New study offers added hope for patients awaiting corneal transplants

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New national research led by Jonathan Lass of Case Western Reserve University School of Medicine has found that corneal donor tissue can be safely stored for 11 days before transplantation surgery to correct eye problems in people with diseases of the cornea. This is four days longer than the current conventional maximum of seven days in the United States.

The findings are published in *JAMA Ophthalmology*.

"Over the past 20 years, corneal transplant specialists have gotten comfortable only using corneas up to one week after they are stored. But our findings show they can safely use them up to 11 days after first being stored," said Lass, the Charles I Thomas Professor in the Department of Ophthalmology and Visual Sciences at Case Western Reserve School of Medicine. "This will help to meet the expected future demand for corneas in this country as well as in patients overseas today, who now receive as many as 30 percent of corneas donated by U.S. citizens."

Patients who need corneal transplants are typically age 50 and older. According to projections by the U.S. Census Bureau, that population will grow from about 109 million currently to about 133 million by 2030 in this country.

The cornea, the eye's clear outer covering, helps focus light so people can see clearly. When it is damaged, incoming light can become distorted, harming quality of vision and often resulting in blindness.

Damage can arise from scarring due to:

- previous surgery, injury or infection;
- corneal ulcers;
- swelling or thinning of the cornea; and
- inherited diseases and conditions of the eye, such as Fuchs' dystrophy.

When the blurred vision and/or pain are serious enough, transplantation of a new cornea may be necessary. Transplanted corneas come from people who chose to donate them when they died.

In the study—which includes 18 other authors—70 eye surgeons at 40 surgical sites nationwide performed a corneal transplant called a Descemet stripping automated endothelial keratoplasty (DSAEK) on 1,090 people (1,330 eyes). In this procedure, doctors or the eye bank take a slice from the back of a healthy donated cornea, open a small slit in the patient's eye, scrape out the diseased endothelial cells and replace them with the donor cells.

The majority of the patients underwent transplantation for Fuchs' dystrophy, which causes a gradual decline in vision due to corneal swelling and clouding. Patients were randomly assigned to one of two treatment groups: those who received corneas preserved for up to seven days and those who received corneas preserved for eight to 14 days.

Lass and the surgeons found that three-year graft success rates were 92.1 percent for corneas preserved for eight to 14 days and 95.3 percent for corneas preserved up to seven days. Probing
further, they discovered that there was no statistically significant difference between patients who received corneas preserved up to seven days and those who received ones preserved eight to 11 days. Rather, much of the difference between the groups was attributed to those who received corneas preserved 12 to 14 days.

"It's important to note that patients who received corneas preserved 12 to 14 days still had high success rates of 89.3 percent," said Lass. "This means that if individual circumstances require it, these longer-preserved corneas may be used with a high degree of success."

Currently, the supply of donated corneas is sufficient to meet the demand in the U.S. In fact, more than a third of donated U.S. corneas are sent to patients in need internationally. But while U.S. eye banks provided about 28,000 corneas for use by patients in other countries in 2015, there are 10 million cornea-blind individuals worldwide.

Although results of the study directly apply only to the use of donor corneas used for this specific operation and these conditions, researchers hope that results could be extended to donor corneas used for other types of transplants and other eye diseases.

Separately, the investigators assessed the degree of corneal endothelial cell loss, which typically occurs after transplantation. The endothelium is a single layer of cells lining the inner surface of the cornea; among its functions, it helps keep the cornea clear and from not swelling.

The surgeons found that in corneas preserved up to seven days, there was a 37 percent loss of cells versus a 40 percent loss in corneas preserved eight-14 days. Again probing further, they discovered a comparable rate of loss in corneas preserved four-13 days.

"This finding also supports the use of corneas stored up to and including 11 days," said Lass.