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Original Article

A 13-year descriptive study of corneal transplants at a tertiary, teaching hospital in northwest Iran

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Abstract

***Background & Aims*:** Corneal transplantation is considered the most transplanted solid tissue in humans. The purpose of the present investigation was to recognize the main indications and risk factors for allograft rejection.

***Materials & Methods*:** The medical files of all subjects who underwent penetrating keratoplasty at a major referral center in Northwest Iran (Urmia Imam Hospital) were retrospectively reviewed, regardless of the indication for transplantation, over a 13-year period, from 20 March 2002 to 19 March 2015.

***Results*:** In total, 327 cases of corneal transplantation were examined (mean age: 53.48 ± 22.44 years). Of these, 170 patients (52%) were male. Out of 327 individuals, 42 cases (12.8%) experienced graft rejection. Nearly three-quarters of rejected transplants (N = 31, 73.8%) occurred in patients ≥ 40 years (p = 0.381). No significant association was detected between graft rejection and gender (p = 0.136). The most frequent indications for corneal transplantation in cases with rejection were leukoma (N = 13, 31.0%), trauma (N = 12, 28.6%), and pseudophakic bullous keratopathy (PBK) (N = 9, 21.4%). The most prevalent causes of graft rejection included delayed follow-up (N = 17, 40.4%), recurrence of corneal dystrophies (N = 9, 21.4%), and graft failure (N = 9, 21.4%). Only 3 out of 17 patients (17.6%) with delayed follow-up achieved graft restoration.

***Conclusion*:** This study suggests a link between delayed follow-up and graft rejection. Prompt intervention improves the chances of regaining graft clarity, and patients must be well informed about the importance of follow-up visits.

***Keywords*:** Bullous Keratopathy, Corneal transplantation, Graft rejection, Trauma

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Introduction

The cornea, as an avascular connective tissue, is the first barrier against infections entering the eye (1). Irregular astigmatism, hereditary opacities such as macular dystrophy and granular corneal dystrophy, acquired opacities resulting from corneal trauma, infectious diseases caused by bacteria and fungi, herpes keratitis, and corneal edema are all associated with reduced vision and require treatment (2). Corneal transplantation is considered the most transplanted solid tissue in humans (3). Generally, indications for corneal transplantation include visual, structural, therapeutic, and cosmetic reasons (4).

Advances in medical equipment, increased expertise among specialists, and immunosuppressive drugs have contributed to the success of corneal transplantation. However, rejection of corneal transplants remains a significant challenge. Long-term survival rates vary widely between different large cohort investigations, ranging from ~50% to ~80%. Allograft rejection is regarded as the most common cause of graft failure, constituting up to 30% of graft failures (5, 6).

Risk factors for corneal graft rejection vary and differ among different populations. Genetic differences among populations, transplantation indications, diagnostic criteria for rejection, and immunosuppressive drug regimens can all contribute to this discrepancy. Factors such as the degree and severity of corneal vascularization in the recipient, secondary anterior segment surgeries, trauma, recurrent herpetic infections, anterior synechiae (adhesions), active inflammation during transplantation, repeat graft procedures, a history of previous graft rejection, irritating sutures, non-central graft ulcers, and uncontrolled intraocular pressure are considered paramount in graft rejection (6-9).

Demographic and population characteristics also play a role in the variability of data related to corneal transplantation indications and graft rejection. Rapid recognition, proactive measures to prevent the effects of rejection-promoting factors, and appropriate management of these parameters can lead to improved graft survival. The aim of this study was to investigate the indications and influential demographic factors related to graft rejection in corneal transplant patients at a referral tertiary teaching hospital in Northwest Iran.

Materials & Methods

This study is a descriptive, retrospective cohort that reviewed the records of all patients who underwent corneal transplantation at Urmia Imam Hospital, a major referral center in Northwest Iran, over a 13-year period, from 20 March 2002 to 19 March 2015. All subjects who underwent penetrating keratoplasty for the first time, regardless of the indication for transplantation, were included in this study. The study was reviewed and approved by the Ethics Committee of the Urmia University of Medical Sciences under the following code: IR.UMSU.REC.1395.597. It adhered to the ethical principles outlined in the Declaration of Helsinki.

All surgeries were conducted under general anesthesia by the main author (N.SA) according to a previously introduced technique (10). Eye tissue for transplants came from recently deceased donors or tissue banks. Corneas were cut using a Barron-Hessburg vacuum trephine. The transplanted cornea was larger than the recipient's button by 0.25 to 0.5 mm. 10-0 nylon (CU-1, Alcon Laboratories, USA) stitches were used to secure the new tissue in place with interrupted, single running, or combined sutures depending on the surgeon's discretion.

Postoperatively, betamethasone 0.1% eye drops were administered every 6 hr to reduce inflammation for 6-8 weeks. The doctors (N.SA and Q.M) adjusted the medication based on the eye's healing process. Topical steroids were gradually reduced over 8 weeks in cases without inflammation. Oral prednisolone (1-2 mg/kg for 1-2 weeks) was administered for corneal or anterior chamber inflammation. Sutures were usually removed 12 to 18 months after the operation. In the case of immunological rejection, topical and systemic steroids were prescribed. This treatment usually involved frequent dexamethasone eye drops (every 1 or 2 hr), subconjunctival injection of dexamethasone (1.2 to 2.0 mg), and oral prednisolone (30–60 mg/day) for 10-15 days. The steroid medication was gradually reduced over time. Signs of rejection were detected by two ophthalmologists (N.SA and Q.M). These signs included a faint line in the cornea's surface layer (epithelial rejection), hazy areas beneath the surface (subepithelial rejection), or swelling of the cornea combined with mild anterior chamber reaction and the presence of white keratic precipitates (endothelial rejection). For the purpose of statistical analysis (i.e., rejection time), only initial rejection episodes were considered. Graft failure was defined as irreversible

opacification of the cornea, preventing visualization of intricate iris details and leading to an estimated visual acuity of less than 20/60.

Variables such as age, gender, rate of graft rejections, time from transplantation to rejection, and transplantation indications were investigated in the current study. Data from the files were entered into a checklist and analyzed using SPSS v.21 statistical software. Qualitative data were reported as frequencies (percentages), and quantitative variables were presented as means ± standard deviation (SD) in tabular format. The Chi-square test or Fisher's exact test was used to compare the qualitative variables. *P* values less than 0.05 were considered statistically significant.

Results

In this descriptive investigation, 327 cases of corneal transplantation were examined. Of these, 170 patients (52%) were male, and 157 (48%) were female. The average age for male patients was 52.27 ± 24.35 years, while for female patients, it was 54.80 ± 20.16 years (mean age of the total population: 53.48 ± 22.44 years).

As demonstrated in Table 1, among the 327 cases, 42 transplants (12.8%) ended in graft rejection, while 285 cases (87.2%) survived. Regarding gender, 17 cases (40.5%) of graft rejection occurred in males, and 25 cases (59.5%) were observed in females. Statistical analysis using Fisher's Exact test failed to reveal a significant association between graft rejection and gender (p = 0.136) [OR = 1.704, CI = 0.882-3.294] (Table 1).

Table 1. Distribution of survived and rejected transplants across gender

Gender	Corneal transplants		*P* *
	Rejected (N = 42), n (%)	Survived (N = 285), n (%)	
Male (N = 170)	17 (40.5)	153 (53.7)	0.136
Female (N = 157)	25 (59.5)	132 (46.3)	

* Computed by Fisher's exact test

When considering age groups, 11 out of 42 rejected cases (26.2%) occurred in patients younger than 40 years, while 31 cases (73.8%) were detected in patients aged 40 years and older (Table 2). The association between graft rejection and recipient age group was not statistically significant (p = 0.381) [OR = 1.4541, CI = 0.701-3.018].

Table 2. Distribution of survived and rejected transplants in patients with < 40 vs. ≥ 40 years of age

Age	Corneal transplants		*P* *
	Rejected (N = 42), n (%)	Survived (N = 285), n (%)	
< 40 years (N = 108)	11 (26.2)	97 (34.0)	0.381
≥ 40 years (N = 219)	31 (73.8)	188 (66.0)	

* Computed by Fisher's exact test

The average duration (± SD) of corneal graft survival in the study population was 6.32 ± 3.13 years. The shortest graft survival time was 1 year, while the longest was 15 years. Among the rejected grafts, 1 case (2.4%) occurred within 1-2 years after transplantation, 7 cases (16.7%) within 2-4 years, 8 cases (19.0%) within 4-6 years, and 26 cases (61.9%) after more than 6 years (Table 3). No significant relationship was found between the frequency of graft rejection and rejection time intervals (p = 0.122).

Table 3. Distribution of survived and rejected transplants according to the post-surgery time intervals.

Post-surgery period	Graft rejection		*P* *
	Yes (N = 42), n (%)	No (N = 285), n (%)	
1-2 years (N = 39)	1 (2.4)	38 (13.3)	0.122
2-4 years (N = 71)	7 (16.7)	64 (22.5)	
4-6 years (N = 52)	8 (19.0)	44 (15.4)	
> 6 years (N = 165)	26 (61.9)	139 (48.8)	

* Computed by Fisher's exact test

As shown in Table 4, the three most frequent indications for corneal transplants among patients who experienced graft rejection (N = 42) were as follows: leukoma (N = 13, 31.0%), trauma (N = 12, 28.6%), and pseudophakic bullous keratopathy (PBK) (N = 9, 21.4%) (Table 4).

Table 4. Distribution of survived and rejected transplants according to the indication of transplantation

Indications for transplants	Graft rejection	
	Yes (N = 42), n (%)	No* (N = 285), n (%)
Leukoma (N = 89)	13 (31.0)	76 (26.7)
Trauma (N = 32)	12 (28.6)	20 (7.0)
PBK (N = 50)	9 (21.4)	41 (14.4)
KC (N = 86)	4 (9.5)	82 (28.8)
Corneal dystrophies (N = 25)	3 (7.1)	22 (7.7)
Adherent leukoma	1 (2.4)	4 (1.4)

Abbreviation. PBK: Pseudophakic Bullous Keratopathy; KC: Keratoconus

* Note that, indications with no rejection entry have not been presented here.

The most prevalent causes of graft rejection included delayed follow-up (N = 17, 40.4%), recurrence of corneal dystrophies (N = 9, 21.4%), and graft failure (N = 9, 21.4%) (Table 5). Among 42 eyes, only 19 (45.2%) regained graft transparency. Of these, 14 subjects maintained clear grafts according to their medical records. In the delayed follow-up category (N = 17) only three patients (17.6%) had restored transplants that preserved their clarity. This rate was 44.4%, 33.3%, 60.0%, and 50.0% among eyes that rejected transplants due to recurrence of corneal dystrophies, graft failure, trauma, and infection, respectively.

Table 5. Graft rejection cause in the studied population

Graft rejection cause	Frequency, N (%)
Delayed follow-up	17 (40.5)
Recurrence of corneal dystrophies	9 (21.4)
Graft failure	9 (21.4)
Trauma	5 (11.9)
Infection	2 (7.4)
Total	42 (100)

Discussion

The reported rates of graft rejection vary widely, ranging from 2.3% to 68%. In our study, the corneal graft rejection rate was 12.8% which is lower than the similar studies performed in Iran. A previous study by Karimian and colleagues, conducted at the Labbafinejad Medical Center (Tehran, Iran) between 1998 and 1999, reported a 31.8% rejection rate (10). This is while, in another study which had been carried out in the same Medical Center, Sanago et al. (1986 to 1992) had reported that 24% of eyes (N = 90) that underwent a single corneal graft and 57% (N = 29) of cases with multiple transplant surgeries experienced rejection (11).

In our study, out of 42 rejected grafts, 17 cases (40.5%) occurred in males, and 25 cases (59.5%) were detected in females. Although there was no statistically significant difference in graft rejection based on the gender (P = 0.07), females had a slightly higher percentage of corneal graft rejection compared to males. These findings align with a study by Stulting and colleagues (2013) conducted in the United States (12). In addition, our results are also consistent with Stulting's study regarding the lack of significant relationship between patient age and rejection rates (12). Bodaglu and colleagues (2014) also failed to find any marked association between recipient age and the risk of graft rejection (13). All in all, there are controversial findings in terms of recipient age and the probability of graft rejection in the literature. While some studies admitted a strong relationship between higher recipient age and lower graft success (14-17), others strongly dismissed such an association (18, 19). There are even evidences suggesting that the rejection rate diminishes with aging (20-22).

Unlike some studies that claim the majority of graft failures occur within the first post-operative year (21, 23), fewer rejections were observed in our study during the initial years following transplantation. Indeed, there is a loose consensus among ophthalmologists and surgeons that the rejection of corneal grafts tends to occur within the first 48 months of the transplant (24-26). However, it has been claimed that more than 10% of the rejected cases often emerge as late as four years after the operation. It must be noted that multiple factors play a key role in the fate of the grafts, some of which includes compatibility of recipients and donors (e.g. human leukocyte antigen (HLA) matching, ABO compatibility), characteristics of the host, surgery-related parameters (e.g. graft dimension, method of transplantation, lens status), postoperative factors (e.g. suture-related issues, topical drugs, immunosuppressive use, infection, etc.) and eye banking (e.g. preservation status, tissue storage media, death to graft time) (26, 27). Thus, variability in the rejection time across different studies could be ascribed to the discrepancy between them in terms of above-mentioned parameters.

In our investigation, trauma, PBK, leukoma, LCC, and corneal dystrophy were the most common indications for corneal transplantation. Similar findings were reported by some other researchers (26, 28-30). Eidizadeh and colleagues (2007), in one of the pioneering studies conducted in Iran, identified corneal scarring (29.5%), bullous keratopathy (PBK+ ABK) (28.7%), and active infective keratitis (20.9%) as the most common indications for corneal transplantation (31). Cornel dystrophies and PBK were also detected to be the most prevalent indications of graft failure in the study of Robinson et al. (1986) (32). Insler and Pechous (1986) claimed that up to 17% of repeated grafts is due to PBK (33). Several investigations have noted that PBK and ABK are considered as the most common primary indications for repeated transplantation (15, 34, 35). It has been suggested that the survival rate of the transplant is around 55% for corneal dystrophies, 49% for infectious leukomas, and 33% for trauma (36).

Delayed follow-up was recognized as the most frequent reason for graft rejection in the current study. Follow-up after corneal transplantation prevents potential problems and ensures that complications are perceived and handled early. During regular post-operative follow-ups, the specialist can optimize the dosage of topical drugs and immunosuppressives, evaluate the clinical presentation of the transplant, and

apply subsequent surgical interventions and hence, increase the chance of graft survival.

This study has some limitations. Firstly, its retrospective nature means researchers could only analyze data already collected in patient charts, potentially introducing bias if data collection wasn't standardized for the purpose of this study. Secondly, information about crucial factors known to influence corneal graft rejection was missing, such as the steroid medication regimen used, the size of the transplanted corneal tissue, and donor characteristics like cell count and age. Additionally, the analysis was limited by the relatively small number of patients involved. Finally, being conducted at a single center restricts the generalizability of the findings to other populations, as different centers may have variations in practices and patient demographics.

Conclusion

In the present study, the most common risk factors for graft failure were corneal dystrophy, bullous keratopathy, trauma and infection. On the other hand, trauma, PBK, and leukoma were recognized as the most prevalent indication of penetrating keratoplasty. Thus, we suggest these factors should be scrutinized by ophthalmologist when considering penetrating keratoplasty.

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Authors' Contributions

Conceptualization: N. SA., Q. M.; Methodology: N. SA., Q. M.; Data collection: N. SA., Q. M, A. S.; Data analysis: N. SA., A. S.; Writing - original draft: N. SA.' Writing - review & editing: Q. M.; Visualization: N. SA., Q. M.; Supervision: Q. M.; Project administration: N. SA., Q. M.; Ethics approval: A. S.; Literature review: N. SA., Q. M., A. S.; Validation: N. SA, Q. M, A. S.

Data Availability

The raw data supporting the conclusions of this article are available from the authors upon reasonable request.

Conflict of Interest

The authors have no conflicts of interest associated with the material presented in this paper.

Ethical Statement

The study was reviewed and approved by the Ethics Committee of the Urmia University of Medical Sciences under the following code: IR.UMSU.REC.1395.597.

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