

Comprehensive Retrospective Analysis of Corneal Donor Characteristics at the National Institute of Traumatology and Orthopedics Eye Bank (2013-2021)

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ABSTRACT

Background. Corneal transplantation success depends on good practices in tissue selection and preservation. This study aimed to assess the relationship between the time from the donor's death to the end of processing and corneal cellularity provided by the Eye Bank.

Methods. This was a retrospective study of 839 donor records (2013-2021) from the Eye Bank of the National Institute of Traumatology and Orthopedics, totaling 1445 corneas. Donors were classified based on cellularity (≤ 2000 and > 2000 cells/mm²) and laterality. The dependent variable was cellularity in the right eye (RE) and left eye (LE), categorized into ≤ 2000 and > 2000 cells/mm² groups. Independent variables included sex, age, cause of death, and Δ -death. The statistical software SPSS 26.0 (IBM SPSS, Inc, Armonk, NY, United States) was used, and $P < 0.05$ was considered significant.

Results. Among 839 donors, most were male (58.2%) and ≥ 60 years old (36.5%). Brain death (BD) was the primary cause of death (66.2%). A time from the donor's death to the end of processing interval of ≥ 10 hours occurred in 35.6% of cases. Cellularity > 2000 cells/mm² was similar for the RE (94.5%) and LE (93.9%). Age showed statistical significance ($P < 0.001$) in both eyes, with cellularity decreasing for donors ≥ 60 years. In BD cases, higher cellularity was observed in the LE ($P < 0.001$; 70.8%). A time from the donor's death to the end of processing interval and cellularity comparison showed relevance for the LE ($P = 0.03$) but no association for the RE.

Conclusions. Corneal cellularity decreased with increasing donor age. Significant differences in Δ -death were associated with cellularity, BD, and right and left cornea.

CORNEAL transplantation is a critical intervention for restoring vision in patients with various corneal disorders and represents the most common type of transplant performed worldwide [1]. In Brazil, corneal transplants accounted for most transplant procedures carried out between 2012 and 2022. Despite the significant number of corneal transplants, the demand continues to outpace the available supply, with 13,979 transplants performed in 2022 against an estimated need of 18,913. As of December, 3749 individuals were on the waiting list for corneal transplants in Rio de Janeiro [2].

The success of corneal transplantation hinges on multiple factors, including the availability and quality of donor corneas.

Donor characteristics, postmortem time, and preservation time heavily influence these factors. According to Brazilian legislation, once a donor has undergone clinical and serologic evaluations and is deemed suitable, ocular tissue may be removed up

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to 6 hours post-cardiac arrest or within 24 hours if the donor's body has been refrigerated between 2°C and 8°C [3].

Despite established guidelines, the scientific community has yet to reach a consensus regarding the optimal time interval between donor death and the end of processing (Δ -death) and its impact on corneal cellularity. Corneal cellularity is a critical determinant of the success and efficacy of corneal transplantation, and it is influenced by various donor factors, including age, postmortem time, and cold storage duration [4].

Given the increasing demand for corneal transplantation and the limited availability of suitable donor corneas, it is essential to understand the factors affecting corneal cellularity and identify the optimal Δ -death interval to enhance the success rate of corneal transplantation. This study investigates the relationship between Δ -death and corneal cellularity, using retrospective data from the Eye Bank of the National Institute of Traumatology and Orthopedics between 2013 and 2021. This research seeks to contribute to the existing body of knowledge and optimize corneal transplantation outcomes.

MATERIALS AND METHODS

This retrospective study analyzed 839 donor records from the Eye Bank of the National Institute of Traumatology and Orthopedics, collected between 2013 and 2021, comprising 1445 corneas.

Statistical Analysis

Data were recorded using a standardized form and tabulated in Excel software (Microsoft, Redmond, Wash, United States). The dependent variable (response) was corneal cellularity (right and left eyes), categorized into 2 groups: ≤ 2000 cells/mm² and >2000 cells/mm². The independent variables (predictors) included sex, age, cause of death, and the time interval between death and final corneal processing.

To examine the data, categorical variable percentage differences were compared using the Chi-square test (χ^2) or Fisher's exact test when appropriate. Scatter plots were created to determine correlations between continuous variables, employing Pearson's correlation coefficient (with data normality) and Spearman's correlation coefficient (without data normality). Data analyses were performed using IBM SPSS 26.0 (IBM SPSS, Inc, Armonk, NY, United States), and *P* values < 0.05 indicated statistically significant differences.

RESULTS

The present study assessed 839 patients, comprising 484 (58.2%) males and 349 (41.8%) females. The age distribution revealed a higher prevalence among individuals aged 60 years or older (36.5%), whereas the lowest frequency was observed among participants under 20 years old (7.9%). Brain death emerged as the primary cause of death, accounting for 552 (66.2%) cases, followed by cardiorespiratory arrest (*n* = 282; 33.8%) (Table 1).

In terms of the interval between the time of death and the end of corneal processing, most corneas exceeded 10 hours (35.6%), followed by 6 to 10 hours (33.0%) and <6 hours

Table 1. Characteristics of Donors and Corneas

Variables	n (%)
Sex (<i>n</i> = 833)	
Female	349 (41.8)
Male	484 (58.2)
Age (y) (<i>n</i> = 839)	
<20	66 (7.9)
20–29	83 (9.9)
30–39	88 (10.5)
40–49	110 (13.1)
50–59	186 (22.2)
60–69	209 (24.9)
70–79	97 (11.6)
Cause of death (<i>n</i> = 834)	
Cardiopulmonary arrest	282 (33.8)
Brain death	552 (66.2)
Δ t time of death and the end of processing (min) (<i>n</i> = 767)	
<360	241 (31.4)
360–600	253 (33.0)
>600	273 (35.6)
LE Cellularity (<i>n</i> = 723)	
≤ 2000	44 (6.1)
>2000	679 (93.9)
RE Cellularity (<i>n</i> = 722)	
≤ 2000	40 (5.5)
>2000	682 (94.5)

Δ t; LE, left eye; RE, right eye.

(31.4%). Most assessed corneas exhibited cellularity >2000 cells/mm², with comparable values in both eyes: 93.9% (*n* = 679) for the left eye and 94.5% (*n* = 682) for the right eye (Table 1).

No significant differences were observed regarding sex concerning cellularity in either group. However, a statistically significant difference (*P* < 0.001) was found in age when evaluating cellularity in both left and right eyes. In both groups, the highest frequency of low cellularity (<2000 cells/mm²) was observed among participants aged ≥ 60 years. Regarding the cause of death variable, a significant difference was observed only in the left cornea cellularity group (*P* < 0.001), with 70.8% of brain death cases exhibiting cellularity >2000 cells/mm². This value was similar in the group with cellularity ≥ 2000 cells/mm² in the right cornea (69.0%) but without statistical significance (*P* = 0.12) (Table 2).

Concerning the time between death and final processing, 430 (66.6%) left eye corneas with cellularity $\geq 2,000$ cells/mm² had up to 10 hours between death and final processing. The comparison between the time of death and final processing and cellularity revealed a statistically significant difference for the left cornea (*P* = 0.03) and no association for the right cornea (*P* = 0.10). However, the frequency of right eye corneas that had up to 10 hours between death and final processing was similar to that of left eye corneas (*n* = 425; 65.6%) (Table 2).

Upon evaluating potential correlations between the cellularity of both corneas (left and right) and the time between death and final processing, weak negative correlations were

Table 2. Association Between the Variables and Cellularity of the Right and Left Corneas

Variables	LE Cellularity		P value*	RE Cellularity		P value*
	≤2000 n = 44 (%)	>2000 n = 678 (%)		≤2000 n = 40 (%)	>2000 n = 681 (%)	
Sex						
Female	25 (56.8)	284 (41.9)	0.14	23 (57.5)	286 (42.0)	0.16
Male	19 (43.2)	394 (58.1)		17 (42.5)	395 (58.0)	
Age (y)						
<40	2 (4.5)	205 (30.2)	0.001 [†]	2 (5.0)	204 (30.0)	0.001 [†]
40–49	3 (6.8)	90 (13.3)		3 (7.5)	89 (13.1)	
50–59	5 (11.4)	156 (23.0)		7 (17.5)	151 (22.2)	
60–69	18 (40.9)	167 (24.6)		12 (30.0)	172 (25.3)	
70–79	16 (36.4)	60 (8.8)		16 (40.0)	65 (9.5)	
Cause of death						
Brain death	19 (43.2)	480 (70.8)	0.001	23 (57.5)	470 (69.0)	0.12
Cardiopulmonary arrest	25 (56.8)	198 (29.2)		17 (42.5)	211 (31.0)	
Δt time of death and the end of processing (min)*						
<360	13 (32.5)	206 (31.9)	0.03	16 (44.4)	198 (30.6)	0.10
360–600	7 (17.5)	224 (34.7)		7 (19.4)	227 (35.0)	
>600	20 (50.0)	215 (33.3)		13 (36.1)	223 (34.4)	

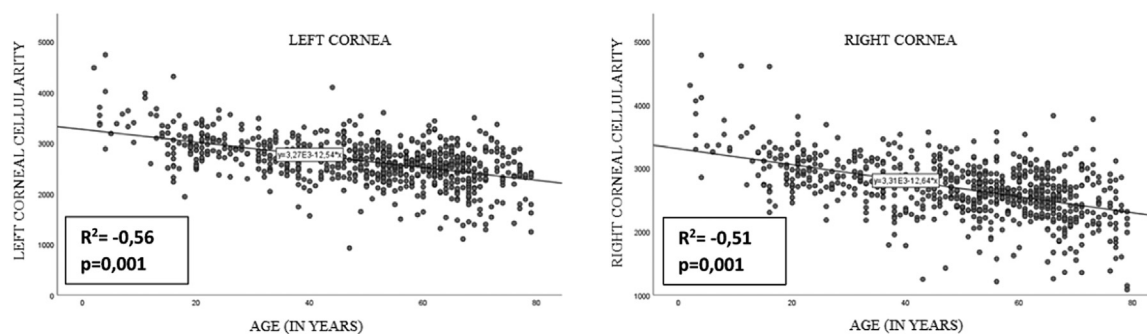
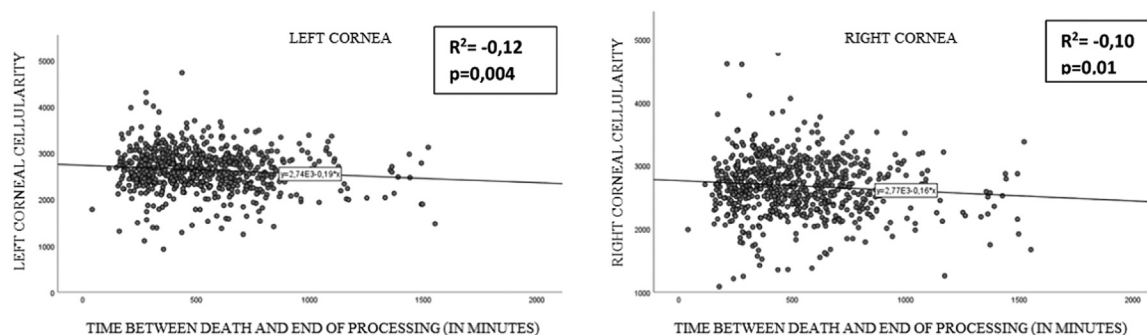
Δt; LE, left eye; RE, right eye.

* Chi-Square Test.

† n = 685 (LE); n = 684 (RE).

observed, with the cellularity of the right cornea yielding $r^2 = -0.10$ ($P = 0.013$) and the cellularity of the left cornea, $r^2 = -0.12$ ($P = 0.004$) (Fig 1). The correlation between cellularity and age showed a negative, statistically

significant correlation of approximately 50% in both corneas (right and left) ($P = 0.001$). This result indicates that for every one-year increase in age, cellularity decreases by 12.64 cells/mm² (Fig 2).

**Fig. 1.** Correlation between corneal cellularity and age.**Fig. 2.** Correlation between corneal cellularity and Δ-death.

DISCUSSION

In this study, conducted at the Eye Bank of Rio de Janeiro, located at the National Institute of Traumatology and Orthopedics, we found a limited and tenuous correlation between the interval from the time of death to the end of corneal processing. This finding has crucial implications for optimizing corneal transplantation protocols, particularly given the region's ongoing demand for donor corneas [5].

Quality assurance protocols for corneal transplantation aim to maintain high safety and efficacy standards for donor corneas [6]. However, these protocols can inadvertently contribute to reduced availability of corneas for transplantation. The Eye Bank of Rio de Janeiro has the potential to capture a significant number of ocular tissue donors in the state, but the number of corneas collected still falls short of the demand [2,5].

There is an inherent trade-off between adhering to a stringent protocol that ensures the quality of the transplanted organ and adopting a more relaxed protocol that increases the number of available corneas. The current findings suggest that the decline in corneal quality occurs relatively gradually as the interval between death and processing increases [7]. This indicates that there may be room to reevaluate the stringency of certain aspects of the quality assurance protocols without significantly compromising corneal quality.

Modifying the temporal parameters within the protocol could potentially enhance the availability of corneas for transplantation. Given that each hour exceeding Δ -death is associated with a decrease of 11.4 cells/mm² in cellularity, the connection between prolonged Δ -death intervals and diminished cell density highlights the necessity for timely recovery and preservation of corneas. This could be particularly beneficial in situations with a high demand for corneal transplants or a shortage of donor corneas, such as in Rio de Janeiro. Furthermore, a more flexible protocol could reduce the logistical challenges of coordinating and transporting donor corneas within a specific timeframe.

It is essential to carefully balance the trade-offs between maintaining the quality of donor corneas and increasing their availability for transplantation. Based on the present study's findings, further research is warranted to explore the potential benefits and risks associated with adjusting corneal processing time constraints. Such research could ultimately inform the development of more flexible and efficient corneal transplantation protocols that optimize both quality and availability, ultimately enhancing patient outcomes and increasing the overall success of corneal transplantation.

As the study was conducted at the Eye Bank of Rio de Janeiro, the findings may also provide valuable insights for the regional health care system, informing potential adjustments to their protocols and practices, given that 68.6% of corneal transplant donors exhibited a Δ -death interval not

exceeding 6 hours, and >94% demonstrated a cell density >2000 cells/mm². By addressing the current shortfall in corneal donations, the Eye Bank could significantly improve access to corneal transplants and ultimately help address the unmet needs of patients awaiting corneal transplantation in Rio de Janeiro.

In conclusion, this study highlights the importance of enhancing corneal transplantation outcomes through protocol optimization and reassessing the correlation between time of death and end of processing for improved efficiency and donor cornea availability.

This study underscores the need to revisit current corneal transplantation protocols to identify optimization opportunities. The observed limited and nuanced relationship between the time of death and the end of corneal processing calls for health care providers and policymakers to devise more adaptable and efficient strategies that can expand the availability of donor corneas without sacrificing their quality.

DATA AVAILABILITY

The data that has been used is confidential.

DECLARATION OF COMPETING INTEREST

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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