Outcomes of Boston keratoprosthesis type 1 reimplantation: multicentre study results

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ABSTRACT ●

Objective: To investigate the visual and anatomical outcomes of Boston keratoprosthesis (Kpro) type 1 reimplantation.

Design: Subgroup analysis of multicentre prospective cohort study.

Participants: Of 303 eyes that underwent Kpro implantation between January 2003 and July 2008 by 1 of 19 surgeons at 18 medical centres, 13 eyes of 13 patients who underwent reimplantation of Boston Kpro type 1 were compared with 13 eyes of 13 diagnosis-matched patients who underwent initial implantation.

Methods: Forms reporting preoperative, intraoperative, and postoperative parameters were prospectively collected and analyzed. Main outcome measures were Kpro retention and logMAR visual acuity.

Results: After a mean follow-up time of 17.1 ± 17.6 months, the retention of both initial and repeat Kpro implantation was 92.3% (12/13 in both groups), and 62% of initial implantation and 58% of repeat implantation eyes achieved visual acuity better than 20/200. Vision worse than 20/200 was often due to glaucoma or posterior segment pathology. Best-recorded logMAR visual acuity was significantly improved postoperatively in both groups ($p < 0.001$), and there was no statistically significant difference in final logMAR visual acuity between the 2 groups ($p = 0.89$). Sterile keratolysis (n = 4) and fungal infection (n = 5) were the most common causes of initial Kpro failure in the repeat Kpro group. The single failure in the repeat Kpro implantation group was due to fungal keratitis, and in the control group it was related to Kpro extrusion.

Conclusions: Repeat Kpro implantation is a viable option after failed initial Kpro, with visual and anatomical outcomes comparable to those of initial procedures.

Since its approval by the FDA in 1992, the Boston keratoprosthesis (Kpro) has emerged as a viable alternative to penetrating keratoplasty in patients with a history of failed grafts for conditions including chemical and thermal injury, congenital aniridia, Stevens–Johnson syndrome (SJS), ocular cicatricial pemphigoid (OCP), bullous keratopathy, and Fuchs dystrophy.

Outcomes of Boston Kpro implantation are generally favourable, with visual acuities improving significantly postoperatively to reach 20/200 or better in more than 40% of patients[1–5] and being sustained for an average of 47.8 months.[6] Retention rates are also high, previously reported at 94% after 1 year,[7] 89% after 2 years,[7] and 67% at 7 years.[2]

Despite these favourable outcomes, significant challenges in the management of Kpros remain. For instance, the monitoring and treatment of glaucoma is difficult and can lead to progressive loss of vision.[8] Despite close follow-up and careful monitoring, some patients may require explantation or replacement of the Kpro. Common causes of Kpro failure include infectious keratitis, endophthalmitis, sterile keratolysis, and extrusion.[7]

Eyes that fail initial Kpro implantation may either be rehabilitated with a tectonic keratoplasty or undergo repeat Kpro implantation. Although much research has focused on the outcomes of initial Kpro implantation, there exists little insight into outcomes of repeat Kpro implantation. One recent study reported that eyes with ocular surface disease, defined as SJS, OCP, atopic disease, severe keratoconjunctivitis sicca, or cicatrizing conjunctivitis from chemical or thermal injury, were more likely to require repeat Kpro implantation. In the study, eyes that achieved 20/200 vision after the first Kpro were statistically more likely to achieve greater than 20/200 vision after repeat Kpro implantation.[9]

In this multicentre study, we report a matched case–control comparison of the visual and anatomical outcomes of 13 eyes that underwent repeat Kpro implantation and 13 eyes that underwent their first Kpro implantation and report notable trends for causes of Kpro failure.

METHODS

The Boston Kpro type 1 is obtained from the Massachusetts Eye and Ear Infirmary. The technique for implanting the Boston Kpro has been previously described, and all surgeons reported using a similar technique.[1]

Data Collection

The Boston Keratoprosthesis Multicenter Study is a large prospective cohort study of patients undergoing

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Boston Kpro type I implantation since January 1, 2003. It is approved by the institutional review board at the Albany Medical Center. Because this study began 2 years before the public launch of the clinicaltrials.gov web site, it is not registered on the site. Data were collected using a mail-in case report form consisting of approximately 70 perioperative variables that was sent to all surgeons known to be performing multiple procedures at the time of study initiation. After each patient was assigned a unique study number in accordance with Health Insurance Portability and Accountability Act regulations, the data forms were sent to a data coordinating centre approved by the institutional review board. Follow-up data were reported by the participating surgeons at intervals of 1 month, 6 months, 12 months, and annually thereafter.

In patients with bilateral Kpro implantation, only the first eye was included because the eyes are not independent data points. However, in some patients, it was their second eye that required repeat Kpro; thus, for this report, the other eye was removed from the database.

Based on previously published prognostic categories,[10] the patients were categorized into the following pathologic groups: severe autoimmune disease (OCP and SJS), chemical injuries, herpes simplex virus keratitis, Fuchs endothelial dystrophy, keratoconus, infectious keratitis, neurotrophic ulcers, limbal stem cell deficiency, pseudophakic bullous keratopathy, trauma, aniridia, miscellaneous, failed penetrating keratoplasty, and unknown.

Cases were defined as those eyes that underwent repeat Kpro implantation. Eyes missing basic demographic data (i.e., patient age and sex) were not considered for control selection. Controls were matched by diagnosis and failure status and were randomly selected using a random number generator (https://www.random.org/; accessed September 16, 2016).

Analysis

A Microsoft Excel spreadsheet (Microsoft, Redmond, Wash.) was used to compile the data, and SAS version 9.3 (SAS Institute Inc, Cary, N.C.) was used for all data analyses. Because some surgeons provided data at follow-up time points (e.g., 6 months, 1 year) without a specific date, a follow-up date was imputed for these patients. Associations between categorical variables were examined using the χ^2 test. For comparisons of continuous variables between 2 groups, Wilcoxon rank-sum was used because of a non-normal distribution of data in the repeat Kpro group.

Visual acuity measurements were obtained using a standard Snellen chart viewed from a distance of 6 m and were converted to 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,[11] although a lower limit of 20/2000 was used. When the 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[12,13] has calculated that hand-motions acuity ranges between 2.28 and 3.60 logMAR units; the upper limit was used for this study. Pairwise comparisons of baseline and final visual acuity measurements in the same eye were compared using the Wilcoxon signed-rank test.

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 Kpros.[4,14] 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,[15] the time to achieve 20/200 vision was analyzed using Kaplan–Meier curves with 95% Hall–Wellner bands,[16] and the log-rank test was used for group comparisons. Time to achieve 20/200 visual acuity was defined as the time 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 before 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 1 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.

Results

Between January 2003 and July 2008, information on 321 Boston Kpro type I implants placed in 303 patients by 19 surgeons at 18 medical centres was collected. Eight eyes of 8 patients who underwent sequential bilateral Kpro implantation were excluded. There were 13 repeat Kpro eyes, and controls matched by diagnosis were randomly selected from 149 eyes with complete demographic data.

There was no difference in age between repeat Kpros and controls ($p = 0.562$; Table 1); the mean age of patients in this cohort was 64.7 ± 14.8 years and ranged from 38.5 to 89.0 years. There were more women and right eyes in the control group, but these differences were not statistically significant ($p = 0.562$ and $p = 0.420$, respectively). Preoperative visual acuity was better in repeat Kpro eyes (1.23 ± 0.61 logMAR units) than control eyes (2.02 ± 0.46 logMAR units) but, again, this difference was not statistically significant ($p = 0.127$). The average time from initial Kpro to repeat Kpro was 14.2 months (range 2–35 months). Detailed baseline clinical characteristics of both repeat Kpro and control groups are shown in Table 1.