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## RESEARCH

### Causas do descarte de córneas captadas pelo banco de tecidos oculares do Rio Grande do Norte

Causes for the discards of corneas collected by the ocular tissues bank from Rio Grande do Norte

Causas de descarte de córneas procesados por el banco de tejidos oculares de Rio Grande do Norte

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### ABSTRACT

**Objective:** To identify the causes for the discards of corneas in the ocular tissue bank from Rio Grande do Norte. **Method:** This was an exploratory descriptive study, with retrospective data and quantitative approach, conducted in the ocular tissue bank from Rio Grande do Norte. The information was collected by means of an instrument containing: number of collected, transplanted, and discarded corneas; causes for the discards. **Results:** Out of the 548 collected corneas, 78.1% were preserved and 21.9% discarded. The prevalent causes for the discards were: stromal infiltrate, positive serology, and expired validity. **Conclusion:** Health professionals should be prepared to decrease the loss of corneas for avoidable reasons. **Descriptors:** Cornea transplant, Tissue donors, Tissue preservation.

### RESUMO

**Objetivo:** Identificar as causas dos descartes de córneas no banco de tecidos oculares do Rio Grande do Norte. **Método:** estudo exploratório descritivo, com dados retrospectivos e de abordagem quantitativa, realizado no banco de tecidos oculares do Rio Grande do Norte. As informações foram coletadas por meio de instrumento contendo: número de córneas preservadas, transplantadas e descartadas; causas dos descartes. **Resultados:** das 548 córneas captadas, 78,1% foram preservadas e 21,9% descartadas. As causas prevalentes dos descartes foram: infiltrado estromal, sorologia positiva e validade inspirada. **Conclusão:** os profissionais da saúde devem diminuir a perda de córneas por motivos evitáveis. **Descritores:** Transplante de córnea, Doadores de tecidos, Preservação de tecido.

### RESUMEN

**Objetivo:** Identificar las causas de los descartes de las córneas de un banco de tejidos oculares de Rio Grande do Norte. **Método:** Estudio exploratorio descriptivo con los datos retrospectivos y enfoque cuantitativo llevado a cabo los tejidos oculares de stock de Rio Grande do Norte. La información se recogió mediante un instrumento que contiene: número de córneas trasplantadas conservadas y descartadas; causas de los descartes. **Resultados:** De 548 trasplantes de córnea, el 78,1% y el 21,9% fueron preservados descartado. Las causas más frecuentes de los descartes fueron: infiltrado estromal, serología positiva y la validez de inspiración. **Conclusión:** Los profesionales de salud deben reducir la pérdida de córneas por razones evitables. **Descriptor:** Trasplante de córnea, Donadores de tejido, Conservación de tejido.

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## INTRODUCTION

**C**orneal diseases are the second most common cause of reversible blindness in the world, affecting more active young people, causing major social and economic loss.<sup>1</sup>

Cornea is defined as the ocular structure that performs the transmission and refraction of light that enters the eye. With the crystalline, it composes and focuses the images on the retina, as well as acts as a lens. The physiological intraocular pressure, absence of vases, low hydration, regular distribution of corneal layers, epithelial smooth surface, osmotic balance, and the proper tear film are factors that contribute to cornea transparency.<sup>1-2</sup>

Thus, the focus of the image of objects on the retina requires complete transparency in the cornea and crystalline. When the cornea and/or crystalline become opaque this function is compromised. Crystalline opacification is called a cataract; its treatment is surgical and consists in the replacement of the opaque crystalline with an artificial one. When the transparency of the cornea is irreversibly affected, corneal transplants or keratoplasty is need.<sup>3</sup>

Keratoplasty is the surgical procedure that replaces or recomposes the cornea, partially or fully. Thus, this treatment enables the visual recovery in patients with visual impairments caused by corneal diseases and the individual's reintegration in society.<sup>2, 4</sup>

Eye banks or Banks of Ocular Tissues (BOCT) take the responsibility for acceptance or refusal of donor tissues and the final decision on availability of corneas for transplant, ensuring their records of traceability for a minimum of 20 years.<sup>6, 7</sup>

Many factors influence the quality of donated corneas, among them, are the elapsed time between donor death and the removal of the cornea because the maximum allowed time is six hours; time in preservation media, even if the cornea is in preservation media for up to 14 days, studies show primary failure after a seven-day period; donor age and cause of death, patients with consumptive diseases show worsen corneal quality compared to those who had sudden death.<sup>1</sup>

According to the rules of the Pan American Association of Eye Banks (APABO) and the Eye Bank Association of America (EBAA), the donor screening protocol includes careful assessment from the interview with the donor's family, hospital chart analysis, and evaluation of the donor's body and the donated tissue. Even if corneas have been captured, they cannot be made available for therapeutic use if after evaluation by the BOCT they show clinical evidence of retinoblastoma, ocular active inflammation, malignant tumors of the anterior ocular segment, donors undergoing eye surgery, and congenital or acquired disorders such as cornea scar, keratoconus, and keratoglobus.<sup>8</sup>

In Brazil, the currently available BOCT protocol of inspection is based on the Collegiate Board Resolution - RDC number 67, from September 30, 2008, which rules on the

Technical Regulation for the operation of BOCTs of human origin.<sup>8</sup> Therefore, the disposal of corneas by the banks is part of the quality and safety control of tissues that will be provided to the population. Only when the discarding process is registered above average, it becomes indicative of some situation that deserves investigation.

Considering that the work developed in the BOCT has direct influence on the final quality of the donated cornea and, consequently, in the surgical result post-transplantation, the following question is prompt: what are the causes for the discard of corneas collected by the BOCT in Rio Grande do Norte?

With the support from these considerations, this study aimed to identify the causes for the disposal of corneas in the BTOC in Rio Grande do Norte.

Therefore, it is expected that this study will bring subsidies for a better control of donated corneas, avoiding their incorrect use or waste.

## METHOD

This was an exploratory descriptive study with retrospective data and quantitative approach, conducted in the BOCT, in Natal-RN, from January of 2011 to March of 2012.

A total of 548 donated corneas were included in the study, collected and processed (evaluated, preserved, reevaluated, and classified) by the staff of that bank. The information were obtained from the BOCT database through an instrument composed of the following information: number of donors in the State, number of preserved corneas, number of transplanted corneas in the State, number of discarded corneas and causes for the discards.

After approval by the Research Ethics Committee from the Onofre Lopes University Hospital under the Ethics Assessment Presentation Certificate (CAAE) nº 0007.0.294.000-10, the information were collected by the researchers in the BOCT database.

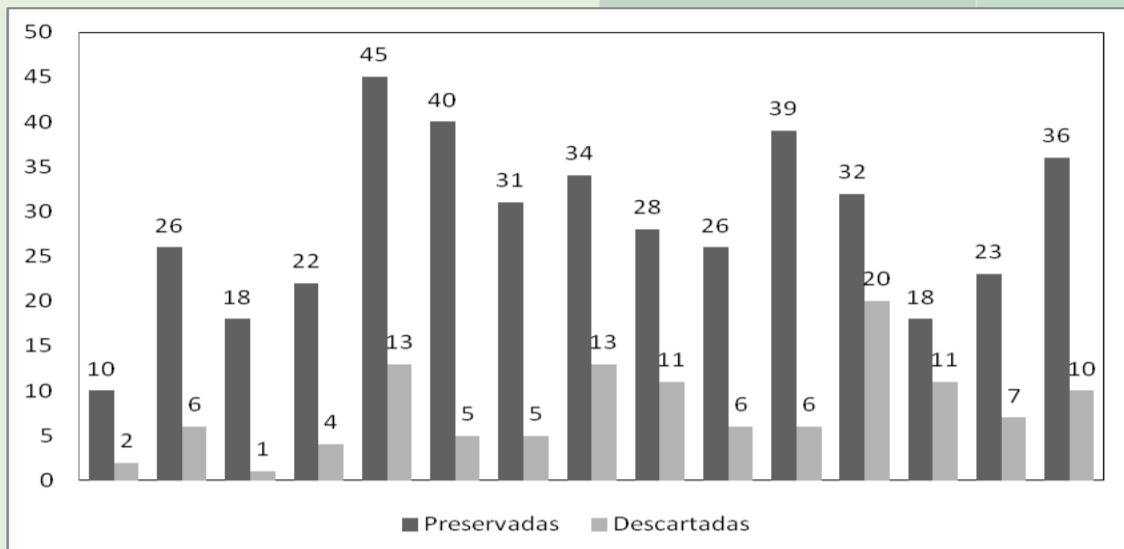
The data were tabulated and analyzed by descriptive statistics and presented in the form of graphs using the Microsoft-Excel and SPSS 15.0 softwares.

## RESULTS E DISCUSSION

According to the BOCT data for Rio Grande do Norte, during the period of 15 months, 548 corneas were donated, collected, and processed (evaluated, preserved, reevaluated, and classified) by the staff of that bank. Of this total, 428 (78.1%) were preserved, and 120 (21.9%) discarded. During the same period, 348 people have benefited from corneal transplants.

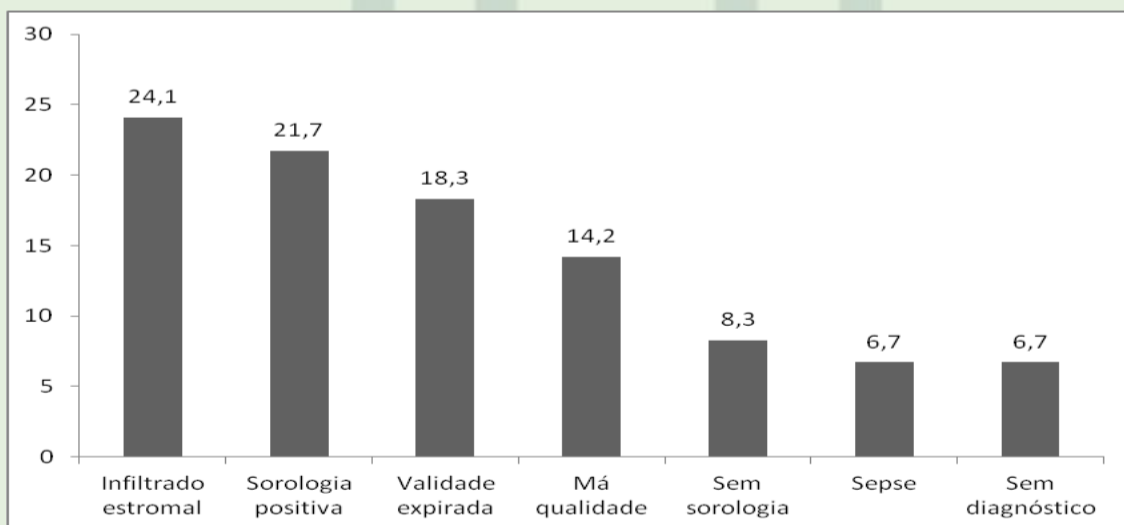
In the 15 studied months, it is observed that the number of discards ranged from 2 to 20 per month as shown in Graph 1.

Graph 01: Distribution of corneas preserved and discarded in the Ocular Tissue Bank in Rio Grande do Norte. Natal, RN. Brazil, 2014.



Stromal infiltrate (24.1%), followed by positive serology (21.7%), and expiration date for transplant (18.3%) are among the causes of corneal discard in Rio Grande do Norte, as presented in Graph 02.

Graph 02: Distribution of causes for the discards of corneas in the Ocular Tissue Bank in the State of Rio Grande do Norte. Natal, RN. Brazil, 2013.



Positive serology was present in 21.7% of the patients.

A considerable number of corneas were discarded because of expiration dates (18.3%) and poor tissue quality (14.2%).

Positive serology for hepatitis C and HIV was present at the percentage of 5% and 1.5%, respectively,

About the data from this research, it should be noted that the Collection and Donation of Organs and Tissues Notification Center (CNCDO) for transplantation in Rio Grande do Norte is increasingly augmenting its indexes in relation to organs and tissues collections for transplant. In January of 2011, there were 129 registered patients waiting for cornea transplants; this line reached zero in December of the same year. In March of 2012,

there were 14 patients in line waiting for corneal transplant in that State. However, the number of cornea discards is considered elevated.<sup>9</sup>

According to research conducted in some banks around the country, it was found that the rates of non-used corneas varies from 10% to 16.3%, which are numbers well below those found in this study.<sup>10</sup>

It is observed that the main cause for corneal discard was stromal infiltrate defined as the infiltrate in the tissue that supports the functional elements of the eye, the stroma. A study conducted in São Paulo showed that 10.9% of corneas were discarded for this reason, a percentage that is lower than that in the BOCT, in Natal.<sup>10</sup>

Tissues with stromal infiltrate become unusable on any type of transplant due to lesions unknown etiology. Tissue necrosis, lack of protection and eye occlusion in patients in intensive care units, emergency sectors or nursing wards are usually the causes for this occurrence. With the exposure of the cornea, epithelial ulcers might occur, paving the way for epithelial stromal infiltration by bacteria.<sup>10</sup>

The percentage of positive serology in this study was superior to that in a study conducted in Porto Alegre, where positive serology contraindicated 19.5% donations.<sup>2</sup>

The legislation in force concerning the standards for the provision of tissues for transplantation requires negative serology for hepatitis B, hepatitis C, and human immunodeficiency virus (HIV). In the case of hepatitis B, which stood out with 15% of discarded corneas, the most commonly used viral markers for sorting are the hepatitis B surface antigen (HBsAg), surface anti-antigen antibody (anti-HBs), core anti-antigen antibody (anti-HBc), and E anti-antigen antibody from hepatitis B (anti-HBe). The Eye Bank Association of America recommends the HBsAg because researchers question the effectiveness of anti-HBs, used in this study, in the cornea sorting process due its low specificity, despite its high sensitivity.<sup>5, 10, 11</sup>

Anti-HBs positive tests can occur in chronic hepatitis cases where the HBsAg did not turnout positive, acute hepatitis with full recovery and false positives. In international studies, positive serology for hepatitis B range from 0.92 to 3.0%; a much smaller number than that was found in this study, indicating flaws in the evaluation process of potential donors before corneas are collected, or the existence of disease underreporting.<sup>12</sup>

The serology for hepatitis C and HIV presented higher indexes compared to those found in the study in São Paulo, where 2.9% of corneas were discarded because positive serology for anti-HCV and 1.0% for HIV were detected. In the serology investigation for HIV, it is necessary to pay attention to the immunological window if the patient is between 4 to 6 weeks after contamination to avoid false data.<sup>13</sup>

It is worth pointing out that serology false positive results can occur due to hemolysis, tissue degradation, changing in pH, and changes that occur due to the extended time between death and venipuncture.<sup>13</sup>

Brazil presents a large number of cornea discards due to expired validity. In 2010 throughout the country, 1,687 corneas were discarded for this reason and in Rio Grande do Norte that number was 34, situation similar in the State of Pernambuco, where 35 corneas were discarded for the same reason.

However, when compared to the southern States, these figures become small because the number of discards increases as collection increases, ranging from 23 corneas in Espírito Santo to 957 corneas in São Paulo. It is emphasized that corneas must be transplanted within 14 days of collection.<sup>14</sup>

Exams to evaluate contamination and tests that assess tissue quality are performed when corneas are removed. A report is issued by the BOCT. This report is forwarded to the doctor who must transplant the patient in the queue. The surgery is scheduled, however, when receiving the material, the doctor often considers that the cornea is not suitable and returns it. Time elapsed during this whole process makes impossible sending the same cornea, still within the validity, to another patient. This cornea usually becomes unfit to be used for transplant after returning to the bank and ends up being discarded.<sup>5, 15</sup>

It should be noted that the quality of the cornea is directly related to the time elapsed between death and preservation; the tissue is unchanged up to six hours. As time increases, the cornea will lose quality, increasing the chances of changes in the corneal endothelium and epithelium. After the first six hours, the cornea is more susceptible to cell loss, the possibility of tissue exposure to trauma and toxicity of medicines and substances increases, and a consequent score reduction in the evaluation occurs. Thus, many donated corneas are unused, leaving those patients on hold, in the queue for a transplant, and in search of a better quality of life.<sup>5, 15</sup>

The poor quality of tissue can also result from anatomical changes, carelessness with the eyes during hospitalization, mistakes during the collection process, or as the result of long preservation. Some simple precautions are essential for the maintenance of a quality cornea such as lubrication of the eyes during hospitalization and closure of eyelids after death.<sup>1</sup>

Another problem that favored the discard of corneas was not conducting the serological tests resulting from hemolysis or insufficient blood sample (8.3%). These results were higher than those found in a study carried out in São Paulo, where 0.53% of corneas were discarded for this reason.<sup>10</sup>

In addition, 6.7% were discarded due to sepsis and no definition of a precise diagnosis in the potential donor. However, if the donor is using antibiotic, sepsis does not invalidate organ donation.<sup>16</sup>

Often, the lack of resources needed for the definition of a precise diagnosis harms the process of organ and tissue donation for transplantation. The determination of a medical diagnosis is one of the essential items to release an organ or tissue for transplant.<sup>17</sup>

## CONCLUSION

Despite the considerable increase in cornea donation and collection in the recent years, there are still people waiting in line for a transplant in hopes of improving their daily life conditions.

Therefore, it is unacceptable that a large number of cornea discards still occurs knowing that much can be done in the search for improved use of these donated tissues by families of potential donors in order to contribute to improvements in the lives of recipients.

It is known that in addition to the problems reported in this study, the decision-making process of organ donation is hampered due to the lack of understanding about brain death. On the other hand, families who opt for a donation take this attitude as a way to help people; they also believe that the donor would feel happy with the donation. In a way, the feeling of hope is generated in the families of donors that despite the loss of a loved one, other people will benefit from his organs.

Thus, it is emphasized that the conditions of the processing of corneas and potential donors should be better evaluated in the search of more accurate data. Macro and microbiological analyses, the conduction of rapid tests to evaluate potential donors before collection are needed in order to decrease the number of donated corneas that result unused for transplants.

Health professionals who deal with transplants and everything that surrounds them should be better trained to perform quality work maximizing the utilization of corneas and reducing losses due to preventable reasons.

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