# **Corneal Preservation Time Study** (CPTS) - 2015



## **Objective**

To establish a preservation timeframe of corneal tissue prior to corneal transplantation that would promote graft success and enlarge the available donor supply.

### **Methods**

**Design:** Prospective multicenter double-masked randomized Clinical Trial

#### Sample Size: 1330 corneal donors

- 49% > 60 yo donors
- 27% diabetic donors
- 1090 recipients of corneal donations

#### **Treatment Groups:**

- Donor cornea stored  $\leq$ 7 days
- Donor cornea stored 8-14 days

#### **Outcome Measures:** Graft

success, Endothelial cell density (ECD) at 3 years

### Results

**Point 1:** Graft failure rates were slightly higher in the group with longer preservation time (8-14 days) compared to shorter time (0-7 days)

- Shorter had 95.3% graft success compared to 92.1% in longer time; unadjusted hazard ratio for graft failure was 1.71 for longer preservation time (P = 0.02)
- In subgroup analysis, the grafts with the longest preservation times (12-14 days) had statistically significantly higher failure rates than all other timelines, including (8-11 days)
- In a post-hoc analysis, there was no statistically significant difference in 3-year graft success rates comparing the 0-7 days group (95.3%) to the 8 to 11 days group (93.8%). (95% CI, -1.3% to 4.4%).

**Point 2**: Longer preservation time was associated with increased endothelial cell loss

- At 3 years, the mean ECD decreased by 37% (21% SD) cells/mm2 in the 0-7 days group and 40% (22% SD) cells/mm2 in the 8-14 days group
- Analysis showed that each additional day of preservation time led to an increase in  $\sim 15$ cells/mm2 loss at year 3 (95% CI 4-26 cells/mm2, P = 0.006)

**Point 3**: Specific factors were associated with reduced endothelial density at 3 years

- Donor: diabetes, lower screening endothelial cell density
- Recipient: diagnosis of pseudophakic/aphakic corneal edema (PACE) and operative complications

### TLDR: This study demonstrated that corneal tissue could be preserved up to <u>11 days</u> prior to transplantation and still be grafted successfully; therefore, substantially increasing the donor pool for corneal transplants

Lass JH, Benetz BA, Verdier DD, et al; Cornea Preservation Time Study Group. Corneal Endothelial Cell Loss 3 Years After Successful Descemet Stripping Automated Endothelial Keratoplasty in the Cornea Preservation Time Study: A Randomized Clinical Trial. JAMA Ophthalmol. 2017 Dec 1;135(12):1394-1400 Rosenwasser GO, Szczotka-Flynn LB, Ayala AR, et al.; Cornea Preservation Time Study Group. Effect of Cornea Preservation Time on Success of Descemet Stripping Automated Endothelial Keratoplasty: A Randomized Clinical Trial. JAMA Ophthalmol. 2017 Dec 1;135(12):1401-1409 Lass JH, Benetz BA, Patel SV, et al D; Cornea Preservation Time Study Group. Donor, Recipient, and Operative Factors Associated With Increased Endothelial Cell Loss in the Cornea Preservation Time Study. JAMA Ophthalmol. 2019 Feb 1;137(2):185-193.