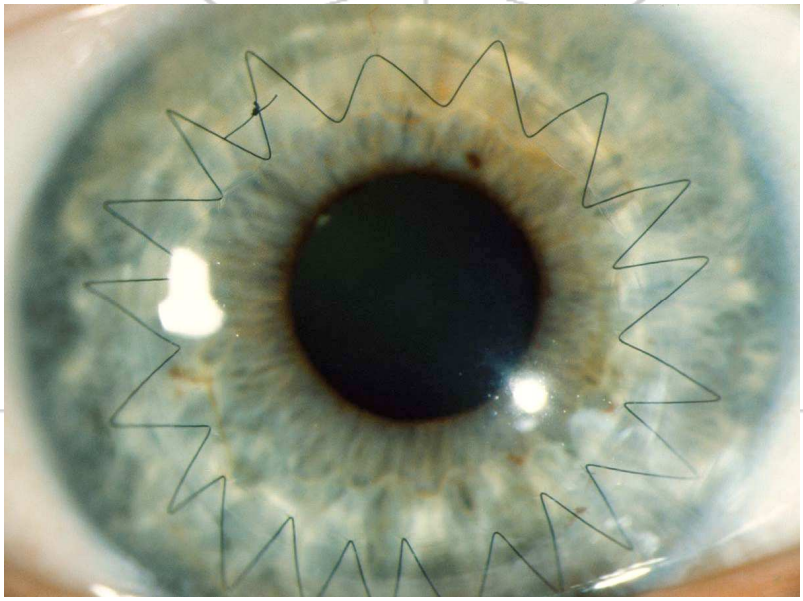
THE AUSTRALIAN CORNEAL GRAFT REGISTRY



2012 REPORT

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2012 REPORT

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& Medical Superintendents of various hospitals.

(n=713)

HOW TO READ OUR KAPLAN-MEIER GRAFT SURVIVAL PLOTS

1. The vertical axis shows the probability of graft survival. "Perfect" survival (no failures) equates to a probability of 1.0. It may help to think of this as 100% survival.

2. The horizontal axis shows time elapsed since the event being considered - in this context, the date of graft.

3. The numbers of recipients "at risk" (ie, being followed) at given times after graft are shown below the curves. At time zero, all patients in the given cohort are at risk. At the furthermost point on the right hand side of any curve, one patient in the cohort (the one who has been followed for the longest time) is at risk.

   We suggest that you interpret the curves with this in mind. A sudden dramatic "dip" in survival at the far right of a given curve may merely mean, for example, that one of only two grafts that have been followed for this length of time has failed.

   When the survival curve drops to zero, the probability of graft survival beyond that time is zero. This means that all grafts that have reached this time elapsed from graft have failed. It does not mean that all grafts in this stratum have failed.

4. The p values shown have been calculated by log-rank analysis and reflect a comparison of the behaviour of the curves as a whole (taking all available data into consideration), rather than at any one time-point.

INTRODUCTION

The Australian Corneal Graft Registry (ACGR) opened in May 1985 and thus has now been in operation for over 26 years. However, the census dates for this report was 01/06/2010 for penetrating grafts and 12/10/2011 for lamellar grafts. Over the years, we have collected data on more than 23,000 corneal grafts. The majority of corneal grafts registered have been penetrating, but increasing numbers of lamellar grafts have also been registered over recent years, as patterns of surgical practice change.

At registration, we seek information on the recipient, the donor, the eye bank practices and the operative procedure. Follow-up then occurs at approximately yearly intervals for an indefinite period, and ceases upon loss of the graft, or the death or loss-to-follow-up of the patient. At each round of follow-up, we request information on the graft and visual outcome, and upon relevant post-operative events and treatments.

The data are entered into an Access database and checked for consistency. Descriptive, univariate and multivariate analyses are subsequently performed using SPSS and Stata software, and the report is eventually collated.

We thank all our many contributors for their tireless efforts on our behalf. We hope you enjoy reading this report and that it may be useful in your clinical practice.

1. OVERVIEW AND CONTRIBUTOR INFORMATION

1.1 CURRENT DATABASE

1.1.1 Synopsis of the current database

A synopsis of the current state of the database is shown in Table 1.1.

Table 1.1 Synopsis of the current database (census date for penetrating and limbal grafts 01/06/2010 and 12/10/2011 for lamellar grafts)

Graft status	Whole database		Penetrating		Lamellar		Limbal	
	No.	%	No.	%	No.	%	No.	%
Number registered	**23048**	**100%**	**19952**	**100%**	**2983**	**100%**	**113**	**100%**
Number followed	**18139**	**79%**	**16291**	**82%**	**1751**	**59%**	**97**	**86%**
Followed for <1 year	4338	24%	3597	22%	701	40%	40	41%
Followed ≥1 & <6 years	10453	58%	9446	58%	959	55%	48	49%
Followed ≥6 & <12 years	2469	14%	2388	15%	74	4%	7	7%
Followed ≥12 & <18 years	740	4%	724	4%	14	<1%	2	2%
Followed ≥18 years	138	<1%	136	<1%	2	<1%	0	0%
Number lost with at least one follow-up	**5414**	**23%**	**4894**	**25%**	**494**	**17%**	**26**	**23%**
Number lost prior to follow-up*	**2114**	**9%**	**1796**	**9%**	**312**	**10%**	**10**	**9%**
Total number lost	**7528**	**33%**	**6690**	**34%**	**806**	**27%**	**36**	**32%**
Number with no follow-up information provided	**2795**	**12%**	**1865**	**9%**	**924**	**31%**	**6**	**5%**
Known recipient deaths	**5168**	**22%**	**4845**	**24%**	**297**	**10%**	**26**	**23%**
Graft has failed	**4222**	**18%**	**3794**	**19%**	**383**	**13%**	**45**	**40%**
Graft surviving when last seen (registration or follow-up)	**18826**	**82%**	**16158**	**81%**	**2600**	**87%**	**68**	**60%**
Grafts currently being followed (not failed, lost or deceased)**	**7455**	**32%**	**5873**	**29%**	**1567**	**52%**	**15**	**13%**

*Though follow-up forms have generally been received from surgeons for these grafts, the only additional information provided is that they have been lost to follow-up (i.e. failed to show for their first follow-up appointment). They are therefore counted as "not followed".

Number of grafted eyes – some recipients have had more than one graft.

**The categories of failed and deceased are not mutually exclusive.

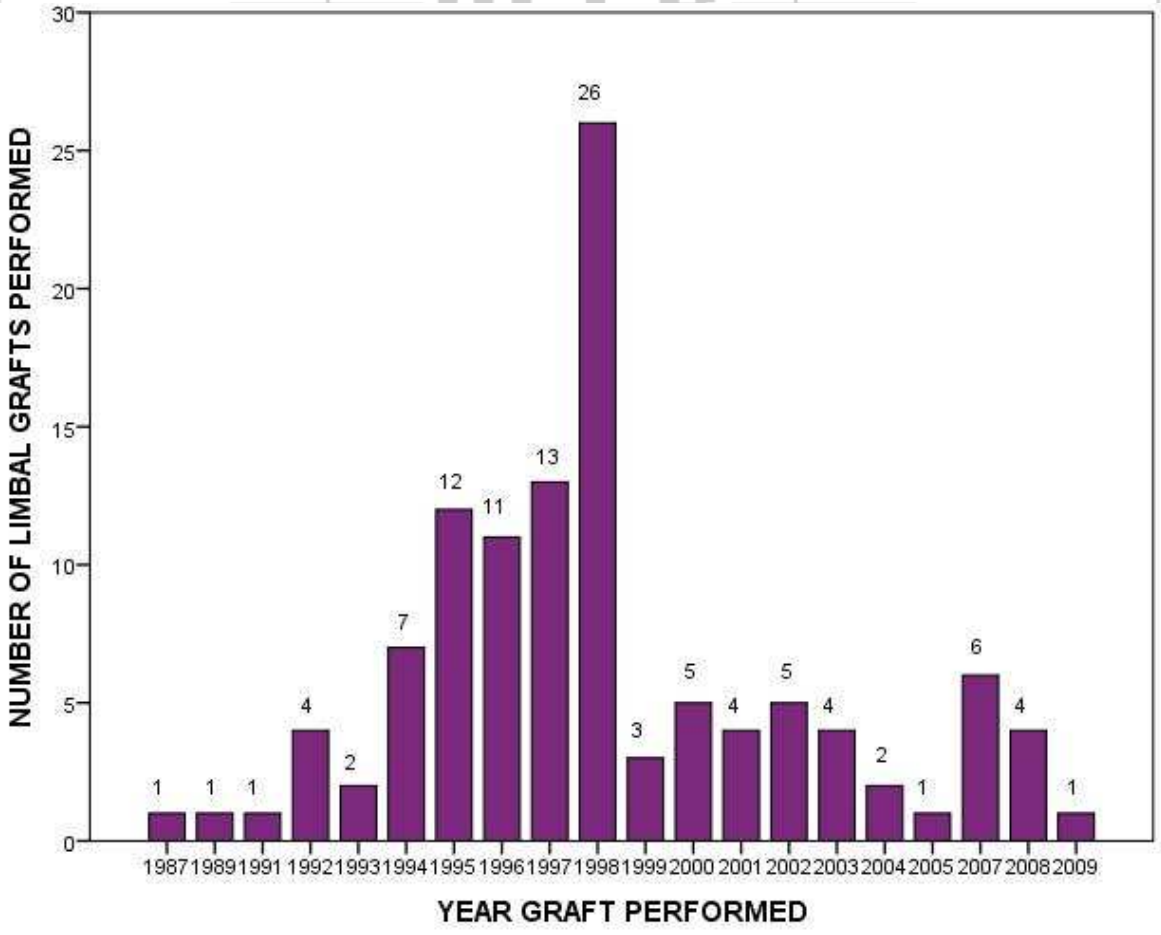
Penetrating grafts	**86.5% of total database**
Lamellar grafts	**13.0% of total database**
Limbal grafts	**0.5% of total database**

The main indication for graft in recipients who were lost to follow-up was keratoconus (50%) with a median age of 38 years. The main indication for recipients who have died since graft is bullous keratopathy (45.6%). This was also the largest group in those patients who died with a surviving graft (46.7%). The median age of these recipients was 77 years.

1.1.2 Limbal Grafts

Figure 1.1 - Number of limbal grafts performed per year

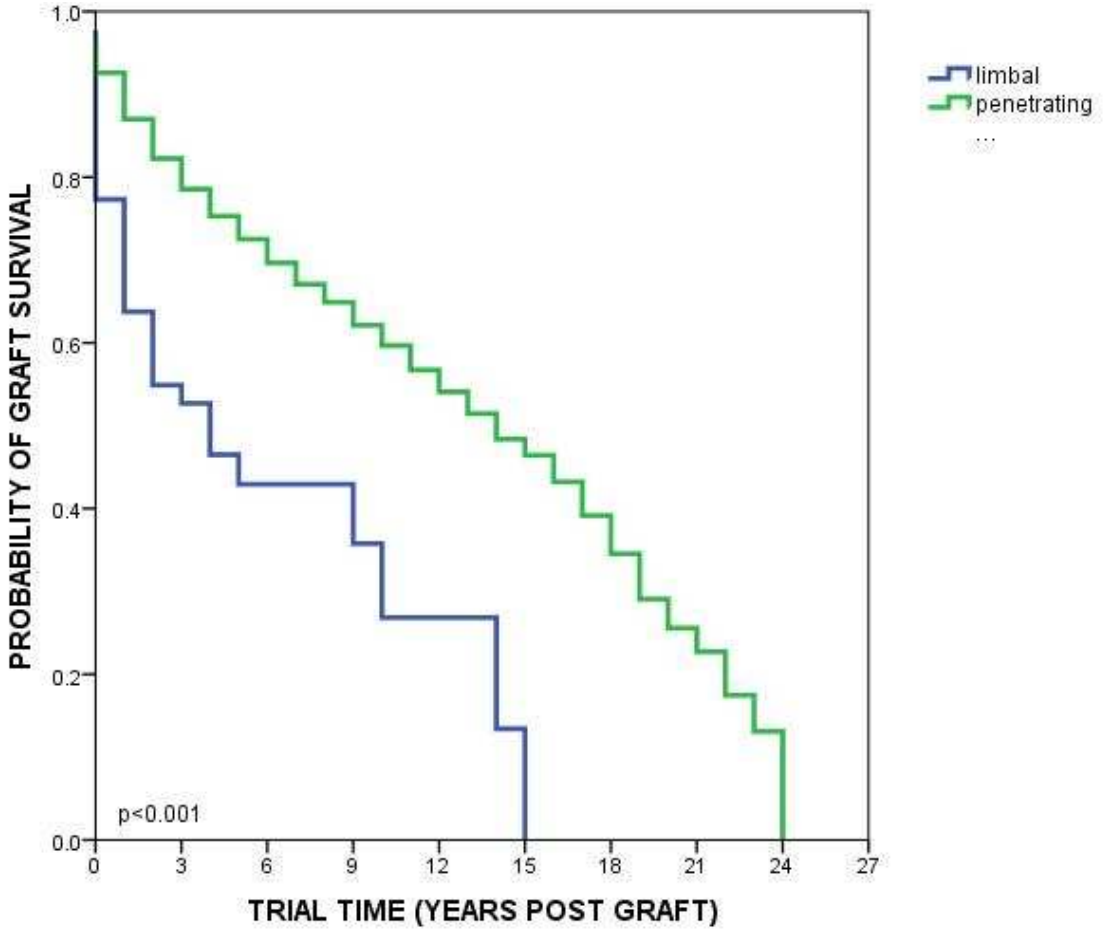
The number of limbal grafts being performed has dwindled since 1998 with only 12 grafts being performed since 2004.



1.1.3 Survival of penetrating, lamellar and limbal grafts

Kaplan-Meier plots of the survival of penetrating and limbal corneal grafts are presented in Figure 1.2 (Log Rank Statistic=50.799; df=1; p<0.001). The census date for this analysis is 1/6/2010.

Figure 1.2 Survival of penetrating and limbal stem cell grafts



Number at Risk

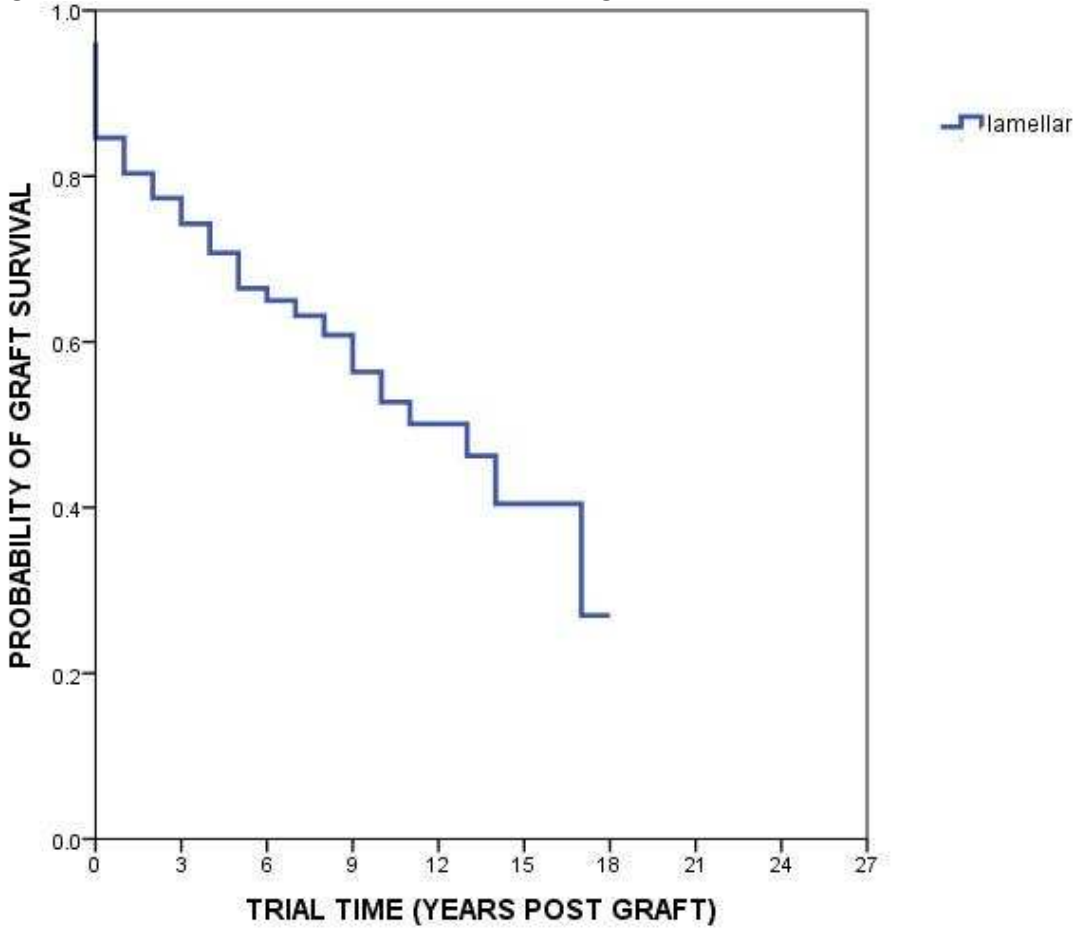
Identity	Initially	3 years	6 years	9 years	12 years	15 years	18 years	21 years	24 years
Penetrating	16291	6660	3252	15857	860	400	136	36	0
Limbal	97	25	11	6	2	0	n/a	n/a	n/a

Type of Graft	No. initially at risk	Probability of Graft Survival (at years post-graft)				
		1	5	10	15	20
Penetrating	16291	.87	.73	.60	.46	.26
Limbal	97	.64	.43	.27	.00	n/a

n/a = not applicable

Since the census date used for analysis of penetrating and limbal grafts, further follow-up data have been recorded on newer lamellar procedures. For this reason all analyses for lamellar grafts in this report were calculated as of the census date 12/10/2011. Further analyses of lamellar grafts can be found in Chapter 8.

Figure 1.3 Survival of lamellar corneal grafts



Number at Risk

Identity	Initially	3 years	6 years	9 years	12 years	15 years	18 years	21 years	24 years
Lamellar	1751	274	90	41	16	5	2	n/a	n/a

Type of Graft	No. initially at risk	Probability of Graft Survival (at years post-graft)				
		1	5	10	15	20
Lamellar	1751	.80	.67	.53	.41	n/a

OVERALL CORNEAL GRAFT SURVIVAL
TYPE OF GRAFT

Penetrating corneal graft survival:	**87% at 1 year**
Mean Survival 12.94 years	**73% at 5 years**
(SE=0.17; 95% CI: 12.61, 13.26)	**60% at 10 years**
Median Survival 14 years	**46% at 15 years**
	26% at 20 years
Lamellar corneal graft survival:	**80% at 1 year**
Mean Survival 10.47 years	**67% at 5 years**
(SE=0.51; 95% CI: 9.47, 11.47)	**53% at 10 years**
Median Survival 13 years	**41% at 15 years**
Limbal corneal graft survival:	**64% at 1 year**
Mean Survival 6.23 years	**43% at 5 years**
(SE=0.88, 95% CI: 4.51, 7.96)	**27% at 10 years**
Median Survival 4 years	**0% at 15 years**

KEY:

n/a	=	not applicable
SE	=	standard error
CI	=	confidence interval
df	=	degrees of freedom
p	=	probability

1.2 GRAFTS REGISTERED BY STATE, TERRITORY AND INDIVIDUAL

1.2.1 Grafts entered by Australian State and territory

Table 1.2 Grafts entered and followed from each Australian State

	PENETRATING			LAMELLAR			LIMBAL			TOTAL		
State	Entered	Followed		Entered	Followed		Entered	Followed		Entered	Followed	
	No.	No.	%	No.	No.	%	No.	No.	%	No.	No.	%
1	7355	5806	79%	1361	773	57%	35	27	77%	8751	6605	75%
2	2096	1956	93%	183	130	71%	44	41	93%	2323	2127	92%
3	4436	3692	83%	368	216	59%	15	13	87%	4819	3921	81%
4	3257	2738	84%	719	402	56%	4	2	50%	3980	3142	79%
5	2347	1682	72%	267	166	62%	12	11	92%	2626	1859	71%
6	461	417	90%	85	64	75%	3	3	100%	549	484	88%
TOTAL	**19952**	**16291**	**82%**	**2983**	**1751**	**59%**	**113**	**97**	**86%**	**23048**	**18138**	**79%**

1.2.2 Contributors in each State

Table 1.3 Percentage of penetrating grafts performed by surgeons with ≥ 50 grafts

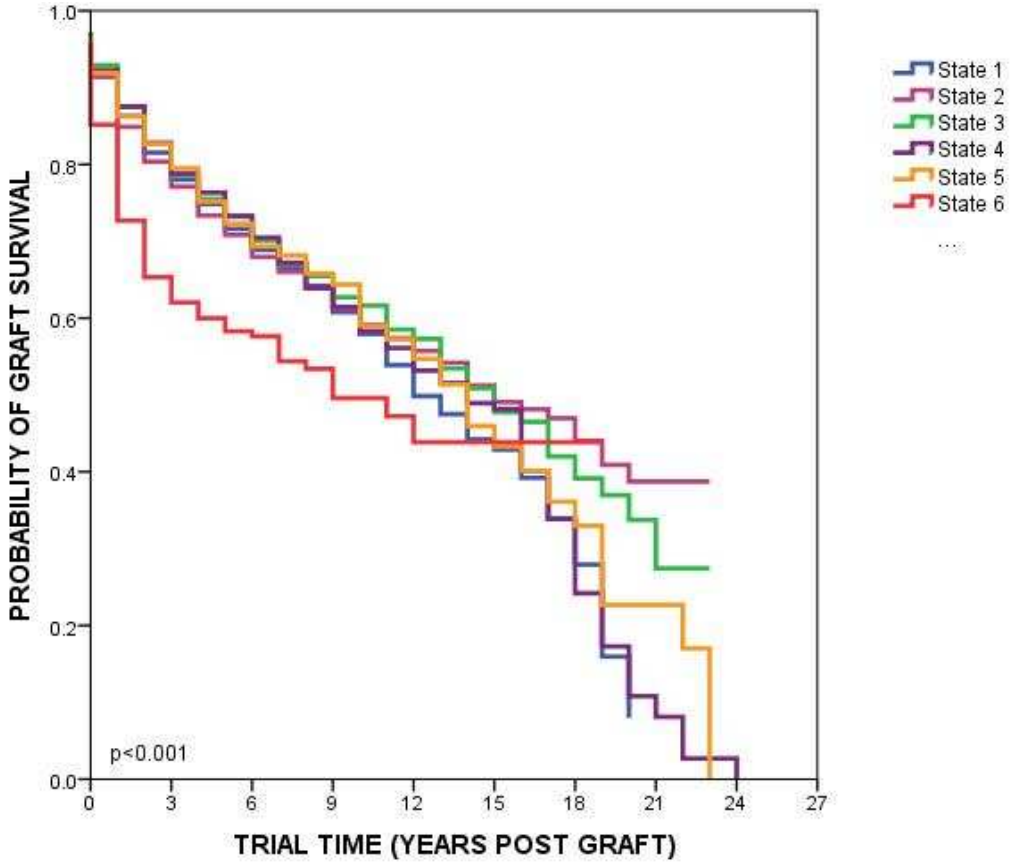
	Total transplant surgeons		Surgeons with total ≥ 50 grafts		
State	No.	Grafts performed	No.	Grafts performed	%
1	122	7355	26	5983	81%
2	44	2096	6	1733	83%
3	115	4436	16	3424	77%
4	34	3257	5	3074	94%
5	60	2347	8	1770	75%
6	9	461	1	337	73%
TOTAL	384	19952	62	16321	82%

It can be seen that 62 ophthalmologists, 16% of transplant surgeons or 9% of all contributors, performed 82% of all penetrating grafts recorded.

All Kaplan-Meier plots and associated tables in the remainder of this chapter have been calculated using penetrating grafts only.

Figure 1.4 compares the graft survival for each state for penetrating grafts only (Log Rank Statistic=37.444; df=5; p<0.001). Individual states have been de-identified.

Figure 1.4 Penetrating graft survival from each Australian State



Number At Risk

Identity	Initially	3 years	6 years	9 years	12 years	15 years	18 years	21 years	24 years
State 1	5806	2359	1101	503	249	99	16	n/a	n/a
State 2	1956	889	472	240	135	69	32	11	n/a
State 3	3692	1506	806	421	239	114	44	16	n/a
State 4	2738	987	433	205	112	61	20	4	1
State 5	1682	703	354	178	111	51	22	5	0
State 6	417	149	82	38	13	6	2	n/a	n/a

Identity	Graft survival (at years post-graft)				
	1	5	10	15	20
State 1	.87	.72	.59	.44	.08
State 2	.85	.71	.59	.50	.40
State 3	.88	.73	.62	.48	.34
State 4	.89	.74	.59	.49	.09
State 5	.87	.73	.60	.44	.23
State 6	.75	.61	.52	.46	n/a

n/a = not applicable

PENETRATING CORNEAL GRAFT SURVIVAL
BY STATE

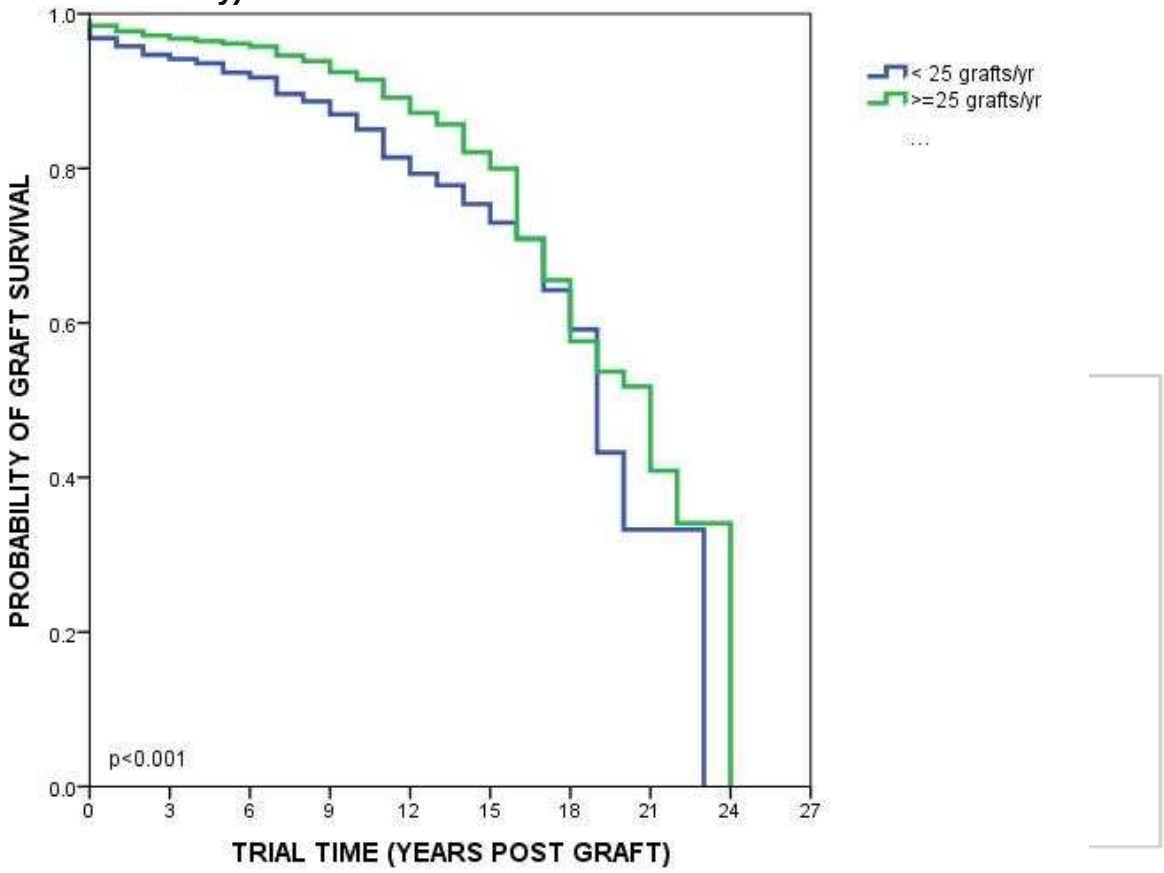
State 1:	**87% at 1 year**
Mean Survival 11.72 years	**72% at 5 years**
(SE= 0.20, 95% CI: 11.32, 12.12)	**59% at 10 years**
Median Survival 13 years	**44% at 15 years**
	8% at 20 years
State 2:	**85% at 1 year**
Mean Survival 13.67 years	**71% at 5 years**
(SE = 0.37, 95% CI: 12.95, 14.402)	**59% at 10 years**
Median Survival 16 years	**50% at 15 years**
	40% at 20 years
State 3:	**88% at 1 year**
Mean Survival 13.40 years	**73% at 5 years**
(SE= 0.29, 95% CI: 12.83, 13.97)	**62% at 10 years**
Median Survival 15 years	**48% at 15 years**
	34% at 20 years
State 4:	**89% at 1 year**
Mean Survival 12.18 years	**74% at 5 years**
(SE = 0.33, 95% CI: 11.55, 12.82)	**59% at 10 years**
Median Survival 14 years	**49% at 15 years**
	9% at 20 years
State 5:	**87% at 1 year**
Mean Survival 12.77 years	**73% at 5 years**
(SE = 0.41, 95% CI: 11.98, 13.579)	**60% at 10 years**
Median Survival 14 years	**44% at 15 years**
	23% at 20 years
State 6:	**75% at 1 year**
Mean Survival 10.64 years	**61% at 5 years**
(SE =0.617, 95% CI: 9.44, 11.84)	**52% at 10 years**
Median Survival 11 years	**46% at 15 years**

KEY: n/a = not applicable
SE = standard error
CI = confidence interval
df = degrees of freedom
p = probability

1.2.3 Outcome: influence of surgeon workload per year

Figure 1.5 shows the survival of all penetrating grafts for keratoconus performed by surgeons with a workload of 25 or more penetrating grafts per year on average, compared with those whose workload was less than 25 grafts per year (Log Rank Statistic=21.56; df=1; p<0.001).

Figure 1.5 Number of grafts performed/year (penetrating grafts for keratoconus only)



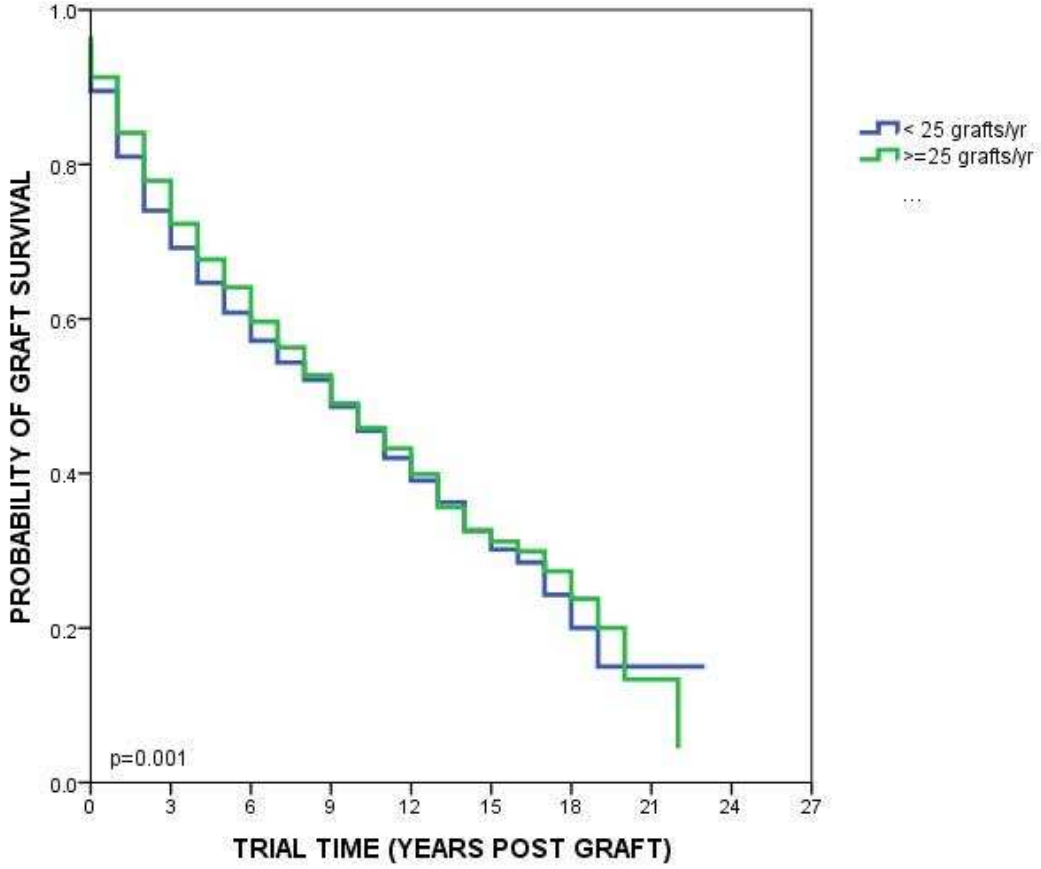
Number At Risk

Identity	Initially	3 years	6 years	9 years	12 years	15 years	18 years	21 years	24 years
≥ 25 grafts/year	2870	1399	773	457	272	154	58	19	1
< 25 grafts/year	2002	1022	584	317	194	94	38	7	0

Identity	No. initially at risk	Graft survival (at years post-graft)				
		1	5	10	15	20
≥ 25 grafts/year	2870	.98	.96	.92	.80	.52
< 25 grafts/year	2002	.96	.92	.85	.73	.33

Figure 1.6 compares graft survival for grafts excluding those first grafts for keratoconus (Log Rank Statistic=10.13; df=1; p=0.001).

Figure 1.6 Number of grafts performed/year (penetrating grafts only, keratoconus excluded)



Number At Risk

Identity	Initially	3 years	6 years	9 years	12 years	15 years	18 years	21 years	24 years
≥ 25 grafts/year	5692	2070	907	392	193	73	23	5	n/a
< 25 grafts/year	5727	2109	988	419	201	79	17	5	n/a

Identity	No. initially at risk	Graft survival (at years post-graft)				
		1	5	10	15	20
≥ 25 grafts/year	5692	.84	.64	.46	.31	.13
< 25 grafts/year	5727	.81	.61	.46	.30	.15

n/a = not applicable

The survival curves appear very similar for both groups, despite the statistically significant difference between them. This suggests that the impact of this variable at a practical, clinical level is likely to be small.

PENETRATING CORNEAL GRAFT SURVIVAL
KERATOCONUS ONLY: EFFECT OF CASE-LOAD

≥ 25 grafts/year:	**98% at 1 year**
Mean Survival 18.84 years	**96% at 5 years**
(SE=0.37; 95% CI: 18.12, 19.55)	**91% at 10 years**
Median Survival 21 years	**80% at 15 years**
	52% at 20 years
< 25 grafts/year:	**96% at 1 year**
Mean Survival 17.35 years	**92% at 5 years**
(SE=0.38; 95% CI: 16.59, 18.09)	**85% at 10 years**
Median Survival 19 years	**73% at 15 years**
	33% at 20 years

PENETRATING CORNEAL GRAFT SURVIVAL
KERATOCONUS EXCLUDED: EFFECT OF CASE-LOAD

≥ 25 grafts/year:	**84% at 1 year**
Mean Survival 10.31 years	**64% at 5 years**
(SE=0.23; 95% CI: 9.86, 10.77)	**46% at 10 years**
Median Survival 9 years	**31% at 15 years**
	13% at 20 years
< 25 grafts/year:	**81% at 1 year**
Mean Survival 10.10 years	**61% at 5 years**
(SE=0.25; 95% CI: 9.60, 10.60)	**46% at 10 years**
Median Survival 9 years	**30% at 15 years**
	15% at 20 years

KEY:

n/a	=	not applicable
SE	=	standard error
CI	=	confidence interval
df	=	degrees of freedom
p	=	probability

1.2.4 The 'centre effect' – penetrating grafts

Penetrating graft survival stratified by individual high volume surgeons is shown in figures 1.7 & 1.8.

Figure 1.7 shows graft survival for those grafts performed by surgeons who performed ≥ 25 penetrating grafts with follow up for keratoconus (Log Rank Statistic=77.96; df=28; p<0.001).

Figure 1.7 Penetrating grafts (keratoconus only) – high volume surgeons

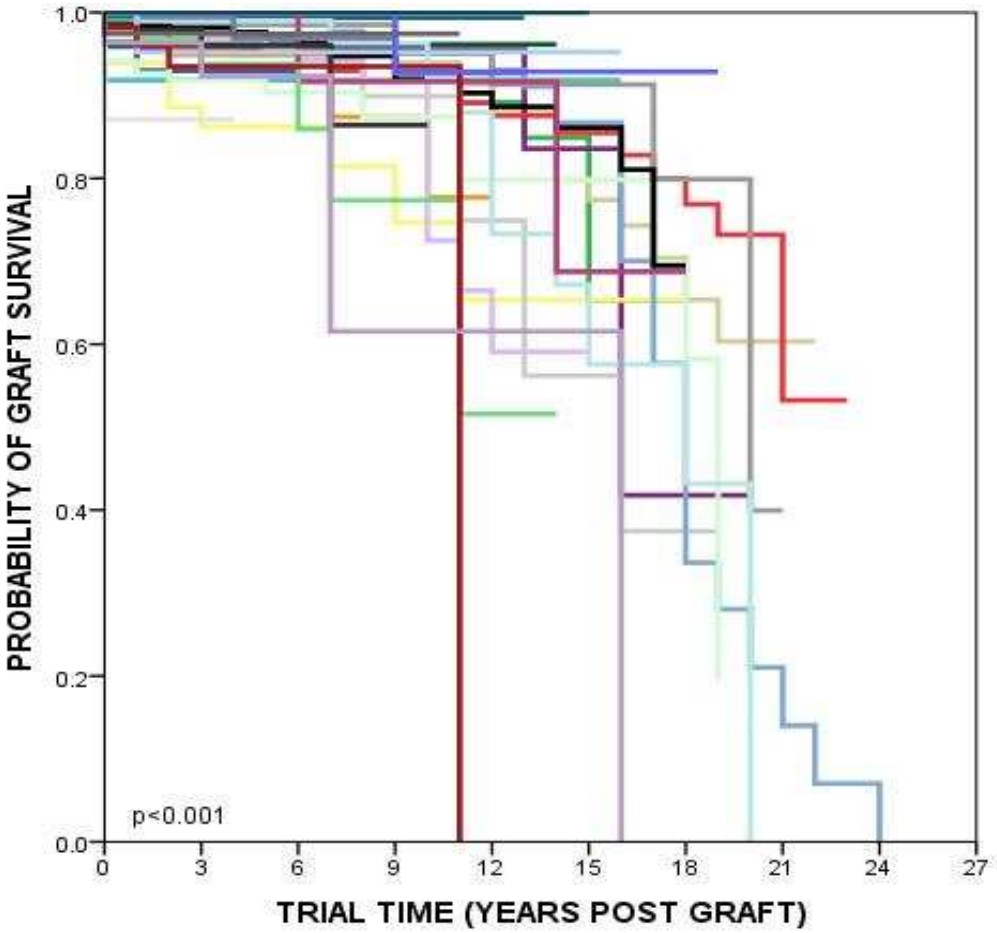
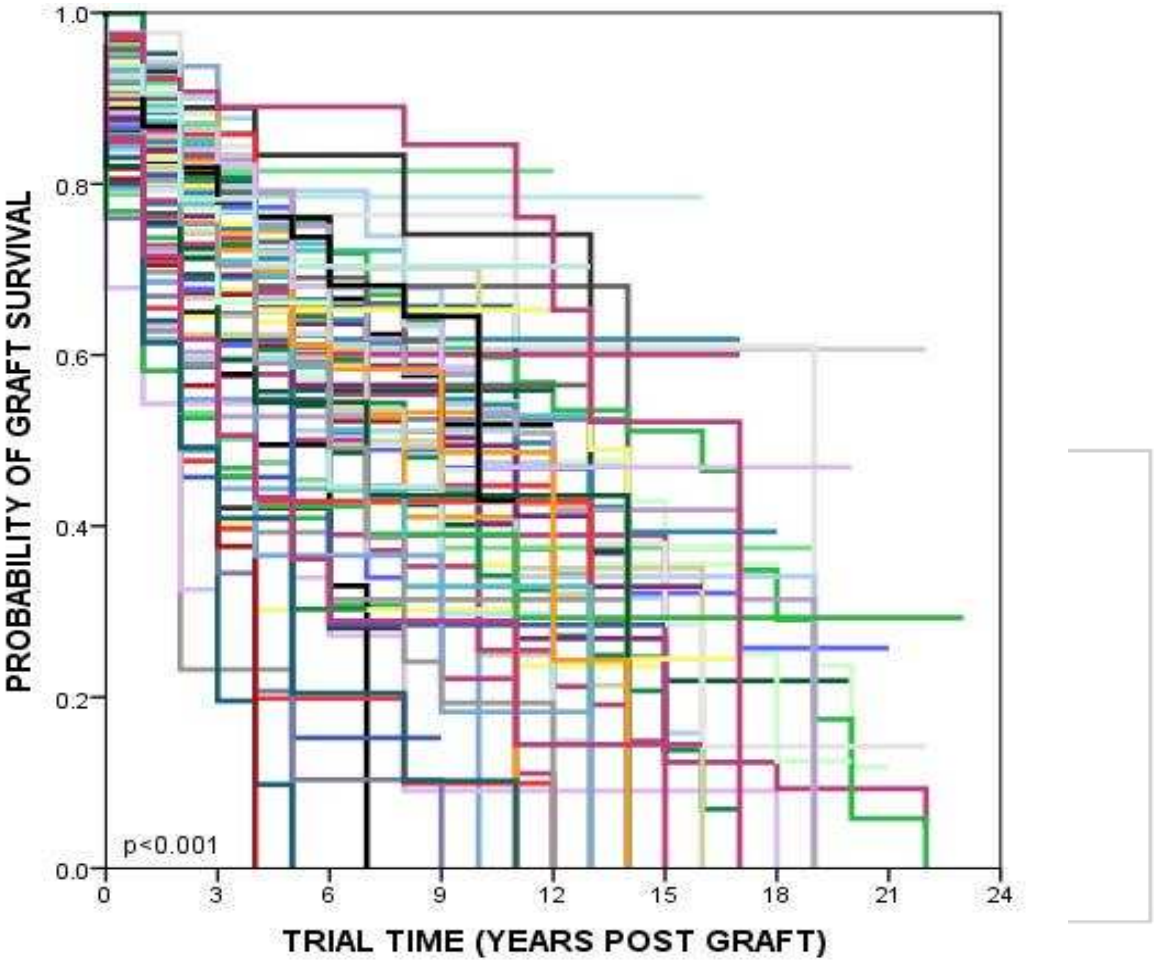


Figure 1.8 shows graft survival for penetrating grafts performed by surgeons who performed ≥ 25 penetrating grafts with follow up, *excluding* those performed for keratoconus (Log rank Statistic=452.45; df=78; p<0.001).

Figure 1.8 Penetrating grafts (keratoconus excluded) - high volume surgeons



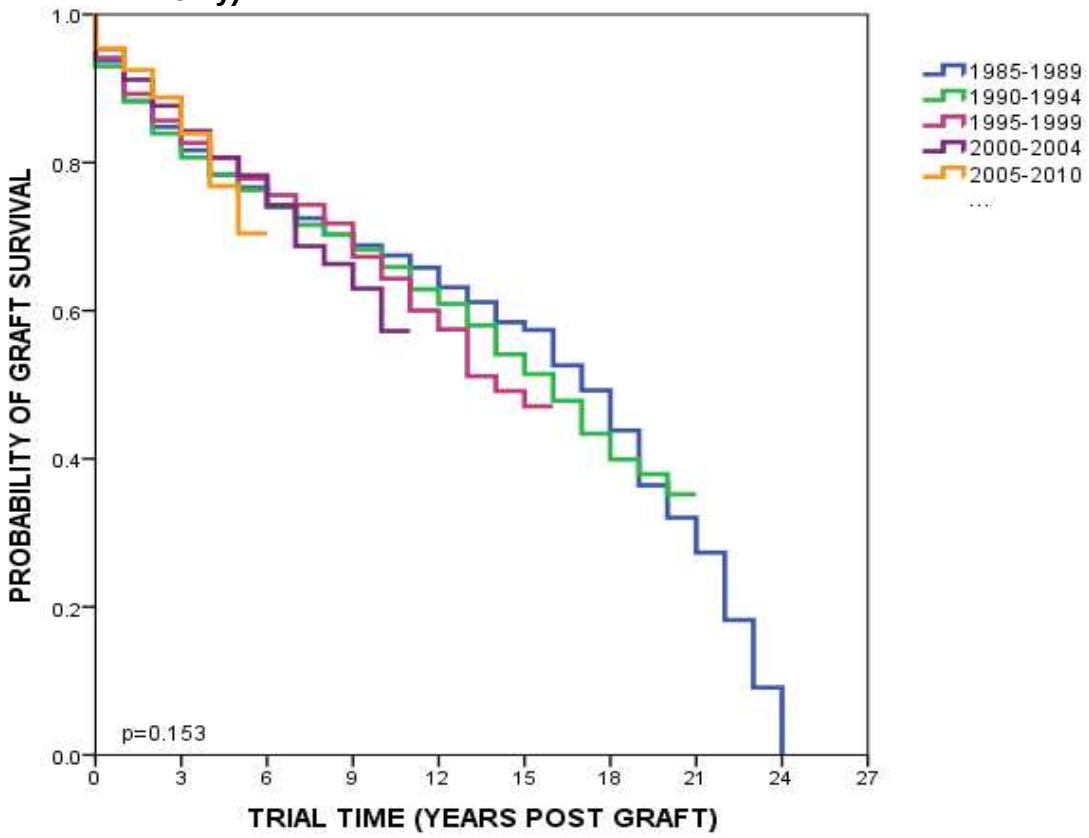
A total of 104 surgeons performed ≥ 25 penetrating grafts with follow-up. Twenty nine surgeons performed these grafts for keratoconus and 79 performed grafts for indicators other than keratoconus. Four surgeons performed ≥ 25 penetrating grafts with follow-up for keratoconus and separately for indications other than keratoconus.

While significant differences were found when comparing surgeons who undertook ≥ 25 penetrating grafts per year to those who did fewer than 25, further exploration of the survival rates for individual surgeons who performed ≥ 25 grafts also showed a large amount of variation, as shown in Figure 1.7 and Figure 1.8. This indicates that, although surgeon workload does appear to have a significant impact on graft survival, there is still an unexplained “centre effect” amongst these surgeons, with some enjoying greater success rates than others. This is even the case when only those grafts performed for keratoconus are examined. However, case-mix is likely to exert some effect (see Chapter 9).

1.2.5 Outcome: according to era

A comparison of graft survival since the Australian Corneal Graft Registry began is shown in Figure 1.9. Due to the nature of this particular analysis, in that grafts performed in earlier eras are more likely to have up-to-date information and longer follow-up than more recent grafts, Figure 1.9 analyses grafts performed to the original census date (01/06/10) using follow-up data to the second census date (12/10/11). Grafts performed in 5 year blocks, 1985-1989, 1990-1994, 1995-2000, 2000-2004 and 2005-2010 were compared (Log Rank Statistic=6.690; df=4; p=0.153). When the graft was performed has no significant influence on graft survival.

Figure 1.9 Graft outcome measured in groups of years (1st penetrating grafts only)



Number At Risk

Identity	Initially	3 years	6 years	9 years	12 years	15 years	18 years	21 years	24 years
1985 - 1989	1860	971	621	391	298	167	91	31	1
1990 - 1994	3795	1764	1043	631	385	224	75	2	n/a
1995 - 1999	2814	1281	699	382	165	24	n/a	n/a	n/a
2000 - 2004	2938	1206	473	80	n/a	n/a	n/a	n/a	n/a
2005 - 2010	1758	488	18	n/a	n/a	n/a	n/a	n/a	n/a

Identity	No. initially at risk	Graft survival (at years post-graft)				
		1	5	10	15	20
1985 - 1989	1860	.88	.77	.68	.57	.32
1990 - 1994	3795	.88	.76	.66	.51	.35
1995 - 1999	2814	.89	.78	.64	.47	n/a
2000 - 2004	2938	.91	.78	.57	n/a	n/a
2005 - 2010	1758	.93	.70	n/a	n/a	n/a

n/a = not applicable

PENETRATING CORNEAL GRAFT SURVIVAL
STRATIFIED BY ERA

1985-1989:	**88% at 1 year**
Mean Survival 14.32 years	**77% at 5 years**
(SE=0.30; 95% CI: 13.73, 14.90)	**68% at 10 years**
Median Survival 17 years	**57% at 15 years**
	32% at 20 years
1990-1994:	**88% at 1 year**
Mean Survival 13.42 years	**76% at 5 years**
(SE=0.21; 95% CI: 13.02, 13.82)	**66% at 10 years**
Median Survival 16 years	**51% at 15 years**
	35% at 20 years
1995-1999:	**89% at 1 year**
Mean Survival 11.28 years	**78% at 5 years**
(SE=0.17; 95% CI: 10.95, 11.62)	**64% at 10 years**
Median Survival 14 years	**47% at 15 years**
2000-2004:	**91% at 1 year**
Mean Survival 8.47 years	**78% at 5 years**
(SE=0.11; 95% CI: 8.25, 8.68)	**57% at 10 years**
Median Survival approx. 11 years	
2005-2010:	**93% at 1 year**
Mean Survival 5.08 years	**70% at 5 years**
(SE =0.06; 95% CI: 4.96, 5.20)	
Median Survival approx. 6 years	

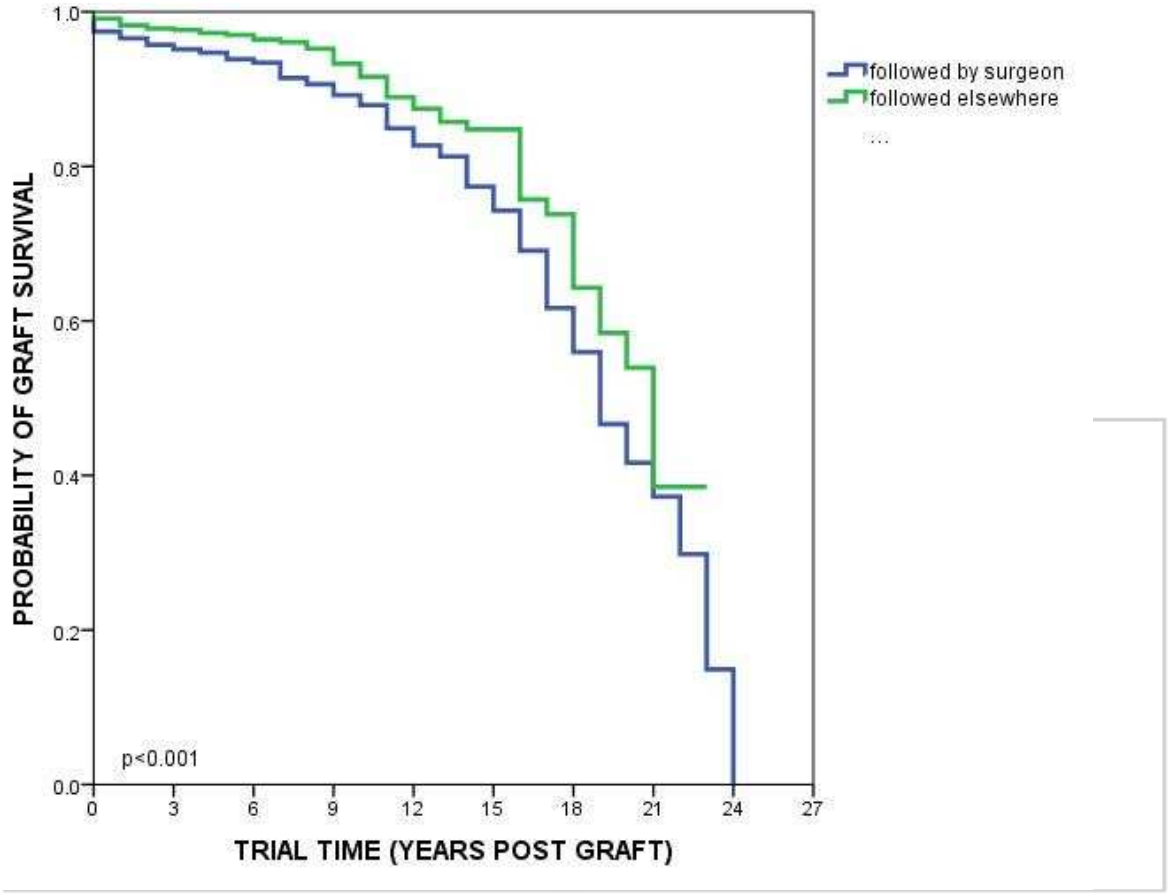
KEY:

n/a	=	not applicable
SE	=	standard error
CI	=	confidence interval
df	=	degrees of freedom
p	=	probability

1.2.6 Outcome: whether followed by contributing surgeon or another practitioner

Figure 1.10 compares penetrating graft outcome for first grafts for keratoconus, stratified by whether the graft was followed by the contributing surgeon or by another practitioner (Log Rank Statistic=12.82; df=1; p<0.001).

Figure 1.10 Follow-up surgeon/other practitioner - 1st graft for keratoconus only



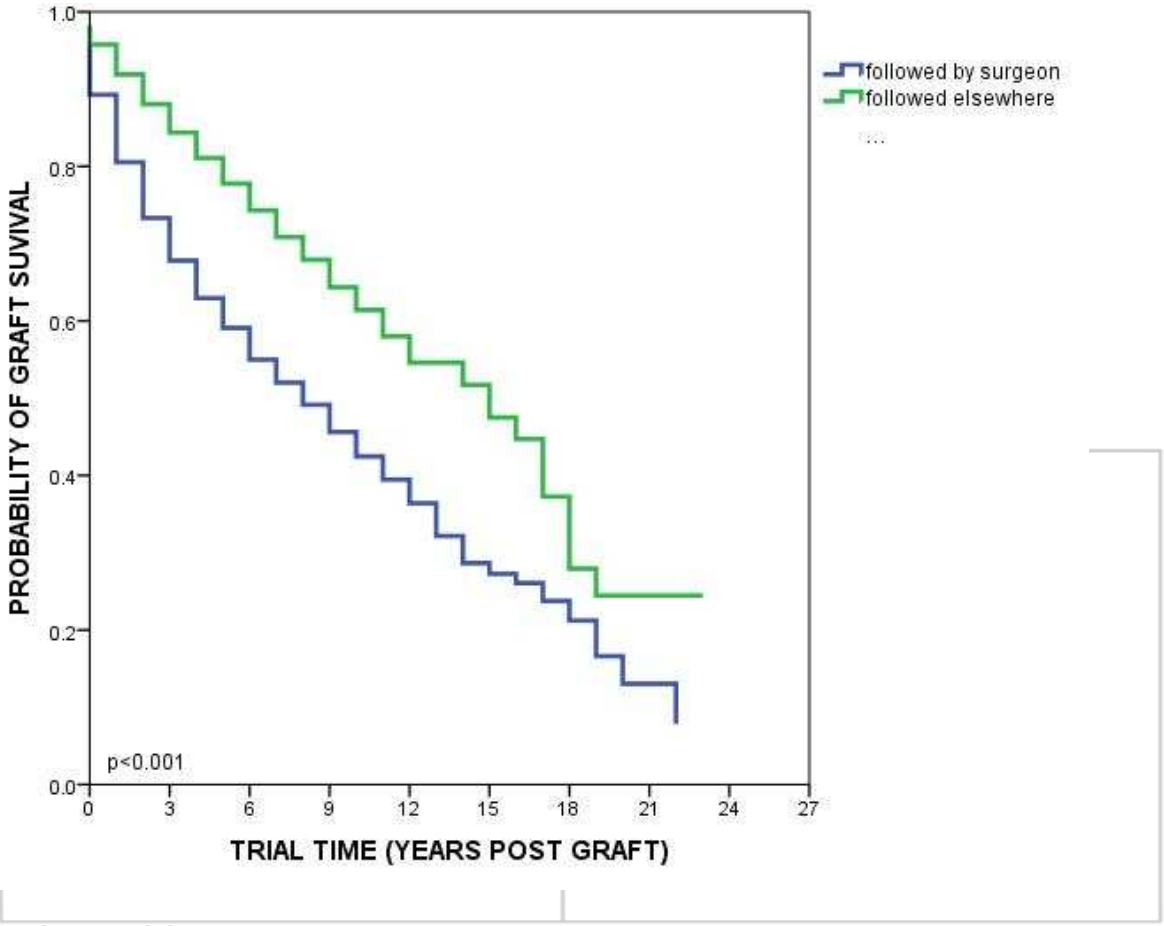
Number At Risk

Identity	Initially	3 years	6 years	9 years	12 years	15 years	18 years	21 years	24 years
Followed by surgeon	3846	1850	1027	577	347	174	65	19	1
Followed elsewhere	1022	570	329	196	118	74	31	7	n/a

Identity	No. initially at risk	Graft survival (at years post-graft)				
		1	5	10	15	20
Followed by surgeon	3846	.97	.94	.88	.74	.42
Followed elsewhere	1022	.98	.97	.96	.85	.54

Figure 1.11 compares the outcome for all penetrating grafts excluding those performed for keratoconus, followed by the contributing surgeon or by another practitioner (Log Rank Statistic=182.96; df=1; p<0.001).

Figure 1.11 Follow-up surgeon/other practitioner - keratoconus excluded



Number At Risk

Identity	Initially	3 years	6 years	9 years	12 years	15 years	18 years	21 years	24 years
Followed by surgeon	9461	3295	1492	641	310	103	28	8	n/a
Followed elsewhere	1962	885	404	172	85	49	12	2	n/a

Identity	No. initially at risk	Graft survival (at years post-graft)				
		1	5	10	15	20
Followed by surgeon	9461	.81	.59	.43	.27	.13
Followed elsewhere	1962	.92	.78	.61	.48	.25

n/a = not applicable

Survival of penetrating grafts was better in both keratoconus and non-keratoconus patients when they were followed elsewhere. We hypothesize that surgeons refer on the follow-up of patients whose grafts are doing well, while continuing to see more complex cases themselves.

PENETRATING CORNEAL GRAFT SURVIVAL
FOLLOWUP SURGEON; KERATOCONUS ONLY

Followed by surgeon:	**97% at 1 year**
Mean Survival 17.84 years	**94% at 5 years**
(SE=0.33; 95% CI: 17.20, 18.48)	**88% at 10 years**
Median Survival 19 years	**74% at 15 years**
	42% at 20 years
Followed elsewhere:	**98% at 1 year**
Mean Survival 18.95 years	**97% at 5 years**
(SE=0.46; 95% CI: 18.05, 19.85)	**96% at 10 years**
Median Survival 21 years	**85% at 15 years**
	54% at 20 years

OVERALL CORNEAL GRAFT SURVIVAL
FOLLOWUP SURGEON; KERATOCONUS EXCLUDED

Followed by surgeon:	**80% at 1 year**
Mean Survival 9.55 years	**59% at 5 years**
(SE=0.18; 95% CI: 9.21, 9.85)	**42% at 10 years**
Median Survival 8 years	**27% at 15 years**
	13% at 20 years
Followed elsewhere:	**92% at 1 year**
Mean Survival 13.32 years	**78% at 5 years**
(SE=0.46; 95% CI: 12.41, 14.23)	**61% at 10 years**
Median Survival 15 years	**47% at 15 years**
	24% at 20 years

KEY:

n/a	=	not applicable
SE	=	standard error
CI	=	confidence interval
df	=	degrees of freedom
p	=	probability

1.3 SUMMARY OF OVERVIEW AND CONTRIBUTOR INFORMATION

- 23,048 registered grafts are considered in this report, of which 86.5% were penetrating, 13% were lamellar, and 0.5% were limbal.
- Overall, 88% of grafts have been followed on at least one occasion, 33% of grafts are known to be lost to follow-up, 22% of grafts can no longer be followed because of recipient death, and 18% of grafts have failed.
- Penetrating corneal graft survival is 73% at 5 years.
  Lamellar corneal graft survival is 67% at 5 years.
  Limbal allograft survival is 43% at 5 years.
- 82% of penetrating grafts have been performed by 16% of transplant surgeons.
- A centre effect operates within the database.
- Surgeons who performed 25 or more penetrating grafts per year on average achieved better results in terms of graft survival than did those who performed fewer grafts, although the difference in terms of graft survival was small.
- Patients with penetrating grafts who were followed up by another practitioner had a better outcome compared with patients who were followed up by the surgeon. This is probably due to case selection.

2. DONORS AND EYE-BANKING

2.1 CAUSE OF DONOR DEATH

The major cause of donor death for all graft types is listed in Table 2.1. Diseases of the cardiac/circulatory system remain the most common cause of death in corneal donors, followed by malignancies, strokes and other haemorrhages.

Table 2.1 Causes of donor death

Cause of death related to	Number of eyes	%
Cardiac/circulatory system	6851	30%
Malignancy	4478	19%
Cerebrovascular system	4423	19%
Trauma/accident/poisoning/medical misadventure	2317	10%
Respiratory system	2220	10%
Other specified cause	1536	7%
Unknown to ACGR	1190	5%
Total	**23015**	**100%**

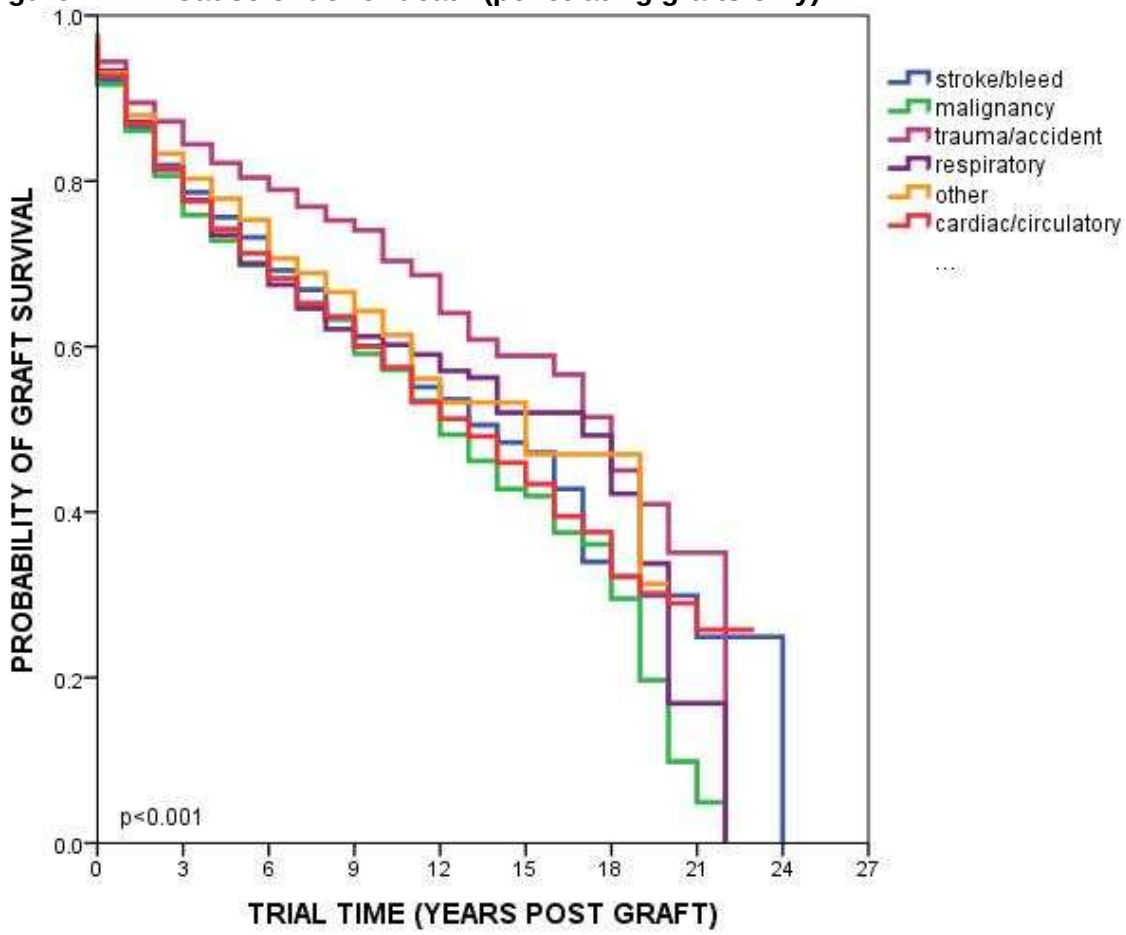
In 33 of the 23,048 grafts performed, the cornea was sourced from the recipient's other eye, not a separate donor.

With the exception of Table 2.1 and Figure 2.2, all Kaplan-Meier plots and associated tables in this chapter have been calculated using penetrating grafts only.

Kaplan-Meier survival curves for penetrating grafts for the most common causes of donor death are shown in Figure 2.1.

When donors dying from trauma are removed from the analysis, there is no longer a significant difference amongst groups (Log Rank Statistic=7.268; df=4; p=0.122).

Figure 2.1 Cause of donor death (penetrating grafts only)



Number At Risk

Identity	Initially	3 years	6 years	9 years	12 years	15 years	18 years	21 years	24 years
Stroke/bleed	3137	1280	603	285	147	78	19	6	1
Malignancy	2761	1035	487	243	130	51	22	2	n/a
Trauma/accident	1628	756	384	187	105	42	16	4	n/a
Respiratory	1664	659	298	144	89	34	14	1	n/a
Other	1134	467	242	88	39	17	3	n/a	n/a
Cardiac/circulatory	4949	2007	1004	485	242	124	42	18	n/a

Identity	No. initially at risk	Graft survival (at years post-graft)				
		1	5	10	15	20
Stroke/bleed	3137	.86	.73	.57	.47	.25
Malignancy	2761	.86	.70	.57	.42	.10
Trauma/accident	1628	.90	.80	.70	.57	.35
Respiratory	1664	.87	.70	.60	.49	.17
Other	1134	.88	.75	.61	.47	n/a
Cardiac/circulatory	4949	.87	.71	.58	.43	.29

OVERALL CORNEAL GRAFT SURVIVAL
CAUSE OF DONOR DEATH

Stroke/bleed:	**86% at 1 year**
Mean Survival 13.03 years	**73% at 5 years**
(SE=0.40; 95% CI: 12.25, 13.81)	**57% at 10 years**
Median Survival 14 years	**47% at 15 years**
	25% at 20 years
Malignancy:	**86% at 1 year**
Mean Survival 11.61 years	**70% at 5 years**
(SE=0.30; 95% CI: 11.02, 12.20)	**57% at 10 years**
Median Survival 12 years	**42% at 15 years**
	10% at 20 years
Trauma/accident:	**89% at 1 year**
Mean Survival 14.69 years	**80% at 5 years**
(SE=0.44; 95% CI: 13.83, 15.55)	**70% at 10 years**
Median Survival 18 years	**57% at 15 years**
	35% at 20 years
Respiratory:	**87% at 1 year**
Mean Survival 12.86 years	**70% at 5 years**
(SE=0.42; 95% CI: 12.03, 13.69)	**60% at 10 years**
Median Survival 17 years	**49% at 15 years**
	17% at 20 years
Other:	**88% at 1 year**
Mean Survival 12.65 years	**75% at 5 years**
(SE=0.47; 95% CI: 11.72, 13.57)	**61% at 10 years**
Median Survival 15 years	**47% at 15 years**
Cardiac/circulatory:	**87% at 1 year**
Mean Survival 12.62 years	**71% at 5 years**
(SE=0.26; 95% CI: 12.10, 13.14)	**58% at 10 years**
Median Survival 13 years	**43% at 15 years**
	29% at 20 years

KEY:

n/a	=	not applicable
SE	=	standard error
CI	=	confidence interval
df	=	degrees of freedom
p	=	probability

2.2 DONOR SEX

The sex of corneal donors continues to show the expected preponderance of males (Table 2.2), given the causes of donor death (see Table 2.1).

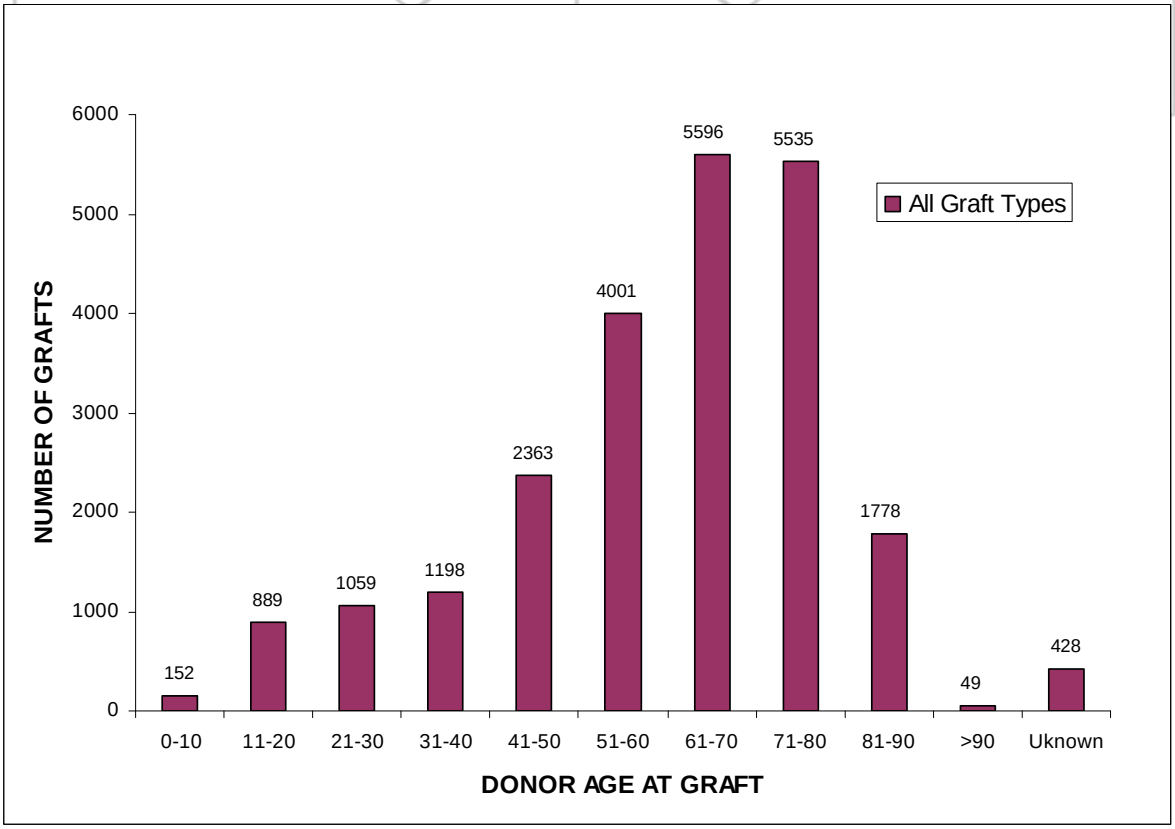
Table 2.2 Donor Sex

Sex	Penetrating grafts		Lamellar grafts		Limbal grafts		Total	
	No.	%	No.	%	No.	%	No.	%
Male	12235	53%	1785	8%	74	<1%	**14094**	**61%**
Female	6889	30%	1141	5%	35	<1%	**8065**	**35%**
Unknown	828	4%	57	<1%	4	<1%	**889**	**4%**
TOTAL	**19952**	**86%**	**2983**	**13%**	**113**	**<1%**	**23048**	**100%**

2.3 DONOR AGE

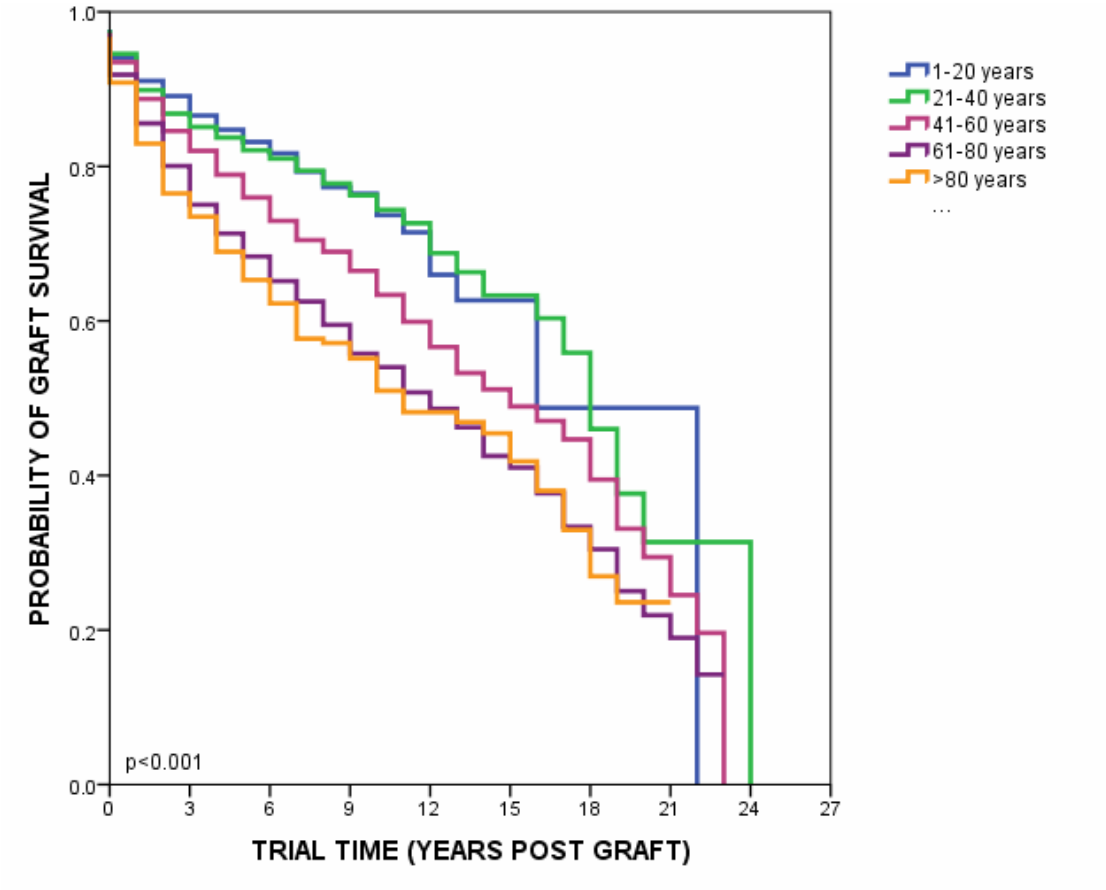
The age distribution is plotted in histogram form in Figure 2.2.

Figure 2.2 Donor age in decades



Figures 2.3, 2.4 and 2.5 show the influence of donor age on corneal graft survival. Figure 2.3 shows the influence of donor age in 20 year blocks on the cohort of penetrating grafts (Log Rank Statistic=164.59; df=4; p=0.001).

Figure 2.3 Donor age in 20 year blocks (penetrating grafts only)



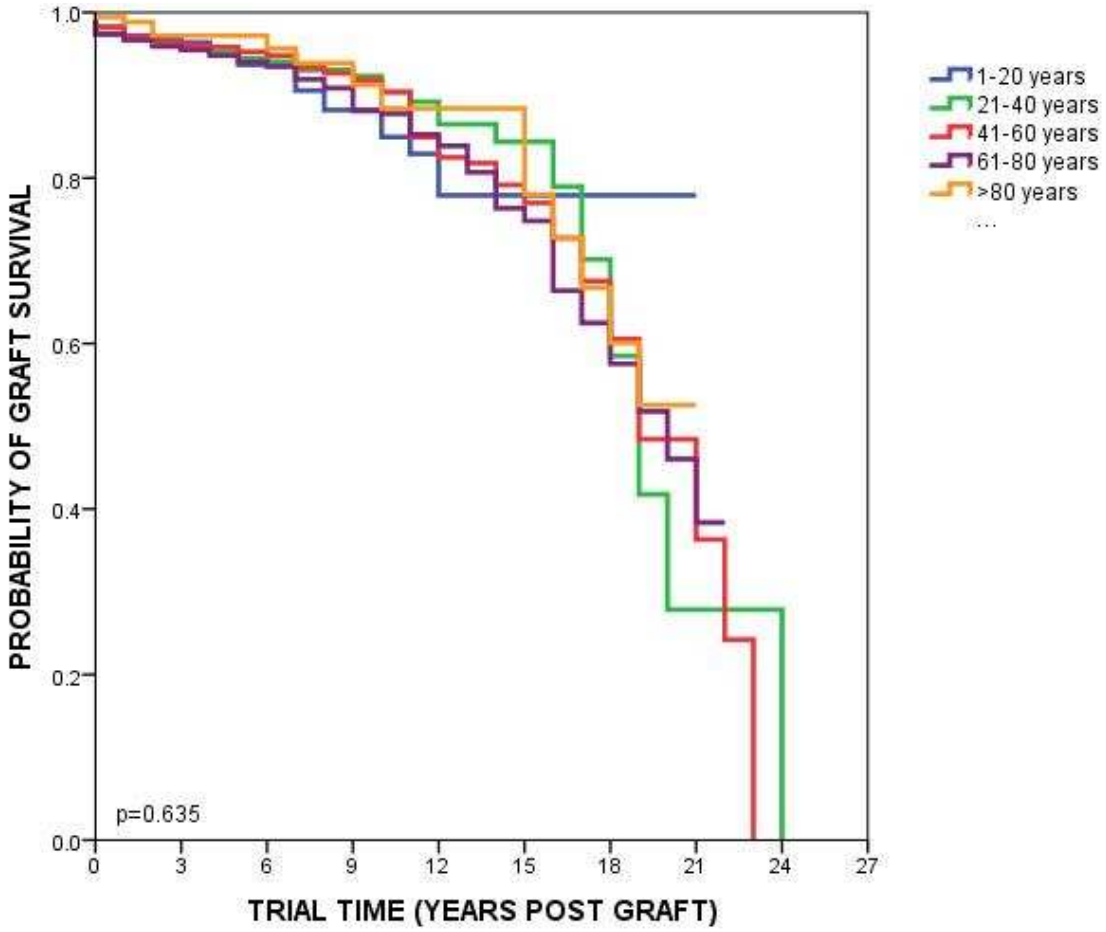
Number At Risk

Identity	Initially	3 years	6 years	9 years	12 years	15 years	18 years	21 years	24 years
1-20 years	767	354	169	93	52	17	4	2	n/a
21-40 years	1602	706	386	204	112	52	17	4	1
41-60 years	4470	1878	931	446	257	116	43	12	0
61-80 years	7881	3082	1467	690	357	169	57	15	n/a
>80 years	1214	409	193	86	44	25	11	2	n/a

Identity	No. initially at risk	Graft survival (at years post-graft)				
		1	5	10	15	20
1-20 years	767	.91	.83	.74	.49	n/a
21-40 years	1602	.90	.82	.74	.63	.31
41-60 years	4470	.89	.76	.63	.49	.29
61-80 years	7881	.86	.68	.54	.41	.22
>80 years	1214	.83	.66	.51	.42	.24

Figure 2.4 shows the influence of donor age on grafts for keratoconus only (Log Rank Statistic=2.555; df=4; p=0.635). The differences are not significant.

Figure 2.4 Donor age (penetrating grafts for keratoconus only)



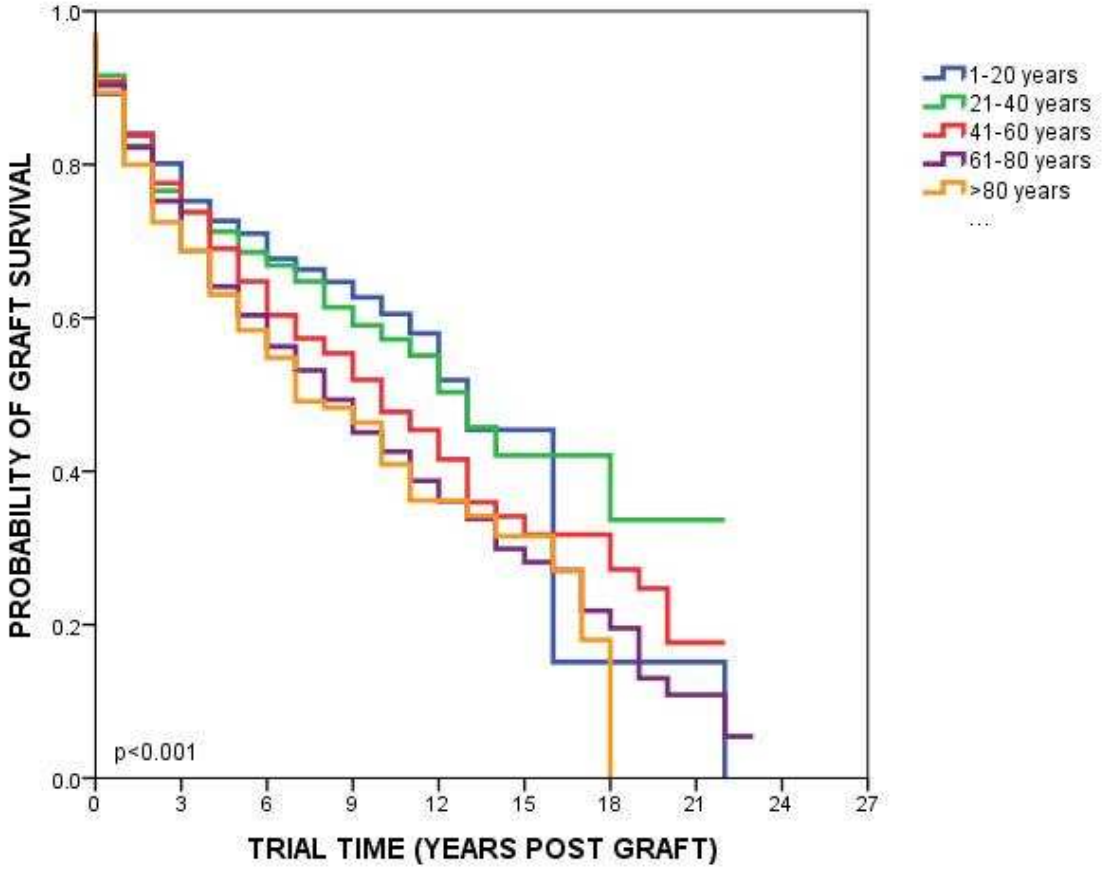
Number At Risk

Identity	Initially	3 years	6 years	9 years	12 years	15 years	18 years	21 years	24 years
1-20 years	406	207	104	61	33	9	3	1	n/a
21-40 years	815	403	227	126	66	35	12	2	1
41-60 years	1628	776	416	223	139	73	29	8	0
61-80 years	1746	876	506	297	183	100	38	12	n/a
>80 years	179	97	62	36	24	17	10	2	n/a

Identity	No. initially at risk	Graft survival (at years post-graft)				
		1	5	10	15	20
1-20 years	406	.97	.94	.85	n/a	n/a
21-40 years	815	.97	.95	.90	.79	.28
41-60 years	1628	.97	.95	.90	.77	.36
61-80 years	1746	.97	.94	.88	.75	.46
>80 years	179	.99	.96	.88	.78	.53

Figure 2.5 shows the influence of donor age on the survival of grafts performed for all indications excluding keratoconus (Log Rank Statistic=30.413; df=4; p=0.001).

Figure 2.5 Donor age (penetrating grafts, keratoconus excluded)



Number At Risk

Identity	Initially	3 years	6 years	9 years	12 years	15 years	18 years	21 years	24 years
1-20 years	361	147	65	32	19	8	1	n/a	n/a
21-40 years	787	303	159	78	46	17	5	2	n/a
41-60 years	2842	1102	515	223	118	43	14	4	n/a
61-80 years	6135	2206	961	393	174	69	19	3	n/a
>80 years	1035	312	131	50	20	8	1	n/a	n/a

Identity	No. initially at risk	Graft survival (at years post-graft)				
		1	5	10	15	20
1-20 years	361	.84	.71	.61	.15	n/a
21-40 years	787	.82	.69	.57	.42	n/a
41-60 years	2842	.84	.65	.48	.32	.18
61-80 years	6135	.82	.60	.43	.28	.11
>80 years	1035	.80	.58	.41	.27	n/a

Figure 2.3 shows that graft survival declines as donor age increases in 20 year blocks, suggesting that survival was better when corneas were sourced from younger donors. This finding could be confounded by the use of corneas from younger donors for grafts in certain categories of recipients, e.g. greater proportions in recipients with keratoconus.

Figure 2.4 illustrates that graft survival in recipients with keratoconus is similar across donor age groups and the differences are not significant. Recipients with keratoconus exhibited good graft survival regardless of donor age.

Having removed recipients with keratoconus from the analysis, a significant difference across donor age groups was present in the balance of the database, as shown in Figure 2.5. This still follows the trend of better graft survival in eyes with corneas sourced from younger compared to older donors. However, donor age is not a significant variable in multivariate analysis (see Chapter 9).

PENETRATING CORNEAL GRAFT SURVIVAL
DONOR AGE IN 20 YEAR BLOCKS

1-20 years:	**91% at 1 year**
Mean Survival 15.35 years	**83% at 5 years**
(SE=0.72; 95% CI: 13.94, 16.76)	**74% at 10 years**
Median Survival 16 years	**49% at 15 years**
21-40 years:	**90% at 1 year**
Mean Survival 15.71 years	**82% at 5 years**
(SE=0.56; 95% CI: 14.60, 16.81)	**74% at 10 years**
Median Survival 18 years	**63% at 15 years**
	31% at 20 years
41-60 years:	**88% at 1 year**
Mean Survival 13.54 years	**76% at 5 years**
(SE=0.28; 95% CI: 12.98, 14.09)	**63% at 10 years**
Median Survival 15 years	**49% at 15 years**
	29% at 20 years
61-80 years:	**86% at 1 year**
Mean Survival 11.80 years	**68% at 5 years**
(SE=0.21; 95% CI: 11.39, 12.21)	**54% at 10 years**
Median Survival 12 years	**41% at 15 years**
	22% at 20 years
>80 years:	**83% at 1 year**
Mean Survival 12.94 years	**65% at 5 years**
(SE=0.17; 95% CI: 12.60, 13.27)	**51% at 10 years**
Median Survival 14 years	**42% at 15 years**
	24% at 20 years

KEY:
n/a = not applicable
SE = standard error
CI = confidence interval
df = degrees of freedom
p = probability

PENETRATING CORNEAL GRAFT SURVIVAL
DONOR AGE; KERATOCONUS ONLY

1-20 years:	**97% at 1 year**
Mean Survival 18.07 years	**94% at 5 years**
(SE=0.59; 95% CI: 16.92, 19.22)	**85% at 10 years**
Median Survival >10 years	
21-40 years:	**97% at 1 year**
Mean Survival 18.30 years	**95% at 5 years**
(SE=0.79; 95% CI: 16.75, 19.85)	**90% at 10 years**
Median Survival 19 years	
41-60 years:	**97% at 1 year**
Mean Survival 18.05 years	**95% at 5 years**
(SE=0.43; 95% CI: 17.20, 18.90)	**90% at 10 years**
Median Survival 19 years	
61-80 years:	**97% at 1 year**
Mean Survival 17.50 years	**94% at 5 years**
(SE=0.34; 95% CI: 16.84, 18.16)	**88% at 10 years**
Median Survival 20 years	
>80 years:	**99% at 1 year**
Mean Survival 17.87 years	**97% at 5 years**
(SE=0.72; 95% CI: 16.45, 19.28)	**88% at 10 years**
Median Survival >20 years	

PENETRATING CORNEAL GRAFT SURVIVAL
DONOR AGE; KERATOCONUS EXCLUDED

1-20 years:	**84% at 1 year**
Mean Survival 11.31 years	**71% at 5 years**
(SE=0.97; 95% CI: 9.41, 13.21)	**61% at 10 years**
Median Survival 13 years	
21-40 years:	**82% at 1 year**
Mean Survival 12.27 years	**69% at 5 years**
(SE=0.62; 95% CI: 11.06, 13.49)	**57% at 10 years**
Median Survival 13 years	
41-60 years:	**84% at 1 year**
Mean Survival 10.72 years	**65% at 5 years**
(SE=0..32; 95% CI: 10.09, 11.35)	**48% at 10 years**
Median Survival 10 years	
61-80 years:	**82% at 1 year**
Mean Survival 9.63 years	**60% at 5 years**
(SE=0.23; 95% CI: 9.18, 10.08)	**43% at 10 years**
Median Survival 8 years	
>80 years:	**80% at 1 year**
Mean Survival 8.86 years	**58% at 5 years**
(SE=0.42; 95% CI: 8.04, 9.69)	**41% at 10 years**
Median Survival 7 years	

KEY:

n/a	=	not applicable
SE	=	standard error
p	=	probability
CI	=	confidence interval
df	=	degrees of freedom

2.4 DEATH-TO-ENUCLEATION AND DEATH-TO-GRAFT TIMES

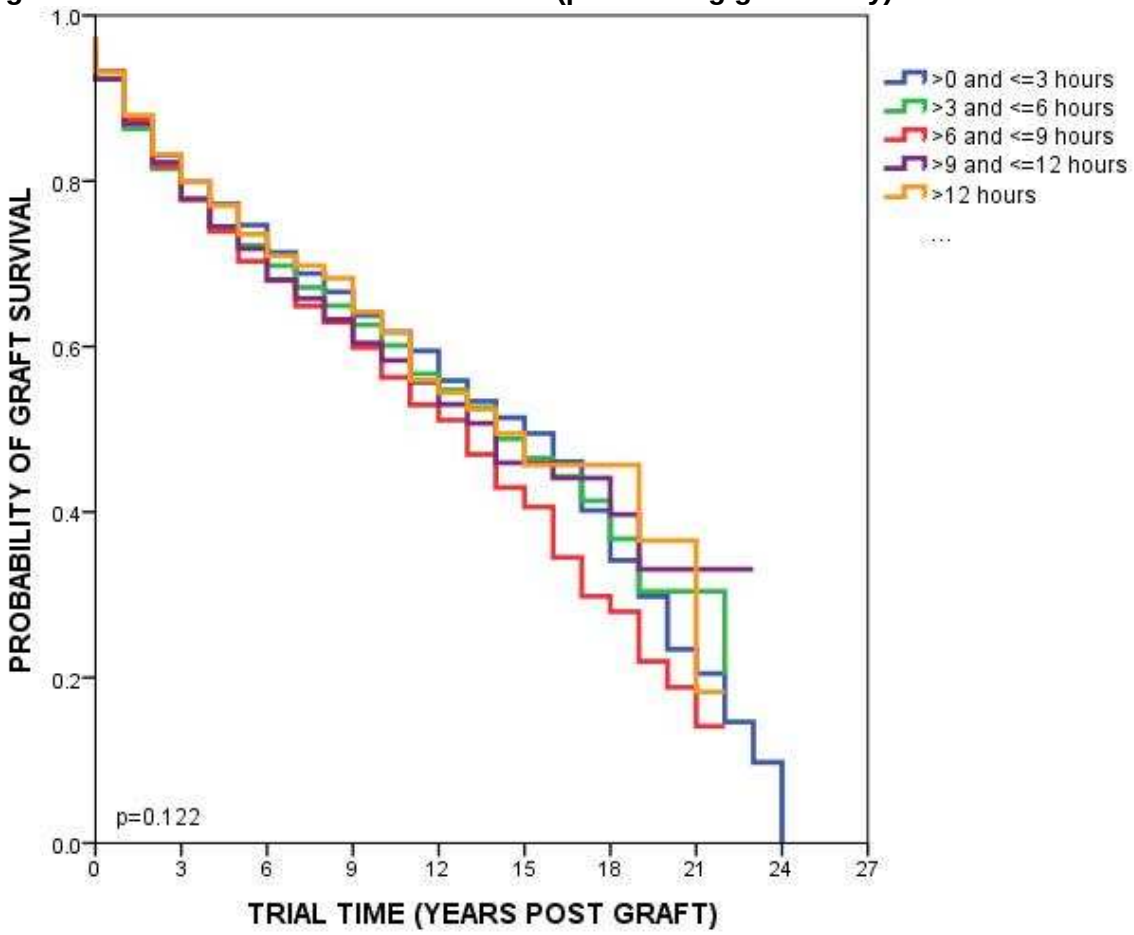
Death-to-enucleation and death-to-graft times for penetrating grafts are shown in Table 2.3.

Table 2.3 Corneal collection times for penetrating grafts

Time	Penetrating Grafts		
	Total	Median time	Range (Days)
		Days	
Death-to-enucleation times	19493	<1	0 - 3
Death-to-graft times	16457	3	0 - 41
Death-to-graft times for storage in:			
Optisol	7789	4	0 - 41
MK medium	4105	<2	0 - 17
CSM	3179	3	0 - 34
K-Sol	644	4	0 - 32
Moist Pot	283	<1	0 - 16
Organ Culture	229	15	1 - 30

The influence of increasing death-to-enucleation time on penetrating graft survival is illustrated in Figure 2.6 (Log Rank Statistic=7.277; df=4; p=0.122). Death to enucleation time exerted no significant difference on graft survival.

Figure 2.6 Death-to-enucleation times (penetrating grafts only)



Number at Risk

Identity	Initially	3 years	6 years	9 years	12 years	15 years	18 years	21 years	24 years
>0 and ≤3 hours	4265	1938	1086	613	363	189	60	16	1
>3 and ≤6 hours	4303	1747	863	418	233	106	45	12	n/a
>6 and ≤9 hours	3680	1446	693	308	144	55	16	4	n/a
>9 and ≤12 hours	2747	1028	440	179	83	37	10	2	n/a
>12 hours	1268	430	169	67	37	13	5	2	n/a

Identity	No. initially at risk	Graft survival (at years post-graft)				
		1	5	10	15	20
>0 and ≤3 hours	4265	.87	.75	.62	.50	.23
>3 and ≤6 hours	4303	.86	.72	.60	.47	.30
>6 and ≤9 hours	3680	.87	.70	.56	.41	.19
>9 and ≤12 hours	2747	.87	.72	.58	.44	.33
>12 hours	1268	.88	.74	.62	.46	.37

PENETRATING CORNEAL GRAFT SURVIVAL
DEATH TO ENUCLEATION TIME

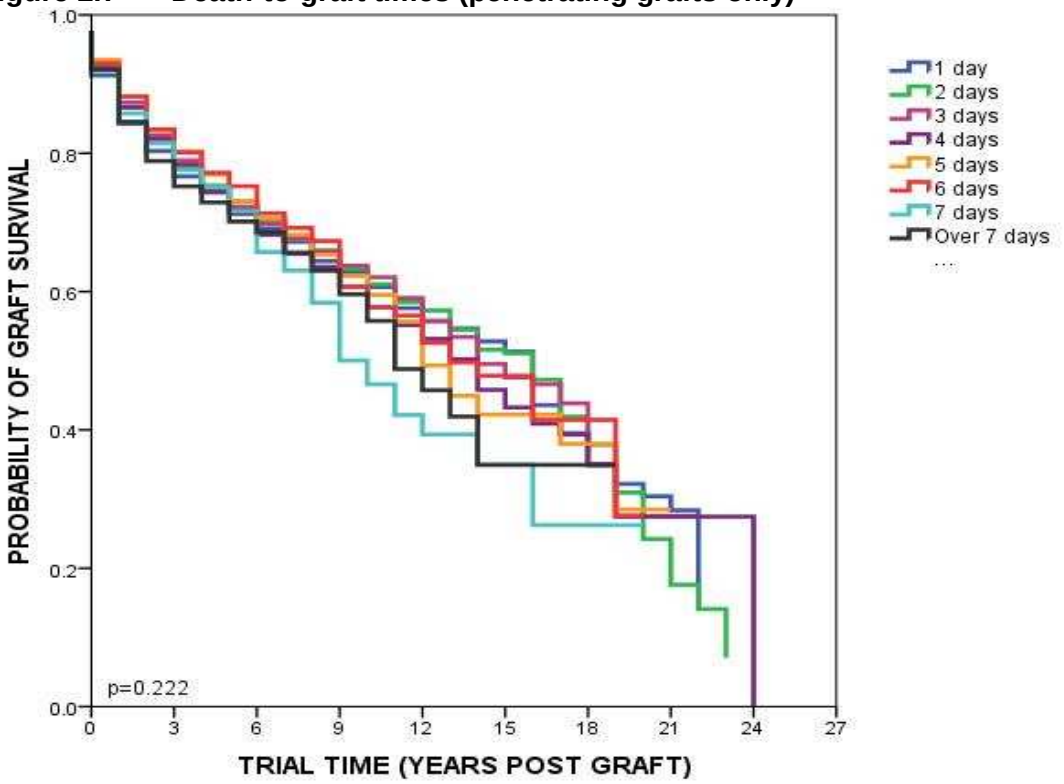
>0 and ≤3 hours:	**87% at 1 year**
Mean Survival 13.15 years	**75% at 5 years**
(SE=0.25; 95% CI: 12.65, 13.65)	**62% at 10 years**
Median Survival 15 years	**50% at 15 years**
	23% at 20 years
>3 and ≤6 hours:	**86% at 1 year**
Mean Survival 12.82 years	**72% at 5 years**
(SE=0.26; 95% CI: 12.31, 13.33)	**60% at 10 years**
Median Survival 14 years	**47% at 15 years**
	30% at 20 years
>6 and ≤9 hours:	**87% at 1 year**
Mean Survival 11.78 years	**70% at 5 years**
(SE=0.30; 95% CI: 11.19, 12.37)	**56% at 10 years**
Median Survival 14 years	**41% at 15 years**
	19% at 20 years
>9 and ≤12 hours:	**87% at 1 year**
Mean Survival 13.13 years	**72% at 5 years**
(SE=0.48; 95% CI: 12.18, 14.08)	**58% at 10 years**
Median Survival 14 years	**44% at 15 years**
	33% at 20 years
>12 hours:	**88% at 1 year**
Mean Survival 13.16 years	**74% at 5 years**
(SE=0.63; 95% CI: 11.93, 14.39)	**62% at 10 years**
Median Survival 14 years	**46% at 15 years**
	37% at 20 years

KEY:

n/a	=	not applicable
SE	=	standard error
CI	=	confidence interval
df	=	degrees of freedom
p	=	probability

Figure 2.7 shows death-to-graft times stratified in number of days for penetrating grafts (Log Rank Statistic=9.45; df=7; p=0.222). There was no significant difference amongst these curves.

Figure 2.7 Death-to-graft times (penetrating grafts only)



Number at Risk

Identity	Initially	3 years	6 years	9 years	12 years	15 years	18 years	21 years	24 years
1 day	1155	**547**	**341**	**203**	**128**	**72**	34	15	n/a
2 days	2592	**1185**	**662**	**349**	**196**	**101**	**41**	11	n/a
3 days	2764	**1229**	**615**	**320**	**193**	**75**	**25**	4	n/a
4 days	2359	**983**	**464**	**222**	**109**	**54**	**18**	3	1
5 days	1890	**698**	**325**	**149**	**70**	**25**	**6**	2	n/a
6 days	1463	**548**	**249**	**82**	**43**	**18**	3	n/a	n/a
7 days	807	**295**	**109**	**42**	**15**	**5**	2	n/a	n/a
Over 7 days	683	**215**	**91**	**37**	**16**	**4**	2	n/a	n/a

Identity	No. initially at risk	Graft survival (at years post-graft)				
		1	5	10	15	20
1 day	1155	.84	.72	.60	.51	.30
2 days	2592	.87	.73	.61	.51	.24
3 days	2764	.87	.72	.62	.48	.28
4 days	2359	.87	.71	.58	.43	.28
5 days	1890	.88	.73	.60	.42	.29
6 days	1463	.88	.75	.58	.42	.28
7 days	807	.86	.72	.47	.35	n/a
Over 7 days	683	.85	.705	.56	.35	n/a

PENETRATING CORNEAL GRAFT SURVIVAL
DEATH TO GRAFT TIME

1 day:	**84% at 1 year**
Mean Survival 12.84 years	**72% at 5 years**
(SE=0.38; 95% CI: 12.12, 13.58)	**60% at 10 years**
Median Survival 16 years	**51% at 15 years**
	30% at 20 years
2 days:	**87% at 1 year**
Mean Survival 13.02 years	**73% at 5 years**
(SE=0.30; 95% CI: 12.44, 13.60)	**61% at 10 years**
Median Survival 16 years	**51% at 15 years**
	24% at 20 years
3 days:	**87% at 1 year**
Mean Survival 12.92 years	**72% at 5 years**
(SE=0.32; 95% CI: 12.29, 13.54)	**62% at 10 years**
Median Survival 14 years	**48% at 15 years**
	28% at 20 years
4 days:	**87% at 1 year**
Mean Survival 13.01 years	**71% at 5 years**
(SE=0.44; 95% CI: 12.14, 13.88)	**58% at 10 years**
Median Survival 14 years	**43% at 15 years**
	28% at 20 years
5 days:	**88% at 1 year**
Mean Survival 12.31 years	**73% at 5 years**
(SE=0.44; 95% CI: 11.45, 13.16)	**60% at 10 years**
Median Survival 12 years	**42% at 15 years**
	29% at 20 years
6 days:	**88% at 1 year**
Mean Survival 12.30 years	**75% at 5 years**
(SE=0.46; 95% CI: 11.40, 13.20)	**58% at 10 years**
Median Survival 13 years	**42% at 15 years**
	28% at 20 years
7 days:	**86% at 1 year**
Mean Survival 10.63 years	**72% at 5 years**
(SE=0.66; 95% CI: 9.33, 11.93)	**47% at 10 years**
Median Survival 10 years	**35% at 15 years**
Over 7 days:	**85% at 1 year**
Mean Survival 10.98 years	**70% at 5 years**
(SE=0.65; 95% CI: 9.70, 12.25)	**56% at 10 years**
Median Survival 11 years	**35% at 15 years**

KEY:

n/a	=	not applicable
SE	=	standard error
CI	=	confidence interval
df	=	degrees of freedom
p	=	probability

2.5 CORNEAL STORAGE MEDIA

The corneal storage media in which donor corneas were preserved are shown in Table 2.4.

Table 2.4 Corneal storage media

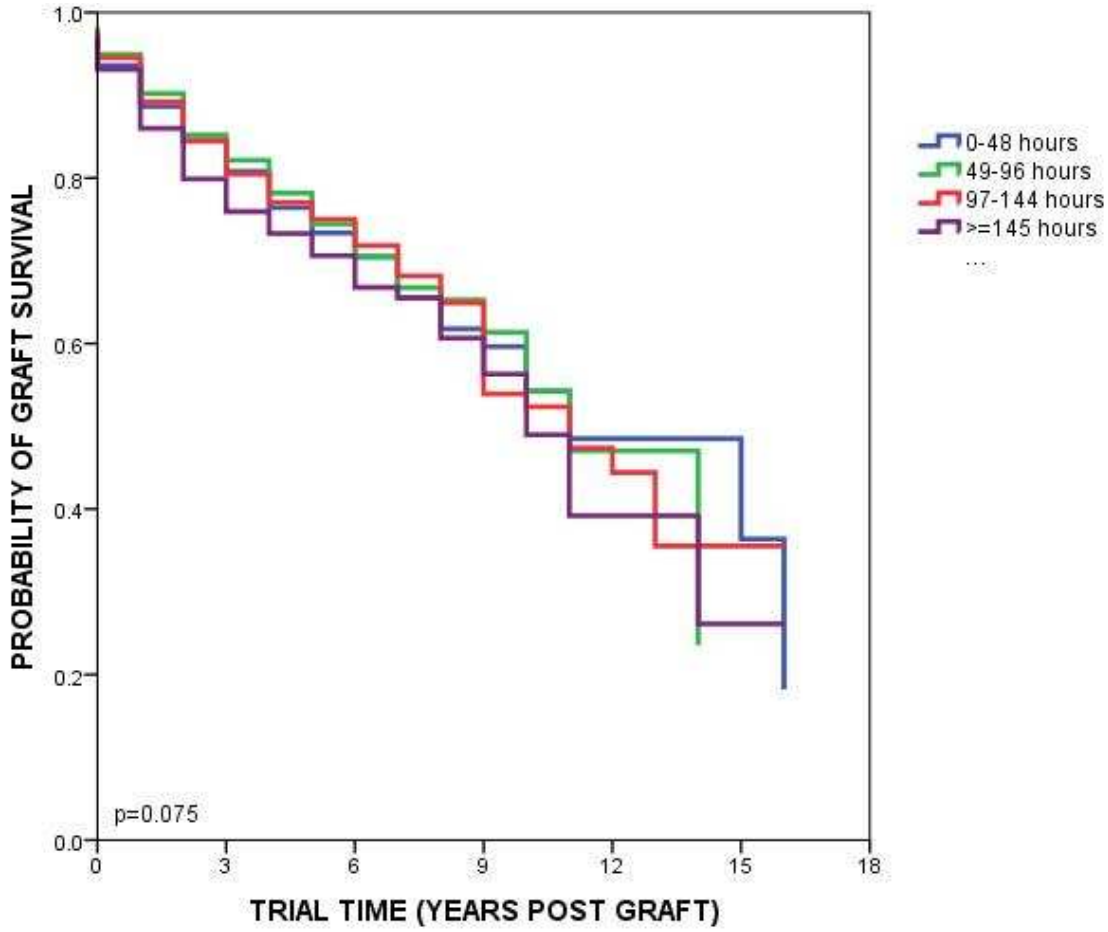
Storage medium	No. of Grafts	
Optisol (1991 – present)	10068	50%
M-K medium (1985 – 2002)	4548	23%
CSM (1987 – 2003)	3554	18%
Moist Pot (1985 – present)	332	2%
K-Sol (1987 – 2000)	681	3%
DexSol (1989 – 1999)	186	<1%
Organ Culture (1985 – 1997)	91	<1%
(2007 – present)	334	2%
Other	3	<1%
Unknown to ACGR	155	<1%
Total	**19952**	**100%**

Several types of storage media have now been superseded. Table 2.4 shows the eras in which each was in use. The majority of corneas used in contemporary grafts were stored in Optisol. Organ Culture, used sparingly from 1985 to 1997, has the advantage of allowing longer storage time than Optisol and has had a recent resurgence in use. Small numbers of corneas have continued to be preserved using the Moist Pot technique since the establishment of the Registry.

2.5.1 Optisol storage time

Figure 2.8 compares graft outcome for Optisol-preserved corneas stored for periods of 0-48 hours, 49-96 hours, 97-144 hours and more than 144 hours (Log Rank Statistic=6.902; df=3; p=0.075). The differences are not significant.

Figure 2.8 Optisol storage time (penetrating grafts only)



Number at Risk

Identity	Initially	3 years	6 years	9 years	12 years	15 years	18 years
<=48 hours	1830	670	276	58	10	4	n/a
49 - 96 hours	1937	726	248	50	14	n/a	n/a
97-144 hours	1732	647	259	53	16	3	n/a
>=145 hours	654	203	74	28	8	1	n/a

Identity	No. initially at risk	Graft survival (at years post-graft)				
		1	5	10	15	20
<=48 hours	1830	.89	.73	.54	.36	n/a
49 - 96 hours	1937	.90	.74	.54	n/a	n/a
97-144 hours	1732	.89	.75	.52	.35	n/a
>=145 hours	654	.86	.71	.49	.26	n/a

PENETRATING CORNEAL GRAFT SURVIVAL
OPTISOL STORAGE TIME

0 - 48 hours:	**89% at 1 year**
Mean Survival 10.39 years	**73% at 5 years**
(SE=0.35; 95% CI: 9.70, 11.08)	**54% at 10 years**
Median Survival 11 years	**36% at 15 years**
49 - 96 hours:	**90% at 1 year**
Mean Survival 9.64 years	**74% at 5 years**
(SE=0.28; 95% CI: 9.09, 10.20)	**54% at 10 years**
Median Survival 11 years	
97 - 144 hours:	**89% at 1 year**
Mean Survival 10.10 years	**75% at 5 years**
(SE=0.37; 95% CI: 9.37, 10.84)	**52% at 10 years**
Median Survival approx. 12 years	**36% at 15 years**
≥145 hours:	**86% at 1 year**
Mean Survival 9.47 years	**70% at 5 years**
(SE=0.51; 95% CI: 8.47, 10.47)	**49% at 10 years**
Median Survival 10 years	**26% at 15 years**

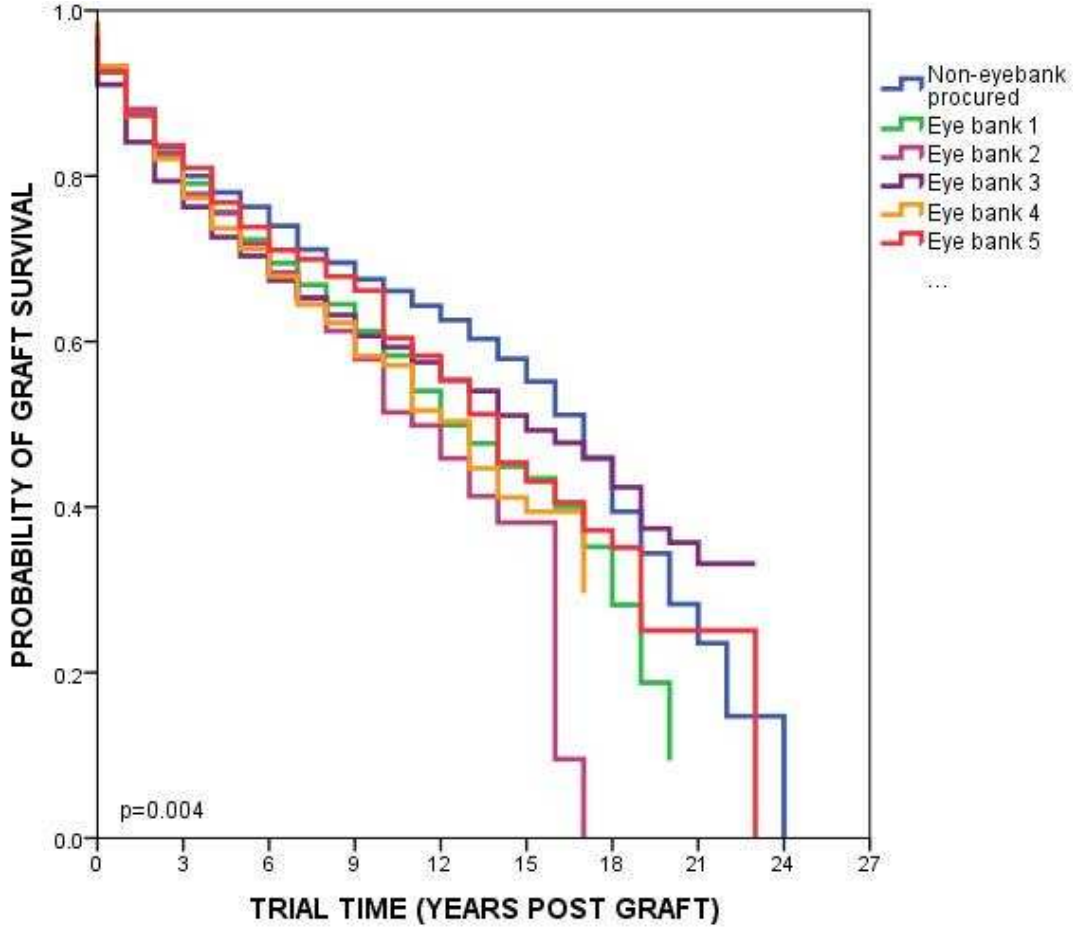
KEY:

n/a	=	not applicable
SE	=	standard error
CI	=	confidence interval
df	=	degrees of freedom
p	=	probability

2.6 DONOR PROCUREMENT SOURCE

Figure 2.9 shows the influence of donor procurement source on corneal graft survival. For the Kaplan-Meier curves below, the Eye Banks have been de-identified. Procurement sources included the Eye Banks in SA, QLD, NSW, WA and VIC (including corneas procured from Victorian Forensic Pathology) and corneas that were privately procured, years ago, by the operating surgeon. Where a surgeon did not record an eye bank number, the graft was included with the eye bank of the State where it was sourced (Log Rank Statistic=17.005, df=5; p=0.004).

Figure 2.9 Corneal procurement source (penetrating grafts only)



Identity	Graft survival (at years post-graft)				
	1	5	10	15	20
Non eye bank	.88	.76	.66	.55	.28
Eye bank 1	.87	.72	.58	.44	.09
Eye bank 2	.88	.72	.51	.38	n/a
Eye bank 3	.84	.70	.59	.49	.36
Eye bank 4	.87	.71	.57	.39	n/a
Eye bank 5	.87	.74	.60	.43	.25

PENETRATING CORNEAL GRAFT SURVIVAL
DONOR CORNEA PROCUREMENT SOURCE

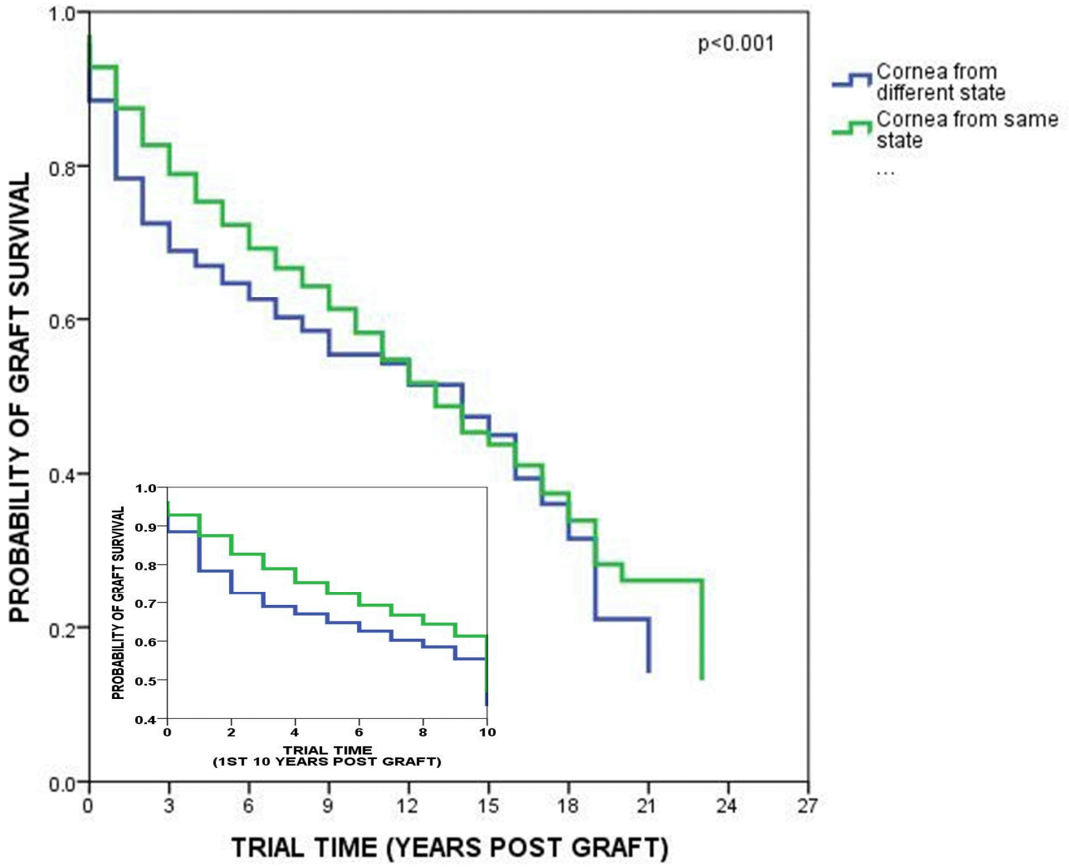
Private procurement:	**88% at 1 year**
Mean Survival 13.99 years	**76% at 5 years**
(SE=0.32; 95% CI: 13.35, 14.62)	**66% at 10 years**
Median Survival 17 years	**55% at 15 years**
	28% at 20 years
Eye bank 1:	**87% at 1 year**
Mean Survival 11.72 years	**72% at 5 years**
(SE=0.21; 95% CI: 11.31, 12.13)	**58% at 10 years**
Median Survival 12 years	**44% at 15 years**
	9% at 20 years
Eye bank 2:	**88% at 1 year**
Mean Survival 10.16 years	**72% at 5 years**
(SE=0.34; 95% CI: 9.50, 10.82)	**51% at 10 years**
Median Survival approx. 11 years	**38% at 15 years**
Eye bank 3:	**84% at 1 year**
Mean Survival 13.32 years	**70% at 5 years**
(SE=0.34; 95% CI: 12.66, 13.99)	**59% at 10 years**
Median Survival 15 years	**49% at 15 years**
	36% at 20 years
Eye bank 4:	**87% at 1 year**
Mean Survival 10.62 years	**71% at 5 years**
(SE=0.23; 95% CI: 10.17, 11.06)	**57% at 10 years**
Median Survival 13 years	**39% at 15 years**
Eye bank 5:	**87% at 1 year**
Mean Survival 12.97 years	**74% at 5 years**
(SE=0.45; 95% CI: 12.09, 13.85)	**60% at 10 years**
Median Survival 14 years	**43% at 15 years**
	25% at 20 years

KEY:

n/a	=	not applicable
SE	=	standard error
CI	=	confidence interval
df	=	degrees of freedom
p	=	probability

Figure 2.10 examines the State in which the cornea was sourced, and the influence that transporting corneas to a different State exerted on graft survival. The inset plot looks in more depth at the first 10 years post graft, where the difference was more apparent. (Log Rank Statistic=27.559; df=1; p<0.001).

Figure 2.10 Cornea origin State and graft operation State



Number At Risk

Identity	Initially	3 years	6 years	9 years	12 years	15 years	18 years	21 years	24 years
Cornea from different State	860	325	178	76	39	20	8	3	n/a
Cornea from same State	13750	5378	2479	1127	562	232	64	15	n/a

Identity	No. initially at risk	Graft survival (at years post-graft)				
		1	5	10	15	20
Cornea from different State	860	.78	.65	.55	.45	.21
Cornea from same State	13750	.88	.72	.58	.44	.26

Grafts performed in the same State from which the cornea originated showed significantly better survival than those performed in a different State. This suggests that something relating to the transportation of corneas from one State to another reduced the likelihood of graft survival. This difference was particularly pronounced in the first 10 years post graft. Sixteen percent of corneas transported interstate were provided for emergency procedures or high risk cases compared to 10% of those performed in the same State, which may be a factor in these analyses.

PENETRATING CORNEAL GRAFT SURVIVAL
CORNEA ORIGIN STATE AND GRAFT OPERATION STATE

Cornea from different State:	**78% at 1 year**
Mean Survival 11.31 years	**65% at 5 years**
(SE=0.497; 95% CI: 10.34, 12.28)	**55% at 10 years**
Median Survival 14 years	**45% at 15 years**
	21% at 20 years
Cornea from same State:	**88% at 1 year**
Mean Survival 12.73 years	**72% at 5 years**
(SE=0.19; 95% CI: 12.36, 13.10)	**58% at 10 years**
Median Survival 13 years	**44% at 15 years**
	26% at 20 years

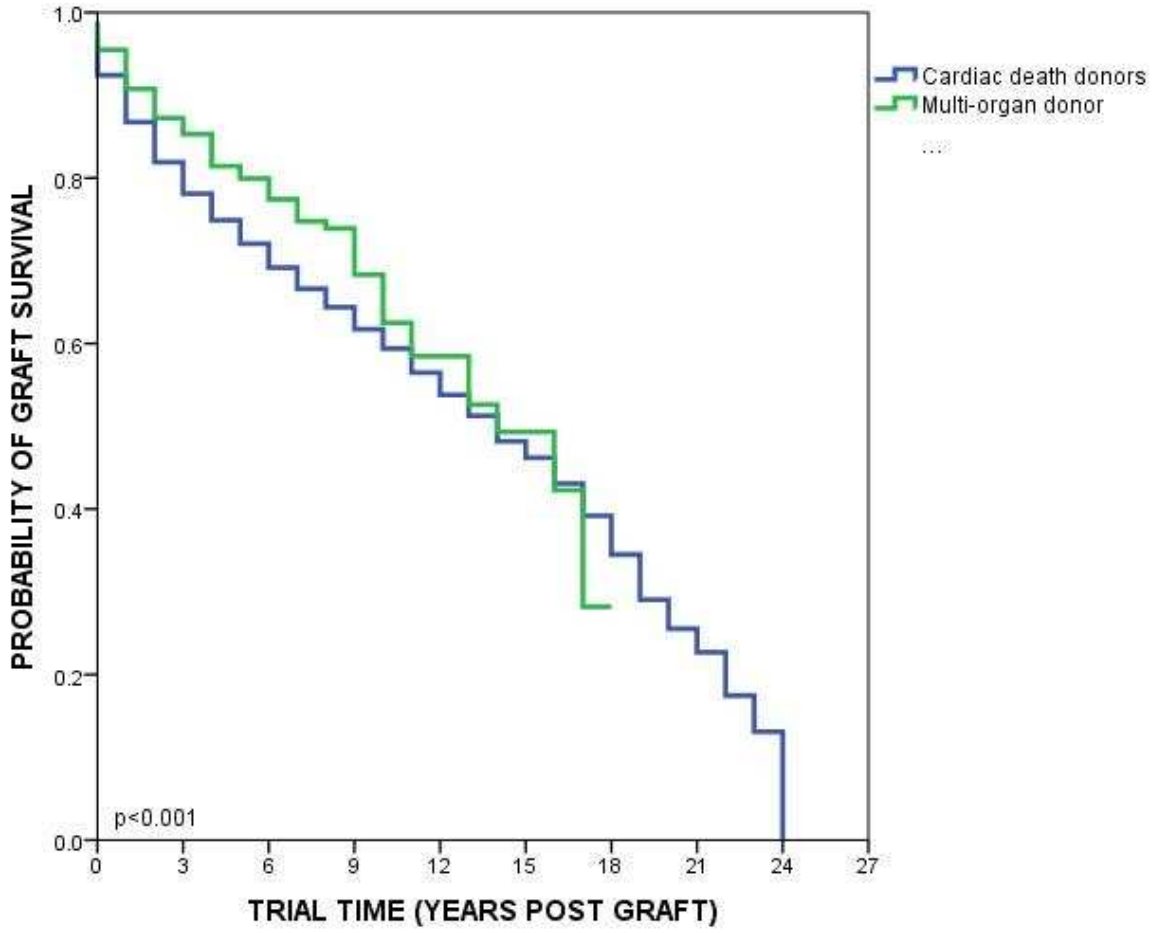
KEY:

n/a	=	not applicable
SE	=	standard error
CI	=	confidence interval
df	=	degrees of freedom
p	=	probability

2.7 MULTI-ORGAN DONORS

One thousand, six hundred and eighty one corneas, representing 7% of those registered, were collected from multi-organ donors and used for 1,414 penetrating, 258 lamellar and 9 limbal grafts. Follow-up after graft has been recorded for 1,019 penetrating grafts, 116 lamellar grafts and 8 limbal grafts. Figure 2.11 shows the survival curve for the 1,019 penetrating grafts for which follow-up was available (Log Rank Statistic=17.351; df=1; p=0.001). Forty four percent of corneas retrieved from multi-organ donors were used for keratoconic recipients.

Figure 2.11 Multi-organ donors (penetrating grafts only)



Number at Risk

Identity	Initially	3 years	6 years	9 years	12 years	15 years	18 years	21 years	24 years
Cardiac death donors	15272	6193	3092	1519	837	388	134	36	1
Multi-organ donors	1019	407	160	66	23	12	2	n/a	n/a

Identity	No. initially at risk	Graft survival (at years post-graft)				
		1	5	10	15	20
Cardiac death donors	15272	.87	.72	.59	.46	.26
Multi-organ donors	1019	.91	.80	.63	.79	n/a

PENETRATING CORNEAL GRAFT SURVIVAL
MULTI-ORGAN DONORS

Cardiac death donors:	**87% at 1 year**
Mean Survival 12.88 years	**72% at 5 years**
(SE=0.17; 95% CI: 12.55, 13.21)	**59% at 10 years**
Median Survival 14 years	**46% at 15 years**
	26% at 20 years
Multi-organ donors:	**91% at 1 year**
Mean Survival 12.16 years	**80% at 5 years**
(SE=0.47; 95% CI: 11.24, 13.07)	**63% at 10 years**
Median Survival 14 years	**49% at 15 years**

KEY:
n/a = not applicable
SE = standard error
CI = confidence interval
df = degrees of freedom
p = probability

2.7.1 Multi-Organ Donors vs. Cardiac Death Donors

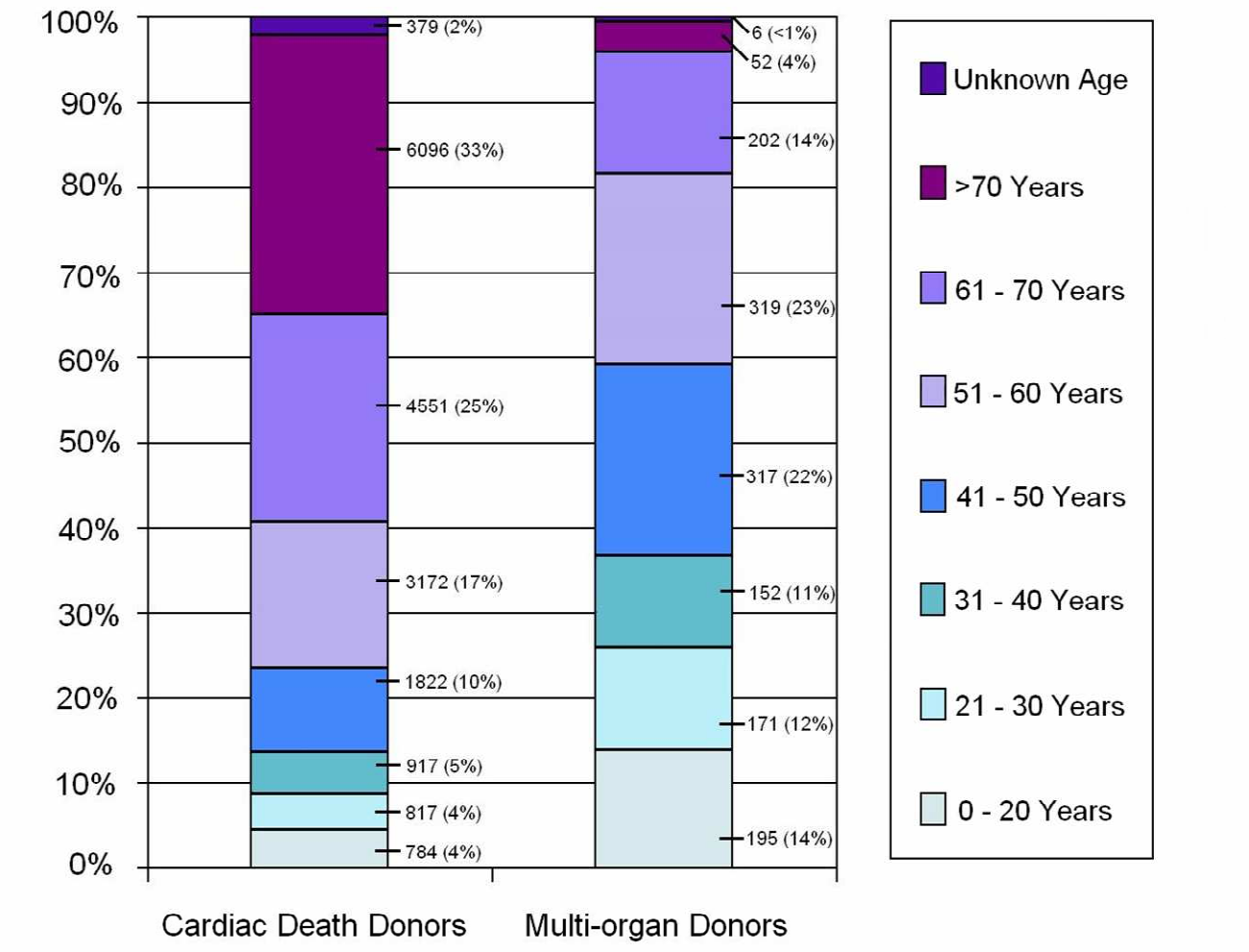
Tables 2.5, 2.6, and 2.7 compare sex, cause of death, death-to-enucleation times and death-to-graft times of multi-organ donors and cardiac death donors.

Table 2.5 Sex of multi-organ donors (penetrating grafts only)

	Multi-organ donors		Cardiac death donors	
Sex	**No. of eyes**	**%**	**No. of eyes**	**%**
Male	784	56%	11451	62%
Female	609	43%	6280	34%
Unknown to ACGR	21	1%	807	4%
Total	**1414**	**100%**	**18538**	**100%**

Figure 2.12 compares age of multi-organ and cardiac death donors.

Figure 2.12 Age of multi-organ donors (penetrating grafts only)



Multi-organ donors were generally younger than were cardiac death donors.

Table 2.6 Cause of donor death in cardiac death and multi-organ donors (penetrating grafts only)

Cause of Donor Death	Multi-organ Donor		Cardiac Death Donors	
	No. of eyes	%	No. of eyes	%
Cardiac/circulatory	84	6%	5887	32%
Malignancy	22	2%	3572	19%
Stroke/bleed	813	57%	3038	16%
Respiratory	19	1%	1931	10%
Trauma/accident/poisoning	319	23%	1798	10%
Other specified cause	152	11%	1206	7%
Unknown	5	<1%	1106	6%
Total	**1414**	**100%**	**18538**	**100%**

Table 2.7 Death-to-enucleation and death-to-graft times for multi-organ donors

	Multi-organ donors		Cardiac Death donors	
	Death-to-enucleation time	**Death-to-graft time**	**Death-to - enucleation time**	**Death-to-graft time**
Median time (hours)	3	83	7	82
Range (hours)	1-23	3-1664	1-129	2-1183
Number of grafts with data available	**1560 (98%)**	**1196 (75%)**	**20222 (98%)**	**17076 (82%)**

An independent samples t-test indicated that the death to enucleation time for corneas from multi-organ donors (M=4.07 hours, SD=3.68) was shorter than for corneas from cardiac death donors (M=7.45 hours, SD=4.64) and that this difference was significant (t=34.47, p<0.001). The magnitude of the differences in the means (mean difference=3.38, 95% CI: 3.19 to 3.57) was small to moderate (eta squared=.053).

2.8 PRIMARY NON-FUNCTIONING GRAFTS

Grafts that fail to clear in the early post-operative period are considered to be primary non-functioning grafts.

Thus far, 243 primary non-functioning grafts have been recorded by 83 surgeons, out of the 18,139 grafts that have been followed. This number represents penetrating, lamellar and limbal grafts (census date 01/06/10 for penetrating and limbal grafts, 12/10/2011 for lamellar grafts). Of these, four 'pairs' of cornea (from the same donor), representing eight (8) primary non-functioning grafts, have been recorded in the Australian Corneal Graft Registry. The remaining 235 primary non-functioning grafts were from separate donors.

151 (62%) of the primary non-functioning grafts were penetrating grafts, including the four pairs of corneas. Table 2.8 shows features of corneas used in primary non-functioning penetrating grafts as compared to the features of all penetrating grafts.

Table 2.8 Features of primary non-functioning grafts (penetrating grafts only)

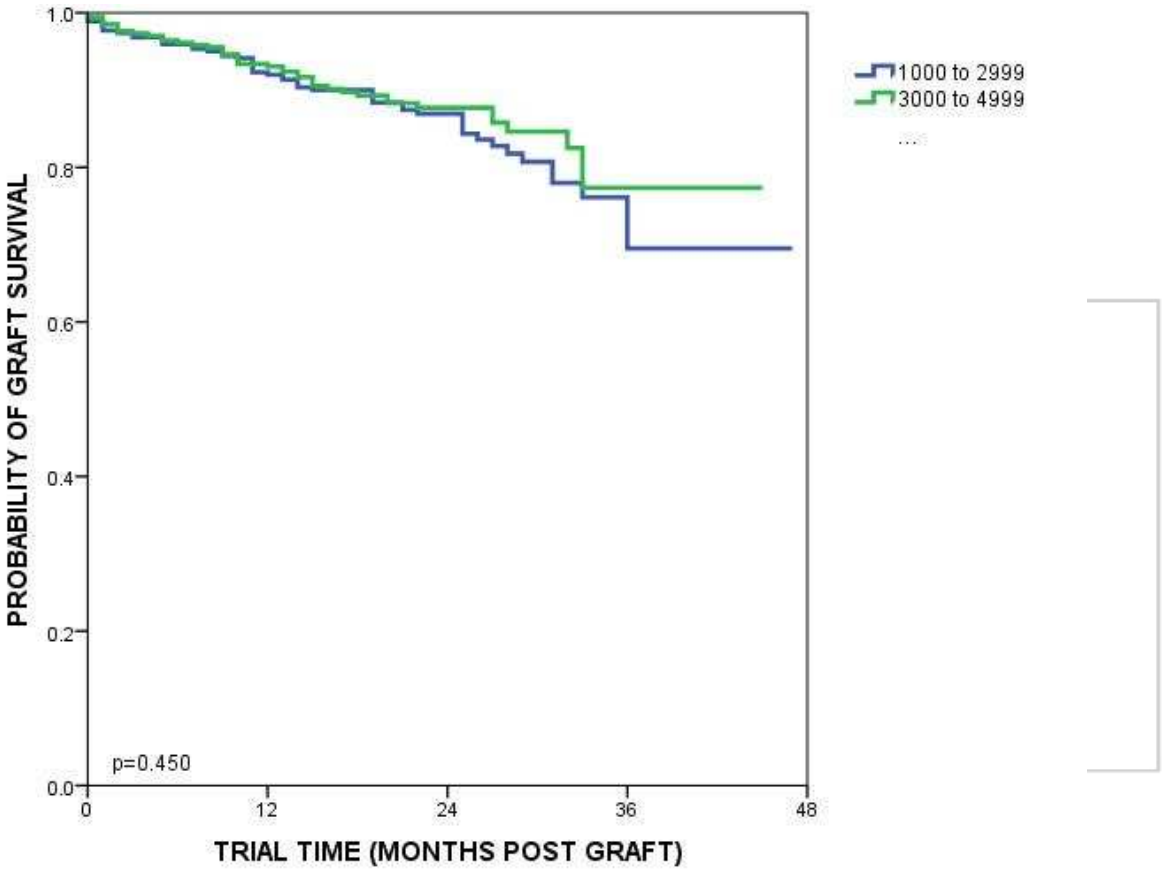
Feature	Primary Failures		All Penetrating Grafts	
	No.	%	No.	%
Procurement source:				
Private:	4	3%	1710	9%
Eyebank:	147	97%	18242	91%
1	79	52%	7137	36%
4	23	15%	3795	19%
3	22	15%	2466	12%
2	15	10%	2819	14%
5	8	5%	2025	10%
Death to enucleation times				
≤6 hours	63	42%	9914	50%
>6 hours	88	58%	9982	50%
Unknown to ACGR	0	0%	56	<1%
Storage medium				
Optisol	59	39%	10066	51%
CSM	53	35%	3556	18%
MK medium	30	20%	4548	23%
Moist pot	3	2%	332	2%
K-Sol	3	2%	681	3%
Other	0	0%	614	3%
Unknown to ACGR	3	2%	155	<1%
Donor age				
≤10 years	1	<1%	143	<1%
11 to 20 years	4	3%	836	4%
21 to 60 years	45	30%	7687	39%
61 to 80 years	84	56%	9439	47%
>80 years	13	9%	1462	7%
Unknown to ACGR	4	3%	385	2%
Main indication for graft				
Keratoconus	43	28%	6149	31%
Pseudophakic bullous keratopathy	39	26%	3850	19%
Previous failed graft	22	15%	3563	18%
Aphakic bullous keratopathy	12	8%	928	5%
Fuchs' dystrophy	9	6%	1243	6%
Scars	6	4%	1282	6%
Perforation	6	4%	465	2%
Interstitial keratitis/abscess	3	2%	232	1%
Peters' anomaly	2	1%	30	<1%
Miscellaneous	9	6%	2210	11%
Total corneas	**151**	**100%**	**19952**	**100%**

A total of 17 primary non-function grafts were recorded in the past 5 years.

2.9 DONOR CORNEAL ENDOTHELIAL CELL COUNT

In recent years, the Registry has been collecting information on donor corneal endothelial cell counts as depicted in Figure 2.13. Due to the short time period over which these data have been collected, all analyses are calculated in months post graft (Log Rank Statistic=0.570; df=1; p=0.450). Donor corneal endothelial cell count, as stratified, exerted no significant influence on penetrating graft survival.

Figure 2.13 Donor corneal endothelial cell count (penetrating grafts only)



Number at Risk

Identity	Initially	12 months	24 months	36 months	48 months
1000 to 2999 cells/mm^2	362	298	146	23	0
3000 to 4999 cells/mm^2	349	287	120	14	n/a

Identity	No. initially at risk	Graft survival (at years post-graft)		
		1	2	3
1000 to 2999 cells/mm^2	362	.92	.87	.70
3000 to 4999 cells/mm^2	349	.93	.88	.77

*Range chosen as only 42 donors available with endothelial cell count below 2400 cells/mm^2, however, when compared, stratification had no effect on graft survival.

PENETRATING CORNEAL GRAFT SURVIVAL
DONOR ENDOTHELIAL CELL COUNT

1000 to 2999 cells/mm^2 :	**92% at 1 year**
Mean Survival 39.53 months	**87% at 2 years**
(SE=0.98; 95% CI: 37.60, 41.45)	**70% at 3 years**
Median Survival approx 47 months	
3000 to 4999 cells/mm^2 :	**93% at 1 year**
Mean Survival 39.32 months	**88% at 2 years**
(SE=0.86; 95% CI: 37.64, 41.00)	**77% at 3 years**
Median Survival approx 45 months	

KEY:

	n/a	=	not applicable
	SE	=	standard error
	CI	=	confidence interval
	df	=	degrees of freedom
	p	=	probability

2.10 SUMMARY OF DONOR AND EYE-BANKING INFORMATION

- The most common causes of donor death were related to diseases of the cardiac/circulatory system, followed by malignancy and strokes and other haemorrhages. No influence of cause of donor death on penetrating graft survival was observed, other than that corneas collected from victims of traumatic or accidental death appeared to show improved survival. However, such corneas were preferentially used for recipients with keratoconus.

- Corneas used for transplantation were collected from men and women in the ratio of approximately 1.8:1.

- Approximately 69% of corneas were retrieved from donors aged 51-80 years at the time of death. Donor age exerted no influence on survival of grafts performed for keratoconus, but for all other indications for penetrating keratoplasty, better survival was achieved with corneas from younger donors, at least in univariate analysis. However, the effect disappears in multivariate analysis (see Chapter 9).

- Median death-to-enucleation time for penetrating grafts was 7 hours. Median death-to-graft time was 79 hours. Neither death-to-enucleation nor death-to-graft time affected corneal graft survival significantly.

- Most corneas are currently stored in Optisol in Eye Banks. Corneal storage time in Optisol did not affect graft survival.

- Over 92% of all corneas used for penetrating grafts were retrieved from cardiac death donors and 8% from multi-organ donors. The multi-organ donor pool had quite different characteristics from the pool from which the majority of corneas were drawn. In particular, multi-organ donors tended to be younger and were more likely to have died from strokes/haemorrhage or from traumatic or accidental death than cardiac death donors. Corneas from multi-organ donors exhibited better survival after transplantation than did those from cardiac death donors, however, 44% of these cornea were used for recipients with keratoconus.

- Fewer than 1% of corneas used in penetrating grafts failed to function in the immediate post-operative period.

- Grafts performed in the same State from which the cornea originated have better graft survival than those performed in a different State. This is particularly pronounced in the first 10 years post graft.

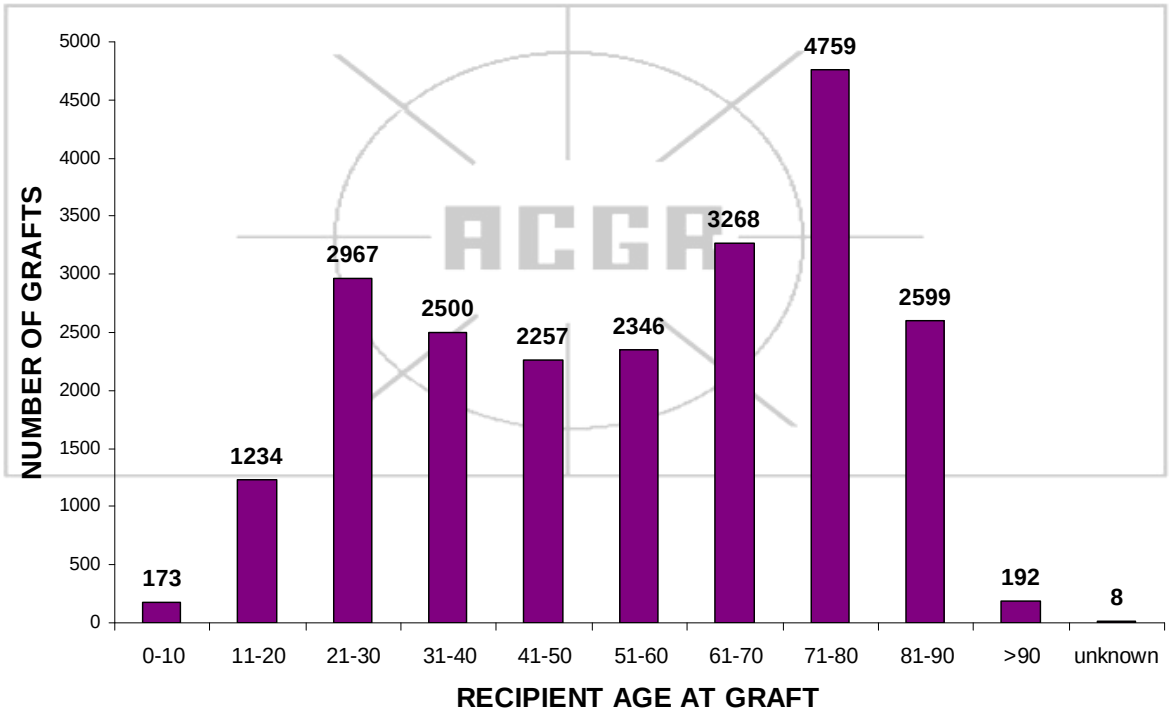
- Donor corneal endothelial cell count has no significant influence on penetrating graft survival.

3. RECIPIENT AGE AND SEX

3.1 RECIPIENT AGE AT GRAFT

Recipient age at graft varied from 14 days to 97 years and 5 months with a median age of 59 years. Figure 3.1 shows the spread of recipient ages, with peaks in the 21-40 and 61-80 age ranges.

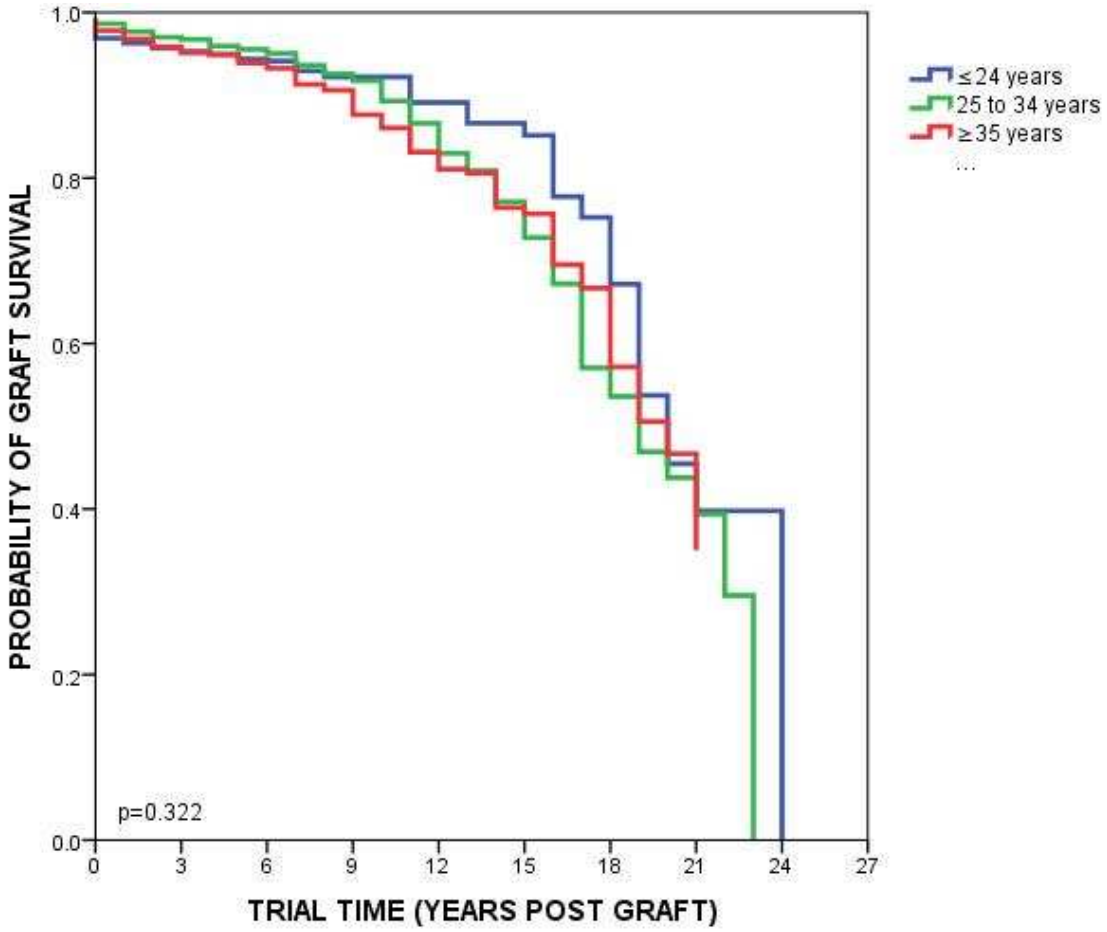
Figure 3.1 Age at graft



Except where indicated, all Kaplan-Meier plots and associated tables in this chapter have been calculated using penetrating grafts only.

Figure 3.2 shows graft survival for all penetrating grafts for keratoconus. Age at graft had no significant effect on survival in this cohort (Log Rank Statistic=2.267; df=2; p= 0.322).

Figure 3.2 Recipient age (keratoconus only)



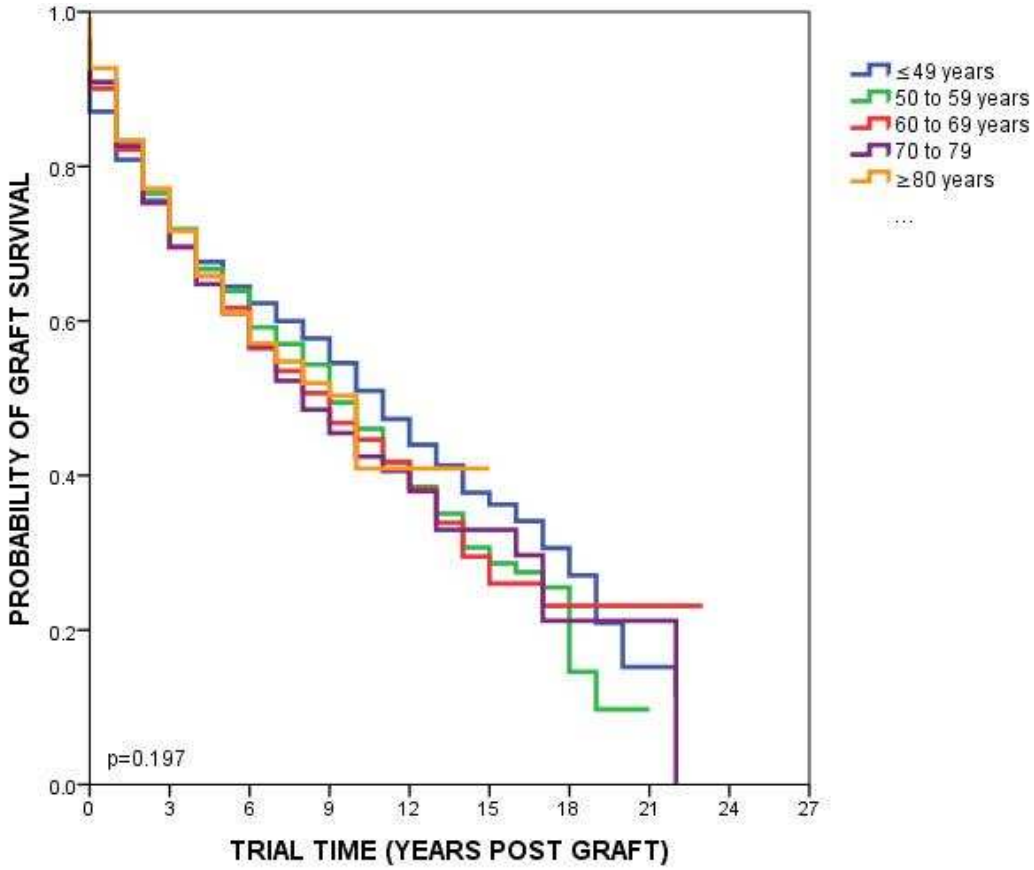
Number at Risk

Identity	Initially	3 years	6 years	9 years	12 years	15 years	18 years	21 years	24 years
≤24 years	1478	737	380	214	122	59	28	8	1
25 - 34 years	1619	754	400	223	143	89	33	10	0
≥35 years	1775	930	577	337	201	100	35	8	n/a

Identity	No. initially at risk	Graft survival (at years post-graft)				
		1	5	10	15	20
≤24 years	1478	.96	.94	.89	.85	.45
25 - 34 years	1619	.98	.96	.89	.73	.44
≥35 years	1775	.97	.94	.86	.76	.47

Figure 3.3 shows graft survival for all penetrating grafts excluding keratoconus. Age at graft had no significant effect on graft survival when keratoconus is excluded (Log Rank Statistic=6.029; df=4; p=0.197).

Figure 3.3 Recipient age (keratoconus excluded)



Number at Risk

Identity	Initially	3 years	6 years	9 years	12 years	15 years	18 years	21 years	24 years
≤49 years	2060	868	454	235	142	73	26	5	n/a
50 - 59 years	1235	529	273	144	77	30	7	n/a	n/a
60 - 69 years	2102	907	471	224	109	34	5	1	n/a
70 - 79 years	3548	1316	541	176	62	14	2	1	n/a
≥80 years	2467	558	156	32	4	1	n/a	n/a	n/a

Identity	No. initially at risk	Graft survival (at years post-graft)				
		1	5	10	15	20
≤49 years	2060	.81	.62	.51	.36	.15
50 - 59 years	1235	.64	.46	.29	.10	n/a
60 - 69 years	2102	.82	.62	.45	.26	.23
70 - 79 years	3548	.83	.61	.42	.30	.21
≥80 years	2467	.83	.61	.41	n/a	n/a

PENETRATING CORNEAL GRAFT SURVIVAL
RECIPIENT AGE; KERATOCONUS ONLY

Aged ≤24 years:	**96% at 1 year**
Mean Survival 19.13 years	**94% at 5 years**
(SE=0.53; 95% CI: 18.08, 20.17)	**89% at 10 years**
Median Survival 20 years	**85% at 15 years**
	46% at 20 years
Aged 25 to 34 years:	**98% at 1 year**
Mean Survival 17.82 years	**96% at 5 years**
(SE=0.41; 95% CI: 17.00, 18.63)	**89% at 10 years**
Median Survival 19 years	**73% at 15 years**
	44% at 20 years
Aged ≥35 years:	**97% at 1 year**
Mean Survival 17.11 years	**94% at 5 years**
(SE=0.29; 95% CI: 16.53, 17.68)	**86% at 10 years**
Median Survival 20 years	**76% at 15 years**
	47% at 20 years

PENETRATING CORNEAL GRAFT SURVIVAL
RECIPIENT AGE; EXCLUDING KERATOCONUS

Aged ≤49 years:	**81% at 1 year**
Mean Survival 10.82 years	**62% at 5 years**
(SE=0.30; 95% CI: 10.24, 11.41)	**51% at 10 years**
Median Survival 11 years	**36% at 15 years**
	15% at 20 years
Aged 50 - 59 years:	**83% at 1 year**
Mean Survival 9.80 years	**64% at 5 years**
(SE=0.25; 95% CI: 9.11, 10.49)	**46% at 10 years**
Median Survival 9 years	**29% at 15 years**
	10% at 20 years
Aged 60 - 69 years:	**82% at 1 year**
Mean Survival 10.31 years	**62% at 5 years**
(SE=0.37; 95% CI: 9.59, 11.03)	**45% at 10 years**
Median Survival 9 years	**26% at 15 years**
	23% at 20 years
Aged 70 - 79 years:	**83% at 1 year**
Mean Survival 10.03 years	**61% at 5 years**
(SE=0.41; 95% CI: 9.22, 10.83)	**42% at 10 years**
Median Survival 8 years	**30% at 15 years**
	21% at 20 years
Aged ≥80 years:	**83% at 1 year**
Mean Survival 8.70 years	**61% at 5 years**
(SE=0.35; 95% CI: 8.02, 9.38)	**41% at 10 years**
Median Survival 10 years	

KEY:

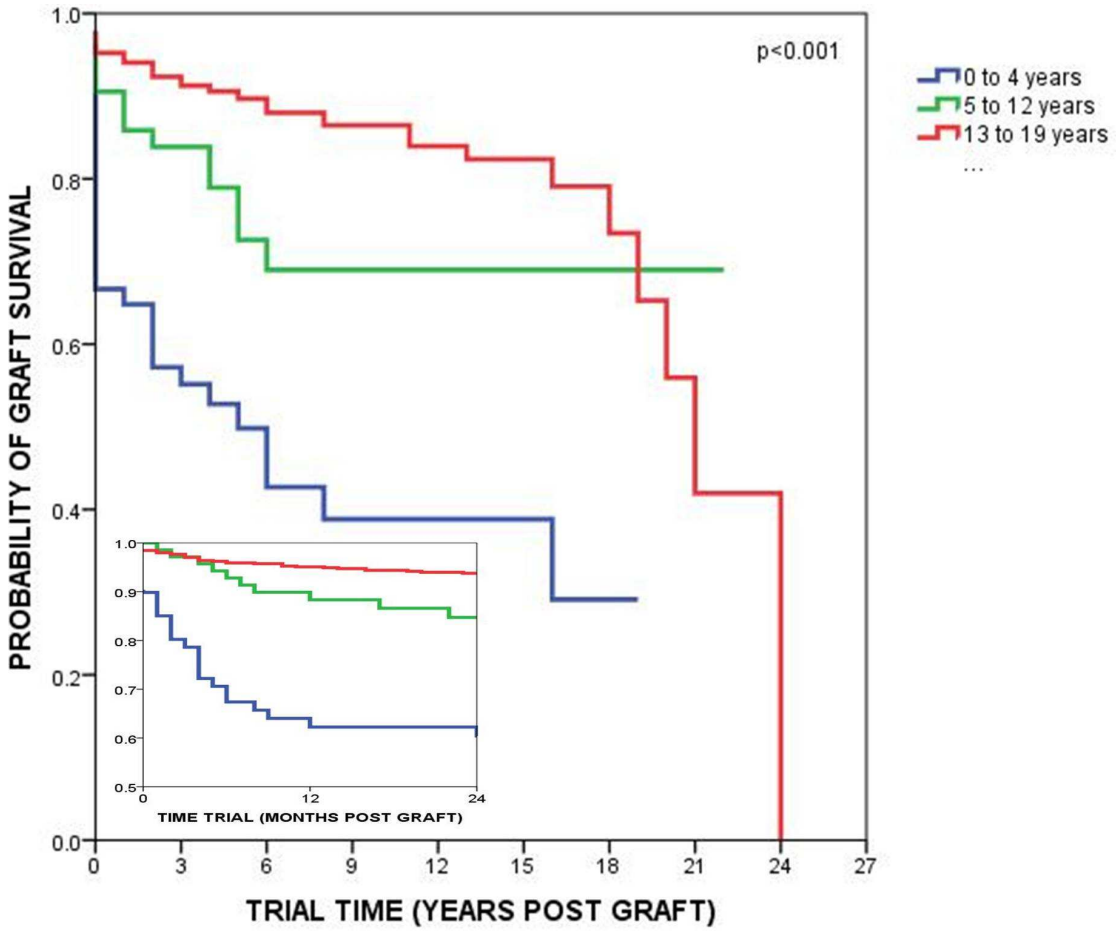
n/a	=	not applicable
SE	=	standard error
CI	=	confidence interval
df	=	degrees of freedom
p	=	probability

3.1.1 Infant, child and adolescent recipients

3.1.1.1 Paediatric recipients

The Registry database has records of 793 penetrating graft recipients who were under the age of 20 years at the time of graft and who had been followed since graft. Figure 3.4 shows the effect of age group of recipients on corneal graft survival (Log Rank Statistic=87.022; df=2; p=0.001). The inset highlights corneal graft survival in the first 24 months post graft.

Figure 3.4 Infant (aged 0-4 years at graft), child (aged 5-12 years at graft) and adolescent (aged 13-19 years at graft) recipients



Number at Risk

Identity	Initially	3 years	6 years	9 years	12 years	15 years	18 years	21 years	24 years
0 – 4 years	69	28	14	8	8	5	2	n/a	n/a
5 – 12 years	74	36	20	11	7	3	2	1	n/a
13 – 19 years	650	342	158	97	58	30	14	4	1

Identity	No. initially at risk	Graft survival (at years post-graft)				
		1	5	10	15	20
0 – 4 years	69	.65	.50	.39	n/a	n/a
5 – 12 years	74	.86	.73	n/a	n/a	n/a
13 – 19 years	650	.94	.90	.84	.79	.56

PENETRATING CORNEAL GRAFT SURVIVAL
INFANT, CHILD AND ADOLESCENT RECIPIENTS

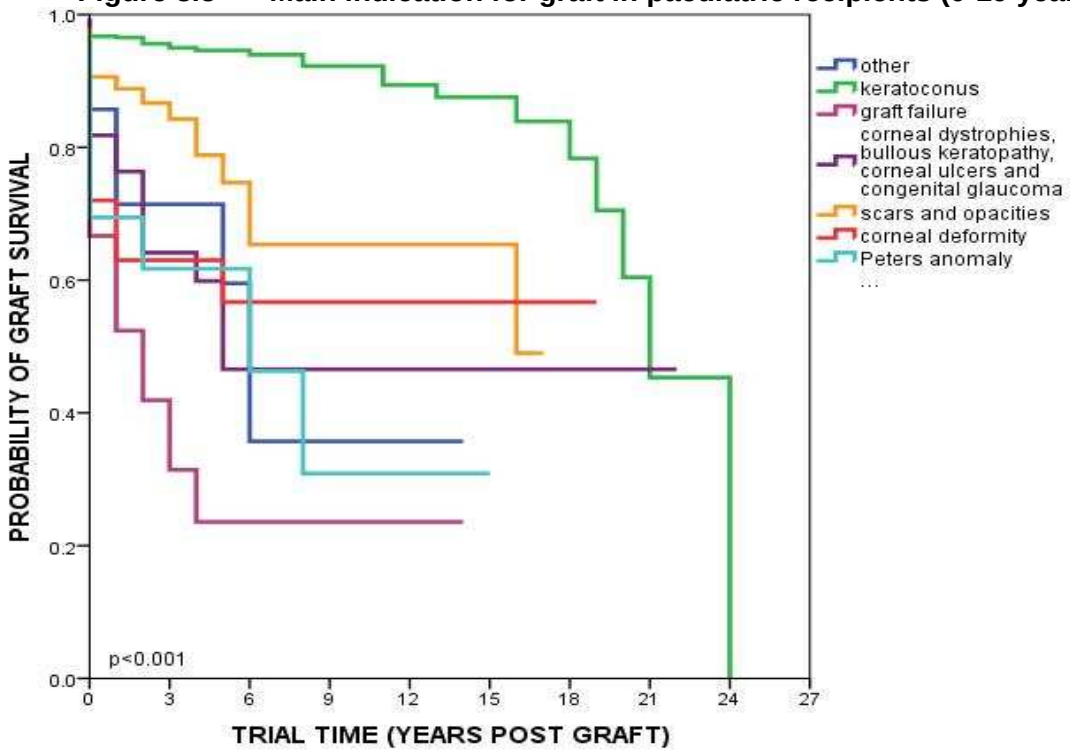
Aged 0 - 4 years:	**65% at 1 year**
Mean Survival 8.30 years	**50% at 5 years**
(SE=1.20; 95% CI: 5.95, 10.65)	**39% at 10 years**
Median Survival 5 years	**29% at 15 years**
Aged 5 - 12 years:	**86% at 1 year**
Mean Survival 15.99 years	**73% at 5 years**
(SE=1.33; 95% CI: 13.38, 18.61)	
Median Survival approx. 22 years	
Aged 13 - 19 years:	**94% at 1 year**
Mean Survival 18.82 years	**90% at 5 years**
(SE=0.75; 95% CI: 17.35, 20.30)	**84% at 10 years**
Median Survival 21 years	**79% at 15 years**
	56% at 20 years

KEY:

n/a	=	not applicable
SE	=	standard error
CI	=	confidence interval
df	=	degrees of freedom
p	=	probability

Figure 3.5 shows main indications for corneal grafts in recipients under 20 years of age at time of graft (Log Rank Statistic=174.190; df=6; p=0.001).

Figure 3.5 Main indication for graft in paediatric recipients (0-19 years)



Number at Risk

Identity	Initially	3 years	6 years	9 years	12 years	15 years	18 years	21 years	24 years
Keratoconus	582	313	149	89	54	29	15	4	1
Failed previous graft	21	8	2	1	1	1	n/a	n/a	n/a
Corneal dystrophies, bullous keratopathy, corneal ulcer and congenital glaucoma	44	20	7	5	3	1	n/a	n/a	n/a
Scars and opacities	64	36	16	10	6	4	0	n/a	n/a
Corneal deformity	25	10	9	7	5	3	2	n/a	n/a
Peters' anomaly	36	12	4	2	2	1	n/a	n/a	n/a
Other	21	7	5	2	2	0	n/a	n/a	n/a

Identity	No. initially at risk	Graft survival (at years post-graft)				
		1	5	10	15	20
Keratoconus	582	.97	.95	.89	.88	.60
Failed previous graft	21	.52	.24	n/a	n/a	n/a
Corneal dystrophies, bullous keratopathy, corneal ulcer and congenital glaucoma	44	.76	.47	n/a	n/a	n/a
Scars and opacities	64	.89	.75	.65	.49	n/a
Corneal deformity	25	.63	.57	n/a	n/a	n/a
Peters' anomaly	36	.62	.46	.31	n/a	n/a
Other	21	.71	.60	.36	n/a	n/a

Note: Corneal dystrophies, bullous keratopathy, corneal ulcer and congenital glaucoma have been combined in these analyses due to small numbers in each category.

PENETRATING CORNEAL GRAFT SURVIVAL
INDICATION FOR GRAFT - PAEDIATRIC RECIPIENTS

Other:	**71% at 1 year**
Mean Survival 7.17 years	**60% at 5 years**
(SE=1.60; 95% CI: 4.03, 10.30)	**36% at 10 years**
Median Survival 6 years	
Keratoconus:	**97% at 1 year**
Mean Survival 19.92 years	**95% at 5 years**
(SE=0.77; 95% CI: 18.41, 21.43)	**89% at 10 years**
Median Survival 21 years	**88% at 15 years**
	60% at 20 years
Failed previous graft:	**52% at 1 year**
Mean Survival 4.28 years	**24% at 5 years**
(SE=1.30; 95% CI: 1.73, 6.83)	
Median Survival 2 years	
Corneal dystrophies, bullous keratopathy, corneal ulcer and congenital glaucoma:	**92% at 1 year**
Mean Survival 11.38 years	
(SE=2.00; 95% CI: 7.47, 15.29)	
Median Survival 5 years	
Scars and opacities:	**89% at 1 year**
Mean Survival 12.06 years	**75% at 5 years**
(SE=1.10; 95% CI: 9.90, 14.23)	**65% at 10 years**
Median Survival 16 years	**49% at 15 years**
Corneal deformity:	**63% at 1 year**
Mean Survival 11.18 years	**57% at 5 years**
(SE=1.90; 95% CI: 7.45, 14.91)	
Median Survival approx. 19 years	
Peters' anomaly:	**62% at 1 year**
Mean Survival 6.94 years	**46% at 5 years**
(SE=1.54; 95% CI: 3.92, 9.97)	**31% at 10 years**
Median Survival 6 years	

KEY:

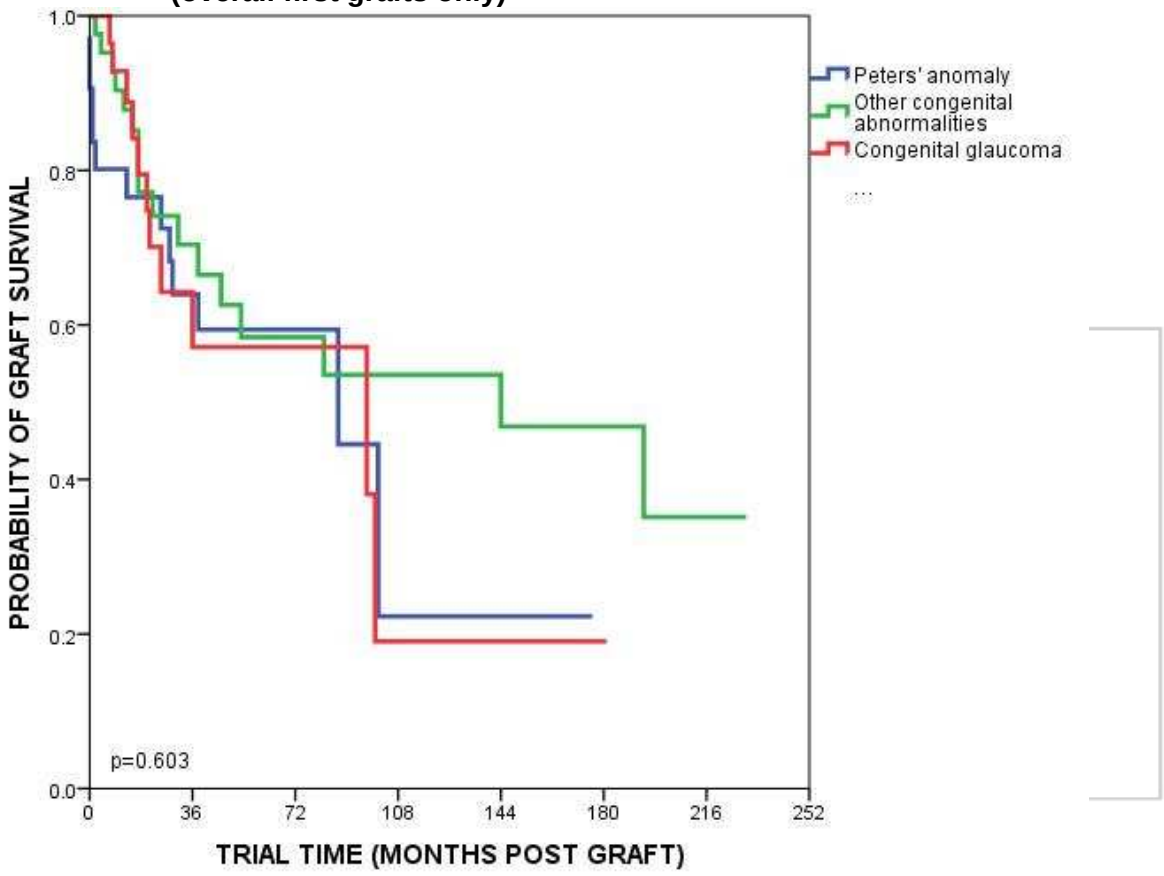
n/a	=	not applicable
SE	=	standard error
CI	=	confidence interval
df	=	degrees of freedom
p	=	probability

3.1.1.2 Congenital abnormalities

One hundred and four *first* ipsilateral grafts were performed for congenital abnormalities, including Peters' anomaly (32), congenital glaucoma (29), aniridia (15), congenital cataract (13), congenital opacities (7), anterior segment anomalies (3), congenital endothelial dystrophy (1), anophthalmos (1) and unspecified anomaly (3).

Figure 3.6 shows the effect of Peters' anomaly, congenital glaucoma or other congenital abnormality as the indication for graft (Log Rank Statistic=0.761; df=2; p=0.603). Trial time is plotted at monthly intervals. Corneal grafts for these conditions were performed at any age, not only during childhood.

Figure 3.6 Peters' anomaly or other congenital abnormalities (overall first grafts only)



Number at Risk

Identity	Initially	3 years	6 years	9 years	12 years	15 years	18 years	21 years	24 years
Peters' anomaly	32	14	4	2	1	n/a	n/a	n/a	n/a
Other congenital abnormality	43	19	13	9	8	4	2	n/a	n/a
Congenital glaucoma	29	9	5	3	1	1	n/a	n/a	n/a

Identity	No. initially at risk	Graft survival (at years post-graft)				
		1	3	8	12	20
Peters' anomaly	32	.78	.61	.23	n/a	n/a
Other congenital abnormality	43	.76	.65	.56	.49	n/a
Congenital glaucoma	29	.75	.61	.20	n/a	n/a

FIRST OVERALL CORNEAL GRAFT SURVIVAL
CONGENITAL ABNORMALITIES

Peters' anomaly:	**78% at 1 year**
Mean Survival 6.49 years	**61% at 3 years**
(SE=1.38; 95% CI: 3.77, 9.20)	**23% at 8 years**
Median Survival 7 years	
Other congenital abnormality:	**76% at 1 year**
Mean Survival 10.65 years	**65% at 3 years**
(SE=1.47; 95% CI: 7.76, 13.53)	**56% at 8 years**
Median Survival 12 years	**49% at 12 years**
Congenital glaucoma:	**75% at 1 year**
Mean Survival 8.61 years	**61% at 3 years**
(SE=1.51; 95% CI: 3.85, 9.77)	**20% at 8 years**
Median Survival 8 years	

KEY:

n/a	=	not applicable
SE	=	standard error
CI	=	confidence interval
df	=	degrees of freedom
p	=	probability

3.1.1.3 Visual Acuity in Paediatric Recipients

Figure 3.7 Best corrected Snellen acuity in grafted eye of paediatric recipients at most recent follow-up, stratified by age group

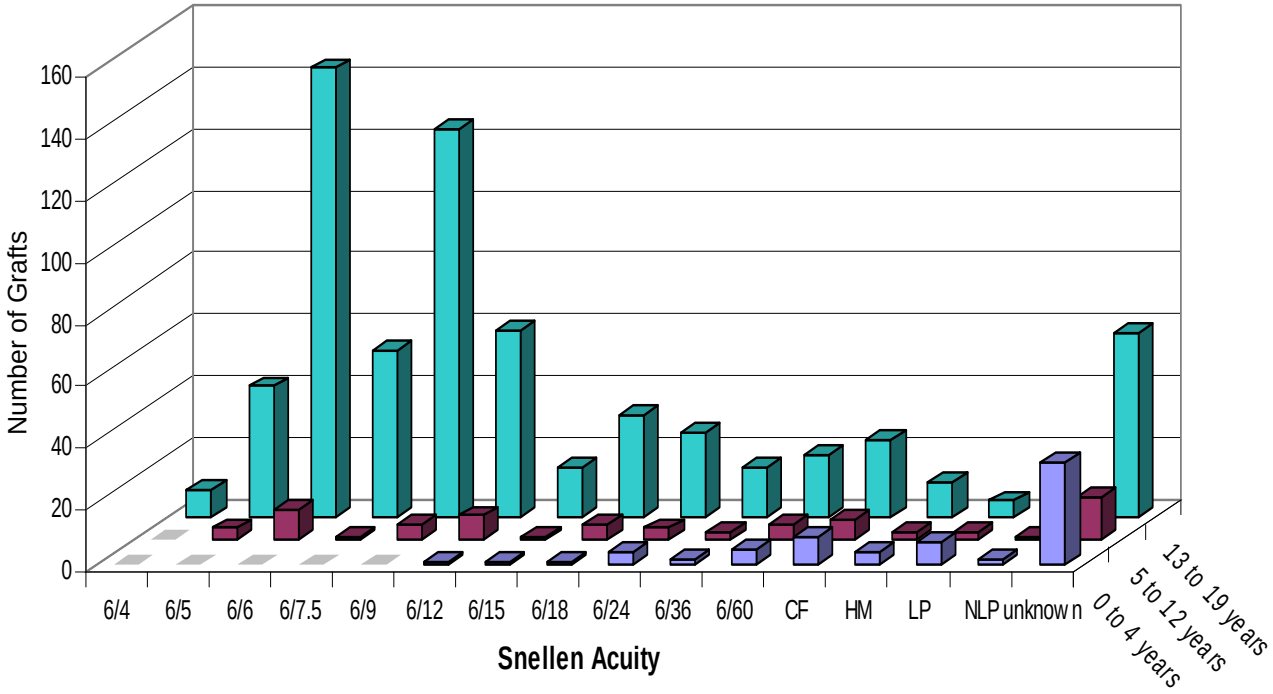
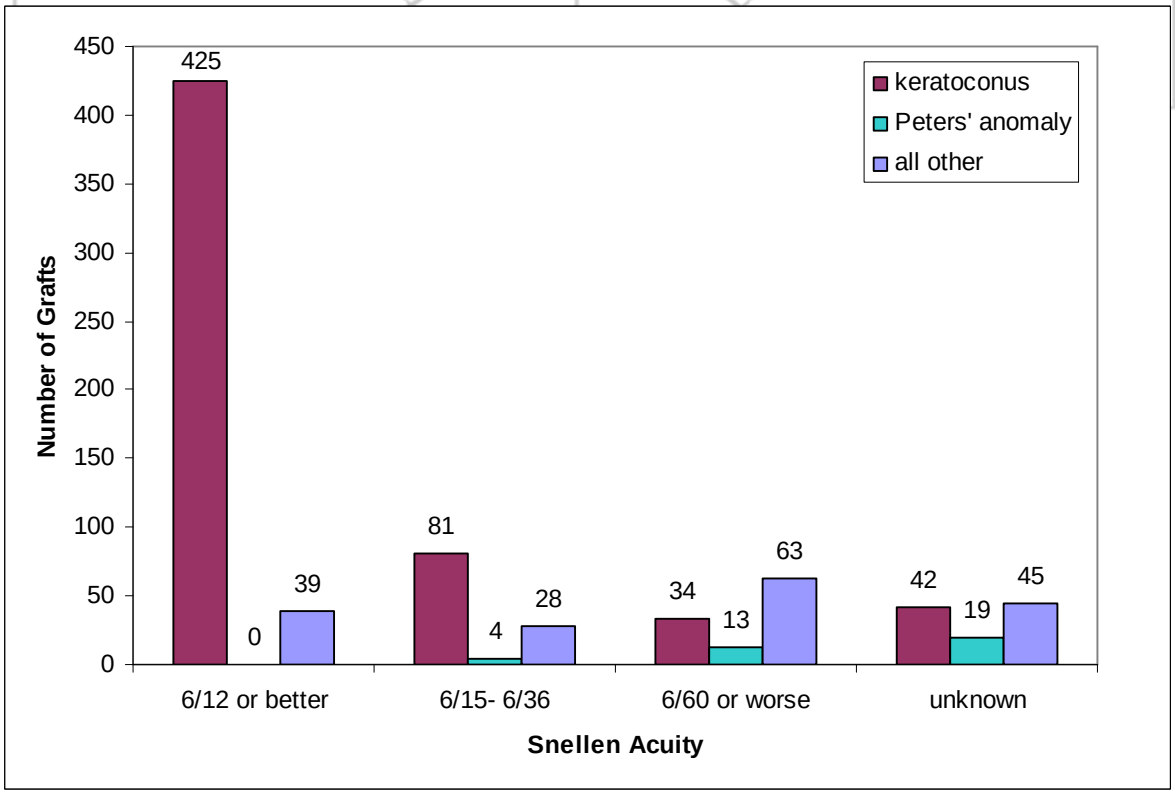
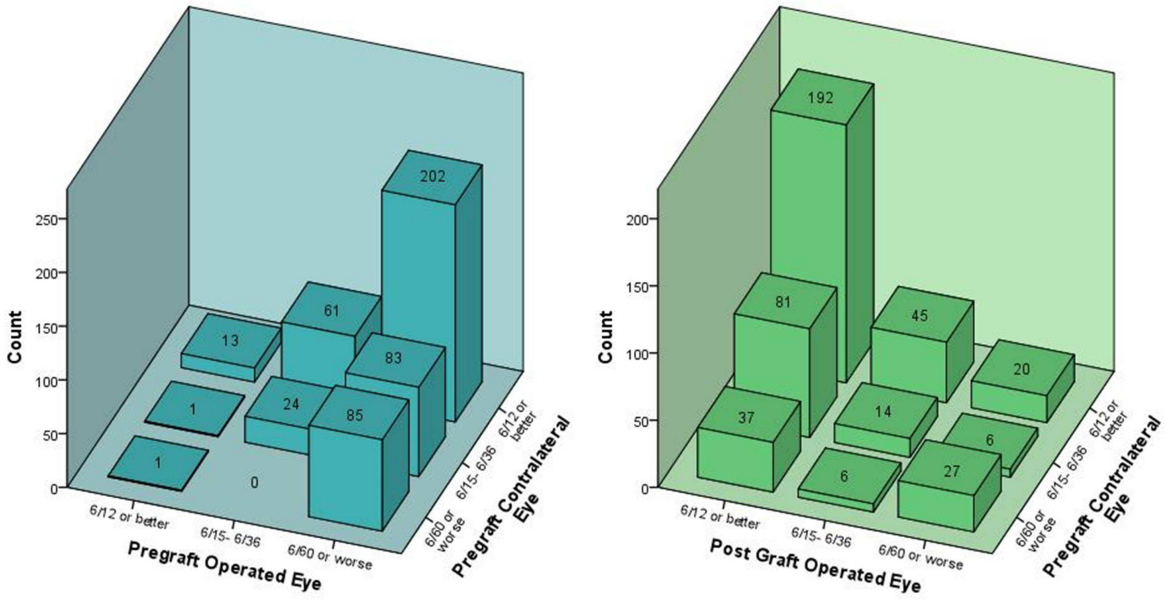


Figure 3.8 Best-corrected Snellen acuity in grafted eye at most recent follow-up, stratified by indication for graft



By plotting Snellen visual acuity in the operated eye against the pre-graft Snellen acuity in the contralateral eye Figure 3.9 compares the overall vision in paediatric patients pre-graft and post-graft.

Figure 3.9 Pre-graft and post-graft best-corrected Snellen acuity in operated and contralateral eyes in paediatric patients

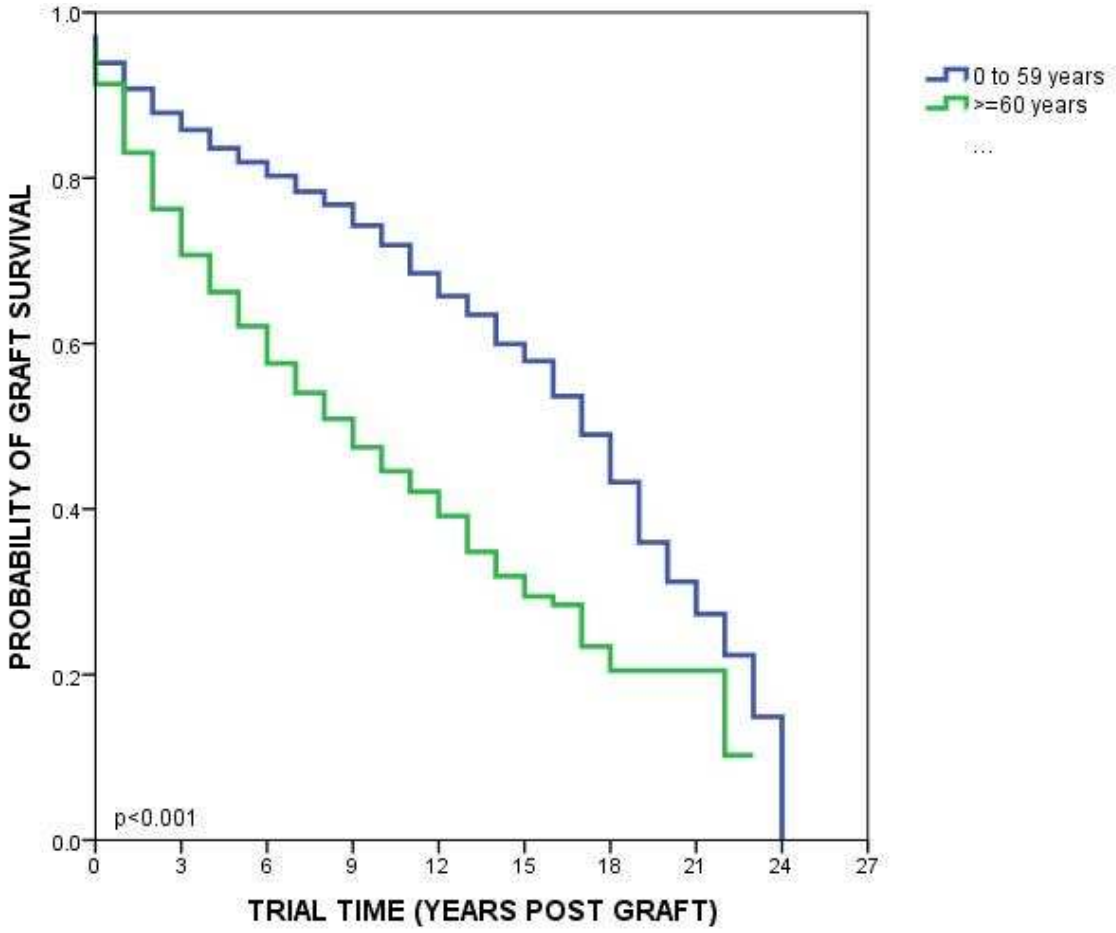


Pre-graft, 41% of patients in the cohort possessed a visual acuity of 6/15 or worse in both eyes. At most recent follow-up overall vision in the paediatric cohort had improved so that this figure reduced to 12%. Pre-graft, 21% had a Snellen acuity of 6/36 or better in both eyes, increasing to 78% at the time of the last follow-up.

3.1.2 Older recipients

Figure 3.10 compares graft survival of those recipients under 60 years of age at the time of graft with recipients over 60 years of age at time of graft (Log Rank Statistic=544.679; df=1; p<0.001).

Figure 3.10 Older recipients compared to younger recipients



Number at Risk

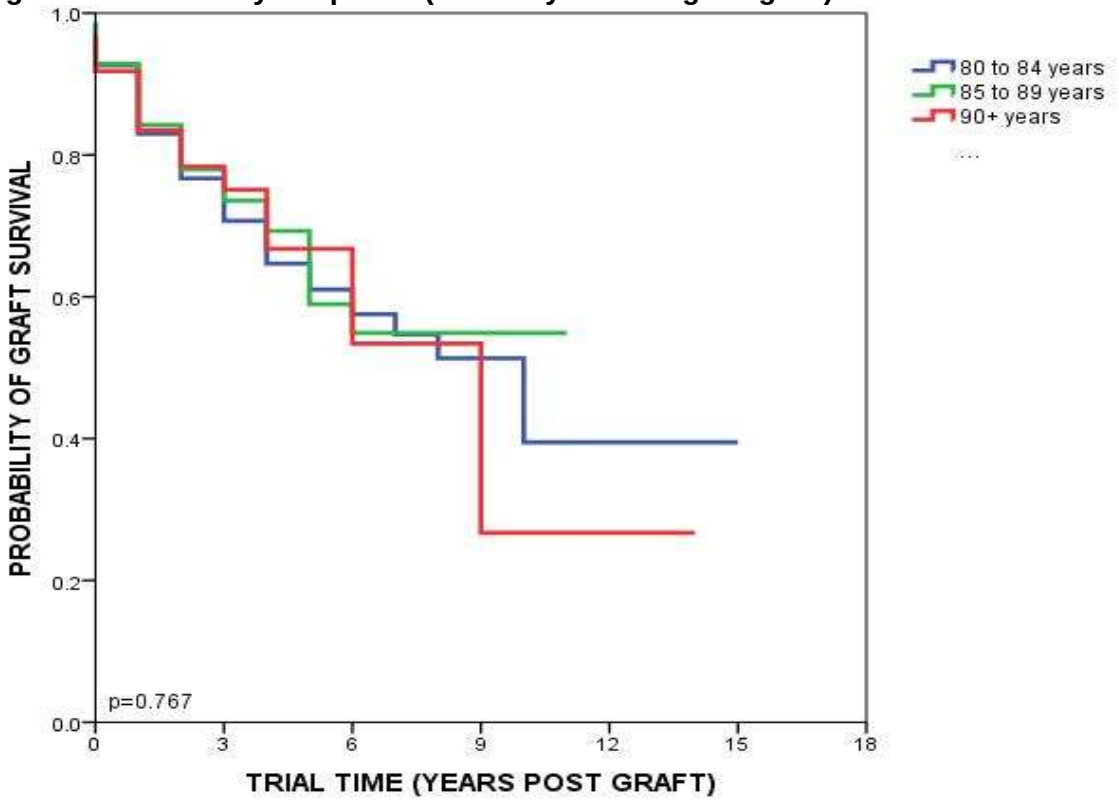
Identity	Initially	3 years	6 years	9 years	12 years	15 years	18 years	21 years	24 years
0 to 59 years	7969	3730	2035	1126	674	348	128	32	1
≥60 years	8315	2869	1217	459	186	52	8	4	0

Identity	No. initially at risk	Graft survival (at years post-graft)				
		1	5	10	15	20
0 to 59 years	7969	.91	.82	.72	.58	.31
≥60 years	8315	.83	.62	.45	.29	.21

Older recipients had a significantly poorer survival rate than younger recipients. This is most likely due to a large proportion (58%) of younger recipients being grafted for keratoconus.

As shown in Figure 3.11, the graft survival rate was not significantly different over the age ranges 80-84, 85-89 and ≥ 90 years at graft (Log Rank Statistic=0.531; df=2; p=0.767).

Figure 3.11 Elderly recipients (over 80 years of age at graft)



Number at Risk

Identity	Initially	3 years	6 years	9 years	12 years	15 years	18 years	21 years	24 years
≥80 & <85 years	1544	396	123	25	3	1	n/a	n/a	n/a
≥85 & <90 years	729	141	29	6	0	n/a	n/a	n/a	n/a
≥90 years	208	24	5	2	n/a	n/a	n/a	n/a	n/a

Identity	No. initially at risk	Graft survival (at years post-graft)				
		1	5	10	15	20
≥80 & <85 years	1544	.83	.61	.40	n/a	n/a
≥85 & <90 years	729	.84	.59	n/a	n/a	n/a
≥90 years	208	.84	.53	.27	n/a	n/a

Of the 208 recipients over 90 years of age, 166 received a first graft and 42 were regrafted. A total of 35 grafts (17%) in the 90 years and over age group had failed. Of the 42 regrafts, 14 had failed.

The most common indication for graft in the 90 years and over age group was pseudophakic bullous keratopathy (51%). The most common cause of graft failure was rejection (31%). Of the 208 recipients 90 years of age or over at time of graft, the longest recorded survival time was 14 years, with the patient having since died. Of the 173 surviving grafts in this group, 34 patients were still alive at the last follow-up. Of the 163 graft recipients recorded as having died, all except 24 died with functioning grafts.

PENETRATING CORNEAL GRAFT SURVIVAL
YOUNGER VERSUS ELDERLY RECIPIENTS

<60 years of age:	**91% at 1 year**
Mean Survival 14.98 years	**82% at 5 years**
(SE=0.21; 95% CI: 14.57, 15.40)	**72% at 10 years**
Median Survival 17 years	**58% at 15 years**
	31% at 20 years
≥60 years of age:	**83% at 1 year**
Mean Survival 10.26 years	**62% at 5 years**
(SE=0.28; 95% CI: 9.70, 10.81)	**45% at 10 years**
Median Survival 9 years	**29% at 15 years**
	21% at 20 years

PENETRATING CORNEAL GRAFT SURVIVAL
VERY ELDERLY RECIPIENTS

≥80 & <85 years of age:	**83% at 1 year**
Mean Survival 8.61 years	**61% at 5 years**
(SE=0.40; 95% CI: 7.82, 9.39)	**40% at 10 years**
Median Survival 10 years	
≥85 & <90 years of age:	**84% at 1 year**
Mean Survival 7.31 years	**59% at 5 years**
(SE=0.33; 95% CI: 6.67, 7.95)	
Median Survival approx. 11 years	
≥90 years of age:	**84% at 1 year**
Mean Survival 7.56 years	**53% at 5 years**
(SE=1.27; 95% CI: 5.08, 10.04)	**27% at 10 years**
Median Survival 9 years	

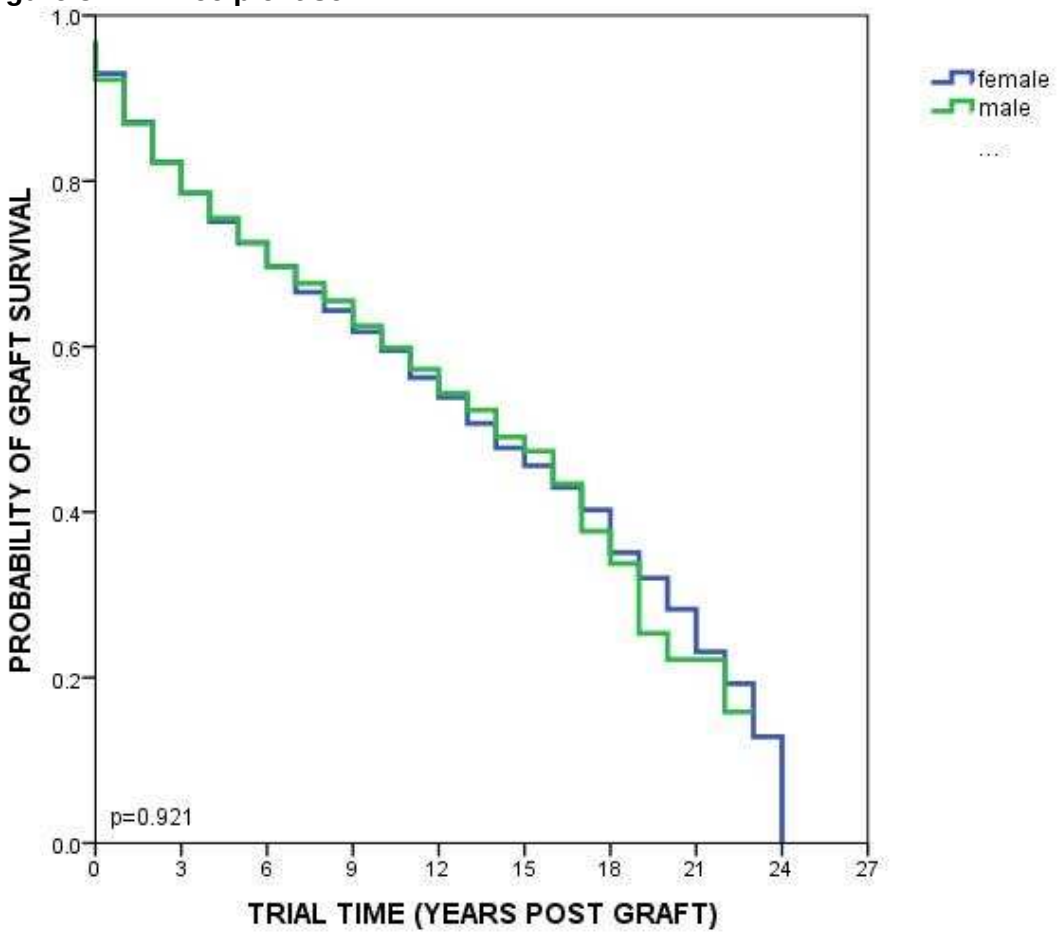
KEY:

n/a	=	not applicable
SE	=	standard error
CI	=	confidence interval
df	=	degrees of freedom
p	=	probability

3.2 RECIPIENT SEX

Figure 3.12 shows the influence of recipient sex on penetrating corneal graft survival (Log Rank Statistic=0.010; df=1; p=0.921). Sex played no significant role in graft survival overall.

Figure 3.12 Recipient sex



Number at Risk

Identity	Initially	3 years	6 years	9 years	12 years	15 years	18 years	21 years	24 years
Female	8053	3387	1687	828	446	201	78	22	1
Male	8238	3213	1565	757	414	199	58	14	n/a

Identity	No. initially at risk	Graft survival (at years post-graft)				
		1	5	10	15	20
Female	8053	.87	.73	.60	.46	.28
Male	8238	.87	.73	.60	.47	.22

PENETRATING CORNEAL GRAFT SURVIVAL
RECIPIENT SEX

Female:	**87% at 1 year**
Mean Survival 12.98 years	**73% at 5 years**
(SE=0.23; 95% CI: 12.54, 13.43)	**60% at 10 years**
Median Survival 14 years	**46% at 15 years**
	28% at 20 years
Male:	**87% at 1 year**
Mean Survival 12.74 years	**73% at 5 years**
(SE=0.21; 95% CI: 12.32, 13.15)	**60% at 10 years**
Median Survival 14 years	**47% at 15 years**
	22% at 20 years

KEY:

n/a	=	not applicable
SE	=	standard error
CI	=	confidence interval
df	=	degrees of freedom
p	=	probability

3.3 SUMMARY OF RECIPIENT AGE AND SEX AT GRAFT

- The distribution of recipient age at graft was bimodal, with peaks at around 20-40 years and around 60-80 years.
- Although recipient age appeared to influence graft survival, it is more likely that the indication for graft associated with different age groups affected survival. Keratoconus was the main indication for graft in 58% of grafts performed in recipients <60 years of age and 73% of recipients <20 years of age.
- Recipient sex had no influence on graft survival.

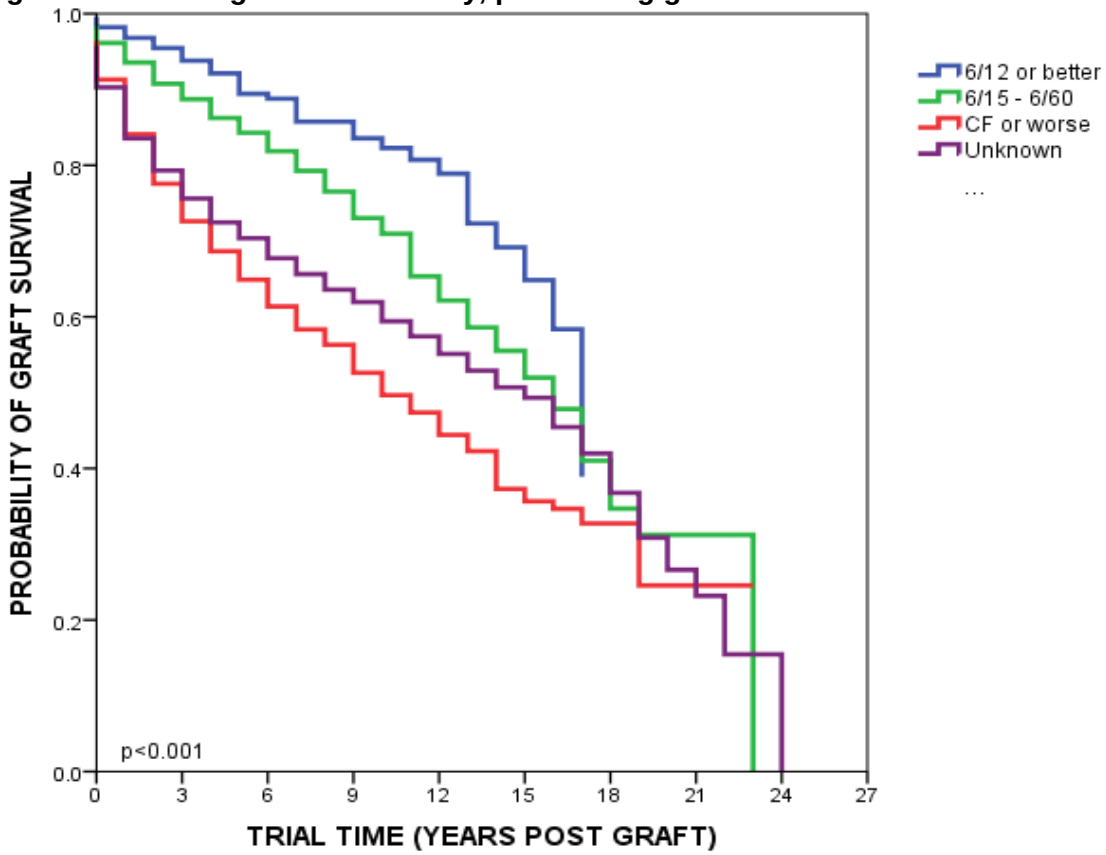
4. RECIPIENT FACTORS

All Kaplan-Meier plots and associated tables in this chapter have been calculated using penetrating grafts only.

4.1 PRE-GRAFT VISUAL ACUITY

Figure 4.1 shows the effect of pre-graft visual acuity on graft outcome. Decreased graft survival was related to worse pre-graft visual acuity (Log Rank Statistic =390.593; df=3; p<0.001). Unknown pre-graft visual acuity was also related to decreased graft survival.

Figure 4.1 Pre-graft visual acuity, penetrating grafts



Number at Risk

Identity	Initially	3 years	6 years	9 years	12 years	15 years	18 years	21 years	24 years
6/12 or better	556	285	141	78	44	16	n/a	n/a	n/a
6/15 – 6/60	4321	1961	963	460	225	94	13	3	0
CF or worse	7770	2648	1155	459	193	69	10	2	n/a
Unknown	3644	1700	989	588	398	221	113	31	1

* CF = count fingers at 6 metres

Identity	No. initially at risk	Graft survival (at years post-graft)				
		1	5	10	15	20
6/12 or better	556	.97	.89	.82	.65	n/a
6/15 – 6/60	4321	.94	.84	.71	.52	.31
CF or worse	7770	.84	.65	.50	.36	.25
Unknown	3644	.84	.70	.59	.49	.27

PENETRATING CORNEAL GRAFT SURVIVAL
PREGRAFT VISUAL ACUITY

6/12 or better:
Mean Survival 14.16 years
(SE=0.37; 95% CI: 13.43, 14.89)
Median Survival 17 years

97% at 1 year
89% at 5 years
82% at 10 years
65% at 15 years

6/15 – 6/60:
Mean Survival 14.63 years
(SE=0.38; 95% CI: 13.90, 15.37)
Median Survival 16 years

94% at 1 year
84% at 5 years
71% at 10 years
52% at 15 years
31% at 20 years

CF or worse:
Mean Survival 11.43 years
(SE=0.38; 95% CI: 10.69, 12.17)
Median Survival 10 years

84% at 1 year
65% at 5 years
50% at 10 years
36% at 15 years
25% at 20 years

Unknown:
Mean Survival 12.91 years
(SE=0.24; 95% CI: 12.43, 13.39)
Median Survival 15 years

84% at 1 year
70% at 5 years
59% at 10 years
49% at 15 years
27% at 20 years

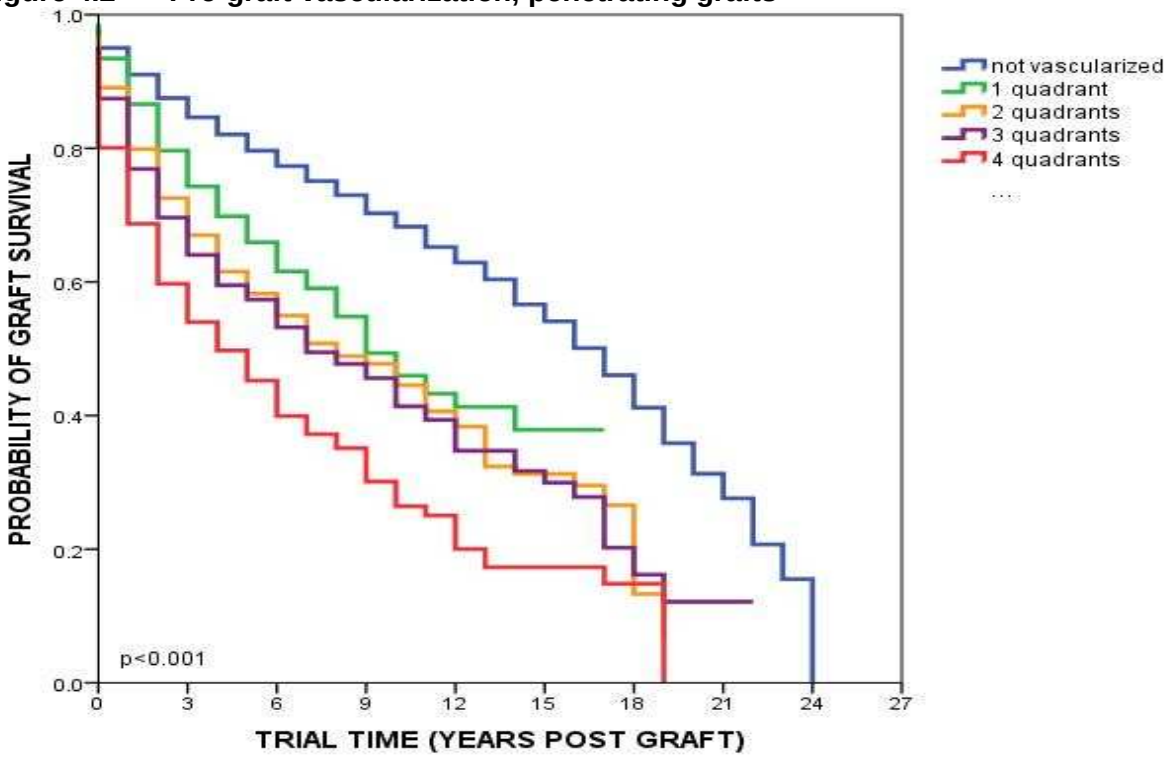
KEY:
n/a = not applicable
SE = standard error
CI = confidence interval
df = degrees of freedom
p = probability

4.2 PRE-GRAFT MORBIDITIES

4.2.1 Vascularization

The effect of pre-graft vascularization on graft outcome is shown in Figure 4.2. Graft survival decreased according to the number of quadrants of the cornea that contained vessels at the time of graft (Log Rank Statistic =1036.175; df=4; p<0.001).

Figure 4.2 Pre-graft vascularization, penetrating grafts



Number at Risk

Identity	Initially	3 years	6 years	9 years	12 years	15 years	18 years	21 years	24 years
Not vascularized	11168	4871	2488	1266	703	336	123	34	1
1 quadrant	1158	417	182	60	22	7	n/a	n/a	n/a
2 quadrants	1721	614	267	136	71	25	4	n/a	n/a
3 quadrants	844	312	153	67	34	18	5	2	n/a
4 quadrants	1400	386	162	63	30	14	4	n/a	n/a

Identity	No. initially at risk	Graft survival (at years post-graft)				
		1	5	10	15	20
Not vascularized	11168	.91	.80	.68	.54	.31
1 quadrant	1158	.87	.66	.46	.38	n/a
2 quadrants	1721	.80	.58	.45	.31	n/a
3 quadrants	844	.77	.57	.41	.30	.12
4 quadrants	1400	.69	.45	.26	.15	n/a

PENETRATING CORNEAL GRAFT SURVIVAL
PREGRAFT CORNEAL NEOVASCULARIZATION

Not vascularized:	**91% at 1 year**
Mean Survival 14.51 years	**80% at 5 years**
(SE=0.20; 95% CI: 14.12, 14.90)	**68% at 10 years**
Median Survival 17 years	**54% at 15 years**
	31% at 20 years
1 quadrant vascularized:	**87% at 1 year**
Mean Survival 9.80 years	**66% at 5 years**
(SE=0.38; 95% CI: 9.06, 10.54)	**46% at 10 years**
Median Survival 9 years	**38% at 20 years**
2 quadrants vascularized:	**80% at 1 year**
Mean Survival 9.18 years	**58% at 5 years**
(SE=0.30; 95% CI: 8.59, 9.78)	**45% at 10 years**
Median Survival 8 years	**31% at 15 years**
3 quadrants vascularized:	**77% at 1 year**
Mean Survival 9.23 years	**57% at 5 years**
(SE=0.48; 95% CI: 8.29, 10.18)	**41% at 10 years**
Median Survival 7 years	**30% at 15 years**
	12% at 20 years
4 quadrants vascularized:	**69% at 1 year**
Mean Survival 6.70 years	**45% at 5 years**
(SE=0.31; 95% CI: 6.09, 7.32)	**26% at 10 years**
Median Survival 4 years	**15% at 15 years**

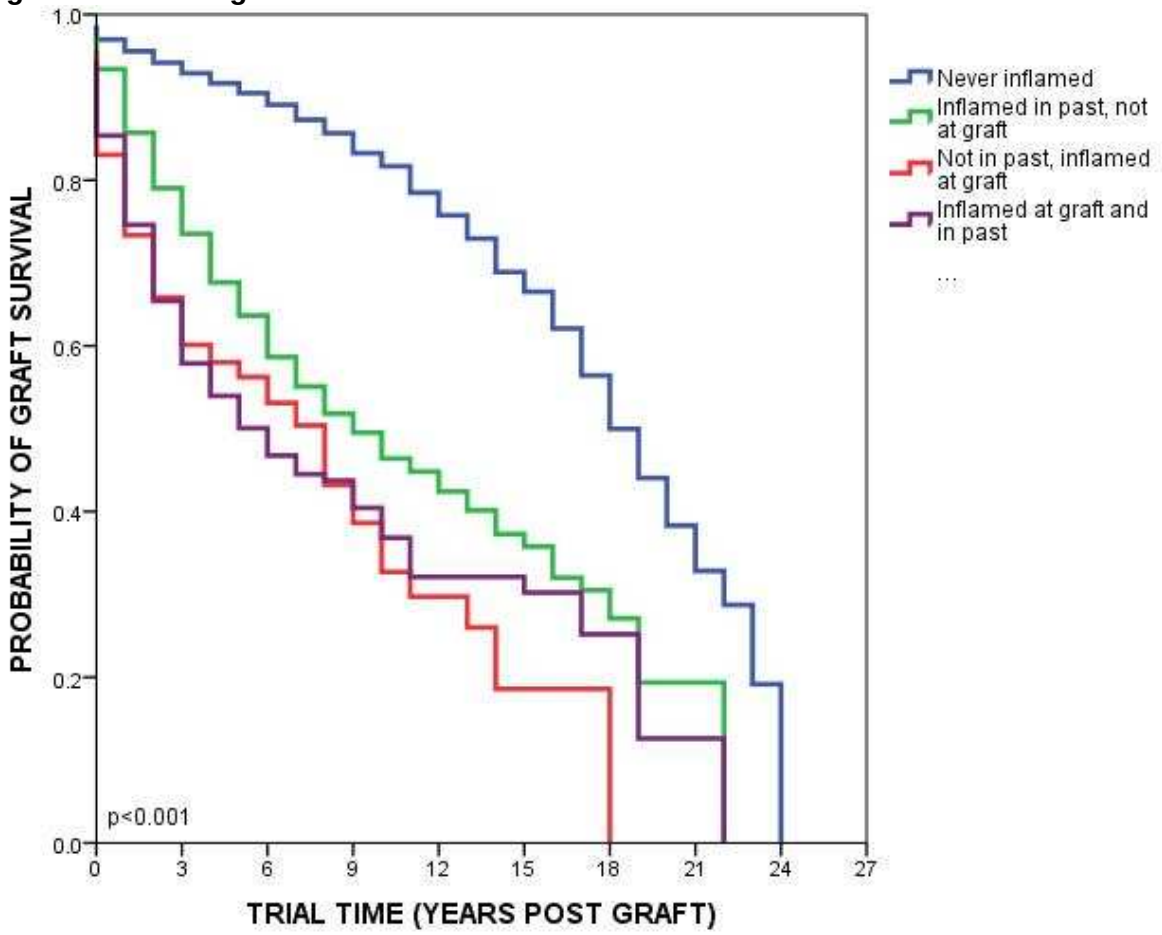
KEY:

n/a	=	not applicable
SE	=	standard error
CI	=	confidence interval
df	=	degrees of freedom
p	=	probability

4.2.2 Inflammation

Figure 4.3 shows the effect of inflammation on graft outcome of first ipsilateral grafts. A history of inflammation was judged to have occurred in any graft where there had been a record of steroids being administered during the 2 week period prior to graft, or where the grafted eye had undergone previous surgery (Log Rank Statistic=1354.38; df=3; p<0.001).

Figure 4.3 Pre-graft inflammation



Number at Risk

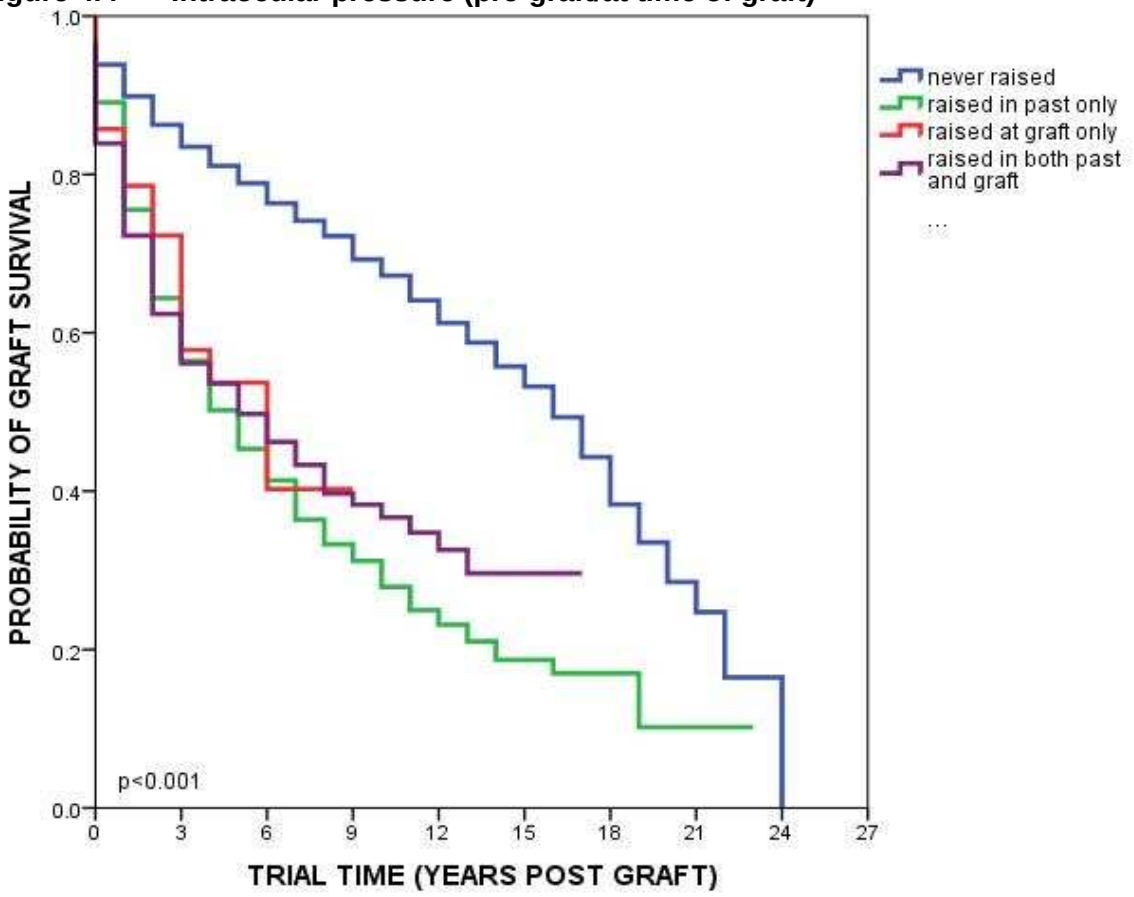
Identity	Initially	3 years	6 years	9 years	12 years	15 years	18 years	21 years	24 years
Never inflamed	7100	3483	1891	1035	604	290	105	28	1
Inflamed in past, not at graft,	3998	1392	585	225	112	50	9	3	n/a
Not in past, inflamed at graft	372	115	54	19	10	3	1	n/a	n/a
Inflamed at graft and in past	1518	451	197	80	28	17	4	1	n/a

Identity	No. initially at risk	Graft survival (at years post-graft)				
		1	5	10	15	20
Never inflamed	7100	.96	.91	.82	.67	.38
Inflamed in past, not at graft	3998	.86	.64	.46	.36	.19
Not in past, inflamed at graft	372	.73	.56	.33	.19	n/a
Inflamed at graft and in past	1518	.75	.50	.37	.30	.13

4.2.3 Intraocular pressure (pre-graft or at graft)

The effect of raised intraocular pressure (IOP) on graft survival is shown in Figure 4.4. Recipients with raised pressure at time of graft and in the past were compared with recipients in whom there had been a history of raised pressure but who had a normal pressure at the time of graft, with those with raised pressure at graft but not in the past, and with those in whom raised intraocular pressure had never been recorded (Log Rank Statistic=842.241; df=3; p<0.001).

Figure 4.4 Intraocular pressure (pre-graft/at time of graft)



Number at Risk

Identity	Initially	3 years	6 years	9 years	12 years	15 years	18 years	21 years	24 years
Never raised	12200	5179	2592	1270	693	331	111	30	1
Raised in past only	2037	675	284	95	41	20	5	2	n/a
Raised at graft only	49	20	4	1	n/a	n/a	n/a	n/a	n/a
Raised in both past and graft	367	120	56	28	16	3	n/a	n/a	n/a

Identity	No. initially at risk	Graft survival (at years post-graft)				
		1	5	10	15	20
Never raised	12200	.90	.79	.68	.53	.29
Raised in past only	2037	.76	.45	.28	.19	.10
Raised at graft only	49	.79	.54	n/a	n/a	n/a
Raised in both past and graft	367	.72	.50	.37	n/a	n/a

PENETRATING CORNEAL GRAFT SURVIVAL
EFFECT OF INFLAMMATION

Never inflamed:	**96% at 1 year**
Mean Survival 16.83 years	**91% at 5 years**
(SE=0.25; 95% CI: 16.35, 17.32)	**82% at 10 years**
Median Survival 18 years	**67% at 15 years**
	38% at 20 years
Inflamed in past, not at graft:	**86% at 1 year**
Mean Survival 10.73 years	**64% at 5 years**
(SE=0.32; 95% CI: 10.09, 11.36)	**46% at 10 years**
Median Survival 9 years	**36% at 15 years**
	19% at 20 years
Not in past, inflamed at graft:	**73% at 1 year**
Mean Survival 7.74 years	**56% at 5 years**
(SE=0.61; 95% CI: 6.56, 8.93)	**33% at 10 years**
Median Survival 8 years	**19% at 15 years**
Inflamed at graft and in past:	**75% at 1 year**
Mean Survival 8.77 years	**50% at 5 years**
(SE=0.45; 95% CI: 7.88, 9.65)	**37% at 10 years**
Median Survival 6 years	**30% at 15 years**
	13% at 20 years

PENETRATING CORNEAL GRAFT SURVIVAL
HISTORY OF RAISED IOP

IOP never raised:	**90% at 1 year**
Mean Survival 14.17 years	**79% at 5 years**
(SE=0.20; 95% CI: 13.78, 14.57)	**67% at 10 years**
Median Survival 16 years	**53% at 15 years**
	29% at 20 years
IOP raised in past only:	**76% at 1 year**
Mean Survival 7.50 years	**45% at 5 years**
(SE=0.34; 95% CI: 6.82, 8.17)	**28% at 10 years**
Median Survival 5 years	**19% at 15 years**
	10% at 20 years
IOP raised at graft only:	**79% at 1 year**
Mean Survival 5.23 years	**54% at 5 years**
(SE=0.66; 95% CI: 3.93, 6.52)	
Median Survival 6 years	
IOP raised in both past and graft:	**72% at 1 year**
Mean Survival 7.68 years	**50% at 5 years**
(SE=0.52; 95% CI: 6.66, 8.70)	**38% at 10 years**
Median Survival 5 years	

KEY: n/a = not applicable; df = degrees of freedom; SE = standard error; p = probability; CI = confidence interval

4.3 MAIN INDICATION FOR GRAFT

Table 4.1 Main indications for penetrating keratoplasty

Indication for graft	Sub-total	Total	%
Keratoconus		**6249**	**31%**
Uncomplicated	5959		
With hydrops	271		
Keratoglobus	19		
Bullous keratopathy		**4338**	**22%**
Pseudophakic	3402		
Aphakic	646		
Phakic pre-graft	290		
Failed previous graft		**4227**	**21%**
Corneal dystrophy		**2156**	**11%**
Fuchs' dystrophy	1902		
Granular dystrophy	57		
Lattice dystrophy	40		
Macular dystrophy	38		
Polymorphous dystrophy	31		
Crystalline dystrophy	15		
Juvenile dystrophy	9		
Anterior dystrophy	2		
Unspecified dystrophy	62		
Herpetic eye disease		**811**	**4%**
Scar resulting from herpetic eye disease	465		
Herpetic perforation	162		
Active HSV	116		
HZO	13		
Scarring - result of HZO infection	55		
Corneal scars and opacities (no history of herpetic disease)		**454**	**2%**
Unspecified scars and opacities[1]	376		
Trachomatous scar	42		
Scarring - result of marginal, central or unspecified ulcer	29		
Possible current trachoma	7		
Corneal ulcers (non HSV)		**403**	**2%**
Perforated	332		
Unperforated	71		
Trauma		**336**	**2%**
Unspecified trauma	273		
Burns	53		
Irradiation damage	8		
Trauma (perforated)	2		
Non-herpetic infections		**295**	**1%**
Corneal abscess	140		
Mycotic	42		
Pseudomonas	40		
Acanthamoeba keratitis	32		
Endophthalmitis	14		
Syphilitic interstitial keratitis	6		
Other bacterial	5		
Other non-herpetic viral	5		
Scleral abscess	1		

Indication for graft	Sub-total	Total	%
Interstitial keratitis		**169**	**<1%**
Corneal degenerations [3]		**148**	**<1%**
Congenital abnormalities		**79**	**<1%**
Peters' anomaly	34		
Other [2]	45		
Descemetocoele		**75**	**<1%**
ICE syndrome		**67**	**<1%**
Metabolic deposits [4]		**48**	**<1%**
Miscellaneous [5]		**60**	**<1%**
Unknown to ACGR		**37**	**<1%**
TOTAL		**19952**	**100%**

1 With: cataract (54); aphakia (25); central opacity (18); neovascularization (9); pterygium (8); keratitis (7); adherent leukoma (6); astigmatism (5); irregular astigmatism (5); keratoconjunctivitis (3); iridocyclitis (2); pseudopterygium (2); acquired keratodermia (1); benign conjunctival neoplasm (1); diplopia (1); glaucoma (1); lacrimal gland disorder (1); metabolism disorder (1); monoclonal paraproteinemia (1) nystagmus (1); pannus (1); retinal detachment (1); retrolental fibroplasia (1); rheumatoid arthritis (1); rosacea (1); scleral degenerative disorder (1); stenosis (1); unspecified (234).

2 Congenital glaucoma (11); aniridia (7); corneal opacities (6); anomalies of anterior segment (3); congenital rubella (2); congenital syphilis (2); ichthyosis (2); microcornea (2); Crouzon's syndrome (1); Rothmund syndrome (1); Russell Silver syndrome (1); unspecified (7).

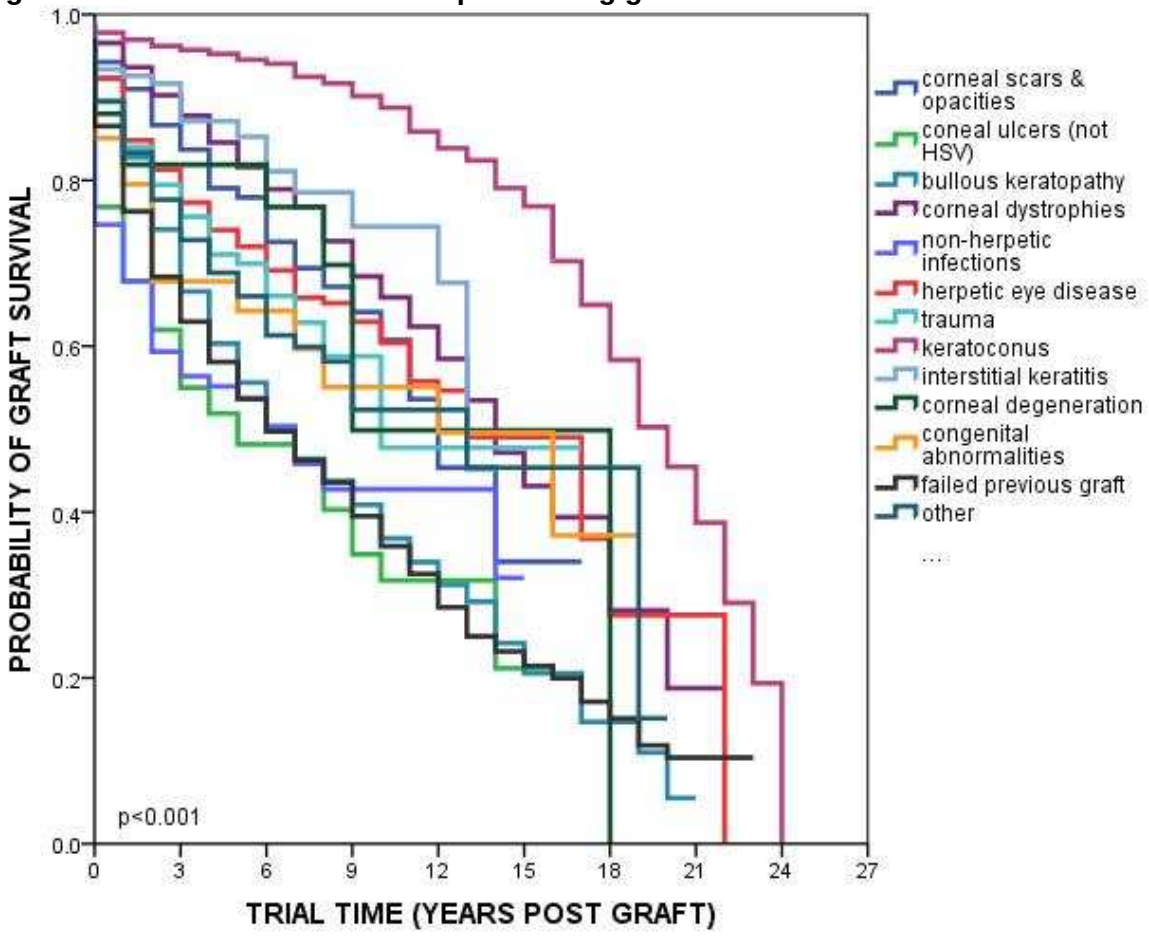
3 Corneal ectasia (92); Salzmann's nodular dystrophy (10); unspecified corneal membrane change (6); rupture in Descemet's membrane (5); macular degeneration (2); myopic degeneration (2); Terrien's marginal degeneration (2); discrete colliquative keratopathy (1); unspecified (28).

4 Band shaped keratopathy (18); deposits associated with metabolic disorders (17); stromal pigmentations (6); calcareous degeneration (4); unspecified (3).

5 Glaucoma (8); patient's other cornea used for autologous graft (7); neovascularization (5); suppurative keratitis (5); astigmatism (4); corneal staphyloma (4); squamous cell carcinoma (4); unspecified keratitis (4); retinal detachment, defect or haemorrhage (3); benign neoplasm (2); keratoconjunctivitis (2) porphyria (2); superficial keratitis (2); amino acid transport disturbance (1); hypopyon (1); monoclonal paraproteinemia (1); pemphigus (1); phthisis (1); scleral disorder (1); synechiae (1); vitamin A deficiency (1).

Figure 4.5 shows the survival curves for the main indications for graft as shown in Table 4.1. (Log Rank Statistic= 1930.605; df=12; p<0.001). There was significant variation across main indicators, with grafts performed for keratoconus faring best and those for failed previous grafts, bullous keratopathy and corneal ulcers faring worst.

Figure 4.5 Main indications for penetrating graft



Number at Risk

Identity	Initially	3 years	6 years	9 years	12 years	15 years	18 years	21 years	24 years
Corneal scars & opacities	314	118	68	22	13	2	n/a	n/a	n/a
Corneal ulcers (not HSV)	349	71	32	15	6	1	n/a	n/a	n/a
Bullous keratopathy	3814	1236	475	168	62	20	4	1	n/a
Corneal dystrophies	1806	872	429	188	96	35	7	2	n/a
Non-herpetic infections	221	60	32	12	7	3	n/a	n/a	n/a
Herpetic eye disease	692	287	151	87	50	26	4	2	n/a
Trauma	266	103	54	21	9	3	n/a	n/a	n/a
Keratoconus	4930	2444	1367	781	471	251	98	27	1
Interstitial keratitis	151	81	41	19	11	n/a	n/a	n/a	n/a
Corneal degeneration	117	33	16	7	3	1	n/a	n/a	n/a
Congenital abnormalities	67	25	15	10	10	5	3	n/a	n/a
Failed previous graft	3277	1152	522	225	105	40	17	4	n/a
Other	287	112	56	30	17	11	3	n/a	n/a

Identity	No. initially at risk	Graft survival (at years post-graft)				
		1	5	10	15	20
Corneal scars & opacities	314	.91	.78	.61	.34	n/a
Corneal ulcers (not HSV)	349	.68	.48	.32	.21	n/a
Bullous keratopathy	3814	.83	.56	.37	.21	.06
Corneal dystrophies	1806	.94	.82	.66	.43	.19
Non-herpetic infections	221	.68	.54	.43	.32	n/a
Herpetic eye disease	692	.85	.72	.60	.49	.28
Trauma	266	.84	.70	.48	n/a	n/a
Keratoconus	4930	.97	.95	.89	.77	.46
Interstitial keratitis	151	.92	.85	.74	n/a	n/a
Corneal degeneration	117	.82	.77	.50	n/a	n/a
Congenital abnormalities	67	.80	.64	.55	.50	n/a
Failed previous graft	3277	.76	.54	.36	.21	.10
Other	287	.83	.66	.52	.45	n/a

It should be noted that:

- the curve for bullous keratopathy includes pseudophakic, aphakic and unspecified bullous keratopathy.
- the curve for corneal dystrophy includes Fuchs' dystrophy, granular, lattice, polymorphous, macular, anterior, juvenile, crystalline and unspecified dystrophies.
- the curve for herpetic eye disease includes active and non-active HSV and HZO.
- non-herpetic infections include bacterial abscess, mycotic infection, endophthalmitis, Acanthamoeba keratitis and Pseudomonas infection.

PENETRATING CORNEAL GRAFT SURVIVAL
INDICATION FOR GRAFT

Corneal scars & opacities:	**91% at 1 year**
Mean Survival 10.93 years	**78% at 5 years**
(SE=0.68; 95% CI: 9.60, 12.26)	**61% at 10 years**
Median Survival 12 years	**34% at 15 years**
Corneal ulcers (not HSV):	**68% at 1 year**
Mean Survival 7.01 years	**48% at 5 years**
(SE=0.58; 95% CI: 5.86, 8.15)	**32% at 10 years**
Median Survival 5 years	**21% at 15 years**
Bullous keratopathy:	**83% at 1 year**
Mean Survival 8.557 years	**56% at 5 years**
(SE=0.28; 95% CI: 8.01, 9.09)	**37% at 10 years**
Median Survival 6 years	**21% at 15 years**
	6% at 20 years
Corneal dystrophies:	**94% at 1 year**
Mean Survival 13.34 years	**82% at 5 years**
(SE=0.46; 95% CI: 12.44, 14.24)	**66% at 10 years**
Median Survival 14 years	**43% at 15 years**
	19% at 20 years
Non-herpetic infections:	**68% at 1 year**
Mean Survival 7.52 years	**54% at 5 years**
(SE=0.61; 95% CI: 6.33, 8.70)	**43% at 10 years**
Median Survival 7 years	**32% at 15 years**
Herpetic eye disease:	**85% at 1 year**
Mean Survival 12.59 years	**72% at 5 years**
(SE=0.63; 95% CI: 11.35, 13.83)	**60% at 10 years**
Median Survival 13 years	**49% at 15 years**
	28% at 20 years
Trauma:	**84% at 1 year**
Mean Survival 10.50 years	**70% at 5 years**
(SE=0.681; 95% CI: 9.16, 11.85)	**48% at 10 years**
Median Survival 10 years	
Keratoconus:	**97% at 1 year**
Mean Survival 18.18 years	**95% at 5 years**
(SE=0.28; 95% CI: 17.63, 18.73)	**89% at 10 years**
Median Survival 20 years	**77% at 15 years**
	46% at 20 years
Interstitial keratitis:	**92% at 1 year**
Mean Survival 11.11 years	**85% at 5 years**
(SE=0.52; 95% CI: 10.10, 12.13)	**72% at 10 years**
Median Survival 13 years	
Corneal degeneration:	**82% at 1 year**
Mean Survival 11.70 years	**77% at 5 years**
(SE=1.39; 95% CI: 8.98, 14.41)	**50% at 10 years**
Median Survival 9 years	
Congenital abnormalities:	**80% at 1 year**
Mean Survival 10.86 years	**64% at 5 years**
(SE=1.27; 95% CI: 8.37, 13.36)	**55% at 10 years**
Median Survival 12 years	**50% at 15 years**
Failed previous graft:	**76% at 1 year**
Mean Survival 8.47 years	**54% at 5 years**
(SE=0.26; 95% CI: 7.65, 8.98)	**36% at 10 years**
Median Survival 6 years	**21% at 15 years**
	10% at 20 years
Other:	**83% at 1 year**
Mean Survival 11.34 years	**66% at 5 years**
(SE=0.75; 95% CI: 9.88, 12.81)	**52% at 10 years**
Median Survival 13 years	**45% at 15 years**

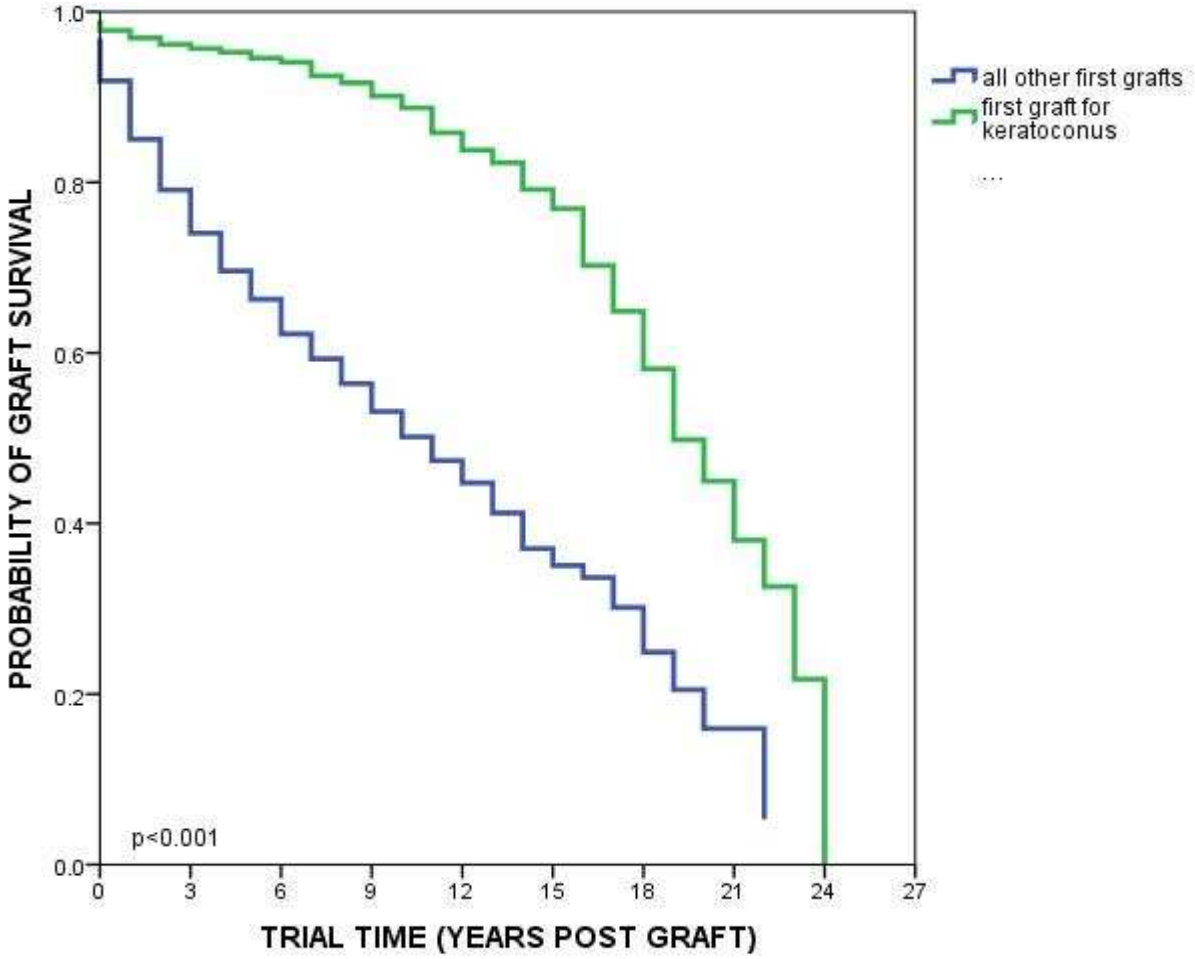
KEY: n/a = not applicable; SE = standard error; CI = confidence interval; df = degrees of freedom; p = probability

4.4 EFFECT OF SPECIFIC INDICATION FOR GRAFT ON GRAFT SURVIVAL

4.4.1 Keratoconus

Figure 4.6 compares graft survival in recipients with first penetrating grafts for keratoconus with all other graft recipients (Log Rank Statistic=990.823; df=1; p<0.001).

Figure 4.6 First penetrating grafts for keratoconus and all other 1st penetrating grafts



Number at Risk

Identity	Initially	3 years	6 years	9 years	12 years	15 years	18 years	21 years	24 years
All other 1st grafts	8120	3018	1369	586	289	112	23	6	n/a
1st graft for keratoconus	4868	2418	1355	773	465	248	96	26	1

Identity	No. initially at risk	Graft survival (at years post-graft)				
		1	5	10	15	20
All other 1st grafts	8120	.85	.66	.50	.35	.16
1st graft for keratoconus	4868	.97	.95	.89	.77	.45

PENETRATING CORNEAL GRAFT SURVIVAL
1ST GRAFT FOR KERATOCONUS

All other 1st grafts:	**85% at 1 year**
Mean Survival 10.94 years	**66% at 5 years**
(SE=0.21; 95% CI: 10.52, 11.35)	**50% at 10 years**
Median Survival 11 years	**35% at 15 years**
	16% at 20 years
1st Graft for Keratoconus:	**97% at 1 year**
Mean Survival 18.22 years	**95% at 5 years**
(SE=0.29; 95% CI: 17.66, 18.78)	**89% at 10 years**
Median Survival 19 years	**77% at 15 years**
	45% at 20 years

KEY: n/a = not applicable; df = degrees of freedom; SE = standard error; p = probability; CI = confidence interval

Figure 4.7 compares graft survival in recipients with first penetrating grafts for keratoconus with all other graft recipients in whom grafts had survived greater than 14 years (Log Rank Statistic=1.103; df=1; p=0.294).

Figure 4.7 First penetrating grafts for keratoconus and all other penetrating grafts that have survived 15 years or more from time of graft

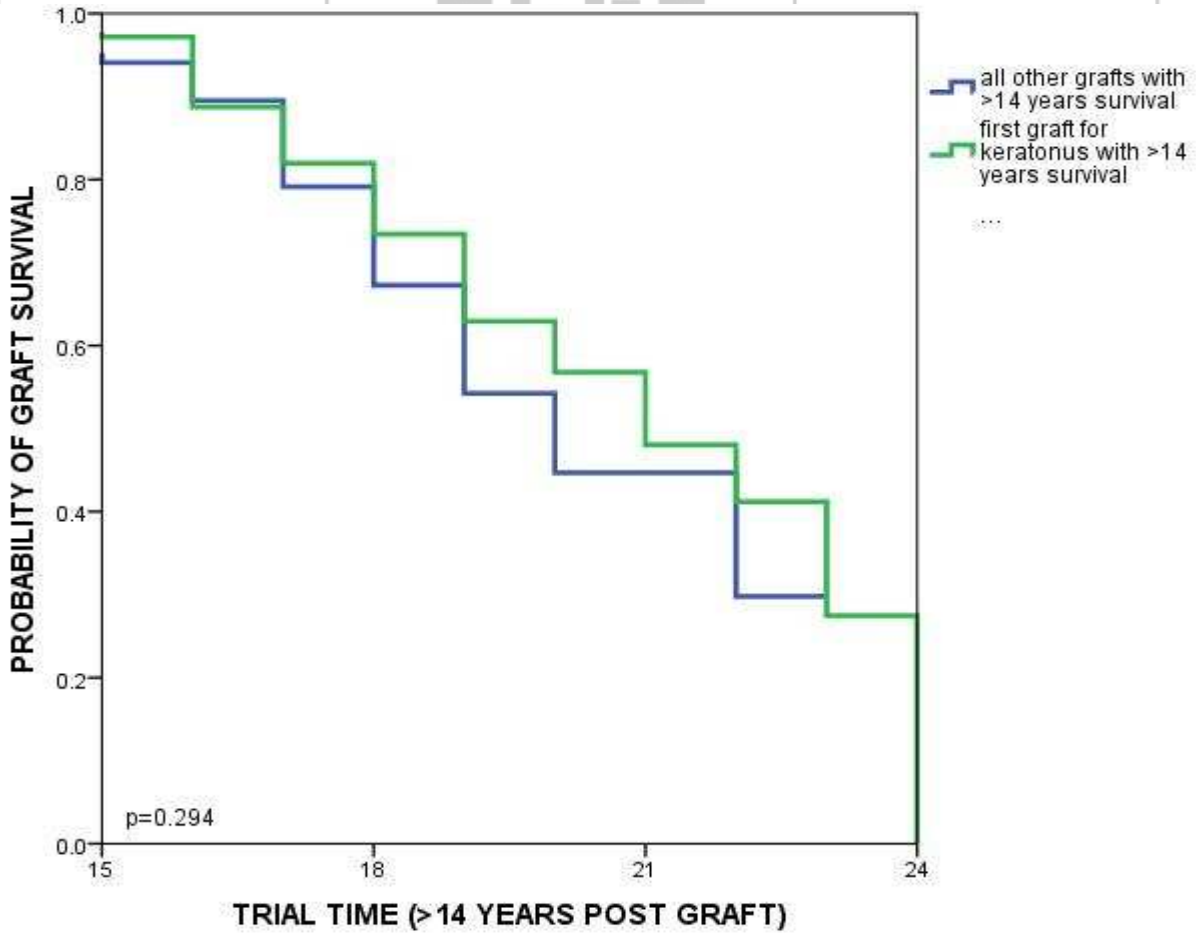
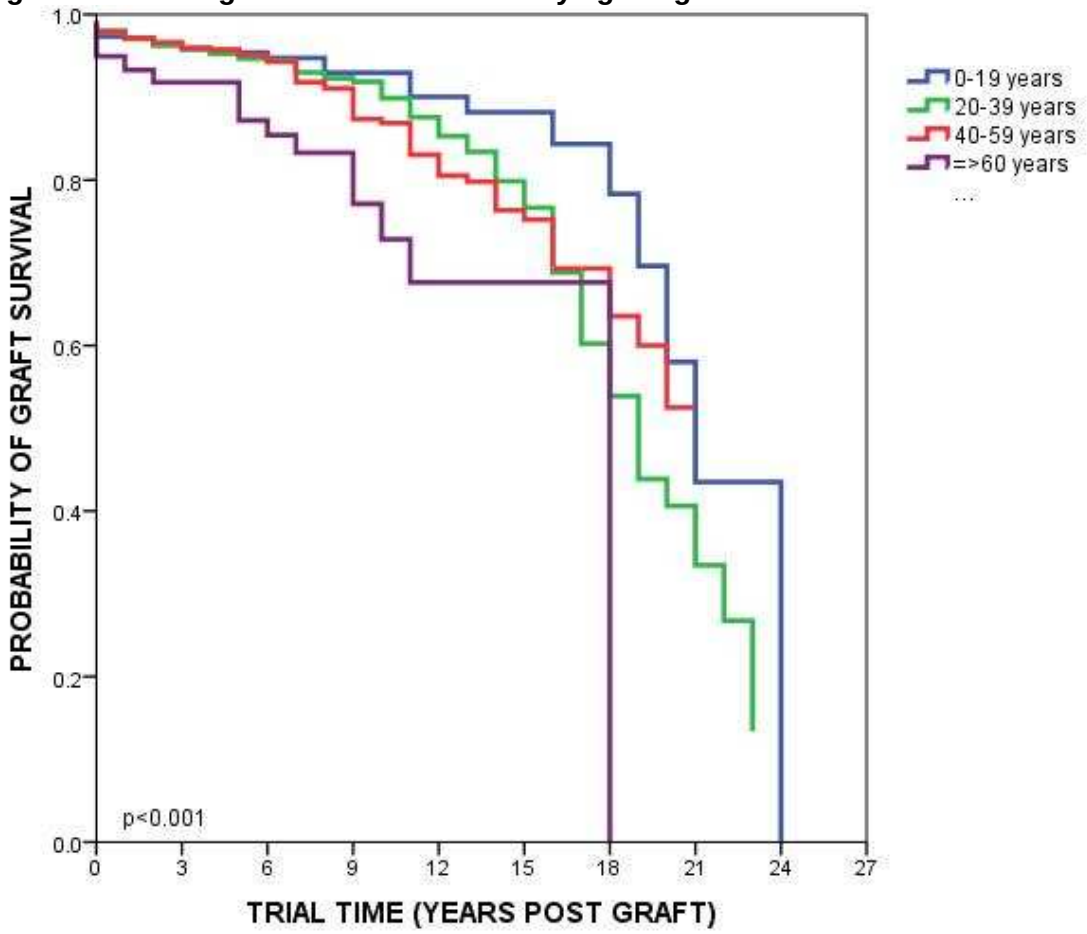


Figure 4.8 compares the survival of first penetrating corneal grafts for keratoconus by age at graft (Log Rank Statistic=19.499; df=3; p<0.001).

Figure 4.8 1st grafts for keratoconus by age at graft



Identity	Initially	3 years	6 years	9 years	12 years	15 years	18 years	21 years	24 years
0 to 19 years	566	309	145	88	53	28	14	4	1
20 to 39 years	3059	1442	797	437	269	149	57	17	n/a
40 to 59 years	1045	579	364	221	132	68	24	5	n/a
≥ 60 years	198	88	49	27	11	3	1	n/a	n/a

Identity	No. initially at risk	Graft survival (at years post-graft)				
		1	5	10	15	20
0 to 19 years	566	.97	.95	.93	.88	.58
20 to 39 years	3059	.97	.95	.90	.77	.41
40 to 59 years	1045	.97	.95	.87	.75	.53
≥ 60 years	198	.93	.87	.73	.68	n/a

Figure 4.9 compares the survival of first penetrating corneal grafts for keratoconus with survival of second, third or subsequent regrafts in the same eye (Log Rank Statistic=359.088; df=2; p<0.001).
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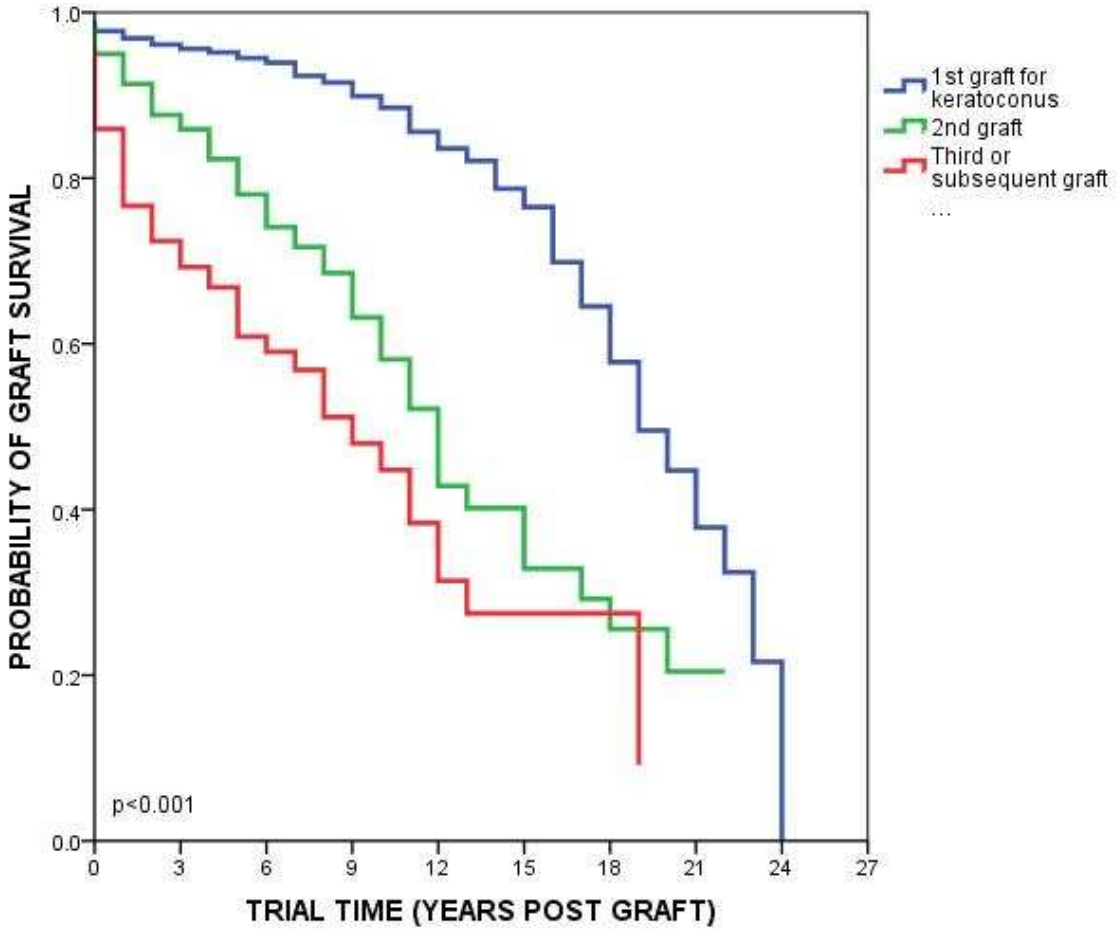
Figure 4.9 1st graft for keratoconus vs 2nd and subsequent grafts



Number at Risk

Identity	Initially	3 years	6 years	9 years	12 years	15 years	18 years	21 years	24 years
1st graft for keratoconus	4949	2442	1361	776	466	248	96	26	1
2nd graft in same eye	659	304	158	64	28	11	8	2	n/a
3rd or subsequent graft in same eye	185	69	33	16	11	6	3	n/a	n/a

Identity	No. initially at risk	Graft survival (at years post-graft)				
		1	5	10	15	20
1st graft for keratoconus	4949	.97	.95	.89	.77	.45
2nd graft in same eye	659	.91	.78	.58	.33	.21
3rd or subsequent graft in same eye	185	.77	.61	.45	.28	n/a

PENETRATING CORNEAL GRAFT SURVIVAL
AGE AT GRAFT - KERATOCONUS

0 to 19 years:	**97% at 1 year**
Mean Survival 19.96 years	**95% at 5 years**
(SE=0.79; 95% CI: 18.40, 21.51)	**93% at 10 years**
Median Survival 21 years	**88% at 15 years**
	58% at 20 years
20 to 39 years:	**97% at 1 year**
Mean Survival 17.79 years	**95% at 5 years**
(SE=0.31; 95% CI: 17.19, 18.39)	**90% at 10 years**
Median Survival 19 years	**77% at 15 years**
	41% at 20 years
40 to 59 years:	**97% at 1 year**
Mean Survival 17.39 years	**95% at 5 years**
(SE=0.36; 95% CI: 16.70, 18.09)	**87% at 10 years**
Median Survival approx. 21 years	**75% at 15 years**
	53% at 20 years
≥60 years:	**93% at 1 year**
Mean Survival 14.26 years	**87% at 5 years**
(SE=0.78; 95% CI: 12.73, 15.79)	**73% at 10 years**
Median Survival 18 years	**68% at 15 years**

PENETRATING CORNEAL GRAFT SURVIVAL
1st, 2nd OR SUBSEQUENT GRAFTS - KERATOCONUS

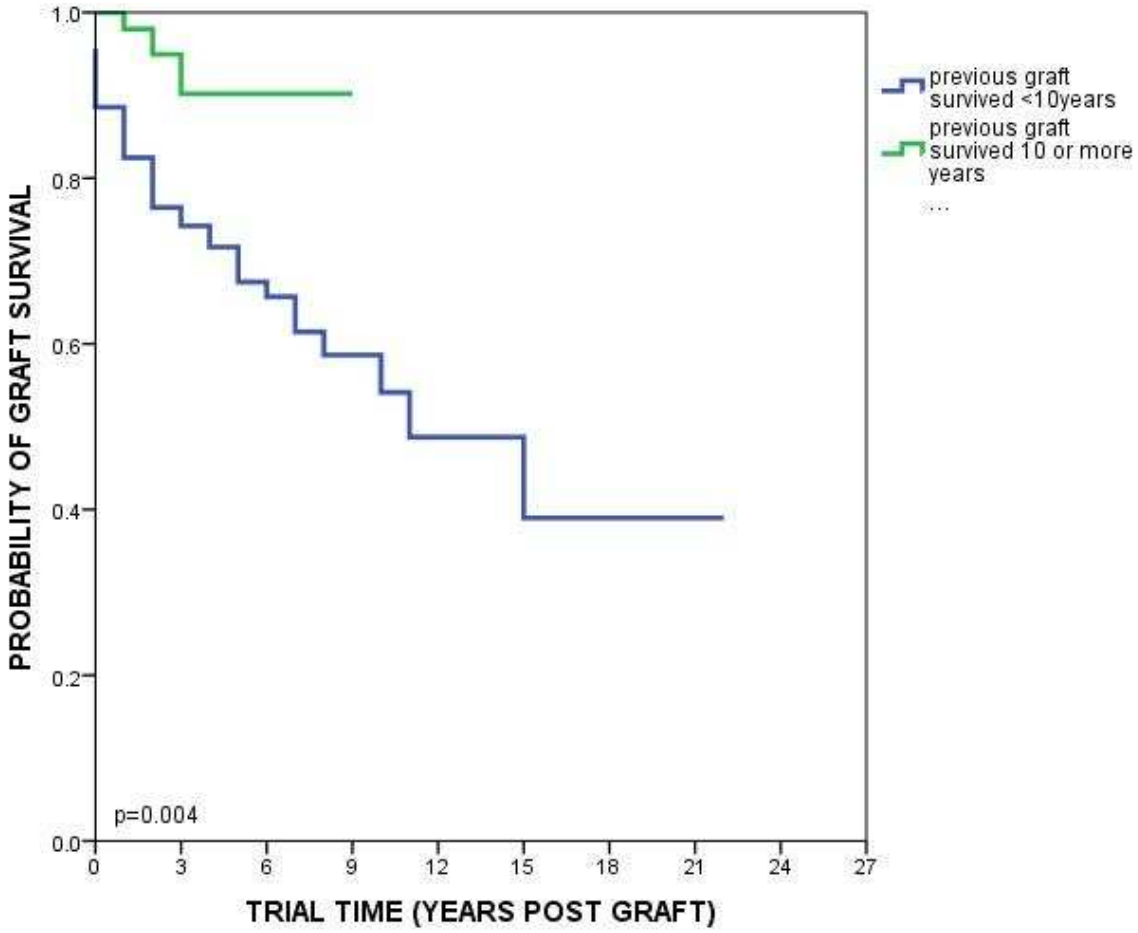
1st graft for Keratoconus:	**97% at 1 year**
Mean Survival 18.17 years	**95% at 5 years**
(SE=0.29; 95% CI: 17.61, 18.76)	**89% at 10 years**
Median Survival 19 years	**77% at 15 years**
	45% at 20 years
2nd graft for Keratoconus:	**91% at 1 year**
Mean Survival 12.18 years	**78% at 5 years**
(SE=0.66; 95% CI: 10.90, 13.47)	**58% at 10 years**
Median Survival 12 years	**33% at 15 years**
	21% at 20 years
3rd or subsequent graft for Keratoconus:	**77% at 1 year**
Mean Survival 9.26 years	**61% at 5 years**
(SE=0.84; 95% CI: 7.62, 10.91)	**45% at 10 years**
Median Survival 9 years	**28% at 15 years**

KEY:

n/a	=	not applicable
SE	=	standard error
CI	=	confidence interval
df	=	degrees of freedom
p	=	probability

Figure 4.10 looks at eyes regrafted for keratoconus in which the previous graft had survived for <10 years compared with regrafts where the previous graft had survived for ≥ 10 years (Log Rank Statistic=8.327; df=1; p=0.004).

Figure 4.10 Regrafts for keratoconus – previous graft surviving <10 or ≥ 10 years.



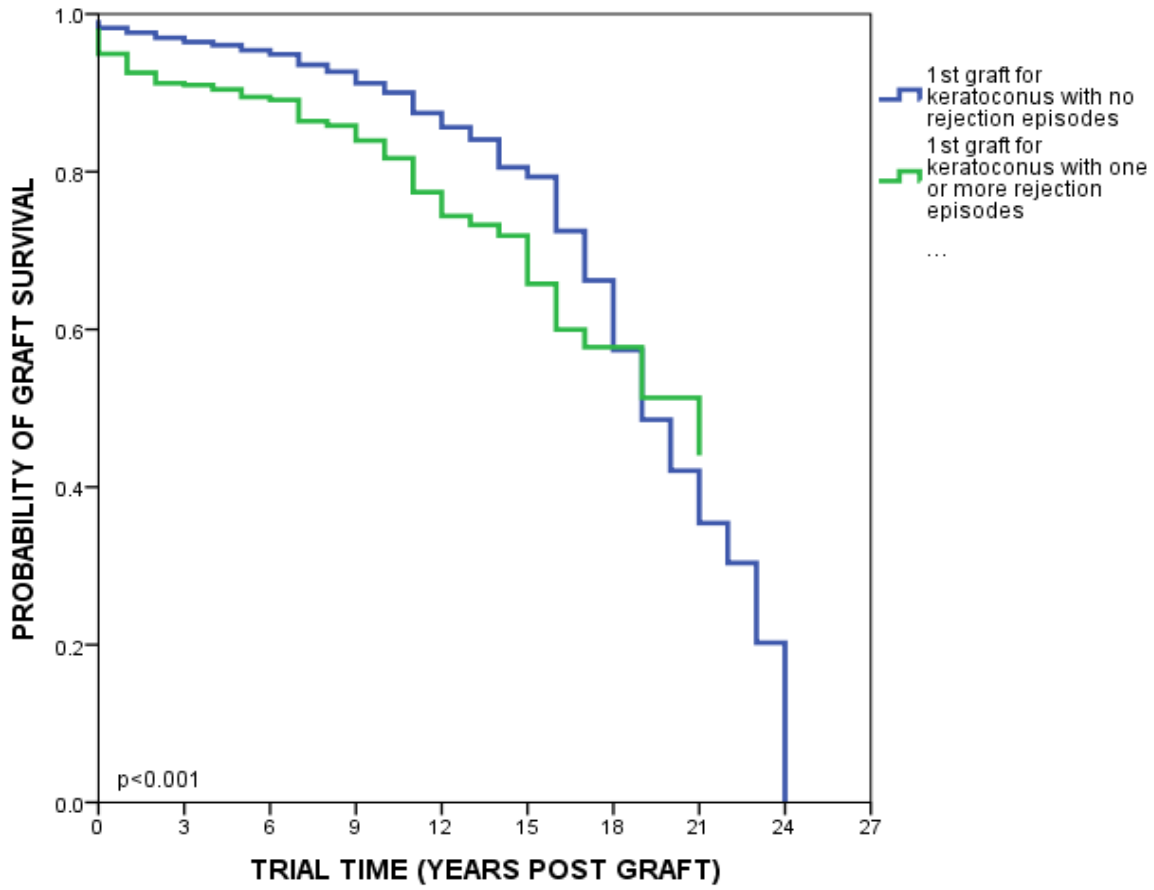
Number at Risk

Identity	Initially	3 years	6 years	9 years	12 years	15 years	18 years	21 years	24 years
Previous graft survived <10 years	166	69	38	15	9	5	4	1	n/a
Previous graft survived ≥10 years	54	20	6	1	n/a	n/a	n/a	n/a	n/a

Identity	No. initially at risk	Graft survival (at years post-graft)				
		1	5	10	15	20
Previous graft survived <10 years	166	.83	.68	.54	.39	n/a
Previous graft survived ≥10 years	54	.98	.90	n/a	n/a	n/a

Figure 4.11 compares graft survival for 1st grafts for keratoconus with and without rejection episodes (Log Rank Statistic=26.148; df=1; p<0.001).

Figure 4.11 Rejection episodes in 1st grafts for keratoconus



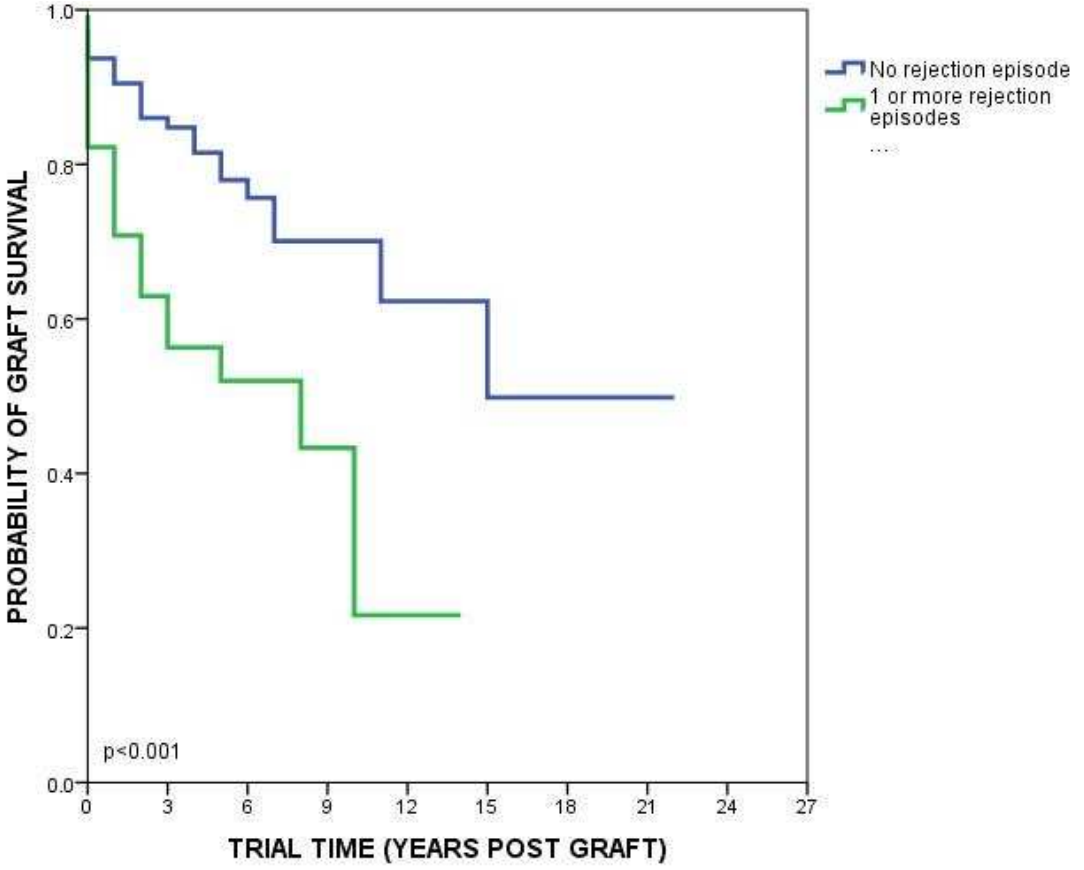
Number at Risk

Identity	Initially	3 years	6 years	9 years	12 years	15 years	18 years	21 years	24 years
1st graft for keratoconus with no rejection episodes	4216	2023	1114	637	388	201	75	19	1
1st graft for keratoconus with one or more rejection episodes	652	395	241	136	77	47	21	7	n/a

Identity	No. initially at risk	Graft survival (at years post-graft)				
		1	5	10	15	20
1st graft for keratoconus with no rejection episodes	4216	.98	.95	.90	.79	.42
1st graft for keratoconus with one or more rejection episodes	652	.93	.86	.82	.66	.51

Figure 4.12 looks at the influence of occurrence of episodes of rejection in regrafted eyes originally grafted for keratoconus (Log Rank Statistic=14.142; df=1; p<0.001).

Figure 4.12 Rejection episodes in keratoconus regrafts



Number at Risk

Identity	Initially	3 years	6 years	9 years	12 years	15 years	18 years	21 years	24 years
No rejection episode	175	70	34	13	8	5	4	1	n/a
1 or more rejection episodes	45	19	10	3	1	n/a	n/a	n/a	n/a

Identity	No. initially at risk	Graft survival (at years post-graft)				
		1	5	10	15	20
No rejection episode	175	.91	.78	.70	.50	n/a
1 or more rejection episode	45	.71	.52	.22	n/a	n/a

PENETRATING CORNEAL GRAFT SURVIVAL
PREVIOUS GRAFT SURVIVAL - KERATOCONUS

<10 years:	**83% at 1 year**
Mean Survival 12.27 years	**68% at 5 years**
(SE=1.22; 95% CI: 9.88, 14.66)	**54% at 10 years**
Median Survival 11 years	**39% at 15 years**
≥10 years:	**98% at 1 year**
Mean Survival 8.34 years	**90% at 5 years**
(SE=0.37; 95% CI: 7.61, 9.07)	
Median Survival approx. 10 years	

PENETRATING CORNEAL GRAFT SURVIVAL
REJECTION EPISODES IN 1ST GRAFTS FOR KERATOCONUS

1st Graft for Keratoconus with no rejection episodes:	**98% at 1 year**
Mean Survival 18.33 years	**95% at 5 years**
(SE=0.31; 95% CI: 17.72, 18.94)	**90% at 10 years**
Median Survival 19 years	**79% at 15 years**
	42% at 20 years
1st Graft for Keratoconus with one or more rejection episodes:	**93% at 1 year**
Mean Survival 16.17 years	**86% at 5 years**
(SE=0.45; 95% CI: 15.29, 17.06)	**82% at 10 years**
Median Survival 21 years	**66% at 15 years**
	51% at 20 years

PENETRATING CORNEAL GRAFT SURVIVAL
EFFECT OF REJECTION ON REGRAFTS - KERATOCONUS

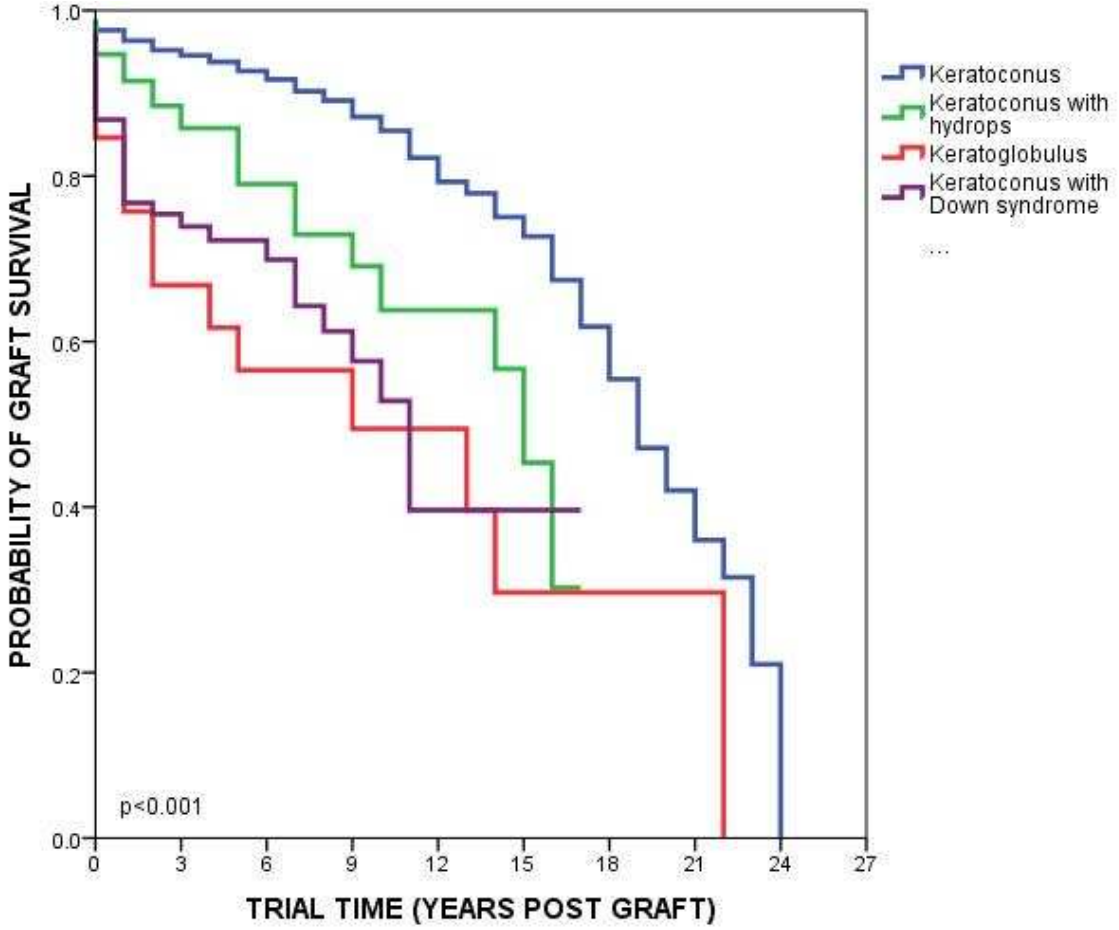
No rejection episode:	**91% at 1 year**
Mean Survival 14.68 years	**78% at 5 years**
(SE=1.36; 95% CI: 12.01, 17.36)	**70% at 10 years**
Median Survival 15 years	**50% at 15 years**
One or more rejection episodes:	**71% at 1 year**
Mean Survival 6.58 years	**52% at 5 years**
(SE=1.07; 95% CI: 4.49, 8.67)	**22% at 10 years**
Median Survival 8 years	

KEY:

n/a	=	not applicable
SE	=	standard error
CI	=	confidence interval
df	=	degrees of freedom
p	=	probability

The effects of uncomplicated keratoconus, keratoconus with acute hydrops, keratoconus with Down syndrome/intellectual disability, or keratoglobus as reasons for graft are shown in Figure 4.13. (Log Rank Statistic=111.899; df=3; p<0.001).

Figure 4.13 Keratoconus, keratoconus with hydrops, keratoconus with Down syndrome/intellectual disability, or keratoglobus



Number at Risk

Identity	Initially	3 years	6 years	9 years	12 years	15 years	18 years	21 years	24 years
Keratoconus	5458	2670	1476	810	482	256	107	28	1
Keratoconus with hydrops	170	66	30	19	10	5	n/a	n/a	n/a
Keratoglobus	26	15	10	8	5	2	2	1	n/a
Keratoconus with Down syndrome	91	50	31	17	5	2	n/a	n/a	n/a

Identity	No. initially at risk	Graft survival (at years post-graft)				
		1	5	10	15	20
Keratoconus	5458	.96	.93	.86	.73	.42
Keratoconus with hydrops	170	.92	.79	.64	.45	n/a
Keratoglobus	26	.76	.57	.50	.30	n/a
Keratoconus with Down syndrome	91	.77	.72	.53	n/a	n/a

PENETRATING CORNEAL GRAFT SURVIVAL
KERATOCONUS, KERATOCONUS WITH HYDROPS, WITH DOWN SYNDROME/INTELLECTUAL DISABILITY OR KERATOGLOBUS

Keratoconus:	**96% at 1 year**
Mean Survival 17.63 years	**93% at 5 years**
(SE=0.27; 95% CI: 17.10, 18.16)	**86% at 10 years**
Median Survival 19 years	**73% at 15 years**
	42% at 20 years
Keratoconus with hydrops:	**91% at 1 year**
Mean Survival 12.07 years	**79% at 5 years**
(SE=0.79; 95% CI: 10.51, 13.62)	**64% at 10 years**
Median Survival 15 years	**45% at 15 years**
Keratoglobus:	**76% at 1 year**
Mean Survival 10.56 years	**57% at 5 years**
(SE=2.07; 95% CI: 6.5, 14.63)	**50% at 10 years**
Median Survival 9 years	**30% at 20 years**
Keratoconus with Down syndrome or intellectual disability:	**77% at 1 year**
Mean Survival 10.01 years	**72% at 5 years**
(SE=0.94; 95% CI: 8.16, 11.86)	**53% at 10 years**
Median Survival 11 years	

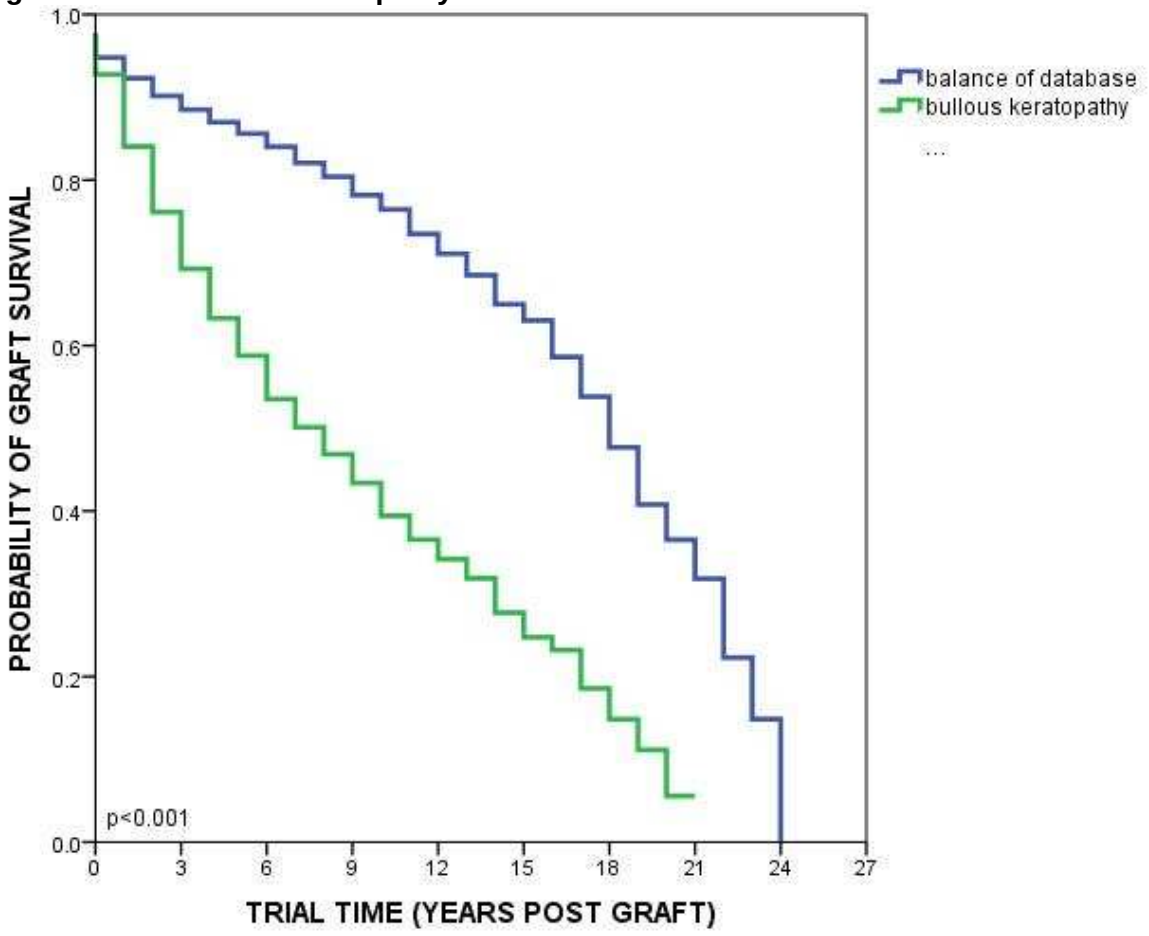
KEY:

n/a	=	not applicable
SE	=	standard error
CI	=	confidence interval
df	=	degrees of freedom
p	=	probability

4.4.2 Bullous keratopathy

Figure 4.14 shows the effect of transplantation for bullous keratopathy on the survival of a first ipsilateral graft (Log Rank Statistic=698.70; df=1; p<0.001).

Figure 4.14 Bullous keratopathy



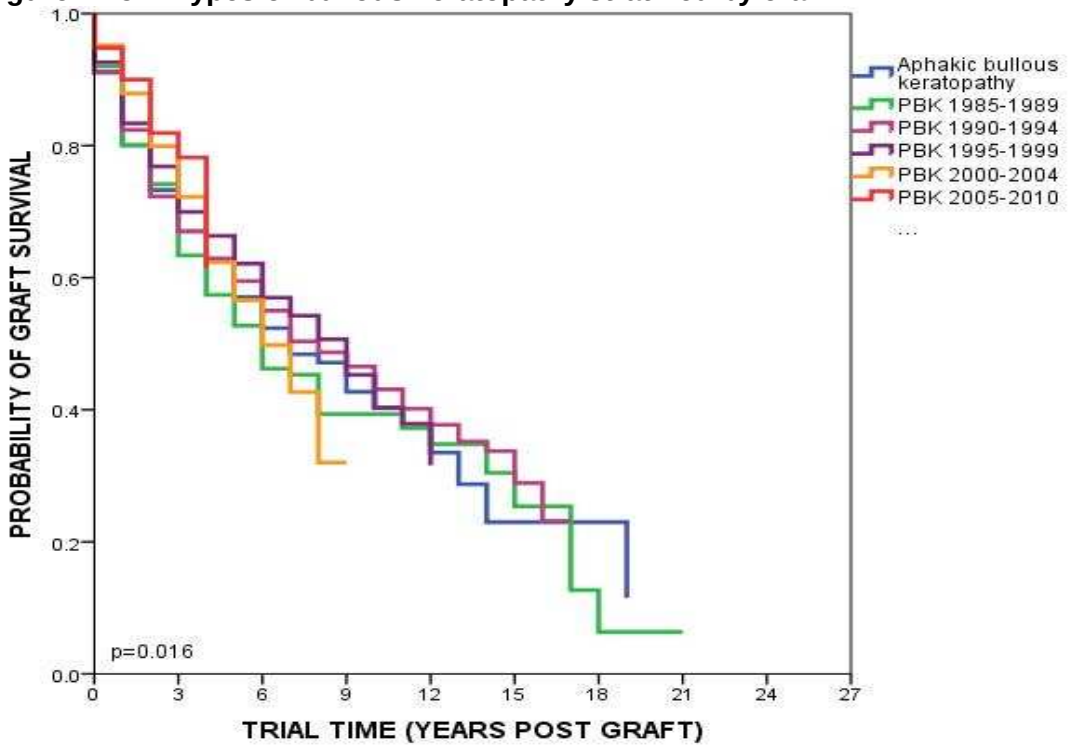
Number at Risk

Identity	Initially	3 years	6 years	9 years	12 years	15 years	18 years	21 years	24 years
Balance of database for first grafts	8628	3962	2147	1153	676	331	114	31	1
Bullous keratopathy	4328	1464	572	203	78	28	5	1	n/a

Identity	No. initially at risk	Graft survival (at years post-graft)				
		1	5	10	15	20
Balance of database for first grafts	8628	.92	.86	.76	.63	.37
Bullous keratopathy	4328	.84	.59	.39	.25	.06

Figure 4.15 compares graft survival for bullous keratopathy in aphakes (ABK) and pseudophakes (PBK). Pseudophakes are analysed by era (Log Rank Statistic=14.003; df=5; p=0.016). The significant difference relates to the better survival of grafts performed for PBK in the latest era, 2005-2010, compared to those in the earlier eras (85-89, 90-94 and 95-99) and those performed for ABK.

Figure 4.15 Types of bullous keratopathy stratified by era



Number at Risk

Identity	Initially	3 years	6 years	9 years	12 years	15 years	18 years	21 years	24 years
ABK	536	176	73	32	10	4	2	n/a	n/a
PBK 1985-1989	338	151	65	25	15	6	2	1	n/a
PBK 1990-1994	1025	342	159	68	33	14	n/a	n/a	n/a
PBK 1995-1999	814	302	132	47	6	n/a	n/a	n/a	n/a
PBK 2000-2004	789	271	75	1	n/a	n/a	n/a	n/a	n/a
PBK 2005-2010	384	66	n/a	n/a	n/a	n/a	n/a	n/a	n/a

Identity	No. initially at risk	Graft survival (at years post-graft)				
		1	5	10	15	20
ABK	536	.80	.57	.40	.23	n/a
PBK 1985-1989	338	.80	.53	.39	.25	.06
PBK 1990-1994	1025	.82	.60	.43	.29	n/a
PBK 1995-1999	814	.83	.62	.40	n/a	n/a
PBK 2000-2004	789	.88	.57	n/a	n/a	n/a
PBK 2005-2010	384	.90	n/a	n/a	n/a	n/a

PENETRATING CORNEAL GRAFT SURVIVAL
BULLOUS KERATOPATHY

Balance of database for first grafts:	**92% at 1 year**
Mean Survival 15.87 years	**86% at 5 years**
(SE=0.22; 95% CI: 15.43, 16.31)	**76% at 10 years**
Median Survival 18 years	**63% at 15 years**
	37% at 20 years
Bullous keratopathy:	**84% at 1 year**
Mean Survival 9.06 years	**59% at 5 years**
(SE=0.26; 95% CI: 8.54, 9.58)	**39% at 10 years**
Median Survival 8 years	**25% at 15 years**
	6% at 20 years

PENETRATING CORNEAL GRAFT SURVIVAL
APHAKIC AND PSEUDOPHAKIC BULLOUS KERATOPATHY

Aphakic bullous keratopathy:	**80% at 1 year**
Mean Survival 8.76 years	**57% at 5 years**
(SE=0.64; 95% CI: 7.52, 10.01)	**40% at 10 years**
Median Survival 7 years	**23% at 15 years**
PBK 1985-1989:	**80% at 1 year**
Mean Survival 8.49 years	**53% at 5 years**
(SE=0.61; 95% CI: 7.29, 9.69)	**39% at 10 years**
Median Survival 6 years	**25% at 15 years**
	6% at 20 years
PBK 1990-1994:	**82% at 1 year**
Mean Survival 8.78 years	**609% at 5 years**
(SE=0.34; 95% CI: 8.11, 9.45)	**43% at 10 years**
Median Survival 8 years	**29% at 15 years**
PBK 1995-1999:	**83% at 1 year**
Mean Survival 7.37 years	**62% at 5 years**
(SE=0.24; 95% CI: 6.90, 7.83)	**40% at 10 years**
Median Survival 9 years	
PBK 2000-2004:	**88% at 1 year**
Mean Survival 5.79 years	**57% at 5 years**
(SE=0.19; 95% CI: 5.42, 6.16)	
Median Survival 6 years	
PBK 2005-2010:	**90% at 1 year**
Mean Survival 3.45 years	
(SE=0.07; 95% CI: 3.31, 3.59)	
Median Survival approx. 4 years	

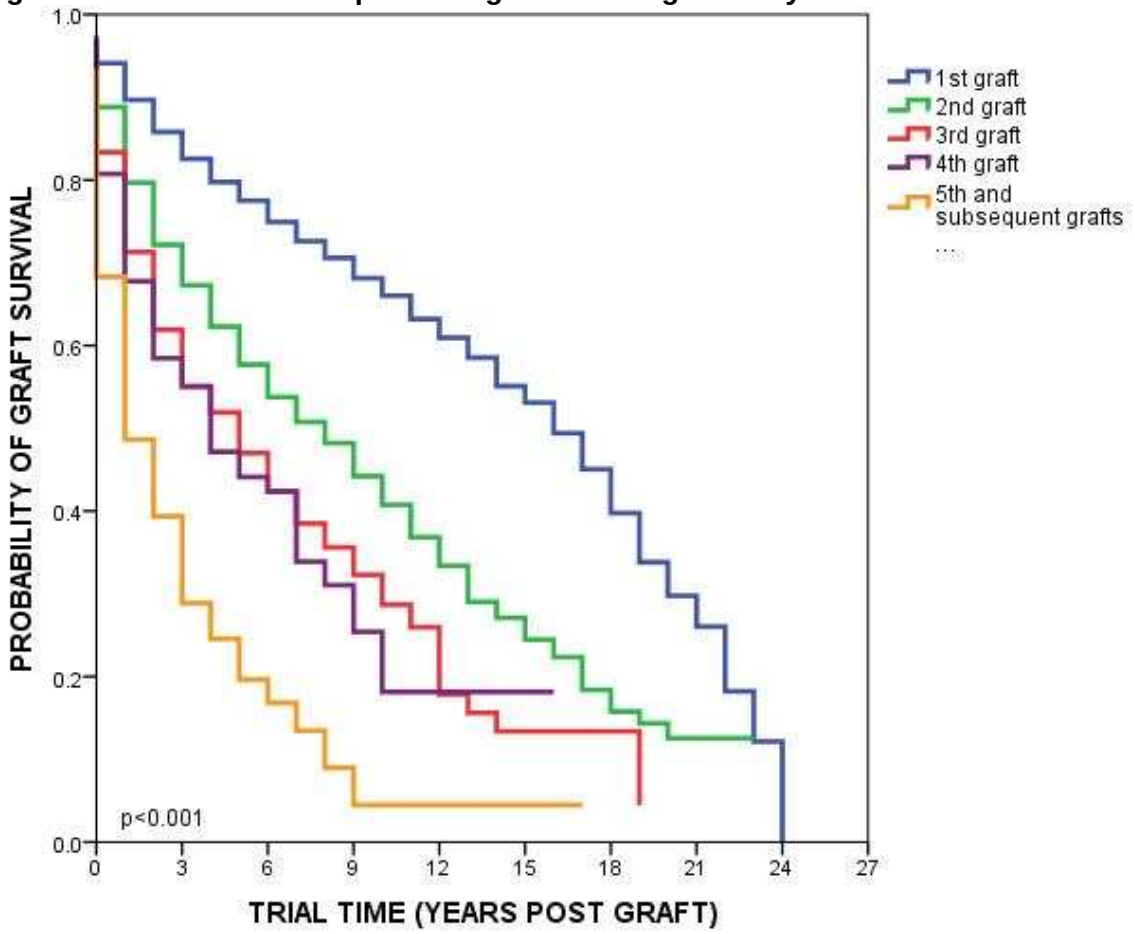
KEY:

n/a	=	not applicable
SE	=	standard error
CI	=	confidence interval
df	=	degrees of freedom
p	=	probability

4.4.3 Previous failed ipsilateral graft

The influence of ipsilateral graft number is shown in Figure 4.16. Graft survival fell with increasing graft number (Log Rank Statistic=880.019; df=4; p<0.001).

Figure 4.16 The effect of previous grafts in the grafted eye



Number at Risk

Identity	Initially	3 years	6 years	9 years	12 years	15 years	18 years	21 years	24 years
1st graft	12988	5441	2727	1359	754	360	119	32	1
2nd graft	2412	887	411	181	86	31	14	4	n/a
3rd graft	607	191	82	32	16	6	3	n/a	n/a
4th graft	161	51	25	11	3	2	n/a	n/a	n/a
5th & subsequent graft	123	30	7	2	1	n/a	n/a	n/a	n/a

Identity	No. initially at risk	Graft survival (at years post-graft)				
		1	5	10	15	20
1st graft	12988	.90	.78	.66	.53	.30
2nd graft	2412	.80	.58	.41	.25	.13
3rd graft	607	.71	.47	.29	.13	n/a
4th graft	161	.68	.44	.18	n/a	n/a
5th & subsequent graft	123	.49	.20	.05	n/a	n/a

PENETRATING CORNEAL GRAFT SURVIVAL
GRAFT NUMBER

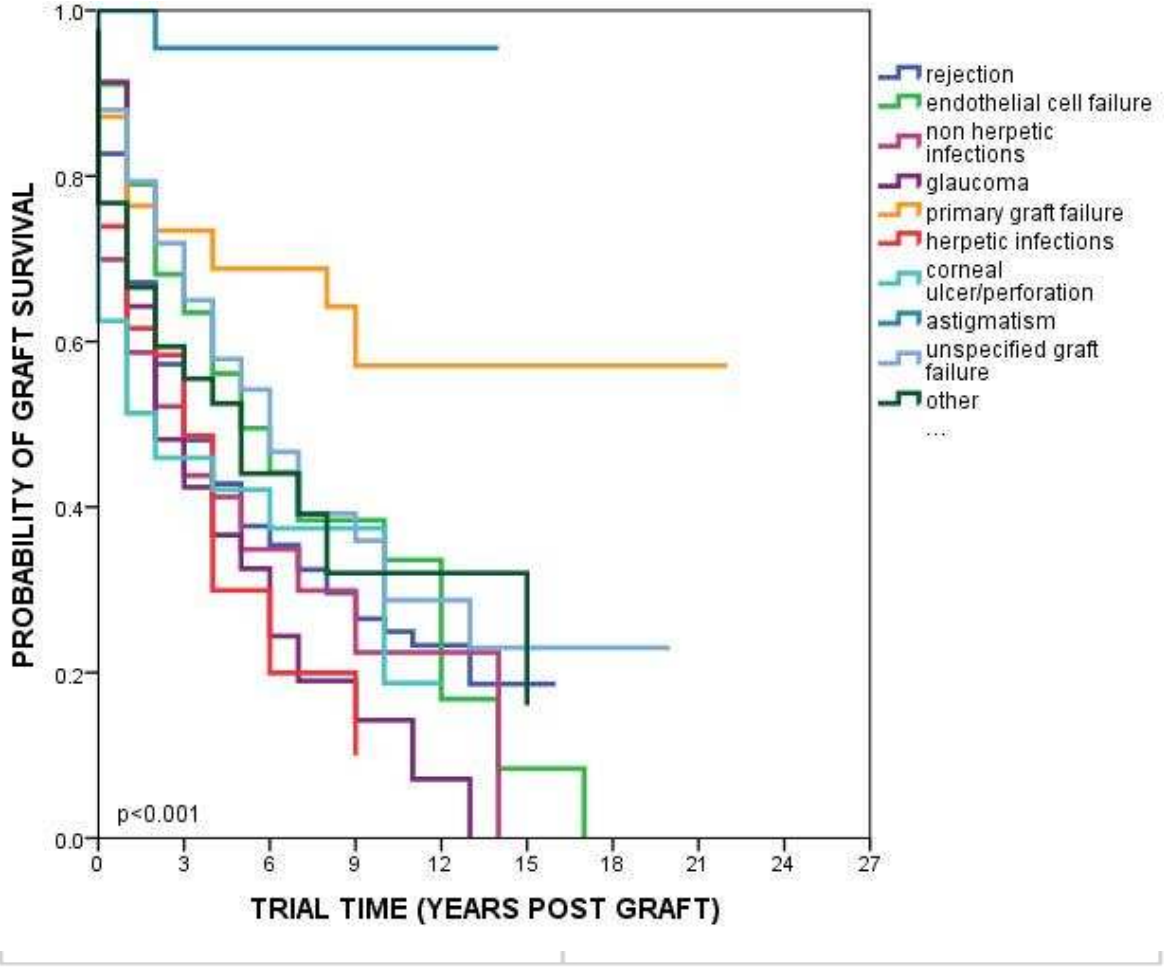
1st graft:	**90% at 1 year**
Mean Survival 14.07 years	**78% at 5 years**
(SE=0.19; 95% CI: 13.69, 14.44)	**66% at 10 years**
Median Survival 16 years	**53% at 15 years**
	30% at 20 years
2nd graft:	**80% at 1 year**
Mean Survival 9.25 years	**58% at 5 years**
(SE=0.32; 95% CI: 8.61, 9.88)	**41% at 10 years**
Median Survival 8 years	**25% at 15 years**
	13% at 20 years
3rd graft:	**71% at 1 year**
Mean Survival 6.74 years	**47% at 5 years**
(SE=0.44; 95% CI: 5.88, 7.61)	**29% at 10 years**
Median Survival 5 years	**13% at 15 years**
4th graft:	**68% at 1 year**
Mean Survival 5.95 years	**44% at 5 years**
(SE=0.63; 95% CI: 4.71, 7.19)	**18% at 10 years**
Median Survival 4 years	
5th and subsequent grafts:	**47% at 1 year**
Mean Survival 3.05 years	**20% at 5 years**
(SE=0.52; 95% CI: 2.02, 4.07)	**5% at 10 years**
Median Survival 1 year	

KEY:

n/a	=	not applicable
SE	=	standard error
CI	=	confidence interval
df	=	degrees of freedom
p	=	probability

Figure 4.17 investigates the effect of different reasons for failure of a previous ipsilateral graft on the survival of the current graft. The data in this figure have been analysed using the reason given at time of failure of the previous graft (Log Rank Statistic=74.014; df=9; p<0.001).

Figure 4.17 The effect of reason for failure of a previous graft



Number at Risk

Identity	Initially	3 years	6 years	9 years	12 years	15 years	18 years	21 years	24 years
Rejection	462	125	49	19	12	5	n/a	n/a	n/a
Endothelial cell failure	257	88	37	11	4	1	n/a	n/a	n/a
Non herpetic infections	103	25	8	4	2	0	n/a	n/a	n/a
Glaucoma	81	25	12	4	1	n/a	n/a	n/a	n/a
Primary graft failure	109	38	22	9	7	4	3	1	n/a
Herpetic infections	46	18	6	2	n/a	n/a	n/a	n/a	n/a
Corneal ulcer/perforation	64	13	9	3	1	n/a	n/a	n/a	n/a
Astigmatism	31	17	8	1	n/a	n/a	n/a	n/a	n/a
Unspecified graft failure	308	94	36	12	7	2	2	n/a	n/a
Other	159	46	20	7	2	2	n/a	n/a	n/a

Identity	No. initially at risk	Graft survival (at years post-graft)				
		1	5	10	15	20
Rejection	462	.67	.38	.25	.19	n/a
Endothelial cell failure	257	.79	.50	.34	.08	n/a
Non herpetic infections	103	.59	.35	.22	n/a	n/a
Glaucoma	81	.64	.33	.14	n/a	n/a
Primary graft failure	109	.76	.69	.57	n/a	n/a
Herpetic infections	46	.62	.30	n/a	n/a	n/a
Corneal ulcer/perforation	64	.51	.42	.19	n/a	n/a
Astigmatism	31	.95	n/a	n/a	n/a	n/a
Unspecified graft failure	308	.79	.54	.29	.23	n/a
Other	159	.67	.44	.32	.16	n/a

Regrafts for astigmatism and primary graft failures showed better graft survival than those for other reasons, whilst those regrafted for infections, glaucoma and ulcers had poorer graft survival.

PENETRATING CORNEAL GRAFT SURVIVAL
REASON FOR FAILURE OF PREVIOUS GRAFT

Rejection:	
Mean Survival 5.87 years	**67% at 1 year**
(SE=0.41; 95% CI: 5.06, 6.68)	**37% at 5 years**
Median Survival 3 years	**25% at 10 years**
	19% at 15 years
Endothelial cell failure:	
Mean Survival 6.93 years	**79% at 1 year**
(SE=0.61; 95% CI: 5.74, 8.11)	**50% at 5 years**
Median Survival 5 years	**34% at 10 years**
	8% at 15 years
Non herpetic infection:	
Mean Survival 5.09 years	**59% at 1 year**
(SE=0.78; 95% CI: 3.55, 6.60)	**35% at 5 years**
Median Survival 3 years	**22% at 10 years**
Glaucoma:	
Mean Survival 4.20 years	**62% at 1 year**
(SE=0.54; 95% CI: 3.14, 5.27)	**33% at 5 years**
Median Survival 2 years	**14% at 10 years**
Primary graft failure:	
Mean Survival 13.92 years	**76% at 1 year**
(SE=1.41; 95% CI: 11.15, 16.69)	**69% at 5 years**
Median Survival approx. 22 years	**57% at 10 years**
Herpetic infection:	
Mean Survival 3.62 years	**62% at 1 year**
(SE=0.56; 95% CI: 2.53, 4.72)	**30% at 5 years**
Median Survival 3 years	
Corneal ulcer/perforation:	
Mean Survival 4.77 years	**51% at 1 year**
(SE=0.78; 95% CI: 3.25, 6.29)	**42% at 5 years**
Median Survival 2 year	**19% at 10 years**
Astigmatism:	
Mean Survival 13.45 years	**96% at 1 year**
(SE=0.53; 95% CI: 12.41, 14.50)	
Median Survival approx 14 years	
Unspecified graft failure:	**79% at 1 year**
Mean Survival 8.24 years	**541% at 5 years**
(SE=0.85; 95% CI: 6.57, 9.92)	**29% at 10 years**
Median Survival 6 years	**23% at 15 years**
Other:	**67% at 1 year**
Mean Survival 6.62 years	**44% at 5 years**
(SE=0.69; 95% CI: 5.27, 7.98)	**32% at 10 years**
Median Survival 5 years	**16% at 15 years**

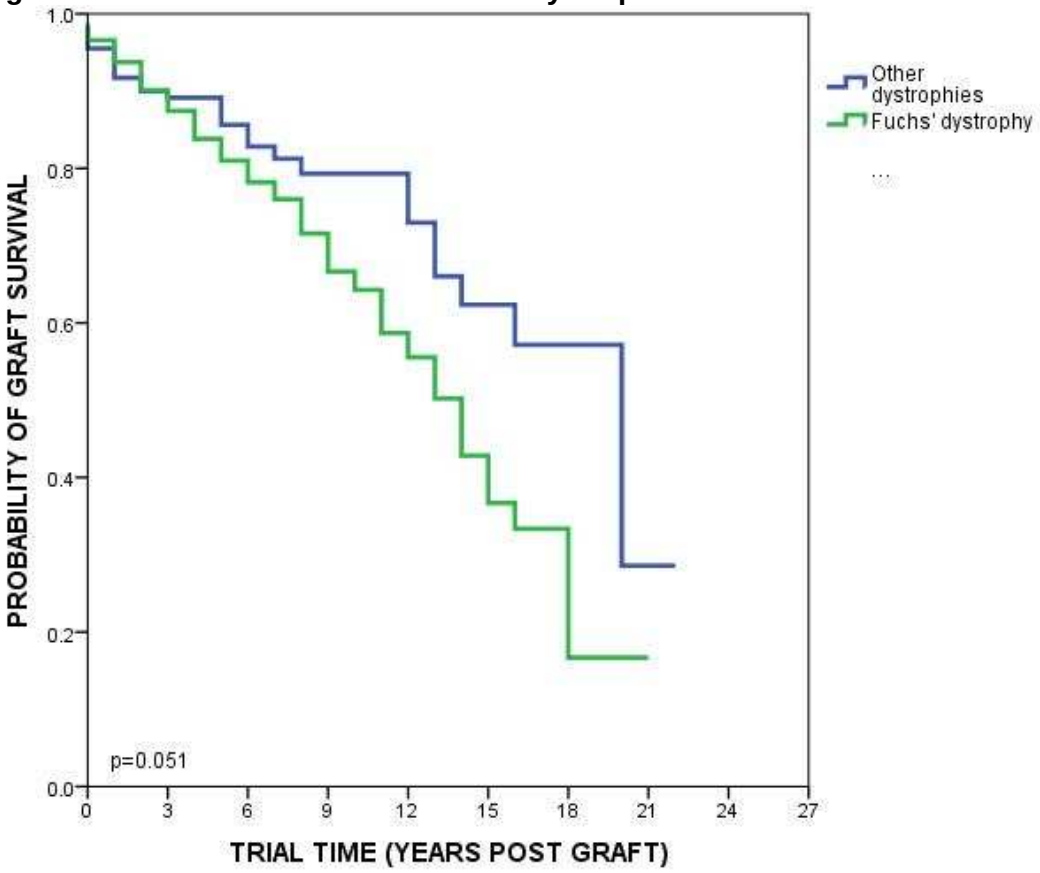
KEY:

	n/a	=	not applicable
	SE	=	standard error
	CI	=	confidence interval
	df	=	degrees of freedom M
	p	=	probability

4.4.4 Corneal dystrophy

Figure 4.18 shows the survival of first grafts for Fuchs' dystrophy compared with other corneal dystrophies (Log rank Statistic=3.814; df=1; p=0.051). The difference does not reach significance.

Figure 4.18 Fuchs' and other corneal dystrophies



Number at Risk

Identity	Initially	3 years	6 years	9 years	12 years	15 years	18 years	21 years	24 years
Fuchs' dystrophy	1609	775	377	160	75	21	4	1	n/a
Other dystrophies	245	112	61	34	25	14	3	1	n/a

Identity	No. initially at risk	Graft survival (at years post-graft)				
		1	5	10	15	20
Fuchs' dystrophy	1609	.94	.81	.64	.37	.17
Other dystrophies	245	.92	.86	.79	.63	.29

PENETRATING CORNEAL GRAFT SURVIVAL
FUCHS' DYSTROPHY

Fuchs' dystrophy:	**94% at 1 year**
Mean Survival 12.50 years	**81% at 5 years**
(SE=0.45; 95% CI: 11.61, 13.39)	**64% at 10 years**
Median Survival 14 years	**37% at 15 years**
	17% at 20 years
Other dystrophies:	**92% at 1 year**
Mean Survival 15.72 years	**86% at 5 years**
(SE=0.91; 95% CI: 13.93, 17.51)	**80% at 10 years**
Median Survival 20 years	**63% at 15 years**
	29% at 20 years

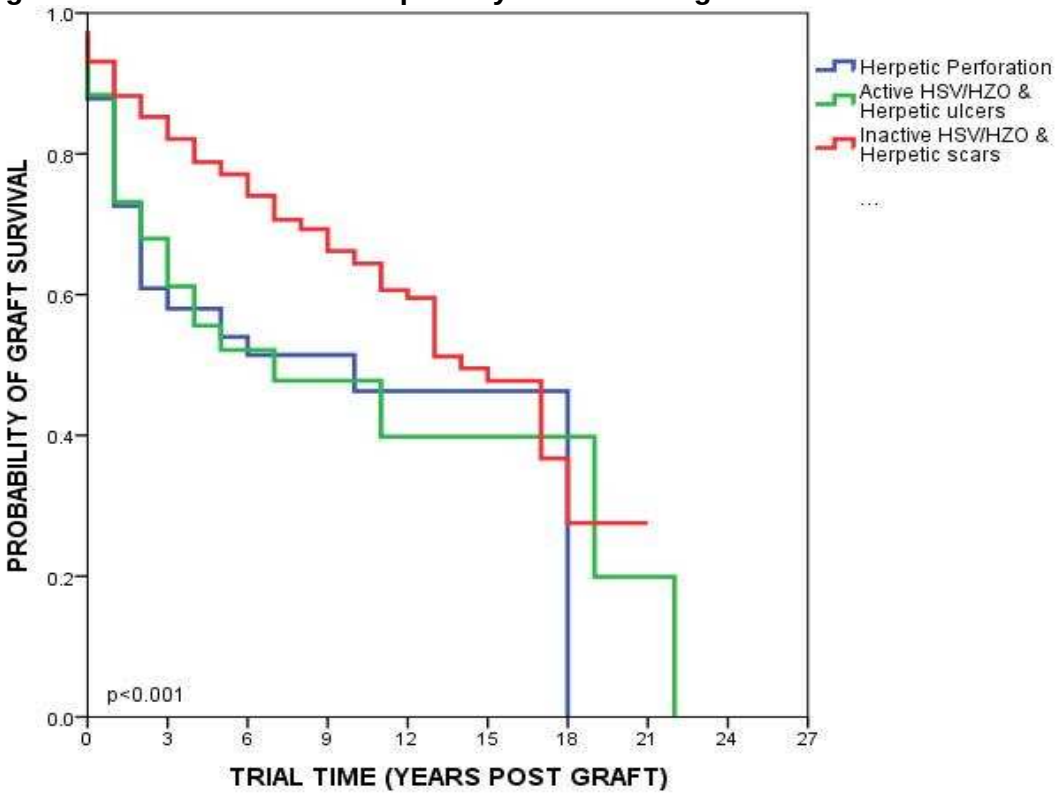
KEY:

n/a	=	not applicable
SE	=	standard error
CI	=	confidence interval
df	=	degrees of freedom M
p	=	probability

4.4.5 Herpetic infection

The effect of herpetic eye disease on a first graft is shown in Figure 4.19. Outcomes of grafts for inactive herpetic disease, active herpetic disease and for perforated herpetic ulcers are compared (Log rank Statistic=26.502; df=2; p<0.001). The major reasons given for the failure of grafts performed for active herpetic infection or herpetic perforation were a recurrence of herpetic infection at some time during the post-graft period (17%) and rejection (17%) followed by herpetic ulcer (10%). In contrast, the major reasons given for the failure of grafts with inactive herpetic disease or scars were rejection (20%), recurrence of herpetic infection (13%) and microbial keratitis (8%).

Figure 4.19 The effect of herpetic eye disease on graft survival



Number at Risk

Identity	Initially	3 years	6 years	9 years	12 years	15 years	18 years	21 years	24 years
Herpetic perforation	148	42	21	11	7	4	1	n/a	n/a
Active HSV/HZO at graft & herpetic ulcers	86	30	13	7	5	3	2	1	n/a
Inactive HSV/HZO & herpetic scars	594	272	151	89	55	28	4	1	n/a

Identity	No. initially at risk	Graft survival (at years post-graft)				
		1	5	10	15	20
Herpetic perforation	148	.73	.54	.46	n/a	n/a
Active HSV/HZO at graft & herpetic ulcers	86	.73	.52	.48	.40	.20
Inactive HSV/HZO & herpetic scars	594	.88	.77	.64	.48	.28

PENETRATING CORNEAL GRAFT SURVIVAL
HERPETIC INFECTION

Herpetic perforation:	**73% at 1 year**
Mean Survival 9.67 years	**54% at 5 years**
(SE=0.93; 95% CI: 7.84, 11.50)	**46% at 10 years**
Median Survival 10 years	
Active HSV/HZO at graft & herpetic ulcers:	**73% at 1 year**
Mean Survival 10.20 years	**52% at 5 years**
(SE=1.48; 95% CI: 7.29, 13.11)	**48% at 10 years**
Median Survival 7 years	**40% at 15 years**
	20% at 20 years
Inactive HSV/HZO & herpetic scars:	**88% at 1 year**
Mean Survival 12.85 years	**77% at 5 years**
(SE=0.57; 95% CI: 11.74, 13.96)	**64% at 10 years**
Median Survival 14 years	**48% at 15 years**
	28% at 20 years

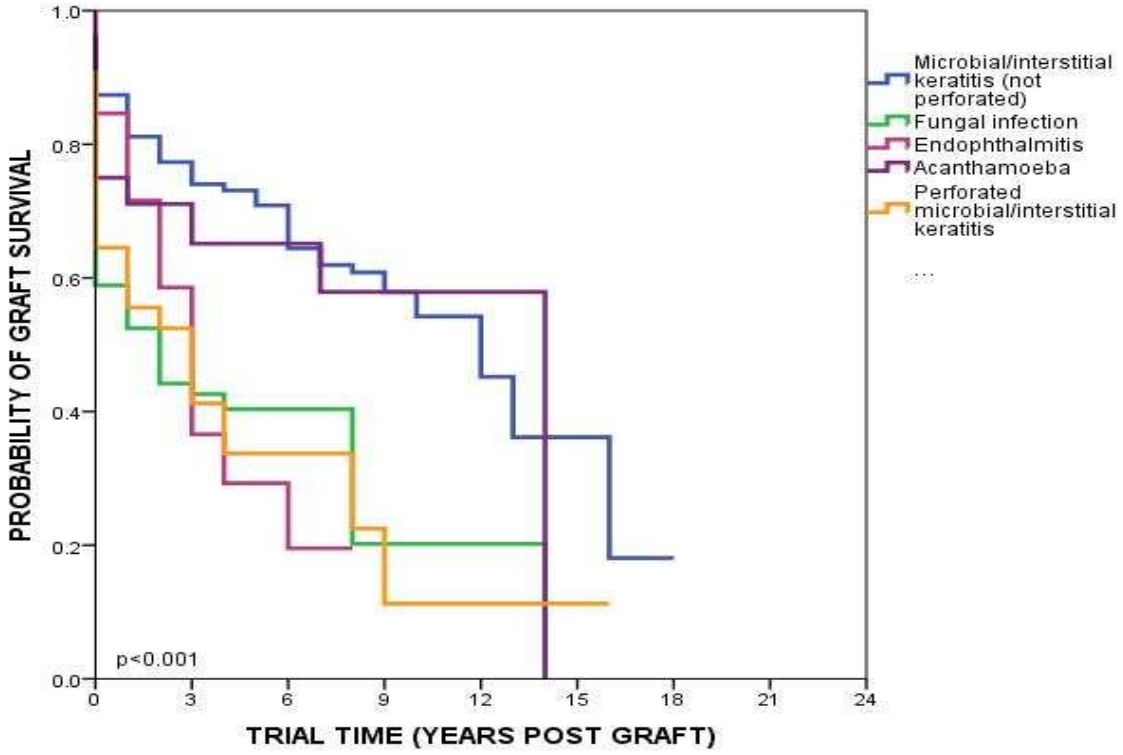
KEY:

n/a	=	not applicable
SE	=	standard error
CI	=	confidence interval
df	=	degrees of freedom
p	=	probability

4.4.6 Non-herpetic infections

Graft survival for various infective indications for transplantation is shown in Figure 4.20 (Log Rank Statistic=70.513, df=4; p<0.001).

Figure 4.20 Non-herpetic infections



Number at Risk

Identity	Initially	3 years	6 years	9 years	12 years	15 years	18 years	21 years
Microbial/interstitial keratitis (not perforated)	547	211	110	41	18	4	1	n/a
Fungal infection	107	28	8	1	n/a	n/a	n/a	n/a
Endophthalmitis	26	8	3	n/a	n/a	n/a	n/a	n/a
Acanthamoeba	28	12	9	3	2	0	n/a	n/a
Perforated microbial/interstitial keratitis	93	14	6	2	1	1	n/a	n/a

Identity	No. initially at risk	Graft survival (at years post-graft)				
		1	5	10	15	20
Microbial/interstitial keratitis (not perforated)	547	.81	.71	.54	.36	n/a
Fungal infection	107	.53	.40	.20	n/a	n/a
Endophthalmitis	26	.72	.29	n/a	n/a	n/a
Acanthamoeba	28	.71	.65	n/a	n/a	n/a
Perforated microbial/interstitial keratitis	93	.56	.34	.11	n/a	n/a

PENETRATING CORNEAL GRAFT SURVIVAL
INFECTIONS

Microbial/interstitial keratitis (not perforated):	**81% at 1 year**
Mean Survival 10.07 years	**71% at 5 years**
(SE=0.56; 95% CI: 8.97, 11.18)	**54% at 10 years**
Median Survival 12 years	**36% at 15 years**
Fungal infection:	**53% at 1 year**
Mean Survival 4.81 years	**40% at 5 years**
(SE=1.03; 95% CI: 2.80, 6.82)	**20% at 10 years**
Median Survival 2 years	
Endophthalmitis:	
Mean Survival 3.49 years	**72% at 1 year**
(SE=0.68; 95% CI: 2.15, 4.83)	**29% at 5years**
Median Survival 3 years	
Acanthamoeba:	
Mean Survival 8.83 years	**71% at 1 year**
(SE=1.36; 95% CI: 6.16, 11.50)	**65% at 5 years**
Median Survival 14 year	
Perforated microbial/interstitial keratitis:	
Mean Survival 4.50 years	**56% at 1 year**
(SE=0.98; 95% CI: 2.57, 6.42)	**34% at 5 years**
Median Survival 3 years	**11% at 10 years**

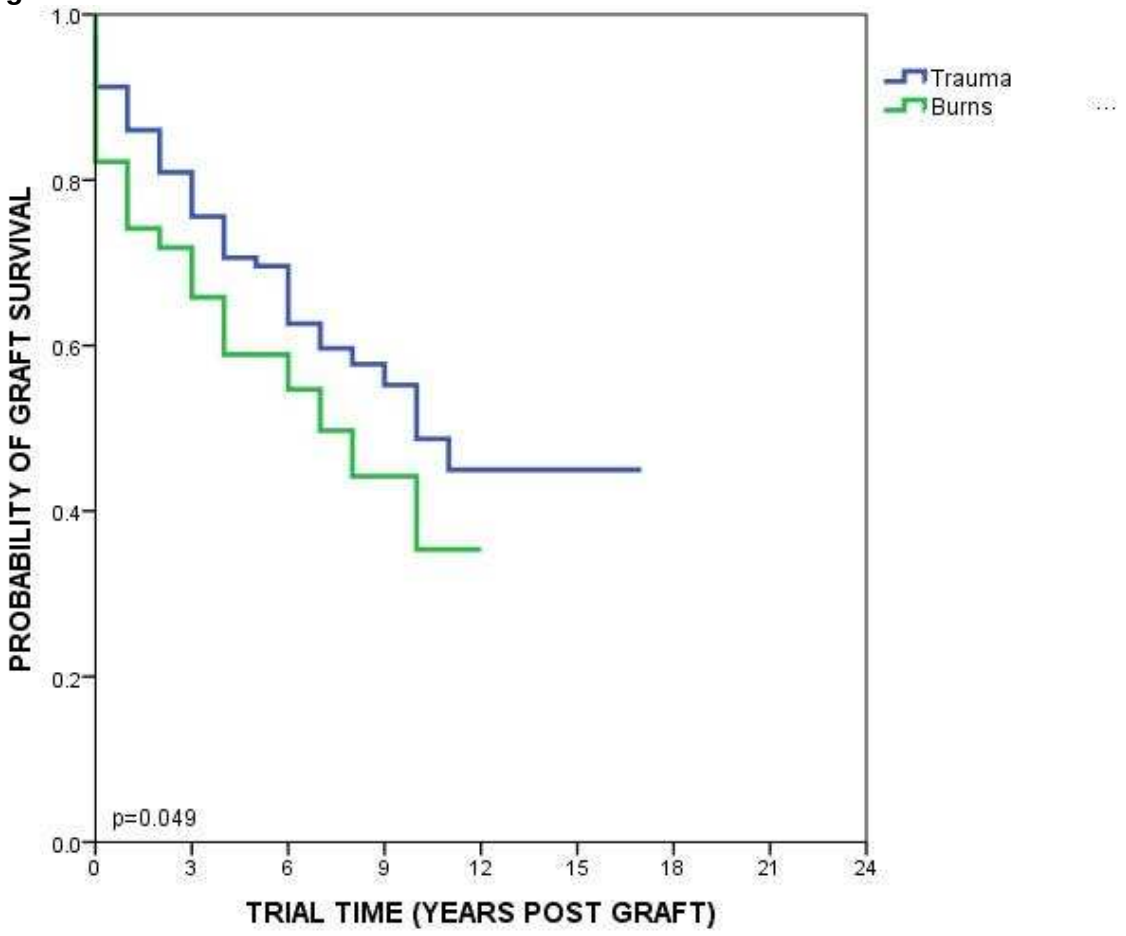
KEY:

n/a	=	not applicable
SE	=	standard error
CI	=	confidence interval
df	=	degrees of freedom
p	=	probability

4.4.7 Burns and trauma

Outcome of first grafts performed for burns (chemical or thermal) or trauma is shown in Figure 4.21 (Log Rank Statistic=3.873, df=1; p=0.049).

Figure 4.21 The effect of burns and trauma



Number at Risk

Identity	Initially	3 years	6 years	9 years	12 years	15 years	18 years	21 years
Trauma	297	121	60	23	8	4	n/a	n/a
Burns	73	24	14	6	3	n/a	n/a	n/a

Identity	No. initially at risk	Graft survival (at years post-graft)				
		1	5	10	15	20
Trauma	297	.86	.70	.49	n/a	n/a
Burns	73	.74	.59	.35	n/a	n/a

PENETRATING CORNEAL GRAFT SURVIVAL
BURNS AND TRAUMA

Trauma:	**86% at 1 year**
Mean Survival 10.28 years	**70% at 5 years**
(SE=0.65; 95% CI: 9.00, 11.55)	**49% at 10 years**
Median Survival 10 years	
Burns:	**74% at 1 year**
Mean Survival 6.75 years	**59% at 5 years**
(SE=0.74; 95% CI: 5.31, 8.20)	**35% at 10 years**
Median Survival 7 years	

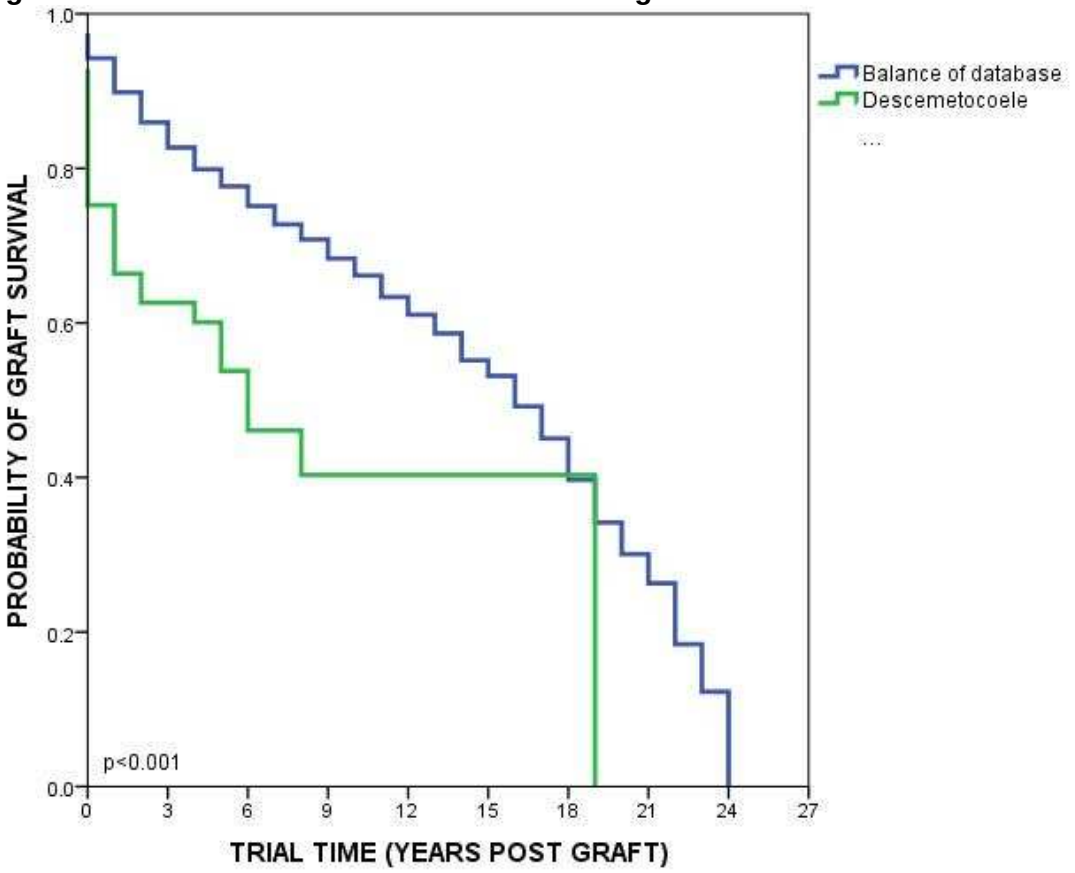
KEY:

n/a	=	not applicable
SE	=	standard error
CI	=	confidence interval
df	=	degrees of freedom
p	=	probability

4.4.8 Descemetocoele

The influence of a descemetocoele as the indication for transplantation on the survival of a first graft is shown in Figure 4.22. The presence of descemetocoele was a risk factor for graft failure (Log Rank Statistic=43.226; df=1; p<0.001).

Figure 4.22 The effect of descemetocoele on graft survival



Number at Risk

Identity	Initially	3 years	6 years	9 years	12 years	15 years	18 years	21 years	24 tears
Balance of database	12887	5408	2710	1353	749	356	118	32	1
Descemetocoele	101	28	14	6	5	4	1	n/a	n/a

Identity	No. initially at risk	Graft survival (at years post-graft)				
		1	5	10	15	20
Balance of database	12887	.90	.78	.66	.53	.30
Descemetocoele	101	.66	.54	.40	n/a	n/a

PENETRATING CORNEAL GRAFT SURVIVAL
DESCEMETOCOELE

Balance of database:	**90% at 1 year**
Mean Survival 14.10 years	**78% at 5 years**
(SE=0.19; 95% CI: 13.72, 14.48)	**66% at 10 years**
Median Survival 16 years	**53% at 15 years**
Descemetocoele:	**66% at 1 year**
Mean Survival 9.17 years	**54% at 5 years**
(SE=1.26; 95% CI: 6.70, 11.63)	**40% at 10 years**
Median Survival 6 years	

KEY:

n/a	=	not applicable
SE	=	standard error
CI	=	confidence interval
df	=	degrees of freedom
p	=	probability

4.5 SUMMARY OF RECIPIENT-RELATED FACTORS

- The sequelae of corneal vascularization, inflammation and raised IOP prior to, or at the time of graft, all exerted significant negative influences on graft survival.

- The main indications for penetrating keratoplasty were keratoconus (30%), bullous keratopathy (26%), failed previous graft (20%), corneal dystrophy (8%), and herpetic eye disease (4%). These broad indications accounted for 88% of penetrating grafts.

- The number of previous ipsilateral grafts influenced the survival of subsequent grafts significantly. However, repeat grafts that had previously failed due to primary non-function or astigmatism showed better graft survival than those that had failed due to rejection or infection.

- Although corneal grafts for keratoconus showed better survival than grafts for all other indications, these grafts were also influenced by rejection episodes, number of previous grafts, age at graft, other pre-graft morbidities and complications.

- Graft survival for uncomplicated keratoconus and for the corneal dystrophies was very good. Graft survival for bullous keratopathy, previous failed graft, burns, trauma, corneal ulcers, active HSV, infection, corneal perforations, endophthalmitis and mycotic ulcers was relatively poor.

5. PROCEDURES AT TIME OF GRAFT AND INFLUENCE OF INTRAOCULAR LENSES

5.1 OPERATIVE PROCEDURES AT GRAFT

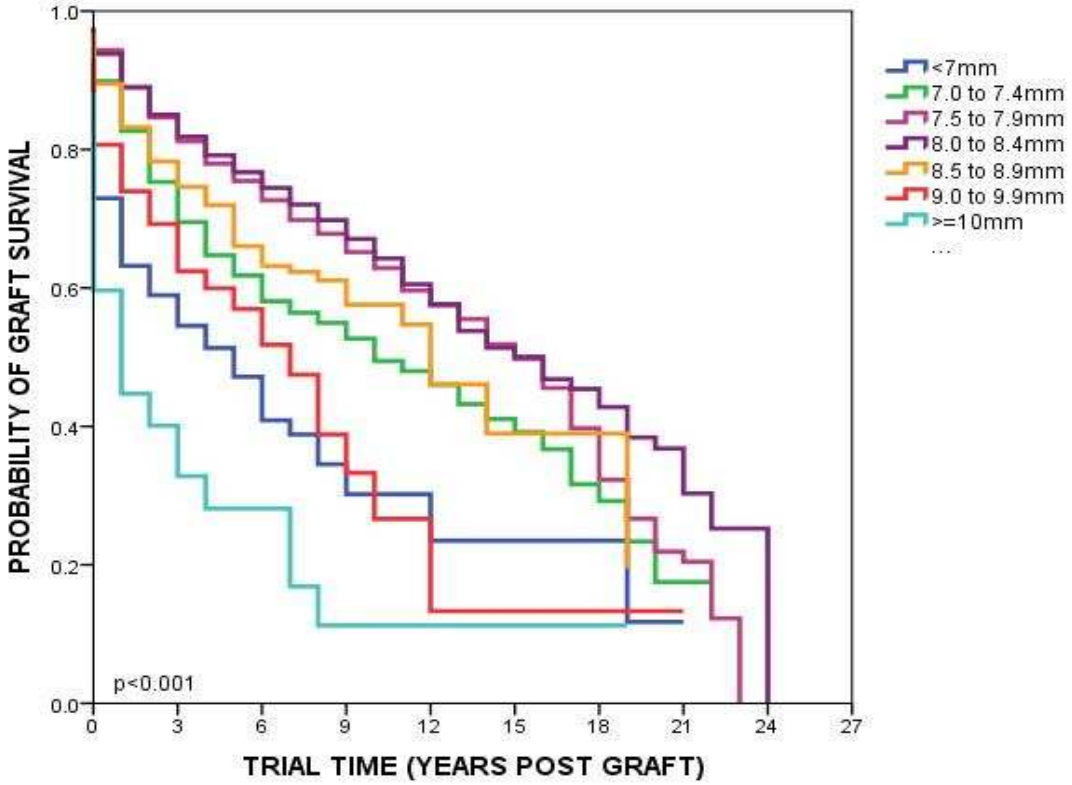
5.1.1 Hostbed size of graft

The hostbed size of the graft was recorded for 18,829 penetrating grafts, and ranged from 2.5 mm to 16.0 mm. Figure 5.1 shows the effect of graft size on the outcome of the 15,440 followed grafts with recorded graft size (Log Rank Statistic=466.63; df=6; p<0.001). Grafts sized between 7.5 mm and 8.5 mm fared better than grafts that are larger or smaller.

Table 5.1 shows the reasons for failure of grafts of different sizes. Rejection was the major cause of failure, except in grafts larger than 9 mm, where infection became a problem.

All Kaplan-Meier plots and associated tables in this chapter have been calculated using penetrating grafts only.

Figure 5.1 Graft size



Number at Risk

Identity	Initially	3 years	6 years	9 years	12 years	15 years	18 years	21 years	24 years
Less than 7 mm	222	67	30	16	9	4	2	1	n/a
7.0 - 7.4 mm	1780	741	365	195	122	66	13	2	n/a
7.5 – 7.9 mm	6633	2789	1437	737	408	193	64	15	0
8.0 - 8.4 mm	5783	2345	1112	537	274	119	52	17	1
8.5 – 8.9 mm	675	257	115	35	19	7	3	n/a	n/a
9.0 – 9.9 mm	233	71	33	7	2	1	1	1	n/a
10.0 mm thru highest	114	22	6	2	2	2	1	n/a	n/a

Identity	No. initially at risk	Graft survival (at years post-graft)				
		1	5	10	15	20
Less than 7 mm	222	.63	.47	.30	.23	.12
7.0 - 7.4 mm	1780	.83	.62	.49	.39	.18
7.5 – 7.9 mm	6633	.89	.75	.63	.50	.22
8.0 - 8.4 mm	5783	.89	.77	.64	.50	.37
8.5 – 8.9 mm	675	.83	.66	.58	.39	n/a
9.0 – 9.9 mm	233	.74	.57	.27	.13	n/a
10.0 mm thru highest	114	.45	.28	.11	.11	n/a

PENETRATING CORNEAL GRAFT SURVIVAL
GRAFT SIZE

< 7.0 mm:	**63% at 1 year**
Mean Survival 7.41 years	**47% at 5 years**
(SE=0.82; 95% CI: 5.80, 9.02)	**30% at 10 years**
Median Survival 5 years	**23% at 15 years**
	12% at 20 years
≥ 7.0 – 7.4 mm:	**83% at 1 year**
Mean Survival 10.89 years	**62% at 5 years**
(SE=0.35; 95% CI: 10.20, 11.58)	**49% at 10 years**
Median Survival 10 years	**39% at 15 years**
	18% at 20years
≥ 7.5 – 7.9 mm:	**89% at 1 year**
Mean Survival 13.14 years	**75% at 5 years**
(SE=0.22; 95% CI: 12.72, 13.57)	**63% at 10 years**
Median Survival 15 years	**50% at 15 years**
	22% at 20 years
≥ 8.0 – 8.4 mm:	**89% at 1 year**
Mean Survival 14.18 years	**77% at 5 years**
(SE=0.31; 95% CI: 13.58, 14.78)	**64% at 10 years**
Median Survival 16 years	**50% at 15 years**
	37% at 20 years
≥ 8.5 – 8.9 mm:	**83% at 1 year**
Mean Survival 11.07 years	**66% at 5 years**
(SE=0.59; 95% CI: 9.92, 12.22)	**89% at 10 years**
Median Survival 12 years	**38% at 20 years**
≥ 9.0 – 9.9 mm:	**74% at 1 year**
Mean Survival 7.48 years	**57% at 5 years**
(SE=1.16; 95% CI: 5.20, 9.76)	**27% at 10 years**
Median Survival 7 years	**13% at 15 years**
≥ 10.0 mm:	**45% at 1 year**
Mean Survival 4.02 years	**28% at 5 years**
(SE=0.92; 95% CI: 2.21, 5.83)	**11% at 10 years**
Median Survival 1 year	**11% at 15 years**

KEY:

n/a	=	not applicable
SE	=	standard error
CI	=	confidence interval
df	=	degrees of freedom
p	=	probability

Table 5.1 Main reasons for graft failure according to hostbed size

Graft size mm	Total followed	Total failed	%	Main reasons for failure	No. failed	%
<7.0	222	106	48%	Rejection	27	25%
				Infection[1]	17	16%
				Unspecified failure	15	14%
				Endothelial cell failure	13	12%
				Glaucoma	6	6%
				Primary non-function	5	5%
				Neovascularization	3	3%
				Scarring or opacity	3	3%
7.0 - <8.5	14196	3130	22%	Rejection	924	30%
				Endothelial cell failure	531	17%
				Unspecified failure	506	16%
				Infection[2]	374	12%
				Glaucoma	214	4%
				Primary non-function	129	4%
				Trauma	73	2%
				Astigmatism	56	2%
				Neovascularization	50	2%
				Corneal degeneration	42	1%
				Scars and opacities	35	1%
8.5 - <9.0	675	176	26%	Rejection	52	30%
				Infection[3]	45	26%
				Unspecified failure	19	11%
				Endothelial cell failure	14	8%
				Glaucoma	11	6%
				Corneal degeneration	6	3%
				Trauma	5	3%
				Primary non-function	4	2%
≥9.0	347	155	45%	Infection[4]	50	32%
				Rejection	39	25%
				Unspecified failure	20	13%
				Corneal degeneration	9	6%
				Endothelial cell failure	7	5%
				Glaucoma	5	3%
				Neovascularization	4	3%

1 Includes: perforated ulcer (6); endophthalmitis (6); abscess (3); HSV (1); mycotic ulcer (1).

2 Includes: abscess (137); HSV (90); perforated ulcer (46); corneal ulcer (40); endophthalmitis (36); mycotic ulcer (12); Streptococcus (4); unspecified viral infection (3); Acanthamoeba (1); Fusarium (1); Gonococcus (1); HZO (1); Pseudomonas (1); trachoma (1).

3 Includes: abscess (13); HSV (9); perforated ulcer (9); mycotic ulcer (4); Acanthamoeba (3); corneal ulcer (3); endophthalmitis (2); Pseudomonas (1); Streptococcus (1).

4 Includes: endophthalmitis (10); mycotic ulcer (10); abscess (8); perforated ulcer (8); HSV (7); corneal ulcer (3); Pseudomonas (3); Acanthamoeba (1).

5.1.2 Accompanying procedures at graft

Table 5.2 lists the operative procedures that took place at the time of graft for all penetrating grafts in the database; 8,728 procedures were carried out during 6,828 graft operations (ie in 34% of the cohort).

It should be noted that data are no longer collected on ECCE/ICCE or the type of intraocular lens. Cataract extraction with an IOL inserted at the time of graft is categorised as a triple procedure.

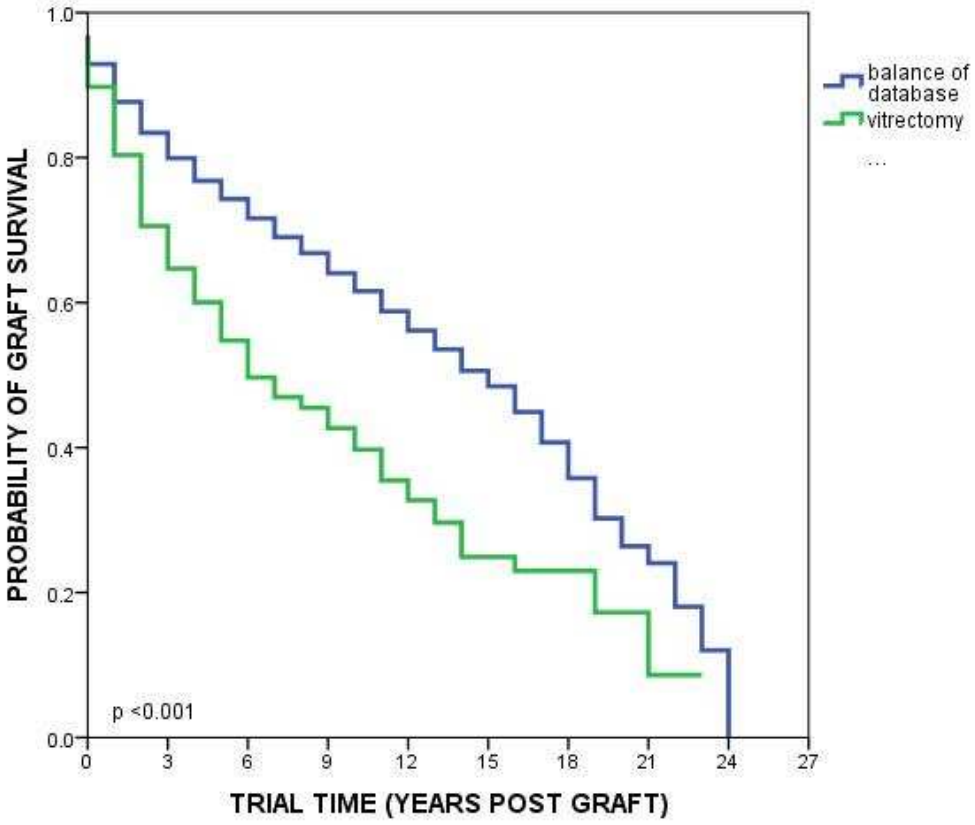
Table 5.2 Overview of operative procedures at graft

Procedure	Sub-total	No.	% of total grafts
Triple procedure		2041	10%
Vitrectomy		1812	9%
Iris procedures:		1709	9%
Peripheral iridectomy	1268		
Pupilloplasty	107		
Iris repair/reconstruction	174		
Sphincterotomy	36		
Synechiolysis	124		
IOL removed and exchanged at graft		1455	7%
Other procedures dealing with IOLs		950	5%
IOL inserted into aphakic eye	552		
Removal of IOL - patient left aphakic	290		
Reposition existing IOL	108		
Cataract removed and patient left aphakic		207	1%
Glaucoma procedures:		120	<1%
Trabeculectomy	62		
Valve (implant/trimming etc)	51		
Cyclodialysis	7		
Tarsorrhaphy		77	<1%
Anterior segment clearance/wash/reconstruction		46	<1%
Gunderson flap/conjunctival flap		24	<1%
Retinal repair		14	<1%
Temporary keratoprosthesis (9 inserted/1 removed)		10	<1%
Miscellaneous other procedures		263	1%
TOTAL PROCEDURES	8728 during 6828 graft operations (34%)		
TOTAL GRAFTS		19952	100%

5.1.3 Influence of vitrectomy

The influence of vitrectomy, performed at the time of graft, on subsequent corneal graft survival is shown in Figure 5.2 (Log Rank Statistic=172.745; df=1; p<0.001).

Figure 5.2 Vitrectomy



Number at Risk

Identity	Initially	3 years	6 years	9 years	12 years	15 years	18 years	21 years	24 years
Balance of database	14689	6088	3033	1488	821	381	132	34	1
Vitrectomy	1602	506	215	97	39	19	4	2	n/a

Identity	No. initially at risk	Graft survival (at years post-graft)				
		1	5	10	15	20
Balance of database	14689	.88	.74	.62	.49	.26
Vitrectomy	1602	.80	.55	.40	.25	.17

The main reasons for failure of grafts where a vitrectomy was performed at the time of graft were rejection (30%), bullous keratopathy and aphakia (14%), glaucoma (12%) and infection (6%). Of the 530 penetrating grafts that failed, 15 cases were reported to be primary non-functions.

PENETRATING CORNEAL GRAFT SURVIVAL
VITRECTOMY

Balance of database:	**88% at 1 year**
Mean Survival 13.28 years	**74% at 5 years**
(SE=0.18, 95% CI: 12.93, 13.62)	**62% at 10 years**
Median Survival 15 years	**49% at 15 years**
	26% at 20 years
Vitrectomy:	**80% at 1 year**
Mean Survival 9.13 years	**55% at 5 years**
(SE=0.45, 95% CI: 8.26, 10.00)	**40% at 10 years**
Median Survival 6 years	**25% at 15 years**
	17% at 20 years

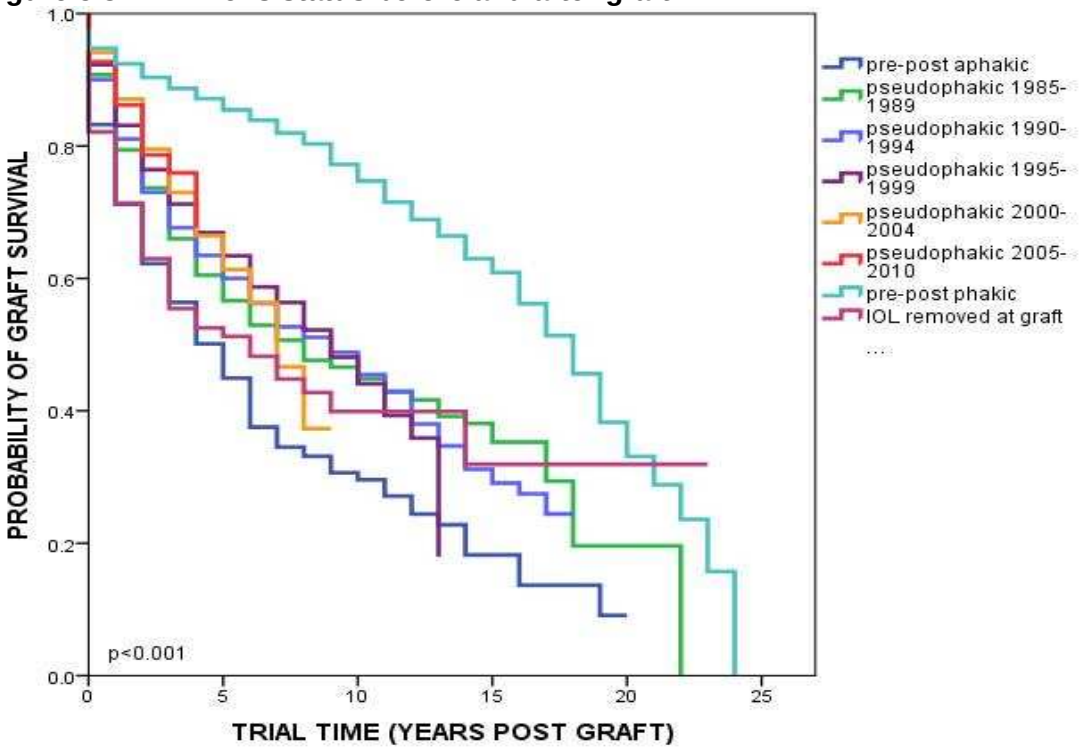
KEY:

n/a	=	not applicable
SE	=	standard error
CI	=	confidence interval
df	=	degrees of freedom
p	=	probability

5.1.4 Lens insertion

Figure 5.3 compares graft survival for those recipients who were phakic, aphakic or pseudophakic at graft (and have remained so), with those recipients who had an IOL inserted or removed at the time of graft (Log Rank Statistic=1051.52; df=7; p<0.001).

Figure 5.3 Lens status before and after graft



Number at Risk

Identity	Initially	3 years	6 years	9 years	12 years	15 years	18 years	21 years	24 years
Aphakic pre & post graft	781	223	91	40	20	7	3	n/a	n/a
Pseudophakic 1985-1989	757	327	169	92	64	27	6	4	n/a
Pseudophakic 1990-1994	2135	779	380	181	89	30	1	n/a	n/a
Pseudophakic 1995-1999	1675	631	311	127	23	n/a	n/a	n/a	n/a
Pseudophakic 2000-2004	1727	632	197	2	n/a	n/a	n/a	n/a	n/a
Pseudophakic 2005-2010	1019	145	n/a	n/a	n/a	n/a	n/a	n/a	n/a
Phakic pre & post graft	7744	3711	2041	1120	652	330	125	31	1
IOL removed at time of graft	263	92	34	15	7	4	1	1	0

Identity	No. initially at risk	Graft survival (at years post-graft)				
		1	5	10	15	20
Aphakic pre & post graft	781	.71	.45	.30	.18	n/a
Pseudophakic 1985-1989	757	.79	.57	.45	.35	.20
Pseudophakic 1990-1994	2135	.81	.60	.46	.29	n/a
Pseudophakic 1995-1999	1675	.83	.63	.44	n/a	n/a
Pseudophakic 2000-2004	1727	.87	.61	n/a	n/a	n/a
Pseudophakic 2005-2010	1019	.86	n/a	n/a	n/a	n/a
Phakic pre & post graft	7744	.92	.86	.75	.61	.33
IOL removed at time of graft	263	.71	.51	.40	.32	.32

PENETRATING CORNEAL GRAFT SURVIVAL
LENS STATUS

Aphakic pre & post graft:	**71% at 1 year**
Mean Survival 6.94 years	**45% at 5 years**
(SE=0.44; 95% CI: 6.08, 7.81)	**30% at 10 years**
Median Survival 5 years	**18% at 15 years**
Pseudophakic 1985-1989:	**79% at 1 year**
Mean Survival 10.10 years	**57% at 5 years**
(SE=0.50; 95% CI: 9.12, 11.08)	**45% at 10 years**
Median Survival 8 years	**35% at 15 years**
	20% at 20 years
Pseudophakic 1990-1994:	**81% at 1 year**
Mean Survival 9.17 years	**60% at 5 years**
(SE=0.25; 95% CI: 8.69, 9.65)	**46% at 10 years**
Median Survival 9 years	**29% at 15 years**
Pseudophakic 1995-1999:	**83% at 1 year**
Mean Survival 7.88 years	**63% at 5 years**
(SE=0.18; 95% CI: 7.53, 8.23)	**44% at 10 years**
Median Survival 9 years	
Pseudophakic 2000-2004:	**87% at 1 year**
Mean Survival 6.02 years	**61% at 5 years**
(SE=0.12; 95% CI: 5.79, 6.25)	
Median Survival 7 years	
Pseudophakic 2005-2010:	**86% at 1 year**
Mean Survival 3.34 years	
(SE=0.05; 95% CI: 3.25, 3.42)	
Median Survival approx 4 years	
Phakic pre & post graft:	**92% at 1 year**
Mean Survival 15.60 years	**86% at 5 years**
(SE=0.22; 95% CI: 15.17, 16.04)	**75% at 10 years**
Median Survival 18 years	**61% at 15 years**
	33% at 20 years
IOL removed at time of graft:	**71% at 1 year**
Mean Survival 9.98 years	**51% at 5 years**
(SE=1.07; 95% CI: 7.88, 12.09)	**40% at 10 years**
Median Survival 6 years	**32% at 15 years**

KEY:

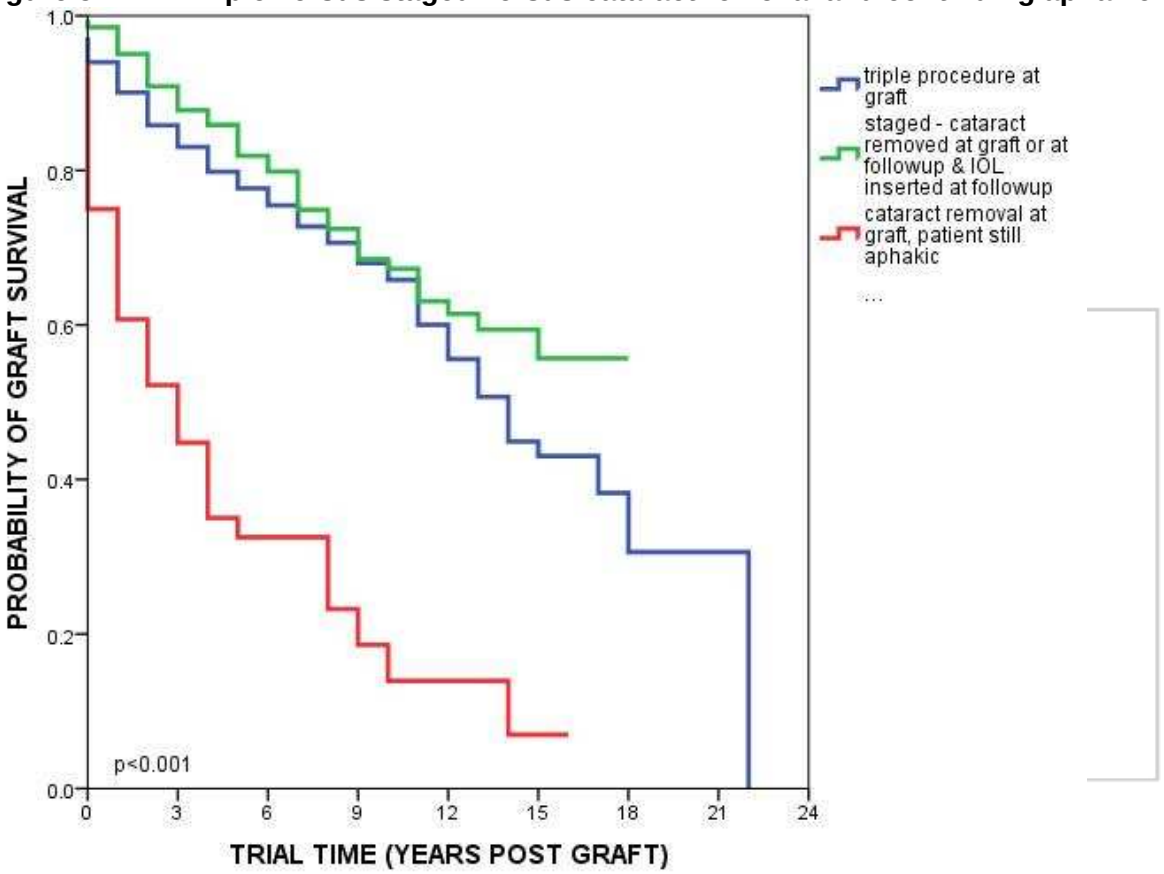
n/a	=	not applicable
SE	=	standard error
CI	=	confidence interval
df	=	degrees of freedom
p	=	probability

5.1.4.1 Triple and staged procedures

Figure 5.4 compares the graft survival of triple and staged procedures, with graft survival in those patients who underwent cataract removal at graft but who had remained aphakic (Log Rank Statistic=170.263, df=2, p<0.001).

Triple procedures are defined as cataract removal and IOL insertion at the time of corneal graft. Staged procedures are defined as cataract removal at time of corneal graft and IOL insertion at some time after the graft, during the follow-up period or cataract removal and IOL insertion concurrently post graft.

Figure 5.4 Triple versus staged versus cataract removal and continuing aphakic



Number at Risk

Identity	Initially	3 years	6 years	9 years	12 years	15 years	18 years	21 years	24 years
Triple procedure	1718	735	352	161	81	24	5	3	n/a
Staged procedure	472	295	160	74	39	16	1	n/a	n/a
Cataract removal at graft, still aphakic	148	28	11	5	3	1	n/a	n/a	n/a

Identity	No. initially at risk	Graft survival (at years post-graft)				
		1	5	10	15	20
Triple procedure	1718	.90	.78	.66	.43	.31
Staged procedure	472	.95	.82	.67	.56	n/a
Cataract removal at graft, still aphakic	148	.61	.33	.14	.07	n/a

We observed a significant difference in graft survival between the cohort who underwent a triple procedure compared with the cohort who underwent a staged procedure (Log Rank Statistic=6.351; df=1, p=0.012). However, both cohorts showed significantly better graft survival than the cohort in whom a cataract was removed at the time of corneal transplantation, but who had remained aphakic. The main reasons for corneal graft failure in the group who underwent cataract removal at graft and who remained aphakic were: rejection (27%), infection (15%) glaucoma (12%), endothelial defects (11%), bullous keratopathy and endophthalmitis (5%) and herpetic eye disease (4%).

PENETRATING CORNEAL GRAFT SURVIVAL
TRIPLE AND STAGED PROCEDURES

Triple procedure:	**90% at 1 year**
Mean Survival 13.21 years	**78% at 5 years**
(SE=0.53; 95% CI: 12.18, 14.24)	**66% at 10 years**
Median Survival 14 years	**43% at 15 years**
	31% at 20 years
Staged Procedure:	**95% at 1 year**
Mean Survival 13.13 years	**82% at 5 years**
(SE=0.45; 95% CI: 12.25, 14.02)	**67% at 10 years**
Median Survival approx. 18 years	**56% at 15 years**
Cataract removal at graft, still aphakic:	**61% at 1 year**
Mean Survival 4.77 years	**33% at 5 years**
(SE=0.66; 95% CI: 3.47, 6.07)	**14% at 10 years**
Median Survival 3 years	**7% at 15 years**

KEY:

n/a	=	not applicable
SE	=	standard error
CI	=	confidence interval
df	=	degrees of freedom
p	=	probability

5.2 SUMMARY OF EFFECT OF PROCEDURES AT TIME OF GRAFT AND INFLUENCE OF INTRAOCULAR LENSES

- Graft size was correlated with graft survival. Grafts within the size range of about 7.5 to 8.5 mm in diameter fared best. By comparison, larger and smaller grafts showed reduced survival. Rejection was a major cause of graft failure across all groups, but infection also caused the loss of very large and very small grafts.

- In 34% of corneal grafts, some other specified procedure was carried out at the same time. The most frequently-performed of these procedures were a manipulation involving the crystalline lens or an intraocular lens (10%) and vitrectomy (9%).

- Graft survival was better in phakic than in aphakic or pseudophakic recipients.

- Graft survival did not differ greatly between the cohorts who had undergone a triple procedure or a staged lens implant but the difference was significant (p=0.01), favouring the staged procedure.

6. POST-GRAFT EVENTS

6.1 REASONS FOR GRAFT FAILURE

Table 6.1 lists the main reasons for failure of 3,794 failed penetrating grafts.

Table 6.1 Reason for graft failure

Reason	Sub-total	Total	%
Rejection		**1161**	**31%**
unspecified/endothelial cell failure	957		
with glaucoma	57		
with non-herpetic infection	27		
with herpetic infection	26		
with vascularization	23		
with ulcer	16		
with scars and opacities	7		
with corneal degeneration	6		
with epithelial defect	6		
with injury	5		
with keratoconus/keratoglobus	3		
with ICE syndrome	3		
with retinal detachment	2		
Other	23		
Endothelial cell failure		**568**	**15%**
with pseudophakic bullous keratopathy	149		
with bullous keratopathy	66		
with aphakic bullous keratopathy	49		
not specified	304		
Non-herpetic infections		**291**	**8%**
Corneal abscess	175		
unspecified	113		
with perforation/dehiscence	17		
with scars	8		
with glaucoma	3		
with endothelial cell failure	2		
Other	32		
Endophthalmitis	62		
Mycotic ulcers	30		
Pseudomonas	7		
Streptococcus	6		
Acanthamoeba	5		
Fusarium	1		
Adenoviral conjunctivitis	1		
Unspecified viral infection	1		
Gonococcus	1		
Scleral abscess	1		
Trachoma	1		
Glaucoma		**287**	**8%**
unspecified	171		
with endothelial cell failure	55		
with iris disorders	11		
with ulcers	8		
with epithelial defect	5		
with vascularization	4		
with corneal degeneration	3		
with scars	3		
Other	27		

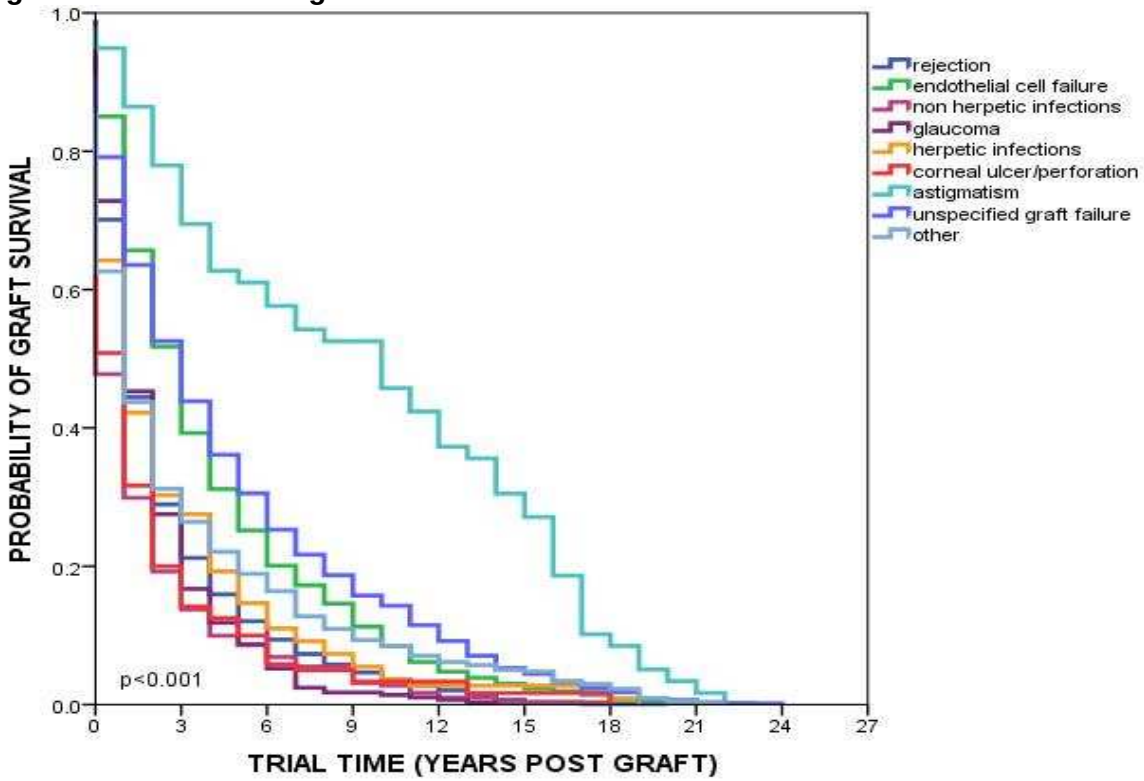
Reason	Sub-total		Total	%
Primary graft failure			**151**	**4%**
Ulcers (not from infection)			**120**	**3%**
perforated		74		
central		10		
with hypopyon		2		
unspecified	20	34		
with neovascularization	4			
with scars	3			
other	7			
Herpetic Infection			**109**	**3%**
HSV		108		
unspecified	61			
with ulcer	16			
with perforation	6			
with endothelial cell failure	5			
with abscess	5			
with neovascularization	5			
other	10			
HZO		1		
Injury/trauma			82	2%
Astigmatism			59	2%
Corneal degeneration			56	2%
Vascularization			51	1%
Epithelial defect			44	1%
Scars and opacities			42	1%
Iris disorders			20	<1%
Phthisis bulbi			18	<1%
Wound dehiscence			14	<1%
Metabolic deposits			13	<1%
Corneal dystrophies			12	<1%
Keratoconus			11	<1%
Retinal detachment			10	<1%
Keratitis			9	<1%
Descemetocoele			9	<1%
Miscellaneous*			48	1%
Unspecified			609	16 %
TOTAL			**3794**	**100%**

* choroidal haemorrhage (7); hypotony (7); buphthalmos (6); cataract (3); dry eye syndrome (3); squamous cell carcinoma (3); conjunctival melanoma (2); vitreous disorders (2); Stevens-Johnson syndrome (2); aniridia (1); complications from cataract removal (1); congenital nystagmus (1); erythroderma (1); meibomianitis (1); nuclear sclerosis (1); ocular Munchausen syndrome (1); ocular pemphigus (1); Peters' anomaly (1); pterygium (1); retinal vein occlusion (1); scleral degeneration (1); unspecified immune deficiency (1).

All Kaplan-Meier plots and associated tables in this chapter have been calculated using penetrating grafts only.

Figure 6.1 uses the same data as for Table 6.1 and therefore represents only failed grafts. Primary graft failure was removed from the dataset as such grafts have a graft survival time of ≤ 1 day (Log Rank Statistic=312.641; df=8; p<0.001).

Figure 6.1 Reason for graft failure



Number at Risk

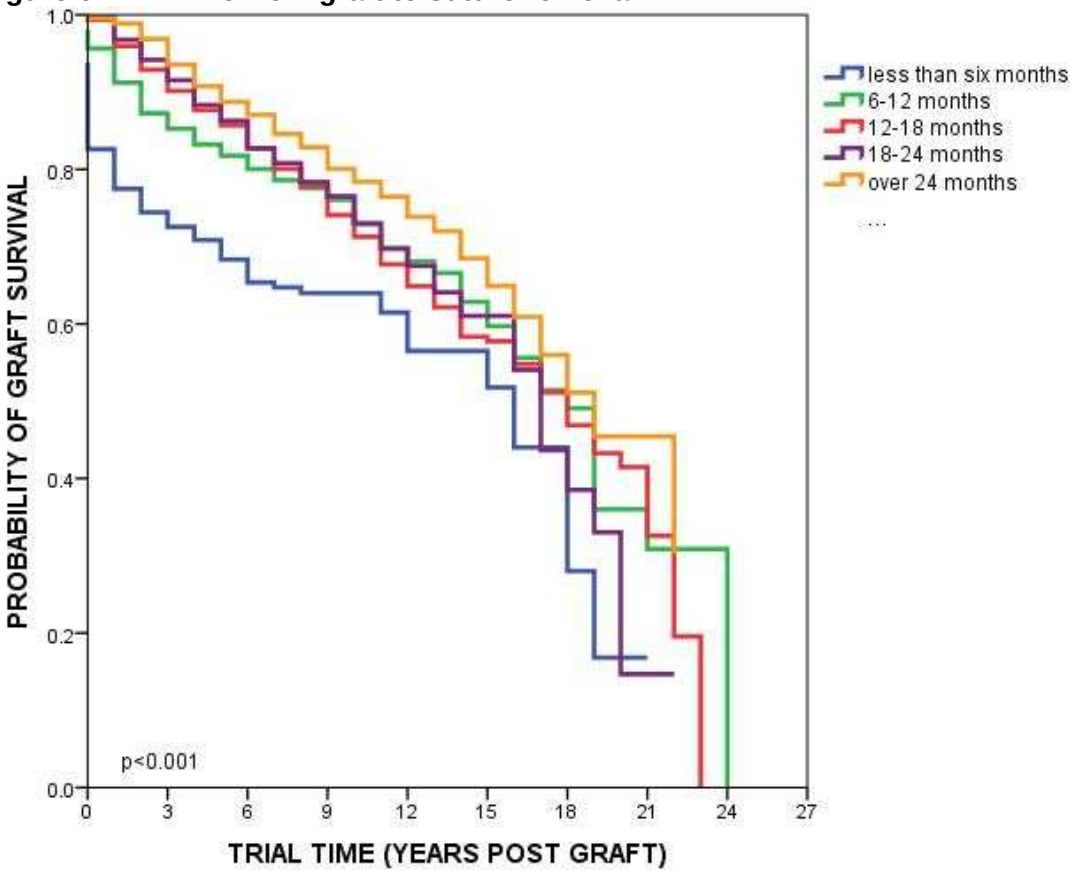
Identity	Initially	3 years	6 years	9 years	12 years	15 years	18 years	21 years	24 years
Irreversible rejection	1161	336	140	67	32	8	1	n/a	n/a
Endothelial failure	568	294	143	83	35	17	8	1	n/a
Infection	291	56	25	16	5	1	1a	n/a	n/a
Glaucoma	287	79	25	5	3	0	n/a	n/a	n/a
Herpetic infection	109	33	16	8	3	3	n/a	n/a	n/a
Ulcers/perforation	120	24	12	6	4	2	2	n/a	n/a
Astigmatism	59	46	36	31	25	18	6	2	n/a
Graft failure	609	320	186	114	70	32	14	4	1
Other	439	137	83	48	31	22	13	2	n/a

Identity	No. initially at risk	Graft survival (at years post-graft)				
		1	5	10	15	20
Irreversible rejection	1161	.44	.12	.04	.003	.00
Endothelial failure	568	.66	.25	.09	.02	.002
Infection	291	.30	.09	.03	.003	n/a
Glaucoma	287	.45	.09	.01	n/a	n/a
Herpetic infection	109	.42	.15	.04	n/a	n/a
Ulcers/perforation	120	.32	.10	.03	.02	n/a
Astigmatism	59	.86	.61	.46	.27	.03
Graft failure	609	.64	.31	.14	.04	.007
Other	439	.44	.19	.08	.05	.005

6.2 TIME TO SUTURE REMOVAL

Figure 6.2 shows the influence of time of suture removal on graft survival (Log Rank Statistic=178.951; df=4; p<0.001). Of the 558 grafts in which sutures were removed by 6 months post graft, 165 (29%) failed.

Figure 6.2 Time from graft to suture removal



Number at Risk

Identity	Initially	3 years	6 years	9 years	12 years	15 years	18 years	21 years	24 years
Less than 6 months	558	198	115	74	37	24	11	1	n/a
6-12 months	1814	876	475	256	163	80	22	7	1
12-18 months	3123	1627	796	388	215	101	48	14	0
18-24 months	1486	787	386	170	93	48	17	3	n/a
Over 24 months	1705	1319	696	357	206	96	23	9	n/a

Identity	No. initially at risk	Graft survival (at years post-graft)				
		1	5	10	15	20
Less than 6 months	558	.78	.68	.64	.52	.17
6-12 months	1814	.91	.82	.73	.60	.36
12-18 months	3123	.96	.86	.71	.58	.42
18-24 months	1486	.97	.86	.73	.61	.33
Over 24 months	1705	.99	.89	.78	.65	.45

The reasons for failure of these grafts are shown in Table 6.2. Reasons for graft failure in the cohort for early suture removal were very similar to those of the whole cohort.

Table 6.2 Reasons for graft failure associated with removal of all sutures by <6 months post-operatively

Reason for failure	Sub-total	Total	%
Rejection		51	31%
with ulcers	4		
with endothelial cell failure	3		
with glaucoma	3		
with vascularization	2		
with scars	2		
with pannus	1		
with dry eye syndrome	1		
with corneal degeneration	1		
with injury	1		
with epithelial defect	1		
with band-shaped keratopathy	1		
unspecified	31		
Infection		21	13%
abscess	8		
herpetic	6		
endophthalmitis	5		
mycotic ulcer	2		
Glaucoma		15	9%
with endothelial decompensation	2		
with iris disorders	2		
with neovascularization	1		
with keratitis	1		
with epithelial defects	1		
unspecified	8		
Endothelial cell failure		14	8%
Ulcers		7	4%
perforated	4		
central	2		
unspecified	1		
Astigmatism		6	4%
Neovascularization		6	4%
Scars and opacities		5	3%
Epithelial defect		3	2%
Miscellaneous[1]		16	10%
Unspecified		21	13%
TOTAL		**165**	**100%**

[1] corneal degeneration (2); keratitis (2); phthisis bulbi (2); retinal detachment (2); trauma (2); buphthalmos (1); choroidal haemorrhage (1); descemetocoele (1); granular dystrophy (1); keratoconus (1); primary graft failure (1).

PENETRATING CORNEAL GRAFT SURVIVAL
TIME TO SUTURE REMOVAL

Less than 6 months:	**78% at 1 year**
Mean Survival 12.01 years	**68% at 5 years**
(SE=0.54; 95% CI: 10.96, 13.06)	**64% at 10 years**
Median Survival 16 years	**52% at 15 years**
	17% at 20 years
6-12 months:	**91% at 1 year**
Mean Survival 15.57 years	**82% at 5 years**
(SE=0.47; 95% CI: 14.64, 16.50)	**73% at 10 years**
Median Survival 18 years	**60% at 15 years**
	36% at 20 years
12-18 months:	**96% at 1 year**
Mean Survival 15.38 years	**86% at 5 years**
(SE=0.32; 95% CI: 14.75, 16.01)	**71% at 10 years**
Median Survival 18 years	**58% at 15 years**
	42% at 20 years
18-24 months:	**97% at 1 year**
Mean Survival 14.70 years	**86% at 5 years**
(SE=0.40; 95% CI: 13.91, 15.49)	**73% at 10 years**
Median Survival 17 years	**61% at 15 years**
	33% at 20 years
Over 24 months:	**99% at 1 year**
Mean Survival 16.41 years	**89% at 5 years**
(SE=0.35; 95% CI: 15.73, 17.10)	**78% at 10 years**
Median Survival 19 years	**65% at 15 years**
	45% at 20 years

KEY:

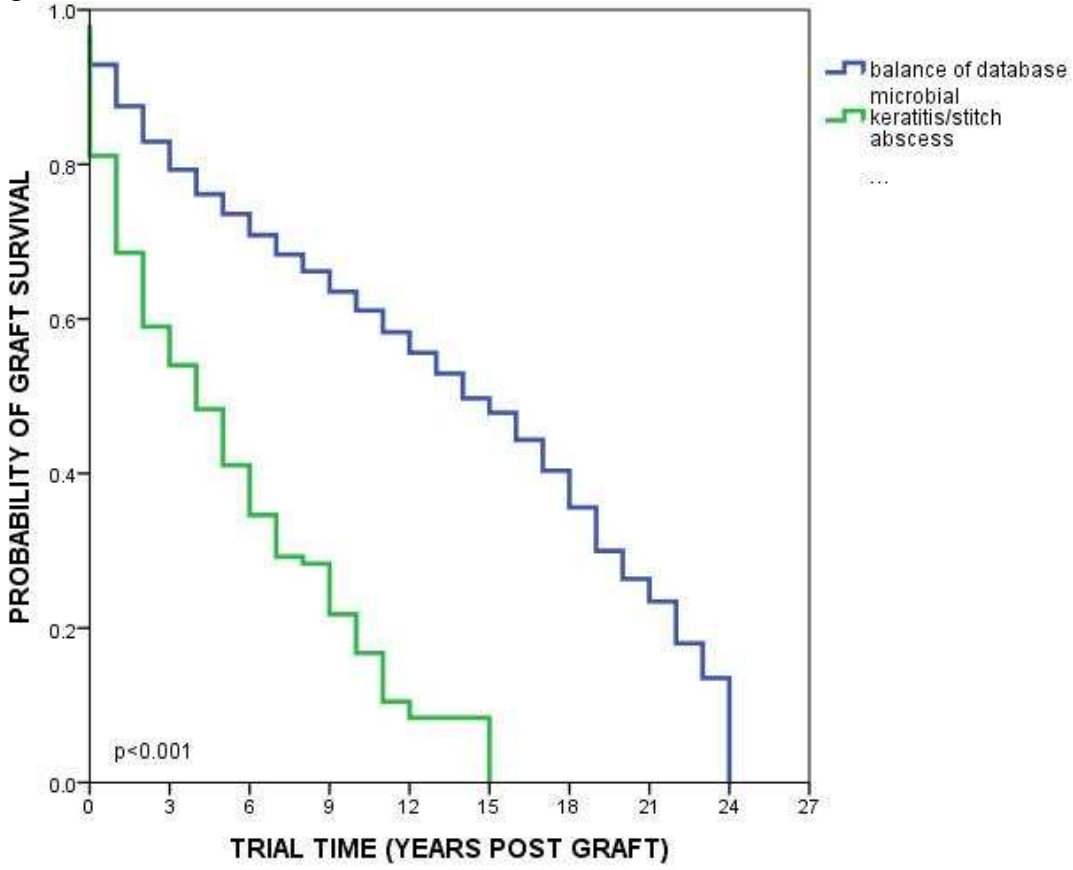
n/a	=	not applicable
SE	=	standard error
CI	=	confidence interval
df	=	degrees of freedom
p	=	probability

6.3 POST-GRAFT COMPLICATIONS

6.3.1 Microbial keratitis/stitch abscess

The development of microbial keratitis or stitch abscess was associated with poor corneal graft survival (Log Rank Statistic=284.398; df=1; p<0.001).

Figure 6.3 Microbial keratitis/stitch abscess



Number at Risk

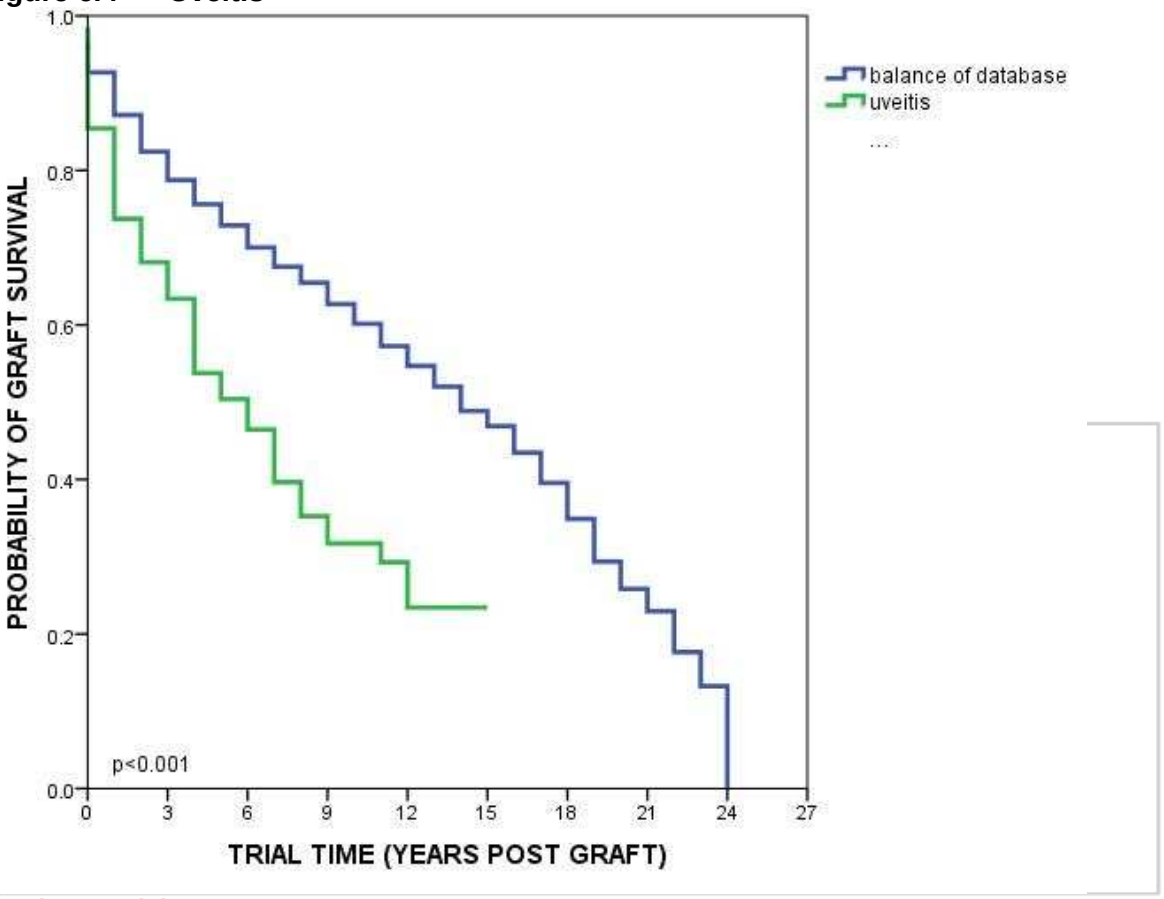
Identity	Initially	3 years	6 years	9 years	12 years	15 years	18 years	21 years	24 years
Balance of database	15862	6417	3178	1559	855	399	136	36	1
Microbial keratitis or stitch abscess	429	177	70	26	5	1	n/a	n/a	n/a

Identity	No. initially at risk	Graft survival (at years post-graft)				
		1	5	10	15	20
Balance of database	15862	.88	.74	.61	.48	.26
Microbial keratitis or stitch abscess	429	.69	.41	.17	.00	n/a

6.3.2 Uveitis

Post-operative uveitis was another risk factor for corneal graft failure (Log Rank Statistic= 62.133; df=1; p=<0.001).

Figure 6.4 Uveitis



Number at Risk

Identity	Initially	3 years	6 years	9 years	12 years	15 years	18 years	21 years	24 years
Balance of database	16085	6493	3197	1565	850	399	136	36	1
Uveitis	206	101	51	20	10	1	n/a	n/a	n/a

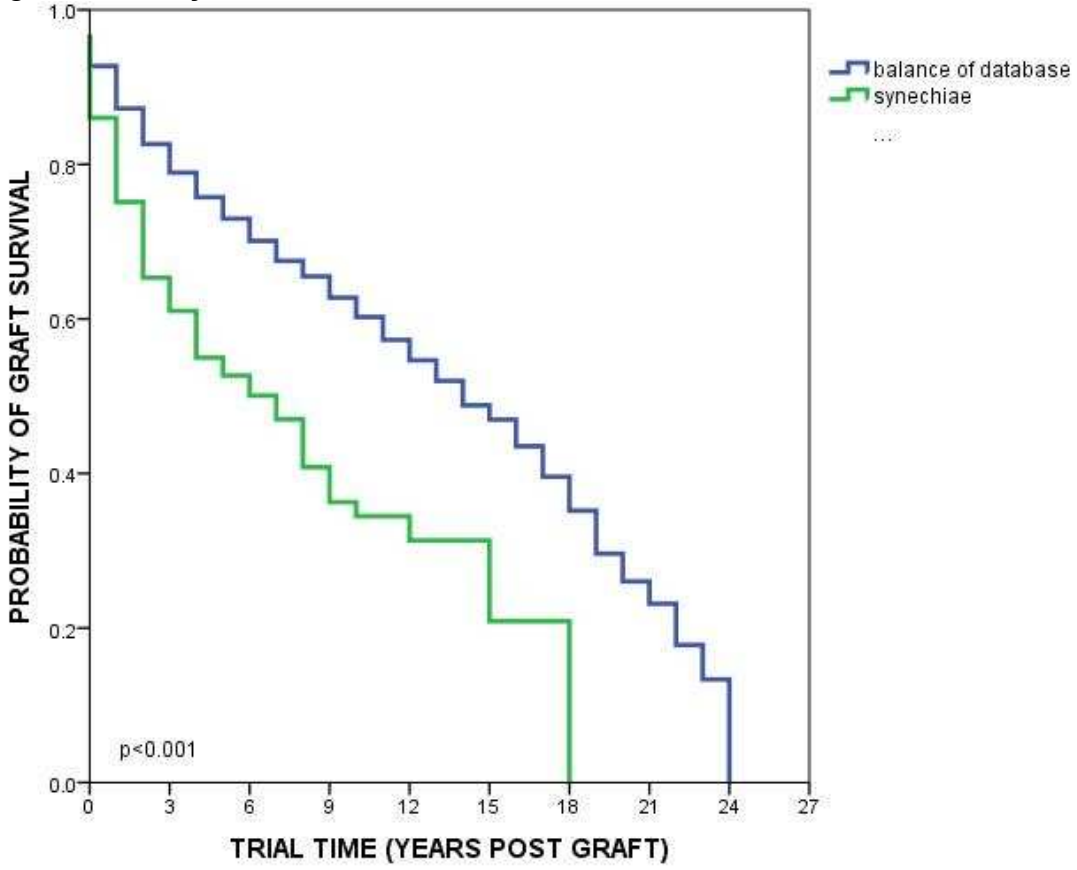
Identity	No. initially at risk	Graft survival (at years post-graft)				
		1	5	10	15	20
Balance of database	16085	.87	.73	.60	.47	.26
Uveitis	206	.74	.50	.32	n/a	n/a

The main indications for grafts with uveitis were failed previous graft (27%), bullous keratopathy (26%) and keratoconus (11%).

6.3.3 Synechiae

Development of synechiae was a risk factor for graft failure, as shown in Figure 6.5 (Log Rank Statistic= 75.333; df=1; p=<0.001).

Figure 6.5 Synechiae



Number at Risk

Identity	Initially	3 years	6 years	9 years	12 years	15 years	18 years	21 years	24 years
Balance of database	15962	6457	3187	1558	849	397	135	36	1
Synechiae	329	137	61	27	11	3	1	n/a	n/a

Identity	No. initially at risk	Graft survival (at years post-graft)				
		1	5	10	15	20
Balance of database	15962	.87	.73	.60	.47	.26
Synechiae	329	.75	.53	.35	.21	n/a

The main indications for grafts with synechiae were bullous keratopathy (38%) and failed previous graft (20%). Sixty eight (21%) of these grafts had vitrectomy at graft.

PENETRATING CORNEAL GRAFT SURVIVAL
MICROBIAL KERATITIS/STITCH ABSCESS

Balance of database:	**88% at 1 year**
Mean Survival 13.18 years	**74% at 5 years**
(SE=0.17; 95% CI: 12.85, 13.52)	**61% at 10 years**
Median Survival 14 years	**48% at 15 years**
	26% at 20 years
Microbial keratitis or stitch abscess:	**69% at 1 year**
Mean Survival 5.18 years	**41% at 5 years**
(SE=0.31; 95% CI 4.58, 5.78)	**17% at 10 years**
Median Survival 4 years	

PENETRATING CORNEAL GRAFT SURVIVAL
UVEITIS

Balance of database:	**87% at 1 year**
Mean Survival 13.02 years	**73% at 5 years**
(SE=0.17, 95% CI: 12.69, 13.35)	**60% at 10 years**
Median Survival 14 years	**47% at 15 years**
	26% at 20 years
Uveitis:	**74% at 1 year**
Mean Survival 6.79 years	**50% at 5 years**
(SE=0.49, 95% CI: 5.85, 7.75)	**32% at 10 years**
Median Survival 6 years	

PENETRATING CORNEAL GRAFT SURVIVAL
SYNECHIAE

Balance of database:	**87% at 1 year**
Mean Survival 13.04 years	**73% at 5 years**
(SE=0.17, 95% CI: 12.71, 13.37)	**60% at 10 years**
Median Survival 14 years	**47% at 15 years**
	26% at 20 years
Synechiae:	**75% at 1 year**
Mean Survival 7.95 years	**53% at 5 years**
(SE=0.59, 95% CI: 6.79, 9.11)	**35% at 10 years**
Median Survival 7 years	**21% at 15 years**

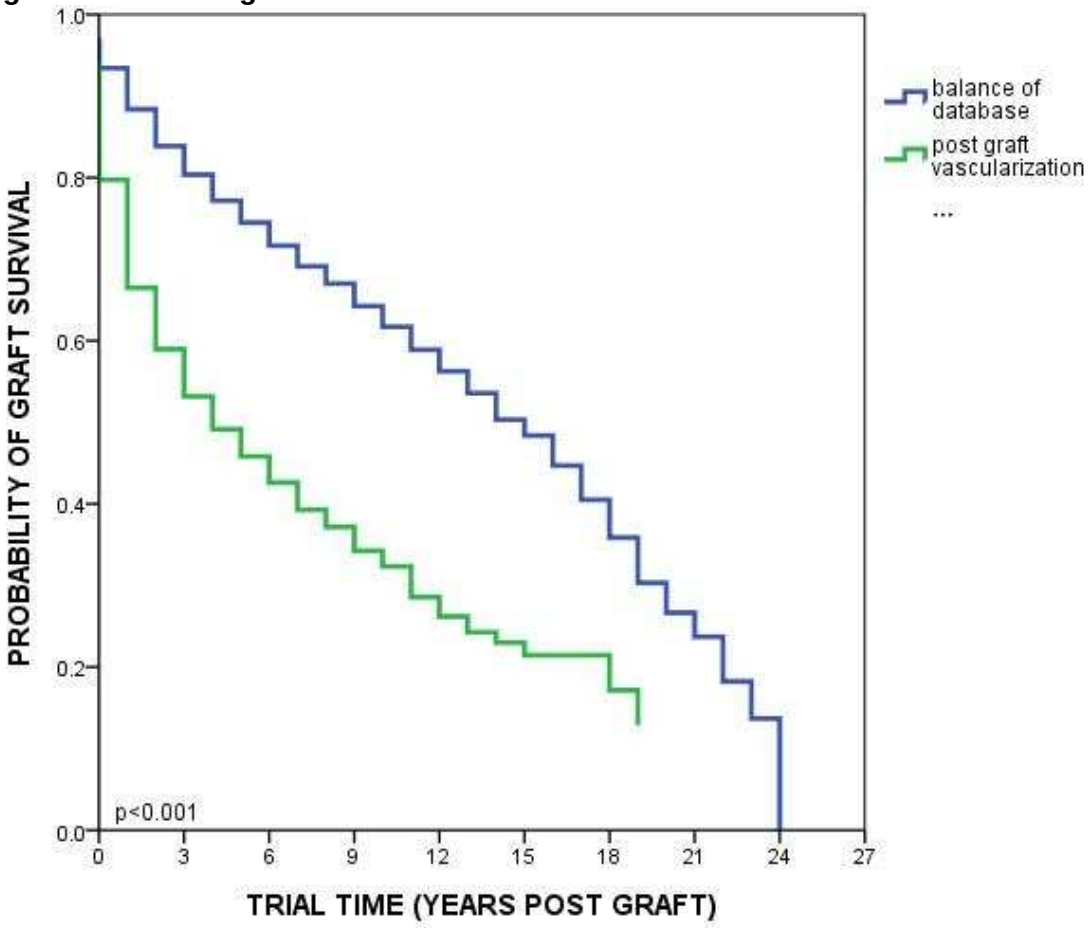
KEY:

n/a	=	not applicable
SE	=	standard error
CI	=	confidence interval
df	=	degrees of freedom
p	=	probability

6.3.4 Post-graft vascularization

The effect of post-graft vascularization on graft survival is shown in Figure 6.6 (Log Rank Statistic=451.148; df=1; p<0.001). Graft neovascularization was a significant risk factor for graft failure.

Figure 6.6 Post-graft vascularization



Number at Risk

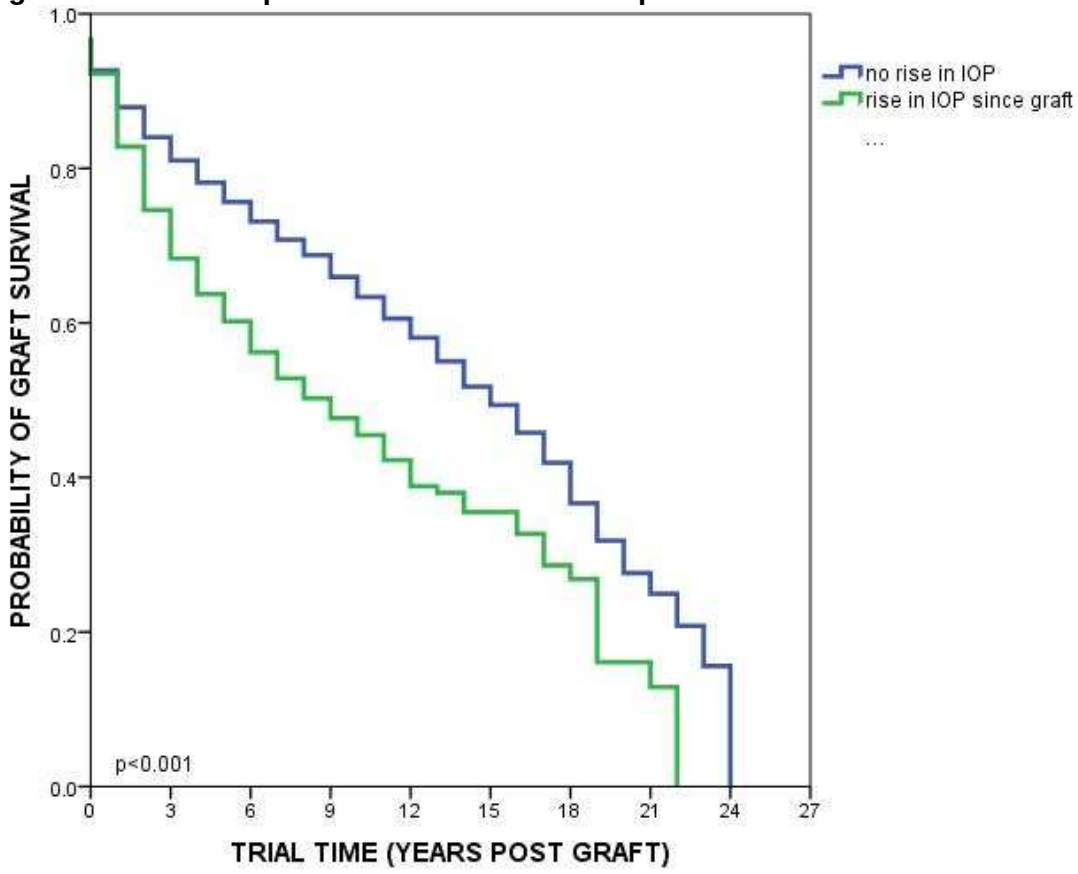
Identity	Initially	3 years	6 years	9 years	12 years	15 years	18 years	21 years	24 years
Balance of database	15314	6218	3077	1509	824	385	131	36	1
Post-graft vascularization	977	376	171	76	36	15	5	n/a	n/a

Identity	No. initially at risk	Graft survival (at years post-graft)				
		1	5	10	15	20
Balance of database	15394	.88	.75	.62	.48	.27
Post-graft vascularization	977	.67	.46	.32	.21	n/a

6.3.5 Post operative rise in intraocular pressure

A post-operative rise in intraocular pressure was a significant risk factor for corneal graft failure (Log Rank Statistic=192.978; df=1; p<0.001).

Figure 6.7 Post-operative rise in intraocular pressure



Number at Risk

Identity	Initially	3 years	6 years	9 years	12 years	15 years	18 years	21 years	24 years
No rise in intraocular pressure since graft	13591	5331	2629	1312	735	347	120	31	1
Post-operative rise in intraocular pressure	2700	1263	619	273	125	53	16	5	n/a

Identity	No. initially at risk	Graft survival (at years post-graft)				
		1	5	10	15	20
No rise in intraocular pressure since graft	13591	.88	.76	.63	.49	.28
Post-operative rise in intraocular pressure	2700	.83	.60	.46	.36	.16

6.3.5.1 Effect of post-operative rise in intraocular pressure

Of the 2,700 penetrating grafts recording a rise in intraocular pressure in the post-graft period, 987 (37%) have failed. The main reasons for failure of these grafts are shown in Table 6.3.

Table 6.3 Reasons for graft failure in cases where raised intraocular pressure was recorded in the post-graft period

Reason	Sub-total	Total	%
Graft rejection		299	30%
no other indication reported	196		
with glaucoma	57		
with endothelial cell failure	17		
with vascularization	5		
with non-herpetic infection	4		
with HSV	3		
with ulcer	3		
Miscellaneous	14		
Glaucoma		287	29%
no other indication reported	171		
with endothelial cell failure	55		
with iris disorders	11		
with ulcers	8		
with epithelial defects	5		
with vascularization	4		
with corneal degeneration	3		
with scars	3		
with metabolic deposits	3		
Miscellaneous	24		
Endothelial cell failure		134	14%
unspecified	66		
with pseudophakic bullous keratopathy	35		
with aphakic bullous keratopathy	17		
with bullous keratopathy	16		
Non-herpetic infections		43	4%
abscess	31		
endophthalmitis	7		
mycotic ulcer	2		
Acanthamoeba keratitis	1		
streptococcus	1		
unspecified viral infection	1		
Herpetic Infections		15	2%
Ulcers		12	1%
Injury		12	1%
Epithelial defects		12	1%
Neovascularization		10	1%
Unspecified		111	11%
Miscellaneous		52	5%
TOTAL		**987**	**100%**

Glaucoma was the primary reason for graft failure in 29% of failed penetrating grafts. This disease featured as a primary or secondary cause of failure in 351 (36%) of the cases listed.

6.3.5.2 Post-graft operative procedures for glaucoma

Post-graft operative surgery for glaucoma was performed on 433 (16%) of grafts in which a post-operative rise in IOP was recorded. Table 6.4 lists the procedures that were performed.

Table 6.4 Operative procedures used to control post-graft raised intraocular pressure

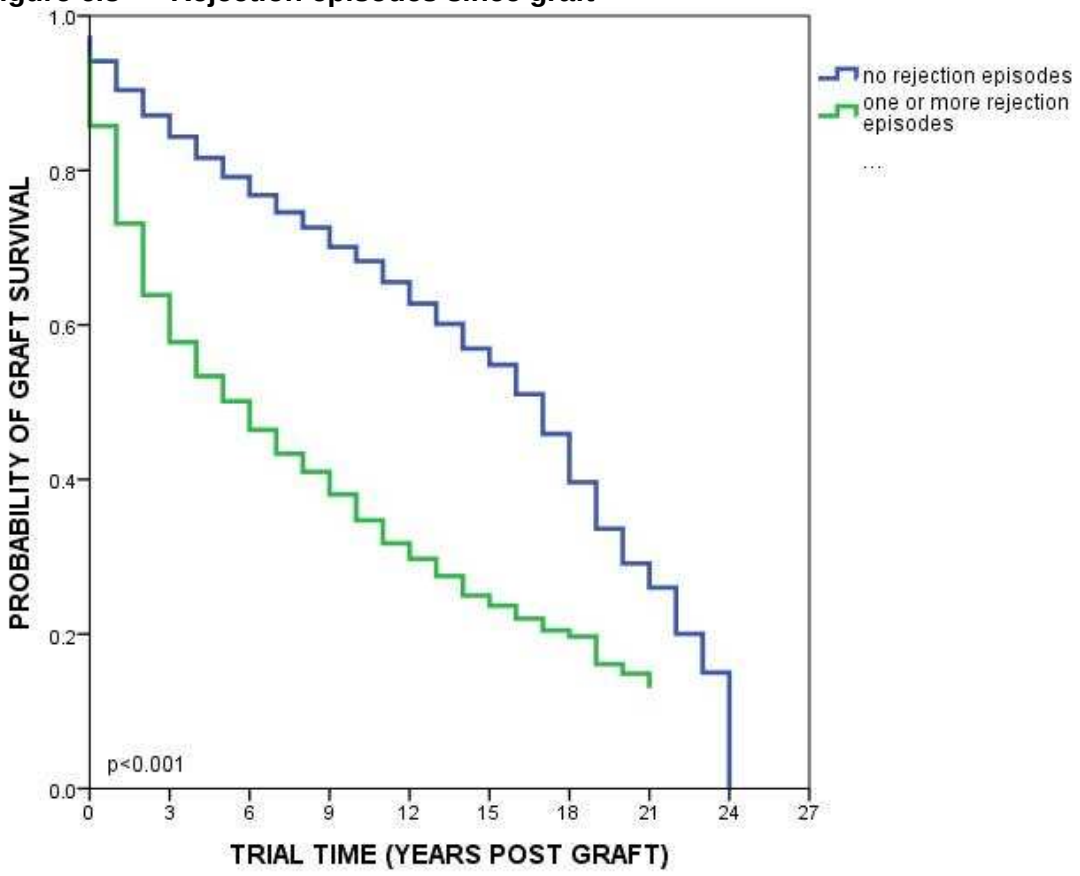
Name	No.	% of grafts
Trabeculectomy	245	57%
Valve implantation	125	29%
Valve adjustments/removals etc	19	4%
Cyclocryotherapy	52	12%
Miscellaneous	65	15%
TOTAL PROCEDURES	**506 over 433 grafts (100%)**	

* Please note that in many cases surgeons have performed two or three operative procedures, and in these cases, all procedures have been included.

6.3.6 Rejection episodes since graft

The effect of occurrence of a rejection episode during the post-operative period is shown in Figure 6.8 (Log Rank Statistic=1037.627; df=1; p<0.001).

Figure 6.8 Rejection episodes since graft



Number at Risk

Identity	Initially	3 years	6 years	9 years	12 years	15 years	18 years	21 years	24 years
No rejection episodes	13328	5228	2534	1236	685	324	110	28	1
One or more rejection episodes	2963	1372	718	349	175	76	26	1	n/a

Identity	No. initially at risk	Graft survival (at years post-graft)				
		1	5	10	15	20
No rejection episodes	13328	.90	.79	.68	.55	.29
One or more rejection episodes	2963	.73	.50	.35	.24	.15

PENETRATING CORNEAL GRAFT SURVIVAL
POST-GRAFT VASCULARIZATION

Balance of database:	**88% at 1 year**
Mean Survival 13.32 years	**75% at 5 years**
(SE=0.17, 95% CI: 12.99, 13.66)	**62% at 10 years**
Median Survival 15 years	**48% at 15 years**
	27% at 20 years
Post-graft vascularization:	**67% at 1 year**
Mean Survival 7.22 years	**46% at 5 years**
(SE=0.33, 95% CI: 6.57, 7.88)	**32% at 10 years**
Median Survival 4 years	**21% at 15 years**

PENETRATING CORNEAL GRAFT SURVIVAL
RISE IN IOP

No rise in intraocular pressure since graft:	**88% at 1 year**
Mean Survival 13.61 years	**76% at 5 years**
(SE=0.19; 95% CI: 13.25, 13.98)	**63% at 10 years**
Median Survival 15 years	**49% at 15 years**
	28% at 20 years
Post-operative rise in intraocular pressure:	**83% at 1 year**
Mean Survival 10.18 years	**60% at 5 years**
(SE=0.29; 95% CI: 9.62, 10.74)	**46% at 10 years**
Median Survival 9 years	**36% at 15 years**
	16% at 20 years

PENETRATING CORNEAL GRAFT SURVIVAL
REJECTION EPISODES

No rejection episodes:	**90% at 1 year**
Mean Survival 14.40 years	**79% at 5 years**
(SE=0.20; 95% CI: 14.00, 14.79)	**68% at 10 years**
Median Survival 17 years	**55% at 15 years**
	29% at 20 years
One or more rejection episodes:	**73% at 1 year**
Mean Survival 8.18 years	**50% at 5 years**
(SE=0.20; 95% CI: 7.79, 8.57)	**35% at 10 years**
Median Survival 6 years	**24% at 15 years**
	15% at 20 years

KEY: n/a = not applicable; SE = standard error; CI = confidence interval; df = degrees of freedom; p = probability

6.4 POST-GRAFT OPERATIVE PROCEDURES

Table 6.5 Post-graft operative procedures

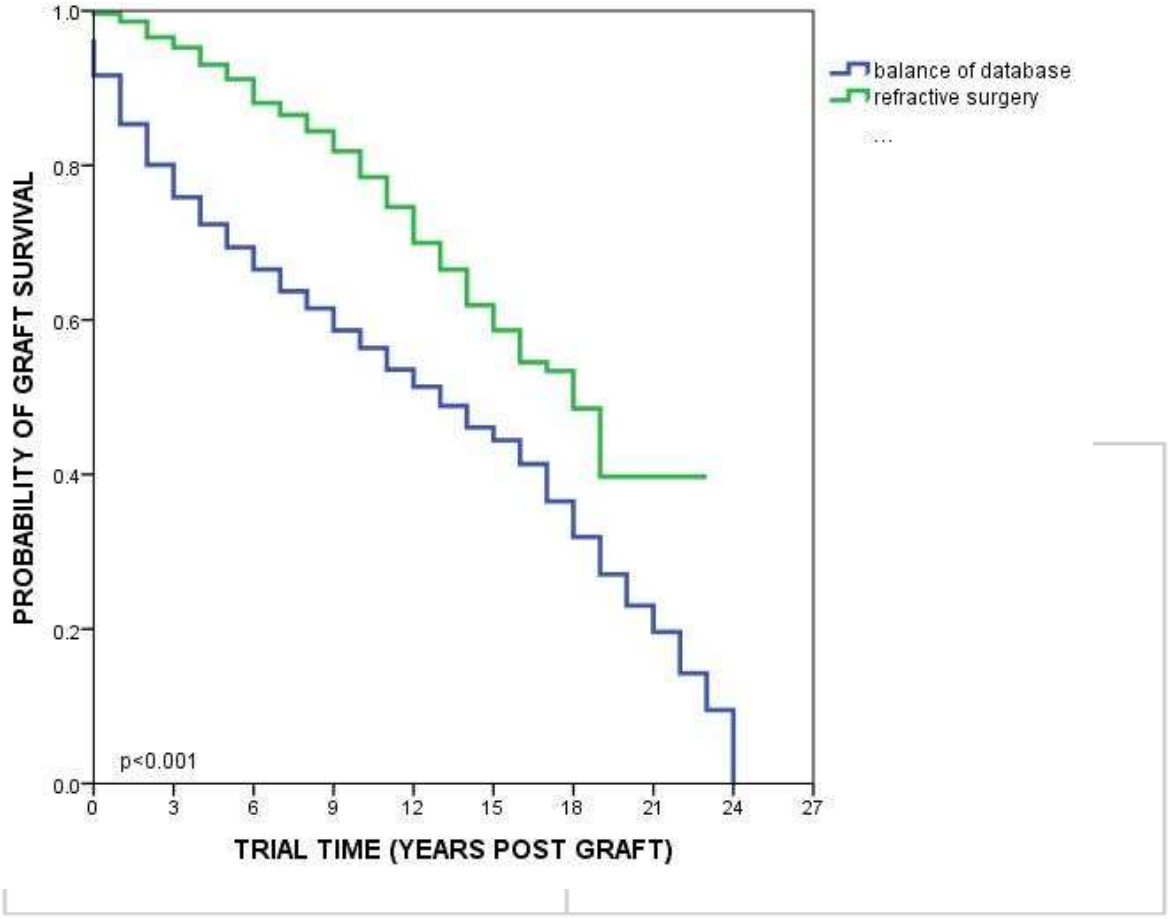
Procedure	Number of grafts[1]		% of grafts followed
	Sub- total	Total	
Refractive surgery		1947 (2469)	12%
Relaxing incision	826		
Suture adjustment	691		
Compression sutures	328		
Excimer laser - LASIK	145		
Wedge resection	96		
Excimer laser - PRK	66		
Other refractive surgery	301 (317)		
Repeat graft (reported to ACGR in follow-up[2])		1729	11%
Cataract extraction and IOL implant		682	4%
Yag laser		591	4%
Glaucoma surgery		450 (535)	3%
Trabeculectomy	252		
Valve implant	126		
Cyclocryotherapy	65		
Other valve procedure	19		
Miscellaneous	65 (73)		
Wound repair		279	2%
Enucleation following graft failure		142	<1%
Vitrectomy/anterior vitrectomy		107	<1%
IOL implant into aphakic eye		105	<1%
Tarsorrhaphy		71	<1%
Gunderson/conjunctival flap		69	<1%
Retinal surgery		59	<1%
Cataract extraction - no IOL implant		52	<1%
Laser (unspecified)		22	<1%
Remove IOL - eye left aphakic		21	<1%
Exchange IOL and replace new IOL		18	<1%
Scraping/biopsy		18	<1%
Ectropion/entropion repair		17	<1%
Ptosis repair		16	<1%
Division of anterior synechiae		16	<1%
Miscellaneous procedures		280 (320)	2%
Total procedures	**7338**		
Total grafts followed	**16291**		

The number of grafts does not necessarily equate to the number of procedures as some grafts have had more than one operative procedure since graft. Where multiple occurrences of the same type of procedure were recorded, the total number of procedures recorded is also shown in parenthesis.

6.4.1 Refractive surgery

Figure 6.9 shows the effect of any form of post-graft refractive surgery on graft survival (Log Rank Statistic=294.318; df=1; p<0.001). Data were carried over from one follow-up to the next.

Figure 6.9 The effect of refractive surgery



Number at Risk

Identity	Initially	3 years	6 years	9 years	12 years	15 years	18 years	21 years	24 years
Balance of database	14343	5352	2548	1227	651	305	103	27	1
Any refractive surgery post-graft	1947	1248	704	358	209	95	33	9	n/a

Identity	No. initially at risk	Graft survival (at years post-graft)				
		1	5	10	15	20
Balance of database	14343	.85	.69	.56	.44	.23
Any refractive surgery post-graft	1947	.99	.91	.79	.59	.40

PENETRATING CORNEAL GRAFT SURVIVAL
EFFECT OF REFRACTIVE SURGERY

Balance of database:	**85% at 1 year**
Mean Survival 12.29 years	**69% at 5 years**
(SE=0.17, 95% CI: 11.95, 12.63)	**56% at 10 years**
Median Survival 13 years	**44% at 15 years**
	23% at 20 years
Any refractive surgery post-graft:	**99% at 1 year**
Mean Survival 16.41 years	**91% at 5 years**
(SE=0.37, 95% CI: 15.68, 17.13)	**79% at 10 years**
Median Survival 18 years	**59% at 15 years**
	40% at 20 years

KEY:

n/a	=	not applicable
SE	=	standard error
CI	=	confidence interval
df	=	degrees of freedom
p	=	probability

6.5 SUMMARY OF POST-GRAFT EVENTS

- The major reasons for failure of penetrating grafts are irreversible rejection (31%), endothelial cell failure (15%), infection including recurrent HSV keratitis (8%), and glaucoma (8%).
- Removal of graft sutures within 6 months of the time of transplantation is a risk factor for graft failure.
- A variety of post-operative events are associated with graft failure. These include development of microbial keratitis or a stitch abscess (affecting 3% of grafts), uveitis (1%), synechiae (2%), graft neovascularization (6%), rejection episodes (18%) and a rise in intraocular pressure (16%) in the grafted eye.
- Over 33% of grafted eyes have undergone some form of operative procedure since the time of corneal transplantation.
- In 12% of cases, a refractive procedure has been performed on the grafted eye.

7. VISUAL OUTCOME

All plots and tables in this chapter have been calculated using penetrating grafts only. Details of visual outcomes for lamellar grafts are analysed in Chapter 8.

7.1 DESIRED OUTCOME

The Australian Corneal Graft Registry has recorded a desired outcome for 16,228 (81%) of the 19,952 penetrating grafts entered. These outcomes are shown in Figure 7.1 and Table 7.1.

Figure 7.1 Desired outcome of graft

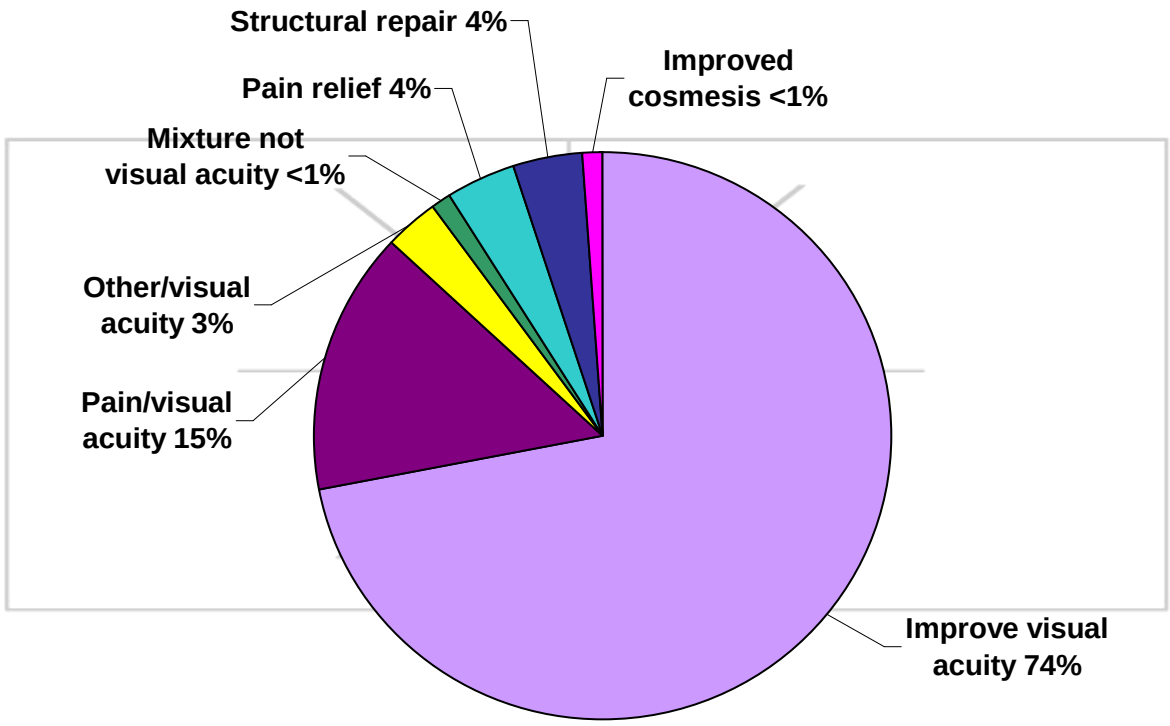


Table 7.1 Desired outcomes

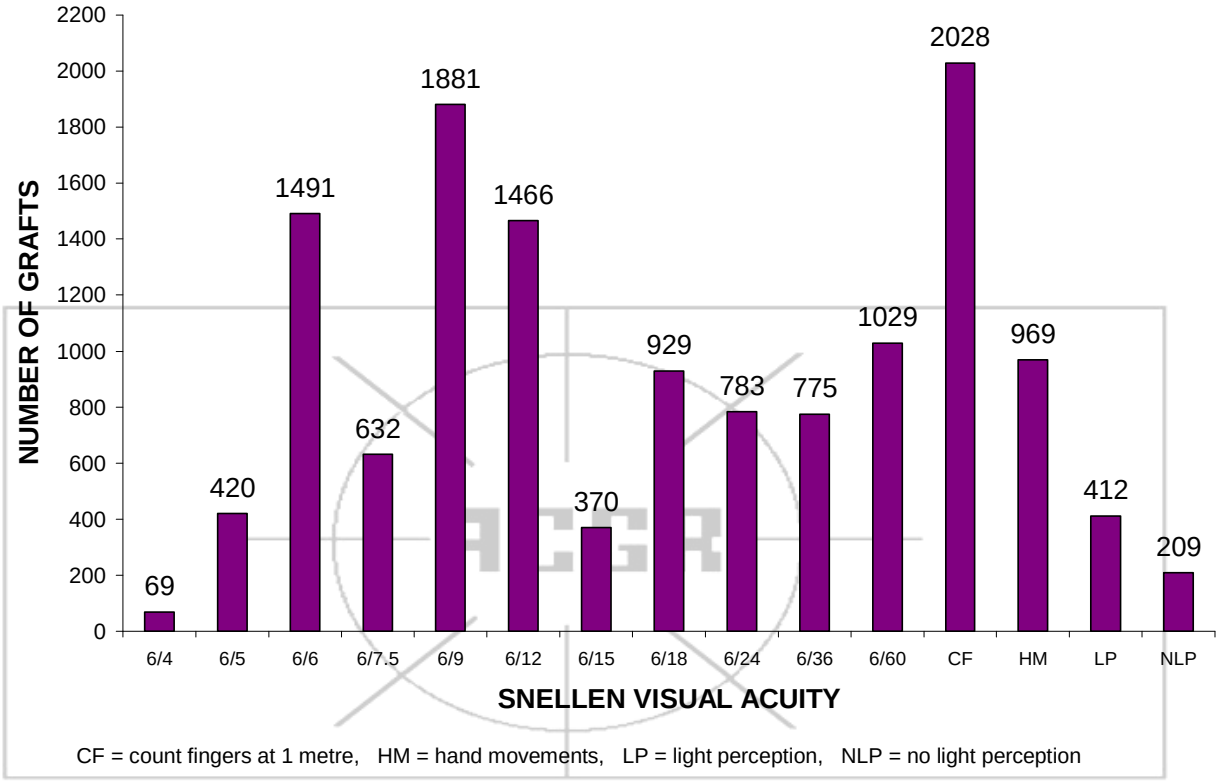
Desired Outcome	Number	%
Improvement in visual acuity only	11935	74%
Structural repair only	597	4%
Pain relief only	578	4%
Improved cosmesis only	26	<1%
Improved visual acuity and pain relief*	2470	15%
Improved visual acuity and other (not pain relief)	560	3%
Mixture of reasons not including improved visual acuity	62	<1%
TOTAL	**16228**	**100%**

*Including where desired outcomes were improved visual acuity, pain relief plus cosmesis, structural repair or both.

7.2 OVERALL VISUAL ACUITY

Figure 7.2 shows the best corrected visual acuity in the grafted eye at the time of the most recent follow-up. Post-graft visual acuity had been recorded for 13,463 penetrating grafts. Of these 5,959 (44%) have recorded a best corrected acuity of 6/12 or better; 7,258 (54%) had achieved 6/18 or better; and 3,618 (27%) record a visual acuity of less than 6/60. In an additional 2,828 cases, information was not available.

Figure 7.2 Best corrected visual acuity in grafted eye at last follow-up



BEST CORRECTED SNELLEN ACUITY AT MOST RECENT POST-OPERATIVE VISIT		
6/12 or better	**5959**	**37%**
6/18 or better	**7258**	**45%**
6/24 - 6/60	**2589**	**16%**
Less than 6/60	**3618**	**22%**
Unknown/not recorded	**2828**	**17%**

Percentages shown in this box are for all 16291 followed penetrating grafts

7.2.1 Comparison of recipient characteristics for whom post-graft visual acuity is ≥ 6/18 or <6/18

The categories below are not mutually exclusive for either set of comparisons.

Table 7.3 Comparison where post-graft vision is ≥6/18 or <6/18

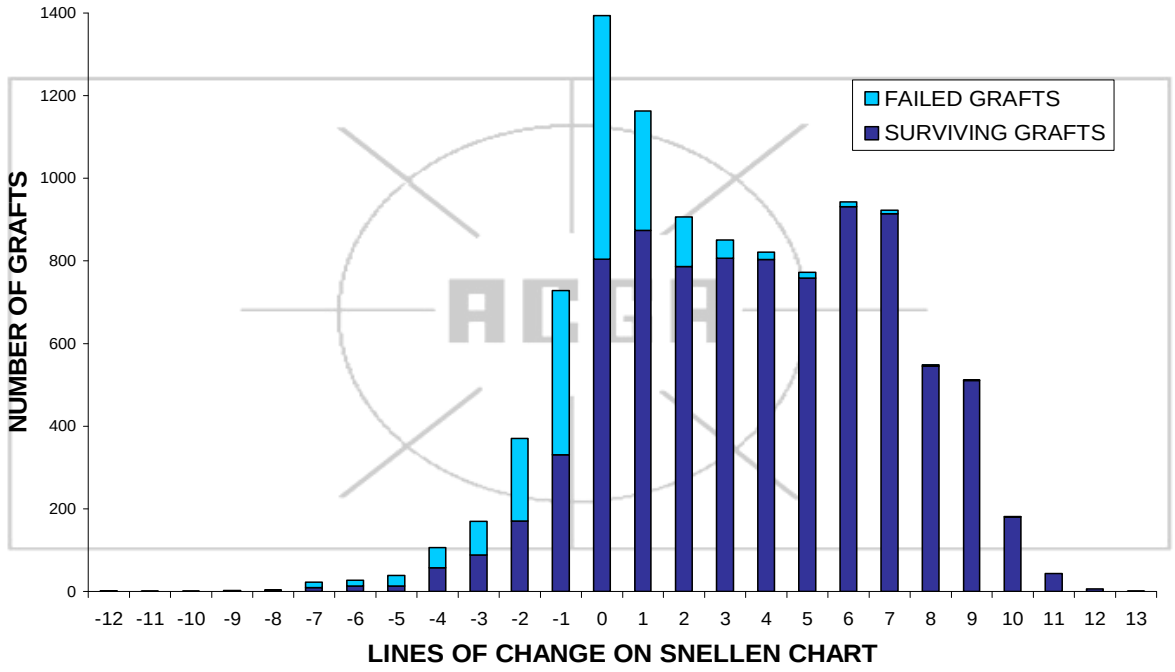
Description	VA equal to or better than 6/18		VA is worse than 6/18	
	No.	%	No.	%
Reasons for grafting				
Vision only	5133	64%	2927	36%
Cosmesis only	7	41%	10	59%
Pain only	71	18%	334	82%
Tectonic only	56	18%	250	82%
Vision and pain	541	36%	976	64%
Other combinations involving vision	147	35%	270	65%
Other combinations not involving vision	4	11%	34	89%
Not advised	1299	48%	1404	52%
Presenting disease				
Keratoconus	4028	80%	996	20%
Keratoconus with hydrops	122	69%	55	31%
Fuchs' dystrophy	954	60%	628	40%
Scar (non-herpetic)	502	51%	485	49%
HSV - history (not at graft)	293	48%	314	52%
Previous graft failure	960	37%	1617	63%
HSV – active at graft	47	29%	116	71%
Pseud. bullous keratopathy	750	27%	2059	73%
Aphakic bullous keratopathy	116	22%	410	78%
Perforation	80	20%	318	80%
Lens at last follow-up				
Phakic	4505	74%	1597	26%
Pseudophakic	2611	40%	3885	60%
Aphakic	142	16%	723	84%
Operative procedure at graft				
Triple procedure	769	54%	655	46%
Cataract removed	785	53%	694	47%
Peripheral iridectomy	271	46%	320	54%
Trabeculectomy	12	25%	36	75%
Anterior vitrectomy	281	23%	925	77%
Operative procedure post-graft				
Refractive surgery performed	831	70%	364	30%
Cataract removed; IOL inserted	270	67%	131	33%
Insertion of IOL	295	63%	171	37%
Yag/mechanical capsulotomy	226	57%	169	43%
Cataract removed; no IOL	14	37%	24	63%
Complications in follow-up				
Major astigmatism	1785	64%	1015	36%
Cataract affecting VA	199	45%	244	55%
Amblyopia	150	36%	265	64%
Rejection episodes	596	31%	1342	69%
Raised IOP post-graft	718	31%	1617	69%
Neovascularization	264	30%	603	70%
Uveitis	49	28%	123	72%
Stitch abscess/microbial keratitis	100	27%	264	73%
HSV in post-operative period	73	26%	213	74%
Maculopathy	315	24%	1017	76%
Synechiae	65	22%	228	78%
CME	154	18%	698	82%
Retinal detachment	28	13%	184	87%
Graft has failed	122	5%	2476	95%
Recipient age				
Recipient age ≥ 80 years	525	28%	1343	72%
Overall	**7258**	**54%**	**6205**	**46%**
TOTAL GRAFTS	**13463 (100%)**			

In summary, slightly more than half of recipients achieved vision of 6/18 or better. This level of vision was proportionately more likely to be achieved by recipients who had undergone their graft for the sole purpose of improved vision, for keratoconus, who were phakic at their last follow-up, and/or who had had post-graft refractive surgery performed, or insertion of an IOL. These recipients were also more likely to report having major astigmatism, likely due to the frequent co-morbidity of this condition with keratoconus. All other specified complications were more likely to have occurred in recipients with post-graft visual acuity worse than 6/18, particularly cystoid macular oedema, retinal detachment or graft failure. The recipients with poor visual outcome were also more likely to have undergone trabeculectomy or anterior vitrectomy at graft, be aphakic, have a history of graft failure, have undergone the graft because of active HSV or bullous keratopathy, and/or have undergone the graft for pain relief or tectonic repair.

7.2.2 Post-graft changes in visual acuity

In 10,543 cases, both pre-operative and post-operative Snellen visual acuities were available. Figure 7.3 shows the number of lines of improvement or worsening in visual acuity since graft, as measured at the most recent follow-up.

Figure 7.3 Changes in Snellen acuity after graft



Number of lines on the Snellen Chart	Surviving grafts No.	%	Failed grafts No.	%	Total Grafts No.	%
VA worse by > 10 lines	2	<1	1	<1	3	<1
VA worse by 5-10 lines	41	<1	56	3	97	<1
VA worse by 2-4 lines	316	4	331	18	647	6
VA worse by 1 line	331	4	398	21	729	7
VA unchanged	804	9	590	31	1394	13
VA better by 1 line	874	10	289	15	1163	11
VA better by 2-4 lines	2397	28	181	10	2578	24
VA better by 5-10 lines	3841	44	40	2	3881	37
VA better by > 10 lines	51	<1	0	0	51	<1
Sub Totals	**8657**	**82%**	**1886**	**18%**	**10543**	**100%**
TOTAL	**10543 (100%)**					

In 73% of cases post graft Snellen acuity was better than pre-graft, 13% showed no change and in 14%, Snellen acuity was worse than pre-graft.

The visual acuity in 14% of these recipients was worse following the graft, in 13% it remained unchanged, while 73% exhibited improvement. Of the 1,476 grafts for which acuity had decreased, 786 (53%) had failed, and of the 1,394 grafts for which visual acuity remained unchanged, 590 (42%) had failed. Interestingly, 510 grafts reported as having failed actually recorded a better visual acuity at the last follow-up than they did at the time of graft. Data stratified by change in visual acuity are examined more closely in Table 6.4. Categories are not mutually exclusive.

Table 7.4 Change in visual acuity post-graft

Description	Better VA		Same VA		Worse VA	
	No.	%	No.	%	No.	%
Reasons for graft						
Vision only	5230	68%	673	48%	832	56%
Cosmesis only	4	<1%	4	<1%	3	<1%
Tectonic only	118	2%	64	5%	59	4%
Pain only	164	2%	84	6%	56	4%
Pain & vision	930	12%	276	20%	231	16%
Other combinations involving vision	262	3%	69	5%	61	4%
Other combinations not involving vision	16	<1%	9	<1%	10	<1%
Not advised	949	12%	215	15%	224	15%
Presenting disease						
Bullous keratopathy (no Fuchs')	164	21%	39	3%	35	2%
Pseudophakic	1335	17%	489	35%	419	28%
Aphakic	220	3%	89	6%	69	5%
Previous graft failure	1288	17%	383	27%	348	24%
Keratoconus (including with hydrops)	3605	47%	239	17%	312	21%
Fuchs' dystrophy	958	12%	149	11%	241	16%
Scar (non-herpetic)	520	7%	94	7%	118	8%
HSV – history (not at graft)	291	4%	70	5%	75	5%
Perforation (non-herpetic)	165	2%	75	5%	59	4%
HSV – active at graft	63	<1%	25	2%	17	1%
Lens status at last follow-up						
Pseudophakic	3459	45%	916	66%	891	60%
Phakic	3915	51%	344	25%	453	31%
Aphakic	299	4%	134	10%	132	9%
Operative procedure at graft						
Triple procedure	846	11%	146	10%	173	12%
Cataract removed	867	11%	158	11%	184	12%
Anterior vitrectomy	520	7%	189	14%	176	12%
Peripheral iridectomy	387	5%	63	5%	74	5%
Trabeculectomy	18	<1%	6	<1%	15	1%
Operative procedure post-graft						
Refractive surgery performed	658	9%	76	5%	91	6%
YAG/mechanical capsulotomy	231	3%	28	2%	32	2%
Cataract removed; IOL inserted	254	3%	27	2%	28	2%
Cataract removed; no IOL	19	<1%	4	<1%	3	<1%
Complications in follow-up						
Graft has failed	510	7%	590	42%	786	53%
Raised IOP post-graft	1041	14%	358	26%	413	28%
Any rejection episodes since graft	789	10%	320	23%	335	23%
Major astigmatism	1866	24%	199	14%	190	13%
Maculopathy	632	8%	242	17%	173	12%
Neovascularization	344	4%	129	9%	141	10%
CME	335	4%	134	10%	97	7%
Stitch abscess or microbial keratitis	125	2%	59	4%	95	6%
Cataract affecting VA	238	3%	57	4%	60	4%
Retinal detachment	58	<1%	35	3%	63	4%
HSV in post-operative period	108	1%	43	3%	46	3%
Synechiae	99	1%	56	4%	38	3%
Uveitis	61	<1%	16	1%	24	2%
Amblyopia	228	3%	47	3%	33	2%
Recipient age						
Recipient age ≥ 80	916	12%	319	23%	285	19%
Overall	**7673**	**73%**	**1394**	**13%**	**1476**	**14%**
TOTAL GRAFTS	**10543 (100%)**					

The change in Snellen acuity following corneal transplantation was unknown in 5,748 cases. In the majority of these, the Registry was unaware of the pre-operative acuity. The overall percentages of recipients in each category can be seen in the box below, along with the percentage of each group as a proportion of all penetrating grafts followed.

CHANGE IN SNELLEN ACUITY AFTER GRAFT

Better	**7673**	**(47%)**
Same	**1394**	**(9%)**
Worse	**1476**	**(9%)**
VA not advised to ACGR	**5748**	**(35%)**

[Calculated as a percentage of all followed penetrating grafts (16,291)]

7.3 VISUAL OUTCOME RELATED TO PRESENTING DISEASE

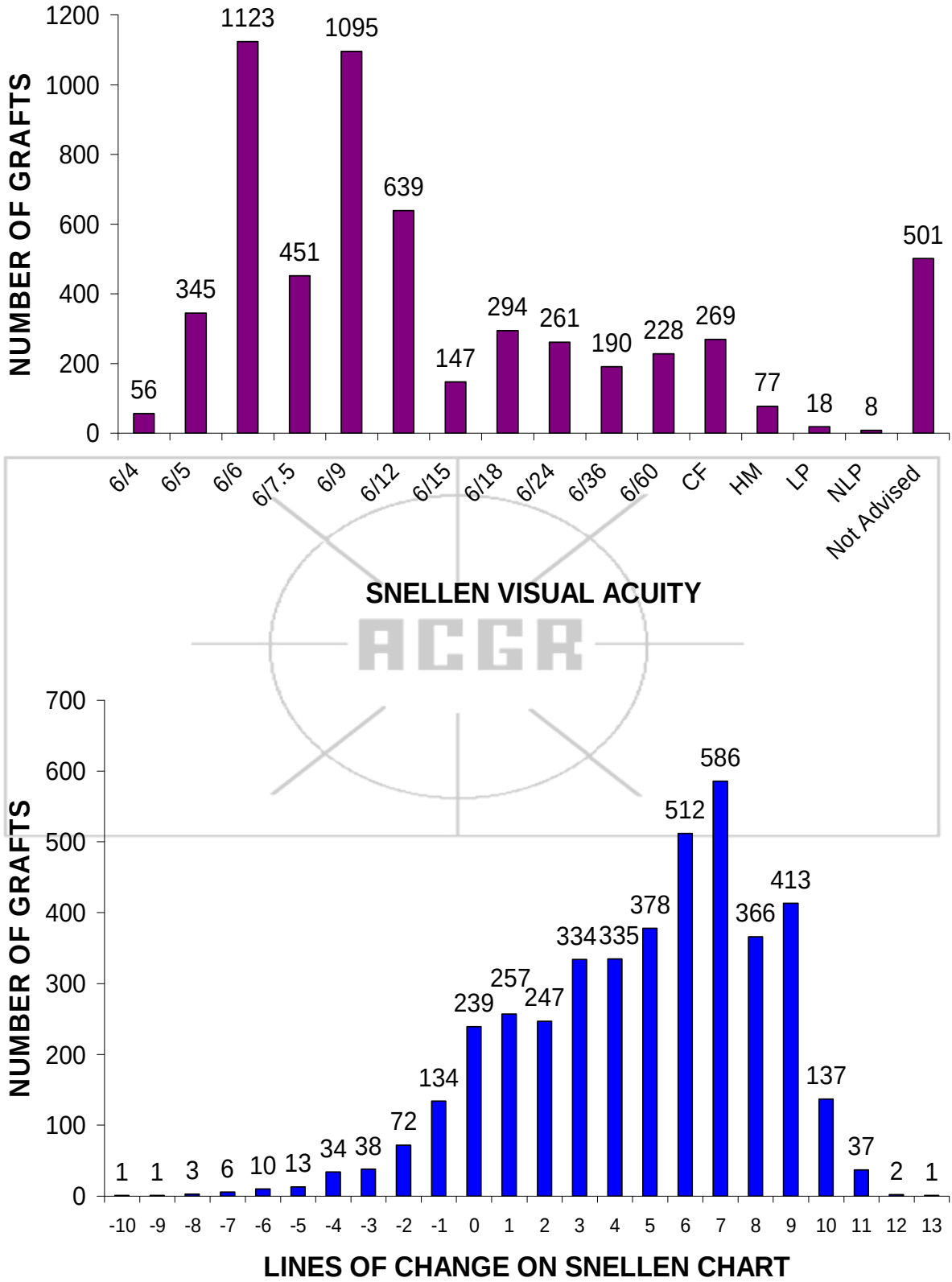
The following pages show the visual outcome of penetrating grafts performed for keratoconus, Fuchs' dystrophy, aphakic or pseudophakic bullous keratopathy, previously failed grafts or herpetic infection. These were the most common indications for penetrating corneal transplantation in our database.

In each case we provide two charts - the first showing the post-graft Snellen visual acuities, and the second showing the number of lines of improvement or worsening in visual acuity compared with the pre-operative acuity.

Where there were multiple reasons for graft provided (e.g. Fuchs' dystrophy AND herpetic infection), the data for these grafts is included in both sections. Failed grafts were included where information is available.

7.3.1 Keratoconus

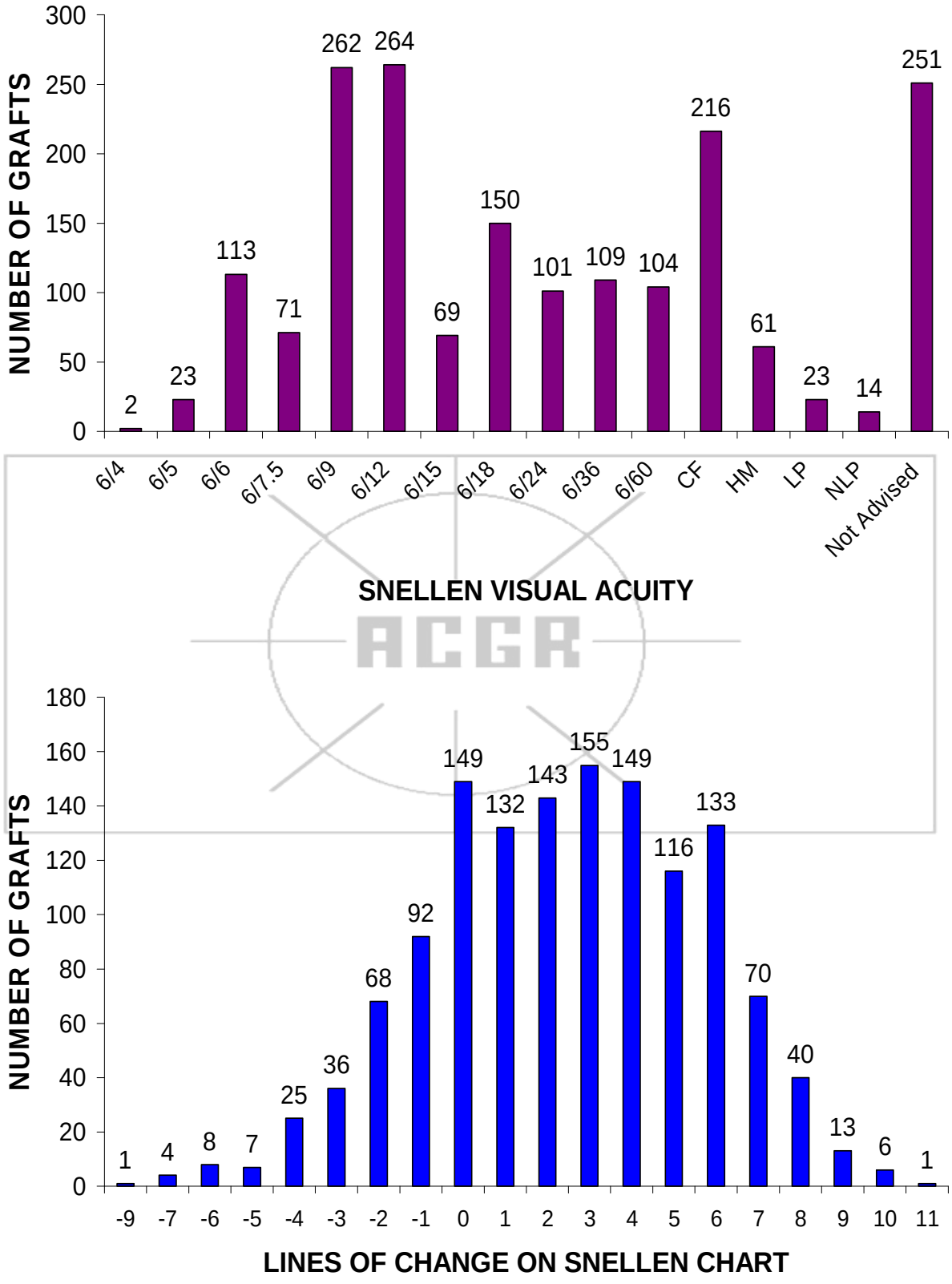
Figure 7.4 Visual outcome: keratoconus



Sixty five percent of all grafts performed for keratoconus achieved a post-graft visual acuity of 6/12 or better, 73% achieved 6/18 or better and 85% achieved 6/60 or better. In 87% of cases where the visual acuity was provided both before and after graft, at least one line of improvement on the Snellen chart was achieved after graft.

7.3.2 Fuchs' dystrophy

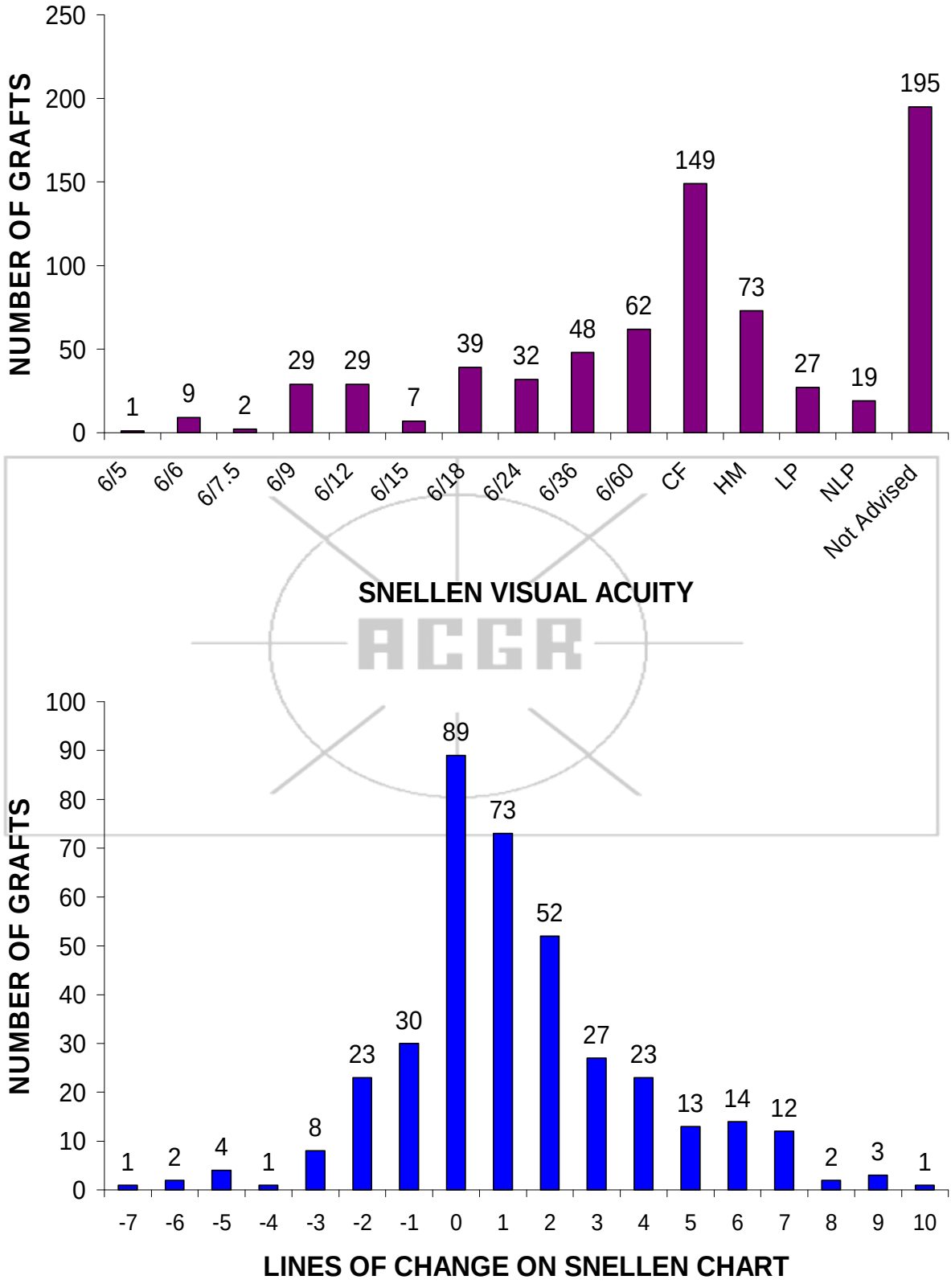
Figure 7.5 Visual outcome: Fuchs' dystrophy



Forty percent of all grafts performed for Fuchs' dystrophy achieved a post-graft visual acuity of 6/12 or better, 52% achieved 6/18 or better and 69% achieved 6/60 or better. In 71% of cases where the ACGR was provided with VA both before and after graft, at least one line of improvement on the Snellen chart was achieved after graft.

7.3.3 Aphakic bullous keratopathy

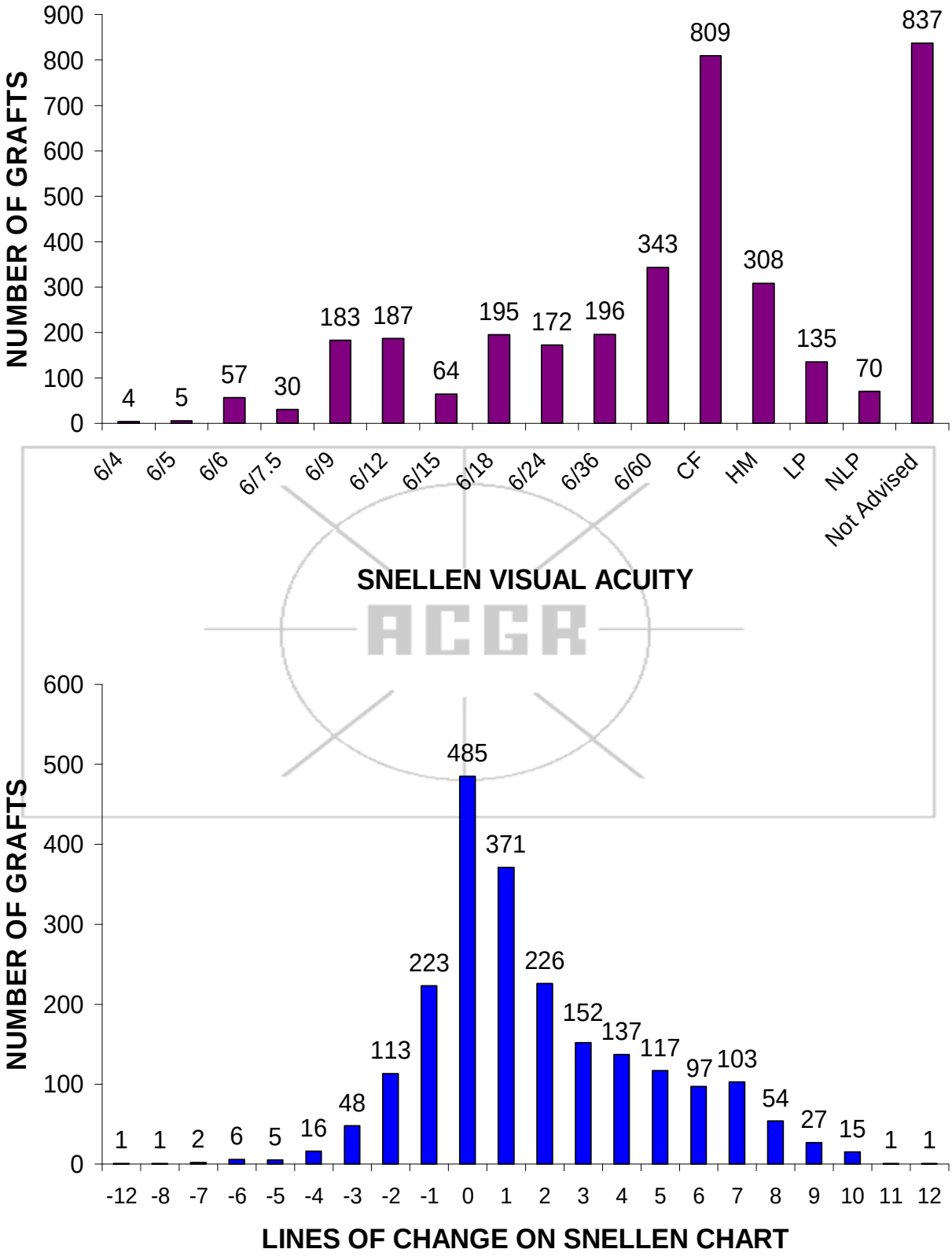
Figure 7.6 Visual outcome: aphakic bullous keratopathy



Ten percent of grafts performed for aphakic bullous keratopathy achieved a visual acuity of 6/12 or better, 16% achieved 6/18 or better and 36% achieved 6/60 or better. In 58% of cases where visual acuities were provided both before and after graft, at least one line of improvement on the Snellen chart was achieved after graft.

7.3.4 Pseudophakic bullous keratopathy

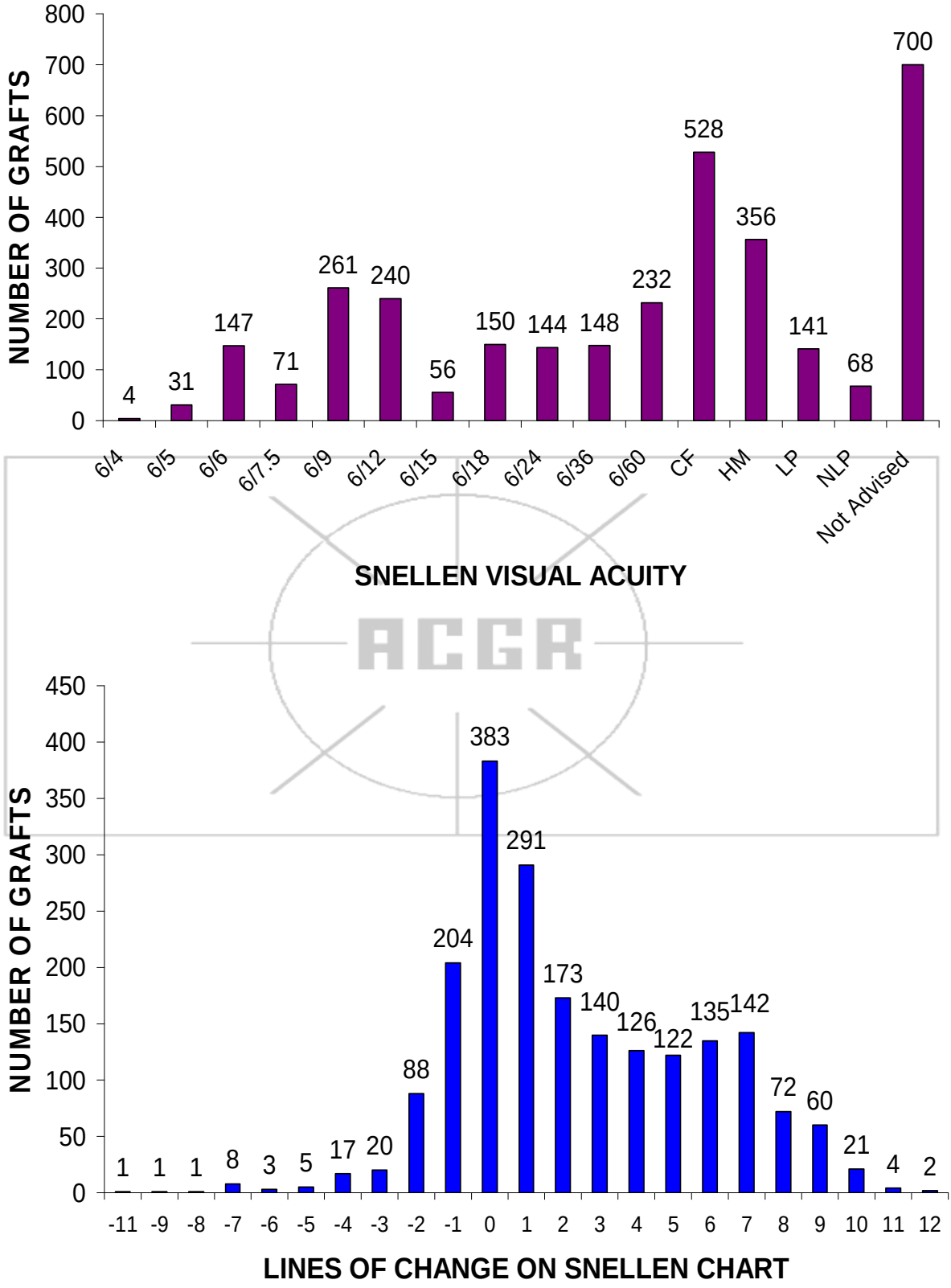
Figure 7.7 Visual outcome: pseudophakic bullous keratopathy



Thirteen percent of grafts performed for pseudophakic bullous keratopathy achieved a post-graft visual acuity of 6/12 or better, 20% achieved 6/18 or better and 40% achieved 6/60 or better. In 57% of cases where visual acuities were provided both before and after graft, at least one line of improvement on the Snellen chart was achieved after graft.

7.3.5 Previous failed graft

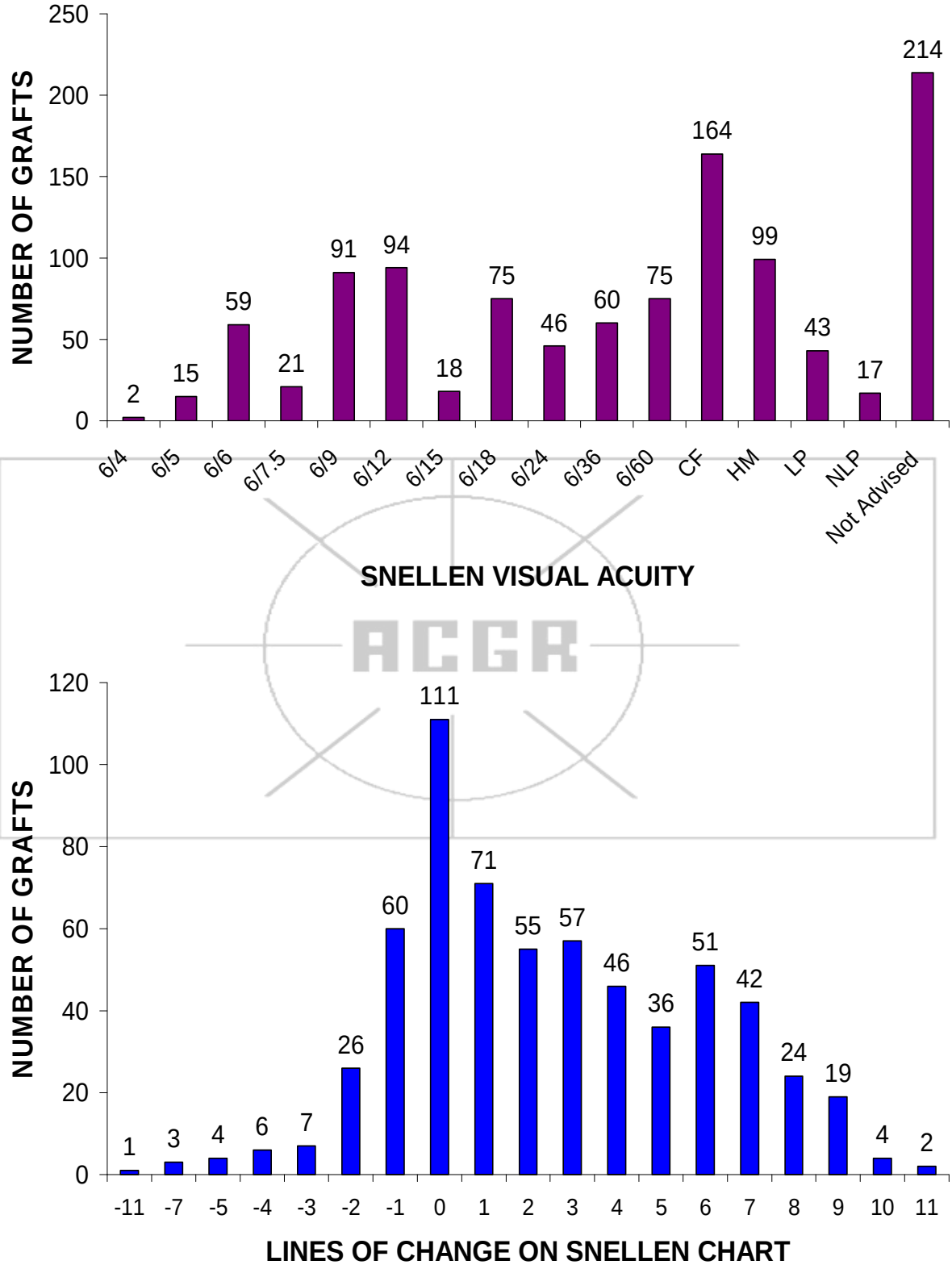
Figure 7.8 Visual outcome: previous failed graft



Twenty three percent of grafts performed for a previously failed graft achieved a post-graft visual acuity of 6/12 or better, 29% achieved 6/18 or better and 45% achieved 6/60 or better. In 64% of cases in which visual acuity was reported both before and after graft, at least one line of improvement on the Snellen chart was achieved after graft.

7.3.6 Herpetic infection

Figure 7.9 Visual outcome: herpetic infection



In recipients in whom HSV infection had been recorded at any time pre-graft, 26% of the cohort achieved a post-graft visual acuity of 6/12 or better, 34% achieved 6/18 or better and 51% achieved 6/60 or better. In 65% of cases where visual acuity was provided both before and after graft, at least one line of improvement on the Snellen chart was achieved after graft.

In those cases where HSV *was* active at the time of graft, 15% achieved a visual acuity of 6/12 or better, 21% achieved 6/18 or better and 39% achieved 6/60 or better (not illustrated).

In those cases where HSV *was not* active at time of graft, 30% achieved a visual acuity of 6/12 or better, 39% achieved 6/18 or better and 56% achieved 6/60 or better (not illustrated).

In 4% of cases where herpetic infection was a reason for graft, it was not known whether this infection was active at the time of graft.

It can be observed that the percentages reporting each level of vision achieved were consistently lower than those documented in the previous Registry report. As these data were based on the most recent follow-up data for each graft, this is possibly due to the increased length of follow-up in the current cohort, with visual acuity decreasing as the grafts (and recipients) become older.

7.4 FACTORS AFFECTING VISUAL POTENTIAL OF THE GRAFTED EYE

Table 7.5 lists some of the factors which have affected the visual potential of the grafted eye (penetrating grafts only). The factors are not necessarily mutually exclusive.

Table 7.5 Factors affecting visual potential of the grafted eye

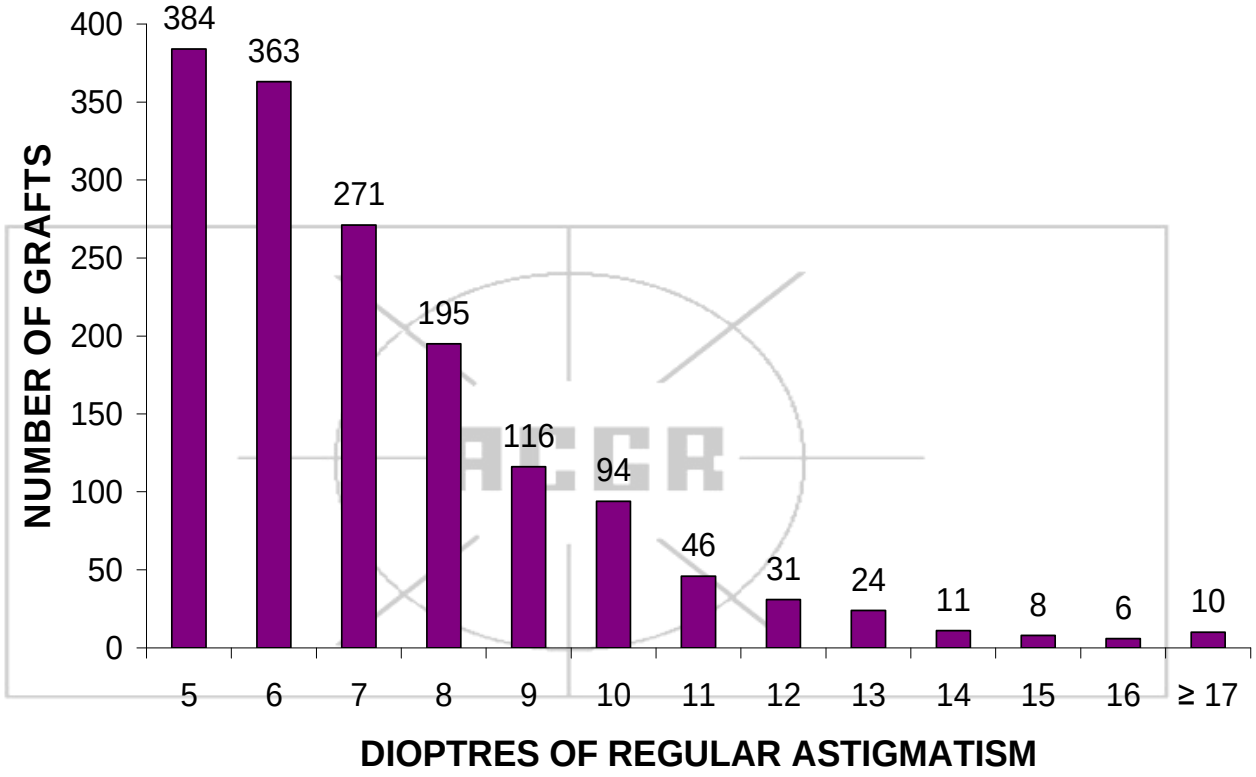
Description	Total	%
Graft failure	3794	23%
Astigmatism (>5D=2868) (irregular=98)	2948	18%
Maculopathy (unspecified)	1514	9%
Anisometropia	1242	8%
Aphakia	1151	7%
Glaucoma	1086	7%
Cystoid macular oedema	954	6%
Opacity/scar	593	4%
Cataract	460	3%
Amblyopia	457	3%
Myopia	449	3%
Retinal detachment	246	2%
Diabetic retinopathy	74	<1%
Other factors	722	4%
Total penetrating grafts	= 16291 (100%)	

7.5 MAJOR ASTIGMATISM

Figure 7.10 shows the most recent post-operative measure of major regular astigmatism, where recorded. 2,868 grafts (18%) were recorded as having major astigmatism (≥ 5 dioptres) at last follow-up. Of these, the specific dioptres of astigmatism were recorded for 1,559 (54%) grafts.

Post-operative astigmatism of less than 5 dioptres is no longer recorded in the Registry.

Figure 7.10 Dioptres of regular astigmatism in the grafted eye at last follow-up



7.6 REFRACTIVE SURGERY

Table 7.6 lists refractive surgical procedures performed on penetrating grafts. One or more procedures were carried out on 1,940 grafts (12% of penetrating grafts followed).

Table 7.6 Refractive surgery

Procedure	Number	%
Relaxing incisions	826	34%
Suture adjustment	690	28%
Compression sutures	328	13%
LASIK	145	6%
Excimer/PARK/laser	109	4%
Wedge resection	94	4%
Other	124	5%
Unknown procedure	147	6%
Total procedures	2463	100%
2463 procedures over 1940 grafts (12% of all followed grafts)		

7.6.1 Correction following refractive surgery

Table 7.7 shows the method of correction used for the 1,940 grafts that had undergone refractive surgery.

Table 7.7 Correction following refractive surgery

Method of correction	Number	%
Spectacles	997	51%
Contact lens	135	7%
Spectacles and contact lens	43	2%
No correction/not advised	765	39%
TOTAL	**1940**	**100%**

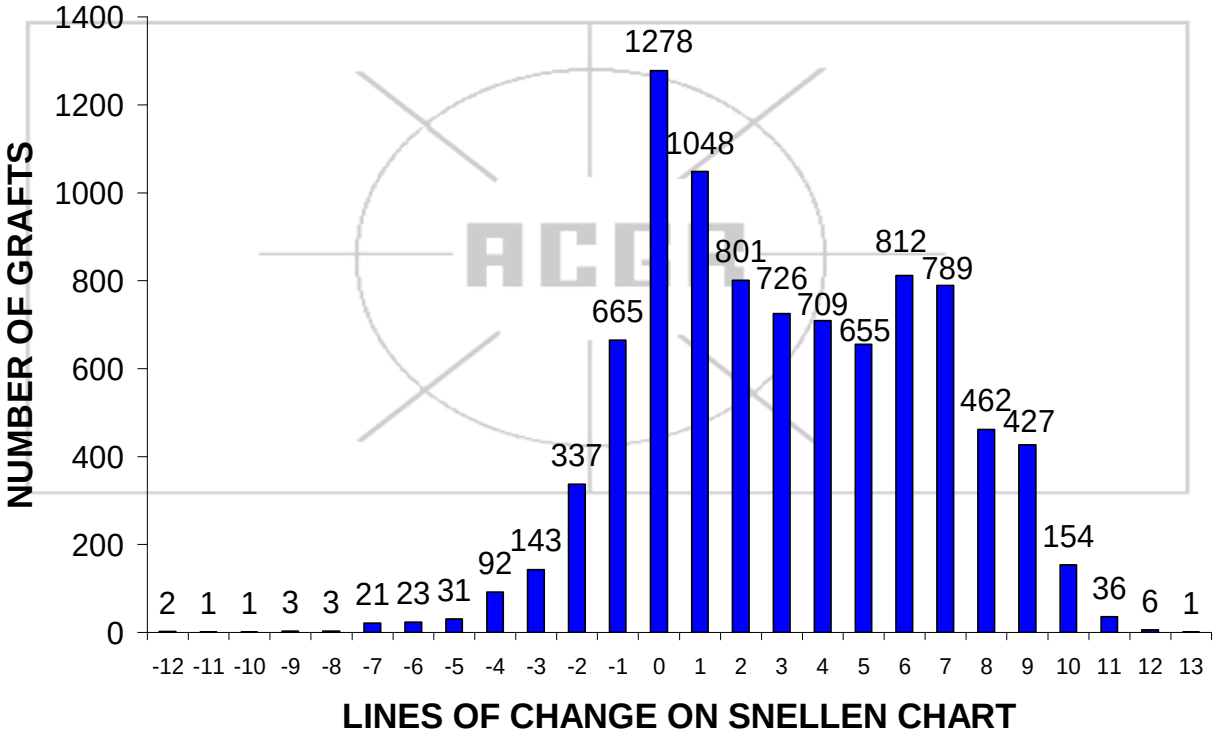
7.6.2 Has refractive surgery improved visual acuity?

The post graft Snellen acuities were provided for 1,940 penetrating grafts that had undergone refractive surgery. Visual acuity was equal to or better than 6/12 in 1,021 (53%) of these cases, better than or equal to 6/18 in 1,227 (63%), and better than or equal to 6/60 in 1,544 (80%). This compares with 37% for 6/12 or better, 45% for 6/18 or better and 60% for 6/60 or better in the database as a whole.

Of these 1,316 also had pre-graft Snellen visual acuity recorded. One thousand and fourty six (79%) showed an improvement in visual acuity, 116 (9%) were unchanged since before graft and 154 (12%) were worse.

Figure 7.11 shows grafts that had not undergone refractive surgery post-operatively.

Figure 7.11 Change in lines on the Snellen chart for grafts that have not undergone refractive surgery



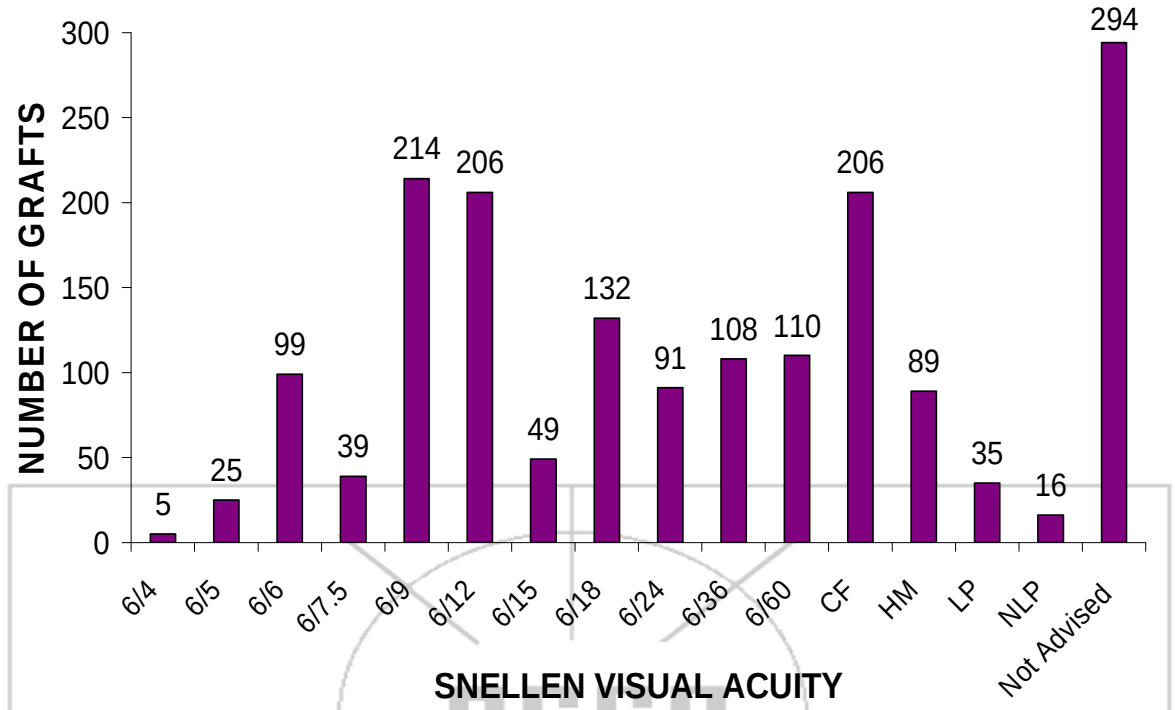
Of those 14,351 grafts that had not undergone refractive surgery, visual acuities, both before and after graft, had been provided for 9,226. Of these, 6,626 (72%) showed an improvement in visual acuity, 1,278 (14%) showed no change since before graft and 1,322 (14%) were worse. Snellen acuity appeared slightly better in the group that has undergone refractive surgery to the graft.

7.7 TRIPLE PROCEDURES

7.7.1 Snellen acuity

Figure 7.12 shows the visual acuity at most recent follow-up for 1,718 triple procedures.

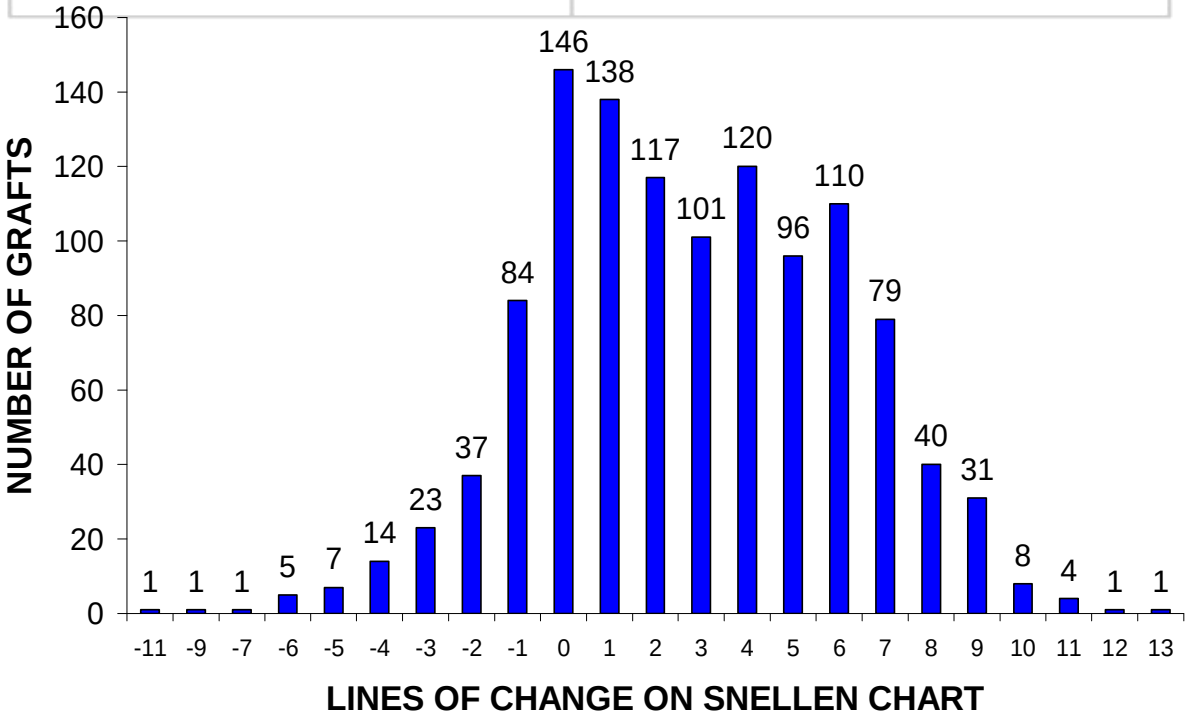
Figure 7.12 Visual acuities for all triple procedure grafts



7.7.2 Visual improvement after graft: triple procedure

Figure 7.13 shows the number of lines of change on the Snellen chart for triple procedures.

Figure 7.13 Triple procedures - lines of change



7.8 POST-GRAFT CORRECTION

At the last follow-up, 6,197 (50%) of recipients with surviving grafts were reported to wear glasses, 5,837 (47%) had an IOL in place and 999 (8%) wore contact lenses.

Table 7.9 shows the post-graft correction prescribed for grafts that had survived for less than 2 years; between 2 and 5 years; between 5 and 10 years and over 10 years.

Table 7.9 Post-graft correction dependent on survival time

Method of correction	Survival time of graft							
	≤2 years		>2 – 5 years		>5 – 10 years		>10 years	
	No.	%	No.	%	No.	%	No.	%
None or none advised	1465	28%	802	20%	357	16%	133	14%
Glasses only	949	18%	1051	26%	677	30%	344	36%
Contact lens only	194	4%	220	6%	164	7%	135	14%
IOL only	1663	32%	649	19%	352	15%	85	9%
Glasses & contact lens	34	<1%	72	2%	47	2%	16	2%
Glasses and IOL	943	18%	1150	34%	650	29%	228	24%
Contact lens and IOL	20	<1%	31	<1%	23	1%	7	<1%
Glasses, contact lens and IOL	7	<1%	15	<1%	6	<1%	8	<1%
Sub-total	**5275**	**100%**	**3990**	**100%**	**2276**	**100%**	**956**	**100%**
TOTAL	**12497 surviving penetrating grafts**							

The data suggest that visual rehabilitation following corneal transplantation may take several years, with adjustments continuing to be made for as long as 10 years. The use of at least one form of visual correction became more likely as time progressed, with 86% of grafts surviving for more than 10 years needing at least one form of correction. In the longest surviving cohort (over 10 years) the majority of recipients wore glasses (62%). For over one-third (36%), this was the only form of correction utilised.

7.9 SUMMARY OF VISUAL OUTCOME AFTER CORNEAL TRANSPLANTATION

- Information on the desired outcome after corneal transplantation was available for 81% of the cohort. In 74% of cases, the major reason for transplantation was improved vision and in a further 15%, the reasons were improved vision plus relief of pain.

- A best-corrected Snellen acuity at last follow-up was available in 83% of cases. A best corrected visual acuity (BCVA) of 6/12 or better at the time of most recent follow-up was achieved in 44% of these eyes, and of 6/18 or better in 54%. A best corrected acuity of less than 6/60 was achieved by 27% of grafted eyes with follow-up BCVA available.

- Where information was available, Snellen acuity improved after corneal transplantation in 73% of cases, remained the same in 13% of cases and worsened in 14% of cases.

- Visual outcome after corneal transplantation depended, to some extent, on indication for graft, lens status and on co-morbidities.

Indication for graft	Percent achieving 6/18 or better in the grafted eye *
Keratoconus	80%
Fuchs' dystrophy	60%
History of HSV infection (not active)	48%
Previous failed graft	37%
Pseudophakic bullous keratopathy	27%
Aphakic bullous keratopathy	22%

***** unknowns excluded from calculations

- The most important factors with a negative influence on the visual outcome of the grafted eye were: graft failure, major astigmatism (≥5D), and maculopathy.

- A refractive surgical procedure was performed on 12% of grafts.

- By 10 years post-graft, 14% of grafted eyes either required no form of correction or had been prescribed none, while a further 9% of eyes had an IOL in situ but were otherwise uncorrected.

8. LAMELLAR GRAFTS

8.1 SYNOPSIS OF LAMELLAR GRAFTS

Lamellar grafts have been registered since the Registry's inception. We refer to these as "traditional" lamellar grafts. In recent years, the newer procedures of deep anterior lamellar keratoplasty (DALK) and various forms of endothelial cell keratoplasty (endokeratoplasty) have been adopted. Tables 8.1 and 8.2 give detailed analyses of each form of these new procedures, along with traditional lamellar grafts.

Table 8.1 Synopsis of lamellar grafts (Census date for all grafts in this Chapter is 12/10/2011)

Type of Lamellar Procedure	Number registered	
	No.	%
Traditional lamellar	**1165**	**39%**
Big Bubble	16	<1%
Melles	6	<1%
DALK[1] unspecified	543	18%
DALK Total	**565**	**19%**
DSEK[2]	799	27%
DMEK[3]	103	3%
DSAEK[4]	135	5%
Endothelial unspecified	216	7%
Endothelial Total	**1253**	**42%**
Total Lamellar	**2983**	**100%**

[1]Deep anterior lamellar keratoplasty
[2]Descemet's stripping endothelial keratoplasty
[3]Descemet's membrane endothelial keratoplasty
[4]Descemet's stripping automated endothelial keratoplasty

Table 8.2 Survival of followed lamellar grafts

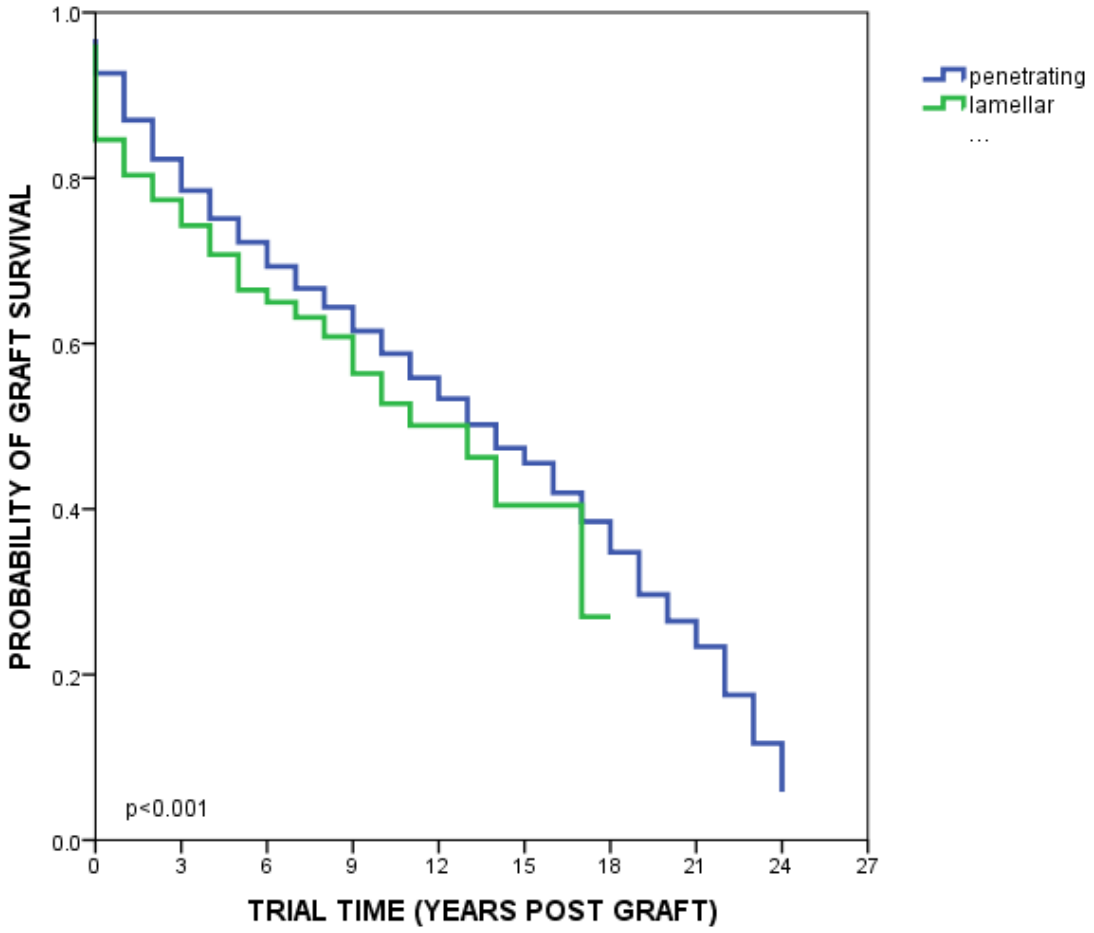
Type of Lamellar Procedure	Number followed		Of followed			
			Failed		Surviving	
	No.	%	No.	%	No.	%
Traditional lamellar	**934**	**100%**	**218**	**23%**	**716**	**77%**
DALK	**264**	**100%**	**23**	**9%**	**241**	**91%**
Endothelial	**553**	**100%**	**142**	**26%**	**411**	**74%**
Total Lamellar	**1751**	**100%**	**383**	**22%**	**1368**	**88%**

Eight hundred and six lamellar grafts had been lost to follow-up comprising 552 traditional lamellar grafts, 154 DALKs and 100 endothelial keratoplasties.

8.2 SURVIVAL OF LAMELLAR GRAFTS

Survival curves for all lamellar and penetrating corneal grafts are presented in Figure 8.1 (Log Rank Statistic=52.402; df=1; p<0.001).

Figure 8.1 Survival of lamellar and penetrating corneal grafts



Number at Risk

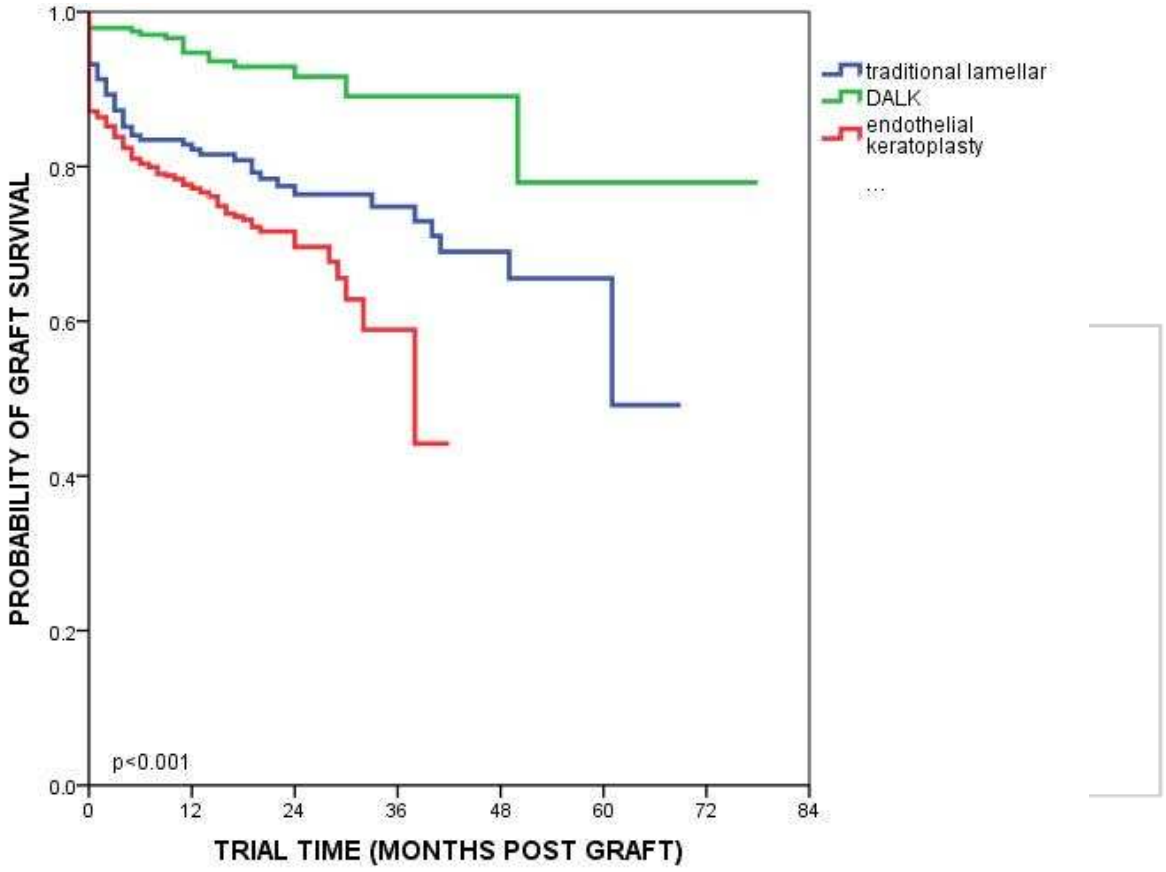
Identity	Initially	3 years	6 years	9 years	12 years	15 years	18 years	21 years	24 years
Penetrating	16736	6960	3428	1761	973	465	187	43	2
Lamellar	1751	274	90	41	16	5	2	n/a	n/a

Identity	No. initially at risk	Probability of Graft Survival (at years post-graft)				
		1	5	10	15	20
Penetrating	16736	.87	.72	.59	.46	.26
Lamellar	1751	.80	.67	.53	.41	n/a

n/a = not applicable

Until 2004, the majority (98%) of lamellar grafts performed were traditional grafts. Since 2004, 792 (78%) of followed lamellar grafts performed were either DALKs or endothelial keratoplasties. The indications for these three types of lamellar grafts are very different. Figure 8.2 compares graft survival of different types of lamellar grafts performed since 2004 and was analysed on a monthly basis (Log Rank Statistic=43.706; df=2; p<0.001). Corneal graft survival was worst for endothelial lamellar grafts.

Figure 8.2 Survival of traditional grafts, DALK and endothelial lamellar grafts (post 2003)



Number at Risk

Identity	Initially	12 months	24 months	36 months	48 months	60 months	72 months	84 months
Traditional	221	133	73	43	20	5	n/a	n/a
DALK	239	195	72	22	11	3	1	n/a
Endothelial	553	320	72	5	n/a	n/a	n/a	n/a

Identity	No. initially at risk	Probability of Graft Survival (at years post-graft)		
		1	3	6
Traditional	221	.82	.75	n/a
DALK	239	.95	.89	.78
Endothelial	553	.77	.59	n/a

CORNEAL GRAFT SURVIVAL
PENETRATING AND LAMELLAR GRAFTS

Penetrating corneal graft survival:	**87% at 1 year**
Mean Survival 12.85 years	**72% at 5 years**
(SE=0.15; 95% CI: 12.55, 13.14)	**59% at 10 years**
Median Survival 14 years	**46% at 15 years**
	26% at 20 years
Lamellar corneal graft survival:	**80% at 1 year**
Mean Survival 10.47 years	**67% at 5 years**
(SE=0.51; 95% CI: 9.47, 11.47)	**53% at 10 years**
Median Survival 13 years	**41% at 15 years**

LAMELLAR CORNEAL GRAFT SURVIVAL
TYPE OF GRAFT (SINCE 2004)

Traditional lamellar:	**80% at 1 year**
Mean Survival 50.01 months	**67% at 5 years**
(SE=2.44; 95% CI 45.24, 54.79)	**53% at 10 years**
Median Survival 61 months (5.1 years)	**42% at 15 years**
	31% at 20 years
Deep anterior lamellar keratoplasty (DALK):	**93% at 1 year**
Mean Survival 68.99 months	**83% at 5 years**
(SE=3.39; 95% CI: 61.36, 74.64)	**69% at 10 years**
Median Survival approx. 87 months (6.5 years)	
Endothelial keratoplasty:	**74% at 1 year**
Mean Survival 29.32 months	
(SE=1.05; 95% CI: 27.25, 31.38)	
Median Survival 38 months (2.6 years)	

KEY:

n/a	=	not applicable
SE	=	standard error
CI	=	confidence interval
df	=	degrees of freedom
p	=	probability

8.3 DESIRED OUTCOME

The Australian Corneal Graft Registry has recorded a desired outcome for 2,637 (88%) of the 2,983 lamellar grafts entered. Of these, 890 (34%) were traditional lamellar grafts, 542 (20%) were DALKs and 1,205 (46%) were endothelial lamellar grafts. Desired outcomes for each type of lamellar graft are shown in Figure 8.3 and Table 8.3.

Figure 8.3 Desired outcome of graft

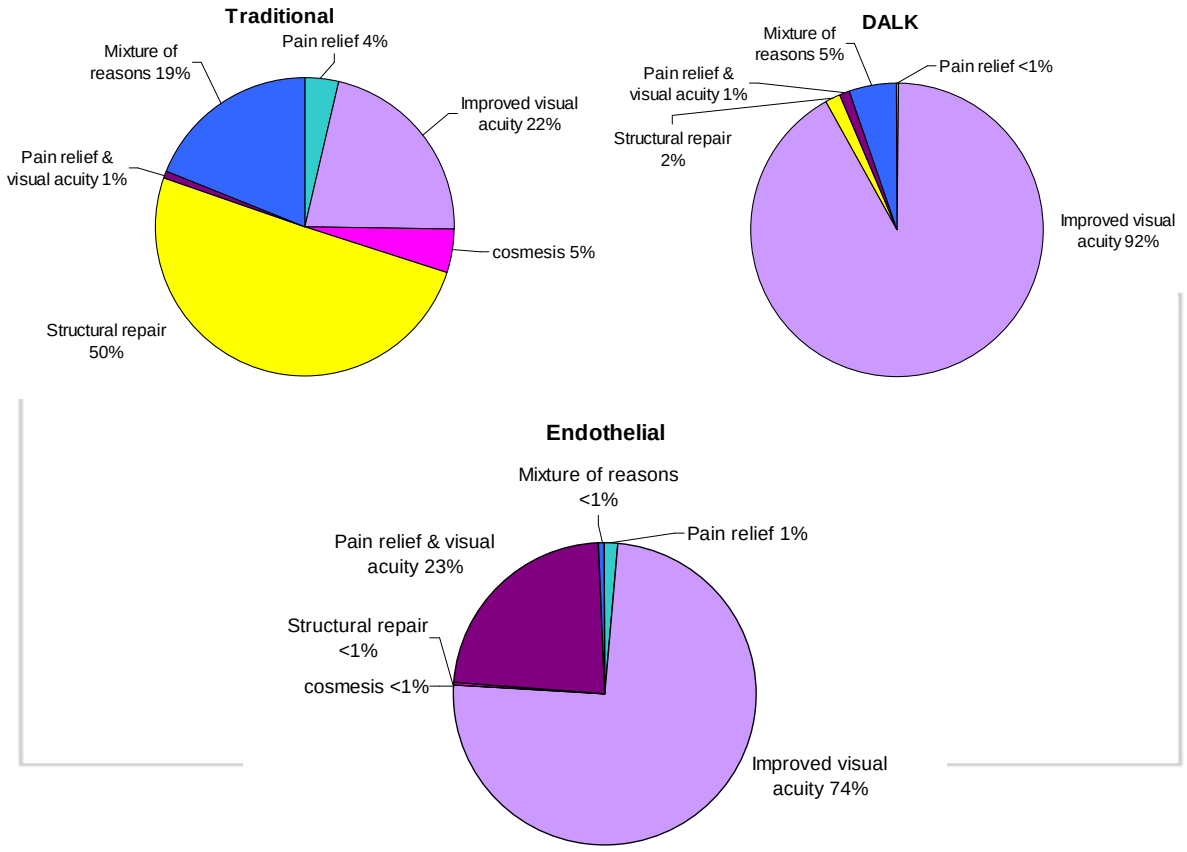


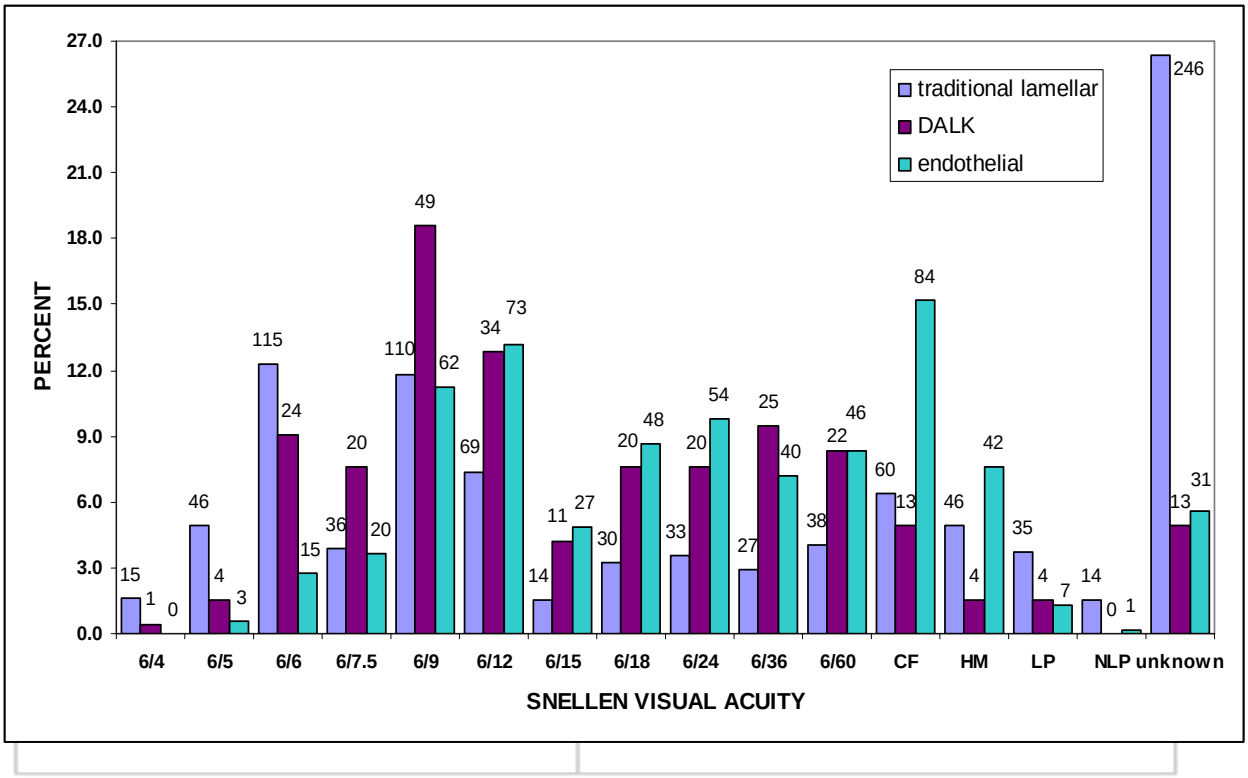
Table 8.3 Desired outcomes

Desired Outcome	Traditional		DALK		Endothelial	
Structural repair	447	50%	9	2%	3	<1%
Improvement in visual acuity	194	22%	498	92%	896	74%
Mixture of reasons	167	19%	28	5%	6	<1%
Pain relief	32	4%	1	<1%	18	1%
Cosmesis	41	5%	0	0%	1	<1%
Pain and visual acuity	9	1%	6	1%	281	23%
TOTAL	**890**	**100%**	**542**	**100%**	**1205**	**100%**

8.4 OVERALL VISUAL ACUITY

Figure 8.4 shows the best corrected visual acuity in the grafted eye at the time of the most recent follow-up for each type of lamellar procedure.

Figure 8.4 Best corrected Snellen visual acuity in grafted eye at last follow-up by percentage of type of lamellar graft



* The numbers above the bars are numbers of grafts.

* Post graft visual acuity has been recorded for 688 traditional lamellar grafts, 251 DALK and 522 endothelial lamellar grafts.

* A best corrected Snellen acuity of 6/12 or better at most recent follow-up was achieved in 34% of cases for traditional lamellar grafts; 37% of DALKs and 18% of endothelial lamellar grafts.

* Forty seven percent of traditional lamellar grafts, 62% of DALKs and 45% of endothelial lamellar grafts achieved 6/18 or better.

* A visual acuity of less than 6/60 at last follow-up was recorded in 21% of traditional lamellar grafts, 16% of DALK and 33% of endothelial lamellar grafts.

* Follow-up visual acuities were not advised for 26% of cases for traditional lamellar grafts, 5% of DALKs and 6% of endothelial lamellar grafts.

8.5 CORNEAL COLLECTION AND STORAGE

Death-to-enucleation and death-to-graft times are shown in Table 8.4.

Table 8.4 Corneal collection times for lamellar grafts

Time	Lamellar Grafts		
	Total	Median time Days	Range (Days)
Death-to-enucleation times	2921	<1	0 – 1
Death-to-graft times	2310	5	0 – 69
Death-to-graft times for storage in:			
Optisol	1549	4	0 – 69
Moist Pot	447	7	0 – 46
Organ Culture	158	16	3 – 27
CSM	69	10	1 – 44
MK medium	55	3	0 – 19
K-Sol	21	5	1 – 29

The corneal storage media in which donor corneas were preserved are shown in Table 8.5.

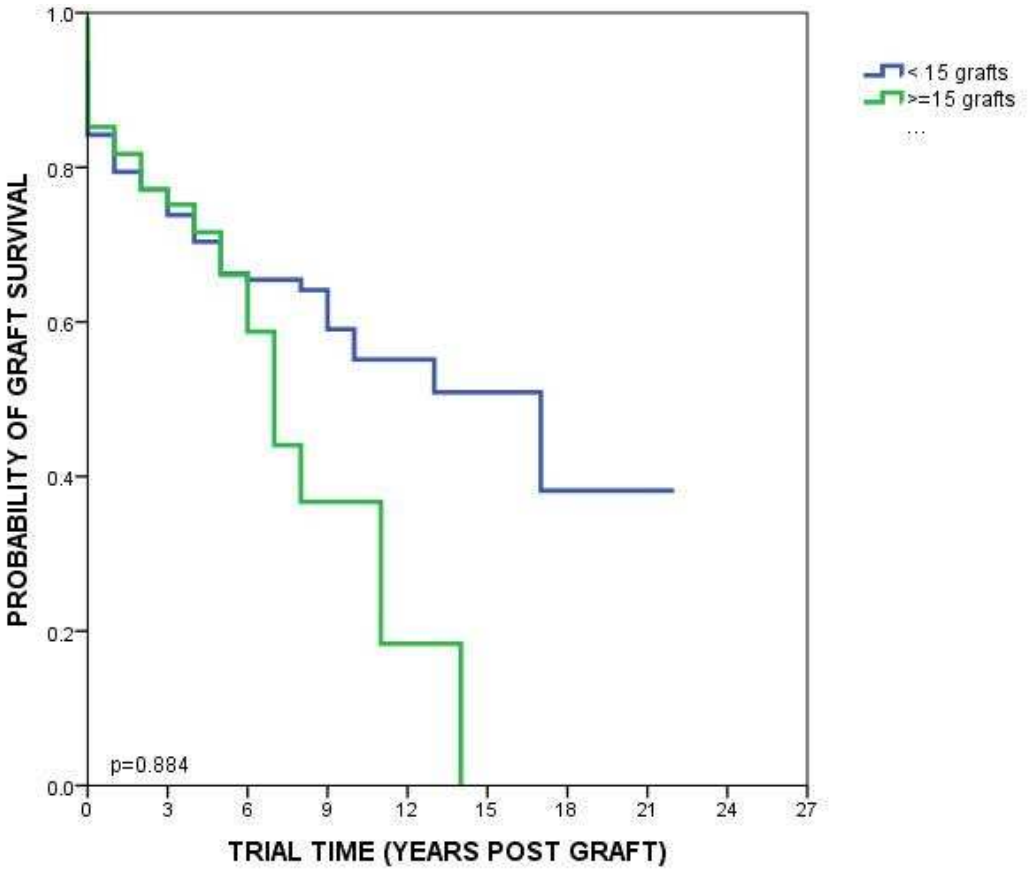
Table 8.5 Corneal storage media

Storage medium	No. of grafts	
Optisol (1991 – present)	1911	64%
M-K medium (1985 – 2002)	72	2%
CSM (1987 – 2003)	79	3%
Moist pot (1985 – present)	613	20%
K-Sol (1987 – 2000)	22	<1%
Organ Culture (1985 – 1997)	2	<1%
(2007 – present)	242	8%
Other	21	<1%
Unknown to ACGR	21	<1%
Total	**2983**	**100%**

8.6 EFFECT OF SURGEON WORKLOAD

Figure 8.5 shows the survival of lamellar grafts by surgeons who performed 15 or more lamellar grafts per year, compared with surgeons who performed fewer than 15 grafts per year (Log Rank Statistic=0.021; df=1; p=0.88). The difference was not significant.

Figure 8.5 Outcome according to number of grafts performed per year



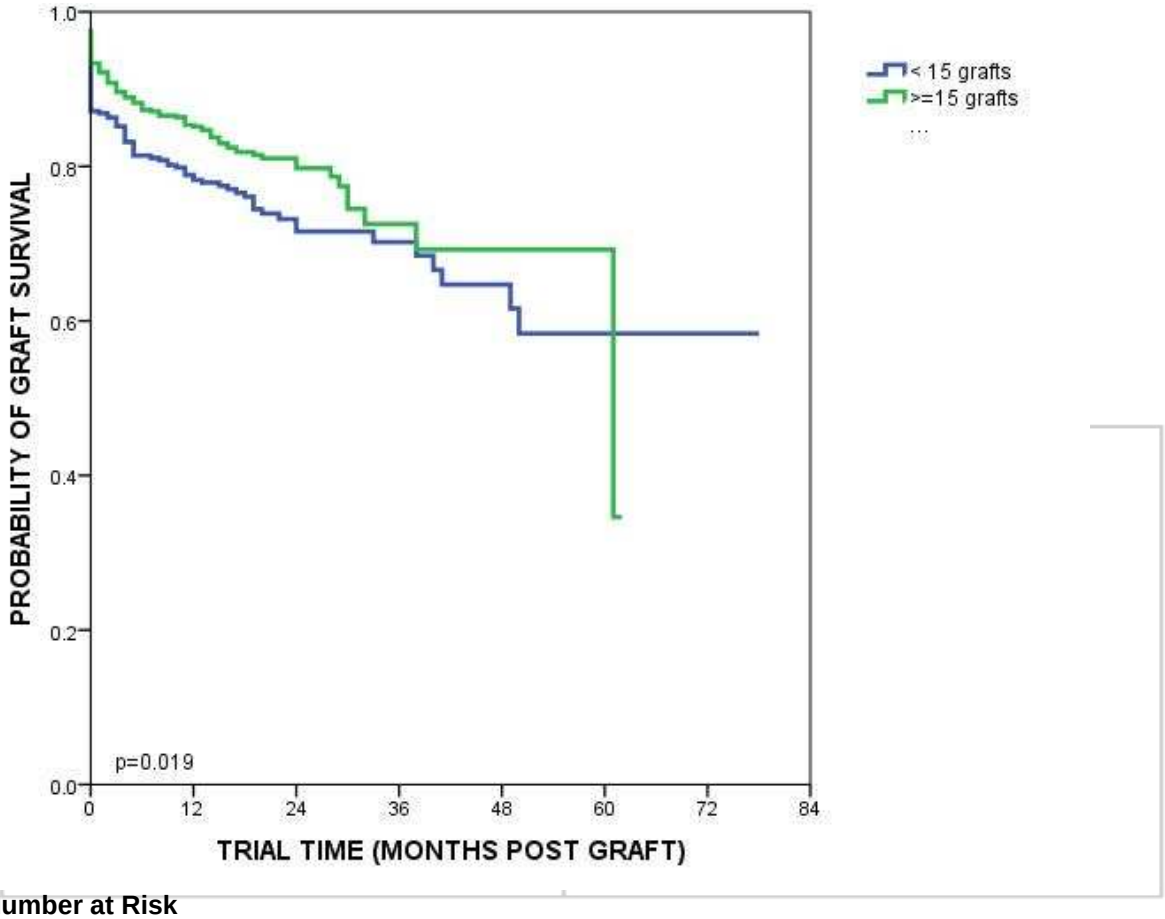
Number at Risk

Identity	Initially	3 years	6 years	9 years	12 years	15 years	18 years	21 years	24 years
< 15 grafts per year	1052	236	82	38	16	6	3	1	n/a
≥15 grafts per year	699	39	9	4	2	0	n/a	n/a	n/a

Identity	No. initially at risk	Graft survival (at years post-graft)				
		1	5	10	15	20
< 15 grafts per year	1052	.79	.66	.55	.51	.38
≥ 15 grafts per year	699	.82	.66	.37	n/a	n/a

Of the 699 followed lamellar grafts carried out by surgeons who performed more than 15 grafts per year, 632 (90%) were performed after 2003. Figure 8.6 looks more closely at lamellar grafts performed from 2004 to 2011 and was analysed on a monthly basis (Log Rank Statistic=5.460; df=1; p=0.019). When these new procedures were considered, a significant difference between surgeons who performed more or less than 15 grafts per year was apparent.

Figure 8.6 Number of lamellar grafts performed/year since 2004



Number at Risk

Identity	Initially	12 months	24 months	36 months	48 months	60 months	72 months	84 months
< 15 grafts per year	381	243	91	45	21	5	1	n/a
≥15 grafts per year	632	405	126	25	10	3	n/a	n/a

Identity	No. initially at risk	Graft survival (at years post-graft)		
		1	3	6
< 15 grafts per year	381	.78	.70	.58
≥15 grafts per year	632	.85	.73	n/a

LAMELLAR CORNEAL GRAFT SURVIVAL
EFFECT OF SURGEON WORKLOAD PER YEAR

Less than 15 grafts**:**	**79% at 1 year**
Mean Survival 12.65 years	**66% at 5 years**
(SE=0.86; 95% CI 10.97, 14.33)	**55% at 10 years**
Median Survival 17 years	**51% at 15 years**
	38% at 20 years
More than 15 grafts**:**	**82% at 1 year**
Mean Survival 7.25 years	**66% at 5 years**
(SE=0.83; 95% CI: 5.63, 8.87)	**37% at 10 years**
Median Survival 7 years	

LAMELLAR CORNEAL GRAFT SURVIVAL
EFFECT OF SURGEON WORKLOAD PER YEAR SINCE 2004

Less than 15 grafts**:**	**78% at 1 year**
Mean Survival 53.14 months	**70% at 3 years**
(SE=2.42; 95% CI 48.39, 57.89)	**58% at 6 years**
Median Survival 80 months (6.6 years)	
More than 15 grafts**:**	**85% at 1 year**
Mean Survival 47.37 months	**73% at 3 years**
(SE=1.55; 95% CI: 44.33, 50.42)	
Median Survival 61 months (5.1 years)	

KEY:

n/a	=	not applicable
SE	=	standard error
CI	=	confidence interval
df	=	degrees of freedom
p	=	probability

8.7 MAIN INDICATIONS FOR LAMELLAR KERATOPLASTY

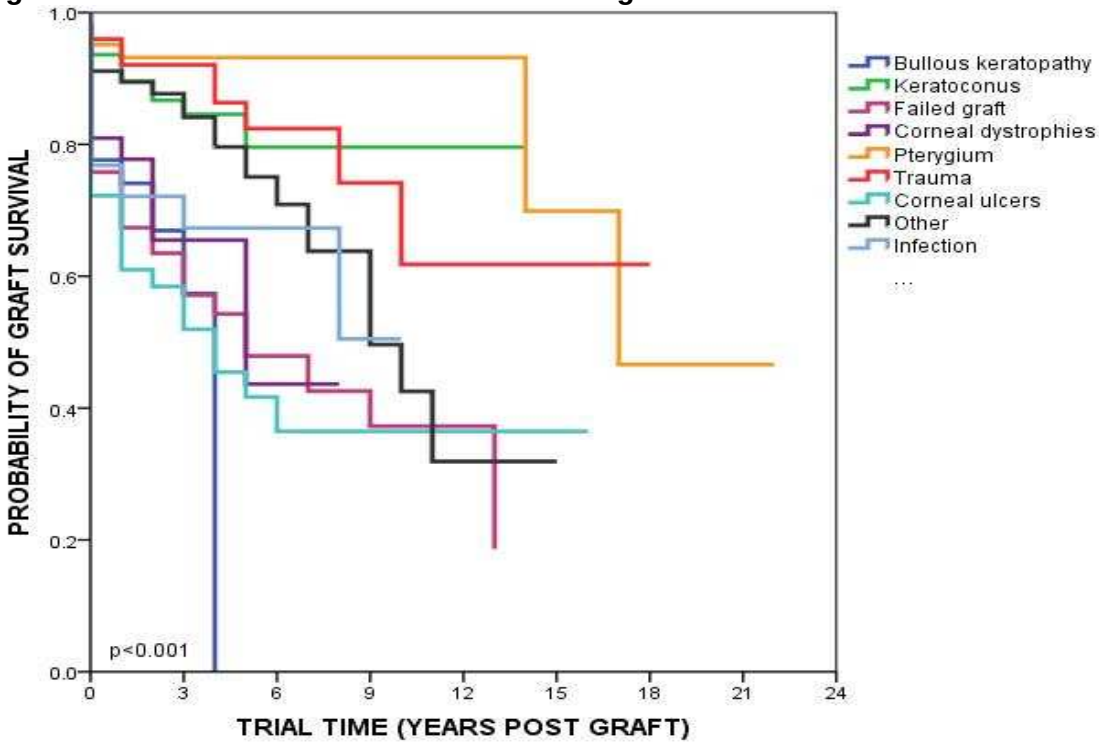
Table 8.6 Main indications for lamellar keratoplasty

Indication for graft	Traditional lamellar		DALK		Endothelial keratoplasty		All lamellar	
	n	%	n	%	n	%	n	%
Bullous keratopathy	**14**	**1%**	**0**	**0%**	**416**	**33%**	**430**	**14%**
Keratoconus & keratoglobus	**110**	**9%**	**427**	**75%**	**3**	**<1%**	**540**	**18%**
Failed previous graft	**182**	**16%**	**18**	**3%**	**223**	**18%**	**423**	**14%**
Corneal dystrophy	**15**	**1%**	**15**	**2%**	**590**	**47%**	**620**	**21%**
Fuchs' dystrophy	4	<1%	4	<1%	590	47%	598	20%
Other dystrophies	11	<1%	11	2%	0	0%	22	<1%
Pterygium	**191**	**16%**	**0**	**0%**	**0**	**0%**	**191**	**6%**
Trauma	**138**	**12%**	**7**	**1%**	**4**	**<1%**	**149**	**5%**
Corneal ulcers (non HSV)	**139**	**12%**	**5**	**<1%**	**0**	**0%**	**144**	**5%**
Corneal degenerations	**69**	**6%**	**26**	**5%**	**1**	**<1%**	**96**	**3%**
Disorders of the sclera	**80**	**7%**	**1**	**<1%**	**0**	**0%**	**81**	**3%**
Neoplasia	**73**	**6%**	**1**	**<1%**	**0**	**0%**	**74**	**2%**
Herpetic eye disease	**45**	**4%**	**25**	**<1%**	**3**	**<1%**	**73**	**2%**
Corneal scars and opacities (no history of herpetic disease)	**31**	**3%**	**13**	**2%**	**0**	**0%**	**44**	**1%**
Non-herpetic infections	**21**	**2%**	**20**	**4%**	**0**	**0%**	**41**	**1%**
Other**	**57**	**2%**	**7**	**<1%**	**13**	**0%**	**77**	**<1%**
TOTALS	**1165**	**100%**	**565**	**100%**	**1253**	**100%**	**2983**	**100%**

*Percentages are totalled down each column.
**Includes - descemetocoele: (19) traditional & (2) DALK; congenital abnormalities: (8) traditional & (4) endothelial keratoplasties; metabolic deposits: (10) traditional & (1) each DALK/endothelial keratoplasty; ICE syndrome: (1) traditional & (8) endothelial keratoplasties; interstitial keratitis: (5) traditional lamellar & (3) DALK; glaucoma: (4) traditional; corneal amyloid: (2) traditional; epithelial defect (1) traditional; neovascularization (1) traditional; Sjogen's syndrome (1) traditional; calcification (1) traditional; infective keratitis (1) DALK;. unknown: (4) traditional lamellar.

Figure 8.7 shows the survival curves for the main indication for lamellar grafts, as shown in Table 8.5 (Log Rank Statistic= 133.75; df=8; p<0.001).

Figure 8.7 Main indications for all lamellar grafts



Number at Risk

Identity	Initially	3 years	6 years	9 years	12 years	15 years	18 years	21 years	24 years
Bullous keratopathy	341	7	n/a	n/a	n/a	n/a	n/a	n/a	n/a
Keratoconus	266	41	12	4	2	n/a	n/a	n/a	n/a
Previous failed graft	252	30	12	8	3	n/a	n/a	n/a	n/a
Corneal dystrophies	126	5	1	n/a	n/a	n/a	n/a	n/a	n/a
Pterygium	163	48	17	11	7	3	2	1	n/a
Trauma	124	37	18	6	2	1	1	n/a	n/a
Corneal Ulcers	126	18	8	2	1	1	n/a	n/a	n/a
Infections	82	15	4	2	n/a	n/a	n/a	n/a	n/a
Other	270	74	18	9	2	1	n/a	n/a	n/a

Identity	No. initially at risk	Graft survival (at years post-graft)				
		1	5	10	15	20
Bullous keratopathy	341	.74	n/a	n/a	n/a	n/a
Keratoconus	266	.90	.80	.80	n/a	n/a
Previous failed graft	252	.68	.48	.38	n/a	n/a
Corneal dystrophies	126	.78	.44	n/a	n/a	n/a
Pterygium	163	.93	.93	.93	.73	.47
Trauma	124	.92	.82	.62	.62	n/a
Corneal Ulcers	126	.61	.42	.37	.37	n/a
Infections	82	.72	.67	.51	n/a	n/a
Other	270	.90	.75	.43	.32	n/a

LAMELLAR CORNEAL GRAFT SURVIVAL
MAIN INDICATION FOR GRAFT

Bullous keratopathy:	**74% at 1 year**
Mean Survival 2.76 years	
(SE=0.13; 95% CI: 2.50, 3.03)	
Median Survival 4 years	
Keratoconus:	**90% at 1 year**
Mean Survival 11.55 years	**80% at 5 year**
(SE=0.57; 95% CI: 10.43, 12.68)	
Median Survival approx. 15 years	
Previous failed graft:	**68% at 1 year**
Mean Survival 6.54 years	**48% at 5 years**
(SE=0.66; 95% CI: 5.24, 7.83)	**38% at 10 year**
Median Survival 5 years	
Corneal dystrophies:	**78% at 1 year**
Mean Survival 4.86 years	**44% at 5 years**
(SE=0.67; 95% CI: 3.55, 6.17)	
Median Survival 5 years	
Pterygium:	**93% at 1 year**
Mean Survival 17.49 years	**73% at 20 years**
(SE=1.64; 95% CI 14.27, 20.70)	
Median Survival 17 years	
Trauma:	**92% at 1 year**
Mean Survival 13.48 years	**82% at 5 years**
(SE=1.34; 95% CI 10.86, 16.11)	**62% at 10 year**
Median Survival approx. 19 years	
Corneal ulcers:	**61% at 1 year**
Mean Survival 6.95 years	**42% at 5 years**
(SE=1.04; 95% CI 4.91, 8.99)	**37% at 10 year**
Median Survival 4 years	
Infections:	**72% at 1 year**
Mean Survival 6.59 years	**67% at 5 year**
(SE=0.62; 95% CI: 5.38, 7.80)	**51% at 10 year**
Median Survival 9 years	
Other:	**90% at 1 year**
Mean Survival 9.25 years	**75% at 5 years**
(SE= 0.84; 95% CI 7.61, 10.89)	**43% at 10 years**
Median Survival approx 10 years	**32% at 15 years**

KEY:

n/a	=	not applicable
SE	=	standard error
CI	=	confidence interval
df	=	degrees of freedom
p	=	probability

8.8 REASON FOR GRAFT FAILURE

Table 8.7 Overall reasons for failure of lamellar grafts

Reason	Traditional lamellar		DALK		Endothelial keratoplasty		All lamellar	
	n	%	n	%	n	%	n	%
Primary graft failure	**15**	**7%**	**4**	**17%**	**70**	**49%**	**89**	**23%**
Corneal degeneration	**31**	**14%**	**0**	**0%**	**2**	**1%**	**33**	**9%**
Ulcers (not from infection)	**25**	**12%**	**1**	**4%**	**0**	**0%**	**26**	**7%**
perforated	17	8%	1	4%	0	0%	18	5%
other	8	4%	0	0%	0	0%	8	2%
Non-herpetic infections	**23**	**11%**	**2**	**9%**	**1**	**<1%**	**26**	**7%**
Endothelial cell failure	**8**	**4%**	**2**	**9%**	**14**	**10%**	**24**	**6%**
Rejection	**8**	**4%**	**0**	**0%**	**12**	**8%**	**20**	**5%**
Scars and opacities	**6**	**3%**	**2**	**9%**	**4**	**3%**	**12**	**3%**
Pterygium	**10**	**5%**	**0**	**0%**	**0**	**0%**	**10**	**3%**
Herpetic infection	**9**	**4%**	**1**	**4%**	**0**	**0%**	**10**	**3%**
HSV	8	4%	1	4%	0	0%	9	2%
HZO	1	<1%	0	0%	0	0%	1	<1%
Astigmatism	**8**	**4%**	**0**	**0%**	**0**	**0%**	**8**	**2%**
Carcinoma	**6**	**3%**	**0**	**0%**	**0**	**0%**	**6**	**2%**
Wound dehiscence	**6**	**3%**	**0**	**0%**	**0**	**0%**	**6**	**2%**
Scleral necrosis	**5**	**2%**	**0**	**0%**	**0**	**0%**	**5**	**1%**
Glaucoma	**0**	**0%**	**0**	**0%**	**4**	**3%**	**4**	**1%**
Vascularization	**3**	**1%**	**1**	**4%**	**0**	**0%**	**4**	**1%**
Miscellaneous*	**11**	**5%**	**4**	**17%**	**1**	**<1%**	**16**	**4%**
Unspecified	**43**	**20%**	**6**	**26%**	**35**	**24%**	**84**	**22%**
TOTALS	**217**	**100%**	**23**	**100%**	**143**	**100%**	**383**	**100%**

*Epithelial defect (3); injury (2); iris disorders (2); keratoconus (2); Stevens-Johnson syndrome (2); corneal dystrophy (1); ocular pemphigoid (1); scleral melt (1); symblepharon (1); Wegener's granulomatosis (1).
**Percentages are totalled down each column.

8.9 POST-GRAFT OPERATIVE PROCEDURES

Post-graft operative procedures were carried out in 525 eyes with lamellar grafts (18%). These included 22 grafts (<1%) that had undergone both refractive and other surgical procedures.

Table 8.8 Post-graft operative procedures

Procedure	Number of grafts Total	% of grafts followed
Repeat graft (reported to ACGR in follow-up)	299	17%
Cataract extraction and IOL implant	82	5%
Yag laser	33	2%
Wound repair	33	2%
Refractive surgery	43 (48)	2%
Glaucoma surgery	18	<1%
Cataract and IOL surgery	11	<1%
Miscellaneous procedures	74 (75)	4%
Total procedures	**599**	
Total grafts followed	**1751**	

The number of grafts does not necessarily equate to the number of procedures as some grafts have had more than one operative procedure since graft. Where multiple occurrences of the same type of procedure were recorded, the total number of procedures recorded is also shown in parentheses.

8.10 PRIMARY NON FUNCTIONING GRAFTS

Table 8.9 Features of primary non-functioning grafts (lamellar grafts only)

Feature	Primary failures traditional		Primary failures DALK		Primary failures endothelial	
	No.	%	No.	%	No.	%
Procurement source						
Eyebank	15	100%	4	100%	70	100%
Donor age						
≤ 20 years	0	0%	0	0%	1	1%
21 – 60 years	2	13%	1	25%	23	33%
61 – 80 years	12	80%	2	50%	39	56%
>80 years	1	7%	1	25%	7	10%
Main indication for graft						
Bullous keratopathy	4	27%	0	0%	38	54%
Keratoconus	1	7%	4	100%	0	0%
Previous failed graft	4	27%	0	0%	15	21%
Corneal dystrophy	0	0%	0	0%	16	23%
Corneal ulcers	4	27%	0	0%	1	1%
Herpetic eye disease	1	7%	0	0%	0	0%
Congenital abnormalities	1	7%	0	0%	0	0%
Total corneas	**15**	**100%**	**4**	**100%**	**70**	**100%**

Seventy nine (89%) of the 89 primary graft failures in lamellar grafts occurred in the past five years. The largest proportion (79%) of primary graft failures occurred in endothelial grafts.

8.11 DEEP ANTERIOR LAMELLAR KERATOPLASTY

8.11.1 Main indications for graft – DALK

Table 8.10 lists the main indications for graft for deep anterior lamellar keratoplasty. The majority of DALKs (76%) were performed for keratoconus.

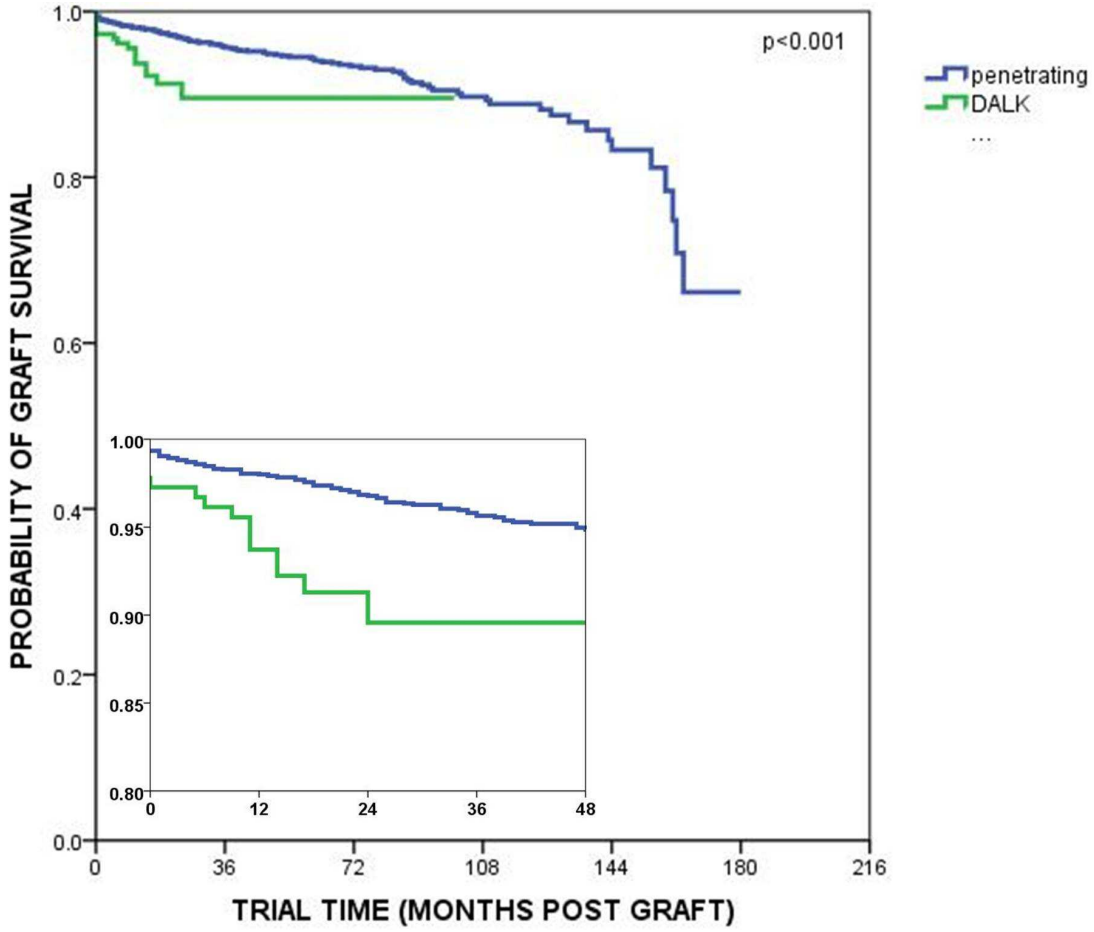
Table 8.10 Main indications for DALK

Indication for graft	Total	%
Keratoconus	427	76%
Corneal degenerations	26	4%
Herpetic eye disease	25	4%
Non-herpetic infections	20	4%
Failed previous graft	18	3%
Corneal dystrophy	15	3%
Corneal scars & opacities	13	2%
Trauma	7	2%
Corneal ulcers (non HSV)	5	<1%
Interstitial keratitis	3	<1%
Descemetocoele	2	<1%
Scleral degeneration	1	<1%
Unspecified keratitis	1	<1%
Corneal neoplasm	1	<1%
Metabolic deposits	1	<1%
TOTAL	565	100%

8.11.2 DALK for Keratoconus

Figure 8.8 compares corneal graft survival for penetrating and deep anterior lamellar keratoplasty (DALK) performed for keratoconus since the first DALK was recorded in 1996 (Log Rank Statistic= 15.826; df=1; p<0.001). Data have been analysed on a monthly basis. The inset plot looks more closely at the first 4 years post graft.

Figure 8.8 Grafts for keratoconus performed post 1995 – penetrating and DALK



Number at Risk

Identity	Initially	3 years	6 years	9 years	12 years	15 years	18 years
Penetrating	2736	1156	498	206	71	1	n/a
DALK	183	18	4	n/a	n/a	n/a	n/a

Identity	No. initially at risk	Probability of Graft Survival (at years post-graft)				
		1	5	10	15	20
Penetrating	2736	.98	.94	.89	.66	n/a
DALK	183	.94	.90	n/a	n/a	n/a

CORNEAL GRAFT SURVIVAL
PENETRATING AND DALK – KERATOCONUS (POST 1995)

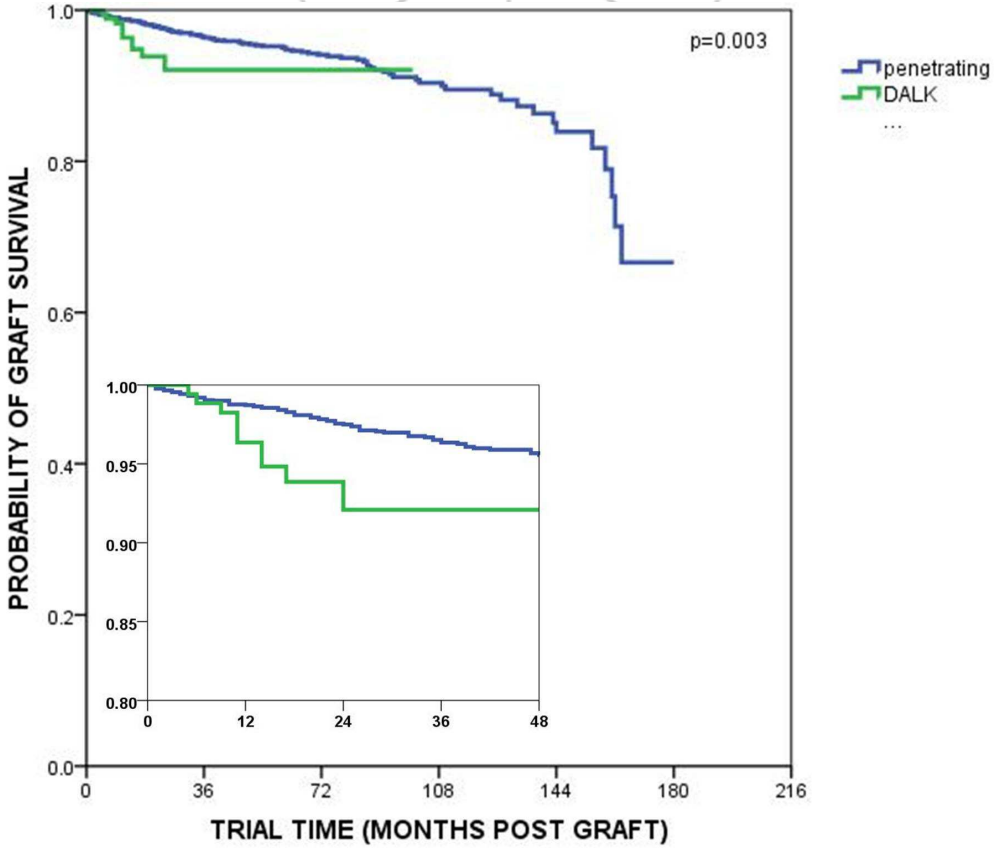
Penetrating:	**98% at 1 year**
Mean Survival 160.37 months	**94% at 5 years**
(SE=2.06; 95% CI 156.33, 164.40)	**89% at 10 years**
Median Survival 180 months (15 years)	**66% at 15 years**
DALK:	**94% at 1 year**
Mean Survival 90.67 months	**90% at 5 years**
(SE=2.42; 95% CI: 85.93, 95.40)	
Median Survival approx. 100 months (8.3 years)	

KEY:

	n/a	=	not applicable
	SE	=	standard error
	CI	=	confidence interval
	df	=	degrees of freedom
	p	=	probability

Figure 8.9 compares graft survival for penetrating and DALK grafts performed for keratoconus since 1996, as in Figure 8.8. However, grafts that survived less than 1 month have been removed, in an attempt to address a possible learning curve for this procedure (Log Rank Statistic=8.574; df=1; p=0.003). The inset plot looks more closely at the first 4 years post graft.

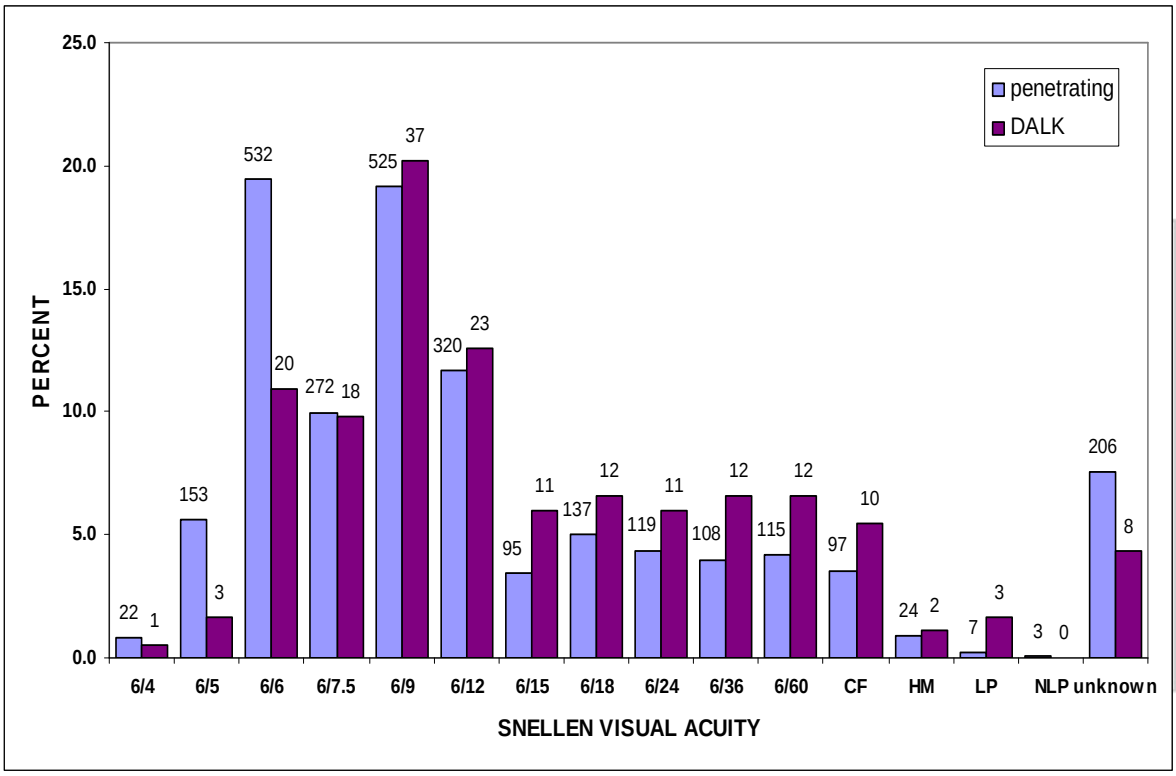
Figure 8.9 Grafts for keratoconus performed post 1995 with survival longer than 1 month – penetrating and DALK



8.11.3 Visual Acuity – Keratoconus

The majority of DALKs (76%) have been performed for keratoconus. Figure 8.10 compares Snellen visual acuity at most recent follow-up for DALK and penetrating grafts performed for keratoconus since 1996.

Figure 8.10 Post graft Snellen visual acuity for DALK vs penetrating grafts performed for keratoconus post 1995 as a percentage of each type of graft



* Fifty six percent of DALKs had a best corrected Snellen visual acuity of 6/12 or better at the time of last follow-up compared to 67% of penetrating grafts performed since 1996.

* Fifteen percent of DALKs had a best corrected Snellen visual acuity of 6/60 or worse in comparison to 9% of penetrating grafts for these indications.

8.12 ENDOTHELIAL KERATOPLASTY

8.12.1 Main indications for graft – endothelial keratoplasty

Table 8.11 lists the main indications for graft for endothelial keratoplasty. The majority (80%) were performed for corneal dystrophies (predominantly Fuchs' dystrophy) and bullous keratopathy.

Table 8.11 Main indications for endothelial keratoplasty

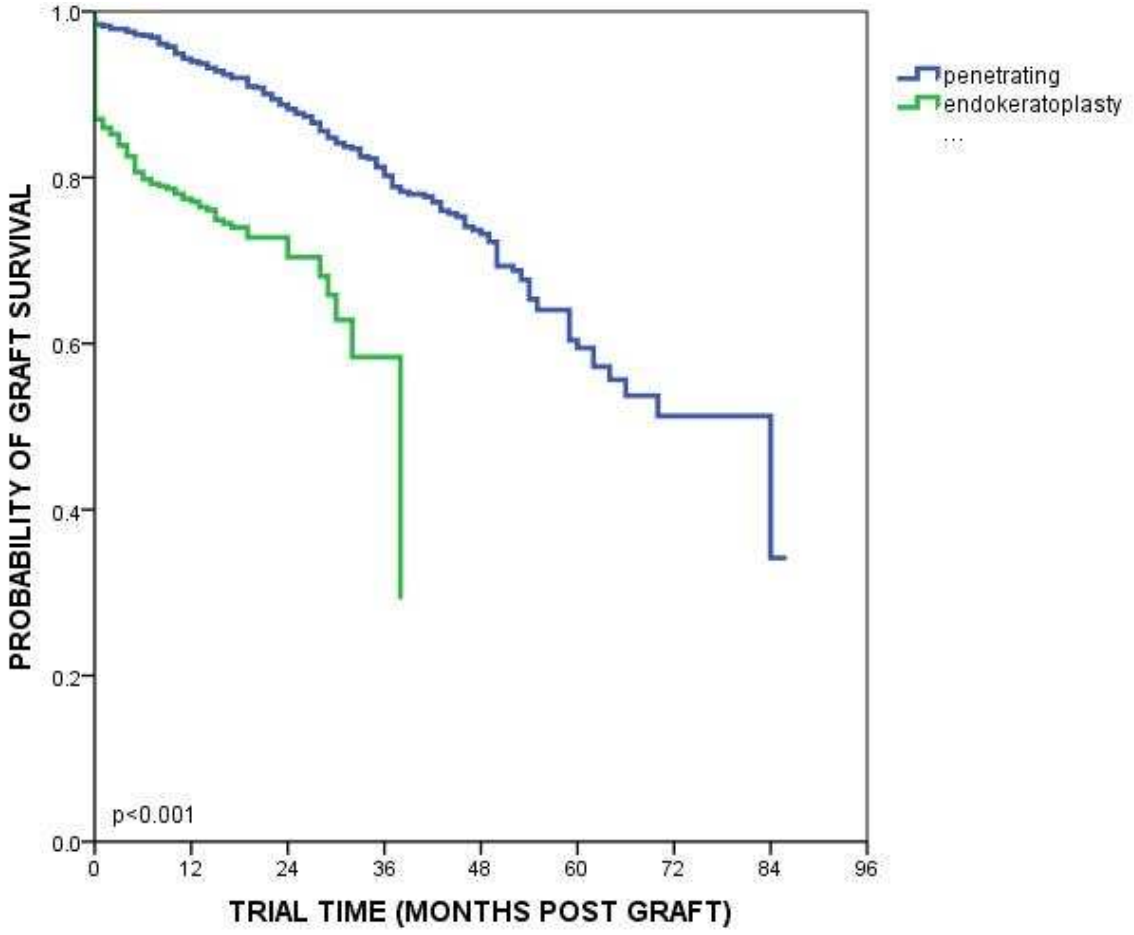
Indication for graft	Total	%
Corneal dystrophy	590	47%
Bullous keratopathy	417	33%
Failed previous graft	127	10%
Primary graft failure	51	4%
Rejection	45	4%
ICE syndrome	8	<1%
Congenital abnormalities	4	<1%
Trauma	4	<1%
Herpetic eye disease	3	<1%
Keratoconus*	2	<1%
Corneal degeneration	1	<1%
Metabolic deposits	1	<1%
TOTAL	1253	100%

* As described by surgeon

8.12.2 Fuchs' Dystrophy and Bullous Keratopathy

Over 80% of all endothelial grafts recorded were performed for either Fuchs' dystrophy or bullous keratopathy. Figure 8.11 compares corneal graft survival for these grafts against penetrating grafts performed for the same indications since 2004, when endothelial grafts were first recorded by the registry (Log Rank Statistic= 86.289; df=1; p<0.001). A significant difference in corneal graft survival was apparent between endothelial and penetrating grafts performed during this period.

Figure 8.11 Penetrating and endothelial corneal grafts for Fuchs' dystrophy and bullous keratopathy post 2003



Number at Risk

Identity	Initially	12 months	24 months	48 months	72 months	96 months
Penetrating	965	778	517	163	19	n/a
Endothelial	417	243	61	n/a	n/a	n/a

Identity	No. initially at risk	Probability of Graft Survival (at years post-graft)			
		1	2	4	6
Penetrating	965	.94	.88	.74	.51
Endothelial	417	.77	.70	n/a	n/a

PENETRATING AND ENDOTHELIAL CORNEAL GRAFT SURVIVAL
FUCHS' DYSTROPHY AND BULLOUS KERATOPATHY (POST 2003)

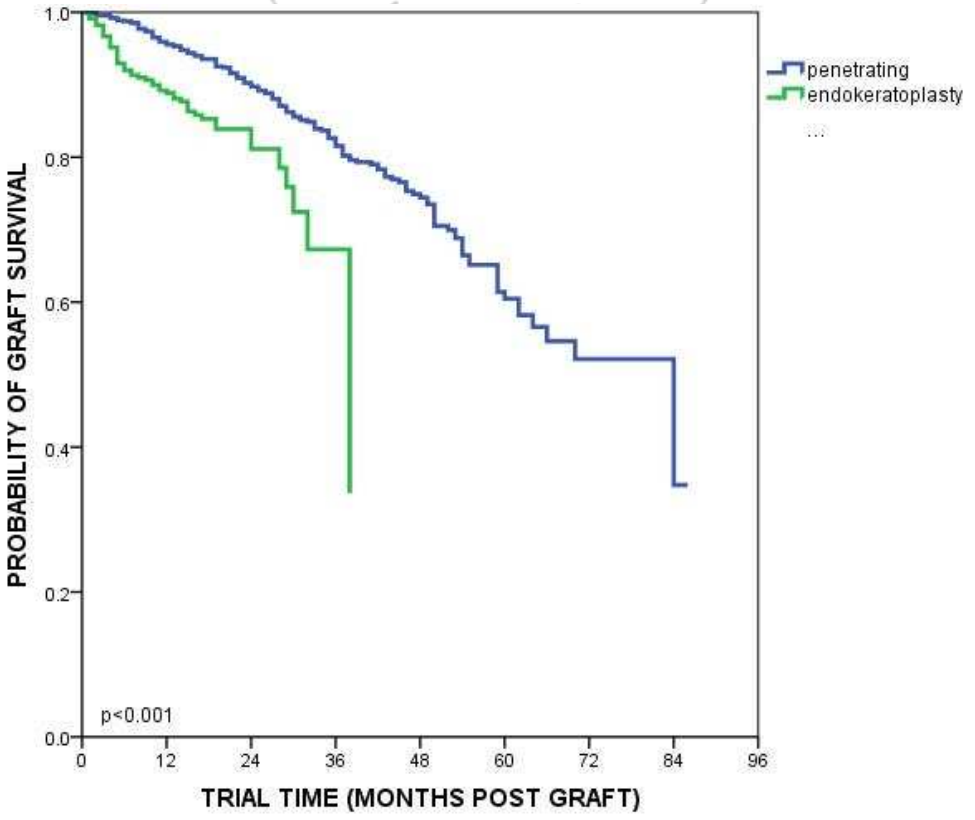
Penetrating:	**94% at 1 year**
Mean Survival 63.51 months	**88% at 2 years**
(SE=1.46; 95% CI 60.65, 66.37)	**74% at 4 years**
Median Survival 84 months (7 years)	**51% at 6 years**
Endothelial:	**77% at 1 year**
Mean Survival 27.60 months	**70% at 2 years**
(SE=0.90; 95% CI: 25.84, 29.36)	
Median Survival 38 months (3.2 years)	

KEY:

n/a	=	not applicable
SE	=	standard error
CI	=	confidence interval
df	=	degrees of freedom
p	=	probability

Figure 8.12 compares corneal graft survival for endothelial grafts with penetrating grafts performed for Fuchs' dystrophy or bullous keratopathy since 2004 as in figure 8.11, however, grafts that survived less than 1 month have been removed in an attempt to address a possible learning curve for this procedure (Log Rank Statistic=22.891; df=1; p<0.001).

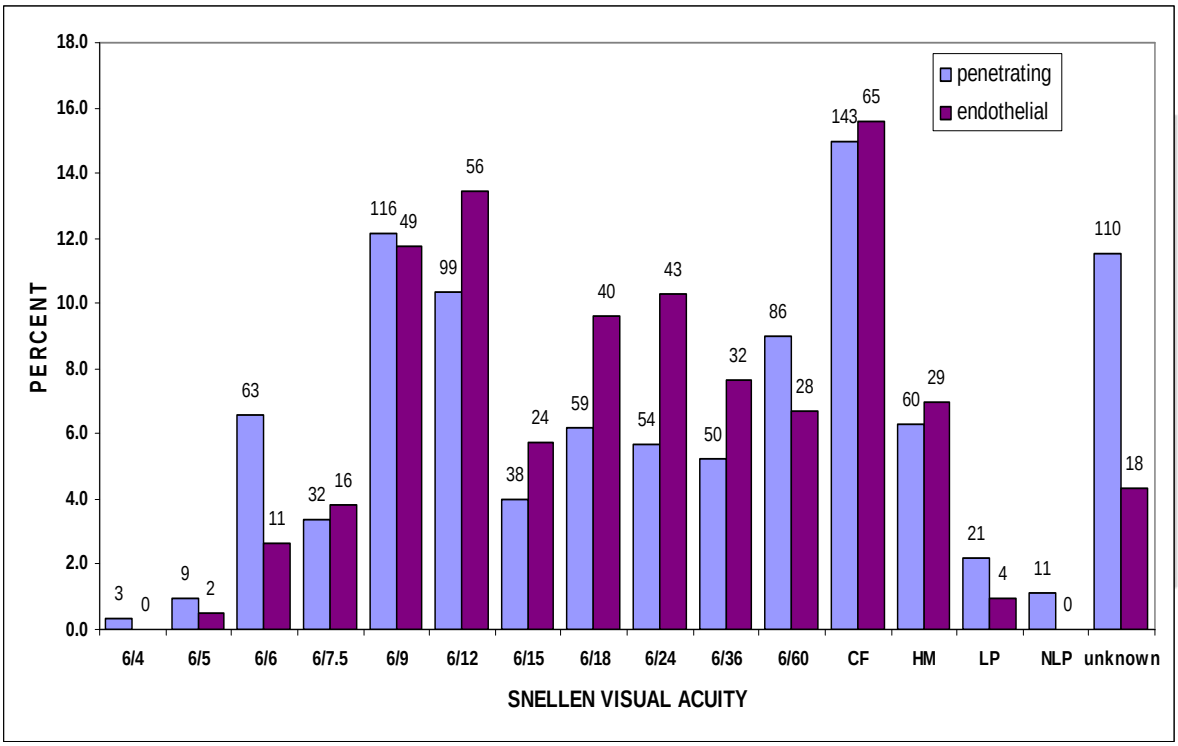
Figure 8.12 Penetrating and endothelial corneal grafts for Fuchs' dystrophy and bullous keratopathy post 2003 with survival longer than 1 month



8.12.3 Visual Acuity – Bullous Keratopathy & Fuchs' Dystrophy

The majority of endothelial keratoplasty (80%) had been performed for Fuchs' dystrophy and bullous keratopathy. Figure 8.13 compares Snellen visual acuity at most recent follow-up for endothelial lamellar grafts and penetrating grafts performed for these indications since 2004.

Figure 8.13 Post graft Snellen visual acuity for endothelial vs penetrating grafts performed post 2003 for bullous keratopathy or Fuchs' dystrophy as a percentage of each type of graft



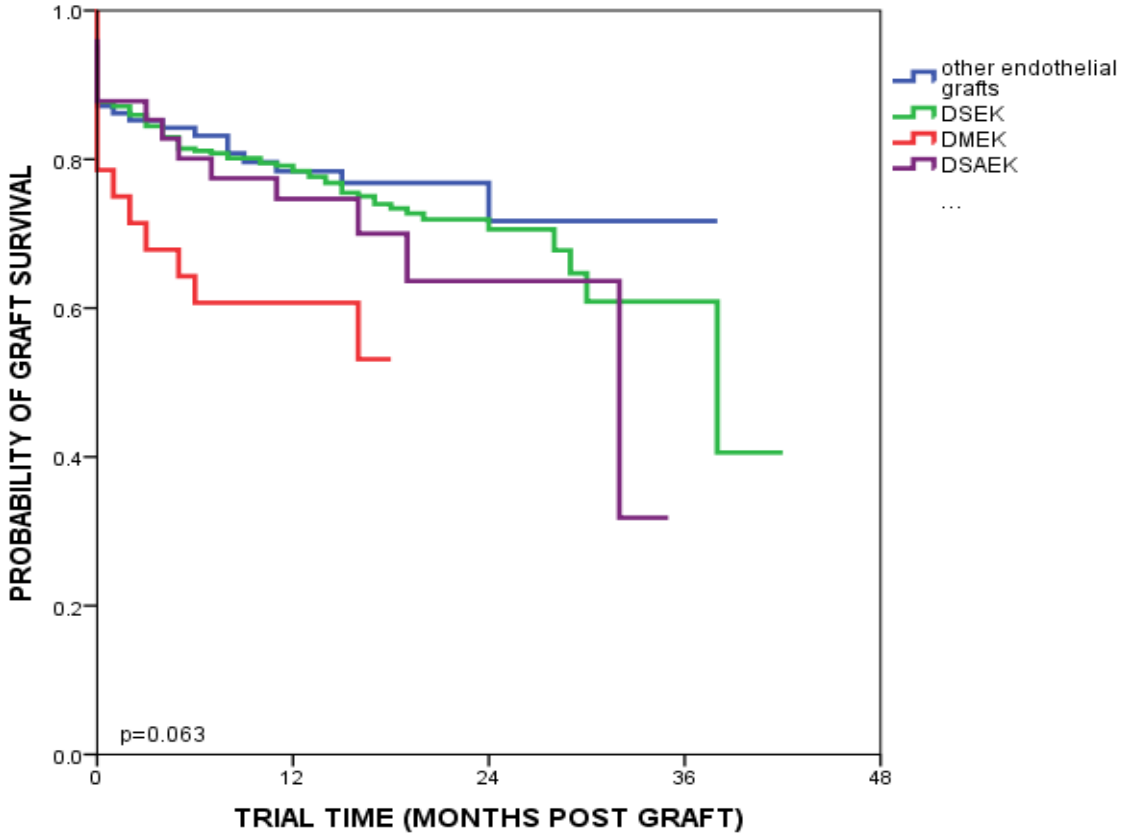
* Thirty two percent of endothelial lamellar grafts exhibited a best corrected Snellen visual acuity of 6/12 or better, compared to 34% of penetrating grafts performed since 2004.

* Twenty four percent of endothelial grafts had a best corrected Snellen visual acuity of 6/60 or worse, in comparison to 34% of penetrating grafts for these indications.

8.12.4 Procedure Type

Three main types of procedures for endothelial keratoplasties have been recorded by the Registry – Descemet's stripping endothelial keratoplasty (DSEK), Descemet's membrane endothelial keratoplasty (DMEK) and Descemet's stripping automated endothelial keratoplasty (DSAEK). The majority (68%) were recorded as DSEK although for a large number, no details were given. It is possible some other endothelial grafts fit into one of the above categories. Figure 8.14 analyses the different procedures used (Log Rank Statistic= 7.30; df=3; p=0.063). No significant difference was seen amongst types of grafts.

Figure 8.14 Types of endothelial grafts



Number at Risk

Identity	Initially	12 months	24 months	36 months	48 months
Other Endothelial grafts	109	64	15	1	n/a
DSEK	375	217	54	4	n/a
DMEK	28	13	n/a	n/a	n/a
DSAEK	41	26	3	n/a	n/a

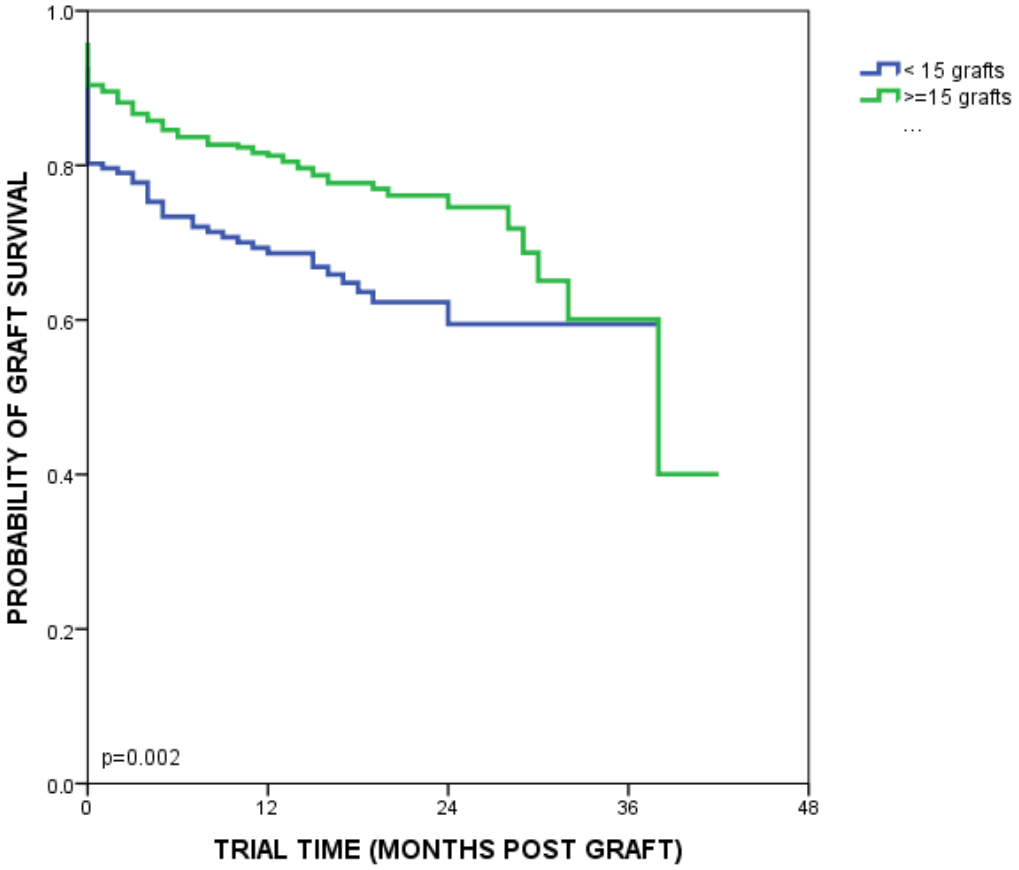
Identity	No. initially at risk	Graft survival (at years post-graft)			
		1	2	3	4
Other Endothelial grafts	109	.78	.72	.72	n/a
DSEK	375	.78	.71	.61	n/a
DMEK	28	.61	n/a	n/a	n/a
DSAEK	41	.75	.64	n/a	n/a

DSEK – Descemet's Stripping Endothelial Keratoplasty
DMEK – Descemet's Membrane Endothelial Keratoplasty
DSAEK – Descemet's Stripping Automated Endothelial Keratoplasty

8.12.5 Effect of surgeon workload - number of grafts performed per year

Until 2004 the majority (98%) of lamellar grafts performed were traditional grafts. Since then, 58% (1,252) of lamellar grafts have been endothelial keratoplasties. Figure 8.15 shows the survival of endothelial lamellar grafts performed by surgeons who had grafted 15 or more per year, compared with surgeons who had performed fewer than 15 grafts per year (Log Rank Statistic=9.445; df=1; p=0.002). The data were analysed on a monthly basis due to the shorter survival time. When the new procedure was considered, a significant difference between surgeons who had performed more or less than 15 grafts per year was apparent.

Figure 8.15 Effect of surgeon workload – endothelial lamellar grafts only



Number at Risk

Identity	Initially	12 months	24 months	36 months	48 months
< 15 grafts per year	177	98	22	2	n/a
≥15 grafts per year	376	222	50	3	n/a

Identity	No. initially at risk	Graft survival (at years post-graft)			
		1	2	3	4
< 15 grafts per year	177	.69	.60	.60	n/a
≥15 grafts per year	376	.81	.75	.60	n/a

ENDOTHELIAL LAMELLAR CORNEAL GRAFT SURVIVAL
TYPE OF GRAFT

Other endothelial grafts: **78% at 1 year**
Mean Survival 29.28 months **72% at 2 years**
(SE=1.60; 95% CI 26.15, 32.40) **72% at 3 years**
Median Survival approx. 38 months (3.2 years)

DSEK: **78% at 1 year**
Mean Survival 29.46 months **71% at 2 years**
(SE=1.26; 95% CI: 26.99, 31.93) **61% at 3 years**
Median Survival 38 months (3.2 years)

DMEK: **61% at 1 year**
Mean Survival 11.38 months
(SE=1.52; 95% CI: 8.40, 14.37)
Median Survival approx. 18 months (1.5 years)

DSAEK: **65% at 1 year**
Mean Survival 24.08 months **64% at 2 years**
(SE=2.36; 95% CI: 19.44, 28.71)
Median Survival 32 months (2.6 years)

ENDOTHELIAL LAMELLAR CORNEAL GRAFT SURVIVAL
EFFECT OF SURGEON WORKLOAD PER YEAR

Less than 15 grafts: **69% at 1 year**
Mean Survival 25.03 months **60% at 2 years**
(SE=1.36; 95% CI 22.37, 27.69)
Median Survival approx 38 months (3.2 years)

More than 15 grafts: **81% at 1 year**
Mean Survival 30.46 months **75% at 2 years**
(SE=1.27; 95% CI: 27.97, 32.95) **60% at 3 years**
Median Survival 38 months (3.2 years)

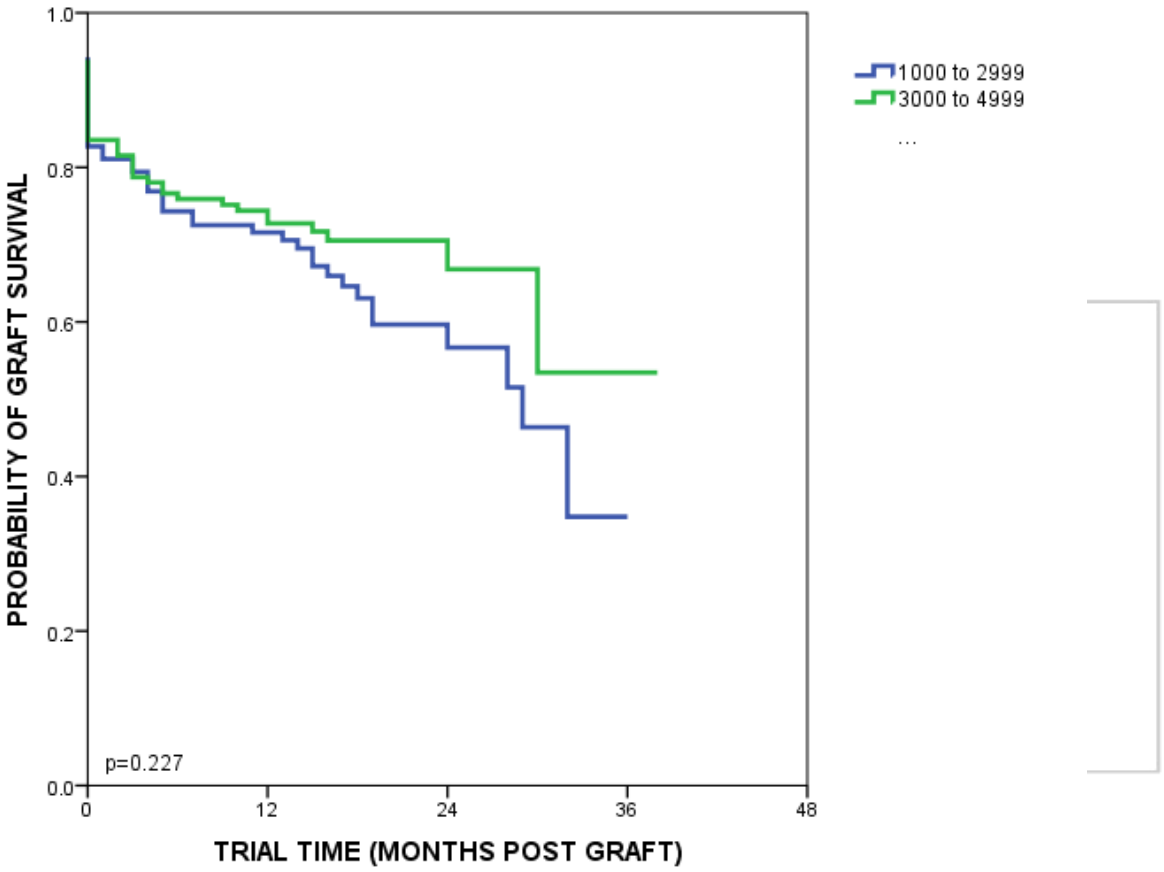
KEY:

n/a	=	not applicable
SE	=	standard error
CI	=	confidence interval
df	=	degrees of freedom
p	=	probability

8.12.6 Endothelial Cell Count

In recent years, the Registry has been collecting information on donor corneal endothelial cell counts as depicted in Figure 8.16. Due to the short time period over which these data have been collected, all analyses were calculated in months post graft (Log Rank Statistic=0.493; df=1; p=0.483). Donor corneal endothelial cell count, as stratified, exerted no significant influence on endothelial lamellar graft survival.

Figure 8.16 Endothelial cell count – endothelial lamellar grafts



Number at Risk

Identity	Initially	12 months	24 months	36 months	48 months
1000 to 2999 cells/mm^2	133	74	20	1	n/a
3000 to 4999 cells/mm^2	158	91	19	1	n/a

Identity	No. initially at risk	Graft survival (at years post-graft)			
		1	2	3	4
1000 to 2999 cells/mm^2	133	.72	.57	.35	n/a
3000 to 4999 cells/mm^2	158	.73	.67	.54	n/a

*Range chosen as too few donors available with endothelial cell count below 2400 cells/mm^2 to analyse.

ENDOTHELIAL LAMELLAR CORNEAL GRAFT SURVIVAL
DONOR ENDOTHELIAL CELL COUNT

1000 to 2999 cells/mm^2: **72% at 1 year**
Mean Survival 22.39 months **57% at 2 years**
(SE=1.46; 95% CI: 19.52, 25.26) **35% at 3 years**
Median Survival 29 months (2.4 years)

3000 to 4999 cells/mm^2: **73% at 1 year**
Mean Survival 26.16 months **67% at 2 years**
(SE=1.63; 95% CI: 22.97, 29.36) **54% at 3 years**
Median Survival approx 38 months (3.1 years)

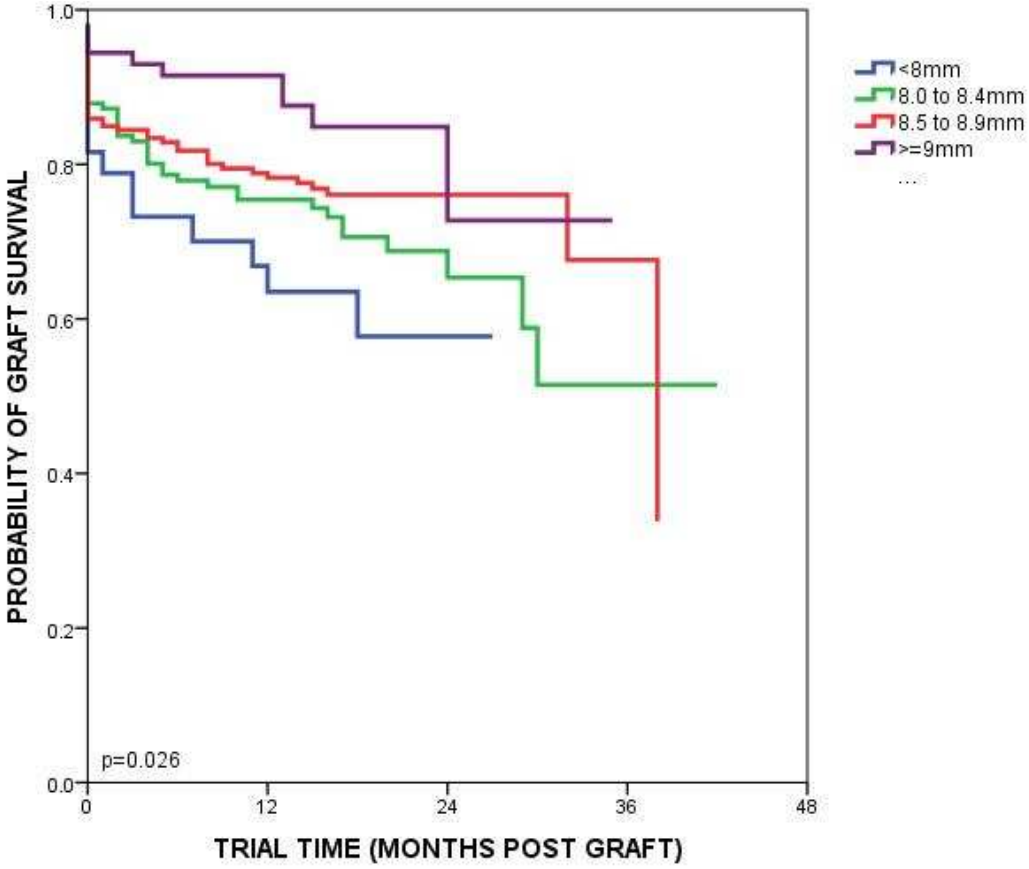
KEY:

n/a	=	not applicable
SE	=	standard error
CI	=	confidence interval
df	=	degrees of freedom
p	=	probability

8.12.7 Endokeratoplasty Graft Size

The graft size was recorded for 1,087 endothelial lamellar grafts, and ranged from 6.0 mm to 9.5 mm. Figure 8.17 shows the effect of graft size on the outcome of the 481 followed grafts with recorded graft size (Log Rank Statistic=9.292; df=3; p=0.026). Endothelial lamellar grafts with a larger size appeared to have better corneal graft survival than smaller grafts.

Figure 8.17 Graft size – endothelial lamellar grafts only



Number at Risk

Identity	Initially	12 months	24 months	36 months	48 months
Less than 8.0 mm	38	20	1	n/a	n/a
8.0 - 8.4 mm	157	83	20	3	n/a
8.5 – 8.9 mm	213	130	36	2	n/a
9.0 mm thru highest	73	49	7	n/a	n/a

Identity	No. initially at risk	Graft survival (at years post-graft)			
		1	2	3	4
Less than 8.0 mm	38	.64	.58	n/a	n/a
8.0 - 8.4 mm	157	.75	.65	.52	n/a
8.5 – 8.9 mm	213	.78	.76	.68	n/a
9.0 mm thru highest	73	.92	.73	n/a	n/a

ENDOTHELIAL LAMELLAR CORNEAL GRAFT SURVIVAL

GRAFT SIZE

< 8.0 mm: **64% at 1 year**
Mean Survival 17.80 months **58% at 2 years**
(SE=1.96; 95% CI: 13.96, 21.64)
Median Survival approx. 27 months (2.3 years)

≥ 8.0 – 8.4 mm: **75% at 1 year**
Mean Survival 28.25 months years **65% at 2 years**
(SE=1.83; 95% CI: 24.67, 31.84) **52% at 3 years**
Median Survival approx. 42 months (3.5 years)

≥ 8.5 – 8.9 mm: **78% at 1 year**
Mean Survival 29.21 months **76% at 2 years**
(SE=1.16; 95% CI: 26.94, 31.48) **68% at 3 years**
Median Survival 38 months (3.2 years)

≥ 9.0 mm: **92% at 1 year**
Mean Survival 29.40 months **73% at 2 years**
(SE=1.76; 95% CI: 25.96, 32.85)
Median Survival approx. 35 months (2.9 years)

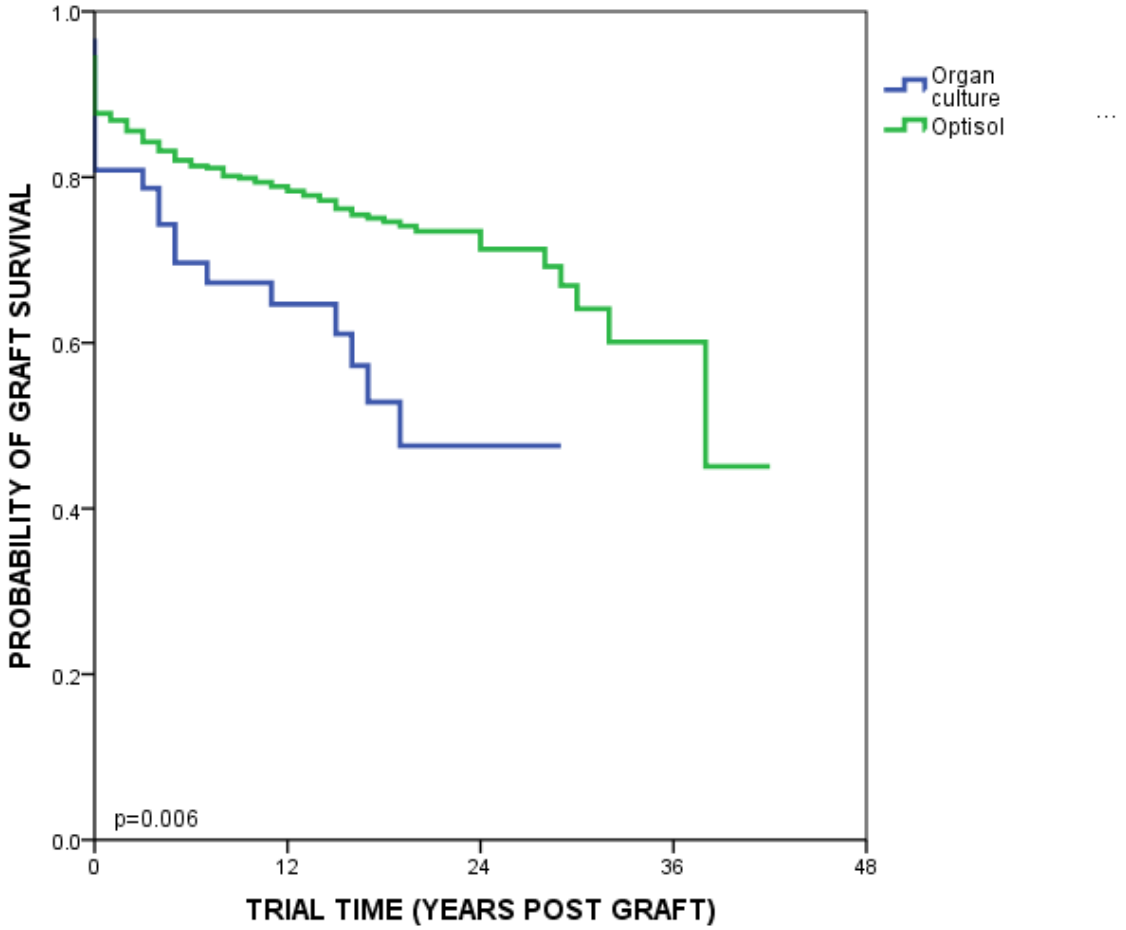
KEY:

	n/a	=	not applicable
	SE	=	standard error
	CI	=	confidence interval
	df	=	degrees of freedom
	p	=	probability

8.12.8 Storage Media – Endothelial Grafts

Figure 8.18 shows the influence of storage medium on survival of endothelial lamellar grafts (Log Rank Statistic=7.686; df=3; p=0.006). These types of grafts have only been stored in Optisol or Organ culture with the former performing better than the latter.

Figure 8.18 Storage media - endothelial lamellar grafts only



Number at Risk

Identity	Initially	12 months	24 months	36 months	48 months
Organ Culture	47	24	4	n/a	n/a
Optisol	505	296	68	5	n/a

Identity	No. initially at risk	Graft survival (at years post-graft)			
		1	2	3	4
Organ culture	47	.65	.48	n/a	n/a
Optisol	505	.78	.71	.60	n/a

ENDOTHELIAL LAMELLAR CORNEAL GRAFT SURVIVAL
STORAGE MEDIA

Organ Culture:	**65% at 1 year**
Mean Survival 17.62 months	**48% at 2 years**
(SE=1.90; 95% CI 13.91, 21.34)	
Median Survival 19 months (1.6 years)	
Optisol:	**78% at 1 year**
Mean Survival 29.83 months	**71% at 2 years**
(SE=1.09; 95% CI: 27.70, 31.96)	**60% at 3 years**
Median Survival 38 months (3.2 years)	

KEY:

n/a	=	not applicable
SE	=	standard error
CI	=	confidence interval
df	=	degrees of freedom
p	=	probability

8.13 TRADITIONAL LAMELLAR KERATOPLASTY

8.13.1 Main indications for graft – traditional lamellar keratoplasty

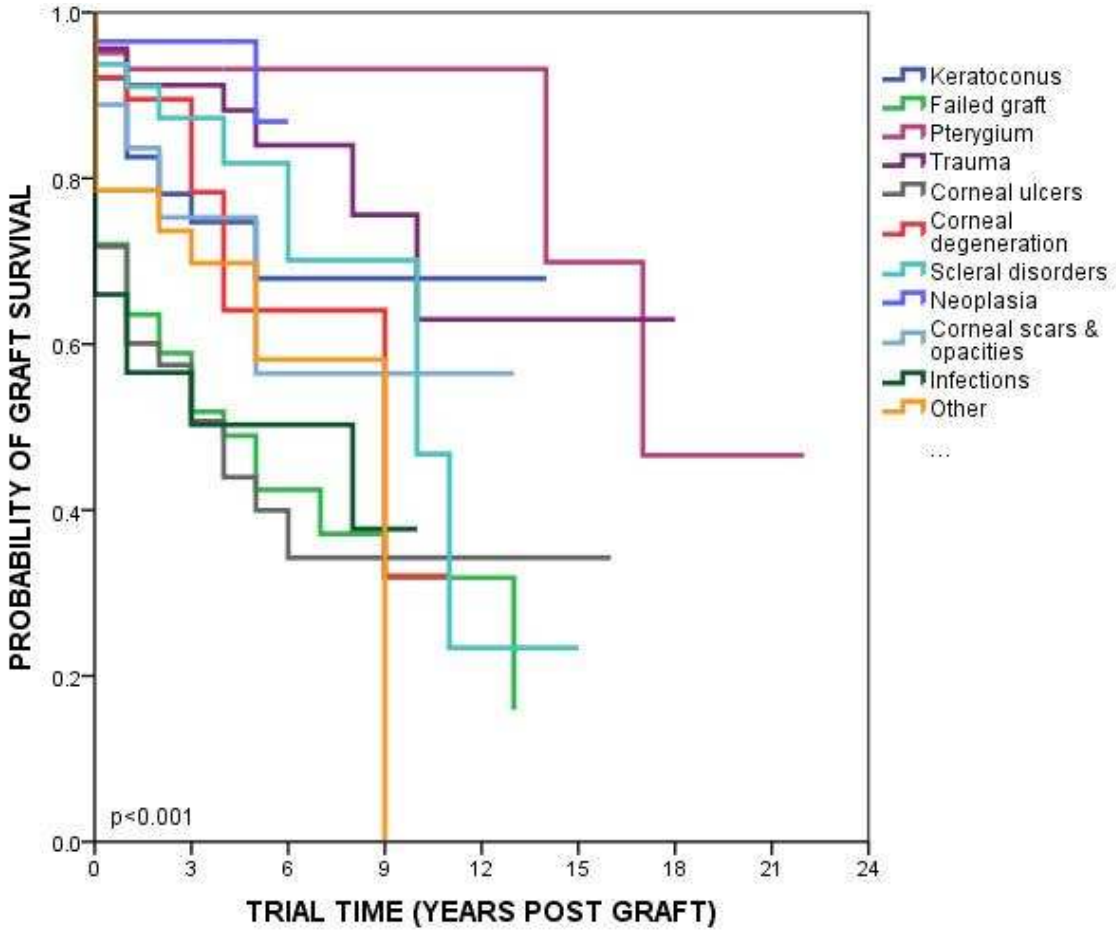
Table 8.12 lists the main indications for graft for traditional lamellar keratoplasty.

Table 8.12 Main indications for traditional lamellar keratoplasty

Indication for graft	Total	%
Pterygium	191	16%
Failed previous graft	182	16%
Corneal Ulcers (not HSV)	139	15%
Trauma	138	12%
Keratoconus	110	9%
Scleral disorders	80	6%
Neoplasm	73	6%
Corneal degeneration	69	6%
Herpetic eye disease	45	4%
Corneal Scars & opacities	31	3%
Non-herpetic infections	21	3%
Descemetoceole	19	2%
Corneal dystrophies	15	1%
Bullous keratopathy	14	1%
Other	38	<1%
TOTAL	1165	100%

Figure 8.19 shows the survival curves for the main indication for lamellar grafts (Log Rank Statistic= 122.695; df=10; p<0.001). Traditional lamellar grafts in eyes that have had a previous failed graft, and those performed for infections and corneal ulcers, had poor survival.

Figure 8.19 Main indicators for graft – traditional lamellar grafts only



Number at Risk

Identity	Initially	3 years	6 years	9 years	12 years	15 years	18 years	21 years	24 years
Keratoconus	76	23	8	4	2	n/a	n/a	n/a	n/a
Previous failed graft	136	25	11	7	3	n/a	n/a	n/a	n/a
Pterygium	164	48	18	11	7	3	2	1	n/a
Trauma	115	35	18	6	2	1	1	n/a	n/a
Corneal ulcers	124	17	7	1	1	1	n/a	n/a	n/a
Corneal degeneration	51	16	2	2	n/a	n/a	n/a	n/a	n/a
Disorders of sclera	64	18	7	3	1	1	n/a	n/a	n/a
Neoplasia	57	16	3	n/a	n/a	n/a	n/a	n/a	n/a
Scars and opacities	27	9	3	1	n/a	n/a	n/a	n/a	n/a
Infections	50	9	4	2	n/a	n/a	n/a	n/a	n/a
Other	70	19	2	1	n/a	n/a	n/a	n/a	n/a

Identity	No. initially at risk	Graft survival (at years post-graft)				
		1	5	10	15	20
Keratoconus	76	.83	.70	.70	n/a	n/a
Previous failed graft	136	.64	.42	.32	n/a	n/a
Pterygium	164	.93	.93	.93	.70	.47
Trauma	115	.91	.84	.63	.63	n/a
Corneal ulcers	124	.60	.40	.34	.34	n/a
Corneal degeneration	51	.90	.64	.32	n/a	n/a
Disorders of sclera	64	.91	.82	.47	.23	n/a
Neoplasia	57	.97	.87	n/a	n/a	n/a
Scars and opacities	27	.84	.57	.57	n/a	n/a
Infections	50	.57	.50	.38	n/a	n/a
Other	70	.79	.58	n/a	n/a	n/a

TRADITIONAL LAMELLAR CORNEAL GRAFT SURVIVAL
MAIN INDICATION FOR GRAFT

Keratoconus:	**83% at 1 year**
Mean Survival 10.14 years	**70% at 5 year**
(SE=0.92; 95% CI: 8.33, 11.94)	
Median Survival approx. 14 years	
Previous failed graft:	**64% at 1 year**
Mean Survival 5.82 years	**42% at 5 years**
(SE=0.71; 95% CI: 4.42, 7.22)	**32% at 10 years**
Median Survival 4 years	
Pterygium:	**93% at 1 year**
Mean Survival 17.49 years	**70% at 10 years**
(SE=1.64; 95% CI 14.28, 20.71)	**47% at 20 year**
Median Survival 17 years	
Trauma:	**91% at 1 year**
Mean Survival 13.65 years	**84% at 5 years**
(SE=1.35; 95% CI 11.00, 16.30)	**63% at 10 year**
Median Survival approx. 18 years	
Corneal ulcers:	**60% at 1 year**
Mean Survival 6.66 years	**40% at 5 years**
(SE=1.07; 95% CI 458, 8.75)	**34% at 10 year**
Median Survival 4 years	
Corneal degeneration:	**90% at 1 year**
Mean Survival 7.34 years	**64% at 5 years**
(SE=0.91; 95% CI: 5.57, 9.12)	**32% at 10 year**
Median Survival 9 years	
Disorders of sclera:	**91% at 1 year**
Mean Survival 9.44 years	**82% at 5 years**
(SE=1.26; 95% CI: 6.97, 11.91)	**47% at 10 year**
Median Survival 10 years	**23% at 15 years**
Neoplasia:	**97% at 1 year**
Mean Survival 5.69 years	**87% at 5 years**
(SE=0.17; 95% CI: 5.36, 6.03)	
Median Survival approx. 6 years	
Scars and opacities:	**84% at 1 year**
Mean Survival 8.50 years	**57% at 5 years**
(SE=1.66; 95% CI: 5.25, 11.76)	
Median Survival approx. 13 years	
Infections:	**57% at 1 year**
Mean Survival 5.06 years	**50% at 5 year**
(SE=0.78; 95% CI: 3.53, 6.59)	**38% at 10 year**
Median Survival 8 years	
Other:	**79% at 1 year**
Mean Survival 6.03 years	**58% at 5 years**
(SE= 0.65; 95% CI 4.75, 7.31)	
Median Survival 9 years	

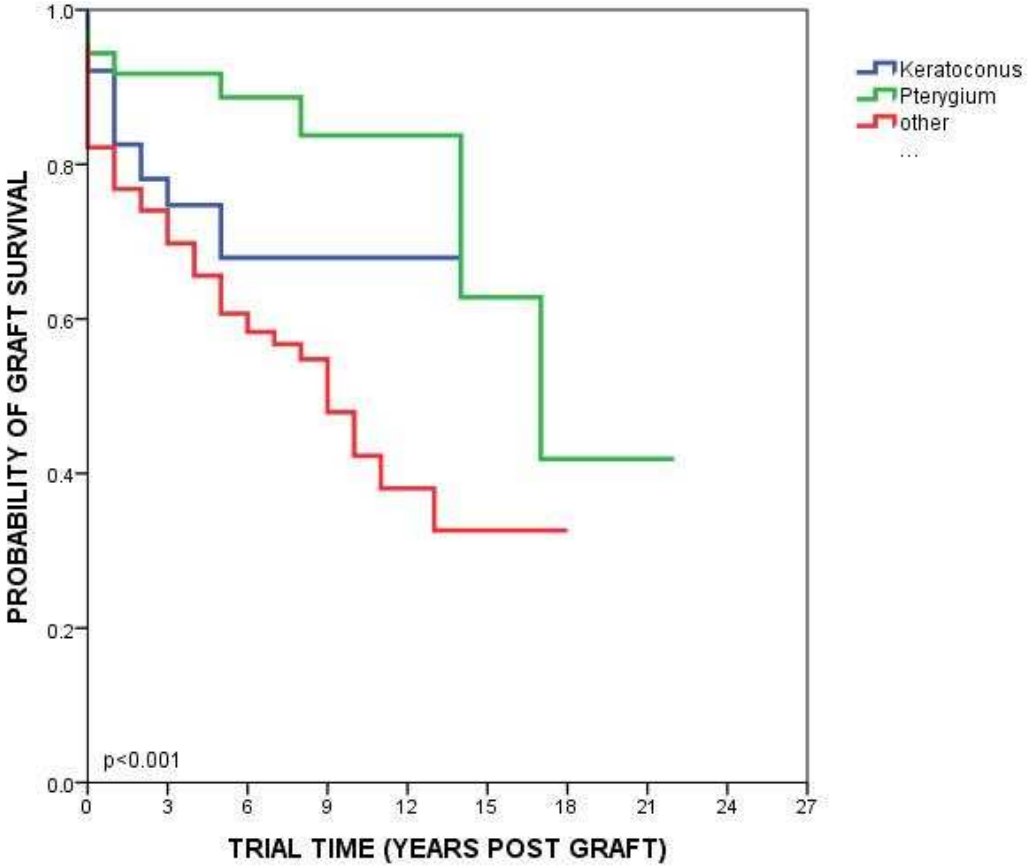
KEY:

n/a	=	not applicable
SE	=	standard error
CI	=	confidence interval
df	=	degrees of freedom
p	=	probability

8.13.2 Pterygium and Keratoconus

Figure 8.20 shows graft survival for patients grafted with a traditional lamellar keratoplasty for pterygium or keratoconus, compared with survival in patients with any other indication (Log Rank Statistic= 29.263; df=2; p<0.001).

Figure 8.20 Effect of pterygium and keratoconus (traditional lamellar grafts only)



Number at Risk

Identity	Initially	3 years	6 years	9 years	12 years	15 years	18 years	21 years	24 years
Keratoconus	76	23	8	4	2	n/a	n/a	n/a	n/a
Pterygium	178	55	24	12	7	3	2	1	n/a
Other	680	157	51	24	8	3	1	n/a	n/a

Identity	No. initially at risk	Graft survival (at years post-graft)				
		1	5	10	15	20
Keratoconus	76	.83	.68	.68	n/a	n/a
Pterygium	178	.92	.89	.84	.63	.42
Other	680	.77	.61	.42	.42	n/a

TRADITIONAL LAMELLAR CORNEAL GRAFT SURVIVAL
PTERYGIUM AND KERATOCONUS

Keratoconus:	**83% at 1 year**
Mean Survival 10.14 years	**68% at 5 years**
(SE=0.92; 95% CI 8.33, 11.94)	
Median Survival approx. 15 years	
Pterygium:	**92% at 1 year**
Mean Survival 16.28 years	**89% at 5 years**
(SE=1.62; 95% CI: 13.10, 19.45)	**84% at 10 years**
Median Survival 17 years	**63% at 15 years**
	42% at 20 years
Other:	**77% at 1 year**
Mean Survival 9.28 years	**61% at 5 years**
(SE=0.66; 95% CI: 8.00, 10.57)	**42% at 10 years**
Median Survival 9 years	

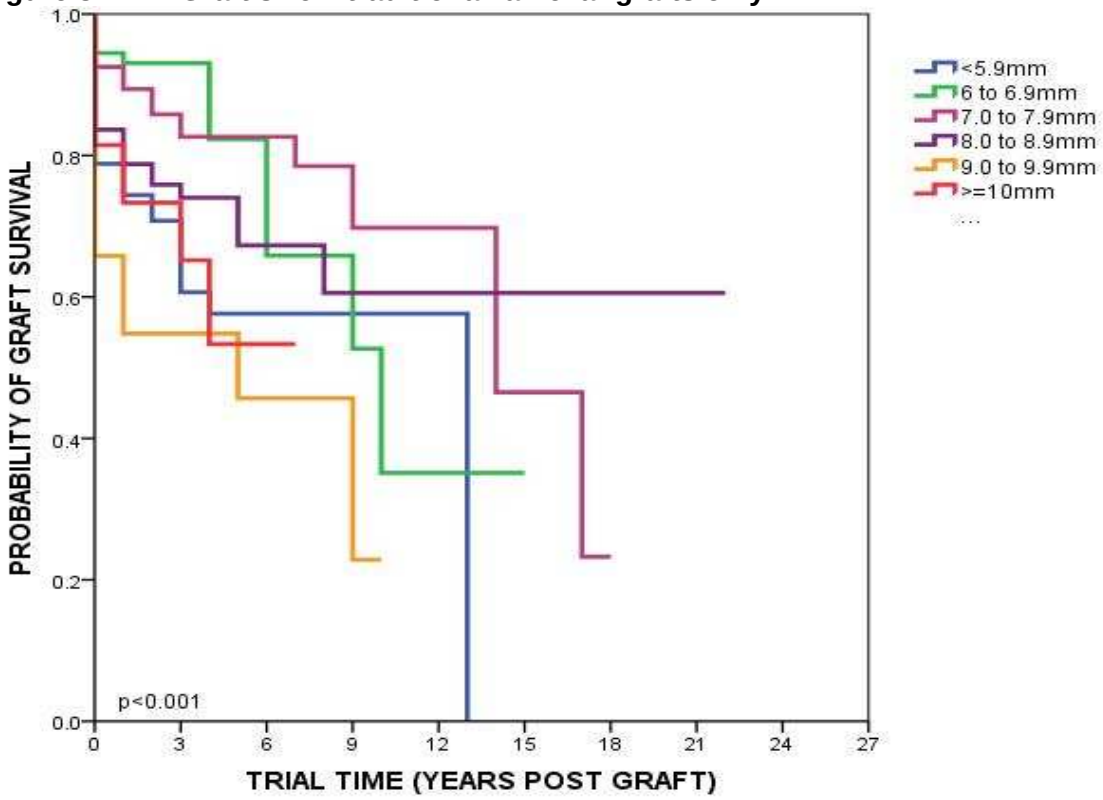
KEY:

n/a	=	not applicable
SE	=	standard error
CI	=	confidence interval
df	=	degrees of freedom
p	=	probability

8.13.3 Traditional Lamellar Graft Size

The hostbed size of the graft was recorded for 868 traditional lamellar grafts, and ranged from 2.0 mm to 15.0 mm. Figure 8.21 shows the effect of graft size on the outcome of the 702 followed grafts with recorded graft size (Log Rank Statistic=38.361; df=5; p<0.001). Grafts sized between 6.0 mm and 7.9 mm fared better than grafts that were larger or smaller.

Figure 8.21 Graft size – traditional lamellar grafts only



Number at Risk

Identity	Initially	3 years	6 years	9 years	12 years	15 years	18 years	21 years	24 years
Less than 5.9 mm	156	28	11	3	1	n/a	n/a	n/a	n/a
6.0 to 6.9 mm	127	32	10	5	1	1	n/a	n/a	n/a
7.0 - 7.9 mm	174	54	23	9	6	2	1	n/a	n/a
8.0 - 8.9 mm	153	41	15	8	4	1	1	1	n/a
9.0 – 9.9 mm	38	8	2	2	n/a	n/a	n/a	n/a	n/a
10.0 mm thru highest	54	18	3	n/a	n/a	n/a	n/a	n/a	n/a

Identity	No. initially at risk	Graft survival (at years post-graft)				
		1	5	10	15	20
Less than 5.9 mm	156	.74	.58	.58	n/a	n/a
6.0 to 6.9 mm	127	.93	.82	.35	n/a	n/a
7.0 - 7.9 mm	174	.89	.83	.70	.47	n/a
8.0 - 8.9 mm	153	.79	.67	.61	.61	.61
9.0 – 9.9 mm	38	.55	.46	.23	n/a	n/a
10.0 mm thru highest	54	.73	.53	n/a	n/a	n/a

TRADITIONAL LAMELLAR CORNEAL GRAFT SURVIVAL

GRAFT SIZE

<5.9 mm:	**74% at 1 year**
Mean Survival 8.03 years	**58% at 5 years**
(SE=0.70; 95% CI: 6.66, 9.4)	
Median Survival 13 years	
≥6.0 – 6.9 mm:	**93% at 1 year**
Mean Survival 9.64 years	**82% at 5 years**
(SE=1.21; 95% CI: 7.27, 12.01)	**35% at 10 years**
Median Survival 10 years	
≥7.0 – 7.9 mm:	**89% at 1 year**
Mean Survival 12.67 years	**83% at 5 years**
(SE=1.10; 95% CI: 10.52, 14.82)	**70% at 10 years**
Median Survival 14 years	**47% at 15 years**
≥8.0 – 8.9 mm:	**79% at 1 year**
Mean Survival 14.36 years	**67% at 5 years**
(SE=1.38; 95% CI: 11.66, 17.06)	**61% at 10 years**
Median Survival approx. 22 years	
≥9.0 – 9.9 mm:	**55% at 1 year**
Mean Survival 4.91 years	**46% at 5 years**
(SE=0.83; 95% CI: 3.27, 6.54)	**23% at 10 years**
Median Survival 5 years	
≥10.0 mm:	**73% at 1 year**
Mean Survival 4.53 years	**53% at 5 years**
(SE=0.47; 95% CI: 3.60, 5.46)	
Median Survival approx. 7 year	

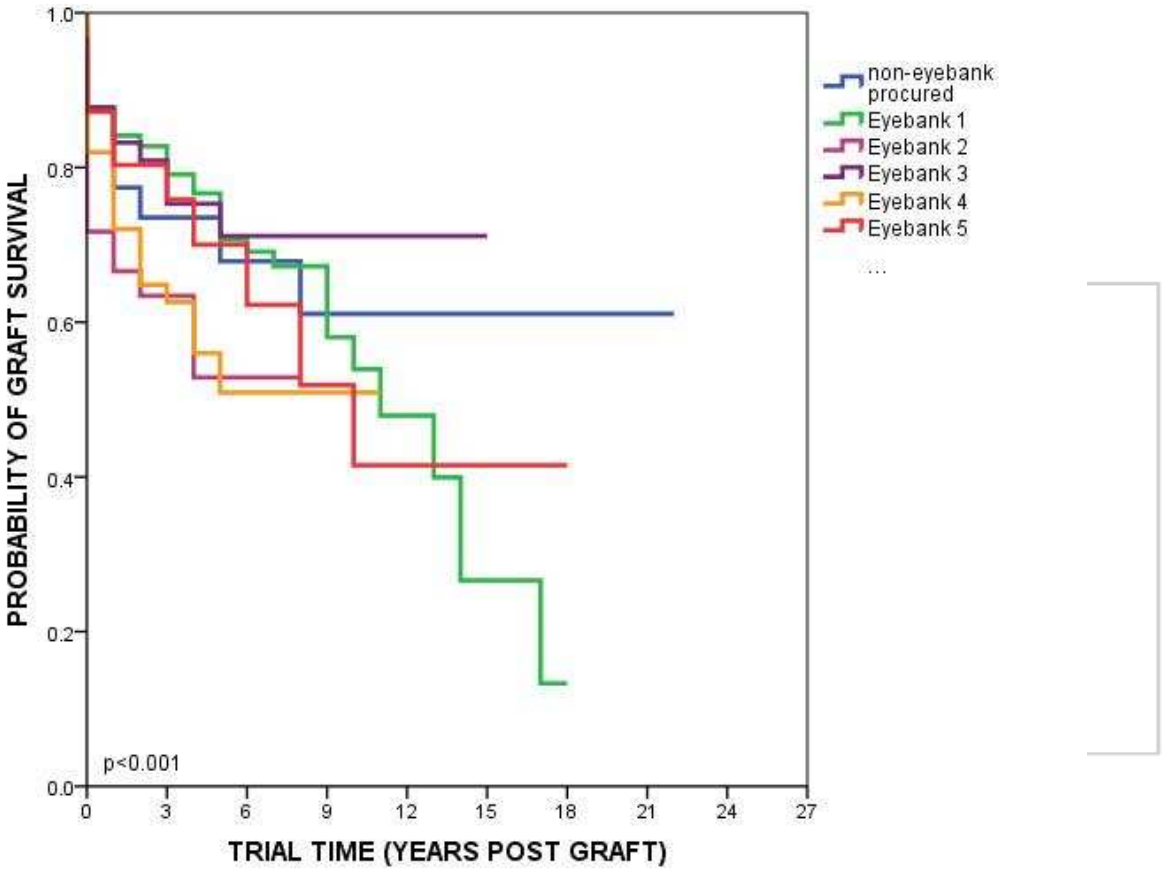
KEY:

n/a	=	not applicable
SE	=	standard error
CI	=	confidence interval
df	=	degrees of freedom
p	=	probability

8.13.4 Traditional Lamellar Procurement Source

Figure 8.22 shows the influence of donor procurement source on corneal graft survival. For the Kaplan-Meier curves below, the Eye Banks have been de-identified. Procurement sources included the Eye Banks in SA, QLD, NSW, WA and VIC (including corneas procured from Victorian Forensic Pathology) and corneas that were privately procured, years ago, by the operating surgeon. Where a surgeon did not record an eye bank number, the graft was included with the eye bank of the State where it was sourced (Log Rank Statistic=22.424, df=5; p<0.001).

Figure 8.22 Donor cornea procurement source – traditional lamellar grafts only



Identity	Graft survival (at years post-graft)				
	1	5	10	15	20
Non-eye bank procured	.77	.68	.61	.61	.61
Eye bank 1	.84	.71	.54	.27	n/a
Eye bank 2	.67	.53	n/a	n/a	n/a
Eye bank 3	.83	.71	.71	.71	n/a
Eye bank 4	.72	.51	.51	n/a	n/a
Eye bank 5	.80	.70	.42	.42	n/a

TRADITIONAL LAMELLAR CORNEAL GRAFT SURVIVAL
DONOR CORNEA PROCUREMENT SOURCE

Non Eye bank procured:	**77% at 1 year**
Mean Survival 14.44 years	**68% at 5 years**
(SE=1.87; 95% CI: 10.77, 18.11)	**61% at 10 years**
Median Survival approx 22 years	
Eye bank 1:	**84% at 1 year**
Mean Survival 10.26 months	**71% at 5 years**
(SE=0.76; 95% CI: 8.76, 11.75)	**54% at 10 years**
Median Survival 11 years	**27% at 15 years**
Eye bank 2:	**67% at 1 year**
Mean Survival 4.77 years	**53% at 5 years**
(SE=0.54; 95% CI: 3.70, 5.83)	
Median Survival approx. 8 years	
Eye bank 3:	**83% at 1 year**
Mean Survival 11.14 years	**71% at 5 years**
(SE=0.84; 95% CI: 9.50, 12.78)	
Median Survival approx. 15 years	
Eye bank 4:	**72% at 1 year**
Mean Survival 6.43 years	**51% at 5 years**
(SE=0.63; 95% CI: 5.19, 7.67)	
Median Survival approx. 11 years	
Eye bank 5:	**80% at 1 year**
Mean Survival 10.24 years	**70% at 5 years**
(SE=1.58; 95% CI: 7.14, 13.34)	**42% at 10 years**
Median Survival 10 years	

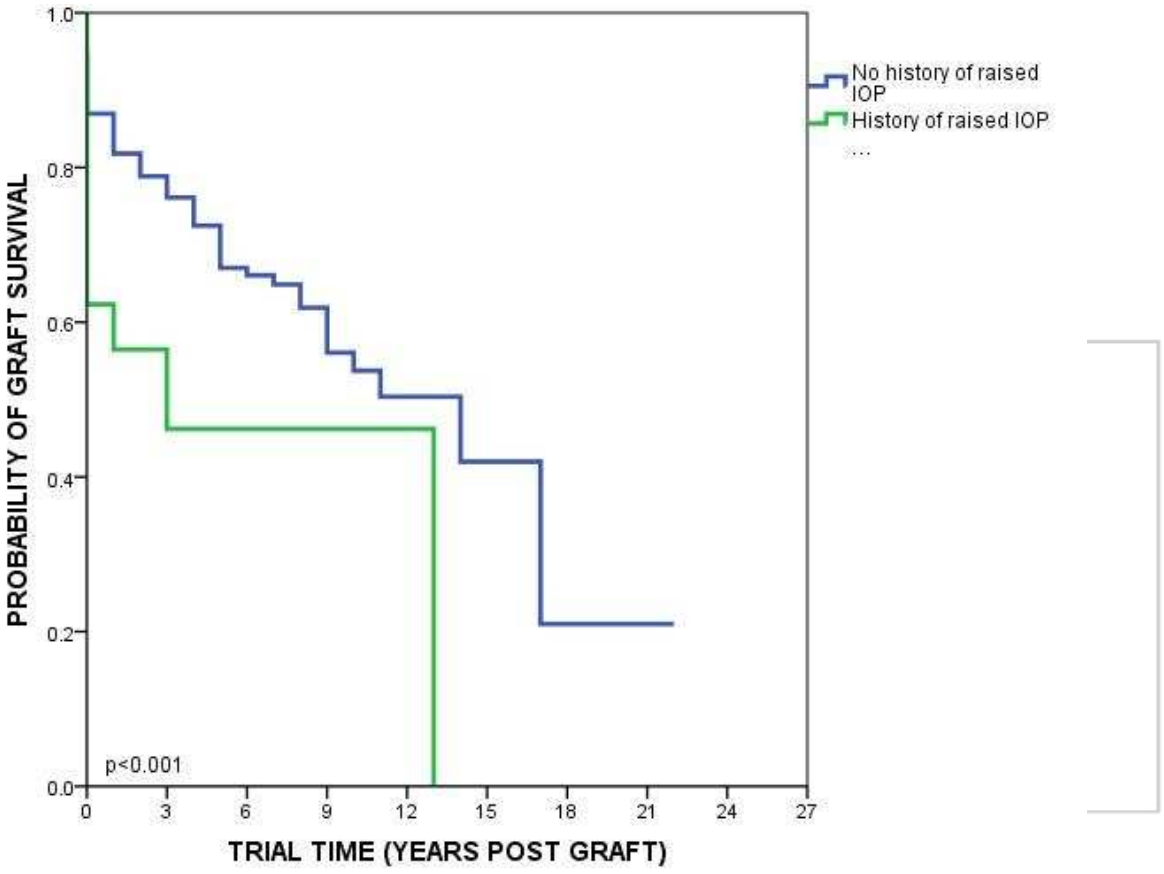
KEY:

n/a	=	not applicable
SE	=	standard error
CI	=	confidence interval
df	=	degrees of freedom
p	=	probability

8.13.5 History of Intraocular Pressure

The effect of raised intraocular pressure (IOP) in the past on graft survival is shown in Figure 8.23. Recipients with a history of raised pressure but who had a normal pressure at the time of graft were compared with those who were recorded as not having a history of raised IOP (Log Rank Statistic=26.187; df=1; p<0.001).

Figure 8.23 History of intraocular pressure – traditional lamellar grafts only



Number at Risk

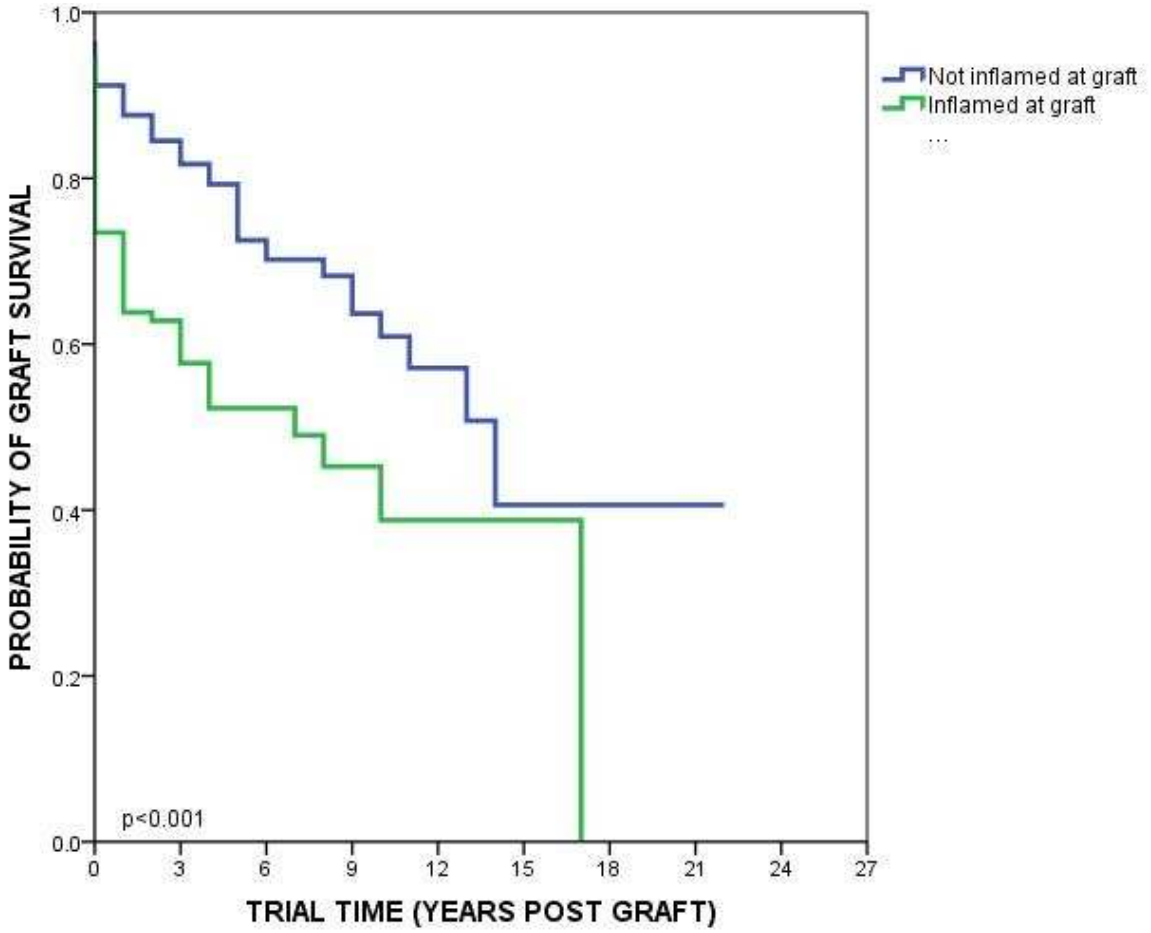
Identity	Initially	3 years	6 years	9 years	12 years	15 years	18 years	21 years	24 years
No history of raised IOP	759	201	70	32	12	4	1	1	n/a
History of raised IOP	68	11	3	2	1	n/a	n/a	n/a	n/a

Identity	No. initially at risk	Graft survival (at years post-graft)				
		1	5	10	15	20
No history of raised IOP	759	.82	.67	.54	.42	.21
History of raised IOP	68	.57	.46	.46	n/a	n/a

8.13.6 Inflammation

Figure 8.24 shows the effect of inflammation at graft on graft outcome (Log Rank Statistic=54.497; df=1; p<0.001). A significant difference in graft survival was apparent between traditional lamellar grafts that were inflamed at graft and those that were not.

Figure 8.24 Pre-graft inflammation – traditional lamellar grafts only



Number at Risk

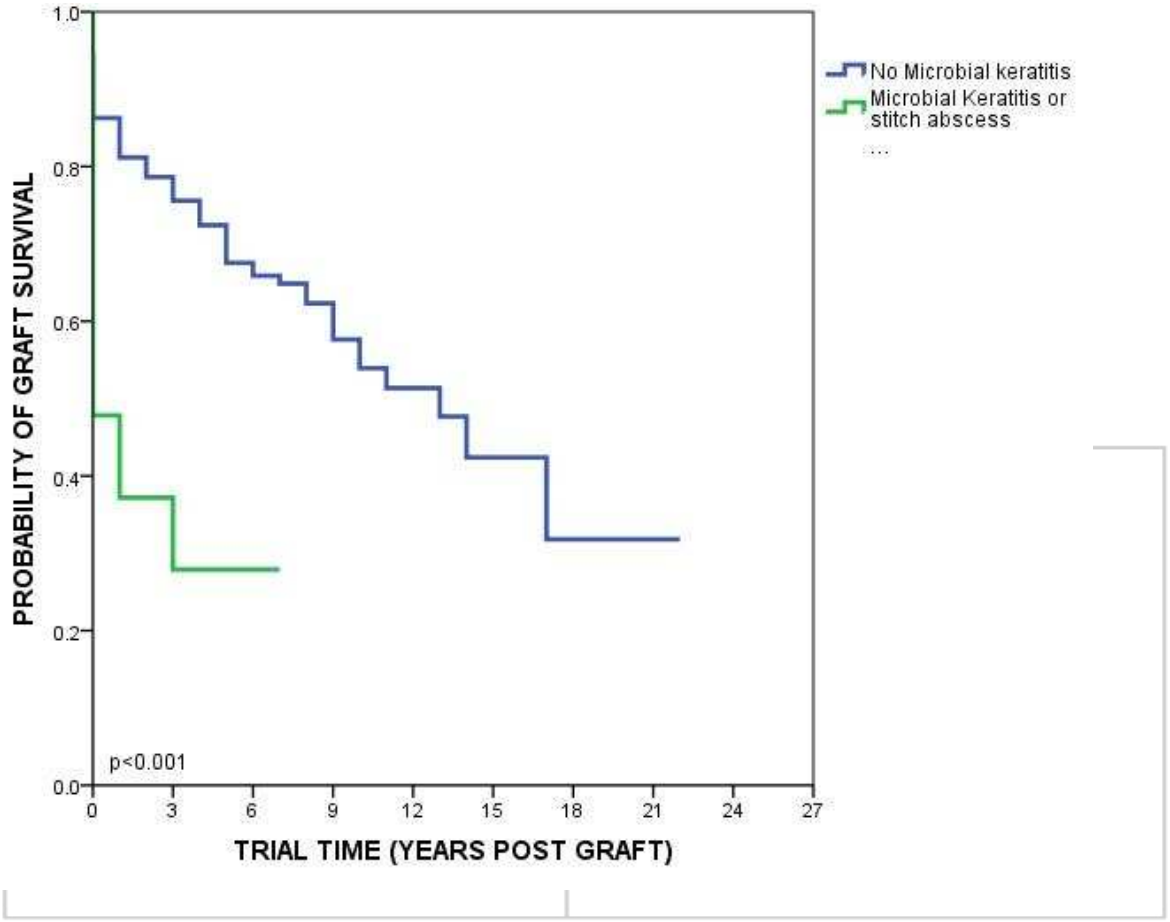
Identity	Initially	3 years	6 years	9 years	12 years	15 years	18 years	21 years	24 years
Not inflamed	613	181	62	30	12	3	3	1	n/a
Inflamed	293	49	18	8	4	3	n/a	n/a	n/a

Identity	No. initially at risk	Graft survival (at years post-graft)				
		1	5	10	15	20
Not inflamed	613	.88	.73	.61	.41	.41
Inflamed	293	.64	.52	.39	.39	n/a

8.13.7 Microbial keratitis/stitch abscess

The development of microbial keratitis or stitch abscess was associated with poor corneal graft survival in traditional lamellar grafts (Log Rank Statistic=27.987; df=1; p<0.001).

Figure 8.25 Microbial keratitis or stitch abscess



Number at Risk

Identity	Initially	3 years	6 years	9 years	12 years	15 years	18 years	21 years	24 years
No microbial keratitis	910	231	81	40	17	6	3	1	n/a
Microbial keratitis or stitch abscess	22	4	2	n/a	n/a	n/a	n/a	n/a	n/a

Identity	No. initially at risk	Graft survival (at years post-graft)				
		1	5	10	15	20
No microbial keratitis	910	.81	.68	.54	.42	.42
Microbial keratitis or stitch abscess	22	.37	.28	n/a	n/a	n/a

TRADITIONAL LAMELLAR CORNEAL GRAFT SURVIVAL
HISTORY OF RAISED IOP

No history of raised IOP:	**82% at 1 year**
Mean Survival 11.48 years	**67% at 5 years**
(SE=1.05; 95% CI: 9.43, 13.53)	**54% at 10 years**
Median Survival 14 years	**42% at 15 years**
	21% at 20 years
History of raised IOP:	**57% at 1 year**
Mean Survival 6.37 years	**46% at 5 years**
(SE=0.96; 95% CI: 4.49, 8.26)	
Median Survival 3 years	

TRADITIONAL LAMELLAR CORNEAL GRAFT SURVIVAL
EFFECT OF INFLAMMATION

Not inflamed at graft:	**88% at 1 year**
Mean Survival 13.20 years	**73% at 5 years**
(SE=1.11; 95% CI: 11.03, 15.38)	**61% at 10 years**
Median Survival 14 years	**41% at 15 years**
Inflamed at graft:	**64% at 1 year**
Mean Survival 8.26 years	**52% at 5 years**
(SE=0.82; 95% CI: 6.65, 9.87)	**39% at 10 years**
Median Survival 7 years	

TRADITIONAL LAMELLAR CORNEAL GRAFT SURVIVAL
MICROBIAL KERATITIS/STITCH ABSCESS

No microbial keratitis:	**81% at 1 year**
Mean Survival 12.03 years	**68% at 5 years**
(SE=0.86; 95% CI: 10.35, 13.70)	**54% at 10 years**
Median Survival 13 years	**42% at 15 years**
Microbial keratitis or stitch abscess:	**37% at 1 year**
Mean Survival 2.34 years	**28% at 5 years**
(SE=0.69; 95% CI: 0.99, 3.69)	
Median Survival <1 year	

KEY:

n/a	=	not applicable
SE	=	standard error
CI	=	confidence interval
df	=	degrees of freedom
p	=	probability

8.14 SUMMARY OF FACTORS RELATING TO LAMELLAR GRAFTS

❖ **Visual acuity when all lamellar grafts were considered:**

- A best corrected Snellen acuity of 6/12 or better was achieved in 48% of cases at most recent follow-up.
- Fifty eight percent of cases achieved a follow-up visual acuity of 6/18 or better and 28% recorded a visual acuity of less than 6/60 at last follow-up.
- Follow-up visual acuities were not advised in 20% of cases.

❖ **Visual acuity when broken down into type of lamellar graft:**

- A best corrected Snellen acuity of 6/12 or better at most recent follow-up was achieved in 34% of cases for traditional lamellar grafts; 37% of deep anterior lamellar grafts (DALK), and 18% of endothelial lamellar grafts.
- Forty seven percent of traditional grafts achieved 6/18 or better, while 62% of DALK and 45% of endothelial lamellar grafts achieved this level of acuity.
- A visual acuity of less than 6/60 at last follow-up was recorded in 21% of traditional lamellar grafts, 16% of DALKs, and 33% of endothelial lamellar grafts.
- Follow-up visual acuities were not advised in 26% of cases for traditional lamellar grafts, 5% of DALK and 6% of endothelial lamellar grafts.

❖ Endothelial cell count had no significant effect on corneal graft survival of DALK or endothelial lamellar grafts. There were insufficient traditional lamellar grafts with endothelial cell count recorded to analyse in this type of lamellar graft.

❖ **Traditional lamellar:**

- The main indications for traditional lamellar grafts were pterygium (16%), failed previous graft (16%), corneal ulcers (15%), trauma (12%), and keratoconus (9%).
- Grafts sized between 6.0 mm and 7.9 mm fared better than grafts that were larger or smaller.
- The main reasons for failure were corneal degeneration (14%), corneal ulcers (12%) and infection (11%).
- Pre-graft inflammation, a history of raised IOP and post graft microbial keratitis or stitch abscess were associated with poor corneal graft survival.

❖ **DALK:**

- The main indication for (DALK) was keratoconus (76%).
- When compared to penetrating grafts for keratoconus, DALKs had poorer graft survival.
- Fifty six percent of DALKs exhibited a post graft best corrected Snellen visual acuity of 6/12 or better compared to 67% of penetrating grafts performed since 1996.
- The main reasons for failure were primary graft failure (17%), infections, endothelial cell failure and scars & opacities (9% each).

❖ **Endothelial keratoplasty:**

- The main indications for endothelial lamellar grafts were reported to be corneal dystrophy (47%), bullous keratopathy (33%) and failed previous graft (10%).
- Endothelial lamellar grafts performed for Fuchs' dystrophy and bullous keratopathy had poorer corneal graft survival than penetrating grafts performed for the same indications.
- Thirty two percent of endothelial lamellar grafts exhibited a post graft best corrected Snellen visual acuity of 6/12 or better compared to 34% of penetrating grafts performed since 2004.
- A significant difference in graft survival was apparent amongst surgeons who had performed a larger number of endothelial lamellar grafts per year (over 15 grafts) and surgeons who had performed fewer grafts per year, favouring the higher volume surgeons.
- Different types of procedures for endothelial lamellar grafts had no significant influence on corneal graft survival.
- Endothelial lamellar grafts with a larger graft size had better corneal graft survival than smaller grafts.
- The main reason for failure of these grafts was primary graft failure (49%).
- Overall, endothelial lamellar grafts exhibited poorer graft survival and displayed a larger proportion of primary non-function grafts than any other type of lamellar graft.

MULTIVARIATE ANALYSIS:

METHODS

AND

FINAL MODELS

9. COX PROPORTIONAL HAZARDS REGRESSION ANALYSIS

9.1 PENETRATING GRAFTS

9.1.1 METHODS

A multivariate model was used to investigate the combined effect of variables on penetrating graft survival, adjusted for all the other variables in the model. Further analysis of the data was undertaken using Stata version 11.

In the preceding univariate analyses, each registered penetrating graft, together with its archival follow-up records, was treated as a separate and independent entity. Some patients had a history of more than one ipsilateral corneal graft and some had a record of one or more grafts in the contralateral eye (Table 9.1). Data are calculated with the census date of the 1st of June 2010.

Table 9.1 Number of grafts and patients in the cohort with penetrating corneal grafts

Group	Number
Registered penetrating *grafts*	19952
Number of *patients* with penetrating grafts	15560
Patients with *one* registered graft	11974
Patients with *more than one* registered graft*	3586

* additional grafts could be penetrating, lamellar or limbal grafts

Following on from the results of the Kaplan-Meier analyses, which were used to indicate variables of interest, Cox Proportional Hazards regression models were used to investigate the joint effects of a subset of variables on penetrating corneal graft failure. To control for potential inter-graft and/or inter-eye dependence in the multivariate analyses, the Cox models were adjusted to allow for clustering by individual patient [see reference 5, Chapter 10.8]. Limbal and lamellar grafts were excluded from consideration. Some variables which were indicated as significant in the univariate analysis were omitted due to non-convergence of the model or collinearity.

The selected variables were: surgeons with more than 25 grafts per year on average, where follow-up occurred, state in which surgery was performed, eye bank, whether the surgery was performed in the same state as the donor cornea was sourced from, donor age, recipient age, pre-graft visual acuity, indication for graft, number of previous ipsilateral grafts, lens status pre- and post-graft, corneal vascularization at time of graft, history of inflammation in the grafted eye, history of raised IOP, presence of descemetocoele, graft diameter, time to removal of graft sutures, post-operative neovascularization of the graft, post-operative rise in IOP, post-operative episodes of immunological rejection, post-operative synechiae, microbial keratitis, uveitis or stitch abscess, refractive surgery in follow-up, vitrectomy at time of graft, multi-organ donor.

The best model was found by a backward elimination process, removing variables not appearing to be predictors of graft failure. The assumption of proportional hazards appeared reasonable as assessed by Kaplan-Meier plots.

9.1.2 FINAL MODEL

The model excluded variables with a p-value of p>0.05 (or global p-value of p>0.5 for variables with more than two categories) in a stepwise manner, beginning with the least significant variable. The variables retained in the final Cox proportional hazards regression models are presented in Table 9.2.

Table 9.2 Variables retained in final model

- Surgeons with more than 25 grafts per year
- Indication for graft
- Lens status pre- and post-graft (phakic, pseudophakic or aphakic)
- Corneal neovascularization at the time of graft
- History of inflammation in the grafted eye
- History of raised intraocular pressure in the grafted eye
- Graft diameter
- Time of removal of graft sutures
- Post-operative neovascularization of the graft
- Post-operative rise in intraocular pressure
- Refractive surgery in follow-up
- Post-operative episodes of immunological rejection
- Arrangements for follow-up

Table 9.3 tabulates the parameter estimates resulting from the fit of the best clustered Cox model. The table shows the variable, the hazard ratio, the standard error of the regression coefficient, the corresponding probability value and the 95% confidence interval for the hazard ratio. The first level of each categorical variable was taken as the referent. The hazard ratios for a given variable are adjusted for all other variables in the model.

9.1.2.1 Model

This model includes variables with a p-value of p<0.05, with variables eliminated in a stepwise manner, beginning with the least significant variable. For categorical variables, a global test was applied to calculate the overall p-value. The overall model was highly significant: chi^2=1755.32, p<0.0001.

Table 9.3 Parameter estimates from final Cox regression model: factors influencing the survival of penetrating corneal grafts

Variable	Hazard ratio	Standard error	P	Global P	95% confidence intervals
Neovascularization of the graft					
Avascular graft	1.00				
Vascularized graft	2.27	0.20	<0.001		1.91 – 2.70
Post-operative rise in intraocular pressure					
None	1.00				
Rise in IOP	1.50	0.13	<0.001		1.62 – 1.78
Refractive surgery in follow-up					
No refractive surgery	1.00				
Refractive surgery	0.66	0.06	<0.001		0.55 – 0.79
Rejection episodes					
None	1.00				
One or more episodes	3.14	0.20	<0.001		2.77 – 3.57
Lens status pre and post graft					
Phakic/Phakic	1.00			<0.01	
Pseudophakic/Aphakic	1.61	0.35	0.028		1.05 – 2.45
Phakic/Pseudophakic	1.15	0.14	0.256		0.90 – 1.46
Aphakic/Aphakic	1.90	0.28	<0.001		1.43 – 2.53
Aphakic/Pseudophakic	1.51	0.31	0.043		1.01 – 2.25
Pseudophakic/Aphakic	1.73	0.33	0.004		1.19 – 2.51
Pseudo/Pseudo 84-89	1.68	0.30	0.004		1.18 – 2.39
Pseudo/Pseudo 90-94	1.57	0.21	0.001		1.21 – 2.05
Pseudo/Pseudo 95-99	1.23	0.18	0.151		0.93 – 1.64
Pseudo/Pseudo 00-04	1.52	0.21	0.003		1.16 – 2.00
Pseudo/Pseudo 05-10	1.54	0.32	0.035		1.03 – 2.31
Time to removal of sutures					
Fewer than 6 months	1.00			<0.001	
6 – 12 months	0.52	0.06	<0.001		0.41 – 0.66
12 – 18 months	0.41	0.05	<0.001		0.32 – 0.51
18 – 24 months	0.38	0.05	<0.001		0.29 – 0.49
Greater than 24 months	0.27	0.03	<0.001		0.21 – 0.35

Variable	Hazard ratio	Standard error	P	global P	95% confidence intervals
Surgeon performing more than 25 grafts					
No	1.00				
Yes	0.80	0.08	0.019		0.66 – 0.96
Follow-up elsewhere					
Follow-up by surgeon	1.00				
Follow-up elsewhere	0.59	0.05	<0.001		0.49 – 0.70
Corneal vascularization at time of graft grafts					
None	1.00			<0.01	
1 quadrant	0.88	0.11	0.301		0.68 – 1.12
2 quadrants	0.89	0.10	0.290		0.72 – 1.10
3 quadrants	1.19	0.14	0.133		0.95 – 1.50
4 quadrants	1.35	0.15	0.006		1.09 – 1.68
Main indication for graft					
Keratoconus	1.00			<0.001	
Corneal ulcers	5.67	1.35	<0.001		3.56 – 9.04
Bullous keratopathy	5.03	0.87	<0.001		3.59 – 7.06
Corneal dystrophies	2.98	0.44	<0.001		2.23 – 3.96
Non-herpetic infections	1.90	0.73	0.096		0.89 – 4.03
Herpetic infections	2.29	0.45	<0.001		1.55 – 3.38
Trauma	2.46	0.69	0.001		1.42 – 4.27
Scars and opacities	2.53	0.84	0.005		1.33 – 4.84
Interstitial keratitis	2.14	0.82	0.046		1.01 – 4.52
Corneal degeneration	2.19	1.06	0.104		0.85 – 5.64
Congenital abnormalities	1.60	0.69	0.279		0.68 – 3.73
Failed graft	4.18	0.75	<0.001		2.95 – 5.93
Other	2.43	0.61	<0.001		1.49 - 3.99
Raised intraocular pressure					
Never	1.00			<0.01	
In past only	1.32	0.11	0.001		1.12 – 1.55
At graft only	1.72	0.74	0.208		0.74 – 4.01
Both in past and at graft	1.24	0.23	0.231		0.87 – 1.78
Inflammation in the grafted eye					
Never	1.00			0.02	
In past only	0.91	0.14	0.526		0.68 – 1.22
At graft only	1.73	0.36	0.008		1.15 – 2.61
Both in past and at graft	1.01	0.16	0.972		0.74 – 1.37
Graft diameter					
<7.5 mm	1.00			<0.001	
7.5 – 8.5 mm	0.74	0.06	<0.001		0.63 – 0.87
> 8.5 mm	1.06	0.22	0.765		0.71 – 1.59

9.2 TRADITIONAL LAMELLAR GRAFTS

9.2.1 METHODS

A multivariate model was used to investigate the combined effect of variables on traditional lamellar graft survival, adjusted for all the other variables in the model. Further analysis of the data was undertaken using Stata version 11.

In the preceding univariate analyses, each registered traditional lamellar graft, together with its archival follow-up records, was treated as a separate and independent entity. Some patients had a history of more than one ipsilateral corneal graft and some had a record of one or more grafts in the contralateral eye (Table 9.4). Data were calculated with the census date of the 12th of October 2011.

Table 9.4 Number of grafts and patients in the cohort with traditional lamellar corneal grafts

Group	Number
Registered traditional lamellar *grafts*	1165
Number of *patients* with traditional lamellar grafts	1059
Patients with *one* registered graft	820
Patients with *more than one* registered graft*	239

* additional grafts could be penetrating, lamellar or limbal grafts

Following on from the results of the Kaplan-Meier analyses, which were used to indicate variables of interest, Cox Proportional Hazards regression models were used to investigate the joint effects of a subset of variables on traditional lamellar corneal graft failure. To control for potential inter-graft and/or inter-eye dependence in the multivariate analyses, the Cox models were adjusted to allow for clustering by individual patient [see reference 5, Chapter 10.8]. Limbal and penetrating grafts were excluded from consideration. Some variables which were indicated as significant in the univariate analysis were omitted due to non-convergence of the model or collinearity.

The selected variables were: where follow-up occurred, eye bank, whether the surgery was performed in the same state as the donor cornea was sourced from, pre-graft lens status, post-graft lens status, donor age, pre-graft visual acuity, indication for graft, corneal vascularization at time of graft, history of inflammation in the grafted eye, history of steroid use in the grafted eye, history of Herpetic infection in the grafted eye, history of raised IOP, graft diameter, storage method, microbial keratitis.

The best model was found by a backward elimination process, removing variables not appearing to be predictors of graft failure. The assumption of proportional hazards appeared reasonable as assessed by Kaplan-Meier plots.

9.2.2 FINAL MODEL

The model excluded variables with a p-value of p>0.05 (or global p-value of p>0.5 for variables with more than two categories) in a stepwise manner, beginning with the least significant variable. The variables retained in the final Cox proportional hazards regression models are presented in Table 9.5.

Table 9.5 Variables retained in final model

- Indication for graft
- History of inflammation in the grafted eye
- History of raised intraocular pressure in the grafted eye
- Graft diameter
- Surgery in same State as donor cornea sourced
- Arrangements for follow-up
- Microbial keratitis in follow-up

Table 9.6 tabulates the parameter estimates resulting from the fit of the best clustered Cox model. The table shows the variable, the hazard ratio, the standard error of the regression coefficient, the corresponding probability value and the 95% confidence interval for the hazard ratio. The first level of each categorical variable was taken as the referent. The hazard ratios for a given variable are adjusted for all other variables in the model.

9.2.2.1 Model

This model includes variables with a p-value of $p<0.05$, with variables eliminated in a stepwise manner, beginning with the least significant variable. For categorical variables, a global test was applied to calculate the overall p-value. The overall model was highly significant: $chi^2=153.60$, $p<0.0001$.

Table 9.6 Parameter estimates from final Cox regression model: factors influencing the survival of traditional lamellar corneal grafts

Variable	Hazard ratio	Standard error	P	global P	95% confidence intervals
Microbial keratitis					
No	1.00				
Yes	1.99	0.52	0.008		1.19 – 3.31
Follow-up elsewhere					
Follow-up by surgeon	1.00				
Follow-up elsewhere	0.39	0.11	0.001		0.22 – 0.67
Donor and recipient State match					
Different States	1.00				
Same State	0.59	0.15	0.044		0.35 – 0.99
Main indication for graft					
Keratoconus	1.00			<0.001	
Failed graft	2.57	0.97	0.013		1.22 – 5.39
Pterygium	0.35	0.19	0.050		0.12 – 1.00
Trauma	0.88	0.45	0.811		0.32 – 2.41
Corneal ulcers	2.46	0.95	0.020		1.15 – 5.26
Corneal degeneration	1.03	0.53	0.947		0.38 – 2.83
Scleral disorders	0.74	0.44	0.619		0.23 – 2.40
Neoplasia	0.44	0.35	0.300		0.10 – 2.06
Herpetic infections	3.08	1.44	0.016		1.24 – 7.68
Scars and opacities	1.39	0.77	0.553		0.47 – 4.12
Other	3.33	1.30	0.002		1.54 – 7.17
Raised intraocular pressure in past					
No	1.00				
Yes	1.95	0.35	<0.00		1.37 – 2.77
Inflammation in the grafted eye in past					
No	1.00				
Yes	1.57	0.28	0.012		1.10 – 2.23
Graft diameter					
<6.0mm	1.00			<0.001	
6.0 – 7.9mm	0.60	0.13	0.014		0.40 – 0.90
≥ 8.0mm	1.38	0.27	0.092		0.95 – 2.02

9.3 INTERPRETATION OF THE MODELS

The hazard ratio can be interpreted in the same manner as a relative risk – the relative hazard of a variable compared with the referent. To calculate the hazard ratio for a combination of variables, the individual hazard ratios were multiplied together. For example, if there was post-operative vascularization of a penetrating graft and it had had at least one rejection episode, the combined hazard ratio using the penetrating graft model is:

Relative hazard (combined) = HR (vascularized graft) x HR (one or more rejection episodes) = 2.27 x 3.14 = 7.13 compared with a reference graft (avascular with no rejection episodes).

This is also the case where the comparison group performs better than the reference group. For example, a traditional lamellar graft for which the donor cornea was sourced from the same state in which the surgery was performed and had a graft diameter of between 6 mm and 7.9 mm, would have a combined hazard ratio of 0.59 x 0.6 = 0.35 compared to a graft where the donor cornea was sourced from a different State and the graft diameter was less than 6 mm.

These models are only relevant in relation to other grafts of the same type; hazard ratios comparing penetrating grafts to traditional lamellar grafts cannot be calculated using these models.

9.4 OTHER LAMELLAR GRAFTS

Multiple significant variables were not detected during the univariate analyses of data relating to DALKs, making multivariate analyses non-applicable to this data. While several significant differences were found across groups in the univariate analyses for endothelial keratoplasties, these variables did not fit together in a multivariate model.

10. SUMMARY

10.1 GRAFTS AND CONTRIBUTORS

Analyses were performed on cumulative data entered into the ACGR from its inception until the census date for this report of 01/06/2010 for penetrating grafts and 12/10/11 for lamellar grafts. Data were available on 23,048 corneal grafts, 86.5% of which were penetrating, 13% of which were lamellar and 0.5% of which were limbal. Of the penetrating corneal grafts, 82% had been followed at least once. Of the lamellar grafts, follow-up was available for 59% and for the limbal grafts, follow-up was available for 86%. Kaplan-Meier survival of penetrating and lamellar grafts was 73% and 67%, respectively, at 5 years. Kaplan-Meier survival of limbal grafts was 43% at 5 years.

Grafts were recorded from each Australian State and territory, with about 60% of all grafts being entered from two States, New South Wales and Victoria. A total of 713 individuals contributed data to the Registry. Of the contributors, 384 performed corneal graft procedures and 329 were involved in patient follow-up. Approximately 82% of all records of graft were registered by 62 ophthalmologists (16% of transplant surgeons).

10.2 CORNEAL DONORS AND EYE BANKING

Historically, corneas were procured privately and from hospital-based banks, but surgeons currently procure donor corneas almost exclusively from Therapeutic Goods Administration-licensed Eye Banks in NSW, QLD, VIC, SA and WA.

Causes of donor death related to the cardiac/circulatory system in 30% of cases, the cerebrovascular system in 19%, to malignancy in 19%, to trauma, accident, poisoning or medical misadventure in 10%, to the respiratory system in 10%, to other specified causes in 7%, and to causes unknown to the ACGR in 5%. Most corneas were retrieved from cardiac death donors, with 7% of all corneas for penetrating grafts obtained from multi-organ donors. Sixty one percent of donors were male and 35% were female. Donors ranged in age from infancy to 99 years at the time of death, but the majority (66%) were aged from 51-80 years.

The median death-to-enucleation time for corneas used for penetrating keratoplasty was 7 hours. Historically, most donor corneas were preserved in McCarey-Kaufman medium but for the past 14 years, Australian eye banks have predominantly used Optisol storage. There has also been a resurgence in the use of Organ Culture as a storage since 2007. The median time between donor death and penetrating corneal graft surgery for corneas stored in Optisol was 102 hours. Storage time in Optisol medium did not affect corneal graft survival.

Grafts performed in the same State from which the cornea originated showed significantly better survival than those performed in a different state. This is particularly pronounced in the first 10 years post graft. The endothelial cell count of the donor had no significant influence on corneal graft survival.

A penetrating corneal graft that never clears and thins in the immediate post-operative period is considered to be a primary non-functioning graft. Thus far, 151 such penetrating grafts have been reported to the ACGR, representing <1% of followed penetrating grafts.

10.3 CORNEAL GRAFT RECIPIENT AGE AND SEX

Recipient age varied from less than one month old to greater than 97 years, with peaks at 20-40 years and 60-80 years. Although recipient age appeared to influence penetrating corneal graft survival in univariate analysis, it was not significant in multivariate analysis. Keratoconus was the main indication for graft in 58% of grafts performed in recipients <60 years of age and 73% of recipients <20 years of age. Approximately equal numbers of women and men received a corneal graft and sex had no influence on graft survival.

10.4 CORNEAL GRAFT RECIPIENT FACTORS

Approximately one third of recipients displayed evidence of corneal neovascularization at the time of graft. In about 45% of cases where information on past history was available, the eye to be grafted had been inflamed in the past or was inflamed at the time of graft. In about 17% of cases, the intraocular pressure in the eye to be grafted had been raised at some time in the past or was raised at graft. Raised intraocular pressure at any time prior to, or at graft, was a significant risk factor for corneal graft failure. The main indications for penetrating keratoplasty were keratoconus (30%), bullous keratopathy (26%), failed previous graft (20%), corneal dystrophy (8%), and herpetic eye disease (4%). These broad indications accounted for 88% of penetrating grafts. Although corneal grafts for keratoconus showed better survival than grafts for all other indications, these grafts were also influenced by rejection episodes, number of previous grafts, age at graft, other pre-graft morbidities and complications. About one-fifth of recipients had previously had a corneal graft in the ipsilateral eye. Graft survival fell with increasing numbers of ipsilateral grafts performed.

10.5 OPERATIVE PROCEDURES

Graft size ranged from 2.0 mm to 16.0 mm in diameter. Grafts within the size range of about 7.5 to 8.5 mm in diameter fared best. Rejection was a major cause of graft failure across all groups, but infection also caused the loss of very large and very small grafts. In 34% of cases, an additional operative procedure was carried out at the time of transplantation. The most common of these procedures were manipulations associated with the lens (10%), vitrectomy (9%) and iris procedures (9%). Graft survival was better in phakic recipients than in pseudophakic or aphakic recipients.

10.6 POST GRAFT EVENTS AFFECTING GRAFT FAILURE

The major reasons for failure of penetrating grafts were irreversible rejection (31%), endothelial cell failure (15%), infection including recurrent HSV keratitis (8%), and glaucoma (8%). Removal of graft sutures within 6 months of transplantation was a risk factor for graft failure. Reasons for graft failure in the cohort with early suture removal were very similar to those of the whole cohort.

A variety of post-operative events were associated with graft failure. These included development of microbial keratitis or a stitch abscess (affecting 3% of grafts), uveitis (1%), synechiae (2%), graft neovascularization (6%), rejection episodes (18%) and a rise in intraocular pressure (16%) in the grafted eye.

10.7 VISUAL OUTCOME AFTER CORNEAL TRANSPLANTATION

In 74% of cases, the sole desired outcome for penetrating corneal transplantation was to improve vision in the grafted eye. In a further 15% of cases, the desired outcomes were improved vision plus relief of pain after surgery.

For patients with penetrating grafts, 44% of the cohort achieved a Snellen acuity of 6/12 or better at the time of the most recent follow-up and 54% achieved 6/18 or better, but for 27%, Snellen acuity was less than 6/60. Where both pre-operative and post-operative Snellen acuities were available an improvement in acuity of at least one line on the Snellen chart was recorded by 73% of recipients after corneal transplantation. In 13% there was no change, and in 14% the acuity was worse after graft.

Factors affecting the visual potential of the grafted eye included graft failure (23%), astigmatism of more than 5 dioptres (18%), and one or more co-morbidity in the grafted eye. Refractive surgery was carried out on 12% of all penetrating grafts with follow-up. At 10 years or more after corneal transplantation, 62% of recipients had been prescribed spectacles and approximately 15% had a contact lens. An intraocular lens was in place in the grafted eye in about 34% of the cohort.

10.8 LAMELLAR GRAFTS

Overall, a best corrected Snellen acuity of 6/12 or better was achieved in 48% of cases at most recent follow-up, 58% of cases achieved a follow-up visual acuity of 6/18 or better, and 28% recorded a visual acuity of less than 6/60 at last follow-up. When broken down into type of lamellar grafts, a best corrected Snellen acuity of 6/12 or better was achieved in 34% of cases for traditional lamellar grafts; 37% of deep anterior lamellar grafts (DALK) and 18% of endothelial lamellar grafts. Forty seven percent of traditional grafts achieved 6/18 or better, while 62% of DALK and 45% of endothelial lamellar grafts achieved this level of acuity. A visual acuity of less than 6/60 at last follow-up was recorded in 21% of traditional lamellar grafts, 16% of DALKs and 33% of endothelial lamellar grafts.

The main indications for traditional lamellar graft were pterygium (16%), failed previous graft (16%), corneal ulcers (15%), trauma (12%), and keratoconus (9%). The main reasons for failure were corneal degeneration (14%), corneal ulcers (12%) and infection (11%). Grafts performed for pterygium exhibited the best corneal graft survival and those sized between 6.0 mm and 7.9 mm fared better than grafts that were larger or smaller. Pre-graft inflammation, a history of raised IOP and post graft microbial keratitis or stitch abscess were associated with poor corneal graft survival.

Seventy six percent of DALK grafts were performed for keratoconus. When compared to penetrating grafts for keratoconus, DALKs had poorer graft survival. The main reasons for failure were primary graft failure (17%), infections, endothelial cell failure and scars and opacities (9% each). The main reason for failure of these grafts was primary graft failure (49%) and graft survival was better for grafts performed by surgeons who had performed >15 of this type of graft per year.

The main indications for endothelial lamellar grafts were corneal dystrophy (47%), bullous keratopathy (33%) and failed previous graft (10%). Endothelial lamellar grafts performed for Fuchs' dystrophy and bullous keratopathy had poorer corneal graft survival than penetrating grafts performed for the same indications. Endothelial lamellar grafts exhibited poorer graft survival and displayed a larger proportion of primary non-function grafts than any other type of lamellar graft.

10.9 RISK FACTORS FOR FAILURE OF PENETRATING GRAFTS

The variables best predicting penetrating corneal graft failure in Cox proportional hazards regression analysis were time of removal of graft sutures, follow-up arrangements, refractive surgery in follow-up, graft diameter, surgeons with a high workload, corneal neovascularization at the time of the graft, history of inflammation in the grafted eye, history of raised intraocular pressure in the grafted eye, lens status, indication for graft, post-operative rise in intraocular pressure, post-operative corneal vascularization, and corneal graft rejection episodes. Further information on these variables, with the associated relative risks for graft failure, is presented in Table 10.1. More comprehensive information is found in Chapter 9.

A number of potential risk factors for graft failure were identified in univariate analyses. Of these, the factors that did *not* influence penetrating corneal graft survival significantly in multivariate analysis were: State, donor age, donor source, donor/recipient State match, multi-organ donor, recipient age, pre-graft visual acuity, descemetocoele, vitrectomy, microbial keratitis/stitch abscess, uveitis, and synechiae.

Table 10.1 Variables best predicting penetrating corneal graft failure

Variable	Hazard ratios
Time to removal of graft sutures (referent: <6 months)	0.27 – 1.00
Follow-up by other than transplant surgeon	0.59
Refractive surgery in follow-up	0.66
Graft diameter (referent: <7.5mm)	0.74 – 1.06
Surgeons with a high workload compared with all others	0.80
Corneal vascularization at graft (referent: none)	0.88 – 1.35
Inflammation of eye in history or at graft (referent: never)	0.91 – 1.73
Raised IOP in history or at graft (referent: never)	1.00 – 1.72
Lens status pre and post graft (referent: phakic/phakic)	1.00 – 1.90
Indication for graft (referent: keratoconus)	1.00 – 5.67
Post-operative rise in intraocular pressure	1.50
Graft neovascularization	2.27
One or more rejection episodes	3.14

10.10 RISK FACTORS FOR FAILURE OF TRADITIONAL LAMELLAR GRAFTS

The variables best predicting traditional lamellar corneal graft failure in Cox proportional hazards regression analysis were indication for graft, follow-up arrangements, donor/recipient state match, graft diameter, history of inflammation in the grafted eye, history of raised intraocular pressure in the grafted eye and post-graft microbial keratitis/stitch abscess.

A number of potential risk factors for graft failure were identified in univariate analyses. Of these, the factors that did *not* influence traditional lamellar corneal graft survival significantly in multivariate analysis were: storage method, State, pre-graft lens status, post-graft lens status, recipient age, pre-graft visual acuity, steroid use in grafted eye, history of surgery in grafted eye, history of herpetic infection in grafted eye and corneal neovascularization at the time of the graft. Further information on these variables, with the associated relative risks for graft failure, is presented in Table 10.2. More comprehensive information is found in Chapter 9.

Table 10.2 Variables best predicting traditional lamellar corneal graft failure

Variable	Hazard ratios
Indication for graft (referent: keratoconus)	0.35 – 3.33
Follow-up by other than transplant surgeon	0.39
Eye bank and surgery in same state	0.59
Graft diameter (referent: <6.0mm)	0.60 – 1.38
History of inflammation in eye	1.57
History of raised IOP	1.95
Post graft microbial keratitis/stitch abscess	1.99

11. METHODS AND DEFINITIONS

11.1 ENTRY AND FOLLOW-UP

Data are entered into the Registry by the contributing surgeon as soon as possible after the graft and follow-up information is requested at intervals of about 12 months. Information is obtained by mail; missing data are routinely sought by follow-up letter. Each graft is followed until graft failure or until the death or loss to follow-up of the patient. The study period for the present analyses was May 1985 to October 2011 (26 years).

11.2 DEFINITION OF RISK FACTORS

A history of past inflammation is recorded if the individual was specifically reported to have had such an episode, if the patient had had one or more previous grafts in the ipsilateral eye, if any intraocular surgery had ever been performed on that eye, or if there was a history of the use of topical corticosteroids in that eye in the weeks immediately preceding the graft.

Vessel ingrowth into the cornea at the time of graft is scored on a scale of 0-4, with 0 representing no growth in any quadrant extending to the graft-host junction, 1 representing such growth in 1 quadrant, 2 representing growth in 2 quadrants, 3 being vessel ingrowth in 3 quadrants and 4 being vessel ingrowth in 4 quadrants. No distinction is made between superficial or deep vessels, patent or ghost vessels, or single or multiple vessel leashes. After corneal transplantation, the presence of even one vessel leash extending into the graft is considered enough to classify that graft as vascularized.

The intraocular pressure (IOP) is generally considered to be raised if a reading of 25 mm of mercury or greater is made by applanation tonometry, but the decision is at the discretion of the ophthalmologist.

Presenting diseases, indications for graft, post-operative complications and reasons for graft failure are coded using the ICD.9.CM system (US Department of Health and Human Services).

Information is collected on both recipient bed size and donor button size, but for the purpose of examining the influence of graft size, the former is used.

11.3 DEFINITION OF GRAFT FAILURE, REJECTION AND COMPLICATIONS

Primary graft non-functions are defined as grafts that never thin and clear in the post-operative period. The trial time for such grafts is arbitrarily adjusted to one day. Any existing graft that is replaced by another in the same eye, irrespective of graft clarity and for whatever reason, is classified as a failed graft. An example in this category would be a clear graft with an unacceptably high degree of irregular astigmatism, not improved by refractive surgery, which is then replaced. In all other cases, graft failure is defined as oedema and irremediable loss of clarity in a previously thin, clear graft. The day of failure is the first day the patient is seen with an oedematous, opaque graft that subsequently fails to thin and clear.

Rejection is defined as the development of a rejection line (epithelial or endothelial) or a unilateral anterior chamber reaction with corneal infiltrates and spreading corneal oedema in a previously thin, clear graft.

Any development with the potential to compromise graft outcome is considered to be a complication. Post-operative complications are collected in two ways. First, a number of specified complications (stitch abscess, microbial keratitis, neovascularization of the graft, synechiae, uveitis, rise in IOP, cataract, rejection episode, herpetic recurrence, early changes of bullous keratopathy), refractive and related errors (anisometropia, ≥5 dioptres astigmatism) and factors potentially affecting visual outcome but unrelated to the graft (cataract, amblyopia, retinal detachment, age related macular degeneration and diabetic retinopathy) are listed, requiring a yes/no answer. Second, contributors are asked to specify any other relevant complications, information or departures from their preferred treatment.

11.4 STATISTICAL ANALYSES

Kaplan-Meier survival functions are constructed to provide a graphical record of graft survival. For surviving grafts, trial time is calculated as the time between the date of graft and the date on which the patient was last seen. For failed grafts, trial time is calculated as the time between the date of graft and the date of failure. For grafts for which we have never received follow-up, the default graft survival period is 0.1 day. Kaplan-Meier plots were constructed using SPSS versions 18, and 19. Cox proportional hazards regression analysis was performed using Stata version 11.

11.5 COMPUTER HARDWARE AND SOFTWARE

Existing hardware comprises a HP Compaq dc7600 computer with 2 hard drives: 74.5 GB, and 149 GB, 2 HP Compaq 8000 Elite computers with 500GB hard drives (one with 2 drives) and a Ricoh Aficio SP4210i printer.

The database is constructed in Microsoft Access. The Access database was designed by Ms Sandra Bobleter and has subsequently been modified by Mrs Helene Holland, Ms Ngaere Hornsby, Ms Carmel McCarthy, Mrs Chris Bartlett and Mrs Marie Lowe. Kaplan-Meier curves generated for the 2012 Report were prepared using SPSS versions 18, and 19. The report was prepared using Microsoft Office 2003.

11.6 CORNEAL GRAFT REGISTRATION FORM

Registry No. Registry use only	**THE AUSTRALIAN CORNEAL GRAFT REGISTRY GRAFT REGISTRATION FORM**

SURGEON	STATE
CONSULTANT	
Performed > 20 of the planned procedure (including this graft) **YES / NO** if No, number	

RECIPIENT IDENTIFICATION

Patient's name _____
SURNAME **FIRST NAME**

Patient's record No. _____ (if applicable)

Patient's date of birth / / Patient gender | Male | Female |

Date of graft / / Eye grafted | R | L |

Time graft performed _____ am/pm

RECIPIENT HISTORY

Original pathology/past history/underlying diseases (in words)

Office use only

Current pathology/current indications for graft (in words)

Desired outcomes

Pain Relief	Improved Visual Acuity	Cosmesis	Tectonic/ Structural Repair

Please circle or tick as many as apply

Pre-graft visual acuity	R	L

Please advise acuity in both eyes

Number of previous grafts in grafted eye (excluding this graft) _____

If this is a **repeat** graft in the grafted eye, reason and date of failure of previous graft

Reason for failure:	Date of failure: / /

Presence of vessels in the recipient cornea

4 Quadrant	3 Quadrant	2 Quadrant	1 Quadrant	None

Please circle/tick the applicable box

	Yes	**No**	**Unknown**
Current inflammation of eye			
Use of topical steroids in 2 weeks prior to graft			
History of intraocular surgery in grafted eye			
Active HSV infection at time of graft			
Does patient have a history of raised intraocular pressure?			
Was intraocular pressure raised at the time of this graft?			
Immediately **prior** to graft, was the eye to be grafted	Phakic	Aphakic	Pseudophakic

DONOR INFORMATION

Donor age (in years) ____ Donor gender | Male | Female |

Multiple Organ Donor | Yes | No |

Eye Bank Source | SA | NSW | VIC | QLD | WA | VIC - Forensic |

Eyebank No. ____

Please circle/tick applicable box

Cause of donor death

OFFICE USE ONLY

(Please fill in as many as are known using a 24 hour clock)

Time and date of donor death		Time		Date
Time and date of enucleation		Time		Date
Time and date of storage of cornea		Time		Date

Storage method Moist Pot ☐ Organ culture ☐ CSM ☐ Optisol ☐ Other ☐

Endothelial cell count (per mm²) ____

Immediately **following** the graft, was the eye grafted | Phakic | Aphakic | Pseudophakic |

OPERATIVE DETAILS

Penetrating and Limbal Grafts

Graft size Donor Button ____ mm Recipient ____ mm

Type of graft Penetrating ☐ Limbal or stem cell /conjunctival ☐

ACCOMPANYING PROCEDURES: (Tick as many as apply)

Peripheral Iridectomy ☐ Removal of cataract ☐ Vitrectomy ☐

Trabeculectomy ☐ Triple procedure ☐

Other procedures ____

Lamellar Grafts

Endokeratoplasty

Tectonic ☐
Lamellar ☐
Other ☐

DSEK ☐
DMEK ☐
DSAEK ☐
Other ☐

Incision size ____ mm Graft size ____ mm

Deep Anterior (Stromal) Lamellar Keratoplasty

Big Bubble ☐
Melles ☐
Other ☐
Graft size ____ mm

Converted to PK | Yes | No |

Insertion Technique (tick as many as apply)

Folded ☐ Glide ☐ Forceps ☐

Suture ☐ Other ____

Describe lamellar procedure if necessary ____

COMMENTS ____

CONSENT: *Please remember that you should gain consent from your patient for data to be forwarded to the ACGR*

PLEASE RETURN THIS FORM TO:

Australian Corneal Graft Registry
Department of Ophthalmology, Flinders Medical Centre
BEDFORD PARK S.A. 5042
PHONE: (08) 8204 5321 FAX: (08) 8277 0899

Version June 2011

11.7 CORNEAL GRAFT FOLLOW-UP FORMS

Registry No. Registry use only	THE AUSTRALIAN CORNEAL GRAFT REGISTRY FOLLOWUP		Date Rec'd Ver March 2008

SURGEON STATE

PATIENT IDENTIFICATION AND GRAFT OUTCOME

GRAFT STATUS

DATE PATIENT LAST SEEN BY YOU / /

GRAFT SURVIVING ON DATE LAST SEEN Yes No (Please mark correct box)

GRAFT FAILED Yes No DATE GRAFT FAILED / /

	Office use only
REASONS FOR GRAFT FAILURE 1.	
2.	

PATIENT STATUS

DECEASED		DATE OF DEATH (if known) / /
LOST TO FOLLOWUP		DATE LOST / /

FOLLOW-UP ELSEWHERE? (Please advise the name and address of the follow-up doctor, if known)

POST OPERATIVE EVENTS

DATE OF FINAL SUTURE REMOVAL: / /

HAVE ANY OF THE FOLLOWING OCCURRED:

NEOVASCULARIZATION OF GRAFT		SYNECHIAE	
SIGNIFICANT RISE IN IOP		UVEITIS	
CATARACT DEVELOPED SINCE GRAFT		STITCH ABSCESS	
RECURRENT HERPETIC DISEASE		OEDEMA	
MICROBIAL KERATITIS			

NUMBER & DATES, OF REJECTION EPISODES SINCE LAST FOLLOWUP				
	/ /	/ /	/ /	/ /
No. of rejections				

	Office use only
ANY OTHER SIGNIFICANT EVENTS?	

OPERATIVE PROCEDURES ON THE GRAFTED EYE

HAS AN OPERATIVE PROCEDURE BEEN PERFORMED ON THE GRAFTED EYE SINCE THE LAST RECORDED FOLLOW-UP?

YES	NO

(Please mark which is applicable)

IF "yes", PLEASE TICK AS MANY AS APPLY:

CATARACT REMOVAL	
INSERTION IOL	
YAG LASER/MECH. CAPSULOTOMY	

GLAUCOMA SURGERY (Please specify)	OTHER OPERATIVE PROCEDURE (Please specify)

HAS ANY REFRACTIVE SURGERY BEEN PERFORMED?

Please mark applicable box	
YES	NO

IF "yes" PLEASE TICK WHERE APPLICABLE:

SUTURE ADJUSTMENT		EXCIMER LASER - PRK	
COMPRESSION SUTURES		EXCIMER LASER - LASIK	
RELAXING INCISION		OTHER (Please state)	
WEDGE RESECTION			

POST-GRAFT VISUAL OUTCOME

SNELLEN ACUITY (with preferred correction and without pinhole)

GRAFTED EYE

Please mark all applicable boxes		
ARE SPECTACLES WORN?	YES	NO
ARE CONTACT LENS WORN?	YES	NO
DOES PATIENT HAVE AN IOL IN PLACE IN THE GRAFTED EYE?	YES	NO

ANISOMETROPIA			
MAJOR DEGREE ASTIGMATISM (>=5D)			
K-READING (if available)			
CENTRAL GRAFT PACHYMETRY		ENDOTHELIAL CELL COUNT (per mm^2)	

FACTORS AFFECTING VISUAL ACUITY IN GRAFTED EYE (Please tick all that apply)

CATARACT		CME		RETINAL DETACHMENT	
AMBLYOPIA		MYOPIA		ARMD	
GLAUCOMA		OPACITY/SCAR		DIABETIC RETINOPATHY	

OTHER (please specify)

EYE HAS NO VISUAL POTENTIAL

IF GRAFTED FOR PAIN, HAS PAIN BEEN RELIEVED?

Yes	No

OTHER COMMENTS

PLEASE RETURN THIS FORM TO:

AUSTRALIAN CORNEAL GRAFT REGISTRY
Department of Ophthalmology, Flinders Medical Centre
BEDFORD PARK S.A. 5042
PHONE: (08) 8204 5321 FAX: (08) 8277 0899

Registry No. Registry use only	**THE AUSTRALIAN CORNEAL GRAFT REGISTRY LAMELLAR FOLLOWUP**		Date Rec'd Ver Mar 2010

GRAFT STATUS

Date patient last seen by you / /

Graft surviving on date last seen Yes No Graft failed Yes No

Date graft failed / /	Reason for failure	Office use only
	1	
	2	

PATIENT STATUS

Deceased / / Lost to follow-up / /

Follow-up elsewhere? (Please advise the name and address of the follow-up doctor, if known)

REJECTION EPISODES

Number and dates of rejections episodes since last follow-up		/ /	/ /	/ /
	Number	date	date	date

Any known trigger? Yes No

(eg. Atopy, loose sutures, recent vaccination)

If Yes, what

METHOD OF CORRECTION

	Please mark all applicable boxes	
Are spectacles worn?	Yes	No
Are contact lenses worn?	Yes	No
Does the patient have an IOL in the grafted eye?	Yes	No

OPERATIVE PROCEDURES ON THE GRAFTED EYE

Operative procedures Yes No

Please specify

POST-GRAFT VISUAL OUTCOME

Corrected visual acuity **grafted eye**		Corrected visual acuity **other eye**	
With pinhole **grafted eye**		With pinhole **other eye**	

IMMEDIATE OPERATIVE OUTCOME

Primary Graft Failure (graft never cleared)		Failed within first 28 days?	Yes	No
Graft dislocation		Successful relocation?	Yes	No
Double anterior chamber		Raised IOP		
Interface opacity		Re-bubbled		

Successful re-bubble? Yes No

Other procedures _____

ANY OTHER FACTORS AFFECTING VISUAL ACUITY IN GRAFTED EYE

Please specify _____

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