CLINICAL SCIENCE

Visual outcome in corneal grafts: a preliminary analysis of the Swedish Corneal Transplant Register

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Aim: To assess visual outcome and the incidence of complications at 2 years postoperatively in corneal grafts reported to the Swedish Corneal Transplant Register.
Methods: Preoperative and 2 year follow up data were submitted to the Swedish Corneal Transplant Register by surgeons in eight corneal transplant clinics in Sweden. Preoperative data on 1957 grafts and 520 grafts with 2 year follow up were included in the analysis. Data were analysed by multiple linear and logistic regression methods, as appropriate.
Results: The major diagnostic categories were keratoconus (29%), bullous keratopathy (21%), and "other diagnosis" (32%). Fuchs' endothelial dystrophy and stromal dystrophies accounted for 15% and 3% of grafts, respectively. At 2 years the overall incidence of complications, other than rejection and regrafting, was 26%, with an increasing frequency from keratoconus < Fuchs' dystrophy < bullous keratopathy < "other diagnosis." Rejection was observed in 15% of grafts and was more likely in the bullous keratopathy (OR 3.1, 95% CI 1.1 to 9.0, p=0.04) and "other diagnosis" (OR 2.6, 95% CI 1.1 to 5.9, p=0.03) groups. Regrafting, which occurred in 10% of cases, was not influenced by diagnosis, but it was related to the incidence of rejection (OR 14.8, 95% CI 6.1 to 35.9, p<0.001) and other complications (OR 4.4, 95% CI 1.9 to 10.4, p=0.001), and to the presence of other sight threatening pathology in the eye (OR 3.6, 95% CI 1.3 to 9.9, p=0.01). Visual acuity was improved in a high proportion of the patients, especially those with keratoconus and Fuchs' dystrophy where, respectively, 86% and 54% of grafts achieved a visual acuity of ≥0.5 at 2 years, compared with only 31% with bullous keratopathy and 35% in the "other diagnosis" group. 60% of grafts for keratoconus and Fuchs' dystrophy achieved a visual acuity equal to or better than the other eye. Postoperative astigmatism was higher in the bullous keratopathy (p=0.01) group. Patients with high astigmatism benefited from refractive surgery, showing a reduction from 7.9 (95%CI 6.9, 8.7) to 3.2 (95% CI 2.6, 3.9) dioptres (p<0.001). A centre effect was evident in visual outcome.
Conclusion: The overall incidence of complications was related to diagnosis. Complications other than rejection and regrafting were most likely in the "other diagnosis" group, and further analysis of this group is therefore planned. The best improvement in visual acuity and the lowest astigmatism were achieved in the keratoconus and Fuchs' dystrophy groups; but the influence of diagnosis on astigmatism was small and, overall, the statistical model accounted for only 8% of the variability in astigmatism. Refractive surgery was, however, effective in reducing astigmatism. It is hoped that a better understanding of the factors that determine the visual outcome of grafts will emerge from future analyses of the Swedish Corneal Transplant Register, helping to refine the criteria for patient selection and to guide clinical practice.

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The main purpose of the majority of corneal grafts is to improve vision, but other benefits for patients include pain relief or even simply saving an eye. With some notable exceptions,[1] many analyses of the outcome of corneal grafting have focused primarily on graft survival and immunological rejection, which still remains the most common cause of early graft failure and the continuing subject of both laboratory and clinical follow up studies.[2] Since many of the factors influencing visual outcome remain uncertain, the Swedish Corneal Transplant Register was started in 1997 to collect data from the 500–600 grafts performed each year in Sweden. The emphasis of the register is on visual outcome with the purpose of providing evidence to support or to change current practice in patient selection and the management of grafts. Sweden is a suitable geographical area for such a register as grafts are performed in only eight clinics and it is usually possible to trace the patients for follow up. Moreover, the group of fewer than 20 corneal graft surgeons is able to meet regularly to discuss the register and results.

In many reports, the end point for follow up is only 1 year. However, healing after corneal transplantation is an extended process and procedures such as suture removal and refractive surgery are most likely to occur after 1 year. We therefore decided to collect data at 2 years when all sutures will have been removed and the eye has a fairly stable refraction.

METHODS

Forms were developed to collect data preoperatively and at 2 years postoperatively. At the time of surgery surgeons provided patient details (age, sex, diagnosis, type of procedure, visual acuity, lens status). The diagnosis was divided into five groups: keratoconus, Fuchs' endothelial dystrophy, bullous keratopathy (corneal oedema resulting from previous ocular surgery), stromal dystrophy, and "other diagnosis." Preoperative visual acuity (visual acuity with best preferred correction) was measured by Snellen charts in both eyes. Type of procedure was defined as penetrating keratoplasty (PKP), triple procedure (penetrating keratoplasty combined with an extracapsular cataract extraction and implantation of an artificial intraocular lens), or other procedure, such as PKP combined with replacement of an intraocular lens, secondary intraocular lens, vitrectomy, iris suture or other reconstructive surgery. All of the corneas were supplied from the five eye

Table 1 Diagnosis and type of operation

Diagnosis	No (%)	Age (years)	Type of operation (%)		
			PKP	Triple	Other
Keratoconus	566 (29)	38 (SD 13, range 7–88)	93	6	1
Fuchs' dystrophy	286 (15)	73 (SD 10, range 29–92)	36	62	2
Bullous keratopathy	414 (21)	76 (SD 11, range 4–94)	85	0	15
Stromal dystrophy	59 (3)	63 (SD 16, range 16–89)	58	40	2
Other	625 (32)	69 (SD 18, range 0–96)	60	28	12
Total	1950*	60 (SD 21, range 0–96)	71	21	8

*7 grafts had no recorded diagnosis.

Table 2 Postoperative astigmatism and complications at 2 years

Diagnosis	Astigmatism (D)*	Complications (%)			Other pathology† (%)
		Rejection	Regraft	Other	
Keratoconus	4.0 (3.5, 4.5, n=105)	11.7	6.3	13.4	9.7
Fuchs' dystrophy	4.2 (3.4, 5.1, n=48)	9.7	9.5	21.6	38.5
Bullous keratopathy	4.7 (4.0, 5.3, n=54)	17.9	14.2	29.2	67.3
Stromal dystrophy	4.4 (2.5, 6.6, n=9)	–	–	–	–
Other	4.3 (3.7, 5.0, n=64)	18.8	11.8	37.9	64.7
Total	4.3 (4.0, 4.6, n=280)	14.9	10.4	26.2	45.7

*Back transformed means (95% CI); †other conditions in the operated eye that may adversely affect sight.

banks in Sweden and Denmark. All of these eye banks routinely use organ culture for storing corneas.

At the 2 year follow up it was recorded whether there had been any rejection episodes or other complications, or whether regrafting had been necessary. Other complications included graft failure, endothelial decompensation, subsequent trauma to the graft, infection, or recurrence of the original disease. Astigmatism was measured in the grafted eye and, if refractive surgery had been performed after suture removal, the astigmatism before refractive surgery was also noted. After a trial period it was decided to use Javal values for describing the astigmatism, rather than keratometry readings, as this was the method most commonly used. The visual acuity with best preferred correction was also recorded in the grafted eye, and whether other pathology (that is, another eye disease possibly affecting the visual outcome) was detected.

The data were stored in a Microsoft Access database and analysed using SPSS (v 10.0.5) statistical software. Multifactorial statistical methods were applied to determine the influence of recipient factors on graft outcome. For astigmatism (dioptres), multiple linear regression was used following square root transformation. Back transformed means and 95% confidence intervals (95% CI) are reported. Logistic regression was used for analysing the influence of factors on visual acuity (≥0.5; ≤0.2; VA operated eye ≥ VA contralateral eye), and on the incidence of rejection, regrafting, and other complications. Odds ratios (OR) and 95% CI are reported from the logistic regression analyses. The final statistical models were derived by backwards stepwise regression. The level of significance was set at 5%.

RESULTS

At the time of analysis 1957 corneal grafts, accounting for 89% of the total performed in Sweden in the same period, were recorded on the register. Approximately 90% of the grafts were reported from five of the eight clinics. Two year follow up was available for 520 grafts from these same five clinics.

Diagnosis

The distribution of diagnoses is shown in Table 1. Keratoconus, bullous keratopathy, and "other diagnosis" were the most frequent indications for grafting. As expected, the mean age of keratoconus patients was substantially lower than for the other diagnostic groups.

Type of operation

In keratoconus, the most common type of operation was PKP (93%), whereas in Fuchs' dystrophy the triple procedure predominated (Table 1). The triple procedure was also common for stromal dystrophies. In the bullous keratopathy group PKP was combined with other procedures in 15% of the cases.

Postoperative complications

The overall incidence of postoperative complications, including rejection and regrafting, was highest in the "other diagnosis" group, followed by the bullous keratopathy group (Table 2). The incidence of rejection was also greater in these two groups compared with the keratoconus group (OR 2.6, 95% CI 1.1 to 5.9, p=0.03 and OR 3.1, 95% CI 1.1 to 9.0, p=0.04, respectively). The risk of rejection was, however, similar in the Fuchs' dystrophy and keratoconus groups (OR for Fuchs' dystrophy 1.4, 95% CI 0.4 to 4.6, p=0.6). A centre effect was evident with the incidence of rejection being higher in just one of the clinics (OR 3.7, 95% CI 1.5 to 9.5, p=0.006). The likelihood of regrafting was higher for grafts that had suffered rejection (OR 14.8, 95% CI 6.1 to 35.9, p<0.001) and when other complications (OR 4.4, 95% CI 1.9 to 10.4, p=0.001), or other pathology (OR 3.6, 95% CI 1.3 to 9.9, p=0.01) were reported in the grafted eye. Other complications were also more likely in grafted eyes that had other pathology (OR 6.1, 95% CI 3.6 to 10.6, p<0.001).

Improvement in visual acuity

Before surgery, 86% of the patients had a visual acuity ≤0.2, whereas at the 2 year follow up 48% had a visual acuity ≥0.5 with only 39% ≤0.2. This was measured with best preferred correction. In the keratoconus group this improvement was even more marked (Fig 1): the percentage of patients with visual acuity ≤0.2 fell from 75% preoperatively to only 8% postoperatively while those with visual acuity ≥0.5 correspondingly increased from 12 to 86%. In Fuchs' endothelial dystrophy there was also a marked improvement after surgery, but to a lesser extent than in keratoconus. Before surgery in the bullous keratopathy group, 99% had a visual acuity ≤0.2,

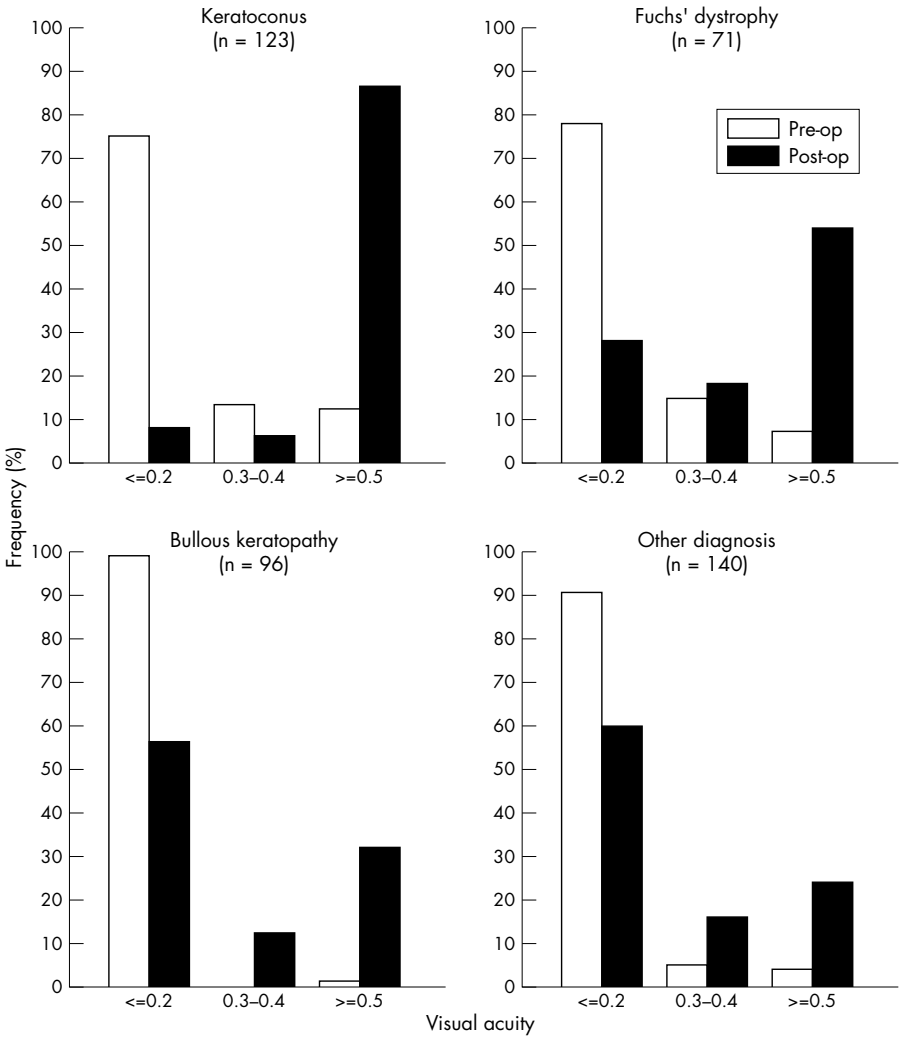

Figure 1 Preoperative and postoperative visual acuity in grafts by diagnosis.

which decreased to 56% after surgery; but only 32% had achieved a visual acuity ≥0.5 after 2 years. As can be seen from Figure 1, the group of "other diagnosis" had the poorest result concerning visual acuity, with only 24% achieving ≥0.5 after grafting. A postoperative visual acuity ≥0.5 was associated with straightforward PKP, high preoperative visual acuity, low astigmatism, and the absence of other sight hindering pathology (Table 3). A centre effect was evident with grafts in two of the clinics more likely to achieve VA≥0.5. Poor visual acuity (≤0.2) was more likely in grafts for Fuchs' dystrophy, bullous keratopathy, and "other diagnosis" than in those for keratoconus (Table 4). Low preoperative visual acuity, the presence of other complications, and other pathology were also associated with low postoperative visual acuity. A centre effect was again evident.

Visual acuity of the grafted eye compared with the other eye

Overall, only 20% (88/446) of eyes to be grafted had a visual acuity equal to or better than the contralateral eye before surgery. After surgery, this more than doubled to 48% (212/446). When split into the different diagnostic groups, the keratoconus group showed the greatest improvement: in only 11% of patients was the eye to be grafted the better eye, but after surgery the grafted eye was better in 59% of patients (Fig 2). The figures for Fuchs' dystrophy were similar. With bullous keratopathy and "other diagnosis" there was rather less improvement in the percentage of grafted eyes having as good as or better visual acuity than the other eye. The postoperative visual acuity was more likely to be as good as or better than the contralateral eye in females and in the absence of other pathology (Table 5). Again, a centre effect was evident.

Astigmatism

The only factors that influenced the level of astigmatism at 2 years were diagnosis and clinic (Table 6). Although astigmatism was highest in the bullous keratopathy group, the difference was not large (Table 2). An alternative analysis of whether grafts had more than 3 dioptres of astigmatism, showed a similar result with grafts for bullous keratopathy being more likely to have higher astigmatism (data not shown).

Refractive surgery

Refractive surgery was performed after suture removal in 32 patients, mostly with keratoconus or Fuchs' dystrophy. This surgery was in all cases relaxing incisions and was mainly carried out in a single clinic. The refractive surgery reduced astigmatism in these grafts from 7.9 (95% CI 6.9, 8.7) to 3.2 (95% CI 2.6, 3.9) dioptres (paired t test: $t = 9.34$, df = 31, $p<0.001$).

DISCUSSION

Corneal grafting is a routine operation, which is most of the time straightforward. However, the rehabilitation time after surgery is long because of a slow healing process and many of the factors that affect visual outcome are uncertain. It is, therefore, especially important with this procedure to try to understand more about what may be achieved in the long

Table 3 Factors influencing the likelihood of postoperative visual acuity being 0.5 or better

Variable	Coefficient b	STD error SE (b)	p Value	Odds ratio exp(b)	Confidence interval 95% CI for exp (b) Lower	Upper
Procedure						
PKP				1.00		
Triple	−1.54	0.56	0.007	0.22	0.07	0.65
Other	−0.60	0.77	0.43	0.55	0.12	2.46
Preoperative visual acuity	0.99	0.36	0.006	2.67	1.33	5.44
Astigmatism	−1.41	0.42	0.001	0.24	0.11	0.55
Other pathology						
No				1.00		
Yes	−4.63	0.65	<0.001	0.01	0.003	0.04
Not known	−2.86	0.79	<0.001	0.06	0.01	0.27
Clinic						
A				1.00		
B	0.66	0.80	0.41	1.94	0.41	9.24
C	−0.44	0.97	0.65	0.65	0.10	4.32
D	3.04	0.72	<0.001	20.80	2.08	85.16
E	3.39	0.75	<0.001	29.52	6.83	127.61
Constant	4.85	1.37				

Final statistical model derived by backwards stepwise logistic regression.
Variables entered initially: age, sex, diagnosis, lens status, type of procedure, preoperative visual acuity, astigmatism, rejection, other complications, other pathology, and clinic.
Odds ratios >1 (OR>1) indicate increased likelihood that VA≥0.5.
OR<1 indicate reduced likelihood that VA≥0.5.
For categorical variables, the likelihood associated with each factor is compared with a baseline factor (OR=1.00); for example, the influence of diagnosis is relative to keratoconus.
For continuous variables, such as astigmatism, OR>1 indicates increased likelihood that VA≥0.5 with increasing values of the variable. Conversely, OR<1 indicates decreased likelihood that VA≥0.5 with increasing values of the variable.

term. In this way we can not only improve patient selection for corneal transplantation, but also better inform our patients, giving them perhaps more realistic expectations. In previous studies much of the interest has often been focused on graft survival. This is of course an important issue; but a major aim of other studies[1 2] and the Swedish Corneal Transplant Register is to understand more about visual outcome in our patients as the majority of grafts are done to improve vision. The register may also be used to monitor changes in the indications for corneal transplantation and provide clinical outcome data when new surgical procedures are introduced. The register thus works as a quality control, providing feedback to the surgeons, the clinics, government and, most importantly, to patients. One advantage with the Swedish Corneal Transplant Register is that only a small group of surgeons covers corneal grafting in the whole country. Meetings are held once a year to

Table 4 Factors influencing the likelihood of postoperative visual acuity being 0.2 or worse

Variable	Coefficient b	STD error SE (b)	p Value	Odds ratio exp (b)	Confidence interval 95% CI for exp (b) Lower	Upper
Age	−0.04	0.019	0.053	0.96	0.93	1.00
Diagnosis						
Keratoconus				1.00		
Fuchs' dystrophy	3.39	1.40	0.02	29.56	1.89	461.45
Bullous keratatopathy	3.23	1.36	0.02	25.30	1.76	363.32
Other	3.19	1.24	0.01	24.21	2.13	274.68
Preoperative visual acuity	−1.41	0.43	0.001	0.25	0.11	0.57
Other complications						
No				1.00		
Yes	2.08	0.79	0.01	7.97	1.69	37.57
Other pathology						
No				1.00		
Yes	4.10	0.69	<0.001	60.84	15.80	234.25
Not known	1.92	0.83	0.02	6.81	1.35	34.33
Clinic						
A				1.00		
B	−0.37	0.79	0.64	0.69	0.15	3.24
C	−0.84	1.88	0.66	0.43	0.01	17.28
D	−1.56	0.65	0.02	0.21	0.06	0.75
E	−2.43	0.67	<0.001	0.09	0.02	0.33
Constant	−2.06	1.44				

Final statistical model derived by backwards stepwise logistic regression.
Variables entered initially: age, sex, diagnosis, lens status, type of procedure, preoperative visual acuity, astigmatism, rejection, other complications, other pathology, and clinic.
OR>1, VA more likely to be ≤0.2; OR<1, VA less likely to be ≤0.2.

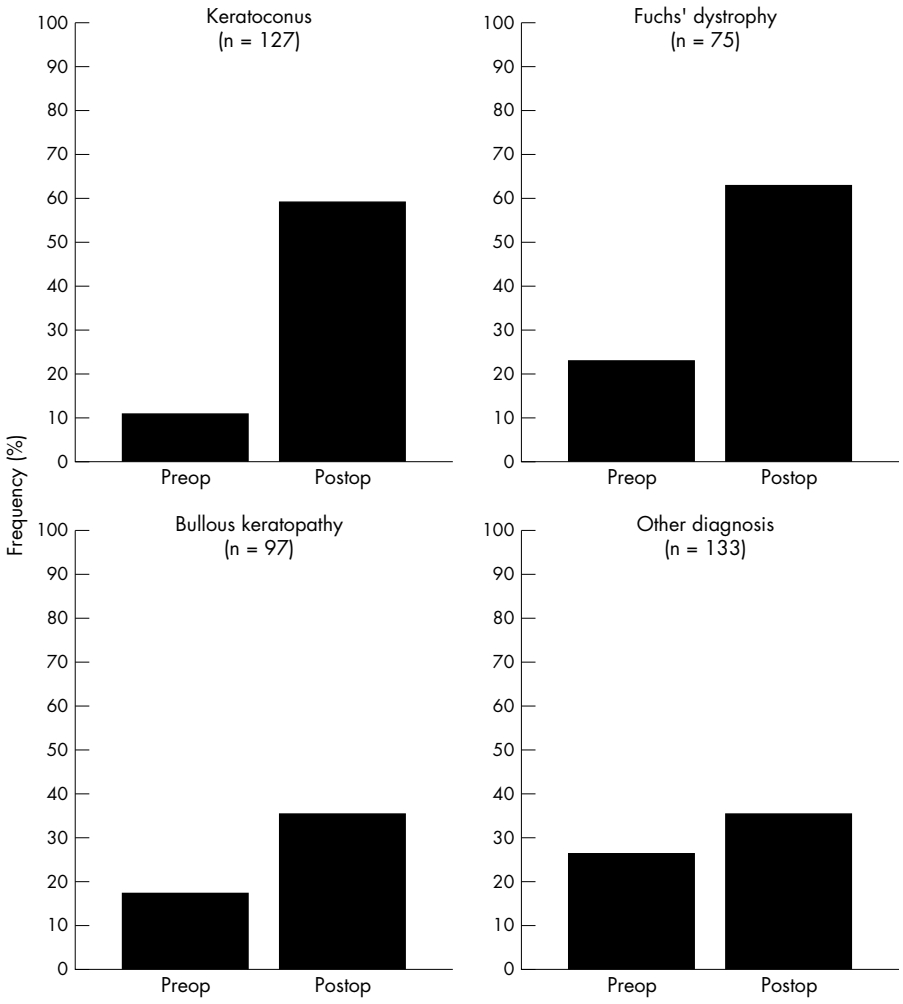

Figure 2 Visual acuity in the grafted eye equal to or better than the contralateral eye preoperatively and postoperatively.

discuss the design of the register and, as a result, there is a good agreement in surgical and clinical interpretation, and improvements can made to the data collection forms with increasing experience. The response rate is good with up to 96% of the grafts in Sweden being reported to the register in any one year (89% overall).

Table 5 Factors influencing the likelihood of postoperative visual acuity in the grafted eye being equal to or better than the contralateral eye

Variable	Coefficient b	STD error SE (b)	p Value	Odds ratio exp (b)	Confidence interval 95% CI for exp (b) Lower	Upper
Sex						
Male				1.00		
Female	0.61	0.30	0.04	1.85	1.03	3.31
Procedure						
PKP				1.00		
Triple	0.67	0.36	0.06	1.95	0.97	3.94
Other	−1.22	0.65	0.08	0.33	0.09	1.16
Other pathology						
No				1.00		
Yes	−1.26	0.34	<0.001	0.28	0.14	0.55
Not known	−0.61	0.54	0.26	0.55	0.19	1.58
Clinic						
A				1.00		
B	1.22	0.57	0.03	3.39	1.10	10.38
C	0.57	0.73	0.44	1.76	0.42	7.38
D	0.75	0.34	0.03	2.12	1.10	4.11
E	1.115	0.37	0.002	3.05	1.49	6.25
Constant	−0.08	0.29				

Final statistical model derived by backwards stepwise logistic regression.
Variables entered: age, sex, diagnosis, lens status, type of procedure, preoperative visual acuity, astigmatism, rejection, other complications, other pathology, and clinic.

Table 6 Factors influencing postoperative astigmatism

Variable	Coefficient b	SE (b)	t	p Value
Diagnosis				
Keratoconus	0.0			
Fuchs' dystrophy	0.14	0.10	1.35	0.18
Bullous keratatopathy	0.27	0.10	2.56	0.01
Other	0.17	0.10	1.66	0.10
Other complication				
No	0.0			
Yes	0.18	0.13	1.41	0.16
Clinic				
A	0.0			
B	0.16	0.15	1.07	0.28
C	0.44	0.22	2.05	0.04
D	0.17	0.09	1.81	0.07
E	–0.27	0.10	–2.79	0.006
Constant	1.764	0.158		

Final statistical model derived by backwards stepwise regression following square root transformation of astigmatism (dioptres).
Adjusted $R^2 = 0.08$, residual standard error = 0.61.
Variables initially entered: age, sex, diagnosis, lens status, type of procedure, rejection, other complications, other pathology, and clinic.

Table 7 Summary of distributions of diagnosis in 20 studies worldwide

Diagnosis	North America* No (%)	Rest of world† No (%)	Total No (%)
Keratoconus	2329 (14%)	5375 (27%)	7704 (21%)
Fuchs' dystrophy	2568 (15%)	1510 (8%)	4078 (11%)
Bullous keratopathy	5478 (32%)	4631 (23%)	10109 (27%)
Stromal dystrophies	231 (1%)	433 (2%)	664 (2%)
Other	6386 (38%)	8068 (40%)	14454 (39%)
Total	16992	20017	37009

*References 4–13; †references 1, 2, 14–21.
North America *v* RoW: $\chi^2_4 = 1570$, p<0.001.

The distributions of diagnoses and patient age were consistent with other studies from outside North America. Table 7 shows the differing distributions of diagnoses between North America and the rest of the world based on data from 20 studies, reflecting differences in the incidence of bullous keratopathy and keratoconus. The "other diagnosis" group in the present report turned out to be substantial, accounting for 32% of grafts. Since these grafts suffered a high proportion of complications and had poor visual outcome, further investigation will be made as to the different diagnoses hiding in this group. The data collection form has been accordingly modified to allow other diagnoses to be specified, and a separate code for regraft (previously included in "other diagnosis") has been added. Overall, grafts for keratoconus and Fuchs' dystrophy suffered fewer complications, including rejection, than grafts for bullous keratopathy or "other diagnosis." The higher incidence of rejection in grafts for bullous keratopathy agrees with the findings of Vail *et al*[2] who reported that the risk of rejection (based on an analysis of rejection-free survival at 1 year) was increased in the bullous keratopathy group.

Visual outcome at 2 years was determined by overall improvement in visual acuity and by the amount of astigmatism. Williams *et al*[3] have suggested (although it is not necessarily accepted by others[23]) that for patients to perceive a visual benefit from a corneal graft, the operated eye has to achieve a visual acuity at least as good as the other eye. In terms of visual acuity, the keratoconus patients did substantially better than the other diagnostic groups: 86% achieved a visual acuity ⩾ 0.5 at 2 years and 59% had a visual acuity in the grafted eye at least as good as the other eye. This success was due in part to the low incidence of other pathology in these eyes. That 41% of grafted eyes in keratoconic patients had poorer visual acuity than the other eye needs to be further investigated; one reason for this could be that the other eye had already been grafted, and, as a consequence, the data collection form has been accordingly modified to collect this information.

Both the Fuchs' dystrophy and the bullous keratopathy patients had a higher incidence of postoperative complications and of accompanying pathology that could adversely affect vision, than the keratoconus group. The visual outcome for Fuchs' dystrophy was, however, substantially better than for bullous keratopathy. Both these groups comprised elderly patients, accounting for the high incidence of accompanying pathology that would have included conditions such as age related macular degeneration. Additionally, however, the bullous keratopathy group would also have been prone to consequences of cataract surgery, such as persistent macula oedema, which was reflected in a 30% greater incidence of accompanying pathology compared with the Fuchs' dystrophy group. That the visual outcome for the bullous keratopathy group was so much poorer than for Fuchs' dystrophy also reflects the fact that many of these grafts would have been primarily for pain relief rather than for visual reasons, and that many of these patients have very low visual acuity in both eyes (99% had a preoperative visual acuity ⩽0.2). Whether pain relief was achieved in those grafts where this was the primary purpose cannot currently be determined from the register, but the data collection form could be modified to seek this information. The worst outcome overall was in the "other diagnosis" group. Sixty five per cent of the eyes in this group had other conditions, such as trauma, affecting sight. This group needs further investigation and these findings have also prompted modification of the data collection forms. The postoperative visual acuities in the different diagnostic groups are broadly similar to those reported in the Australian Corneal Graft Registry. Overall, 47% of the 7335 grafts included in the latest Australian report[1] achieved a visual acuity ⩾0.5 compared with 48% in the Swedish register, which is also a similar result to UK data, albeit at only 1 year follow up.[2]

Postoperative astigmatism clearly contributes to an unsatisfactory visual result after grafting. As with previous analyses,[2] the variables included in the statistical model accounted for only a small proportion (8%) of the variation in postoperative astigmatism. The number of grafts with ⩽3 D of astigmatism was 27%, which is similar to the 34% reported in the Australian registry.[1] A centre effect was noted and astigmatism tended to be higher in the bullous keratopathy group, although the effect was small. Keratoconic corneas would have had high astigmatism preoperatively whereas Fuchs' dystrophy and bullous keratopathy should have had levels of astigmatism within the range for normal eyes. The fact that grafting seemingly reduced astigmatism in keratoconus but increased it in the other groups further supports the contention that this seemingly intractable problem is related more to the procedure of corneal grafting itself than to the nature of the underlying corneal disease or other recipient factors. On the positive side, however, there was a clear benefit of relaxing incisions, which did reduce astigmatism, albeit in a small number of patients.

As data continue to be reported to the Swedish Corneal Transplant Register, it is expected that different questions will be formulated and answered on the basis of clinical evidence. This process, along with discussion of the nature of the centre effect and the information supplied by other follow up studies and corneal graft registers,[1 2 22] should lead to a better understanding of the factors that influence the visual outcome of corneal transplantation and thereby improve the postoperative management of grafts.

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