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ORIGINAL ARTICLE

Comparison of Medium-Term Visual Outcomes and Complications of Boston Keratoprosthesis Type 1 and Fascial Flap Augmented Osteo-odonto-keratoprosthesis

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Abstract

Aim: The aim of this study was to contribute to the growing international data available on outcomes and complication rates for keratoprosthesis (KPro) surgery.

Background: This investigation reports of medium-term outcomes of the osteo-odonto-keratoprosthesis (OOKP), osteokeratoprosthesis (OKP), and Boston Type 1 KPro (Boston KPro Type 1) offered through Sydney Eye Hospital since 2014. Due to our geography, the service is low volume, but well resourced.

Methods: This is a retrospective observational study of 15 eyes from 15 patients. All patients that underwent KPro surgery from 2014 have been included in the study. Outcomes of visual acuity, complication rates, and returns to theater have been extracted and presented as per internationally recommended framework.

Results: All 15 patients followed for a mean of 32.1 months (range 6–67). Predominant indication for Boston KPro Type 1 was failure of penetrating keratoplasty in 53% and autoimmune disease in 80% of biologic haptics (OKP, OOKP). Visual acuity showed statistically significant improvement both across the entire cohort from 2.21 logMAR to 0.85 (P <0.001) and short-term and 0.86 (P = 0.001). This result is consistent across all subset analyses; Boston KPro Type 1 mean acuity preoperatively 2.12 logMAR to 1.12 (P = 0.004) at short-term, statistical significance lost thereafter. Biologics mean acuity preoperatively 2.37 logMAR to 0.33 (P < 0.001) and maintained at intermediate-term.

Conclusions: These results validate keratoprostheses as an effective option in a low volume quaternary referral setting, offering significant improvements in visual acuity in the short- and intermediate-term. At a medium-term timepoint, retention rates and visual acuity are superior in the Biologic cohort.

Introduction

Diseases afflicting the cornea are a major cause of blindness worldwide.[1] Penetrating keratoplasty continues to be one of the most successful forms of solid tissue transplantation in patients with severe corneal blindness.[2,3] However, in cases of repeated rejection, or in cases with more severely distorted ocular anatomy, a traditional corneal transplant is not a viable option.[4] Repeated corneal rejection also increases the rejection risk of subsequent grafts. Keratoprosthesis (KPro) techniques were first conceptualized by French ophthalmologist Guillaume Pellier de Quengsy, in 1789, for the treatment of corneal opacification and have since developed as a response to the need for alternative treatment in patients with poor prognoses for traditional corneal transplantation.[5,6] Of the three types of KPro examined; here, the Boston KPro Type 1 (Boston KPro Type 1) is more frequently utilized, and there are more centers performing this procedure worldwide.[5,7] In comparison, the osteo-odonto-keratoprostesis (OOKP) and the osteokeratoprosthesis (OKP) procedures are relatively rare.

There has been great interest in evaluating the effectiveness of both the Boston KPro and OOKP, and the findings of such

research reports have enhanced patient selection, surgical technique, and post-operative care with resultant improved patient outcomes.[3] Researchers have also attempted to identify prognostic factors of visual outcomes and complications in patients undergoing Boston Kpro Type 1 and OOKP procedures which have allowed for greater accuracy in the prediction of successful outcomes.[8-11] The inclusion of electrophysiology in the pre-operative assessment of KPro surgeries has also contributed to successful outcomes and best practice guidelines.[12]

In planning for KPro surgery, the pre-operative discussion will be necessarily impacted by patient motivations, psychological resiliency, and a frank discussion surrounding the possible complications and likely visual outcomes. Analyzing KPro surgery outcomes are therefore a vital process that provides the body of evidence required for effective pre-operative discussions.

In 2014, in response to an unmet need for this service nationally, the Sydney Eye Hospital established a KPro program with the intention of providing a pathway for suitable Australian patients to access this much needed form of visual rehabilitation from within our state health care system. In this report, we review the outcomes of the Boston KPro Type 1, OKP, and OOKP procedures that have been performed at Sydney Eye Hospital since the program was introduced. Key factors analyzed include: pre-operative assessment, pre- and post-operative best spectacle, and any adverse outcomes.

Materials and Methods

This is a retrospective review of the charts of all patients that underwent surgery for a Boston KPro Type 1, OKP, or OOKP at the Sydney Eye Hospital from September 2014 to November 2020 (all patients are included without exception). Outcomes collected included patient demographics, indication for the KPro, ocular comorbidities, KPro type implanted, related complications, pre- and post-operative best-corrected visual acuity (BCVA), and retention/failure rates.

This study meets criteria set out in the National Statement on Ethical Conduct in Human Research (2007) (Updated May 2015) as set out by the National Health and Medical Research Council of the Australian Government in accordance to the tenets of the Declaration of Helsinki. It has also been scrutinized by South Eastern Sydney Local Health District Human Research and Ethics Committee and met with their approval.

Visual acuity was assessed using standard Snellen charts and annotation. Snellen was converted to LogMAR for statistical manipulation. No light perception has been converted to 3.0 in LogMAR, light perception 2.7, hand movements 2.28, and counting fingers 1.98. International guidelines for reporting on KPro were adhered to; short-term being defined as 6 months to less than 2 years, intermediate-term 2 years to less than 5 years, and long-term 5 years and beyond.[7] Our use of the term failure pertains to those patient who did not retain the prosthesis.

Definitions for glaucoma relate to their time of diagnosis. Pre-existing glaucoma was defined as either, or any combination of, elevated intra-ocular pressure (IOP [>21 mmHg]), previous glaucoma surgery, ongoing IOP controlling drugs. *De novo* glaucoma defined as increased cup-to-disk ratio, visual field (VF) defects consistent with high pressure or the introduction of new IOP controlling drugs in those patients without pre-existing glaucoma. Progressive glaucoma was defined as worsening VF defects, need for advancing conservative medical options or any surgical intervention required in those patients with a diagnosis of pre-existing glaucoma.

All patients underwent thorough multidisciplinary assessment of retina, glaucoma, and cornea as well as electrophysiology to establish candidacy. As per accepted indications, the type of Kpro chosen was predominantly dictated by the health of the ocular surface; those with an intact tear film and lids received a Boston Kpro while those suffering with dry and keratinized ocular surfaces received an OKP or OOKP.[13] In this cohort, there was one exception; an OOKP patient who suffered with severe necrotizing stromal HSK and recurrent atopic keratoconjunctivitis but retained a wet ocular surface.

All implantations were performed by a multi-surgeon team, headed by one surgeon (GM) at the Sydney Eye hospital. The multidisciplinary group comprises glaucoma (CC), retina (MG), and maxillofacial (SW) surgical consultants. Training in the OOKP and OKP procedures was provided by Dr Konrad Hille.

The KPro procedures largely adhered to the standardized surgical techniques for Boston Kpro, OKP, and OOKP outlined by Hille *et al.*[14] Patients receiving the Boston Kpro underwent a single surgery, while those undergoing a biologic procedure had a two-stage procedure. There were a couple of notable modifications to the OOKP procedure which included the addition of an endoscopic vitrectomy before Stage 1. The goal was to visualize the posterior pole in an attempt to exclude poor candidates as well as to induce a posterior vitreous detachment where possible to help minimize the future risk of retinal detachment. In one case, lens fragmentation was added at the time of endoscopic vitrectomy to avoid and open sky lensectomy. A further modification to the OOKP surgical technique was the novel addition of a temporalis flap step in an attempt to delay/avoid bone resorption which has been described and published previously.[15]

All OKP and OOKP patients received a Morcher 91L OOKP optic of varying dioptric power. Standard of care was for Baerveldt 350 – glaucoma drainage tubes were inserted at the same time as the prosthesis unless a drainage tube was already in situ. Table 1 summarizes the various Boston Kpro specifications and identifies those requiring concomitant procedures.

The standard post-operative treatment regimen for Boston Kpro recipients consisted of a combination of Gram-positive (vancomycin and later chloramphenicol) and Gram-negative (ofloxacin) antibiotic coverage in addition to topical steroid in the form of dexamethasone phosphate 1%. This is continued indefinitely. OKP

Table 1: Boston KPro Type 1 Materials and concomitant procedures

Boston KPro Type 1 materials	Concomitant procedures
KPro: Pseudophakic, 9 mm donor cornea/Kpro complex inserted into 8.75 mm, 8.00 mmm backplate.	Baerveldt tube inserted
KPro: pseudophakic, 8.5 mm host trephined, 8.75 mm donor trephined.	Baerveldt tube inserted
KPro: pseudophakic, 8.5 mm corneal button+3.00 mm central optic+7 mm pediatric backplate.	
Kpro: pseudophakic, 7.0 mm backplate, PMMA backplate	
Kpro: pseudophakic, 9 mm donor corneal button, central 3 mm hole punched, titanium ring+donor cornea+PMMA back plate (8.00 mm), host trephined 8.75 mm	Baerveldt tube inserted Endovit
Kpro, aphakic, 8.00 mm backplate; 3 mm central trephine; 9 mm peripheral trephine; HOST: 360° peritomy, 8.5 mm trephine.	Molteno tube repositioned
Kpro, aphakic, 7.00 mm backplate (682-design for vision Aust pty ltd)	Molteno tube repositioned
KPro: pseudophakic, 7.0 mm (small) backplate	Endocyclophotoablation
KPro: aphakic, 7.00 mm backplate	
Kpro: aphakic, donor tissue trephined 9.00 mmm, 8.00 mm backplate, host trephined 8.75 mm	Baerveldt tube inserted

and OOKP recipients received intravenous antibiotic coverage for 2 days postoperatively followed by oral antibiotics for 10 days, and finally daily or second daily betadine rinses.

Follow-up with patients was maintained with the help of local specialist referrers and through a monthly multidisciplinary clinic. Follow-up visits included B-scan ultrasound examination of the retina as well as optic nerve head and macular optical coherence tomography.

Data were analyzed using parametric student *t*-test to assess the significance in change of BCVA from pre-operative to short-, intermediate-, and long-term results. Survival rates (loss of VA, prosthesis, and other complications) were plotted using Kaplan–Meier curves. Follow-up time was calculated from the date of surgery for Boston Kpro patients and from date of second stage procedure for the biologics.

Results

A total of 15 eyes from 15 patients were included in the study. Table 1 displays their demographics, underlying diagnoses and ocular comorbidities. Of these 46% had pre-existing glaucoma and 85% of this subset had previous glaucoma surgery. Table 2 provides a breakdown of ocular pre-operative co-morbidities

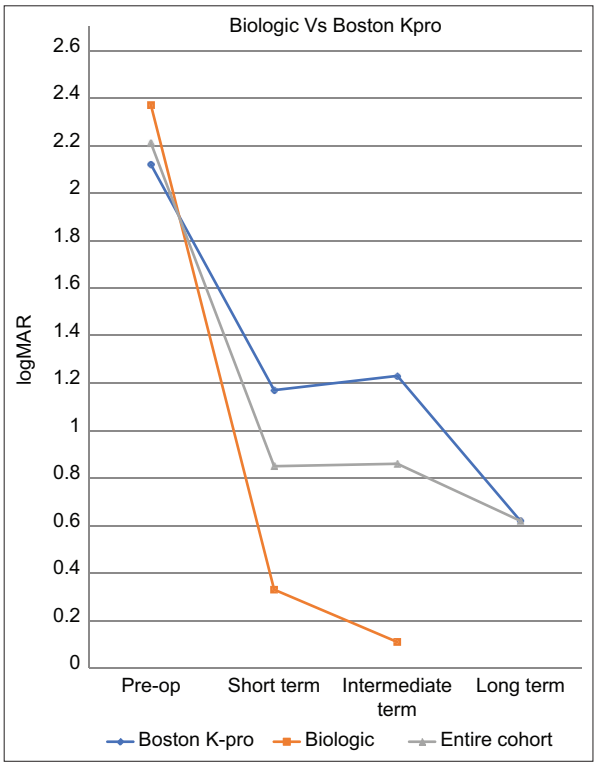

Figure 1: Representation of mean best-corrected visual acuity (BCVA) data from pre-operative to post-operative time periods for biologic versus Boston KPro. Each graph has the same BCVA data for the entire cohort in green for ease of reference

All patients were followed up for a minimum period of 9 months, at which time the first failure occurred due to fungal keratitis. All patients experienced an initial improvement in vision with the most modest improvement being from light perception to hand movements. From pre-operative BCVA to short-term, we see an improvement in vision from 2.21 to 0.85 ($P < 0.001$). International guidelines prevent us from including visual acuity date within the first 6 months of surgery; however, it is worth noting that 33% of our patients had their best recorded visual acuity within this period. An overall improvement in vision was generally maintained throughout the cohort except in those patients who were deemed failures and went on to undergo either an explanation or enucleation for varied reasons. Within the intermediate-term window, visual acuity remained almost perfectly stable from 0.85 LogMAR to 0.86. While the number of patients in the "intermediate-term" decreased from 15 to 9, statistical significance was maintained ($P = 0.001$). The "long-term" data set consisted of only two patients with clinic visits at >60 months, and a non-statistically significant BCVA of 0.62 was recorded for this group ($P = 0.116$). Both of these long-term patients were Boston Kpro candidates with recurrent immunological rejection being their underlying indication for the procedure. Figure 1shows the BCVA divided into biologic and Boston Kpro cohorts across the follow up period, as well as the averaged sum of BCVA outcomes

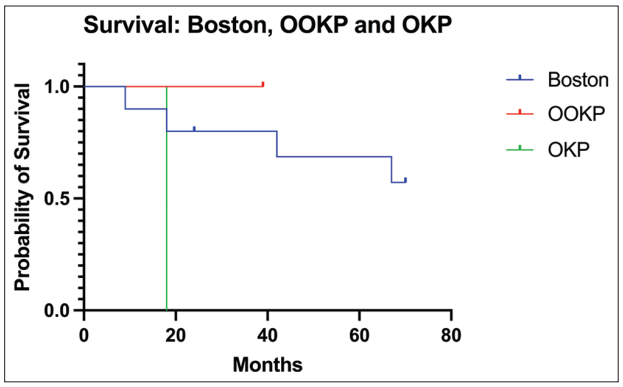

Figure 2: Kaplan–Meier survival curve of retention rates in the Boston KPro Type 1 cohort against the osteo-odonto-keratoprosthesis and osteokeratoprosthesis patients

A Kaplan–Meier survival curve was used to analyze the keratoprostheses retention rates in the Boston Kpro and OOKP groups [Figure 2]. While Table 3 provides a full breakdown of the complications and their frequencies across the different groups.

Discussion

Given modern KPro surgery was first conceptualized in 1951, these results represent a very recent data set with only two patients entering the long-term result window of >60 months.[16] While the procedure remains uncommon, there are numerous published series to which we compared our cohort. Only one of these included Boston Type 1, OKP, and OOKP in their series.[17]

The retrospective paper from de la Paz *et al.* (2019) sought to compare outcomes of the Boston Kpro Type 1, OKP, and OOKP methods by specifically selecting clinically comparable cases of chemical injury and autoimmune disease, in an even distribution across the three surgical methods with much larger numbers to each subset; 25, 22, and 23 respectively. For this reason, their outcomes was not directly comparable to our series. Their summative findings concur with those found here, in that the biologic systems have fewer complications; however, we did not find a higher rate of retention as did de la Paz *et al*. Their study also described better functional results at 5 years among the biologics; however, this did not reach statistical significance on comparison.

This cohort was made up of patients with significant underlying pathologies for which medical and surgical management had been exhausted. KPro surgery has been accepted as a last resort for most patients. Post-operative gains, while cherished by patients, can have a pending nugatory outcome.[18] Best outcomes must, therefore, be considered within this context. Both the entire cohort and the various subsets analyzed earlier have made considerable gains in visual acuity.

Our mean BCVA data is comparable with those presented in the literature. Chew *et al.* (2009) saw an improvement from

Table 2: Demographics, underlying diagnosis, and ocular comorbidities for 15 patients undergoing keratoprosthesis surgery

Demographics	
Mean age (range)	66.1 (44.7–87.9)
Male gender (number, %)	5, 33
Mean duration of follow-up in months (SD)	32.1 (16.0)
Range of follow-up in months	9–67
Mean LogMAR vision in operated eye (SD)	2.21 (0.53)
Underlying indication for prosthesis	
Recurrent immunological rejection	9
Autoimmune disease	4
Invasive BCC	1
Limbal stem cell failure	1
Ocular Comorbidities	
Glaucoma	7
No previous glaucoma surgery	9
Previous trabeculectomy	3
Previous tube shunt	3
Stevens Johnson Syndrome	4
Limbal stem cell deficiency	3
Aniridia	3
BCC cornea	2
Congenital cataracts	2
Fuchè endothelial dystrophy	1
Toxic epidermal necrolysis	1
HSV	1
Marfans Syndrome	1

CF to 6/15 of statistical merit ($P \leq 0.001$) within the short-term time frame for 37 patients who had a Boston KPro Type 1.[19] A recent Moorfields study of 39 eyes describes an initial gain from HM to 1/60 before a decline to CF at the short-term interval with glaucoma being the chief cause of loss. Comparatively, the subset of patients without posterior segment disease had a mean acuity of 6/15 which was maintained.[18] Our cohort achieved mean gains of hand movements to 6/44 which was maintained up to 5 years. When those with retinal disease contributing to poor BCVA or "guarded" prognosis are excluded from this calculation, the short-term mean is 6/25 and the intermediate-term mean is 6/35.

Several studies use a cutoff of 6/60 at various time frames to assess visual acuity[19-22] the largest of these demonstrated visual acuity of >6/60 of 70%, 68% and 59% at 6, and 12 and 24 months interval, respectively. Our results showed 66% of patient have BCVA >6/60 at the short and intermediate time frames. Although the long-term data were limited to just 2 patients and does not merit a statistical significance, the good BCVA results are, nevertheless, encouraging.

Table 3: Complications rates for entire cohort separated into constituent subsets as described in international guidelines

Entire cohort *n*15 R 60% F 33% D 7%		Biologic *n*5 R 80% F 20%	Boston K-pro n10 R 50% F 40% D 10%	Primary *n*6 R 67% F 33%	Previous transplant *n*9 R 56% F 33% D 11%	Dry Ocular surface *n*4 R 75% F 25%	Wet Ocular surface *n*11 R 55% F 36% D 9%	AD *n*4 R 100%	RIR *n*8 R 63% F 38%	Other *n*3 R 0% F 67% D 33%
Glaucoma 5	33%	20%	40%	33%	33%	25%	36%		36%	66%
De novo 2	13%	20%	40%	17%	11%	25%	36%		36%	33%
Progressive 3	20%			17%	22%					33%
Vitreous hemorrhage 4	27%	40%	20%	50%		50%		25%	13%	33%
Retroprosthetic membrane 4	27%		40%	17%			36%		38%	33%
Epiretinal membrane 4	27%	20%	30%	17%	33%	25%	36%	25%	38%	
Hypotony 4	27%		30%	17%	33%		36%		38%	33%
Corneal rim melt 2	13%		20%		22%		18%		25%	
Aniridic fibrosis syndrome 2	13%		20%	17%	33%		18%		13%	33%
Fungal keratitis/ keratitis 2	13%		20%		22%		18%		25%	
Glaucomatous optic neuropathy 2	13%		20%		22%		18%		25%	
Retinal detatchment 2	13%	40%		33%		50%		50%		
CME 1	7%		10%		11%		9%		13%	
Choroidal detatchment 1	7%		10%	17%			9%			33%
Sterile vitritis 1	7%		10%		11%		9%			
Scleromalacia 1	7%		10%		11%		9%		13%	
Mucosal retraction 1	7%	20%		17%		25%		25%		
Mucosal overgrowth 1	7%	20%		17%		25%		50%		
Focal osteonecrosis 1	7%	20%		17%		25%				33%
Tumour invasion 1	7%	20%		17%		25%				33%

R: Retention, F: Failure, D: Death, AD: Autoimmune disease, RIR: Recurrent autoimmune rejection

Of the patients for whom Kpro surgery failed, before conclusive surgery, 60% had retinal pathology contributing to loss of visual acuity before developing anterior segment disease which led to the failure of the prosthesis. Primary KPro procedures have been correlated with visual acuity loss following Boston KPro Type 1; however, our figures do not reflect this association.[23] The ability to preoperatively identify patients who have poor outcomes would be ideal; this would aid in both patient and clinician expectation and help with decision to take on the burden of post-operative care. Patients with aniridia appear to fit this characterization, with two of the three aniridic patients in our dataset resulting in failure of the implant (all three underwent Boston KPro Type 1). Aniridic fibrosis syndrome played a significant role in their outcome with risk of precipitating this response increasing with each intervention. This tendency is not in keeping with a 2007 study following up 15 post-Boston KPro Type 1 for 17–85 months without a single loss of prosthesis or case of aniridic fibrosis syndrome.[24] In that series, no intraocular interventions were required after KPro surgery. In our two aniridic failures, one had multiple prior intraocular surgeries, while the other required multiple post-KPro intraocular interventions. In our single aniridic patient with device retention at 7 years, no post-KPro surgery has been necessary. The success of Kpro in aniridia likely relates to the

avoidance of aniridic fibrosis syndrome and the minimization of any intraocular scarring response.

Our most common procedure performed at a return to theater was a vitrectomy (40% of patients who returned to theater); nine in total. This was performed for a variety of reasons, three of which occurred in the same patient. A total of two vitreous hemorrhages, two epiretinal membrane peels, one lensectomy and Baerveldt tube insertion, one removal of retroprosthetic membrane and one for Baerveldt tube adjustment, and one for retinal detachment and one to remove heavy oil following a retinal membrane peel. Vitrectomy was the most frequent procedure, given it's a common step in many posterior segment operations. Mucosal graft modifications were the next most common cause for return to theater, with a total of seven procedures among three patients, all within the biologic group. The rate of return to theater was double in biologic group as compared to the Boston KPro Type 1 group: there were 17 returns to theater for the five patients in the biologic group and 17 for the ten patients in the Boston Kpro Type 1 group.

The most frequent complication was that of glaucoma in 33% of the entire cohort and was relatively evenly spread across the various axis of discrimination. Overall, data were not available on IOP for 31% of the cohort, so is not amenable to statistical scrutiny. Of those who had records of pressure recorded, one instance of high pressure was recorded post-operatively. There were two cases of de novo glaucoma; one patient commenced acetazolamide for optic disk changes, and the other was started on Lumigan. Progressive glaucoma was found in three patients; one requiring reinsertion of their Baerveldt tube, one requiring Baerveldt tube modification, and one requiring a cyclodiode procedure.

Glaucoma is the most common complication associated with the KPro procedures and a common countermeasure is to insert a prophylactic tube at the time of surgery regardless of patient's previous IOP status[18,23,25] Other studies of Boston KPro Type 1 outcomes cite pressure problems in the range of 14–33% postoperatively making it one of the more common complications.[18,19,21,22,26] In one study, it was the most common obstruction to attaining better than logMAR 1.0.[27] However, overall, there is a reliable reduction in glaucoma following the procedure with pre-operative rates of 58–74% in these same studies. This is attributed to concomitant tube insertion and difficulty in detecting glaucoma postoperatively.[22]

One literature review into the biologic KPro approach describes wide variation in the rates of glaucoma postoperatively, ranging as far as 7–47%.[13] The de la Paz *et al*. Study comparing Boston KPro Type 1 and biologics associates higher rates of glaucoma among the Boston KPro patients.[17]

Retention rates are best described using the Kaplan–Meier graph in Figure 2. This shows a greater survival rate among the OOKP cohort – currently standing at 100% at this stage of follow-up. The single OKP patient was removed shortly before 20 months of follow-up, which was an expected outcome given the progressive natures of the BCC, while 40% of the Boston Kpro subset were removed. Clearly, the cohort sizes are small, but our investigation would associate significantly higher survival rates among the OOKP group.

This investigation was unique in terms of the inclusion of data from three surgical methods. Despite the proportionately short follow-up period with a relatively modest number of patients, we were able to recognize trends observed elsewhere in the literature, specifically, a better functional prognosis in the biologics group and rates of patients experiencing gains >6/60.[17,21] The biologic systems provide better final visual acuity as a cohort which was also more reliably maintained, but with greater surgical difficulty and higher returns to theater. This impression of improved outcomes in the biologic group may reflect the relative health of the posterior pole with less pre-operative pathology in this cohort.

In summary, an initial review of the outcomes from this relatively newly established service at Sydney Eye Hospital is encouraging in that they correlate well with published outcomes of KPro surgery and identify disease entities that may potentially be associated with higher complication rates and adverse outcomes post-KPro surgery.

Conclusions

This investigation was unique in terms of the inclusion of data from 3 surgical methods. Despite the proportionately short follow up period with a relatively modest number of patients we were able to recognise trends observed elsewhere in the literature, specifically, a better functional prognosis in the biologics group and rates of patients experiencing gains >6/60. [17, 21] The biologic systems provide better final visual acuity as a cohort which were also more reliably maintained, but with greater surgical difficulty and higher returns to theatre. This impression of improved outcomes in the biologic group may reflect the relative health of the posterior pole with less pre-operative pathology in this cohort.

In summary, an initial review of the outcomes from this relatively newly established service at Sydney Eye Hospital are encouraging in that they correlate well with published outcomes of keratoprosthesis surgery and identifies disease entities that may potentially be associated with higher complication rates and adverse outcomes post keratoprosthesis surgery.

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