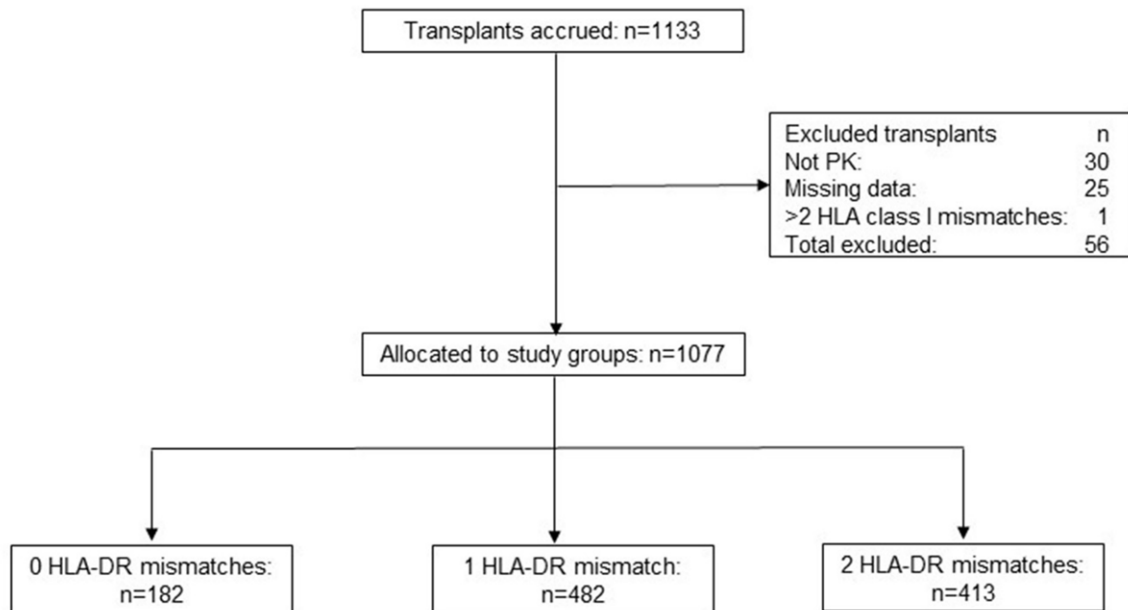


Participant flow



Baseline characteristics

Eye donor variables by study group (0, 1 or 2 HLA-DR mismatches). Mean (SD) given for continuous variables.

Donor variables n (%)	Number of HLA-DR mismatches		
	0 182 (17)	1 482 (44)	2 413 (39)
Age (y)	51.1 (14.1)	49.9 (13.1)	49.5 (14.2)
Sex (% male)	52	53	56
Death-Enucleation (h)	20.3 (6.9)	19.6 (7.1)	19.3 (7.2)
Enucleation-excision (h)	17.8 (6.7)	17.3 (6.9)	18.2 (6.4)
Storage time (d)	20.8 (4.1)	21.0 (4.1)	21.0 (4.1)
ECD (cells/mm ²)	2681 (219)	2676 (225)	2694 (241)

Distribution of indications for corneal transplantation, mean (SD) recipient and donor ages, and sex (percent male).

Indication	n (%)	Recipient age (y)	Male (%)	Donor age (y)	Male (%)
Ectasias	75 (7)	41.6 (13.9)	60	50.1 (13.6)	75
Dystrophies	235 (21)	67.3 (13.3)	55	50.7 (12.2)	32
Previous ocular surgery	310 (27)	69.8 (13.9)	54	50.2 (14.0)	53
Infection	200 (18)	58.5 (17.3)	58	48.3 (14.7)	51
Injury	75 (7)	48.9 (16.3)	52	49.8 (14.1)	88
Ulcerative keratitis	21 (2)	57.1 (17.6)	57	49.6 (13.4)	38
Opacification	61 (5)	58.7 (18.4)	57	51.7 (12.9)	49
Miscellaneous	156 (14)	58.7 (16.9)	45	49.9 (14.7)	30
Total	1133	61.7 (17.3)	54	50.0 (13.7)	52

Distribution of pre-operative risk factors for allograft rejection by indication for corneal transplantation in the recipients included in the final analysis (n=1077).

Indication	Vascularization	Inflammation	Glaucoma	Regraft	Other
	n (%)	n (%)	n (%)	n (%)	n (%)
Ectasias	20 (27)	19 (25)	7 (9)	61 (81)	18 (24)
Dystrophies	46 (20)	22 (9)	30 (13)	116 (49)	39 (17)
Previous ocular surgery	84 (27)	52 (17)	124 (40)	132 (43)	74 (24)
Infection	122 (61)	79 (40)	24 (12)	80 (40)	42 (21)
Injury	39 (52)	21 (28)	21 (28)	53 (71)	31 (41)
Ulcerative keratitis	14 (67)	13 (62)	1 (5)	11 (52)	17 (81)
Opacification	33 (54)	14 (23)	14 (23)	26 (43)	23 (38)
Miscellaneous	52 (33)	24 (15)	53 (34)	132 (85)	37 (24)

NB The total number of pre-operative risk factors (1701) is higher than the number of transplants included in the final analysis because more than half of the recipients had more than 1 risk factor.

Outcome measures

Time to first allograft rejection episode:

Five-year rejection-free survival estimates from Kaplan-Meier plots for the 3 study groups defined by the number of HLA class II mismatches.

HLA Class II match grade	N	Survival (%)	95% CI	P
0 mismatches	182	67	58-74	0.6
1 mismatch	482	68	63-73	
2 mismatches	413	65	60-70	

Cox proportional hazards regression model for 5-year risk of allograft rejection.

Graft rejection over five-year period				
Factor	Number	Hazard Ratio	95% CI	P
Factors at transplant				
Number of risk factors (p<0.0001)				
0 risk factors	136	1	-	-
1 risk factor	293	1.489	0.887-2.501	0.1319
2 risk factors	348	2.105	1.279-3.465	0.0034
3+ risk factors	301	2.791	1.691-4.604	<.0001
Recipient age (p=0.0015)				
≤40	162	1	-	-
41-60	295	0.706	0.488 - 1.020	0.0639
61-80	480	0.513	0.359 - 0.734	0.0003
≥81	141	0.490	0.297 - 0.809	0.0053
HLA Class II mismatches (p=0.7104)				
0DR MM	182	1	-	-
1DR MM	483	1.022	0.711 - 1.470	0.9055
2DR MM	413	1.132	0.785 - 1.633	0.5071
Donor-recipient sex match (p=0.8175)				
All other matches	802	1	-	-
Male donor to female recipient	276	0.964	0.717 - 1.297	0.8100
Post-operative factors				
Selective suture adjustment/removal (p=0.0980)				
No	562	1	-	-
Yes	516	0.768	0.557 - 1.058	0.1065
Cataract Surgery (p=0.0003)				
No	1005	1	-	-
Yes	73	3.675	1.948 - 6.933	<0.0001

Adverse events

There were no serious (life-threatening) adverse events.

Non-life-threatening adverse events in this cohort of 1133 corneal transplant recipients included 41 (3.6%) primary graft failures (i.e., the corneal graft never clears). This is higher than the typical corneal transplant primary failure rate of about 1% but all the patients in this study were at increased risk of allograft rejection and graft failure and therefore more susceptible to primary graft failure. Depending on the indication for transplantation and the presence of pre-operative risk factors, allograft rejection is an anticipated non-life-threatening adverse event in corneal transplantation and is the leading cause of graft failure. There were 298 first rejection episodes in the 1077 transplants included in the final analysis.