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Comparison of Visual and Anatomic Outcomes of Eyes Undergoing Type I Boston Keratoprosthesis with Combination Pars Plana Vitrectomy to Eyes without Combination Vitrectomy

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Abstract

Purpose—To determine whether one year visual and anatomic results after surgery combining pars plana vitrectomy, Boston keratoprosthesis and a glaucoma drainage device as needed are similar, better, or worse than Boston keratoprosthesis initial implantation alone.

Methods—We performed a retrospective review of adult patients undergoing Boston keratoprosthesis at our institution. Visual acuity outcomes, anatomic results and complication rates of patients undergoing combination surgery (including pars plana vitrectomy and a posterior glaucoma drainage device) were compared to those undergoing keratoprosthesis placement alone.

Results—There were 70 eyes in the keratoprosthesis alone group and 55 eyes in the keratoprosthesis with pars plana vitrectomy group. Mean follow-up durations were 54.67 months in the keratoprosthesis alone group and 48.41 months in the combination group. Baseline mean Snellen equivalent visual acuities were worse for the combination group compared with the keratoprosthesis alone group ($P=0.027$). Visual acuities improved postoperatively by one month after keratoprosthesis implantation for both groups and improved three or more lines of Snellen acuity in the majority of eyes for both groups (72% by 12 months). Eyes undergoing pars plana vitrectomy had lower rates of de novo ($p=0.015$) and significantly lower rates of secondary procedures ($p=0.002$) at one year. One year complications rates for retroprosthetic membrane formation, retinal detachment, hypotony, cystoid macular edema, epiretinal membrane formation, endophthalmitis and corneal melting were similar for both groups.

Conclusions—Compared with keratoprosthesis alone, combining keratoprosthesis with pars plana vitrectomy and a glaucoma drainage device as needed, resulted in lower rates of de novo glaucoma, lower rates of additional surgical procedures, similar visual acuity outcomes at one year and did not result in higher complication rates.

Keywords

Boston type I keratoprosthesis; pars plana vitrectomy; glaucoma; endophthalmitis; complications

Introduction

The Boston keratoprosthesis, approved for use by the Food and Drug Administration in 1992, represents a major advancement in the management of patients with corneal opacities that are not suitable for penetrating keratoplasty (PKP) such as chemical burns, multiple failed PKPs, aniridia and autoimmune disorders including Stevens Johnson Syndrome (SJS).^{1,2} Although vision can be partially, or in some cases, fully restored, there are complications related to the keratoprosthesis that limit the visual outcomes.^{1–5} While several series report sight limiting complications including retroprosthetic membranes, glaucoma, endophthalmitis and posterior segment complications that require pars plana vitrectomy, it is well documented that the most common cause of permanent vision loss is glaucomatous optic neuropathy.^{1–7} Because of the high prevalence of preoperative glaucoma,^{4,5} and the risk of glaucoma development or progression after keratoprosthesis, the combination of keratoprosthesis with a glaucoma drainage device at the time of initial surgery has been recommended.^{8,9} To avoid crowding of the anterior chamber and occlusion of the glaucoma implant by progressive peripheral anterior synechiae commonly seen after keratoprosthesis implantation,^{10, 11} placement of the glaucoma shunt into the pars plana is an increasingly popular approach. This necessitates a pars plana vitrectomy. In other eyes, the presence of concomitant posterior segment pathology (epiretinal membrane, anterior vitreous base scar tissue or retinal detachment) with corneal opacification is another indication for pars plana vitrectomy combined with keratoprosthesis surgery.

Combination surgery consisting of pars plana vitrectomy, posterior glaucoma drainage device placement and the Boston keratoprosthesis has been recommended to manage patients with limited vision resulting from corneal opacities with or without associated posterior segment disease.¹² Our group has transitioned to performing pars plana vitrectomy with a posteriorly placed glaucoma drainage device at the same time as the initial Boston keratoprosthesis.¹³ The purpose of this study was to compare anatomic and visual outcomes of eyes undergoing combined Boston keratoprosthesis and pars plana vitrectomy with eyes undergoing Boston keratoprosthesis without pars plana vitrectomy. We were particularly interested in the rates of complications between these two groups.

Materials and Methods

We performed a retrospective review of the medical records of all patients who underwent a Boston keratoprosthesis implantation at our institution between 2006 and 2016. Investigational Review Board approval was obtained prior to initiating this study. The patient medical records were reviewed to determine patient demographics, indications for Boston keratoprosthesis surgery, baseline anterior and posterior segment findings, visual acuities at baseline and follow-up, and post-operative complications. The operative reports were reviewed to determine the procedures performed, intraoperative findings and presence or absence of intraoperative complications. Patients over age 15 years and with at least one year of follow-up after implantation of a type 1 Boston keratoprosthesis were included.

Patients underwent pre-operative ultrasonography to rule out posterior segment pathology before keratoprosthesis implantation. Pars plana vitrectomy, when performed, was

accomplished via the use of a temporary keratoprosthesis.¹⁴ For combined keratoprosthesis implantation and glaucoma drainage device placement, our group has performed pars plana vitrectomy with a posteriorly placed glaucoma tube at the time of the initial keratoprosthesis for over 10 years, therefore most of our patients received pars plana tubes when glaucoma drainage device surgery was indicated. During the pars plana vitrectomy, care was taken to excise any anterior segment scar tissue. A complete pars plana vitrectomy with shaving of the vitreous base was performed. This vitreous base dissection was especially meticulous at the site of the planned posterior glaucoma drainage device. Adjuvants were utilized, and laser performed as needed. Following completion of the pars plana vitrectomy, the temporary keratoprosthesis was removed and the Boston keratoprosthesis was sewn into place using 10-0 nylon sutures. When a glaucoma drainage device was implanted, the plate was sutured in place prior to opening the eye. After implantation of the Boston keratoprosthesis, the glaucoma shunt was introduced through the pars plana (approximately 4 millimeters posterior to the limbus) and accurate placement confirmed by direct visualization by the retina surgeon.

Rates of development of retroprosthetic membranes, de novo or worsening glaucoma, endophthalmitis, hypotony, choroidal detachments and retinal detachment were determined for eyes undergoing Boston keratoprosthesis without pars plana vitrectomy and were compared with eyes undergoing Boston keratoprosthesis with pars plana vitrectomy using Chi-square test (for high occurrence rate) or Fisher's exact test (for low occurrence rate). Potential risk factors for complications were assessed using logistic regression.

For glaucoma surveillance and monitoring, intraocular pressure was measured by palpation and pneumotonometry on the inferotemporal sclera^{15, 16} at each follow-up visit. In addition, visual field testing, optic nerve photography and imaging were performed annually. De novo glaucoma was defined as absence of pre-existing glaucoma plus significantly increased intraocular pressure and/or worsening visual field or optic nerve that required medical, laser or surgical treatment. Worsening pre-existing glaucoma was defined as a significantly increased intraocular pressure and/or worsening visual field or optic nerve that required medical, laser or surgical treatment. There was not an absolute IOP criteria for de novo or worsening glaucoma, but instead we defined it as "the need for glaucoma treatment." De novo retinal detachment was defined as a new onset retinal detachment at any time after keratoprosthesis implantation (eyes with prior retinal detachment were excluded). Visual acuity measurements were obtained from the medical records for baseline (pre-operatively) and 1, 3, 6, 9 and 12 months postoperative visual acuities. Logarithm of the minimal angle of resolution (LogMAR) equivalents were calculated using the method described by Holladay and summarized as the means and standard errors.¹⁷ Post-operative changes in visual acuity were calculated as the difference between postoperative and baseline logMAR visual acuities. Linear regression models were used to compare the group difference in visual acuity improvement at each follow up by controlling for baseline visual acuity.

Results

A total of 70 eyes (mean age 54 years) underwent Boston keratoprosthesis implantation without concurrent vitrectomy and 55 eyes (mean age 56 years) underwent Boston

keratoprosthesis implantation with combined pars plana vitrectomy. Of the 70 eyes, six had undergone prior vitrectomy; three of which had a prior glaucoma drainage implant (pars plana tube) already in place and were included in the analysis. Of the eyes undergoing combination surgery, eight eyes had undergone prior vitrectomy for retinal detachment (5), endophthalmitis (1), hypotony (1), proliferative diabetic retinopathy (1). The most common indications for placement of the keratoprosthesis included multiple failed corneal grafts, prior chemical burn, aniridia and limbal stem cell deficiency. The groups did not differ with respect to the indications for keratoprosthesis. There was a higher proportion of eyes with preoperative glaucoma in the keratoprosthesis combined with vitrectomy group than in the keratoprosthesis alone group [42 of 55 (76%) versus 41 of 70 (59%) eyes respectively, $p=0.037$]. In addition, the keratoprosthesis alone group had one eye with a prior retinal detachment repair, whereas the combination group had six eyes with a history of retinal detachment repair (1 scleral buckle and 5 pars plana vitrectomies, $p=0.043$), two of which had a recurrent detachment as one of the indications for combined keratoprosthesis and pars plana vitrectomy (Table 1).

The main indication for combining Boston keratoprosthesis with pars plana vitrectomy was to allow for placement of the glaucoma drainage device into the posterior segment (62%). Indications for combined pars plana vitrectomy with keratoprosthesis included uncontrolled glaucoma (25 eyes), prevention of glaucoma in high risk eyes (6) or repositioning of tube into posterior segment (5), presence of silicone oil (2), hypotony (5), PVR (2), anterior fibrosis (3), removal of a subluxated lens (1), epiretinal membrane removal (1), vitreous hemorrhage (3) or fibrosis (2). Eyes were defined as high risk if there was borderline pre-operative intraocular pressure elevation (20-28 mmHg) with or without anterior segment angle abnormalities. There were no differences in the rates of *intraoperative* complications between those eyes which underwent pars plana vitrectomy and those that did not undergo vitrectomy. In the combination group, one eye required laser for treatment of a retinal tear which was found intraoperatively to be the cause of the vitreous hemorrhage.

Table 1 lists postoperative complications for both groups. Of the eyes without baseline glaucoma, 14 of 29 (48%) eyes developed glaucoma (de novo) in the keratoprosthesis group without vitrectomy versus one of 13 eyes (8%) in the combination group ($p = 0.015$). Progression of pre-existing glaucoma requiring additional surgical procedures was seen in 4 of 41 (10%) eyes in the keratoprosthesis without pars plana vitrectomy group versus 3 of 42 (7%) eyes in the combination group ($p = 1.0$). Secondary procedures to control glaucoma were required in 22 (10 in year 1) of the 70 keratoprosthesis alone eyes and 4 of the 55 keratoprosthesis with pars plana vitrectomy eyes (1 in year 1, $p = 0.002$). Endophthalmitis procedures were required in 10 (4 in year 1) of the 70 keratoprosthesis alone eyes and 5 of the 55 (4 in year 1) keratoprosthesis with pars plana vitrectomy eyes ($p = 0.581$). YAG laser procedures were performed in 29 (13 in year 1) of the 70 keratoprosthesis alone eyes and 16 of the 55 (9 in year 1) keratoprosthesis with pars plana vitrectomy eyes ($p = 1.000$). Retinal detachment procedures for de novo retinal detachment were performed in 11 of the 70 (6 in year 1) keratoprosthesis alone eyes and 8 of the 55 (4 in year 1) keratoprosthesis with pars plana vitrectomy eyes ($p = 1.000$). The total number of secondary procedures was greater for the keratoprosthesis alone eyes (72 total, 33 in year 1) versus 33 for the combination group (33 total, 18 in year 1, $p < 0.001$).

Secondary pars plana vitrectomy after the initial Boston keratoprosthesis was required in 27 of the 70 eyes that did not have combined pars plana vitrectomy at the time of the initial Boston keratoprosthesis. Indications included placement of a posterior glaucoma drainage device for management of uncontrolled glaucoma (5), endophthalmitis (7), retinal detachment (9), epiretinal membrane (2), vitreous hemorrhage (2), hypotony with an epiretinal membrane (1) and dense retroprosthetic membranes not amenable to YAG laser treatment (1). Secondary pars plana vitrectomy was required in 7 of 55 eyes that had initial combination surgery. Indications included management of choroidal hemorrhage with drainage (1), retinal detachment (2), recurrent detachment (2-prior trauma in one eye and PVR in one eye), retinal neovascularization requiring endolaser (1) and endophthalmitis (1). The number of patients requiring secondary pars plana vitrectomy was significantly lower in the combination surgery group ($p = 0.002$).

The keratoprosthesis without pars plana vitrectomy group had marginally better baseline acuity (20/5902; logMAR = 2.47 (0.11) vs. 20/13837; logMAR 2.84 (0.13), $p = 0.027$). The mean follow-up durations were 54.67 (se=4.31) months in the keratoprosthesis without pars plana vitrectomy group and 48.41 (se=3.97) months in the combination group ($p=0.297$). Postoperative visual acuities are given in Table 2. Visual acuity improvement was better for eyes undergoing primary Boston keratoprosthesis without pars plana vitrectomy at one month (1.37 (se=0.13)) logMAR vs. 1.22 (se=0.14) logMAR, $p = 0.059$) but then did not differ between the groups by 3 to 12 months postoperatively (Table 2). Most eyes in both groups improved as compared to baseline as shown by the change in mean logMAR visual acuities compared to baseline. This represented an improvement of 12 lines of Snellen acuity at one year for both groups.

The proportion of eyes undergoing improvement in visual acuity at 1 month, 3 months, 6 months, 12 months and at last follow-up is shown on Tables 3 and 4. Improvement of 3 or more lines of visual acuity was seen in the majority of eyes in both groups (Table 3). At one month, 79% of keratoprosthesis implanted eyes without pars plana vitrectomy and 74% of keratoprosthesis with pars plana vitrectomy eyes improved three or more lines, with the corresponding values at one year of 78% and 72%, respectively. At last follow-up, 58% of the keratoprosthesis alone group and 77% of the keratoprosthesis with vitrectomy group had improved 3 or more lines of vision ($p=0.036$).

By one year, 32 of 70 (58%) eyes undergoing keratoprosthesis without pars plana vitrectomy improved by one or more logMAR and 3 eyes (5%) had decreased more than one logMAR unit of visual acuity. By one year, 21 of 55 (64%) combination surgery eyes had improved more than one logMAR unit and 3 eyes (8%) decreased more than 1 logMAR unit compared to baseline visual acuity (Table 4) At one year postoperatively, there were a total of 5 of 70 (7.1%) eyes that were no light perception (NLP) in the keratoprosthesis alone group versus 1 of 55 (1.8%) eyes in the combination group ($p=0.39$). Three of the 5 eyes in the keratoprosthesis alone group had either a retinal detachment or endophthalmitis in contrast to none in the combination group.

The visual acuity decreased over time for the keratoprosthesis alone group after one year. At the last follow-up, visual acuities tended to be better for the keratoprosthesis with pars plana

vitrectomy eyes than for the keratoprosthesis without pars plana vitrectomy eyes: mean logMAR improvements were 1.21 vs. 0.56 ($p=0.126$) respectively. (One logMAR unit is equivalent to 10 lines of Snellen visual acuity improvement.)

Discussion

The use of the Boston keratoprosthesis has enabled rehabilitation of patients with severe corneal blindness who would otherwise have been visually disabled. Prior researchers have reported posterior segment complications are associated with the Boston keratoprosthesis. Modjtahedi and Elliott, in a review of the literature, noted retroprosthetic membranes, infectious endophthalmitis, sterile vitritis, vitreous hemorrhage, vitreous opacities, retinal detachment, cystoid macular edema, choroidal detachments, retinal vascular occlusion, and epiretinal membrane formation were significant causes of morbidity in patients with keratoprostheses.⁶ Later, Rishi and coworkers reported a large proportion of eyes (23 of 45 eyes) undergoing keratoprosthesis developed vitreoretinal complications.⁷ These included retroprosthetic membranes ($n = 11$), retinal detachment ($n = 6$), endophthalmitis ($n = 4$), epiretinal membrane ($n = 4$), vitreous hemorrhage ($n = 2$), and choroidal detachment ($n = 1$). Our study evaluated whether performance of pars plana vitrectomy at the time of the keratoprosthesis would impact the rates of these complications or whether vitrectomy itself resulted in increased complications.

Our study has showed that pars plana vitrectomy and glaucoma drainage implantation at the same time as the initial keratoprosthesis placement results in decreased postoperative de novo glaucoma without added complications. Prior case series have shown the combination of a posterior drainage tube with the Boston keratoprosthesis to be effective.⁸ This is important as uncontrolled glaucoma is a major cause of visual morbidity post-keratoprosthesis. Our group advocates placement of pars plana tubes for three main reasons. Firstly, there is limited space for a glaucoma tube in the anterior chamber after keratoprosthesis implantation; the average functional anterior chamber depth is 0.21 mm.^{18, 19} Secondly, angle closure in eyes with keratoprosthesis is prevalent, extensive and progressive.¹⁹ Anterior segment OCT has demonstrated that anterior chamber depth and anterior chamber angle dimension are dynamic in these eyes and previous reports have documented anterior chamber tube occlusion.²⁰ Robert et al. reported tube occlusion in 22% of eyes with keratoprosthesis—the tube occlusion was mainly caused by vitreous incarceration.²¹ Thirdly, a posteriorly placed tube in the pars plana optimizes contact lens fitting, which is critical to promote corneal hydration and to maximize vision. In addition, tinted contact lenses also decrease glare and improve esthetic appearance in these eyes. Our group reported that patients who had a posteriorly placed tube had a high rate of intraocular pressure control (85%) and contact lens retention (75%).²² For these reasons, pars plana tube placement with a complete vitrectomy is now our preferred approach.

In our series, the largest reported to date of patients who underwent posterior segment glaucoma tube placement, all but one patients had pars plana tube placement and vitrectomy at the time of the initial keratoprosthesis. We showed a lower rate of postoperative glaucoma without a higher rate of complications. A concern of performing combined surgery is the potential for additional intraoperative and postoperative complications. In our study, we did

not find any significantly increased risk of intraoperative complications. Rather, our series also showed a lowered risk of secondary procedures in the combined pars plana vitrectomy with Boston keratoprosthesis group. This decreased rate for additional procedures is partially attributable to better control of the intraocular pressure and hence a decreased need for additional glaucoma procedures. However, not all secondary procedures were for glaucoma in the keratoprosthesis implanted eyes. Secondary procedures were also required to manage choroidal detachments, fibrosis, retinal detachment and endophthalmitis. The need to perform secondary procedures for these indications was lower in the combined surgery group than in the keratoprosthesis alone group. Thus, we feel that vitrectomy itself also contributes to a better outcome. The use of vitrectomy may also decrease the risk of posterior segment complications by removal of the vitreous scaffold, thereby decreasing the potential for scarring and tractional forces on the retina. This was suggested by Kiang et al in their series of 23 procedures in 14 eyes, some of which underwent combined pars plana vitrectomy with keratoprosthesis placement.²³

In a recently published case series, Petrou et al noted 22% of Boston keratoprosthesis eyes (6 of 27 eyes) developed severe PVR retinal detachments.²⁴ They described a specific pattern of serous elevation of the retinal with subsequent severe anterior PVR. In these eyes, visual acuity was usually very poor despite anatomic success. In our series, there were fewer eyes with de novo PVR retinal detachments in the keratoprosthesis with combined pars plana vitrectomy group compared with the keratoprosthesis alone group. Further follow-up and work is required to determine if the rates of epithelial downgrowth and subsequent retinal detachment are indeed lowered by combination pars plana vitrectomy.

A recent publication by Perez et al reviewed the impact of a complete vitrectomy (22 eyes) versus partial or anterior vitrectomy (26 eyes) in patients undergoing a snap-on Type I Boston keratoprosthesis.²⁵ They found lower rates of both retroprosthetic membranes ($p=0.049$) and glaucoma requiring intervention ($p=0.046$); visual acuities were similar in both groups. In addition, similar to our findings, there was also a trend for less postoperative complications, including endophthalmitis, requiring intervention. This smaller study supports our larger study findings of both lowered glaucoma and other complications requiring a secondary vitrectomy when pars plana vitrectomy is performed at the time of the keratoprosthesis.

It is well established that the risk of endophthalmitis is higher in eyes with a Boston keratoprosthesis because of the lack of complete biointegration of the keratoprosthesis, even with prophylactic antibiotics.^{26–30} In fact, rates of endophthalmitis range from 1.2 – 11.4%, depending on the length of follow-up.²⁷ Robert et al, in their review of endophthalmitis following Boston keratoprosthesis, reported a prevalence of 5.4% between 2001 and 2011.²⁷ The rate of infectious endophthalmitis has been reported to be 2.7% per patient year.²⁸ It has been reported that prophylaxis with topical antibiotics has resulted in lower rates of post-operative endophthalmitis as compared to before its adoption.^{26–30} Vigilance is imperative in this group of patients.

In our series, there was a trend towards lower rates of endophthalmitis in the combined keratoprosthesis and vitrectomy eyes. In addition, eyes that had undergone prior pars plana

vitrectomy responded well to intravitreal antibiotic injections to manage the endophthalmitis. It is well established in prior series that development of endophthalmitis is frequently associated with poor visual outcomes³⁰; Wagoner et al's reported 54% of infected eyes lost more than two lines of visual acuity. Thus, we maintain a low threshold for treating suspected endophthalmitis with antibiotics in our institution. Our series herein did include cases that were culture negative in the endophthalmitis group; some of these may have been cases of sterile vitritis, a well-recognized complication that occurs occasionally in patients with keratoprosthesis.

Visual acuity improvement did not significantly differ between the two groups three months after surgery, although a greater percentage of eyes gained one more line of vision in the group without vitrectomy compared with the group that received vitrectomy at one month. This is due, in part, to the eyes with concomitant retinal detachment that required intraocular tamponade, which temporarily limits visual acuity improvement in the combined group. There was no other difference between the groups in the rates of epiretinal membrane formation, cystoid macular edema or retinal detachment to explain this difference. At the last follow-up, the greater maintenance of visual improvement after combined vitrectomy and Boston keratoprosthesis (mean of 12 lines improvement) than of the eyes without combined vitrectomy (mean of 6 lines improvement) is probably related to better IOP control as well as lower rates of complications requiring intervention.

For both groups, comparison of the post-operative visual acuity with preoperative acuity in our series revealed an improvement of three or more lines of visual acuity for over 70% of eyes. This significantly impacts the patient's quality of life.³¹ Although the visual acuity in some patients may decrease over time because of retroprosthetic membranes and require either YAG laser or surgery, the patient's visual acuity at one year is often better than the initial visual acuity. Expected risk factors for visual loss post-keratoprosthesis included development of retroprosthetic membranes, endophthalmitis, hypotony and retinal detachment. Of these, retroprosthetic membranes were most amenable to treatment with return of visual function. There were however some eyes which developed recalcitrant and recurrent membranes, despite pars plana vitrectomy removal. At present, these eyes remain with limited visual acuity.

In summary, our study showed that combination of the Boston keratoprosthesis combined with pars plana vitrectomy and posterior segment placement of a glaucoma drainage device as needed appears to offer an advantage over Boston keratoprosthesis alone. Lower rates of de novo glaucoma, lower secondary procedures and no increased risk of complications, suggest that this combined surgery is a safe alternative that may obviate the need for additional surgery to control intraocular pressure. The combination of pars plana vitrectomy with Boston keratoprosthesis implantation and a glaucoma drainage device partially alleviates the reliance on subjective evaluation and interpretation of intraocular pressure in keratoprosthesis patients. It helps to prevent visual loss from glaucoma. In addition, when there are other posterior segment diseases requiring pars plana vitrectomy, vitrectomy combined with keratoprosthesis implantation appears to be safe, resulting in improved visual acuity. The combination of pars plana vitrectomy with Boston keratoprosthesis can result in improved visual acuities and lower rates of complications than keratoprosthesis alone.

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Summary statement

Combination pars plana vitrectomy with posterior glaucoma drainage implant and Boston keratoprosthesis results in lower rates of de novo glaucoma without increased risks of complications as compared to Boston keratoprosthesis implantation alone.

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Baseline and Complication rates for eyes undergoing Boston keratoprosthesis combined with pars plana vitrectomy versus no pars plana vitrectomy

Table 1

	Keratoprosthesis without vitrectomy			Keratoprosthesis with vitrectomy		
	70	55		55		
	54 years	56 years		56 years		
Total Number of eyes	N	N	%	N	%	P value
Baseline characteristic						
Glaucoma	41	42	59%	42	76%	0.037
Prior vitrectomy	6	8	9%	8	15%	0.393
Prior retinal detachment	1	6	1%	6	11%	0.043
Recurrent retinal detachment	0	2	0%	2	4%	0.192
Prior glaucoma tube shunt	6	14	9%	14	25%	0.014
Operation						
Placement of posterior glaucoma tube shunt*	3	34*	4.3%	34*	62%	<0.0001
* includes 9 eyes with revision of pre-existing anterior tube shunt into posterior segment						
Complication Type						
Retroprosthetic membrane	36	27	51%	27	49%	0.858
De Novo Glaucoma	14/29	1/13	48%	1/13	8%	0.015
Progression of Glaucoma	4/41	3/42	10%	3/42	7%	1.000
Cystoid macular edema	15	14	21%	14	26%	0.671
Endophthalmitis	10	5	14%	5	9%	0.420
Epi-retinal membrane	12	10	17%	10	18%	1.000
Corneal Melt	12	3	17%	3	5%	0.055
De novo Retinal detachment	11/70	8/49	15%	8/49	16%	1.000
Exudative retinal detachment	15	7	21%	7	13%	0.243
Hypotony	8	7	11%	7	13%	1.000
Choroidal	6	6	9%	6	11%	0.763

Table 2

A comparison of postoperative visual acuity improvements relative to baseline for eyes undergoing Boston keratoprosthesis with combined pars plana vitrectomy to eyes without pars plana vitrectomy during follow up *

	KPRO without PPVx (N=70)		KPRO with PPVx (N=55)		P-value
	Snellen(logMAR) Mean VA	N	Snellen(logMAR) Mean VA	N	
Baseline	20/5902 (2.47)	69	12/13837 (2.84)	53	0.027
Follow Up (months)	Snellen Lines (logMAR lines) of Improvement	N	Snellen Lines (logMAR lines) of Improvement	N	
1	13.7 (1.37)	68	12.2 (1.22)	54	0.059
3	13.6 (1.36)	60	12.9 (1.29)	47	0.158
6	12.0 (1.20)	57	12.1 (1.21)	47	0.447
9	10.9 (1.09)	54	12.1 (1.21)	37	0.878
12	11.7 (1.17)	55	11.5 (1.15)	36	0.512
Last Follow up Duration(months)	54.67 +/- 4.31		48.41 +/- 3.97		0.297
Acuity Improvement Last Follow Up	Snellen Lines (logMAR lines) of Improvement	N	Snellen Lines (logMAR lines) of Improvement	N	P-value
	5.8 (0.58)	62	12.1 (1.21)	48	0.138

* NLP visual acuities excluded from logMAR calculations

Table 3

Improvement of visual acuity by three or more lines from baseline: A comparison of outcomes for eyes undergoing Boston keratoprosthesis without pars plana vitrectomy to eyes with pars plana vitrectomy *

Post-operative time (Months)	Keratoprosthesis without pars plana vitrectomy		Keratoprosthesis with pars plana vitrectomy			P-value
	Total number of eyes	Number of Eyes Improved 3 or more lines	% Eyes Improved 3 or more lines	Total number of eyes	Number of Eyes Improved 3 or more lines	% Eyes Improved 3 or more lines
1	68	54	79%	54	40	74%
3	60	48	80%	47	37	78%
6	57	46	81%	47	33	70%
9	54	38	70%	37	27	73%
12	55	43	78%	36	26	72%
Last follow-up	62	36	58%	48	37	77%

* NLP eyes excluded from analyses

Table 4

Change in log MAR Visual Acuity from baseline: A comparison of outcomes for eyes undergoing Boston keratoprosthesis without pars plana vitrectomy to eyes with pars plana vitrectomy*

Post-operative time (Months)	Keratoprosthesis without pars plana vitrectomy			Keratoprosthesis with pars plana vitrectomy			P value
	Total number of eyes	Number of Eyes Improved 1 or more logMAR	% Eyes Improved 1 or more logMAR	Total number of eyes	Number of Eyes Improved 1 or more logMAR	% Eyes Improved 1 or more logMAR	
1	68	41	60%	54	34	63%	0.764
3	60	42	70%	47	31	66%	0.656
6	57	35	61%	47	27	57%	0.682
9	54	31	57%	37	23	62%	0.650
12	55	32	58%	36	21	58%	0.989
Last follow-up	62	27	44%	48	29	60%	0.079
Post-operative time (Months)	Total number of eyes	Number of Eyes Decreased 1 or more logMAR	% Eyes Decreased 1 or more logMAR	Total number of eyes	Number of Eyes Decreased 1 or more logMAR	% Eyes Decreased 1 or more logMAR	
1	68	1	1%	54	2	4%	0.583
3	60	2	3%	47	0	0%	0.503
6	57	5	9%	47	3	6%	0.726
9	54	3	6%	37	2	5%	1.000
12	55	3	5%	36	3	8%	0.678
Last follow-up	62	14	23%	48	6	13%	0.217

* NLP visual acuities excluded from logMAR calculations