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CORNEA

Expanding corneal tissue availability

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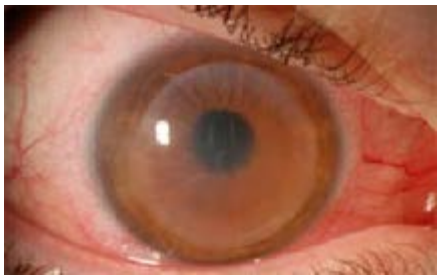
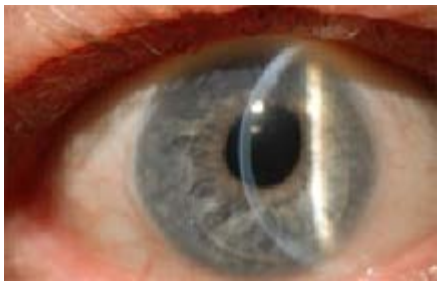
Largest cornea clinical trial right now compares preservation time





The largest clinical trial in the field of cornea diseases and surgery at the moment eventually may increase the number of corneal grafts available for transplantation.

The Cornea Preservation Time Study (CPTS) will track the transplantation success rate in endothelial keratoplasty with donor cornea preserved in storage medium at 4 degrees Celsius for up to seven days versus donor cornea preserved in storage media for eight to 14 days.

"Right now, surgeons and eye banks are reluctant to go beyond seven days," said study chair Jonathan H. Lass, M.D., director, University Hospitals Eye Institute, and Charles I. Thomas Professor and chair, Department of Ophthalmology and Visual Sciences, Case Western Reserve University School of Medicine, Cleveland.

However, the U.S. FDA has approved the storage of cornea tissue in approved media at 4 degrees Celsius for up to 14 days, leading investigators to believe that there may be a waste of good tissue occurring.

"The eye banks many times are hitting one week to place the tissue and must then explore other options with surgeons out of the country so that the tissue gets utilized," Dr. Lass said.

Study details

To compare the results of cornea donor tissue at one week versus eight to 14 days, study investigators at 40 participating clinical sites nationwide are enrolling up to 1,330 patients. As of the beginning of January, the study had enrolled 556 eyes, said Dr. Lass. Patients are randomized into one of two groups. Eyes in the first group receive tissue that has been preserved for up to seven days. Eyes in the second group receive tissue that has been preserved for eight to 14 days. Neither the surgeon nor the patient know to which group the eye was

randomized.

Investigators will follow patients for up to three years to see if the two groups have any difference in transplantation success or differences in the number of transplanted endothelial cells.

Investigators believe they will find no significant difference in outcomes comparing the two groups.

CPTS corneal recipient stroma clarity grading scale for endothelial keratoplasty. Source: George Rosenwasser, M.D.

The trial began in April 2012. Because of the three-year follow-up, early 2017 is the soonest point at which results will be available, Dr. Lass said.

The CPTS is supported with a $12.3 million grant from the National Eye Institute, Dr. Lass said. The Jaeb Center for Health Research in Tampa is collecting the study data.

Research benefits

Although the U.S. does not currently have a shortage of donor corneas, there could be numerous benefits if the study shows that the longer storage time is just as effective as the shorter storage time.

First, there's an expected increase in demand for corneal tissue as the U.S. population ages, Dr. Lass said. "If we can show preservation time doesn't make a difference, we could double the supply that people would be willing to use," he said.

In addition, the donor pool is at a greater risk from emerging infections like the West Nile virus, and the eye banks need more time to screen donors because of the concerns about infections surrounding drug addiction, including hepatitis B. This kind of research will provide actual evidence regarding best practices for corneal preservation timing and usage, Dr. Lass said. "We want to have an evidence-based approach to deal with perceptions surrounding the donor cornea and provide greater flexibility for eye banks in placing tissue," he explained.

George Rosenwasser, M.D., Central Pennsylvania Eye Institute, Hershey, Pa., whose practice is participating in the trial, is eager to see if the results provide proof that the longer preservation time is just as clinically acceptable as the shorter preservation time. He routinely has used tissue that has been preserved for 10-11 days and has found no difference in outcomes or quality compared with tissue preserved for a shorter time.

Currently, the U.S. has the most organized eye banking process in the world and often shares its excess supply around the world, said Kevin Ross, president and CEO, Midwest Eye-Banks, Ann Arbor, Mich. There were about 46,000 corneal transplants performed in the U.S. in 2011, according to Eye Bank Association of America statistics, Mr. Ross said. However, there were 67,590 donor tissues available in 2011. The tissue that are not used—for 2011, that was a little over 30%—are typically shipped overseas.

Although the U.S. does not have a shortage of donor tissue, there's a "tremendous shortage" elsewhere, Mr. Ross said. "There are about 100,000 to 150,000 corneal grafts in the world each year," Mr. Ross said. "The number needed is closer to a million."

The CPTS results may help close that gap. "We could provide a major benefit for the restoration of sight in many places, first and foremost in the U.S. This could also give us the opportunity to support corneal surgery programs around the world," Mr. Ross said, noting that many U.S. eye banks are involved with supporting cornea surgery programs

globally.
That said, if the U.S. has an increasing need for donor tissue, the study results could help meet the demand in the U.S., Dr. Lass said.
The results will affect eye banks' policies and procedures that guide for how long donor tissue can be used, Mr. Ross added. They also will likely affect tissue criteria selection worldwide, he said.
The study is actively recruiting patients between the ages of 30 and <91. Patients at participating centers with either Fuchs' dystrophy or pseudophakic bullous keratopathy undergoing Descemet's stripping endothelial keratoplasty (DSEK) must be available for follow-ups at one day, one week, one month, and six months, and one, two, and three years. The study's website is cpts.jaeb.org.

***Editors' note**: The physicians have no financial interests related to this article.*

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