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Visual Acuity Outcomes of the Boston Keratoprosthesis Type 1: Multicenter Study Results

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Abstract

Purpose: To report logarithm of the minimum angle of resolution (logMAR) visual outcomes of the Boston Keratoprosthesis Type 1.

Design: Prospective, cohort study.

Methods: Pre-, intra-, and postoperative parameters of 300 eyes of 300 patients who underwent implantation of a Boston Keratoprosthesis Type I device between January 2003 and July 2008 by one of 19 surgeons at 18 medical centers were collected.

Results: After an average of 17.1 ± 14.8 months, visual acuity improved significantly (p<0.0001) to a mean final value of 0.89 ± 0.64 (20/150). There were also significantly fewer eyes with light perception (6.7%; n=19; p<0.0001), although 3.1% (n=9) progressed to no light perception. There was no association between age (p=0.08), gender (p=0.959), operative side (p=0.167), or failure (p=0.494) and final visual acuity. The median time to achieve 20/200 visual acuity was 1 month (95% CI 1.0 – 6.0) and it was retained for an average of 47.8 months. Multivariate analysis, controlling for preoperative visual acuity, demonstrated two factors associated with final visual outcome: chemical injury was associated with better final vision (p=0.007), whereas age-related macular degeneration (p<0.0001) was associated with poorer vision.

Conclusions: The Boston Keratoprosthesis Type 1 is an effective device for rehabilitation in advanced ocular surface disease, resulting in a significant improvement in visual acuity. Eyes achieved a mean value of $20/150 (0.89 \pm 0.64 \log MAR units)$ after 6 months and this was relatively stable thereafter. The best visual prognosis is observed in chemical injury eyes, whereas the worst prognosis is in aniridia, although the latter has limited visual potential.

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Keratoprostheses (KPRO) were first implanted in animals in 1853, followed by the first human implantation by Heusser in 1859.^{1,2} The initial devices were made from glass and had poor retention, with none retained more than 6 months. While other investigators attempted to improve on the design, long-term retention was still poor, with most KPROs extruded.^{3–5} With improvement in both donor corneal storage and techniques of full-thickness corneal transplantation, the interest in an artificial cornea waned. As with intraocular lenses, the discovery of inert plastics (e.g. PMMA) in the mid-20th century prompted a resurgence in both the design of and interest in KPROs.

Numerous KPRO designs emerged in the latter part of the 20th century, with the Boston KPRO being the most popular. Originally called the Dohlman-Doane Keratoprosthesis, it received US Food and Drug Administration clearance in 1993.⁶ Further advances in the refinement of the design and use of topical antibiotic prophylaxis improved the overall retention rate and made keratoprosthesis surgery a viable option for patients who would be poor candidates for penetrating keratoplasties.^{7,8}

In spite of these improvements, keratoprosthesis surgery remained a rarity. In 2003 while over 50,000 transplants were being performed annually in the United States, only 57 Boston KPROs were implanted world-wide. Over the last ten years the acceptance of the Boston KPRO and its use has grown exponentially; in 2012 over 1,500 Boston KPROs were implanted world-wide.⁹

The increased utilization of the Boston KPRO lead to the first large scale multi-center study in 2006.¹⁰ The original paper analyzed 141 procedures and reported an overall retention rate of 95%. The study was limited by a short follow-up time of 8.5 months (range 3 - 24 months). In 2013 we reported on the long-term retention in an expanded study population of over 300 eyes with an additional four years of follow-up.¹¹ Additional papers from the expanded study database analyzed factors that were associated with retroprosthetic membrane formation.¹² The purpose of our current paper is to report on the long-term visual outcomes in 300 Boston KRPO eyes.

Methods

The Boston Keratoprosthesis Type 1 is obtained from the Massachusetts Eye and Ear Infirmary. The technique for implanting the Boston Keratoprosthesis has been previously described and all surgeons reported using a similar technique.¹⁰

Data Collection:

The Boston Keratoprosthesis Multicenter Study is a large prospective cohort study gathering data under institutional review board approval (Cornea Consultants of Albany, Albany Medical Center Department of Ophthalmology) on Boston Keratoprostheses Type I implanted since January 1, 2003. This study was initiated 2 years prior to the public launch of the clinicaltrials.gov website and is therefore not registered on the site. At the time the study was initiated, all surgeons known to be performing multiple procedures were contacted and encouraged to participate. Surgeons reported data using a mail-in Case Report Form evaluating approximately 70 perioperative variables. Data submissions were

voluntary, although all participating surgeons were encouraged to submit data as complete as possible, regardless of the outcome. In compliance with Health Insurance Portability and Accountability Act regulations, patients were assigned a unique study number. These forms were sent to a data coordinating center, under institutional review board approval. In general, follow-up visits at one month, six months, twelve months, and annually thereafter were reported by participating surgeons.

For patients who underwent repeat implantation after keratoprosthesis failure, only data from the first implant was included in this study. If a patients underwent bilateral keratoprosthesis implantation, then only the first eye of the patient was included in the study because the eyes are not independent data points.

Analysis:

Based on previously published prognostic categories,¹³ the patients were categorized into the following pathologic groups: severe autoimmune disease (ocular cicatricial pemphigoid [OCP] and Stevens Johnson Syndrome [SJS]), chemical injuries, herpes simplex (HSV) keratitis, Fuchs endothelial dystrophy, keratoconus, infectious keratitis, neurotrophic ulcers, limbal stem cell deficiency (LSCD), pseudophakic bullous keratopathy (PBK), trauma, aniridia, miscellaneous, failed penetrating keratoplasty (PK) and unknown.

A Microsoft Excel spreadsheet was used to compile the data and SAS version 9.2 (SAS Institute Inc., Cary NC, USA) was used for all data analyses. Because some surgeons provided data at follow-up time points (e.g. 6 months, 1 year, etc.) without a specific date, a follow-up date was imputed for these patients. Association between categorical variables were examined using Fisher's exact test or Chi-square test. For comparisons of continuous variables between two groups, two-sample t-tests were used, and when comparisons of pre / post visual acuity measurements were performed, paired t-tests were employed. To analyze the relationship between two continuous variables, simple linear regression was performed.

Visual acuity measurements were obtained using a standard Snellen chart viewed from a distance of 6 meters and were converted to logarithm of the minimum angle of resolution (logMAR) units for the analysis, which was the primary outcome of interest. Visual acuity measurements that were recorded as counting fingers were converted to a Snellen equivalent using the conversion algorithm described by Holladay,¹⁴ although a lower limit of 20/2000 was utilized. When a distance at which finger counting was measured was not recorded, the distance was assumed to be 2 feet, which is equivalent to 20/2000. One research group^{15,16} has calculated that hand motions acuity ranges between 2.28 and 3.60 logMAR units; the upper limit was used for this study.

Eyes with light perception (LP) and no light perception (NLP) visual acuity were excluded in initial analyses of visual acuity, although they were summarized in the figures using the format previously published for Boston keratoprostheses.^{17,18} In addition, the same analysis was performed by assigning Snellen values of 20/40,000 for LP and 20/60,000 for NLP. Results for these analyses are presented only when they differed from the primary approach.

Based on the recommendations by Jabs,¹⁹ the time to achieve 20/200 vision was analyzed using Kaplan-Meier curves with 95% Hall-Welner Bands²⁰ and the log-rank test was used for group comparisons. Time to achieve 20/200 visual acuity was defined as from the date of surgery to the first follow-up visit at which 20/200 visual acuity was observed, including preoperatively. As such, eyes with better than 20/200 visual acuity prior to KPro placement were censored at time zero. For those eyes, time to loss of 20/200 visual acuity was analyzed as well. For the latter analysis, fluctuation in vision was discounted such that, for example, an eye that had hand motions vision preoperatively, 20/50 vision at 1 week, 20/200 at one month, 20/400 at 6 months, 20/100 at 1 year, and hand motions at 2 years would be recorded as having lost 20/200 vision after 22.77 months. Cox proportional hazards regression analysis, using stepwise selection, was utilized to determine which surgical indication was significantly associated with the time to achieve 20/200 visual acuity. The Kaplan-Meier curves and cumulative residuals were sued to evaluate the proportional hazards assumption.

Pearson correlation coefficients were calculated to evaluate the correlation of final visual acuity with pre-operative visual acuity. A scatter plot was created to demonstrate the relationship between preoperative and final logMAR visual acuity levels and linear regression was utilized to fit a summary line with 95% confidence intervals. A multivariate linear regression model, controlling for baseline visual acuity was fit using stepwise selection to determine which covariates were significantly associated with final visual acuity. Covariates were considered for inclusion in the model if univariate analyses demonstrated a p 0.1).

Results

Between January 2003 and July 2008, information on 321 Boston Keratoprostheses Type I implants placed in 303 patients by 19 surgeons at 18 medical centers was collected. Thirteen eyes were excluded because they represented re-implantation of a keratoprosthesis; only data from the first implant was included. Eight eyes of 8 patients that underwent sequential bilateral keratoprosthesis implantation were also excluded. The final analysis included 300 eyes of 300 patients.

The mean age at the time of implantation was 62.6 ± 18.9 years (range 10.5 - 96.7 years); age was not associated with final visual acuity outcome (p=0.09). Patients were nearly equally split between genders, with 48.1% being female; there was no association between final visual acuity and gender (p=0.959). The procedure was performed in the right eye for 53.6% of the cases and there was no relationship to final visual acuity (p=0.167). Overall, 7.0% (n=21) of keratoprostheses failed; our initial analysis with actual VA measurements showed that final visual outcome was not associated with failure (p=0.494). However, there were 4 eyes that failed had non-numeric visual acuity (LP or NLP) at the final visit. We performed additional analyses assigned Snellen values of 20/40,000 for LP and 20/60,000 for NLP and there was still no association between final visual outcome and failure (p=0.167).

Pre-operative visual acuity was recordable on the Snellen chart for 47.3% of eyes (n=142) and was equivalent to $1.78 \pm 0.62 \log MAR$ units (20/1205). Of those eyes that did not have

vision measurable using a Snellen chart, 33.3% of eyes (n=100) had hand motions acuity and 14.3% (n=43) had only light perception. Over the follow-up period, which averaged 17.1 \pm 14.8 months and ranged between one week to over 6.1 years, visual acuity improved (Figures 1 & 2) significantly (p<0.0001) for 84.7% (n=254) eyes, to a mean final value of 0.89 \pm 0.64 (20/150). At the final visit, there were significantly fewer eyes with hand motions acuity (8.5%; n=24; p=0.263) and light perception (6.7%; n=19; p<0.0001), but 3.1% (n=9) progressed to no light perception (Figure 3). The mean change in visual acuity was -0.89 \pm 0.91 logMAR units, representing a significant improvement in vision.

The relationship between preoperative and final logMAR visual acuity is illustrated in Figure 4; the Pearson correlation coefficient is 0.13 (p=0.05) indicating the positive correlation between these two variables.

The median time to achieve 20/200 visual acuity was 1 month (95% CI 1.0 – 6.0; Figure 5). Of those, the median time to loss of 20/200 visual acuity was 47.8 months (Figure 6). From the Kaplan-Meier curve itself, approximately $\frac{3}{4}$ of eyes retained 20/200 acuity for most of the study period. Eyes with a preoperative etiology of multiple failed graft and limbal stem cell deficiency achieved 20/200 faster, with median times of 1.0 (p=0.012; 95% confidence interval [CI] 1.0 – 6.0) and 0.23 (p=0.002; 95% CI 0.00 – 0.23) months respectively. Multivariate (Cox) proportional hazards regression analysis confirmed that eyes with limbal stem cell deficiency (hazard ratio [HR]=3.73; 95% CI 1.81, 7.70; p=0.0004), multiple failed grafts (HR=1.98; 95% CI 1.33, 2.94; p=0.0008), chemical injuries (HR=1.81; 95% CI 1.16, 2.85; p=0.0096) and traumatized eyes (HR=2.27; 95% CI 1.17, 4.40; p=0.015) experience rapid recovery. It is also noteworthy that no aniridia patients achieved 20/200 vision, which is not surprising given the co-existing macular pathology associated with the condition. For time to loss of 20/200, eyes that received a KPro for limbal stem cell deficiency did the best (p<0.0001), with none losing 20/200 acuity once it was achieved.

There were three categories of implant-types: primary (no previous PK; 13.3%), repeat (previous keratoprosthesis undergoing replacement; 7.5%) and denovo (previous PK; 79.2%). Of those that had a failed PK prior to keratoprosthesis (n=244), an average of 2.3 ± 1.3 prior corneal transplants (range 1 – 8) were performed. There was no difference in final visual acuity by implant category (p=0.621) or in relation to the number of prior failed PK (p=0.567). The Boston Keratoprosthesis Type 1 was utilized for a wide variety of ocular surface diseases (Table 1). All etiologies except aniridia (p=0.08) demonstrated a statistically significant improvement (p = 0.04) in visual acuity after keratoprosthesis implantation. The best final visual acuity was observed in (non-aniridic) limbal stem cell deficiency patients, with a mean final logMAR acuity of 0.47 \pm 0.30. Chemical injuries (0.55 \pm 0.56 logMAR units) and keratoconus (0.68 \pm 0.44 logMAR units) were similarly successful.

Eyes with a chemical injury had a significantly better prognosis, with final visual acuity $(0.55 \pm 0.57 \log MAR \text{ units})$ significantly higher in comparison to all other etiologies $(1.05 \pm 0.71 \log MAR \text{ units})$; p=0.0003). However, eyes with pseudophakic bullous keratopathy had poorer final visual acuity $(1.14 \pm 0.67 \log MAR \text{ units})$ in comparison to the others $(0.97 \pm 0.72 \log MAR \text{ units})$, but this result was significant only on a sensitivity analysis that included non-numeric visual acuity levels (p=0.03). Similarly, eyes with aniridia were also

more likely to have worse final vision (1.54 \pm 0.48 logMAR units; p=0.04) in comparison to other etiologies.

At the time of keratoprosthesis implantation, many patients underwent concomitant surgical procedures (Table 2). Eyes that underwent combined cataract extraction had better final visual acuity (0.83 ± 0.75 logMAR units) than those not undergoing cataract extraction (1.03 ± 0.70 logMAR units; p=0.022). No other additional procedures were associated with final visual outcome (p>0.05). There was no association between the use of either a pseudophakic (p=0.899) or aphakic keratoprosthesis (p=0.899) with final visual acuity.

Eyes that had age-related macular degeneration (AMD) had significantly worse final visual acuity ($1.81 \pm 0.52 \log$ MAR units) in comparison to all others combined (Table 3; $0.94 \pm 0.68 \log$ MAR units; p<0.0001). In contrast, eyes with exposure keratopathy had remarkably better final visual acuity ($0.36 \pm 0.28 \log$ MAR units) in comparison to all others ($1.00 \pm 0.71 \log$ MAR units), although this comparison was only significant on sensitivity analysis (p=0.041). Apart from glaucoma, there were relatively few ocular comorbidities, and as such most of these comparisons were underpowered.

Multivariate analysis, controlled for preoperative logMAR acuity, considered 7 additional covariates: chemical injuries, PBK, LSCD, aniridia, combined cataract extraction, and history of exposure keratopathy or AMD. This demonstrated three covariates associated with final visual outcome: AMD (p<0.0001), chemical injury (p=0.007), and preoperative logMAR acuity (p=0.01). The regression coefficient was negative for chemical injuries, indicating that these eyes have a better visual prognosis. In contrast, AMD had a positive coefficient, indicating, that these eyes have suboptimal visual outcomes.

Discussion:

This relatively large, multicenter study demonstrates that keratoprosthesis are an excellent option to restore functional visual acuity for debilitating corneal surface disease. More than half of keratoprosthesis eyes will achieve better than 20/200 visual acuity. The average visual improvement was 9 lines (mean change in visual acuity was -0.89 ± 0.91 logMAR units) and the average final visual acuity was 20/150 (0.89 ± 0.64 logMAR units). It is important to note that this average value describes 80.9% (n=241) of the sample; almost 20% of eyes will remain profoundly visually impaired after keratoprosthesis implantation. In contrast, for eyes that achieved 20/200 visual acuity, vision was maintained at that level, on average, for 4 years, although many of the eyes were censored near this time point.

Visual prognosis varied depending on the specific underlying ocular surface disease. With the exception of aniridia, which has inherently lower visual potential due to macular hypoplasia,²¹ all eyes experienced a significant improvement in visual acuity. The best prognosis was observed in chemical injuries, which was an independent predictor of better final visual acuity even after controlling for other significant covariates. It is unclear why chemical injury eyes respond to keratoprostheses so well, although one hypothesis considered was whether this result was driven by a propensity for chemical injury eyes to

develop retroprosthetic membranes (RPM) less frequently¹²; post-hoc multivariate analysis adding RPM as a covariate on these eyes did not change the results.

Unfortunately, the vast majority of keratoprosthesis eyes, even when successful, remain visually impaired; only 6.0% of eyes had a final visual acuity > 20/60. This result conflicts with Dunlap et al,²² which reported on 126 keratoprosthesis eyes and observed that approximately 16% achieved 20/40 or better vision after 6 months. Similarly, Chew et al¹⁷ observed that 43% of patients achieved 20/50 or better at their last follow- up visit, which had an approximate mean of 12 months. Explanations for these differences could be a shorter duration of follow-up than reported here, or a difference in the visual potential of patients between studies. However, Greiner et al,¹⁸ reporting on a small number of eyes (n=35) but with longer follow-up (mean 33.6 months) found results more similar to this study, with approximately 11% of eyes achieving 20/60 vision. This less-than-optimistic perspective does not negate the visual acuity benefit experienced after keratoprosthesis. Instead, it indicates that physicians should be give patients realistic expectations as to the vision over the long-term and empowers ophthalmologists and patients with information that enables informed decision-making.

The only comorbidity that independently predicted final visual acuity was AMD, although it is very likely that glaucoma is also associated with poorer visual outcomes.^{18,23–25} Unfortunately, intraocular pressure is difficult to reliably measure in KPRO eyes. Due to the heterogeneous manner in which IOP was reported in this study, its impact on this cohort cannot be described. However, given that eyes in this cohort invariably had or developed glaucoma, the results are inclusive of the effect of glaucoma and as such still provide accurate prognostic information for patients and ophthalmologists.

The Boston Keratoprosthesis Type 1 is an effective device for rehabilitation in advanced ocular surface disease, resulting in a significant improvement in visual acuity. From a mean preoperative acuity of 20/1625, eyes improved to a mean value of 20/150 after 6 months, and this was relatively stable thereafter. The best visual prognosis is observed in chemical injury eyes, whereas the worst prognosis is in aniridia, although the latter has limited visual potential secondary to macular hypoplasia.

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Biography

Christopher J. Rudnisky is an Associate Professor with the University of Alberta, Department of Ophthalmology. He completed both his MD (with distinction) and residency at the University of Alberta. In 2009, he completed a Master of Public Health at the Harvard School of Public Health. He is co-Director of the University of Alberta Teleophthalmology Reading Centre, has published 50 peer-reviewed articles and was awarded "Best Surgical Teacher" for 5 years in a row: 2011 - 2015.



Appendix

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Rudnisky et al.



Figure 1:

Comparison of preoperative Snellen visual acuity (light bars) versus the visual acuity at the last reported follow-up visit (dark bars) for eyes that underwent placement of a Boston Keratoprosthesis Type 1. Bars represent the proportion of eyes with the corresponding level of vision (x-axis), or better, in each category. The proportion of eyes with a Snellen visual acuity 20/200 increased from 9.7% pre-operatively to 55.0% post-operatively. HM = hand motions. LP = light perception.

Rudnisky et al.



Figure 2:

Change in logarithm of the minimum angle of resolution (logMAR) visual acuity in Boston Keratoprosthesis Type 1 eyes. Mean logMAR visual acuity (y-axis) at each time point (x-axis) during the study period. Error bars indicate the standard deviation. On average, the visual outcome is evident and table after 6 months of follow-up.

Rudnisky et al.



Figure 3:

Graphs of the number of Boston Keratoprosthesis Type 1 eyes (y-axis) with either light perception (LP: solid line) or no light perception (NLP: dashed line) visual acuity at each time point (x-axis). Note the rapid reduction in the number of eyes with LP vision preoperatively. Very few eyes develop NLP vision after keratoprosthesis implantation.

Rudnisky et al.



Figure 4:

Scatter plot of preoperative and final logarithm of the minimum angle of resolution (logMAR) visual acuity in eyes that underwent placement of a Boston Keratoprosthesis Type 1, with best-fit line calculated using linear regression (n=285; mean squared error = 0.6295; R-square = 0.0281; adjusted R-square = 0.0246). Note that there is a positive slope indicating that keratoprosthesis implantation results in a definitive improvement in visual acuity.



Figure 5:

Kaplan-Meier curve with 95% Hall-Wellner bands of the time to achieve 20/200 visual acuity after implantation of a Boston Keratoprosthesis Type 1. The median time was 1 month (95% confidence interval: 1.0 - 6.0).



Figure 6:

Kaplan-Meier curve with 95% Hall-Wellner bands of the time to lose 20/200 visual acuity in the subgroup of Boston Keratoprosthesis Type 1 eyes that reached 20/200 visual acuity postoperatively. These eyes retained at least 20/200 visual acuity for a median time of 47.8 months.

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Table 1:

A comparison of preoperative and final logarithm of the minimum angle of resolution (logMAR) visual acuity, in eyes undergoing implantation of a Boston Keratoprosthesis Type 1, for each diagnostic category.

Autoimmune 31 1.83 ± 0.63 1.1 Chemical Injury 31 2.03 ± 0.40 0.0 HSV d 21 2.03 ± 0.40 0.1 HSV d 21 2.03 ± 0.40 0.1 HSV d 21 2.00 ± 0.44 1.1 HSV d 21 2.00 ± 0.44 1.1 Fuchs Endothelial Dystrophy 8 1.64 ± 0.50 1.1 Keratocouus 11 2.00 ± 0.47 0.1 Infectious Keratifs 19 1.76 ± 0.47 0.1 Neurotrophic Keratopathy 4 2.30 ± 0.67 1.1 Umbal Stem Cell Deficiency 9 1.76 ± 0.47 0 Bullous Keratopathy 55 1.92 ± 0.46 1.1	1.20 ± 0.76 0.55 ± 0.56 0.51 ± 0.80 1.14 ± 0.80 1.14 ± 0.80 1.24 ± 0.79 0.68 ± 0.44 1.04 ± 0.61 1.21 ± 0.41	20/317 20/71 20/276 20/348 20/348 20/96 20/219 20/325	 <0.0001 0.006 <0.001 0.04 0.006 0.01 0.01
Chemical Injury 31 2.03 ± 0.40 0 HSV d 21 2.00 ± 0.44 1 HSV b 21 2.00 ± 0.44 1 Fuchs Endothelial Dystrophy 8 1.64 ± 0.50 1 Fuchs Endothelial Dystrophy 8 1.64 ± 0.50 1 Keratoconus 11 1.84 ± 0.47 0 Infectious Keratitis 19 1.76 ± 0.67 1 Neurotrophic Keratopathy 4 2.30 ± 0 1 Limbal Stem Cell Deficiency 9 1.76 ± 0.47 0 Bullous Keratopathy 55 1.92 ± 0.46 1	$\begin{array}{c c} 0.55 \pm 0.56 \\ 1.14 \pm 0.80 \\ 1.24 \pm 0.79 \\ 0.68 \pm 0.44 \\ 1.04 \pm 0.61 \\ 1.21 \pm 0.41 \end{array}$	20/71 20/276 20/348 20/96 20/219 20/325	0.006 <0.0001 0.04 0.04 0.006 0.01
HSV d 21 2.00 ± 0.44 1 Fuchs Endothelial Dystrophy 8 1.64 ± 0.50 1 Fuchs Endothelial Dystrophy 8 1.64 ± 0.50 1 Keratoconus 11 1.84 ± 0.47 0. Infectious Keratitis 19 1.76 ± 0.67 0. Infectious Keratitis 55 1.76 ± 0.47 0. Inibial Stem Cell Deficiency 55 1.92 ± 0.46 1. Bullous Keratopathy 56 1.92 ± 0.46 1.	1.14 ± 0.80 1.24 ± 0.79 0.68 ± 0.44 1.04 ± 0.61 1.21 ± 0.41	20/276 20/348 20/96 20/219 20/325	<0.0001 0.04 0.04 0.006 0.01
Fuchs Endothelial Dystrophy 8 1.64 ± 0.50 1 Keratoconus 11 1.84 ± 0.47 0. Infectious Keratitis 19 1.76 ± 0.67 1. Infectious Keratitis 19 1.76 ± 0.67 1. Neurotrophic Keratopathy 4 2.30 ± 0 1. Inbal Stem Cell Deficiency 9 1.76 ± 0.47 0. Bullous Keratopathy 55 1.92 ± 0.46 1.	$\begin{array}{c c} 1.24 \pm 0.79 \\ 0.68 \pm 0.44 \\ 1.04 \pm 0.61 \\ 1.21 \pm 0.41 \end{array}$	20/348 20/96 20/219 20/325	0.04 0.04 0.0006 0.01
Keratoconus 11 1.84 ± 0.47 0. Infectious Keratitis 19 1.76 ± 0.67 1. Neurotrophic Keratopathy 4 2.30 ± 0 1. Limbal Stem Cell Deficiency 9 1.76 ± 0.47 0. Bullous Keratopathy 55 1.92 ± 0.46 1.	0.68 ± 0.44 1.04 ± 0.61 1.21 ± 0.41	20/96 20/219 20/325	0.04 0.0006 0.01
Infectious Keratitis 19 1.76 ± 0.67 1. Neurotrophic Keratopathy 4 2.30 ± 0 1. Limbal Stem Cell Deficiency 9 1.76 ± 0.47 0. Bullous Keratopathy 55 1.92 ± 0.46 1.	1.04 ± 0.61 1.21 ± 0.41	20/219 20/325	0.0006 0.01
Neurotrophic Keratopathy4 2.30 ± 0 1.Limbal Stem Cell Deficiency9 1.76 ± 0.47 0.Bullous Keratopathy55 1.92 ± 0.46 1.	1.21 ± 0.41	20/325	0.01
Limbal Stem Cell Deficiency9 1.76 ± 0.47 0Bullous Keratopathy55 1.92 ± 0.46 1non-state1 1.02 ± 0.46 1			
Bullous Keratopathy55 1.92 ± 0.46 $1.$ m1.1. 1.02 ± 0.26 $1.$	$0.4/ \pm 0.30$	20/59	0.0004
	1.14 ± 0.67	20/276	<0.0001
$1.83 \pm 0.29 \qquad 1.83 \pm 0.29 \qquad 0.1$	0.87 ± 0.55	20/148	0.0004
Amiridia 7 2.10 ± 0.45 1	1.54 ± 0.48	20/693	0.08
Miscellaneous35 1.94 ± 0.50 $1.$	1.03 ± 0.81	20/215	0.0004
Unknown 6 2.06 ± 0.34 1.	1.00 ± 1.19	20/200	undefined ^e
Multiple Failed Graft50 1.93 ± 0.49 0	0.97 ± 0.69	20/187	<0.0001

 a Logarithm of the Minimum Angle of Resolution

Am J Ophthalmol. Author manuscript; available in PMC 2021 October 28.

b Standard Deviation

cpaired t-test

dHerpes Simplex Virus

 $\overset{e}{}_{\rm S}$ statistical analysis was not calculable due to missing data.

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Table 2:

Keratoprosthesis Type 1 implantation. Note that the mean logMAR acuity for each procedure only records eyes that had counting figures or better visual Final logarithm of the minimum angle of resolution (logMAR) visual acuity levels in eyes undergoing additional procedures at the time of Boston acuity.

			Performed	Not Performed	
Procedure	rate (%)	u	Final logMAR a Acuity ($\pm \mathrm{SD}^b$)	Final logMAR a Acuity ($\pm \mathrm{SD}^{b}$)	p-value ^c
Intracameral Steroid	50.0	143	1.00 ± 0.70	0.98 ± 0.71	0.817
Glaucoma Surgery	7.3	21	1.15 ± 0.75	0.97 ± 0.70	0.358
Pars Plana Vitrectomy	24.5	70	1.06 ± 0.74	0.97 ± 0.70	0.377
Cataract Extraction	19.2	55	0.83 ± 0.75	1.03 ± 0.70	0.022
IOL ^d Removal	11.2	32	1.05 ± 0.68	0.99 ± 0.71	0.515
Iridectomy	12.6	35	0.96 ± 0.62	1.00 ± 0.72	0.930
Iridoplasty	5.6	16	1.16 ± 0.84	0.98 ± 0.70	0.430
Iridocorneal Synechiolysis	5.2	15	0.97 ± 0.67	0.99 ± 0.71	0.890
Tarsorrhaphy	7.0	20	1.19 ± 0.85	0.98 ± 0.70	0.353
Punctal Occlusion	2.1	9	0.73 ± 0.44	1.00 ± 0.71	0.643
Miscellaneous	5.9	17	0.88 ± 0.74	0.99 ± 0.71	0.433

 a Logarithm of the Minimum Angle of Resolution

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bStandard Deviation

 $^{\mathcal{C}}$ Wilcoxon Rank-sum

d Intraocular Lens Author Manuscript

Table 3:

Boston Keratoprosthesis Type 1. Note that the mean logMAR acuity for each procedure only records eyes that had counting figures or better visual acuity. Ocular comorbidities and their relationship to final logarithm of the minimum angle of resolution (logMAR) visual acuity level after implantation of a

		C0)	morbidity Present	Not Present	
Procedure	rate (%)	u	Final logMAR a Acuity ($\pm \mathrm{SD}^b$)	Final logMAR a Acuity ($\pm \mathrm{SD}^{b}$)	p-value ^c
Glaucoma	54.2	156	1.04 ± 0.70	0.93 ± 0.71	0.110
Dry Eye	5.2	15	1.00 ± 0.79	0.99 ± 0.70	0.826
Retinal Detachment	5.2	15	0.93 ± 0.65	1.00 ± 0.71	0.947
Diabetes mellitus	5.2	15	1.01 ± 0.71	0.99 ± 0.71	0.808
Age-related Macular Degeneration	4.9	14	1.81 ± 0.52	0.94 ± 0.68	<0.0001
Aphakia	2.4	7	0.80 ± 0.40	1.00 ± 0.71	0.750
Diabetic Retinopathy	2.1	9	1.21 ± 0.71	0.99 ± 0.71	0.315
Amblyopia	1.0	3	1.33 ± 0.35	0.99 ± 0.71	0.270
Exposure Keratopathy	1.4	4	0.36 ± 0.28	1.00 ± 0.71	090.0

 a Logarithm of the Minimum Angle of Resolution

b Standard Deviation $^{\mathcal{C}}$ Wilcoxon Rank-sum