Impact of the COVID-19 Pandemic on Keratoplasty and Corneal Eye Banking

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Purpose: The purpose of this study was to assess the impact of COVID-19 guidelines for corneal donor tissue screening and the utility of routine postmortem COVID-19 testing of donors intended for surgical use at a single eye bank.

Methods: A retrospective analysis of referrals to and eligible donors from an eye bank between March 1, 2020, and June 30, 2020, was performed, with the same time period in 2019 as a control. Referrals who were not procured because of Eye Bank Association of America COVID-19 guidelines and eye bank–specific restrictions were noted. The results of 1 month of routine postmortem testing performed by the eye bank were examined. Analysis of variance tests were performed to assess the change between donors from 2019 to 2020.

Results: There was a significant reduction in both the number of total referrals to the eye bank ($P = 0.044$) and donors eligible for surgical transplantation ($P = 0.031$). Eye Bank Association of America COVID-19 guidelines reduced the number of referrals over this period by 4% to 14%. Of the 266 surgically eligible donors who received postmortem COVID-19 testing in June by the eye bank, 13 resulted positive (4.9%).

Conclusions: Despite a reduction in referrals and eligible corneal transplant donors at a single eye bank, there was a surplus of surgically suitable corneal tissue during the first wave of the COVID-19 pandemic. Eye banks should consider routine postmortem COVID-19 testing to identify asymptomatic infected donors although the risk of transmission of COVID-19 from infected donors is unknown.

Key Words: COVID-19, eye bank, corneal transplant

(*Cornea* 2021;40:1018–1023)

Since the first confirmed case of COVID-19 in the United States on January 22, 2020, the pandemic has grown exponentially, killing hundreds of thousands of individuals.[1] To limit the spread of COVID-19 in the United States, essentially all nonemergent medical and surgical procedures were paused.[2] This included transplant surgeries[3] because the potential of transmission of the novel coronavirus (SARS-CoV-2) through organ and tissue transplantation was and is not yet fully understood.[4] The various organizations who govern transplantation procedures have created guidelines to mitigate the risk of transmission.[5]

Management of care with corneal transplants was notably affected by the COVID-19 pandemic. Most corneal transplants are nonemergent and were postponed during the height of the pandemic. In addition, early studies indicated the presence of SARS-CoV-2 RNA in tears and conjunctival secretions,[6–8] raising the concern of the presence of the virus within ocular tissue. SARS-CoV-2 may infect ocular tissue by gaining cellular entry through ACE2 receptors,[9] which have been isolated in the conjunctiva and cornea.[10–12] The SARS-CoV-2 antigen has been isolated intracellularly within the ocular tissues of a previously infected patient[13]; however, there are conflicting reports of the presence of viral particles within postmortem ocular tissue. One study found no detectable levels of SARS-CoV-2 RNA within postmortem ocular tissues of infected patients,[14] whereas another was able to detect SARS-CoV-2 RNA within the anterior and posterior cornea.[15] Miner et al[16] reported that SARS-CoV-2 may not be able to replicate within corneal explants, decreasing the potential risk of transmission through transplantation. However, there is still an unknown potential risk of transmission from an infected donor. In response, the Eye Bank Association of America (EBAA) created guidelines limiting the eligibility of donors for tissue transplantation.[17] These precautionary measures limited both the supply of and demand for corneal tissue. It is unclear exactly how these measures affected patient care.

With the implementation of new donor restrictions during COVID-19, eye bank operations were significantly

Received for publication January 5, 2021; revision received February 22, 2021; accepted March 10, 2021. Published online ahead of print May 20, 2021.

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This work was funded by the Targeted Research Grant on COVID-19 provided by the Eye Bank Association of America (EBAA).

S. I. Mian is a medical director for the Eversight eye bank. The remaining authors have no funding or conflicts of interest to disclose.

Presented at the Cornea and Eye Banking Forum, November 2020.

Supplemental digital content is available for this article. Direct URL citations appear in the printed text and are provided in the HTML and PDF versions of this article on the journal's Web site (www.corneajrnl.com).

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affected according to a recent EBAA survey.[18] The aim of this study was to identify the extent to which corneal demand, EBAA guidelines, and eye bank restrictions limited the corneal supply at a single eye bank. We also explore the impact of routine postmortem COVID-19 testing by the eye bank of all potential donors intended for surgical use.

MATERIALS AND METHODS

Eye Bank Data Acquisition

A retrospective analysis of eye bank referrals and eligible donors was performed at the Eversight eye bank facilities (Michigan, Ohio, Illinois, New Jersey, and Connecticut) from March 1 to June 30 of 2019 and 2020. A number of corneas exported for international use during the study period were also collected. Referrals to the eye bank were determined by organ procurement organizations (OPOs) based on OPO COVID-19 screening guidelines and eye bank weekly demand for corneal tissue. The study and data accumulation conformed with all federal and state laws and that this study was in adherence to the tenets of the Declaration of Helsinki and was considered exempt by the Institutional Review Board at the University of Michigan. Because of Eversight data sharing protocols, percent changes were used instead of specific numbers of referrals and donors.

Deaths by State

The number of deaths per state in which the Eversight eye bank procures was obtained from the Centers for Disease Control and Prevention National Center for Health Statistics.[19] A COVID-related death, as defined by the Centers for Disease Control and Prevention database, is based on ICD-10 code U07.1 in which COVID-19 was an underlying or part of multiple causes of death. Deaths unrelated to COVID-19 were compared from 2019 to 2020 to ensure no difference in the potential total donor pool.

COVID-19 Donor Guidelines

The eye bank followed the evolving guidelines recommended by the EBAA (see Table 1, Supplemental Digital Content 1, http://links.lww.com/ICO/B202).[17] Referrals to the eye bank are defined as donors for which the eye bank was called for potential tissue procurement. Eligible donors are defined as procured donors who were eligible for surgical transplantation. Referrals ruled out because of EBAA guidelines are donors who were referred to the eye bank for potential procurement, but then they were found to meet at least one of the EBAA guidelines in place at the time of donor death and were not procured. Referrals ruled out because of eye bank restrictions are donors who were referred to the eye bank for potential procurement but were not procured because of specific restrictions in place by the eye bank because of the lack of demand for tissue to increase recovery efficiency and limit dispatching of staff. These restrictions included time restrictions for procurement, geographical restrictions, deferral for specific medical conditions outside of EBAA guidelines (such as diabetes), and changing age cutoffs (ie, only procuring donors below the age of 70 years). These restrictions were adjusted at the discretion of the eye bank based on the fluctuating demand for corneal tissue.

Postmortem Testing

Beginning June 1, 2020, the Eversight eye bank implemented a protocol to perform postmortem COVID-19 nasopharyngeal swabs of potential donors. All donors who had not received SARS-CoV-2 nasopharyngeal swabs within 72 hours from death who were recovered with surgical intent were tested. Postmortem nasopharyngeal swabs were collected before donor preparation with povidone-iodine. These donors were screened by the EBAA guidelines in effect before recovery and therefore before testing. The FDA and EBAA had not recommended postmortem testing of donors when this procedure was put in place.[17] Donors with postmortem swabs that resulted as inconclusive or positive were deemed ineligible for tissue donation. Individual organ procurement organizations had their own protocol for postmortem testing donors. These were not standardized across OPOs. Postmortem testing was used by some OPOs as early as April 2020.

Nasopharyngeal swab specimens were sent for laboratory virus nucleic acid testing with quantitative real-time polymerase chain reaction. Tests were performed at Eurofins VRL Laboratories (Denver, CO) and Viracor Laboratories (Lees Summit, MO). VRL Laboratories initially used BD BioGX SARS-CoV-2 reagents for the BD MAX System assay (sensitivity: 95% and specificity: 100%). On June 22, the laboratory began using the Procleix SARS-CoV-2 assay by Grifols Diagnostic Solutions (sensitivity: 95% and specificity: 100%). Viracor Laboratories used the Abbott RealTime SARS-CoV-2 assay (sensitivity: ≥95% and specificity: 100%). BD BioGX SARS-CoV-2 and Abbott RealTime SARS-CoV-2 assays were approved by the US Food and Drug Administration (FDA) Emergency Use Authorization. The Procleix SARS-CoV-2 assay has been validated, but FDA's independent review of validation is still pending. The cost for each RT-PCR test was $125. The average time from donor death to COVID test results was 53 hours. Routine postmortem COVID-19 testing did not result in a delay in tissue processing or delivery.

Statistical Analysis

Monthly totals from March 1 to June 30 were used to assess any statistically significant decline in 2020 compared with 2019. Analysis of variance tests were performed using SAS version 9.4 (SAS Institute, Cary, NC).

RESULTS

The first confirmed case of COVID-19 within 4 of the 5 states the eye bank procures was in March 2020. The study period of March through June of 2020 was chosen to assess the impact of the first wave of COVID-19 in the procurement area on the eye bank. The total number of deaths from these 5

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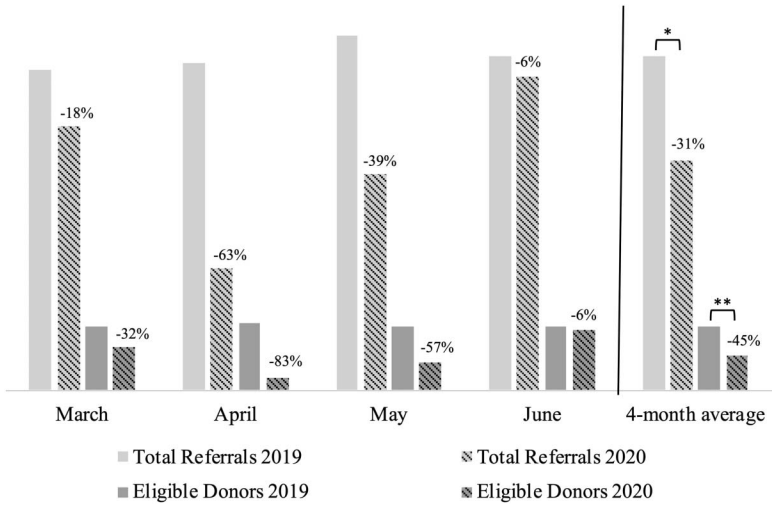

FIGURE 1. Total referrals to and resulting eligible donors from the eye bank with percent changes from 2019 to 2020. Total referrals: donors for which the eye bank was called for potential tissue procurement; eligible donors: procured donors who were eligible for surgical transplantation. *Total referrals $P = 0.044$ and **eligible donors $P = 0.031$.

states over the study period is shown in Supplemental Digital Content 2 (see Table 2, http://links.lww.com/ICO/B203). There was no significant difference in the number of deaths between regions from underlying cause unrelated to COVID between 2019 and 2020.

Effect of the COVID-19 Pandemic on Referrals Received by an Eye Bank

There was a significant decrease in both the number of referrals ($P = 0.044$) and eligible donors ($P = 0.031$) between 2019 and 2020 over the 4-month period (Fig. 1). Total referrals, as determined by OPOs, decreased by 31%, and eligible donors decreased by 45% over the 4-month period compared with 2019. The number of eligible donors was affected by both lack of demand for surgical tissue and the guidelines in place by the EBAA to limit COVID exposure. The number of scheduled surgeries in 2019 and 2020, domestically and internationally, is used as a proxy for demand for surgical tissue (Fig. 2). There was a significant decrease in the number of scheduled surgeries over this 4-month period from 2019 to 2020 ($P = 0.011$). When comparing the number of tissues determined to be suitable for surgical use with those used in the scheduled surgeries, there was a surplus of tissue during this 4-month period ranging from 18% to 44% (Table 1). Corneas exported for global use were also significantly reduced by 65% from 2019 to 2020 ($P = 0.0042$).

Figure 3 shows the donor referrals who were ruled out because of COVID restrictions, either in place by the eye bank or the EBAA (see Table 1, Supplemental Digital Content 1, http://links.lww.com/ICO/B202). The percentage refers to the proportion of referrals who were ruled out because of each of these COVID-specific restrictions. There was an increase in COVID-positive donors in June, likely reflecting the initiation of routine postmortem testing of all donors by the eye bank. Because scheduled surgeries increased in May and June, resulting in an increase in demand for tissue, eye bank restrictions comprised a lower proportion of COVID rule outs.

Outcomes of Postmortem PCR Testing

Figure 4 illustrates the COVID-19 testing of donors intended for surgical use in June 2020. Five hundred five donors were intended for surgical use after EBAA COVID-19 screening. Sixty donors were not procured for issues unrelated to COVID-19, including timing of procurement, bilateral intraocular lenses, infiltrates found on penlight examination, and/or additional information that was obtained. Of the 445 remaining donors, 126 had COVID-19 swabs

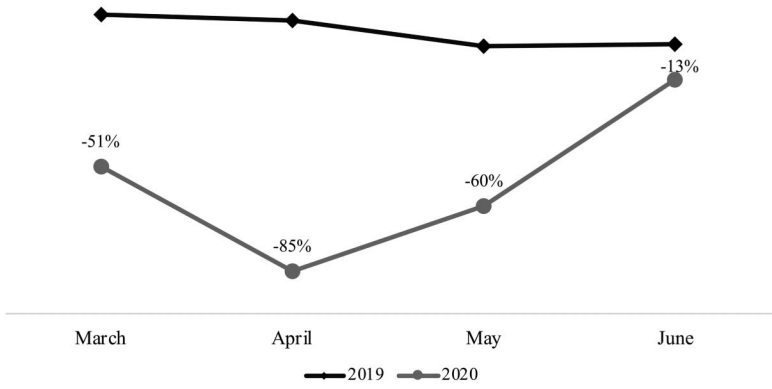

FIGURE 2. Scheduled surgeries requiring corneal tissue from the eye bank with percent changes from 2019 to 2020. Total decrease in scheduled surgeries during the 4-month period from 2019 to 2020 was 53% ($P = 0.011$).

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TABLE 1. Percentage of Excess Surgically Suitable Corneas in 2020

March	44%
April	21%
May	18%
June	28%
Total	30%

when still living, performed by the hospital or by the OPO if they were an organ donor. Three hundred fourteen donors received postmortem swabs: 48 by an OPO and 266 by the eye bank. Fifteen total postmortem swabs were positive (4.8%) (Table 2).

EBAA guidelines allowed medical directors for review of cases to assess final determination of donor eligibility in cases based on COVID-19 signs and symptoms, exposure, and COVID-19 swab results. From April 15 through June 30, 230 cases required medical director review because of COVID-19 concerns; 201 of the 230 (87%) were approved for transplantation. Medical director reviews reduced eligible donors over this 10-week period by 5.2%. In June, with the initiation of routine postmortem testing of surgically intended donors, medical director decisions were able to be compared with COVID-19 postmortem test results. One hundred eleven of the total 119 medical director reviews for COVID-19 concerns in June were approved for surgical transplantation and thus underwent a postmortem test, of which 4 resulted positive (4/111, 3.6%) (Table 2).

DISCUSSION

We report a single eye bank study describing the impact of the first wave of the COVID pandemic on eye bank volume. The data from the eye bank are comparable with the results of EBAA survey conducted on US eye banks, which found that corneal transplantation procedures decreased to 7% in April and increased back to 71% by June.[18] Corneal grafts supplied by the eye bank decreased to 15% in April but had increased to 87% by June. Most of this decrease in eye bank volume, a 31% decrease in referrals despite no difference in the overall donor pool, is representative of the lack of demand for corneal tissue, which caused a decrease in OPO referrals to the eye bank but returned to near-normal levels by June. However, EBAA guidelines did result in a reduction of 4% to 14% of donors because of COVID-19 screening.

In March through June of 2020, there was a surplus of corneal tissue despite more stringent donor restrictions. Although patients in the United States were still able to obtain the corneal transplant they required, this was likely not true for many patients abroad. The eye bank exported 65% fewer corneas internationally during this 4-month period compared with 2019. Eye banks in the United States exported 28,000 donor corneas to be transplanted internationally in 2019.[20] Gain et al[21] previously found that the United States provides 85% of exported corneas worldwide for the millions of individuals on the waitlist; internationally for every 70 corneas needed, only one was available. The COVID-19 pandemic likely further worsened this disparity.

This study also highlights the utility of asymptomatic donor screening. Asymptomatic patients with COVID-19 consist of approximately 15.6% of all confirmed cases,[22] although this is likely an underestimation of the true proportion of asymptomatic infections. Asymptomatic patients have been shown to play a large role in the transmission of COVID-19.[23] In our study, during 1 month of routine postmortem testing, 4.8% of patients tested positive despite not being detected by EBAA clinical screening guidelines. These donors had no noted exposure to COVID-19. Those who had symptoms or chest x-ray results did not meet EBAA guidelines for exclusion. Of the 4 donors whose cases were reviewed by medical directors, all were cleared for transplantation. Twenty-four corneas that would have been used for surgical transplantation had no postmortem testing completed. Our results are similar to a recent study combining data from 3 US eye banks in which 13 potential corneal donors tested positive of the 625 tested (2.1%).[24] Although there have been no reported cases of COVID-19 transmission through organ or tissue

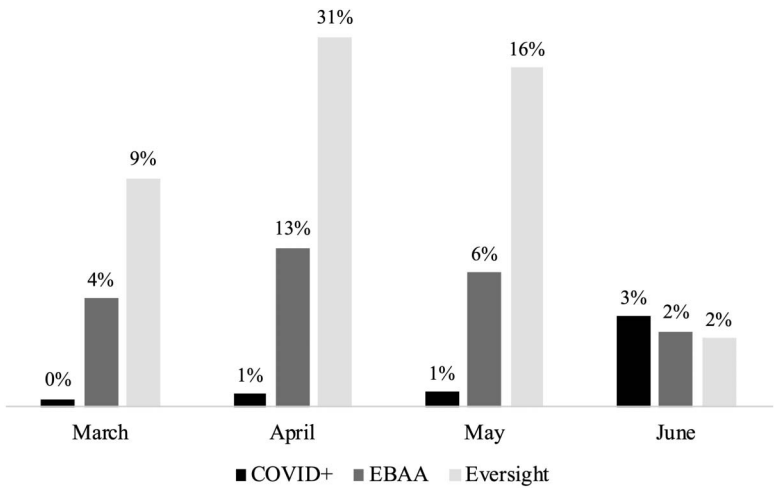

FIGURE 3. Causes for COVID-related rule outs of referrals to the eye bank with percentage of total referrals. COVID-positive donors were considered ruled out because of EBAA guidelines but separated for data analysis.

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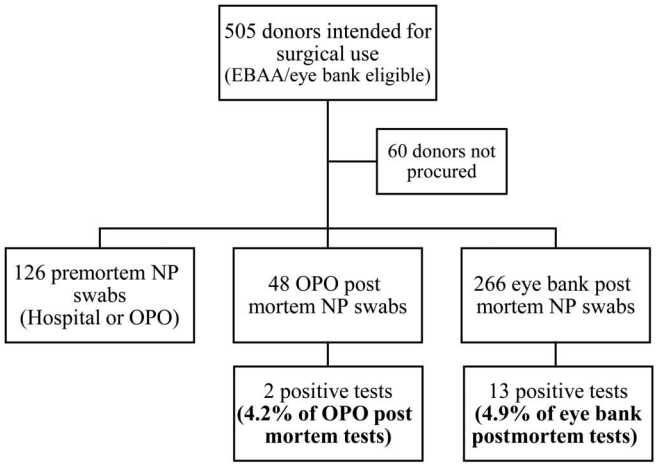

FIGURE 4. COVID-19 testing of donors intended for surgical use in June 2020.

transplantation, the presence of SARS-CoV-2 RNA within the ocular tissue of previously infected patients[13,15] raises concern for COVID-19 transmission and the long-term effect of SARS-CoV-2 in ocular tissue. Although it is possible that corneal tissue from an infected donor has already been transplanted, eye banks should work to limit this possibility until there is enough evidence to confirm the lack of viral transmission and clinical disease. Our study, in addition to the results of Heck et al, reveals that EBAA screening alone is not sufficient in capturing all COVID-positive donors; other methods, such as postmortem testing, may be an important supplement in ensuring the safety of corneal tissue.

The limitations of this study include that the data were obtained from a single eye bank that procures most of its donors from the midwestern United States. Eye banks in other parts of the country may have had markedly different clinical operations, depending on the incidence of COVID-19 and number of scheduled surgeries in that area. In addition, the number of procured donors that the eye bank has access to is dependent on the organ procurement organizations. Organ procurement organizations created their own unique guidelines during the COVID-19 pandemic. Future studies should examine how the differing restrictions and procedures of OPOs affected referrals to eye banks during the pandemic.

The results of this study indicate that guidelines restricting corneal tissue supply did not affect patients requiring corneal transplantation with tissue obtained from a single eye bank during the COVID-19 pandemic. Routine postmortem testing was shown to capture asymptomatic donors who were infected with COVID-19 and would have been used for surgical transplantation. Eye banks should consider routine postmortem testing of donors although the effect of SARS-CoV-2 in ocular tissue is still unknown. Future studies should examine the costs of postmortem testing to eye banks, impact on corneal preservation time, and safety concerns that accompany routine testing.

TABLE 2. Recovered Donors Testing Positive for SARS-CoV-2 With Postmortem Testing

Donor	Donor Age	Cause of Death	Testing Site	COVID Exposure	Potential COVID Symptoms	Chest X-Ray	Days Before Death With Negative Test	Medical Director Consulted
1	51	Heart disease	Eversight	None	Dry cough and weakness that resolved 1 day before death	N/A		Yes
2*	66	Heart disease	Eversight	None	None	N/A		No
3	67	Heart disease	Eversight	None	Chronic cough because of medication	N/A		No
4	64	Other	Eversight	None	None	N/A		No
5*	72	Respiratory disease	Eversight	None	None	Unremarkable	4	No
6	66	Cancer	Eversight	None	None	N/A	5	No
7*	59	Cerebrovascular accident	Eversight	None	Developed pneumonia in hospital	Stable dense retrocardiac consolidation	13	Yes
8	72	Respiratory disease	Eversight	None	Difficulty breathing for 2 days and a dry cough for a few weeks	N/A		Yes
9	57	Cerebrovascular accident	Eversight	None	Respiratory complaints for 1 day	Diffuse interstitial infiltrates bilaterally		Yes
10	17	Trauma	Eversight	None	None	N/A		No
11	70	Cancer	Eversight	None	None	N/A	11, 16, and 21	No
12	35	Trauma	Eversight	None	None	Unremarkable	5	No
13	70	Cerebrovascular accident	Eversight	None	None	Unremarkable	9	No
14	60	Heart disease	OPO	None	None	N/A		No
15	41	Other	OPO	None	None	N/A		No

*Donors would not have been released for transplant because of issues with tissue unrelated to COVID (eg, positive serologies and low cell counts).

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