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Recipient Risk Factors for Graft Failure in the Cornea Donor Study

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Abstract

Purpose—Identify recipient factors which may be related to risk of corneal graft failure

Design—Multi-center prospective, double-masked, controlled clinical trial

Participants—1090 subjects undergoing corneal transplantation for a moderate risk condition (principally Fuchs' dystrophy or pseudophakic corneal edema)

Methods—Donor corneas were assigned using a random approach without respect to recipient factors, and surgeons were masked to information about the donor cornea including donor age. Surgery and post-operative care were performed according to the surgeons' usual routines and subjects were followed for five years. Baseline factors were evaluated for their association with graft failure.

Main Outcome Measures—Graft failure, defined as a regraft or a cloudy cornea that was sufficiently opaque to compromise vision for a minimum of three consecutive months.

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Results—Preoperative diagnosis of pseudophakic/aphakic corneal edema increased graft failure risk approximately 4-fold compared with Fuchs' dystrophy (27% vs. 7%). Prior glaucoma surgery with preoperative glaucoma medication use substantially increased the graft failure rate. Factors not strongly associated with graft failure included age, gender, diabetes, smoking, and graft size.

Conclusion—The risk of graft failure is significantly increased in eyes with pseudophakic or aphakic corneal edema compared with Fuchs' dystrophy, independent of lens status, and in eyes with a history of glaucoma.

Introduction

The Cornea Donor Study (CDS) is a large multi-center prospective double-masked, controlled clinical trial designed to evaluate the effects of the age of corneal transplant donors on graft outcomes in patients with a corneal condition considered to be at moderate risk for failure, principally pseudophakic corneal edema and Fuchs' dystrophy. The five-year primary outcomes were recently reported, showing no clinically or statistically significant effect of donor age, up to 75 years, on the rate of graft failure.[1, 2] The large number of prospectively studied corneal grafts makes this population a valuable resource for addressing many other objectives. The purpose of the present report from the CDS is to evaluate the effects of corneal graft recipient factors on rates of corneal graft failure up to 5 years post transplantation.

Methods

Study Protocol

Details of the CDS protocol have been previously reported[1, 3, 4] and pertinent information is briefly summarized here. The study protocol was approved by the institutional review boards at each investigational site and written informed consent was obtained from each participant. Subject eligibility criteria included age between 40 and 80 years, and a corneal disease associated with endothelial dysfunction and moderate risk of graft failure (principally Fuchs' dystrophy and pseudophakic corneal edema). The recipient diagnosis was made on the basis of the surgeon's assessment of the primary indication for transplant. Donor eligibility criteria included age between 10 and 75 years and an eye bank-measured endothelial cell density of 2300 to 3300 cells/mm^2. Clinical investigators and subjects were masked to certain characteristics of the donor corneal tissue, including age and endothelial cell density. The assignment of donor tissue was made without regard to age or any other subject characteristics. Preoperative management, surgical technique, and postoperative care (including prescription of medications), were provided according to each investigator's customary routine.

Visits throughout the initial 6 months after penetrating keratoplasty were left to each investigator's routine. Thereafter, the minimum follow-up visit schedule included a visit between months 6 and 12 and then annual visits through 5 years.

At each visit, graft clarity was assessed. The definition of graft failure, based on the definition used in the Collaborative Corneal Transplantation Studies (CCTS),[5, 6] was a regraft or, in the absence of regraft, a cloudy cornea in which there was loss of central graft clarity sufficient to compromise vision for a minimum of three consecutive months. Further details of the classification scheme for graft failures have been published.[1]

Statistical Methods

The analysis included the 1,090 eligible subjects in the CDS. Cumulative probabilities of graft failure (subsequently referred to as "graft failure rates") according to levels of baseline variables were calculated using the Kaplan-Meier method. Proportional hazards regression was used to assess the association of baseline factors with graft failure in two multivariate analyses:

an initial model and a final model that was generated through backward elimination of covariates with significance level of 0.05. A forward selection procedure resulted in the same model. Multiple comparisons were not adjusted for in the final model. No significant deviation from the proportional hazards assumptions was detected for factors included in the final multivariate model. All reported p-values are two-sided. Statistical analyses were conducted using SAS version 9.1 software (SAS Institute Inc., Cary, NC).

Results

The baseline characteristics of the 1,090 subjects have been reported previously;[1] their distributions are indicated in the 'N' column of Table 1. Most subjects had a preoperative diagnosis of either Fuchs' dystrophy (676, 62%) or aphakic/pseudophakic corneal edema (A/PCE) (369, 34%).

In univariate and multivariate analyses, factors that were strongly associated with graft failure were corneal diagnosis and glaucoma history (Tables 1 and 2). The risk of graft failure was approximately four times higher with a pre-operative diagnosis of A/PCE than with Fuchs' dystrophy (27% versus 7%). The difference was not attributable to lens status alone as eyes with a diagnosis of Fuchs' dystrophy that were pseudophakic/aphakic prior to surgery and post-operatively pseudophakic (posterior chamber intraocular lens) had a 5-year failure rate of 9% (5% in phakic eyes with Fuchs' dystrophy) (Table 3). A history of glaucoma or ocular hypertension substantially increased the failure rate in both Fuchs' dystrophy and A/PCE cases, particularly if there had been surgery for glaucoma and the subject was being treated with medication to lower intraocular pressure at the time of transplant. The risk of failure was lower in white non-Hispanic subjects compared with non-white or Hispanic subjects. The number of non-white or Hispanic subjects was too small to separately evaluate each race/ethnicity. Factors with an association with graft failure in univariate analyses with a p value ≤ 0.05 that were no longer significant at this level in multivariate analyses included maximum intraocular pressure during the first postoperative month, performance of a vitrectomy at the time of transplant and graft size. The principal confounding factor accounting for the differences between the univariate and multivariate analyses was corneal diagnosis. Factors that were not strongly associated with graft failure in either univariate or multivariate analyses included age, gender, history of diabetes, history of smoking, and donor-recipient size disparity (data not shown).

The association of post-operative lens status with graft failure varied according to the corneal diagnosis (Table 3). Among eyes with Fuchs' dystrophy, the presence of an intraocular lens (IOL), primarily posterior chamber IOLs, did not substantially increase the risk of graft failure. Among eyes with A/PCE, the presence of an anterior chamber IOL after transplant increased the graft failure risk 2-fold compared with a posterior chamber IOL (42% respectively versus 21%).

Discussion

In this study of 1,090 intermediate risk corneal transplants followed for up to 5 years, large statistically significant associations with graft failure were found for corneal diagnosis and history of glaucoma surgery and to a lesser extent race. Among eyes with A/PCE, the graft failure rate was higher with anterior chamber IOLs than with posterior chamber IOLs. These findings confirm the findings in previous, generally retrospective, studies of corneal transplants. Our analysis is similar to the analysis of risk factors for failure in the CCTS, a study of the effects of tissue matching performed almost 20 years ago.[7] That study was the largest prospective randomized trial related to corneal transplantation prior to the CDS. The CCTS, however, evaluated a population at high risk for graft rejection and failure. Unlike the CCTS and most other large studies of corneal transplant outcomes, the CDS excluded eyes at

high risk for failure, such as those with significant corneal vascularization or previous rejection, and also excluded eyes with very low risk for failure, particularly those with keratoconus or stromal dystrophies. While our findings are, thus, strictly applicable only to this group of intermediate risk eyes, mostly with Fuchs' dystrophy and A/PCE, many principles may be more broadly relevant.

The role of diagnosis is not surprising based on the prior literature. Eyes with a diagnosis of A/PCE had a substantially higher rate of failure (27%) than those with Fuchs' dystrophy (7%). Fuchs' dystrophy eyes have been reported to have a 10 to 11% failure rate at 8 to 10 years.[8, 9] Many studies have reported much higher failure rates for pseudophakic eyes, but the older literature on PCE is confounded somewhat by the variety of IOL types present, with high failure rates in eyes with some past, now abandoned, IOL styles.[10] In the CDS, among eyes with A/PCE the failure rate was substantially higher with an anterior chamber IOL than a posterior chamber IOL. However, the failure rate in these eyes with a posterior chamber IOL was still substantially higher than the failure rate in eyes with Fuchs' dystrophy and a posterior chamber IOL. This difference in outcome for posterior chamber IOL according to corneal diagnosis is likely due to the fact that the corneal edema requiring transplantation in the Fuchs' group was presumably not attributable to the presence of the IOL but rather to the underlying endothelial disease. In the A/PCE group, in contrast, the presence of the IOL, or the process of cataract extraction and IOL insertion, largely independent of preoperative endothelial abnormality,[11] led to corneal decompensation. We did not have data to evaluate the possible role of complications during or after the cataract surgery. If the presence of an IOL in some way caused ongoing insult to the endothelium, then this process could continue after corneal transplantation. Another view of this would be that PCE eyes were selected from the population of all eyes with posterior chamber IOLs, the vast majority without corneal edema, because of the abnormal response of those eyes to an IOL, a process that is not eliminated by corneal replacement in many of these eyes. In eyes with Fuchs' dystrophy having cataract/IOL surgery, the rate of continuing IOL induced inflammation, abnormal fluid dynamics, altered endothelial nutrition or endothelial trauma, would be expected to be low and similar to that in eyes without Fuchs' dystrophy having cataract surgery, since these eyes are selected for corneal edema because of the endothelial disease rather than an abnormal response to the presence of an IOL. Consistent with this theory, Langenbucher et. al., found the rate of endothelial cell loss after keratoplasty to be higher in eyes with A/PCE than those with Fuchs' dystrophy, although they did not evaluate confounding by pre-operative lens status.[12]

The role of glaucoma in corneal graft failure has been recognized for many years, but is poorly understood. In the CCTS, a history of preoperative glaucoma increased the graft failure rate from 29% to 48%.[7] A similar effect has been seen in other retrospective series.[13] An Australian Corneal Graft Registry analysis attributed 8.5% of graft failures to glaucoma and its treatment.[14] In the current study there was a gradation of effect with 11% failure without glaucoma and 20%, 29% and 58% failure if glaucoma had been treated with medications alone, surgery alone, or both, respectively. The mechanism of this effect is unknown, but it may not be related to intraocular pressure alone. The potential role of aggressive lowering of postoperative intraocular pressure is unclear.

Vitrectomy was associated with a greater than 2.5 fold increased risk of graft failure, but this effect was not confirmed in multivariate analysis because of its association with A/PCE. Other studies have shown a significant effect in multivariate analysis.[14] Graft size smaller than 8.0 mm was also associated with an increased risk of graft failure only in univariate analysis. An association of smaller graft size with graft failure and rejection has been reported previously in a population at high risk for graft failure.[15]

Non-white race was associated with increased risk of graft failure. The CCTS found an increased risk of rejection episodes, but not of failure, in non-whites.[7] The reasons for this difference are unknown and this information is unlikely to have clinical utility. Patient age was not associated with the risk of graft failure after adjusting for diagnosis.

The sample size and the number of graft failures were sufficiently large that most analyses could be conducted with good precision. A notable exception is the analysis involving race/ethnicity for which there were an insufficient number of African-American and Hispanic patients to evaluate risk of failure separately for each group.

As the procedures studied in the CDS all involved full-thickness keratoplasty, the applicability of these data and conclusions to newer endothelial keratoplasty procedures such as Descemet's stripping endothelial keratoplasty, increasingly used in this intermediate risk population, cannot be predicted with certainty. From a biologic perspective, however, the relationships of these recipient factors to corneal graft outcomes are likely to remain important.

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Table 1

Association between Baseline Factors and Graft Failure According to Corneal Diagnosis

			Preoperative Diagnosis[a]			
	Total		Fuchs' Dystrophy		Pseudophakic/Aphakic corneal edema	
Baseline Factors	**N**	**5-yr Graft Failure[b] ± 95% CI**	**N**	**5-yr Graft Failure[b] ± 95% CI**	**N**	**5-yr Graft Failure[b] ± 95% CI**
Overall	1,090	14% ± 2%	676	7% ± 2%	369	27% ± 5%
Gender						
Male	393	14% ± 4%	210	7% ± 4%	158	24% ± 7%
Female	697	14% ± 3%	466	8% ± 3%	211	29% ± 7%
Race/Ethnicity						
White (Non-Hispanic)	1,011	13% ± 2%	651	7% ± 2%	322	26% ± 5%
Non-White (including Hispanic)	79	29% ± 11%	25	18% ± 16%	47	36% ± 16%
Black	50	35% ± 15%	19	24% ± 21%	27	42% ± 22%
Hispanic	13	*	2	*	9	*
Other	16	8% ± 14%	4	*	11	*
Age at Surgery						
<60 years	162	12% ± 5%	126	5% ± 4%	29	48% ± 20%
60–<70 years	284	10% ± 4%	201	8% ± 4%	70	14% ± 9%
≥70 years	644	16% ± 3%	349	8% ± 3%	270	28% ± 6%
Smoker (at time of surgery)						
No	988	13% ± 2%	628	7% ± 2%	325	27% ± 5%
Yes	102	19% ± 8%	48	9% ± 8%	44	30% ± 15%
History of Diabetes[c]						
No	899	13% ± 2%	587	7% ± 2%	276	26% ± 6%

			Preoperative Diagnosis[a]			
	Total		Fuchs' Dystrophy		Pseudophakic/Aphakic corneal edema	
Baseline Factors	**N**	**5-yr Graft Failure[b] ± 95% CI**	**N**	**5-yr Graft Failure[b] ± 95% CI**	**N**	**5-yr Graft Failure[b] ± 95% CI**
Yes	141	15% ± 6%	67	7% ± 7%	69	24% ± 11%
Post-operative Intraocular Pressure[d]						
≤25 mmHg	953	13% ± 2%	608	7% ± 2%	301	25% ± 5%
>25 mmHg	130	23% ± 8%	63	10% ± 8%	66	36% ± 13%
Prior Glaucoma Surgery/Medications						
No Medications and No Surgery	920	11% ± 2%	627	7% ± 2%	259	22% ± 6%
Medications and No Surgery	99	20% ± 9%	34	16% ± 13%	61	20% ± 11%
No Medications and Surgery	26	29% ± 18%	8	*	15	43% ± 26%
Medications and Surgery	45	58% ± 16%	7	*	34	67% ± 18%
Recipient Bed Size[e]						
<8.0 mm	464	17% ± 4%	240	9% ± 4%	198	27% ± 7%
=8.0 mm	523	11% ± 3%	365	6% ± 3%	144	27% ± 8%
>8.0 mm	102	13% ± 7%	70	8% ± 6%	27	30% ± 19%
Vitrectomy During Transplant						
No	931	12% ± 2%	645	7% ± 2%	242	25% ± 6%
Yes	159	28% ± 8%	31	17% ± 14%	127	32% ± 9%

CI = Confidence interval

* = Graft failure rates not reported for groups with N < 15.

[a] 45 subjects with "Other" diagnosis not included.

[b] Kaplan-Meier estimates.

[c] 50 subjects with unknown history of diabetes.

[d] Maximum intraocular pressure during initial 30 days following surgery. Missing intraocular pressure measurements for 7 subjects.

[e] 1 subject with missing recipient bed size.

Table 2

Multivariate Analysis of Baseline Factors Predictive of Graft Failure

		Univariate Models			Multivariate Models					
					Model 1[a]			Model 2[b]		
Baseline Factors	**N**	**Hazard Ratio**	**95% CI**	**P-value**	**Hazard Ratio**	**95% CI**	**P-value**	**Hazard Ratio**	**95% CI**	**P-value**
Race/Ethnicity				<0.001			0.02			0.05
White (Non-Hispanic)	1011	1.00			1.00			1.00		
Non-White (including Hispanic)	79	2.60	1.60, 4.22		1.82	1.09, 3.04		1.65	1.01, 2.71	
Diagnosis				<0.001			<0.001			<0.001
Fuchs' Dystrophy	676	1.00			1.00			1.00		
Pseudophakic/Aphakic Corneal Edema	369	4.08	2.84, 5.85		2.75	1.78, 4.25		3.12	2.12, 4.60	
Other	45	2.31	0.99, 5.41		1.63	0.68, 3.94		1.66	0.70, 3.93	
Glaucoma History				<0.001			<0.001			<0.001
No Medications and No Surgery	920	1.00			1.00			1.00		
Medications and No Surgery	99	1.97	1.17, 3.31		1.26	0.73, 2.17		1.27	0.75, 2.17	
No Medications and Surgery	26	2.97	1.38, 6.42		2.13	0.96, 4.71		2.01	0.92, 4.39	
Medications and Surgery	45	7.18	4.49, 11.46		3.84	2.30, 6.42		4.18	2.56, 6.83	
Gender				0.88			0.37			
Male	393	1.00			1.00					
Female	697	1.03	0.72, 1.46		1.18	0.82, 1.71				
Age at Surgery				0.08			0.30			
<60 years	162	1.00			1.00					
60–<70 years	284	0.81	0.45, 1.46		0.70	0.38, 1.27				
≥70 years	644	1.30	0.79, 2.13		0.97	0.58, 1.63				
Smoker (at time of surgery)				0.11			0.16			

		Univariate Models			Multivariate Models					
					Model 1[a]			Model 2[b]		
Baseline Factors	**N**	**Hazard Ratio**	**95% CI**	**P-value**	**Hazard Ratio**	**95% CI**	**P-value**	**Hazard Ratio**	**95% CI**	**P-value**
No	988	1.00			1.00					
Yes	102	1.52	0.92, 2.53		1.47	0.87, 2.48				
History of Diabetes[c]				0.46			0.70			
No	899	1.00			1.00					
Yes	141	1.21	0.73, 1.99		0.90	0.54, 1.51				
Post-operative Intraocular Pressure[d]				0.04			0.48			
≤25 mmHg	953	1.00			1.00					
> 25 mmHg	130	1.89	1.23, 2.91		1.18	0.75, 1.86				
Vitrectomy				<0.001			0.21			
No	931	1.00			1.00					
Yes	159	2.59	1.78, 3.77		1.31	0.86, 1.99				
Recipient Bed Size[e] **(per mm)**				0.01			0.76			
< 8.0 mm	464	1.00			1.00					
= 8.0 mm	523	0.65	0.46, 0.93		0.91	0.63, 1.32				
> 8.0 mm	102	0.75	0.40, 1.38		1.12	0.59, 2.12				

CI = Confidence interval

[a] Initial multivariate model included all variables listed in Table 1 regardless of level of significance.

[b] The final multivariate model was generated through backward elimination of variables, if level of significance was >0.05.

[c] Unknown for 50 subjects.

[d] Maximum intraocular pressure value during initial 30 days following surgery. P-value obtained by treating IOP measurements as continuous variable in the univariate Cox model. IOP measurements missing for 7 subjects.

[e] P-value obtained by treating the recipient bed size as continuous variable in the univariate Cox model. Recipient bed size missing for 1 subject.

Table 3

Association of Lens Status and Graft Failure According to Corneal Diagnosis

			Multivariate Models[b]		
	N	5-yr Graft Failure[a] ± 95% CI	Hazard Ratio	95% CI	P-value
Fuchs' Dystrophy					0.34
Pre-operative phakic, post-operative phakic	153	5% ± 3%	1.00		
Pre-operative phakic, post-operative pseudophakic[c]	299	7% ± 3%	1.61	0.67, 3.84	
Pre-operative pseudophakic/aphakic, post-operative pseudophakic[d]	202	9% ± 4%	1.92	0.78, 4.72	
Post-operative aphakic[e]	22	14% ± 15%	3.26	0.80, 13.30	
Pseudophakic/Aphakic Corneal Edema					0.001
Post-operative pseudophakic (PC IOL)[f]	218	21% ± 6%	1.00		
Post-operative pseudophakic (Sutured PCL)[g]	54	24% ±13%	1.20	0.61, 2.37	
Post-operative pseudophakic (AC IOL)[h]	89	42% ± 12%	2.72	1.65, 4.49	
Post-operative aphakic[i]	8	*	*	*	

CI = Confidence interval

[a] Kaplan-Meier estimates.

[b] Models adjusted for glaucoma history and race

[c] IOLs: 288 posterior chamber, 8 sutured posterior chamber, and 3 anterior chamber. Graft failure rate was similar in an analysis limited to posterior chamber IOLs

[d] IOLs:195 posterior chamber, 3 sutured posterior chamber, and 4 anterior chamber. Graft failure rate was similar in an analysis limited to posterior chamber IOLs

[e] Pre-operatively, 13 aphakic, 8 phakic, and 1 pseudophakic

[f] Pre-operatively, 213 pseudophakic and 5 aphakic

[g] Pre-operatively, 45 pseudophakic and 9 aphakic

[h] Pre-operatively, 85 pseudophakic and 4 aphakic. IOLs: 87 anterior chamber and 2 iris-fixated.

[i] Pre-operatively, 2 pseudophakic and 6 aphakic