Surgical outcomes of concomitantly performed penetrating keratoplasty with intrascleral haptic fixation

Rinky Agarwal, Saumya Yadav, Prafulla K Maharana, Rahul K Bafna, Chetan Shakarwal, Namrata Sharma

Purpose: To describe the surgical results of concomitantly performed optical penetrating keratoplasty (PKP) with glued intrascleral haptic fixation (ISHF). Methods: Retrospective review of 18 patients (15–72 years) with best-corrected visual acuity (BCVA) of ≤1/60 subjected to unilateral concomitant optical PKP with ISHF and followed up for 13.11 ± 5.83 months (6-26 months) was undertaken. Results: The most common diagnoses were failed PKP (9/18, 50%) followed by aphakic bullous keratopathy (5/18, 27%). Preoperative glaucoma, peripheral anterior synechiae (PAS), and deep vascularization were present in 7/18 (38.88%), 12/18 (61.11%), and 5/18 (27.77%) patients, respectively. Intraoperatively, concomitant procedures such as pupilloplasty and intraocular lens explant were undertaken in 5/18 (27.277%) patients and 1/18 patients (5.55%) experienced suprachoroidal hemorrhage. At final follow-up, BCVA was ≥6/60 in 50% patients (mean astigmatism: 4.79 ± 1.68D), and 55.55% cases experienced graft failure (90% failed within one year of surgery). The most common causes of graft failure were glaucoma (50%), glaucoma with rejection (20%), rejection (10%), retinal detachment (10%), and suprachoroidal hemorrhage (10%). The ODDS ratio (OR) of having graft failure with the following factors was postoperative secondary interventions (OR: 6), postoperative complications (OR: 2.25), prior failed graft (OR: 1.8), preoperative PAS (OR: 1.75), intraoperative concomitant procedures (OR: 1.5), preoperative glaucoma (OR: 1.33), previous surgeries (OR: 1.24), and deep corneal vessels (OR: 0.66). Conclusion: All patients underlying PKP combined with glued ISHF must be counseled about suboptimal surgical outcomes. Emphasis is laid on appropriate case selection and stringent follow-up during the first year after surgery. Secondary interventions should be undertaken cautiously and judiciously in these patients.



Key words: Glaucoma, penetrating keratoplasty, scleral fixation

Penetrating keratoplasty (PKP) continues to be the definitive corneal transplant technique for treating full-thickness corneal opacities due to various causes. Aphakic patients with insufficient capsular support undergoing PKP can be optically rehabilitated with a scleral-fixated intraocular lens (SF-IOL) performed either concomitantly or sequentially.^[1,2] A single-stage therapy avoids the need for a second surgery, is cost-effective, and offers faster visual recovery. However, this adds to the surgical complexities, requires experienced surgeons, and prolongs surgical time.

Previously, sutured SFIOLs were undertaken for this purpose, but they unnecessarily prolonged surgical time, were surgically challenging, and carried a risk of suprachoroidal hemorrhage, hypotony, anterior chamber inflammation, suture-related complications, and IOL dislocation. With recent tremendous advancements in microsurgical techniques, sutureless intrascleral haptic fixation (ISHF) procedures have surpassed the sutured fixation due to their inherent advantages.^[3] When placed properly, a posterior chamber IOL supported by ISHF maintains minimal contact with the iris,

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Received: 02-Apr-2021 Accepted: 16-Aug-2021 Revision: 07-Jul-2021 Published: 23-Dec-2021 ensures a deep anterior chamber, and establishes a safe distance from the graft. Glued ISHF is one such sutureless technique of fixing IOL to the sclera and was first introduced by Agarwal *et al.*⁽⁴⁾ in 2008. Although the technique has occasionally been combined with PKP with successful short-term anatomical and functional results, large long-term studies in this regard are presently limited in the peer-reviewed literature.

In the present study, we describe the anatomical and functional outcomes of PKP combined with glued IHSF at our center.

Methods

A retrospective review of medical records of all patients subjected to concomitant PKP with glued ISHF for unilateral full-thickness corneal opacity with aphakia between July 2017 and December 2019 was undertaken. The study was approved by the institutional ethics committee and adhered to the tenets of the Declaration of Helsinki. All patients/guardians had provided written informed consent before the surgery.

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Cite this article as: Agarwal R, Yadav S, Maharana PK, Bafna RK, Shakarwal C, Sharma N. Surgical outcomes of concomitantly performed penetrating keratoplasty with intrascleral haptic fixation. Indian J Ophthalmol 2022;70:100-6.

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Data collected from the patient medical records included demographic details, indication for surgery, preoperative best-corrected visual acuity (BCVA), number of prior surgeries, baseline anterior segment details (gross iris anatomy, corneal vascularization, and previous size of graft, if any), intraocular pressure (IOP), intraoperative complications and concomitant procedures, postoperative complications, duration of follow-up, IOP, graft clarity, fundus findings, and BCVA. The IOL power was calculated using the SRK/T formula with an axial length obtained using A-scan ultrasonography and a constant keratometry of 43.5D based on the previous keratoplasty procedures. Patients noncompliant with follow-up or with a follow-up period of <6 months were excluded from the study.

Surgical technique

All surgeries were performed under peribulbar or general anesthesia. Preoperative glaucoma was medically controlled before surgery and these patients were administered 20% mannitol 1 g/kg weight intravenously over half an hour immediately before surgery. The donor corneal tissues (endothelial counts: \geq 2500 cells/mm²) were prepared at the beginning of the procedure. The donor corneal button was punched from the endothelial side by using a disposable trephine of 0.5 mm larger diameter than the planned recipient bed. The size of the donor button ranged from 7.5 to 8.0 mm. No Flieringa ring was used during surgery.

After performing two diagonally opposite localized peritomies, the sclera was marked with a radial keratotomy marker at 3- and 9-o'clock positions and 1.5 × 1.5 mm lamellar scleral flaps were created with a microcrescent blade [Fig. 1, Video 1]. Two 1.5-mm-long scleral tunnels were dissected anticlockwise from these scleral flaps. Further, 80% of the central corneal thickness was trephined (7-7.5 mm), and two sclerotomies were fashioned with a microvitreoretinal (MVR) blade 1.5 mm away from the limbus underneath the previously created scleral flaps. The cornea was stabbed in its full thickness with an MVR blade through the prior trephination site at the 11-o'clock position. This was gradually extended circumferentially and the opacified host cornea was excised in toto. Anterior vitrectomy and explantation of previous IOL were undertaken whenever necessary. A 3-piece IOL (MA60MA, Alcon Laboratories, Inc, USA) held with a McPherson forceps was introduced directly through the superior part of the trephined cornea, and the haptics were exteriorized with serrated microforceps using the hand-shake technique (open globe fixation).^[4] Concomitant procedures such as pupilloplasty and synechiolysis were undertaken as and when required. An appropriately sized donor graft was secured to the host with eight interrupted 10-0 nylon sutures. Following this, the haptics were tucked inside the scleral pockets after checking for IOL centration. The remaining eight sutures were placed, the anterior chamber was formed with an air bubble (air was preferred as it provides good tamponade, thereby decreasing the chances of aqueous leak besides reducing the risk of IOP rise associated with retained viscoelastic in the anterior chamber), and fibrin glue (Tisseel VH, Baxter Healthcare Corp, Deerfield, IL) was applied to appose the scleral flaps and conjunctival peritomies.

Postoperatively, all patients underwent an overnight pressure patching. From the first postoperative day (POD), prednisolone acetate 1% and moxifloxacin 0.5% were administered four-hourly and six-hourly, respectively. Antiglaucoma medications (carbonic anhydrase inhibitor, timolol, brimonidine, latanoprost, and pilocarpine singly or in combination) were added to the regime when IOP was >21 mm Hg. Collaboration was established with a glaucoma specialist and filtering surgery was undertaken when IOP was not controlled (≤21 mm Hg) on antiglaucoma medications. Topical steroids were tapered according to the patient's response and the surgeon's discretion (6, 5, 4, 3, and 2 times per day during the 1st, 2st, 3rd, 4th, and 5th-month follow-up, respectively, followed by once-daily dosage lifelong). All patients were examined on POD 1, 3, and 7, then monthly for 6 months, quarterly till one year, and a half-yearly later or according to the discretion of the treating corneal surgeon. IOL stability, centration, and tilt were determined clinically (depending on the graft clarity) and on ultrasound biomicroscopy at every follow-up. Loose/tight/broken suture removal was attempted only after 2 months of surgery; before that, suture replacement was undertaken. Routine suture removal was performed after one year of surgery.

A clear graft was defined as the absence of stromal or epithelial edema with clearly visible iris details on slit-lamp examination. Grafts that did not clear within the first 2 weeks of transplantation were considered primary donor failures.^[5] Secondary donor failure was labeled as graft edema starting after 2 weeks of surgery and persisting till \geq 3 months. Graft rejection was defined as the occurrence of sudden onset congestion and graft edema with keratitic precipitates/anterior chamber reaction, without any other signs of infection. Grafts that failed because of endothelial decompensation not pertaining to immunological reactions were deemed endothelial failures. Glaucoma was diagnosed based on the prior records (IOP \geq 21 mm Hg with disc changes/visual field defects) and hypotony as IOP \leq 6 mm Hg with Goldmann applanation tonometry.

Statistical analysis

The data were analyzed using Stata 12.1 software. Chi-Square/ Fischer Exact test and two-sample Wilcoxon rank-sum (Mann– Whitney) tests were applied. The presumed preoperative (number or previous surgeries, failed PKP, deep vessels, peripheral anterior synechiae (PAS), and glaucoma), intraoperative (concomitant procedures), and postoperative (glaucoma, rejection, and secondary interventions) risk factors for graft failure were analyzed, and a logistics regression analysis was performed to assess the odds of graft failure with each risk factor. P < 0.05 was deemed statistically significant.

Results

Demographics

The demographic and clinical details of all patients are summarized in Table 1. Eighteen eyes (9R, 9L) of 18 patients (13M, 5F) subjected to PKP with glued ISHF were enrolled in the study. The mean age of patients was 43.17 ± 21.64 years (15–72 years). There was one child in the study (age: 15 years). The mean duration of follow-up was 13.11 ± 5.83 months (6–26 months). Further, 5/18 patients (27.77%) had systemic comorbidities (1 asthma, 4 hypertension).

Indications, preoperative and intraoperative findings

The most common indication for surgery was failed PKP graft (9/18, 50%) followed by aphakic bullous keratopathy (ABK, 5/18, 27.77%). Pseudophakic bullous keratopathy (PBK), healed

Table 1: Cl	Table 1: Clinical characteristics of all patients in our study	stics of all	patient	s in our (study										
Age/sex/SI	Diagnosis	Previous	Prior		Baseline	line		Intra/post op			Follc	Follow-up			
		donor size	surgery	BCVA	lris/cornea BV per quadrant	Glaucoma	AL (mm)	manipulation	POD1 IOP	Duration	Duration Complication	D∆	Final BCVA	Graft clarity	Repeat Grafting
52/m	Traumatic ABK		N	HMCF	PAS/1		27.68	Pupilloplasty/Nil	Low	6 mon		6D	6/36	Clear	
62/m/HTN	Failed PKP	8 mm	N	Ъ		Yes	21.91		High	8 mon	Glaucoma	7D	6/36	Clear	
64/m/asthma	HK		0	FCCF			24.06		Normal	6 mon	Glaucoma	6D	6/60	Clear	
66/f/HTN	Surgical ABK		-	FCCF			22.09		Normal	8 mon		ЗD	6/18	Clear	
22/m	Failed PKP	7.75 mm	Ю	FCCF	PAS/3	Yes	22.87	Pupilloplasty/-	High	6 mon	Glaucoma	5D	6/24	Clear	
19/f	Failed PKP	11 mm	-	Ч	PAS	Yes	21.45	Nil/S/R	Normal	9 mon	Loose suture	4D	6/60	Clear	
20/f	Failed PKP	13 mm	N	Ч	PAS	Yes	23.00	-/S/R	Normal	12 mon	Glaucoma, rejection, loose suture	8D	6/36	Failure	DSAEK
19/m	Failed PKP	9 mm	-	HMCF	PAS	Yes	24.50	·	High	13 mon	Glaucoma, rejection	2D	1/60	Failure	PKP, refused KPro
46/m	Traumatic ABK		-	HMCF	ı		22.24	Nil/Trab	Normal	11 mon	Glaucoma	3D	FCCF	Failure	РКР
22/m	pIOL + decompensation	ı	N	FC at 1/2 m	PAS		27.88	Nil/VRSX + SOI	high	12 mon	ВD	4D	No LP	phthisis	
15/m	Failed PKP	7.75 mm	ю	FCCF	PAS	Yes	23.98	Pupilloplasty/trab	Normal	12 mon	Glaucoma	3.5D	1/60	Failure	DSAEK
68/m	Surgical ABK		-	HMCF	PAS		24.20		Normal	13 mon	Glaucoma	7D	1/60	Failure	Refused
61/f/HTN	Failed PKP	8 mm	-	FCCF	PAS/2		22.96		Low	16 mon		5D	6/24	Clear	
20/f	Traumatic scar		0	1/60			20.46	IOL explant/nil	Normal	17 mon	Glaucoma	4D	6/9	Clear	
53/m	Failed PKP	7.75 mm	2	FCCF	PAS		21.27	ı	Low	19 mon	Glaucoma	6D	1/60	Failure	Refused KPro + PKP
72/m/HTN	Surgical ABK		-	HMCF	PAS/1		27.57	SCH/SCH drainage	Low	20 mon	ı		No LP	phthisis	
29/m	Failed PKP	8.5 mm	-	HMCF	-/1		23.27		Normal	22 mon	Rejection	5D	FCCF	Failure	DSAEK
67/m	PBK + misaligned IOL	·	-	HMCF	PAS	Yes	21.96	Pupilloplasty + IOL explant/trab	Normal	26 mon	Glaucoma	3D	2/60	Failure	Refused
HTN - hyperte HMCF - Hand Trab - Trabecu automated enc	HTN - hypertension; PKP - Penetrating Keratoplasty; HK - Healed kera HMCF - Hand motion close to face; FCCF - Finger counting close to face; Trab - Trabeculectomy; VRSX - Vitreoretinal surgery; SOI - Silicone oil inje automated endothelial keratoplasty; KPro-Keratoprosthesis	ating Kerator FCCF - Finge soretinal surg	olasty; HK er counting ery; SOI - : prosthesis	- Healed k close to fa Silicone oil i	ceratitis; ABK - ce; LP - light pe injection; SCH -	Aphakic bullot rception; BV - f · Suprachoroids	us keratol Blood ves: al hemorrt	HTN - hypertension; PKP - Penetrating Keratoplasty; HK - Healed keratitis; ABK - Aphakic bullous keratopathy; P IOL - (phakic) intraocular lens; PBK - pseudophakic IOL; BCVA - Best-corrected visual acuity; HMCF - Hand motion close to face; FCCF - Finger counting close to face; LP - light perception; BV - Blood vessel; PAS - Peripheral anterior synechiae; IOP: Intraocular pressure; AL - Axial length; S/R - Suture removal; Trab - Trabeculectomy; VRSX - Vitreoretinal surgery; SOI - Silicone oil injection; SCH - Suprachoroidal hemorrhage; POD1 - Postoperative day 1; RD - Retinal detachment; AD-Astigmatism; DSAEK - Descemet stripping automated endothelial keratoplasty; KPro-Keratoprosthesis	intraocular iterior synec itive day 1; 1	· lens; PBK chiae; IOP: I RD - Retinal	- pseudophakic IC htraocular pressure detachment; ∆D-A	L; BCV »; AL - A stigmati	A - Best xial leng sm; DSA	-corrected th; S/R - S EK - Deso	visual acuity; uture removal; emet stripping

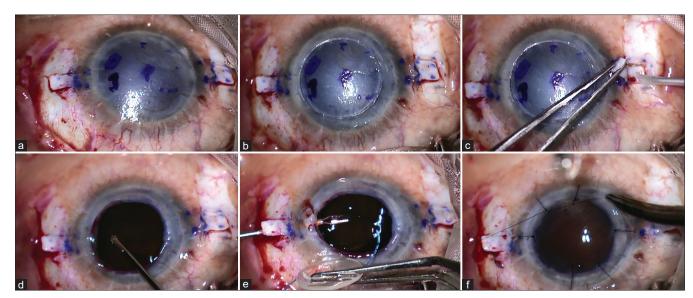


Figure 1: Steps showing concomitant PKP with ISHF; a: creating two diagonally opposite partial-thickness scleral flaps; b: performing partial-thickness trephination; c: fashioning sclerotomies underneath scleral flaps; d: deroofing the host cornea and performing anterior vitrectomy; e: implanting IOL by hand-shake technique; f: suturing the graft to host bed

keratitis with self-absorbed lens, phakic IOL associated decompensation (operated pIOL explant with lens aspiration, weak zonules), and traumatic corneal scar with self-absorbed lens contributed to one case (5.55%) each. The patients were subjected to an average of 1.38 ± 0.84 (range: 0–3) prior surgeries such as PKP, open globe injury repair, lens extraction, and IOL explant. PAS, preexisting glaucoma, and deep corneal vascularization were present in 12/18 (66.67%), 7/18 (38.88%), and 5/18 (27.77%) patients, respectively. Further, 3/18 (16.66%) patients had axial myopia. Baseline visual acuity was light perception (LP), hand motion (HM), counting fingers and 1/60 in 3/18 (16.66%), 7/18 (38.88%), 7/18 (38.88%), and 1/18 (5.55%) patients, respectively. These patients were not offered endothelial keratoplasty due to a combination of limited view, significant stromal scarring, and/or extensive PAS or large iris defects.

Intraoperatively, concomitant procedures were undertaken in 5/18 (27.277%) patients and included pupilloplasty (3/18, 16.66%), IOL explant (1/18, 5.55%), and pupilloplasty with IOL explant (1/18, 5.55%), respectively. One (5.55%) patient experienced intraoperative suprachoroidal hemorrhage (SCH) immediately after deroofing the host cornea and before implantation of the IOL. In this patient, the SCH was severe enough to prevent IOL implantation and was managed by immediate suturing of the graft to the host with 8-0 vicryl sutures. No anterior segment bleed, haptic slippage, or posterior dislocation of IOL was noted intraoperatively.

Postoperative findings

Complications

On POD-1, 4/18 (22.22%) patients had raised IOP, 4/18 (22.22%) had hypotony, and 10/18 (55.55%) patients had normal IOP.

Overall, 14/18 (77.77%) patients experienced postoperative complications till the final follow-up. These included new cases of glaucoma, worsening of preexisting glaucoma, rejection, glaucoma with rejection, retinal detachment, and loose sutures in 6 (33.33%), 3 (16.66%), 1 (5.55%), 2 (11.11%), 1 (5.55%) and

1 (5.55%), respectively. Another patient (5.55%) with loose suture had coexistent glaucoma and rejection.

After a combined PKP with ISHF, secondary interventions were undertaken in 7/18 (38.88%) patients and included suture replacement, trabeculectomy, SCH drainage, and RD surgery in 2 (11.11%), 3 (16.55%), 1 (5.55%), and 1 (5.55%) patient, respectively. No IOL-related complications were noted.

Surgical outcomes

The final acuity was $\geq 6/60$ in 9/18 (50%) patients; 2/18 patients (11.11%) lost more than 2 lines of BCVA after surgery (1 SCH, 1 RD). The mean astigmatism was 4.79 + 1.68D (2–8D). The suboptimal visual gain was attributed to glaucoma, RD, SCH, astigmatism, and graft failure.

No primary donor failures were recorded in our study [Fig. 2]. Further, 10/18 (55.55%) cases experienced secondary graft failure till the final follow-up; 9/10 (90%) grafts failed within 12 months of surgery, and 1/10 (10%) failed at 18 months after surgery. The various causes of graft failure were glaucoma (5/18, 33.33%), glaucoma with rejection (2/18, 11.11%), rejection (1/18, 5.55%), and phthisis (2/18, 11.11%, due to RD and SCH, one each). A repeat intervention was planned for 5/10 patients with failed grafts (2 PKP (one patient was also offered keratoprosthesis), 3 endothelial keratoplasty); however, 3/10 refused further interventions (all aged >65 years; one was offered keratoprothesis), and 2/10 suffered phthisis bulbi.

Logistic regression analysis

A list of risk factors and the timing of failure are mentioned in Table 2. All patients had ≥2 risk factors for graft failure. The surgical outcomes were not related to age, gender, or systemic illness. An ODDS ratio (OR) of graft failure with presumed risk factors (as determined by logistic regression analysis; Table 3) was in the following order: secondary interventions (OR: 6), presence of postoperative complications (OR: 2.25), prior failed graft (OR: 1.8), preoperative PAS (OR: 1.75),

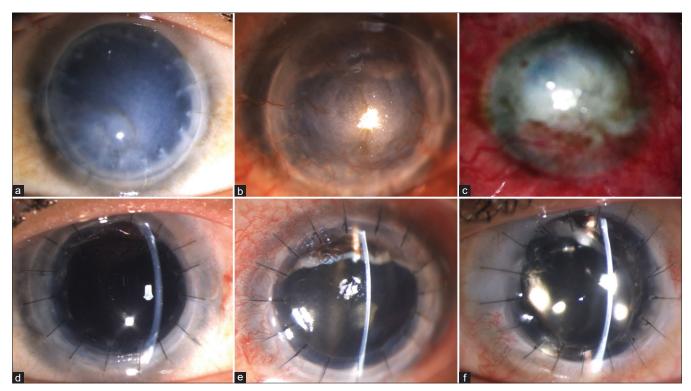


Figure 2: Preoperative (a-c) and postoperative (d-f) photographs of patients subjected to combined PKP with ISHF. Note partial to total aniridia in all patients

Table 2: Risk factors	in failed graft	patients in our study
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Failed PKP	Deep vessels	Preexisting glaucoma	PAS	Postoperative glaucoma	Secondary Intervention	Rejection	Others	Time to failure
++	-	++	++	-	++	++	-	6 mon
++	-	++	++	-	-	++	-	7.5 mon
-	-	-	-	++	++	-	-	3 mon
-	-	-	++	-	++	-	RD	3 mon
++	-	++	++	-	++	-	-	6 mon
-	-	-	++	++	-	-	-	11.5 mon
++	-	-	++	++	-	-	-	5 mon
-	++	-	++	-	++	-	SCH	0.1 mon
++	++	-	-	-	-	++	-	10 mon
-	-	++	++	-	++	-	-	18 mon

PKP - Penetrating keratoplasty; RD - Retinal detachment; SCH - Suprachoroidal hemorrhage; PAS - Peripheral anterior synechiae

Table 3: Results of	loaistic rearession	analysis in our study

Parameter	ODDS ratio	95% CI	Р
Number of previous surgeries	1.24	0.68-2.24	0.72
Prior failed graft	1.80	0.56-5.34	0.121
Preoperative PAS	1.75	0.51-5.97	0.372
Preoperative glaucoma	1.33	0.29-5.95	0.38
Preoperative deep corneal vessels	0.66	0.11-3.98	0.657
Intraoperative procedures	1.5	0.25-8.97	0657
Intraocular pressure on POD1	1	0.41-2.40	1.000
Secondary procedures	6	0.722-49.83	0.097
Postoperative complication	2.25	0.692-7.306	0.177

POD1 - Postoperative day 1; CI - confidence interval

intraoperative concomitant procedures (OR: 1.5), preoperative glaucoma (OR: 1.33), previous surgeries (OR: 1.24), and deep corneal vessels (OR: 0.66). None of them was statistically significant most probably due to a low number of subjects.

Outcomes according to diagnosis

In 9/18 (50%) patients, prior failed PKP (8 therapeutic PKP, 1 optical PKP) was the indication for combined PKP with ISHF; 1/9 (11.11%) patients had twice failed PKP, 6/9 (66.66%) patients had preexisting glaucoma, 1/9 (11.11%) developed postoperative glaucoma, 5/9 (55.55%) failed anatomically, and 5/9 (55.55%) maintained a visual acuity of \geq 6/60 till final follow-up. The size of the previous graft ranged from 7.75 to 13 mm and did not correlate significantly (*P*=0.133) with graft failure. Two patients with suture replacement belonged to this group.

Further, 3/5 cases (60%) with ABK witnessed graft failure and 2/5 (40%) gained a visual acuity of \geq 6/60 at final follow-up. None had preoperative glaucoma, whereas 2/5 (40%) developed postoperative glaucoma; 2/3 (66.66%) patients with axial myopia (axial length: \geq 27 mm) suffered from complications (1 intraoperative SCH and 1 postoperative RD).

Discussion

Prior peer-reviewed studies depicting results of concomitantly performed PKP with ISHF are limited, and most of these have reported reasonably good outcomes with the surgery [Table 4]. On the contrary, we noted graft failure in 55.55% of our patients, with only 50% maintaining a visual acuity of $\geq 6/60$ till final follow-up. Suboptimal surgical outcomes in our study could be attributed to the choice of our case selection.[1,2,6-11] At the time of surgery, the majority of our patients had the presence of well-known risk factors for graft failure such as failed graft (50%), PAS (66.67%), deep vascularization (27.77%), and glaucoma (38.88%) either singly or in combination.^[5,12,13] All these preoperative factors could have also increased the chances of postoperative complications such as glaucoma and rejection in our patients. In 50% of patients with failed graft, a repeat graft was planned. While PKP, endothelial keratoplasty, or keratoprosthesis can be undertaken in such patients, we offered endothelial keratoplasty to patients with a prior rejection episode and keratoprosthesis with twice failed grafts, respectively. However, 30% of patients with failed grafts, all aged >65 years, refused a repeat keratoplasty owing to prolonged follow-up and poor primary outcomes.[13]

Myopic patients were particularly prone to intraoperative SCH and postoperative RD in our series.^[14] This implies that myopic patients subjected to combined procedures need to be counseled appropriately before surgery and rigid steps should be taken for timely identification and management of these complications. Or else, whenever possible, staged procedures can be performed for these patients. Although the age, gender, and systemic illness did not correlate significantly with graft failure in our retrospective study; the only child in this series experienced graft failure along with minimal visual gain and worsening of preoperative glaucoma.

In our study, 61.11% of patients suffered from glaucoma (preexisting or postoperative), which is higher than the 25%, 33%, and 50% glaucoma reported by Karadag, Rocha, and Kasim, respectively.^[1,2,9,15] A failure rate of 63.63% in eyes with glaucoma in our study suggests that these eyes have an inherently inconducive aqueous microenvironment for graft survival attributable to the disease process as well as to the antiglaucoma medications. Additionally, 85.71% of patients with preoperative glaucoma worsened after surgery and 33.33% were unresponsive to medical management and needed filtering surgery for IOP control. While the IOP got controlled after the filtering surgery in all patients, the grafts (3/3) failed later. This fact needs to be considered before undertaking concomitant PKP with ISHF and approaches with minimal conjunctival manipulation must be preferred in patients with preexisting glaucoma.

Notably, we observed that 44.44% of cases subjected to combined PKP and ISHF experienced dramatic fluctuations in IOP [Table 1] on the first POD. Although all of them recovered by the third POD and this did not jeopardize the

Table 4: Comp	Table 4: Comparison of different studies undertaken on	rent studies	undertaken on	n concomitant PKP with ISHF	ith ISHF				
Parameter <i>n</i>	Prakash, 2009 <i>n</i> =3	Sinha 2012 <i>n</i> =6	Sethi, 2016 <i>n</i> =10	Karadag, 2016 <i>n</i> =4	Rocha, 2019 <i>n</i> =3	Kasim, 2020 <i>n</i> =6	Petrelli, 2020 <i>n</i> =1	Angelis, 2021 <i>n</i> =2	Present study <i>n</i> =18
Age	46 yr	63-78 yr		38-65 yr	41-74 yr	36-70 yr	61 yr		15-72 yr
Diagnosis	PBK	PBK (4), ABK (2)	Aphakic	ABK (1), PBK (2), Trauma (1)	Trauma (1), Aphakia (1), Failed PKP (1)	ABK (2), Trauma (2), Failed PKP (1), PBK (1)	Failed PKP	Corneal failure, aphakia, vitrectomized (2)	Failed PKP (9), ABK (5), PBK (1), others (3)
Technique of ISHF	Glued	Glued	Needle assisted	Trocar-assisted glueless sutureless	Double needle flanged	Double needle flanged	Glueless/ needleless	Glueless, hand-shake	Glued
Concomitant procedure	IOL explant (3)	IOL explant (4)		IOL explant (2)		IOL explant (1)			Pupilloplasty (3), IOL explant (2)
GHD	0.2 mm		0.5 mm	0.5 mm	0.25 mm				0.5 mm
Follow-up	4 m	6 m	1.5 m	28.3 m	3-6 m	6 m	6 m	12 m	13.11 m
Failed graft	0	0	0	0	0	0	0	0	10 (55.55%)
Complications	Incomplete cut (1)	·	Macular pathology (1)	Glaucoma (1), rejection (1), ARMD (1), CRVO (1)	Haptic exposure (1), glaucoma (1)	Glaucoma (3), VMT (1), retinal scar (1)	ı	Retinal pathology (1)	SCH (1), Glaucoma (11), Rejection (3), RD (1), loose suture (2)
PKP - Penetrating macular degenera	keratoplasty; ISHF tion; CRVO- Centra	- Intrascleral haג ו retinal vein occl	otic fixation; PBK - lusion; VMT - Vitre	PKP - Penetrating keratoplasty; ISHF - Intrascleral haptic fixation; PBK - Pseudophakic bullous keratopathy; ABK - Aphakic bullous keratopathy; IOL - Intraocular lens; GHD- Graft host disparity; ARMD - Age-related macular degeneration; CRVO- Central retinal vein occlusion; VMT - Vitreomacular traction; RD - Retinal detachment	topathy; ABK - Aphak tinal detachment	c bullous keratopathy; IC)L - Intraocular lei	ns; GHD- Graft host dis	parity; ARMD - Age-related

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final surgical outcome significantly, it would be desirable to titrate the antiglaucoma medications accordingly and keep these patients on a close follow-up to avoid any untoward complications. Certain intraoperative modifications such as smaller gauge sclerotomies, limited anterior vitrectomy, and adequate wound apposition, and postoperative care such as appropriate titration of dose and frequency of antiglaucoma medications and steroids may be undertaken to prevent such IOP fluctuations. Often it may be helpful to do a staged technique to avoid hypotony both intraoperatively and postoperatively. Additionally, closed-globe IOL fixation may avoid an open-sky IOL fixation in a non-pressurized eye.

Logistic regression analysis in our study proved that secondary interventions after the combined surgery had the highest risk (6 times) of graft failure (statistically nonsignificant). This could be because most of these patients were subjected to multiple surgeries (1.38 ± 0.84) in the past and IOP fluctuation or inflammation associated with additional interventions could have incited a rejection episode or aggravated endothelial cell loss that subsequently compromised the graft clarity. However, larger, longer randomized comparative studies are required to confirm or refute this observation. Till then, we recommend that any second procedure be planned judiciously and cautiously in similar eyes. In addition, as seen in the present series, 90% of the grafts suffered failure within one year of surgery. This emphasizes a frequent follow-up in the first year after surgery for the best results. It is also advocated that the patient's age, geographic location, socioeconomic status, compliance with medications, follow-up, and keenness for repeat surgeries be aptly assessed before planning a combined PKP with ISHF. Although our study suggests that combined procedures are not prone to additional IOL-related complications, further comparative studies are required in this regard.

To the best of our knowledge, ours is the largest study on single-stage PKP with ISHF, which is also inclusive of pediatric patients. Moreover, ours is the first comprehensive study analyzing the effect of various pre, intra, and postoperative factors on graft survival in these patients. Certain limitations of the study include the absence of control groups and lack of objective measurement of IOL tilt and endothelial cell counts. In addition, any inference on graft survival or failure in our study is prone to period bias due to nonuniform and short-term follow-up (<1 year) for most cases with clear graft.

Conclusion

To conclude, all patients undergoing a concomitant PKP with ISHF must be counseled effectively about suboptimal surgical outcomes. An appropriate case selection ruling out the preoperative absence of prior failed graft, PAS, deep vascularization, and glaucoma; vigilant intraoperative management, particularly in axial myopes; and limited postoperative secondary surgical interventions may improve the rates of surgical success. As the chances of graft failure remain particularly high within the first year after surgery, the emphasis is laid on stringent follow-up during this time.

Acknowledgements

We thank our Institute for allowing us to continue with our research work.

Financial support and sponsorship Nil.

Conflicts of interest

There are no conflicts of interest.

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