

# Quality Indicators For The Processing And Use Of Sclera For Transplantation In Brazil: An Ecological Study

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Section editor: Ilka de Fátima Santana F. Boin 

Received: Mar. 4, 2026 | Approved: June 1, 2026

## ABSTRACT

**Introduction:** The scarcity of ocular tissues available for transplantation still represents a challenge for the Brazilian National Transplant System. The sclera has clinical importance in reconstructive surgeries, and its procurement, preservation, and distribution depend on the efficiency of Human Eye Tissue Banks. The analysis of quality indicators allows for the identification of weaknesses and guides strategies for optimizing therapeutic use. **Objective:** To generate quality indicators for analyzing the processing and use of sclera for transplantation in Brazil. **Method:** A quantitative, ecological, descriptive, observational study based on the Brazilian Production Report of Human Eye Tissue Banks from the National Health Surveillance Agency. Forty-six Human Eye Tissue Banks distributed across the five Brazilian regions were included. The values were relative per million population and calculated using five indicators: utilization rate of preserved sclera, disqualification rate, therapeutic use rate, transplant rate relative to the total preserved tissue, and overall efficiency index. Regional comparisons were performed using the Kruskal-Wallis test, the Dwass-Steel-Critchlow-Fligner post-hoc test, and the epsilon squared test to assess the magnitude of the differences found, all with a significance level of 0.05. **Results:** Human Eye Tissue Banks preserved 2,741 sclerae in one year, mainly concentrated in the Southeast (33.4%) and South (24.4%) regions. The national disqualification rate was 23.5%, ranging from 11.6% in the Central-West to 66.1% in the North ( $p < 0.01$ ). The utilization rate was higher in the South (94.5%) and lower in the North (26.6%), while the therapeutic use rate stood out in the Southeast (61.8%) and South (57.9%). The transplantation rate as a percentage of the total preserved tissue reached 74.9% in the Southeast and 76.5% in the Midwest, in contrast to 32.9% in the Northeast. The overall efficiency index ranged from 40.0% (Northeast) to 90.0% (Midwest), highlighting significant regional inequality. **Conclusion:** Regional inequalities were observed in the production and utilization of scleral tissue, with better performance in the Midwest, Southeast, and South regions. The North and Northeast presented operational and structural weaknesses. The findings reinforce the need for process standardization, team training, and strengthening of the national network to expand the availability and therapeutic use of scleral tissue.

**Descriptors:** Sclera; Eye Banks; Tissue Banks; Efficiency; Tissue Transplantation.

## *Indicadores de Qualidade do Processamento e Uso de Escleras para Transplante no Brasil: Estudo Ecológico*

### RESUMO

**Introdução:** A escassez de tecidos oculares disponíveis para transplante representa um desafio para o Sistema Nacional de Transplantes brasileiro. A esclera tem importância clínica em cirurgias reconstrutivas e sua captação, preservação e distribuição dependem da eficiência dos Bancos de Tecidos Oculares Humanos. A análise de indicadores de qualidade permite identificar fragilidades e orientar estratégias para otimização do uso terapêutico. **Objetivo:** Gerar indicadores de qualidade para análise do processamento e uso de escleras para transplante no Brasil. **Método:** Estudo quantitativo, ecológico, descritivo, observacional, baseado no Relatório Nacional de Produção dos Bancos de Tecido Ocular Humano da Agência Nacional de Vigilância Sanitária. Foram incluídos 46 Bancos de Tecido Ocular Humano distribuídos pelas cinco regiões brasileiras. Os valores foram relativizados por milhão de população e calculados em cinco indicadores: taxa de aproveitamento de escleras preservadas, taxa de desqualificação, taxa de uso terapêutico, taxa de transplantes sobre o total de tecido preservado e índice de eficiência global. Comparações regionais foram realizadas com uso do teste de Kruskal-Wallis, pós-teste de Dwass-Steel-Critchlow-Fligner e épsilon quadrado para avaliar a magnitude das diferenças encontradas, todos com nível de significância de 0,05. **Resultados:** Os Bancos de Tecido Ocular Humano preservaram 2.741 escleras em um ano, concentradas principalmente nas regiões Sudeste (33,4%) e Sul (24,4%). A taxa de desqualificação nacional foi de 23,5%, com variação de 11,6% no Centro-Oeste a 66,1% no Norte ( $p < 0,01$ ). A taxa de aproveitamento foi maior no Sul (94,5%) e menor no Norte (26,6%), enquanto a taxa de uso terapêutico destacou-se no Sudeste (61,8%) e Sul (57,9%). A taxa de transplantes sobre o total de tecido preservado atingiu 74,9% no Sudeste e 76,5% no Centro-Oeste, em contraste com 32,9% no Nordeste. O índice de eficiência global variou de 40% (Nordeste) a 90% (Centro-Oeste), evidenciando desigualdade regional significativa. **Conclusão:** Observaram-se desigualdades regionais na produção e no aproveitamento do tecido escleral, com melhor desempenho nas regiões Centro-Oeste, Sudeste e Sul. Norte e Nordeste apresentaram fragilidades operacionais e estruturais. Os achados reforçam a necessidade de padronização de processos, capacitação de equipes e fortalecimento da rede nacional com vistas a ampliar a disponibilidade e o uso terapêutico do tecido escleral.

**Descritores:** Esclera; Bancos de Olhos; Bancos de Tecidos; Eficiência; Transplante de Tecidos.

### INTRODUCTION

The eye is a complex, delicate organ essential for vision and, consequently, indispensable to an individual's interaction with the environment. Its structure consists of different internal and external components that perform specific functions, including optical structures such as the cornea and lens; sensory structures such as the retina; and structural tissues such as the sclera<sup>1</sup>.

The word "sclera" originates from the Greek word *skleros*, meaning "hard" or "rigid," referring to its main structural characteristic. Anatomically, it is the outermost layer of the eyeball, covering approximately 5/6 of the eye's surface, continuous with the cornea anteriorly and with the optic nerve sheath posteriorly<sup>2</sup>.

The sclera consists of a collagenous tissue composed of three main layers: the episclera, the outermost and highly vascularized layer; the scleral stroma, the intermediate layer, predominantly comprised of dense, irregular collagen fibers that provide mechanical resistance; and the lamina fusca, the innermost layer, characterized by pigmented cells<sup>3</sup>.

Its main function is to maintain the shape of the eye and protect internal structures, such as the retina and choroid, against trauma and fluctuations in intraocular pressure<sup>4</sup>. Furthermore, it plays an important role in supporting and maintaining the shape of the eyeball and serves as the insertion point for the extraocular muscles, which are responsible for eye movement<sup>5</sup>. Therefore, scleral alterations or lesions can significantly compromise the integrity of the eye and result in functional and aesthetic impairments, affecting people's quality of life, especially when visual capacity is reduced<sup>6</sup>.

Among the main conditions affecting the sclera are scleromalacia, characterized by progressive thinning of the tissue and frequently associated with autoimmune diseases such as rheumatoid arthritis; surgical complications resulting from the use of grafts to cover exposed antiglaucoma valves; and perforations resulting from trauma, ulcers, or infections<sup>7</sup>. In these cases, scleral transplantation becomes necessary to restore or reinforce the structural integrity of the tissue, which is of great importance in specific situations such as advanced scleromalacia, ocular trauma with tissue loss, orbital reconstructions, and coverage of devices implanted in glaucoma surgeries<sup>8</sup>.

The sclera also has surgical indications in cases of tumors, when it is used for aesthetic reconstruction of the orbit. There are reports of its use in cases of enucleation due to tumors with subsequent implantation of acrylic orbits covered with sclera donated for transplants<sup>9</sup>.

Scleral tissue is obtained from deceased donors, and its procurement occurs through ocular enucleation. Generally, this process is managed by Human Eye Tissue Banks (HETB), which are institutions responsible for the procurement, processing, storage, and serological and microbiological screening of ocular tissues, in compliance with the Collegiate Directorate Resolution (RDC, *Resolução da Diretoria Colegiada*) No. 707 of Jul. 1, 2022, issued by the Brazilian Health Regulatory Agency (ANVISA, *Agência Nacional de Vigilância Sanitária*)<sup>10</sup>.

Due to its avascular nature, the sclera has low immunogenic potential, making transplantation relatively safe and effective. Therefore, scleral transplantation represents a valuable alternative for maintaining ocular form and function across various clinical conditions<sup>11</sup>.

In Brazil, no current studies have been identified that address epidemiological data on the procurement, utilization, and efficiency of scleral tissue distribution and use for transplantation. While the scientific literature focuses mainly on corneal transplants, the sclera remains underexplored, underscoring the lack of evidence regarding the prevalence of this procedure in Brazil and across its regions.

That said, this article aimed to develop quality indicators to analyze the processing and use of sclera for transplantation in Brazil.

## METHOD

The present study is an ecological study of institutional aggregates, with a quantitative, descriptive, and observational approach, conducted in Brazil based on national data regarding all scleral tissue processing and release from 2024, made available by Anvisa through HETB production reports.

The time frame is justified because it represents the most recent year for which complete data were available at the time of this research. This report was prepared in accordance with the Revised Standards for Quality Improvement Reporting Excellence (SQUIRE 2.0) guidelines.

The study population comprised aggregated data from 46 HETBs distributed across the five Brazilian macro-regions (North, Northeast, Central-West, Southeast, and South). All records available in the "Tissue Production 2024" database were included, relating to preserved sclera, disqualified sclera, sclera made available for therapeutic use, and transplants performed during the same year. Records relating to corneal production were excluded.

The data used in this study are secondary and within the public domain. To obtain the information extracted from the spreadsheet in .xlsx format, titled "Produção dos Bancos de Tecidos – 2024" and available on the official Anvisa website, the following navigation path was followed: initially, "Anvisa" was entered into a browser search bar, and upon accessing the institutional homepage (<https://www.gov.br/anvisa/pt-br>), the "Centrais de Conteúdo" section was selected.

The 'Publicações' tab was then accessed, and the 'Sangue, tecidos, células, órgãos e terapias avançadas' category was selected. Within this category, the item 'Relatórios de produção dos Bancos de Tecidos' was located, and the file named 'Dados Brutos de Produção dos Bancos de Tecidos – 2024' was downloaded.

This material, available in a spreadsheet format, compiles standardized information from the institutions responsible for the collection and distribution of tissues throughout the country and includes data on the different types collected, stored, rejected, destined for treatment, or actually transplanted.

After downloading the file, the data were organized and tabulated to begin statistical processing. Initially, all information regarding corneas was excluded. Subsequently, the annual production sum for each HETB was calculated, since the database provides semi-annual data. Afterward, the information provided by the municipality where each HETB is located was grouped and aggregated by Brazilian macro-region. Upon completion of this stage, the data were statistically analyzed.

Descriptive analyses were employed using absolute and relative frequencies, measures of central tendency (medians), and measures of dispersion (Interquartile Range – IQR).

To calculate the quality indicators for HETB production and for inferential analyses related to scleral tissue, population-relative values were used to allow for comparisons. Thus, the absolute values of sclera preserved, disqualified, made available, and delivered for therapeutic use, as well as the number of transplants performed, were divided by the population of the respective region in 2024 and multiplied by the population per million (PMP), resulting in relative regional rates. After relativizing the absolute PMP values, five indicators were calculated, as shown in Table 1 below.

To assess whether the data for the investigated variables were normally distributed, the Shapiro-Wilk test was applied, followed by Q-Q plots and boxplots. Since the data did not conform to a normal distribution, non-parametric tests were employed for the inferential analysis.

**Table 1.** Indicators developed for the analysis of production in Brazilian Human Ocular Tissue Banks, with their respective calculations and interpretations.

| Developed Indicators                  | Indicator Calculation                                                                        | Indicator Interpretation                                                                         |
|---------------------------------------|----------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------|
| Utilization rate of preserved scleras | Sclerae made available for therapeutic use /<br>Escleras preservadas (PMP) $\times$ 100      | Proportion of preserved sclerae made available for therapeutic use.                              |
| Disqualification rate                 | Disqualified sclerae (PMP) /<br>Preserved sclerae (PMP) $\times$ 100                         | Proportion of preserved sclerae disqualified during the process.                                 |
| Therapeutic use rate                  | Transplants performed (PMP) /<br>Sclerae made available (PMP) $\times$ 100                   | Proportion of sclera transplants that were made available that actually resulted in transplants. |
| Transplant-to-total-preserved ratio   | Transplants performed (PMP) /<br>Preserved sclerae (PMP) $\times$ 100                        | Final utilization efficiency of preserved sclerae in transplant procedures.                      |
| Global efficiency index               | Transplants (PMP) /<br>Preserved scleras (PMP) - Disqualified sclerae<br>(PMP) $\times$ 100. | Overall yield of scleral tissue management, accounting for losses due to disqualification.       |

Source: Elaborated by the authors.

Considering that the outcome variables are quantitative and the grouping variable has more than two levels, the Kruskal-Wallis test followed by the Dwass-Steel-Critchlow-Fligner (DSCF) post-test was used to investigate possible statistically significant differences between the prevalence of preserved sclera, sclera disqualified after preservation, sclera made available and delivered for therapeutic use, and sclera transplants reported to the HETB in 2024, in the five Brazilian macro-regions (Midwest, Northeast, North, Southeast, and South). Epsilon-squared ( $\epsilon^2$ ) was used to evaluate the magnitude of the differences identified in the Kruskal-Wallis test. For all inferential tests, a 5% significance level ( $\alpha=0.05$ ) was adopted.

Since this study was based on de-identified secondary data from the public domain, it was exempt from submission to a Research Ethics Committee (*Comitê de Ética em Pesquisa*) for prior evaluation and approval.

## RESULTS

The study included information from 46 HETBs distributed across the five regions of Brazil. Data on the number of preserved sclerae, post-preservation losses, tissues made available for therapeutic use, effective delivery for therapeutic use, and transplants performed were analyzed, providing a comprehensive view of national production during the period analyzed.

In absolute terms, 2,741 sclerae were preserved in 2024. The distribution showed significant regional inequality: the Southeast accounted for the largest share (33.42%), followed by the South (24%) and the North (17.44%). The Northeast (13.97%) and the Midwest (11.16%) had less significant shares. The median number of HETB preservasions was 72 (IQR: 16.5–159), indicating an asymmetrical distribution across the country's macro-regions.

The population-adjusted analysis (PMP) showed a distinct pattern: the highest preservation rate occurred in the North region (25.60 PMP), followed by the South (21.15 PMP) and Midwest (17.93 PMP), whereas the Southeast and Northeast had the lowest PMP preservation rates.

One noteworthy finding was the post-preservation loss rate, which totaled 646 disqualified sclera. The North region showed a particularly unfavorable performance, with a discard rate of 16.93 PMP, which was higher than in the other regions. In contrast, the South (2.83 PMP) and Southeast (1.35 PMP) had lower rates.

After screening, 2,086 sclerae were made available for therapeutic use. In this context, the South (17.87 PMP) and Midwest (13.18 PMP) regions stood out, while the North region showed reduced participation (6.80 PMP). Regarding actual delivery, 1,416 sclerae were delivered for therapeutic use. The South region had the highest rate (13.66 PMP), followed by the Southeast (6.41 PMP), while the North recorded the lowest rate (0.64 PMP).

A total of 1,370 sclera transplants were reported to the HETB, accounting for approximately 49.98% of preserved tissues. The highest PMP indicators were found in the South (15.65 PMP) and Midwest (13.71 PMP), while the North (0.75 PMP) and Northeast (2.21 PMP) showed the lowest prevalence of the procedure (Table 2).

Regarding the utilization of preserved sclera, the Southeast region presented the highest percentage (90.17%), followed by the South (84.50%) and Northeast (81.20%). In contrast, the North region had the lowest utilization rate at 26.57%. In terms of the disqualification rate, the North also stood out negatively, with 66.11%, while the lowest rates were observed in the Southeast (13.10%) and South (13.37%).

The highest rates of therapeutic use were observed in the Midwest (104%) and the South (87.59%). In contrast, the lowest rates occurred in the Northeast (40.51%) and North (11.02%). Regarding the proportion of transplants to the total preserved, the Midwest (76.47%) and Southeast (74.01%) had the highest percentages, while the North recorded the lowest value (2.93%).

**Table 2.** Scleral tissue processing by Human Eye Tissue Banks/HETB (*Bancos de Tecido Ocular Humano- BTOH*) in Brazil in 2024, by macro-region. Campo Grande/MS, Brazil, 2026 (n = 46).

| Variables                                  | Region           |                    |                |                    |                | Median (IQR)       | Total |
|--------------------------------------------|------------------|--------------------|----------------|--------------------|----------------|--------------------|-------|
|                                            | Midwest<br>n (%) | Northeast<br>n (%) | North<br>n (%) | Southeast<br>n (%) | South<br>n (%) |                    |       |
| Preserved sclerae                          | 306 (11.16)      | 383 (13.97)        | 478 (17.44)    | 916 (33.42)        | 658 (24.00)    | 72.0<br>(16.5–159) | 2,741 |
| PMP Proportion                             | 17.93            | 6.71               | 25.60          | 10.34              | 21.15          | x                  | -     |
| Disqualified sclerae after preservation    | 46 (7.12)        | 75 (11.61)         | 316 (48.92)    | 121 (18.73)        | 88 (13.62)     | 8.0<br>(2.25–20.3) | 646   |
| PMP Proportion                             | 2.69             | 1.31               | 16.93          | 1.35               | 2.83           | x                  | -     |
| Sclerae made available for therapeutic use | 255 (12.22)      | 311 (14.91)        | 127 (6.09)     | 835 (40.03)        | 558 (26.75)    | 34.5<br>(5.0–132)  | 2,086 |
| PMP Proportion                             | 13.18            | 5.45               | 6.80           | 9.32               | 17.87          | x                  | -     |
| Sclerae delivered for therapeutic use      | 250 (17.65)      | 156 (11.02)        | 12 (0.85)      | 573 (40.47)        | 425 (30.01)    | 13.5<br>(3.5–89)   | 1,416 |
| PMP Proportion                             | 14.65            | 2.73               | 0.64           | 6.41               | 13.66          | x                  | -     |
| Transplants performed                      | 234 (17.08)      | 126 (9.20)         | 14 (1.02)      | 509 (37.15)        | 487 (35.55)    | 13.0<br>(4.0–65.5) | 1,370 |
| PMP Proportion                             | 13.71            | 2.21               | 0.75           | 5.69               | 15.65          | x                  | -     |

Note: IQR: interquartile range; PMP: per million population. Source: Anvisa.

Finally, the overall efficiency index was higher in the Midwest (90%) and South (85.44%) than in the North (8.64%), which had the lowest efficiency in the country during the period analyzed (Table 3).

**Table 3.** Sclera processing quality indicators by Human Eye Tissue Banks/ HETB (*Bancos de Tecido Ocular Humano- BTOH*) in Brazil in 2024, by macro-region. Campo Grande/MS, Brazil, 2026 (n = 46).

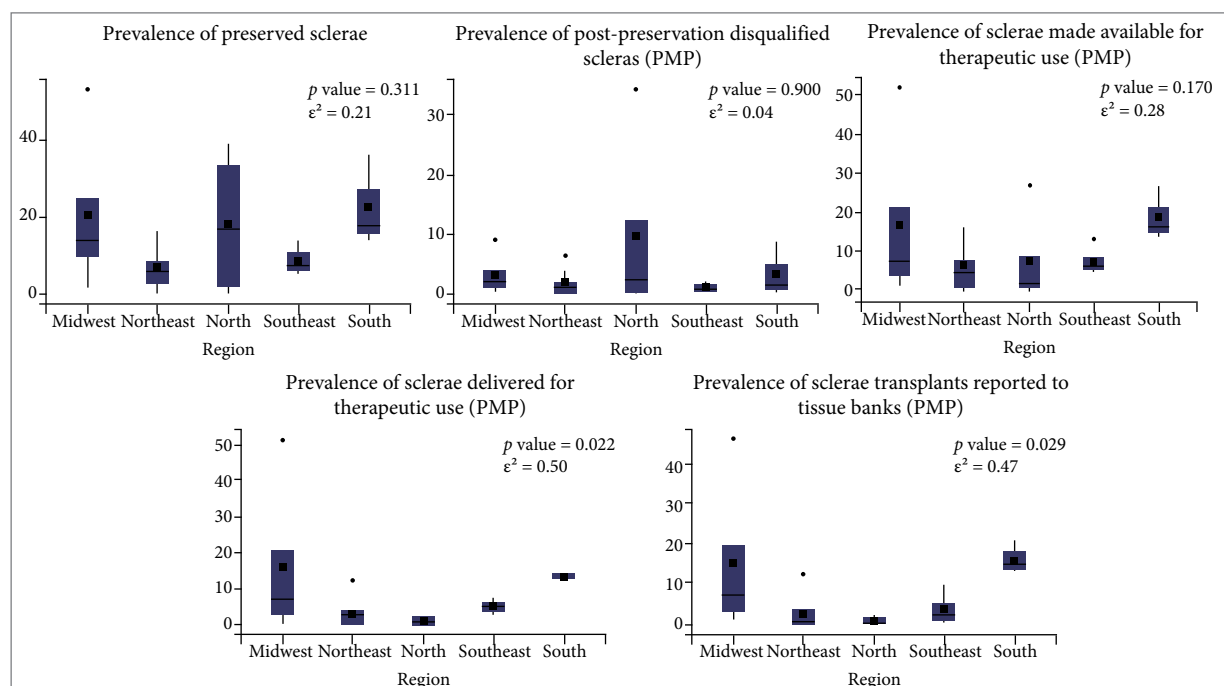
| Variables                            | Region  |           |       |           |       |
|--------------------------------------|---------|-----------|-------|-----------|-------|
|                                      | Midwest | Northeast | North | Southeast | South |
| Utilization rate of preserved sclera | 73.53   | 81.20     | 26.57 | 90.17     | 84.50 |
| Disqualification rate                | 15.03   | 19.58     | 66.11 | 13.10     | 13.37 |
| Therapeutic use rate                 | 104.00  | 40.51     | 11.02 | 61.02     | 87.59 |
| Transplant-to-total-preserved ratio  | 76.47   | 32.90     | 2.93  | 74.01     | 55.02 |
| Global efficiency index              | 90.00   | 40.91     | 8.64  | 63.32     | 85.44 |

Source: Anvisa.

To analyze the occurrence of statistically significant differences in preservation, disqualification, availability, delivery, and transplants among the eye banks across the five Brazilian macro-regions, the applied tests revealed significant variations in the final stages of the process, particularly for sclerae delivered for therapeutic use ( $p=0.022$ ;  $\epsilon^2=0.50$ ) and scleral transplants reported to the eye banks ( $p=0.029$ ;  $\epsilon^2=0.47$ ).

Based on the effect size, the magnitude of the differences found was high. However, when analyzing pairwise comparisons to identify which regions differed, no statistically significant differences were observed. This result may indicate that, although there is an overall difference among the five macro-regions, when analyzed together, this effect does not hold up in individual comparisons, possibly due to high variability across locations.

Thus, while the stages of sclera preservation, disqualification, and availability exhibited similar patterns across regions, the final stages of actual delivery and transplantation showed significant regional differences (Fig. 1).



Note:  $p$ -value:  $p$ -value from the Kruskal-Wallis test;  $\epsilon^2$ : epsilon-squared. Source: Anvisa.

**Figure 1.** Prevalence of preserved, disqualified, made available and delivered sclera for therapeutic use and transplants reported to Human Eye Tissue Banks/HETB (*Bancos de Tecido Ocular Humano- BTOH*) in Brazil in 2024, Campo Grande/MS, Brazil, 2026.

## DISCUSSION

The results demonstrated that, although there is a significant national production of preserved sclera, the distribution and efficiency of the process showed regional disparities. It was found that the use of absolute indicators can mask relevant differences between regions, whereas standardization PMP yields more precise comparisons.

The Northern region presented the highest preservation rate in the country (25.60 PMP), but also registered high disqualification (16.93 PMP), low delivery (0.64 PMP), and a reduced number of transplants performed (0.75 PMP). These findings indicate operational vulnerabilities in tissue processing and storage. Sclera preservation requires specific sterilization and conservation conditions, such as using absolute alcohol or glycerin. Furthermore, inadequate infrastructure in HETBs can compromise compliance with the requirements of the Collegiate Board (RDC, *Resolução da Diretoria Colegiada*) of Anvisa No. 707/2022 and result in high disqualification rates<sup>10</sup>.

The vast territory and low population density of the Northern region (4.51 inhabitants/km<sup>2</sup>)<sup>12</sup> directly impact the chain of donation and transplantation of eye tissues. Difficulties in accessing healthcare services, structural limitations, and insufficient technical training contribute to the low number of transplants performed<sup>13</sup>. These findings reflect patterns previously observed in the National Transplant System (SNT, *Sistema Nacional de Transplantes*). The Southeast, South, and Midwest regions have shorter waiting times and higher service rates, while the North and Northeast face low coverage and organizational challenges<sup>14</sup>.

Data from the Brazilian Council of Ophthalmology (CBO, *Conselho Brasileiro de Oftalmologia*) corroborate this scenario and highlight the unequal concentration of specialists: the Southeast region accounts for more than half of the country's ophthalmologists (12,147). In contrast, the North (1,043) and Northeast (4,050) regions register significantly lower numbers<sup>15</sup>.

Analysis of HETB quality indicators reveals that the Southeast region had the highest utilization rate of preserved sclera (90.17%), followed by the South (84.50%) and Northeast (81.20%). In comparison, the North showed a significantly lower utilization rate (26.57%). This difference may be associated with the limited availability of specialized centers and insufficient training for proper processing<sup>16</sup>. This scenario highlights that regions with better operational infrastructure and a larger number of professionals tend to exhibit greater efficiency and lower rates of disqualification<sup>17</sup>.

In addition to these differences, one aspect that deserves special attention was the therapeutic use rate exceeding 100% in the Midwest (104%), mainly due to the use of accumulated stocks, tissues imported from other HETB centers in other regions, or inconsistencies in data recording. Even considering that sclera can be stored for up to 180 days, values above 100% may reflect the inclusion of tissues from previous periods or inconsistencies in the completion of the electronic forms for Anvisa<sup>18,19</sup>.

It is also worth considering, in this situation, that one of the possible reasons for values above 100% may be related to the possibility that a single sclera may be used for more than one patient, when only a small fragment of sclera may be used, for example, in cases of glaucoma surgery<sup>20</sup>.

Post-preservation loss rates also showed significant differences between regions, with the North region standing out negatively (66.11%), much higher than the Southeast (13.10%) and South (13.37%). This variation suggests inefficiencies in tissue screening, processing, and storage, possibly related to the operational structure of the HETB, lower investment in technical training, or laboratory limitations<sup>16</sup>.

The global efficiency index indicated that the Midwest (90%) and South (85.44%) regions exhibited the best performance, whereas the Southeast, despite its higher volume of preservations, presented a lower index (63.32%). This demonstrates that a higher number of procedures does not necessarily translate into better tissue utilization. Structural and organizational factors, such as inventory management and standardized routines, may be more crucial to eye bank performance than regional socioeconomic development itself<sup>20</sup>. In this regard, the study analyzing the eye banks in Sorocaba/SP and Campo Grande/MS reinforces that objective protocols, process standardization, and efficient inventory management are essential to maximize tissue utilization<sup>21</sup>.

Another relevant aspect of the research demonstrates that although the initial phases of scleral management, such as preservation, disqualification, and availability, show relatively homogeneous behavior across regions, the final stages of therapeutic delivery and transplantation exhibit significant differences. Statistically relevant variations were identified in delivery for therapeutic use ( $p = 0.022$ ;  $\epsilon^2 = 0.50$ ) and in reported transplants ( $p = 0.029$ ;  $\epsilon^2 = 0.47$ ), suggesting the influence of structural and operational factors of the HETB.

These disparities reinforce the need for continuous management and monitoring policies aimed at standardizing procedures, optimizing processes, reducing losses, and promoting greater equity in sclera transplantation<sup>17</sup>. Standardization of protocols and regional integration, with regulated redistribution of tissues, can increase the system's efficiency, ensuring quality, traceability, and safety throughout the processes<sup>22</sup>.

The sclera plays a strategic role in various ophthalmological interventions, with scleral grafting being a safe and versatile alternative. In glaucoma surgery, it is widely used to cover drainage valves and filtering devices, prevent complications, and increase the longevity of implants. Furthermore, it is indicated for treating scleral thinning and perforations, reconstructing the eyeball after trauma, correcting fistulas, and protecting orbital implants. The availability of this tissue in HETBs is an irreplaceable resource, essential for ensuring the anatomical and functional integrity of the eye and for expanding surgical possibilities in ophthalmology<sup>23</sup>.

The results of this study demonstrate that the efficiency of HETBs depends not only on production capacity, but also on the quality of management, operational structure, and inter-institutional integration. Therefore, the continuous improvement of HETBs, coupled with integration between regions, represents an essential step towards consolidating national self-sufficiency in ocular tissues and reducing historical inequalities in access to sclera transplantation.

This study presents methodological limitations, such as the use of secondary data, where the original information may be subject to errors or inconsistencies in the HETB's reports, potentially affecting atypical indicators, such as rates exceeding 100%. Furthermore, the absence of clinical and operational variables in the Anvisa databases limits the understanding of the underlying reasons for the observed regional differences. Finally, the ecological design prevents the individualized analysis of factors that directly influence the procurement, preservation, and transplantation of scleral tissue.

The results presented contribute to the field of health by analyzing scleral tissue procurement, preservation, and transplantation in Brazil, highlighting regional inequalities and significant losses of this tissue. By filling gaps in the scientific literature, the results support managers in developing strategies to optimize tissue distribution, reduce losses, and strengthen HETB.

Thus, this work not only advances knowledge in the academic field but also helps improve equitable access to and the quality of care for patients who need sclera transplantation to achieve a better quality of life.

## CONCLUSION

Human Eye Tissue Banks (HETB) are responsible for procuring and producing scleral tissue for therapeutic use in Brazil. However, this study identified regional inequalities in the processes of preservation, provision, and transplantation of these tissues.

The North region had high disqualification rates, while the Southeast had the highest utilization rate, which corresponds to the greater volume of materials made available for therapeutic use. These findings suggest the presence of structural and organizational factors that may be associated with the differences observed across regions, although these factors were not directly evaluated in this study.

Therefore, strengthening the HETBs, standardizing processes, and promoting greater coordination between regions are relevant strategies to reduce losses, increase efficiency, and promote greater equity in access to sclera transplants.

## CONFLICT OF INTEREST

Nothing to declare.

## AUTHOR'S CONTRIBUTION

**Substantive scientific and intellectual contributions to the study:** Dias M, Ferreira Júnior MA, Frota OP, Mota FM; **Conception and design:** Dias M, Ferreira Júnior MA, Mota FM; **Data analysis and interpretation:** Dias M, Ferreira Júnior MA, Mota FM; **Article writing:** Dias M, Ferreira Júnior MA, Frota OP, Mota FM, Ribeiro AFA, Menezes BKA, Ribeiro KAA, Fernandes GE, Ferreira GAO, Shinohara GYO, Martins MDS; **Critical revision:** Dias M, Ferreira Júnior MA, Mota FM, Martins MDS; **Final approval:** Ferreira Júnior MA.

## DATA AVAILABILITY STATEMENT

All dataset were generated or analyzed in the current study.

## FUNDING

Coordenação de Aprimoramento de Pessoal de Ensino Superior   
Finance code 001

## DECLARATION OF USE OF ARTIFICIAL INTELLIGENCE TOOLS

The authors declare that no artificial intelligence tools were used in the preparation, writing, data analysis, or review of this manuscript.

## ACKNOWLEDGEMENT

To the Brazilian National Health Surveillance Agency (Anvisa) for making the data publicly available.

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