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Older Corneas Suitable for Transplantation, Study Shows *Could Expand Donor Pool Significantly*

The age pool of corneas for transplant should be expanded to include donors up to 75 years of age, based on findings from a study funded by the National Eye Institute (NEI), one of the National Institutes of Health (NIH). Corneal transplants using tissue from older donors have similar rates of survival to those using tissue from younger donors.

The five-year transplant success rate was the same – 86 percent – for transplants performed with corneas from donors ages 12 to 65 years and from donors ages 66 to 75, said the study published in the April issue of *Ophthalmology*. The cornea, a clear dome-shaped surface that covers the front of the eye, offers protection and helps focus light entering the eye.

The availability of donor corneas has been adequate for the past 10 years in the United States, where more than 33,000 corneal transplants are performed each year. However, according to the study authors, recent changes in U.S. Food and Drug Administration (FDA) regulations will likely cause a decrease in the supply of donated corneas. These new regulations that took effect in June 2007 require additional screening and testing of potential donors for contagious diseases, registration of eye banks, more detailed records and labels, and stricter quarantine procedures.

“With the expected decrease in the pool of eligible cornea donors in the United States and the existing shortage of corneal tissue internationally, it is encouraging that we now have scientific evidence showing that older corneas can be used reliably in corneal transplantations,” said Elias A. Zerhouni, M.D., director of NIH.

In addition, many eye banks previously set the age limit for donors at 65 years or younger because some surgeons have been reluctant to use older corneas. According to the study authors, their findings could lessen these restrictive policies. They estimate that use of older donor tissue could expand the donor pool by as much as 20 percent to 35 percent.

“This new research has come at a good time,” said Paul A. Sieving, M.D., Ph.D., director of NEI. “The pressure on eye banks to provide corneas is increasing. The results of this study will expand the available donor pool and should persuade surgeons to use corneas from older donors. These changes will greatly benefit the growing number of individuals who need corneal transplants.”

“Surgeons and patients now have scientific evidence that older donor corneas are suitable for transplantation,” said Edward J. Holland, M.D., professor of ophthalmology at the University of Cincinnati, director of the Cornea Service at the Cincinnati Eye Institute, and co-chair of the study. “Further, when corneas are readily available, transplant procedures can be scheduled more efficiently, allowing both surgeons and patients to plan for them.”

The Cornea Donor Study (CDS), which was coordinated by the Jaeb Center for Health Research in Tampa, Fla., is a prospective cohort study conducted with 1,101 participants enrolled by 105 surgeons at 80 sites across the United States. A prospective cohort study is one in which health outcomes in a group of participants are monitored over the duration of the study. Participants were between 40 and 80 years of age and were chosen for the study if they were in need of a corneal transplant for a corneal disease that put them at moderate risk for clouding of the transplanted cornea. Donor corneas were provided by 43 participating eye banks. All donor corneas met the Eye Bank Association of America’s standards for human corneal transplantation and were consistent with eye banks’ tissue ratings of good to excellent quality. After the transplant surgery, the participants were followed for five years. The transplant was considered a failure if a repeat corneal transplant was required or if the cornea was cloudy for at least three months.

In a secondary study, the researchers examined the fate of the corneas’ endothelial cells. These are flat cells that live on the back of transplanted corneas and are essential for keeping the cornea clear. “Though there was cell loss in both age groups, in 86 percent of the cases the corneas remained clear after five years,” said Jonathan H. Lass, M.D., professor and chair of the Department of Ophthalmology and Visual Sciences at Case Western Reserve University and University Hospitals Case Medical Center, and medical director of the study’s endothelial image reading center. “These findings suggest the opportunity for further research to continue to perfect corneal transplants.”

“The CDS is a landmark study,” added study co-chair Mark J. Mannis, M.D., professor and chair of the Department of Ophthalmology at the University of California, Davis. “It is the largest study of its type on corneal transplantation ever done. Its size and five-year patient follow-up, along with a simple trial design, have provided us with clear and important insights into contemporary transplantation.”

Overall, the demand for organs and tissue is greater than the supply available for transplantation. The U.S. Department of Health and Human Services' Health Resources and Services Administration (HRSA) oversees the Organ Transplantation Program that is responsible for developing strategies and administering programs to promote organ and tissue donation. For more information, go to www.organdonor.gov/.

Additional support for the Cornea Donor Study was provided by: Eye Bank Association of America, Bausch & Lomb, Inc., Tissue Banks International, Vision Share, Inc., San Diego Eye Bank, The Cornea Society, Katena Products, Inc., ViroMed Laboratories, Inc., Midwest Eye-Banks (Michigan Eye-Bank, Illinois Eye-Bank), Konan Medical Corporation, Eye Bank for Sight Restoration, SightLife, Sight Society of Northeastern New York (Lions Eye Bank of Albany), and Lions Eye Bank of Oregon.

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