

The New Zealand National Eye Bank: Survival and Visual Outcome 1 Year After Penetrating Keratoplasty

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Purpose: To identify potential donor, recipient, surgical, and postoperative factors that may influence survival and visual outcome of penetrating keratoplasty (PKP).

Methods: As part of a prospective longitudinal study, the electronic records of the New Zealand National Eye Bank were analyzed for the 10-year period from 1994–2003. Both univariate and multivariate analysis was performed.

Results: During the study period, the New Zealand National Eye Bank supplied 1820 corneas for PKP and 1629 (90%) had 1-year follow-up data. Overall, the 1-year survival rate was 87% (n = 1429). Donor factors including age, donor source, cause of death, death-to-preservation interval, endothelial cell density, donor lens status, and storage duration, were not significantly associated with decreased survival. The leading cause of PKP failure was irreversible rejection (7%, n = 114). Independent risk factors identified for decreased PKP survival were: 1 or more episodes of reversible rejection, active inflammation at PKP, preexisting corneal vascularization, intraoperative complications, small graft size (≤ 7.25 mm), large graft size (≥ 8.5 mm), preoperative glaucoma, and a preoperative diagnosis of regraft or trauma. A best-corrected Snellen visual acuity of 6/12 or better was achieved in 60% of eyes [mean: 6/15 (logarithm of the minimum angle of resolution 0.40)]. Keratoconus and Fuchs endothelial dystrophy were the diagnoses with best survival and visual outcome, whereas, bullous keratopathy, trauma or noninfective keratitis were associated with poorer visual outcome.

Conclusions: Several independent risk factors were identified that significantly influenced PKP first year survival outcome. This information is valuable to patients and surgeons with respect to determining prognosis and clinical decision making.

Key Words: penetrating, keratoplasty, survival, visual, outcome

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The New Zealand National Eye Bank (NZNEB), established in 1991, is the major supplier of donor tissue for keratoplasty in New Zealand. Over 200 keratoplasties are performed annually in New Zealand with over 95% of donor tissue provided by the NZNEB. The highest international standards (Eye Bank Association of Australia and New Zealand Standards, based on standards of both the Eye Bank Association of America and the European Eye Bank Association) are observed in all areas of the NZNEB operation, including the maintenance of a comprehensive database, supported by New Zealand ophthalmic surgeons, in which prospective data are collected on all aspects of corneal donation and transplantation.

In this study, the NZNEB database was analyzed with respect to survival and visual outcome 1 year postoperatively for all keratoplasties performed between 1994 and 2003. The purpose was to study potential donor, recipient, surgical, and postoperative factors that may affect short- to medium-term survival outcome after keratoplasty. A better knowledge and understanding of such risk factors will be invaluable to both patients and surgeons with regard to determining prognosis and clinical decision making.

METHODS

As a part of a longitudinal prospective study, the electronic records of the NZNEB were analyzed for the 10-year period from 1994–2003, with respect to donor, recipient, surgical, and postoperative factors influencing penetrating keratoplasty (PKP) survival 1 year postoperatively. Data are entered into the computerized NZNEB database in a prospective manner by the eye bank staff. Donor information is entered at the time of tissue procurement and includes demographic data, donor source and cause of death, death-to-preservation interval (DPI), endothelial assessment, and storage duration. Recipient and surgical information was collected from surgeons in the form of a questionnaire completed at the time of operation. Recipient information collected includes demographic data, preoperative diagnosis, ocular history, and associated ocular conditions. Surgical information collected includes graft size, additional operative procedures, suture type and technique, and any intraoperative complications. Follow-up data were collected from surgeons at 1 year postoperatively by way of a mailed questionnaire sent out at the appropriate time. Data collected include PKP survival (defined as a clear corneal transplant), visual outcome,

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suture adjustment or removal, episodes of reversible rejection, and postoperative complications. Missing data were routinely sought from surgeons by way of follow-up letters.

Statistical analysis was performed using SPSS software (version 12) in consultation with a medical statistician from the Epidemiology Department of the University of Auckland. Both univariate and multivariate analyses were performed. Statistical methods were the Fisher exact test and χ^2 testing to compare proportions between groups, Student *t* test was used to compare means between groups, and binary logistic regression modeling was used to identify variables independently associated with decreased PKP survival outcome. The level of statistical significance was $P < 0.05$, unless stated otherwise.

RESULTS

Overall PKP Survival

During the study period, 1820 PKPs were performed, of which 1629 (89.5%) had 1-year follow-up data available. There were 182 patients (10.0%) lost to follow-up and 9 patients (0.5%) who died during the follow-up period. Table 1 summarizes patient demographic data as categorized by the preoperative diagnosis at the time of PKP. The overall 1-year survival rate was 87.3% ($n = 1429$). Reasons for PKP failure are presented in Table 2.

Donor Factors Influencing PKP Survival Outcome

There was no significant difference in the survival rate between donor tissue procured from the Coroner's service (88.6%, 1187 of 1340), public hospitals (86.5%, 206 of 238), or multiorgan donors (92.9%, 73 of 78) ($P = 0.72$). No particular donor cause of death was associated with a reduced survival rate (range: 84.0%–90.6%, $P = 0.27$). DPI was analyzed by stratification into 5-hour intervals with no significant difference in survival rate between the intervals identified ($P = 0.47$).

An endothelial cell density (ECD) greater than or equal to 2500 cells per square millimeter is the threshold required for a cornea to be accepted for PKP according to the NZNEB protocol. Mean donor ECD was not significantly different between PKPs that survived (3020 cells per square millimeter, SD: 334 cells per square millimeter) and those that failed (3013 cells per square millimeter, SD: 330 cells per square

millimeter) ($P = 0.77$). Further analysis of donor ECD by categorization into 300 cells per square millimeter intervals also failed to identify an association between ECD and survival rate (range: 87.1%–90.7%, $P = 0.94$). The effect of donor lens status on survival rate was analyzed highlighting no significant difference in survival rate among phakic (88.6%, 1374 of 1551), pseudophakic (81.8%, 31 of 38), or aphakic (91.6%, 11 of 12) donors ($P = 0.80$).

All donor tissue was stored using warm organ culture storage at 34°C, with the maximum storage duration 25 days as per NZNEB protocol. No difference in the mean storage duration was identified between PKPs that survived (12 days, SD: 4.3 days) and those that failed (11.8 days, SD: 4.1 days) ($P = 0.54$). Storage duration was further analyzed by stratification into 5-day intervals, with no significant difference in the survival rate identified between intervals ($P = 0.39$).

Donor age was not significantly associated with survival rate in this study. Donor age was analyzed by stratification into 10-year intervals. The highest survival rate was 93.1% for donor age of 21–30 years and the lowest was 85.7% for donor age of 81–85 years (upper age limit acceptable for keratoplasty according to NZNEB protocol). The difference in survival rate between donor age of 81–85 years and donor age less than 81 years (88.0%) did not reach statistical significance ($P = 0.20$).

Recipient Factors Influencing PKP Survival Outcome

Survival rate was affected by preoperative diagnosis with the results presented in Table 3. For regrant procedures, the survival rate decreased with each successive graft; 88.9% (1168 of 1313) for first grafts, 85.7% (234 of 273) for second grafts, 62.1% (18 of 29) for third grafts, and 64.3% (9 of 14) for fourth grafts. No significant difference in the survival rate among phakic (88.0%, 1180 of 1370), aphakic (86.4%, 13 of 15), and pseudophakic (86.1%, 41 of 49) recipients was identified ($P = 0.64$).

Preexisting vascularization of the recipient cornea was significantly associated with decreased survival rate ($P < 0.001$). Recipients with preexisting corneal vascularization had a survival rate of 78.1% (373 of 478), compared with 92.9% (1056 of 1137) in those with no vascularization. One quadrant of preexisting vascularization was associated with a survival rate of 81.4% (118 of 145); 2 quadrants, 80.5% (99 of 123); 3 quadrants, 75.0% (54 of 72); and 4 quadrants, 67.6% (75 of 111).

TABLE 1. A Summary of Patient Demographic Data Based on the Preoperative Diagnosis at the Time of PKP

Preoperative Diagnosis	Total No (%)	Mean Age, Yrs (SD)	Age Range (Yrs)	% Female
Keratoconus	735 (45.1)	31.9 (12.6)	6–86	40.3
Bullous keratopathy	276 (16.9)	72.3 (12.9)	11–95	56.0
Viral keratitis	120 (7.4)	54.5 (19.9)	7–96	46.2
Regrant	115 (7.1)	52.3 (17.6)	9–94	42.7
Fuchs ECD	81 (5.0)	70.9 (8.2)	45–86	70.1
Trauma	78 (4.8)	42.9 (19.4)	5–94	18.4
Stromal dystrophy	65 (4.0)	57.3 (20.9)	3–93	34.1
Infection (nonherpetic)	42 (2.6)	55.3 (19.7)	22–92	60.7
Noninfective keratitis	25 (1.5)	66.6 (17.5)	27–89	61.0
Not specified	92 (5.6)	54.7 (20.3)	11–88	52.3

TABLE 2. Reported Causes for PKP Failure at 1 Year After Surgery

Cause of PKP Failure	Total No	% of all PKPs
Irreversible rejection	114	7.0
Presumed primary tissue failure	17	1.0
Vascularization	14	0.9
Trauma	11	0.7
Glaucoma	9	0.6
Corneal melt	5	0.3
Hypotony	3	0.2
Other	17	1.0
Unknown	10	0.6

Active anterior segment inflammation at the time of PKP was associated with a significantly lower survival rate ($P < 0.001$). Recipients with active inflammation had a survival rate of 68.6% (131 of 191) compared with 91.2% (1271 of 1394) in cases with no inflammation. Recipients with preoperative glaucoma also had a lower survival rate (76.8%, 149 of 194) compared with those in whom elevated intraocular pressure had never been recorded (90.6%, 1208 of 1333) ($P < 0.001$).

Recipient sex and age were not significantly associated with a decreased survival rate in this study. Analysis of each preoperative diagnosis separately failed to identify any significant association between recipient age and survival rate.

Surgical Factors Influencing PKP Survival Outcome

There was a significant association identified between graft diameter size and survival rate. The survival rate was significantly decreased for graft sizes equal to or less than 7.25 mm ($P = 0.01$) and for graft sizes greater than or equal to 8.50 mm ($P < 0.01$), when compared with the “medium” graft size range (7.50 to 8.25 mm).

The performance of an additional operative procedure at the time of PKP was associated with a significant decrease in survival rate ($P < 0.01$). The survival rate reduced from 90.2% (1114 of 1235), if “PKP only” was performed, to 82.5% (311 of 377), if there were 1 or more additional procedures. Anterior vitrectomy ($P < 0.01$) resulted in a significant decrease in the survival rate, whereas, the observed decrease in the survival rate

TABLE 3. 1-Year Survival Rates Based on Preoperative Diagnosis

Preoperative Diagnosis	One-year Survival Rate
Fuchs ECD	95.1% (77 of 81)
Keratoconus	94.6% (694 of 735)
Stromal dystrophy	87.7% (57 of 65)
Bullous keratopathy	85.1% (235 of 276)
Viral keratitis	85.0% (102 of 120)
Unspecified	81.6% (74 of 92)
Noninfective keratitis	80.0% (20 of 25)
Trauma	76.9% (60 of 78)
Regraft	70.4% (81 of 115)
Infection (nonherpetic)	69.0% (29 of 42)

associated with extracapsular cataract extraction (ECCE) + posterior chamber intra ocular lens (PCIOL) ($P = 0.07$), exchange of intraocular lens ($P = 0.08$), and removal of intraocular lens ($P = 0.2$) failed to reach statistical significance.

Postoperative Factors Influencing PKP Survival Outcome

Episodes of reversible rejection significantly decreased the survival rate ($P < 0.001$). The survival rate was 93.6% (1163 of 1243) for no episodes, 68.8% (172 of 250) for 1 episode, 67.3% (33 of 49) for 2 episodes, and 61.4% (27 of 44) for 3 or more episodes. The most common complications reported and the corresponding 1-year survival rates are presented in Table 4.

Multivariate Analysis of PKP Survival Outcome

Factors identified as significantly associated with a decreased PKP survival rate in univariate analysis were further analyzed by multifactorial modeling using binary logistic regression. The results of this analysis are presented in Table 5.

Visual Outcome

Keratoplasty was performed to improve the visual function in 87.5% ($n = 1430$) of cases, for structural reasons in 6.8% ($n = 112$), for pain in 4.6% ($n = 76$), and for a combination of reasons in 1.1% ($n = 17$). Visual outcome [in terms of best-corrected Snellen visual acuity (BCSVA) at 1 year postoperatively] for all surviving PKPs is presented in Figure 1. The mean BCSVA for each preoperative diagnosis is presented in Table 6.

DISCUSSION

The overall 1-year survival rate identified in this study (87%) was comparable to that of the other published reports, with 1-year survival rates in the literature typically ranging from 80% to 91%.¹⁻⁸ Irreversible rejection followed by endothelial failure and vascularization were identified as the most common reasons for PKP failure in this study. Other published reports also cite glaucoma and infection as common reasons for PKP failure.^{2,6,9,10} Overall visual outcome was also similar to that of other published reports, with 60% of recipients achieving a 1-year postoperative

TABLE 4. Most Commonly Reported Postoperative Complications (Statistical Significance Compares the Specified Complication to PKPs Without Complications)

Complication	No. Keratoplasties	No. Survived (%)	<i>P</i>
Uveitis	31	25 (80.6)	0.08
Suture related	27	24 (88.8)	0.24
Glaucoma	26	19 (73.1)	0.02
Persistent epithelial defect	18	14 (77.8)	0.08
Infection	13	11 (84.6)	0.27
Wound leak	13	12 (92.3)	0.70
Trauma	6	5 (83.3)	0.60
Iridocorneal adhesion	4	4 (100)	—
Shallow anterior chamber	3	3 (100)	—
HypHEMA	3	1 (33.3)	—
Retinal detachment	3	1 (33.3)	—

TABLE 5. Multivariate Analysis of Risk Factors Influencing PKP Survival Outcome

Variable	Odds Ratio	Significance	CI (95%)
Donor age	1.01	0.79	0.99–1.02
Recipient age	0.99	0.52	0.98–1.01
Indication			
Bullous keratopathy	1.54	0.25	0.74–3.18
Fuchs endothelial dystrophy	1.13	0.84	0.34–3.81
Infection (nonherpetic)	1.68	0.28	0.63–4.51
Keratoconus	0.85	0.67	0.40–1.80
Noninfective keratitis	2.79	0.08	0.88–8.90
Stromal dystrophy	1.29	0.62	0.48–3.45
Regraft	2.90	0.004	1.39–6.00
Trauma	2.85	0.015	1.22–6.69
Viral keratitis	1.35	0.78	0.65–3.68
Active inflammation	2.41	<0.001	1.55–3.74
Corneal vascularization	1.75	0.005	1.19–2.58
Preoperative glaucoma	1.65	0.04	1.10–2.30
Small graft size (≤7.25 mm)	2.41	0.01	1.50–3.89
Large graft size (≥8.5 mm)	1.88	0.03	1.18–2.60
Anterior vitrectomy	1.74	0.15	0.82–3.72
Operative complications	1.87	0.04	1.03–3.40
≥1 reversible rejection episodes	5.43	<0.001	3.80–7.76
Postoperative glaucoma	2.22	0.14	0.77–6.46

CI, confidence interval.

TABLE 6. Mean Postoperative Best-Corrected Visual Acuity (BCVA) for Each Indication

Preoperative Diagnosis	Mean BCVA LogMAR (SD)	Equivalent Snellen VA
Keratoconus	0.25 (0.20)	6/10
Fuchs endothelial dystrophy	0.40 (0.46)	6/15
Viral keratitis	0.46 (0.45)	6/18
Stromal dystrophy	0.47 (0.48)	6/18
Regraft	0.50 (0.55)	6/20
Infection (nonherpetic)	0.60 (0.59)	6/24
Trauma	0.72 (0.70)	6/30
Bullous keratopathy	0.80 (0.61)	6/40
Noninfective keratitis	0.99 (0.73)	6/60
Overall	0.40 (0.49)	6/15

LogMAR, logarithm of the minimum angle of resolution; VA, visual acuity.

BCSVA of 6/12 or better compared with the range of 48% to 70% reported in the literature.^{1,2,6,8,11}

Donor factors (donor age, donor source, donor cause of death, DPI, ECD, and storage duration) were not significantly associated with decreased keratoplasty survival in this study. The results of this large New Zealand–based study tend to confirm trends that have previously been reported with respect to donor-related risk factors.^{7,12–17} Donor lens status did not significantly influence survival outcome, suggesting that a history of cataract surgery alone should not be a contraindication for corneal donation, as long as endothelial cell count is acceptable and other inclusion/exclusion criteria are met.

The results of this study were consistent with those of the earlier reports, with the highest survival rates identified in

keratoconus followed by Fuchs endothelial dystrophy and the lowest associated with trauma and regraft.^{1–5,8–10,18–21} For regraft, the survival rate further decreased according to the number of previous grafts, also in concordance with the literature.^{2–5,9,20} Reasons cited for poor survival outcome in regraft and trauma included the presence of high-risk preoperative conditions, the need for additional surgical procedures, and the increased incidence of postoperative complications.^{20,22,23}

Keratoconus and Fuchs endothelial dystrophy were identified as the preoperative diagnoses associated with the most successful visual outcome. In contrast, noninfective keratitis, bullous keratopathy, and trauma were associated with poor visual outcome. Other published studies reported similar results with keratoconus having the best visual outcome overall, followed by Fuchs endothelial dystrophy, and viral keratitis.^{1–4,11,24,25} In these studies, bullous keratopathy, trauma, and regraft were recognized as having the least successful visual outcome.

As been previously reported, preexisting vascularization of the recipient cornea was identified as a significant independent risk factor for decreased keratoplasty survival.^{1–5} Furthermore, the decrease in survival rate was proportional to the number of quadrants of preexisting vascularization, with 4 quadrants of vascularization resulting in a significantly lower survival rate than 1 or 2 quadrants. The presence of active anterior segment inflammation at the time of PKP was identified as one of the most significant independent risk factors for decreased keratoplasty survival in this study and other reports.^{1,2} This study also confirmed that a history of preoperative glaucoma is a significant independent risk factor for decreased PKP survival.^{1,2,5,10,26}

After accounting for the differences in preoperative diagnosis between age groups, this study identified no significant decrease in survival rate with advancing recipient age. Again, this is in concordance with other studies that report no association or only a marginal association between advancing recipient age and survival rate.^{1,2,10,14,18} Although there are conflicting reports in the literature regarding the influence of recipient sex on survival rate, with some studies reporting male sex to be a significant risk factor for decreased PKP survival, this study identified no relationship between recipient sex and survival rate.^{2,10,13,18}

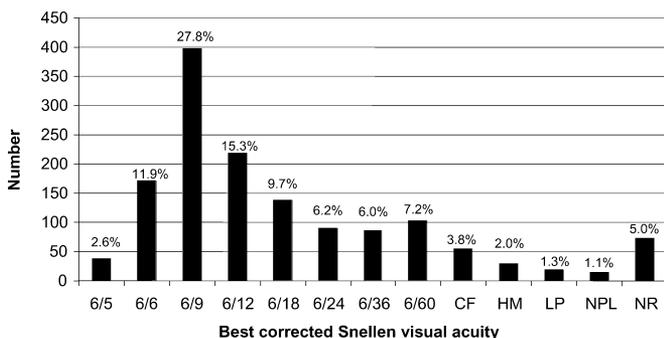


FIGURE 1. Distribution of BCSVA 1-year postoperatively. CF, counting fingers; HM, hand movements; LP, light perception; NPL, no perception of light; NR, not recorded.

Both small and large graft diameter sizes were identified as independent risk factors for decreased PKP survival in multivariate analysis. Several large studies have identified small graft size to be significantly associated with decreased PKP survival.^{1,2,10,13} Price et al¹⁰ cited higher rates of endothelial failure because of a reduced number of transplanted intact endothelial cells as a possible reason for this association. Increased risk of rejection failure with smaller graft sizes has also been reported.^{2,10,13} Several studies, including the preceding, have also identified large graft size to be significantly associated with decreased keratoplasty survival, with a higher rate of endothelial rejection cited as the reason for this association.^{1,2,10,12,13,27}

In the current study, the performance of an anterior vitrectomy at the time of PKP was associated with a significant decrease in the survival rate at the univariate level. However, in multivariate analysis, the relationship was no longer apparent. A possible explanation is the association identified between the performance of an anterior vitrectomy and the preoperative diagnoses with lower survival rates (trauma, regrant, and bullous keratopathy). In the literature, a significant association between vitreous surgery and decreased PKP survival has been frequently reported, both at the univariate and multivariate levels.^{1,2,12,18,20} In concordance with other published reports, the performance of additional lens surgery was not significantly associated with decreased PKP survival in this study.^{1,2,8,18,28,29}

This study confirmed the association previously recognized between postoperative episodes of reversible rejection and decreased PKP survival.^{2,18} Indeed, only 1 episode of reversible rejection was required to significantly decrease the survival rate. The survival rate further decreased with increasing episodes of reversible rejection. In multivariate analysis, the occurrence of 1 or more episodes of reversible rejection was recognized as the most significant factor predictive of poor keratoplasty survival.

In conclusion, the prospective NZNEB database has enabled detailed statistical analysis of this large series of PKPs performed in New Zealand over a 10-year period. Several independent risk factors were identified that significantly influenced PKP survival outcome. This information should be useful to patients and surgeons with respect to determining prognosis and clinical decision making in relation to PKP.

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