

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 ≤ 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 ~ 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 11 days prior to transplantation and still be grafted successfully; therefore, substantially increasing the donor pool for corneal transplants