKP and KPro as second interventions after one failed corneal graft. Overall, KPro patients tended to develop more glaucoma-related complications and vitreoretinal disease, which can compromise visual potential, as well as melt and extrusion which often cause device failure. The impact of these complications is in balance with

the high failure and regrant rates in PKP. As it is, KPro is a valid alternative to PKP in reliable patients who prefer not to receive multiple subsequent grafts. However, our findings also suggest the need for better complication management in KPro, which could eventually favor its implantation.

### Summary

What was known before

- Patients with corneal blindness usually receive PKP as a first intervention. If the first graft fails, they often undergo multiple additional PKPs before being considered for KPro.
- There is insufficient evidence comparing long-term outcomes of PKP and KPro after a single failed corneal graft.

What this study adds

- In this large study with a long follow-up duration, visual outcomes were similar between the PKP and KPro groups.
- Complication profiles were different, with more posterior segment complications in the KPro group, and more corneal complications in the PKP group.
- PKP failed and necessitated regrant more often than KPro.

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### AUTHOR CONTRIBUTIONS

JEK and DK contributed equally to this work; *Research design*: JEK, RD, MHD; *Data acquisition*: all authors; *Data analysis*: all authors; *Manuscript preparation*: all authors.

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