
Epidemiological analysis of corneal donors and patients queuing for keratoplasty

Análise epidemiológica de doadores de córneas e pacientes em fila de espera para ceratoplastia

Mayk Penze Cardoso¹, Marcos Antonio Ferreira Junior^{1*}, Oleci Pereira Frota¹, Elen Ferraz Teston¹, Maria Eduarda Gonçalves Zulin¹

ABSTRACT

Purpose: To characterize corneal donors and patients on the waiting list for keratoplasty clinically and epidemiologically. **Methods:** Epidemiological, cross-sectional study with a sample of 1,303 donors and 938 patients on the waiting list were analyzed. Performed in MS State Transplant Center (STC) and the Human Ocular Tissue Bank, from January to June 2019. For the qualitative variables, descriptive analysis was performed. In the quantitative variables, trend and data dispersion measures were analyzed. **Results:** Of the 2,606 corneas, 31.73% were transplanted, 21.64% of donors were reagents for infectious diseases that contraindicated transplantation, with a higher percentage of reagents in donors aged over 50 years ($p < 0.001$). Keratoconus stood out as the main ocular diagnosis in the frequency distribution. The average age found for patients in the waiting line was 49.05 years. Regarding the average waiting time to perform the transplant, it was 108.46 days for elective transplants and 11.0 days for emergency transplants. **Conclusion:** More than 40% of the tissues taken from donors were discarded, with emphasis on epithelial defects and reagent serologies. Keratoconus was the main indication of patients queuing for keratoplasty.

Keywords: Corneal transplantation; Cornea; Free tissue flaps; Tissue donors; Blindness;

RESUMO

Objetivo: Caracterizar clínica e epidemiologicamente os doadores de córneas e os pacientes em fila de espera para ceratoplastia. **Método:** Estudo epidemiológico, de delineamento transversal, com análise de 1.303 doadores e 938 pacientes em lista de espera. Realizado junto a Central Estadual de Transplantes de Mato Grosso do Sul e um Banco de Tecido Ocular Humano, de janeiro a junho de 2019. Para as variáveis qualitativas realizou-se análise descritiva, enquanto nas quantitativas foram analisadas medidas de tendência e de dispersão dos dados. **Resultados:** Das 2.606 córneas, 31,73% foram transplantadas, 21,64% dos doadores foram reagentes para doenças infectocontagiosas que contraindicaram o transplante, com maior percentual de reagentes em doadores com idades acima de 50 anos ($p < 0,001$). Ceratocone se destacou como o principal diagnóstico ocular na distribuição de frequências. A idade média encontrada dos pacientes em fila foi de 49,05. **Conclusão:** Mais de 40% dos tecidos captados dos doadores foram descartados, com destaque para defeitos epiteliais e sorologias reagentes. O ceratocone foi a principal indicação dos pacientes em fila para realização da ceratoplastia.

Palavras-chave: Transplante de córnea; Córnea; Retalhos de tecido biológico; Doadores de tecidos; Obtenção de tecidos e órgãos; Cegueira;

¹ Universidade Federal de Mato Grosso do Sul.

*E-mail: marcos_junior@ufms.br

INTRODUCTION

Corneal diseases represent one of the main causes of reversible blindness in the world and keratoplasty, the most performed transplant in the world, consists of surgical and therapeutic treatment to restore visual function and improve the quality of life of patients on waiting lists through free tissue flaps (CRUZ et al., 2017).

Corneal blindness represents the fourth leading cause of blindness in the world. Programs to prevent injuries and diseases that affect the corneas have been implemented globally to avoid complications that lead to more intensive treatments such as keratoplasty. Access to transplantation is still hampered by the scarcity of corneal tissues available for lack of donors, however, even in developed countries (PINEDA, 2020; WHO, 2019).

Brazil has the largest public transplant system in the world, serving approximately 96% of the demand of the Unified Health System (UHS), through its National Transplant System (NTS). The NTS is responsible for the process of capturing and distributing the donated organs and tissues nationally, as well as for the management of waiting lists (BRAZIL, 2019).

The year 2019 showed a 1% increase in the rate of corneal transplants in Brazil when compared to the previous year, however, it was not possible to reach the planned goal, which made it difficult to reach the “zero list” of patients waiting for the procedure. This situation reflects the insufficient notification of potential tissue donors, effective donors and brain death in the country.

In this context, nursing plays a crucial role, since the Federal Council of Nursing regulated by Resolution no. 292/2004 the role of nurses throughout the process of donation and transplantation, and it is up to enforce the term of tissue donation, in addition to carrying out the enucleation of the eyeballs, as long as they are enabled, with follow-up, supervision and quality assurance of the process. Thus, nursing professionals must be aware of the conditions of donors and the waiting demand for keratoplasties in all authorized services (COFEN, 2004).

Thus, measures are necessary in Brazil to end this stagnation in all spheres involved in the transplantation process (ABTO, 2019). This study aims to characterize corneal donors and patients on the waiting list for keratoplasty clinically and epidemiologically in the state of MS, Brazil.

METHOD

This is a quantitative, cross-sectional and descriptive study, based on secondary data collected from the MS State Transplant Center (STC) and the Human Ocular Tissue Bank, from January to June 2019.

A census study was carried out, whose data were collected from information in medical records and record sheets. A pilot study was initially carried out in order to make the collection instrument more complete and accurate, including the medical records used in that phase in the final sample. An adapted instrument was used, based on a previous study (CRUZ, 2015), with prior authorization, referring to donors and patients on the waiting list registered in the STC, for a period of 5 years, from January 2014 to December 2018.

This time frame of analysis was due to the objective of conducting a quantitatively robust study, with a sample above the statistically necessary for analysis, carried out with a census sample and also capable of correcting a punctual change in the absolute number of corneal transplant procedures performed pmp in 2014, which presented a decrease when compared to previous years, with an increase in this number in the following years. During this period, data were obtained from corneal donors and patients on the waiting list for keratoplasties.

The data collected related to the donors and the patients on the waiting list during the data collection period. Both the patients actually on the waiting list and those who had already been transplanted on within the timeframe were studied. This inclusion criterion aimed to analyze in a longer time interval, which was the time expected to perform the intervention, and the characterization of the subjects.

Thus, the total population consisted of 1,303 donors and 938 patients on the waiting list. Of these, 796 had already undergone keratoplasty and 142 were awaiting the procedure during the data collection period.

The medical records of all those who met the pre-established criteria, of both sexes, without age limitation, regardless of the clinical condition indicating for registration in the NTS, were included, as there was logistical and operational feasibility to justify the population census. Patients whose medical records were not located or whose information was illegible, essential to meet the proposed objectives according to the variables studied, were excluded.

The database was built in a spreadsheet using Microsoft Excel® version 2017. For the data analysis, construction of descriptive tables and application of statistical tests, the free statistical software R, version 3.0.0 was used. For the qualitative

variables, the descriptive analysis was carried out through absolute and relative frequency distribution. For the quantitative variables evaluated, of trend and data dispersion measures were analyzed. When comparing the general characteristics of donors and patients on the waiting list with the clinical data, the Chi-square and Fisher's exact tests were applied. For all tests, the significance level adopted was 5%. The variables investigated concerning the donors were: sex, age group, color, place of residence, size of the corneal button, cause of death, donated cornea, serological status, abnormalities; and concerning the patients on the waiting list: gender, age group, eye diagnosis, transplanted eye, surgical purpose, type of surgery and transplantation.

The research protocol was previously approved by the Research Ethics Committee of the Federal University of Mato Grosso do Sul, considering the ethical and methodological aspects, under opinion nº. 3.177.423 and CAAE nº. 02619618.5.0000.0021, in accordance with National Health Council Resolution No. 466/2012 of the Brazilian Ministry of Health, which sets the guidelines and regulatory standards for research involving human beings nationally and internationally.

RESULTS

The profile of the corneal donor in the state did not differ from that found in other regions/states of Brazil and other countries in the world, as well as their causes of death. During the study period, 1,303 corneal donors were registered in the state of MS, whose sociodemographic characteristics are shown in Table 1 below.

Table 1. Sociodemographic characteristics of corneal donors in the state of Mato Grosso do Sul. Campo Grande/MS, 2021 (n=1,303).

Characteristics	n	%
Sex		
Male	861	66,08
Female	442	33,92
Age		
Over 50 years old	815	62,55
Up to 50 years old	488	37,45
Breed/color		
Mulatto	677	51,96
White	566	43,44
Black	58	4,45
Yellow	02	0,15
Residence*		
Campo Grande (capital)	1.077	83,04
Others cities (interior)	212	16,35

Others states	08	0,62
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* Six records did not contain this information.

External causes represented the main cause of death in young adults. The age group up to 50 years old showed a higher percentage of deaths from trauma, suicide, gunshot wounds and traffic accidents, when men were the main victims of this situation ($p < 0.001$).

The causes of death for the donors were cardiovascular (35.00%), cerebrovascular (21.11%), traumatic (14.35%), respiratory (8.29%), firearm injuries (4.60%), neoplasms (2.76%) and others (13.89%). Among women, vascular and respiratory causes showed a statistically significant relationship. Men, on the other hand, more frequently presented external causes ($p < 0.001$) – Table 2.

Table 2. Causes of death, ocular abnormalities and results of corneal donor serology. Campo Grande/MS, 2021 (n=1,303).

Characteristics	Sex		p
	Female (442) n (%)	Male (861) n (%)	
Causes of death			
Traffic accident	05 (1,13)	18 (2,09)	
Indeterminate	07 (1,58)	05 (0,58)	
Cardiovascular	163(36,88)	293 (34,03)	
Cerebrovascular	121 (27,38)	154 (17,89)	
Gastrointestinal	02 (0,45)	05 (0,58)	
Kidneys	08 (1,81)	13 (1,51)	
Respiratory	44 (9,95)	64 (7,43)	
Hepatical cirrhosis	01 (0,23)	02 (0,23)	
Metabolic disorders	03 (0,68)	02 (0,23)	<0,001
Multiple organ failure	07 (1,58)	13 (1,51)	
White weapon injury	02 (0,45)	18 (2,09)	
Firearm Injury	06 (1,36)	54 (6,27)	
Murder	01 (0,23)	07 (0,81)	
Neoplasm	16 (3,62)	20 (2,32)	
Sepsis	06 (1,36)	13 (1,51)	
Suicide	10 (2,26)	22 (2,56)	
Trauma	36 (8,15)	151 (17,55)	
Others	04 (0,90)	07 (0,81)	
Ocular abnormality			
No	370 (83,71)	685 (79,56)	0,071
Yes	72 (16,29)	176 (20,44)	
Serology *			
Non-reactive	336 (78,69)	651 (77,32)	0,578
Reactive	91 (21,31)	191 (22,68)	

Note: *Some records did not contain this information.

Of the 2,606 corneas from 1,303 donors, 44.40% were discarded, 23.45% were destined for other states, 31.73% were transplanted and 0.42% did not contain information in the medical records. Corneal abnormalities were present in 28.55% of donors, the main ones being epithelial defects (33.27%), pterygium (32.28%) and stromal infiltrate (27.42%), among others (7.03%).

Regarding the serological situation, 21.64% of donors were reagents for infectious diseases that contraindicated the transplant, particularly hepatitis B (59.05%), Human Immunodeficiency Virus (HIV) (27.30%), Human T-cell Lymphotropic Virus (HTLV) (7.52%) and hepatitis C (6.13%). Furthermore, a higher percentage of reactive serological situations was found in donors aged over 50 years ($p < 0.001$).

Regarding the patients on the waiting list, data were collected from 938 patients who were enrolled in the pre-established period of the study, registered in the NTS by authorized physicians, at the State Transplant Center. The average age found was 49.05 ± 22.28 years, ranging between 11.01 and 95.11 years. Regarding the average waiting time to perform the transplant, it was 108.46 days for elective transplants and 11.0 days for emergency transplants. The other characteristics are presented in table 3.

Table 3. Clinical-epidemiological profile of patients on the waiting list for keratoplasty in Mato Grosso do Sul. Campo Grande/MS, Brazil, 2021 (n=938).

Characteristics	n	%
Operated eye		
Right	469	50,00
Left	469	50,00
Surgical purpose		
Optics	923	98,40
Tectonics	15	1,60
Type of surgery		
Elective	877	93,50
Urgency	61	6,50
Transplanted		
Yes	796	84,86
No	142	15,14
Sex		
Female	498	53,09
Male	440	46,91
Age		
Over 50 years old	485	51,71
Up to 50 years old	453	48,29
Breed/color		
Mulatto	462	49,25
White	428	45,63

Black	31	3,30
Yellow	17	1,82
Residence		
Campo Grande (capital)	515	54,90
Others cities (interior)	380	40,52
Others states	43	4,58

Statistically significant differences were found when analyzing the variables "eye diagnosis" crossed with the characterization variables such as gender, age group, surgical purpose and type of surgery (Table 4).

Table 4. Ocular diagnosis versus clinical and epidemiological characteristics of patients on the waiting list. Campo Grande/MS, Brazil, 2019 (n=938).

Characteristics	Ocular Diagnosis									Total	p*
	Keratoconus	Bullous keratopathy	Leucoma	Fuchs' Dystrophy	Secondary or late bankruptcy	Interstitial keratitis	Other corneal dystrophies	Eorneal degeneration	Eye burn		
	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	
Sex											
Female	154 (30,92)	151 (30,32)	57 (11,45)	61 (12,25)	32 (6,43)	21 (4,22)	10 (2,00)	09 (1,81)	03 (0,60)	498 (100)	<0,001
Male	195 (44,32)	84 (19,09)	71 (16,14)	16 (3,64)	32 (7,27)	25 (5,68)	13 (2,95)	03 (0,68)	01 (0,23)	440 (100)	
Age											
Over 50 years old	328 (67,63)	18 (3,71)	69 (14,23)	2,27 (11)	24 (4,95)	21 (4,33)	10 (2,06)	02 (0,41)	02 (0,41)	485 (100)	<0,001
Up to 50 years old	21 (4,64)	217 (47,90)	59 (13,02)	66 (14,57)	40 (8,83)	25 (5,52)	13 (2,87)	10 (2,21)	02 (0,44)	453 (100)	
Operated eye											
Right	185 (39,45)	117 (24,95)	52 (11,09)	42 (8,96)	37 (7,89)	18 (3,84)	12 (2,55)	04 (0,85)	02 (0,42)	469 (100)	0,174
Left	164 (34,97)	118 (25,16)	76 (16,20)	35 (7,46)	27 (5,76)	28 (5,97)	11 (2,35)	08 (1,71)	02 (0,42)	469 (100)	
Surgical purpose											
Optics	349 (37,82)	235 (25,46)	125 (13,54)	76 (8,23)	63 (6,83)	41 (4,44)	22 (2,38)	10 (1,08)	02 (0,22)	923(100)	<0,001
Tectonics	-	-	03 (20,00)	01 (6,67)	01 (6,67)	05 (33,33)	01 (6,67)	02 (13,33)	02 (13,33)	15 (100)	
Type of surgery											
Elective	347 (39,57)	228 (26,00)	117 (13,34)	76 (8,66)	61 (6,69)	20 (2,28)	17 (1,94)	10 (1,14)	01 (0,11)	877 (100)	<0,001
Urgency	02 (3,28)	07 (11,48)	11 (18,03)	01 (1,64)	03 (4,92)	26 (42,62)	06 (9,83)	02 (3,28)	03 (4,92)	61 (100)	
Transplanted											
Yes	289 (36,30)	210 (26,37)	106 (13,32)	65 (8,17)	51 (6,41)	43 (5,40)	21 (2,64)	08 (1,01)	03 (0,38)	796 (100)	0,098
No	60 (42,25)	25 (17,61)	22 (15,49)	12 (8,45)	13 (9,15)	03 (2,11)	02 (1,41)	04 (2,82)	01 (0,71)	142 (100)	

* Chi-Square and/or Fisher's Exact statistical tests.

Keratoconus stood out as the main ocular diagnosis in the frequency distribution, with 37.21% of the cases, and showed statistically significant differences for the variables male gender, age group up to 50 years, optical surgical purpose and for elective surgery ($p < 0.001$).

Bullous keratopathy was the second most frequent ocular diagnosis in patients on the waiting list with 25.05% of cases, with a statistically significant difference for female patients, aged over 50 years, optical surgical purpose and elective surgery ($p < 0.001$). Next, leukoma corresponded to 13.65% of the diagnoses, with a statistically significant difference for male patients, aged up to 50 years, tectonic surgical purpose and emergency surgery ($p < 0.001$).

Fuchs' dystrophy was prevalent in 8.21% of the cases, with a statistical difference in relation to the female gender, age over 50 years, optical surgical purpose and elective surgery ($p < 0.001$).

DISCUSSION

The results found in the research corroborate with similar studies, where a greater number of corneal donations from male patients prevailed (66.08%). The description of this variable is relevant, as there are studies that demonstrate the influence of gender incompatibility between donor and recipient on the patient's prognosis after the transplantation (HOPKINSON et al., 2017; ROCON; ALMEIDA; PARO, 2015; SILVA et al., 2016; VICTER et al., 2019)

The age group above 50 years of age predominated among the donors, in line with studies carried out both nationally and internationally. The results are similarly to the United States, a reference country in corneal transplants in the world. Current Brazilian legislation allows donors from two to eighty years, as long as the tissue is viable for transplantation. Thus, the need to assess the quality of donated tissue is essential to guarantee the viability for transplantation. A study carried out in the state of Rio Grande do Sul, Brazil, highlighted the specular microscopic endothelial evaluation of corneas from donors over 70 years old and demonstrated the importance of uptake in this age group, since it had a good endothelial cell count, so that it was viable for transplantation, either with tectonic or optical availability (LASS et al., 2015; BRAZIL, 2017; LOPES; CASTILHOS, 2017).

As for race, mulatto (51.96%) and white (43.44%) patients were found more frequently in the study, followed by black (4.45%) and yellow (0.15%) individuals. The

racial ethnic differences of each region of Brazil need to be taken into account when analyzing this study variable. According to the latest demographic census of the Brazilian Institute of Geography and Statistics (IBGE), the state of MS had a significant majority of self-declared white and brown people, with 47.28% and 43.59%, respectively (GOVERNMENT OF THE STATE OF MATO GROSSO DO SUL)

Most donors lived in Campo Grande (83.04%), this fact can be explained by the fact that the referral services, such as STC and the main hospital transplant services, are located in the state capital. In addition, the demographic density of Campo Grande is the largest among the cities of MS (IBGE, 2010).

In some studies analyzed in Brazil, such as the Organ and Tissue Search Organization of the Clinics Hospital of the Campinas State University, as well as in the Brazilian Transplant Registry, vascular and traumatic causes figure as the main cause of death among the donors (BERTASI et al., 2019; ABTO, 2018).

The serological testing of corneal donors is mandatory to exclude infection by the hepatitis B virus, infection by HIV 1 and 2, infection by the hepatitis C virus and infection by HTLV 1 and 2. These data diverged from other studies conducted in Brazil. In a study in Paraná, positive serology was the reason for discarding in 49.6%, against 68% in a study in the Federal District. The significant statistical relationship found between donors over 50 years of age and seropositivity for contagious infectious diseases that contraindicate transplantation is justified by the increase in life expectancy coupled with the advance in health technologies that prolonged sexual life in the elderly. Another justification is that the population in general and even health professionals still treat sexuality in old age as a taboo (VICTER et al., 2019; FREITAS et al., 2019; BRAZIL, 2015; BASTOS et al., 2018).

Regarding the patients on the waiting list for keratoplasty, there was a considerable increase in the number of registrants in the last five years, from 22 in 2014 to 130 in 2018. The number of effective pmp donors rose from 5.7 to 16.6 though, higher than the annual target. This situation can be justified by the excessive demand from patients who have been placed in the queue in recent years, as well as by the increase in family refusal during the interview to attract donors, so that the system was not able to meet all the demands necessary to zero the queue (ABTO, 2019; ABTO, 2014).

In similar studies, an oscillation of the gender variable was observed among patients on the waiting list. A higher prevalence was found, sometimes in male patients,

sometimes in female individuals, however, there was no statistically significant relationship in the analysis of raw or relative data. This fact can be justified by the different population characteristics of each region (ALMEIDA; SOUZA, 2014; BORGES et al., 2016; PEREIRA et al., 2019).

Regarding the waiting time for the transplant, there is a disparity in relation to states in the North, such as Pará, where patients waited an average of 365 days, a fact that is justified by the difficulty in the North in relation to the structuring of the transplant service, in view of logistical problems, lack of support between state and municipal governments and reduction in notifications from potential donors (ALMEIDA SOBRINHO; NEGRÃO; ALMEIDA, 2011).

As for the higher prevalence of keratoconus, similar results were found in studies conducted in the Brazilian state of Rio Grande do Norte and in developed countries such as Canada. On the other hand, differences were found in other Brazilian state such as Pernambuco, which revealed leukoma as the most frequent indication. This divergence can be justified by the availability of new treatments for keratoconus, other than corneal transplantation, such as special contact lenses, cross linking and implantation of the intra-stromal ring, which permits a delay in the progression of the disease (ABTO, 2014; ALMEIDA SOBRINHO; NEGRÃO; ALMEIDA, 2011; BENSON et al., 2018; CRUZ et al., 2018; LOPES; PINTO; SOUZA, 2015).

Bullous keratopathy was the second most frequent ocular diagnoses in patients on the waiting list, with 25.05% of cases. Studies carried out in São José do Rio Preto/SP and in countries in the Middle East demonstrated similar results. This prevalence is justified by the high incidence of bullous keratopathy after cataract surgery. There has been an exponential growth of phacoemulsification in recent years, which has directly interfered in the incidence of bullous keratopathy due to corneal edema from surgical trauma (ALTAY et al., 2016; BARBOSA et al., 2012; ZARE et al., 2012).

A study carried out in the interior of the state of São Paulo demonstrated that leukoma affected male patients more frequently, however, with an average age of 52.3 years. Men tend to develop leukoma more frequently due to the higher incidence of trauma and keratitis, although the frequencies increase with age. This result is similar to studies carried out in the state of Minas Gerais, with a frequency of 14.09%, and in other countries such as Colombia, with a prevalence of 16.22% of cases. Although leukoma is categorized as an elective disease, some of its causes can lead to an

emergency situation such as post-trauma leukoma (BRAZIL, 2017; BARBOSA et al., 2012; COLL; URIBE; MOLANO-GONZÁLEZ, 2019; NEVES; BOTEON; SANTIAGO, 2010).

The level of education and knowledge of the patient in relation to the procedure that will be submitted are as important as the surgical act itself, so the performance of the nursing team becomes essential for monitoring the client who will perform the corneal transplant throughout the process from preoperative to hospital discharge. Thus, the transplant becomes a safe process with adequate recovery for the transplanted. The cornea harvested by nurses had increased chance of positive outcomes (NOGUEIRA; SILVA; SANTOS, 2019; SOUZA; CERQUEIRA; NOGUEIRA, 2011).

When considering the data obtained from this study, noted that patients queuing for keratoplasty maintained a significant number throughout the investigated period, which refers to a demand not met by the corneal transplant system, due to an insufficient number of corneas suitable for the procedure. It is noteworthy that almost half of the corneas collected after donation were discarded, due to clinical and laboratory screening criteria. This way, if the losses were smaller, the lines would be reduced or even eliminated.

Reactive serologies and the structural and functional conditions of the captured corneas were the limiting factors, which indicates the need to improve the screening process of potential donors for more effective captures, with the need for more studies to assess the weight of these factors to target services of corneal transplants.

This study allows to identify factors related to the clinical and epidemiological characterization of donors and patients on waiting lists and to cover variables with a view to expanding the knowledge about this process, thus improving the corneal capture system in the state, as the discards of this ocular tissue present expressive numbers when compared to other countries. In addition, family refusal is still a limiting factor in the uptake of ocular tissue, and thus needs further research with a view to sustaining government strategies to reduce the waiting list to zero.

One limitation in this study is the absence of some donor data due to incorrect or nonexistent completion, so that not all information could be used for description and analysis. This corresponds to a very small part of the research sample though. Thus, the total number of subjects analyzed in the study reduced the possible bias deriving from these losses.

CONCLUSION

The discards stood out in relation to the tissues used for transplantation, as 44% of all donated tissue was discarded, with epithelial defect as the main cause. Serologies were significantly present in donors over 50 years old, with a predominance of reactive serologies for the identification of the hepatitis B virus.

The average age of patients on the waiting list was 49.05 years. Keratoconus was the main clinical condition that indicated transplantation in the description of clinical data. Male patients had a higher prevalence of keratoconus and leukoma. In women, bullous keratopathy and Fuchs' dystrophy were the prevalent diagnoses. The average waiting time for transplantation was 108.46 days in elective surgeries and 11.0 days in urgent cases.

Thus, MS stands out with a reduced waiting times compared to other Brazilian states, mainly in the North and Northeast, where waiting times were much longer than those found in this study. This enhances the quality of life of patients who are waiting for a corneal transplant, so that the procedure is performed in a timely manner and avoids complications arising from the conditions that indicate keratoplasty.

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