

COVID-19 and the Prevalence of Reactive Tests in Three Eye Banks

Ellen Heck, BS, ASCP, MA,¹ Patricia Dahl, BS, CEPT,² Chris Hanna, MBA, CEPT,³ Valerie Corder, BSN, RN, JD, CTBS,⁴ Matthew Petroll, PhD,⁵ Dwight Cavanaugh, MD, PhD⁵

COVID-19, the virus that causes the acute severe respiratory syndrome, has dominated the global healthcare industry for most of 2020. It has affected elective surgery, corneal donation and corneal transplantation surgery. This report of testing results from three eye banks across the country—east coast, central and west coast—demonstrates the ratio of reactive versus non-reactive cornea donors over an eight-month period in 625 collective donor tests. The ratio of all reactive tests to total tests is 2%, indicating an effective screening process and a minimal risk of transmission to cornea transplant recipients from donated ocular tissue.

METHODS

Swab samples from the nasal pharynx were taken at the time of tissue retrieval and submitted to a testing laboratory for analysis. The testing laboratories included a commercial reference laboratory, State Health Department laboratories, and laboratories within University programs with which the eye banks were affiliated. The testing modality utilized was the RT-PCR, SARS-CoV-2. Data was subject to small sample analysis utilizing z-test.

RESULTS

There were 625 total donor samples submitted for testing. Of these, only 13 were reactive/positive for the COVID-19 virus; the distribution of positives within the three locations was a six, four and three. These were examined utilizing z-test for small group analysis. Although a higher proportion of ocular donors tested positive in-Group One as compared to Groups Two and Three, there were no statistically significant differences (figure1).

Figure 1 Z-Test Results

The difference of sample proportions = 0.0249.
The pooled estimate for p = 0.0231.
Standard error of difference of sample proportions = 0.0151.
z= 1.316; P = 0.188
95 percent confidence interval for difference: -0.00467 to 0.0545

Z-test for small sample analysis utilized to determine relationship between three participating centers.

DISCUSSION

As nationwide COVID-19 testing numbers escalated, there was an increase in reactivity and a corresponding increase in hospitalized cases.¹ This occurred during the months between March and October and eye bank positive cases remained low. Testing for COVID-19 occurs after the screening process for medical history according to the Food and Drug Administration (FDA) recommendation CFR21 1271.² Specific questions were added to the DRAI (Donor Risk Assessment Interview) to help determine whether potential donors were positive for or suspected of having COVID-19. (figure2).

Figure 2 COVID 19 Screening

nCoV1 In the last 28 days was she/he told by a healthcare professional she/he was infected with the novel corona virus (COVID-19)?
 No Yes

nCoV2 In the last 28 days did she/he have close contact with a person under investigation (PUI) for or diagnosed with corona virus?
 No Yes

Author Affiliation: ¹UT Southwestern Medical Center, Departments of Surgery and Ophthalmology, ²The Eye Bank for Sight Restoration – New York ³Utah Lions Eye Bank-John A Moran Eye Center

⁴UT Southwestern Medical Center, Transplant Services Center
⁵UT Southwestern Medical Center-Department of Ophthalmology

With this screening process, symptomatic donors: those who had a history of recent fever, shortness of breath, lower lobe pneumonia without other documentation of cause, those under investigation for COVID-19, or those with personal contact with someone suspected of or confirmed to have COVID-19, would have been deemed to be ineligible for donation.³ With the elimination of donors with histories as indicated above, it may be assumed that in part, accounts for the low number of positives. These 13 individuals would be asymptomatic or potential donors for whom the medical record was unremarkable or the individual providing recent history was unaware of these symptoms. However, it is possible, according to the National Institutes of Health (NIH) and the Centers for Disease Control (CDC), to have individuals who are in an early stage of infectivity who are asymptomatic and do not test positive. This then might offer the opportunity for them to enter the donor pool inadvertently. Report of the isolation of the COVID-19 virus in tears and conjunctiva⁴ can raise a concern for ocular tissue for transplantation. At this time, there have been no reported corneal transplantation transmission cases.⁵ The impact of the COVID-19 pandemic on corneal transplantation may have long lasting effects. The concern within eye banking is for the potential for disease transmission and the alterations in “elective surgery” and donor availability.^{6,7}

CONCLUSION

Corneal transplantation is a necessary treatment for severe cases of visual loss from disease or trauma. Corneal transplantation is widely performed around the world, with the United States being the nation with the greatest availability per capita and the leading exporter to help meet global needs.⁸

To preserve this availability, eye banks must continue the rigorous screening and testing protocols currently practiced to ensure the safety of recipients. Eye banks must also be continually aware of changes in disease transmission potential and developing technology to assure the delivery of allografts that can be transplanted with minimal risk and maximum function. Now that the possibility of vaccine becomes reality, it might lead to a lessening of concern for COVID-19. However, it may be months before widespread vaccination occurs, and even longer before the effectiveness and longevity of immunity will be assessed. Therefore, screening and testing for COVID-19 must continue to assure maximum safety for ocular tissue recipients.

REFERENCES

- 1 <http://www.cdc.gov/coronavirus/2019-ncov/index/html>
- 2 FDA CFR-Code of Federal Regulations Title 21 Section 1271
- 3 Restoresight.org/covid-19-updated. Eye Bank Association of America Covid-19 Regulatory Updates
- 4 Dockery D, Rowe S, Murphy M, Krzystolik M. The Ocular Manifestations and Transmission of Covid-19: Recommendations for Prevention. *The Journal of Emergency Medicine* Vol 59, Issue 1, July 2020 137-140
- 5 Bayyoud T, Iftner A, Iftner T, et al Absence of Severe Acute Respiratory Syndrome Coronavirus – 2 RNA in Human Corneal Tissue. *Cornea* 2020 June 29 (published online ahead of print)
- 6 of the Covid-10 Pandemic: an international perspective. *British Journal of Ophthalmology*. 2020;104:1477-1481
- 7 AIMutlak M, Li JY, Bin Helayel H, Fairaq R. Future of Corneal Donation and Transplantation: Insights From the COVID-19 Pandemic [published online ahead of print, 2020 Nov 25]. *Cornea*. 2020;10.1097/ICO.0000000000002538. doi:10.1097/ICO.0000000000002538
- 8 Gain P, Jullienne R, He Z, et al. Global Survey of Corneal Transplantation and Eye Banking. *JAMA Ophthalmol*. 2016;134(2):167–173. doi:10.1001/jamaophthalmol.2015.4776