

Utilizing Study Results to Change Surgeons' Standard of Practice: One Eye Bank's Experience with CPTS Data

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ABSTRACT

Maximizing donated ocular tissue while insuring the best transplantation outcome for the patient is the goal for all eye banks. Maximizing tissue placement is challenging for eye banks due to the difficulties associated with controlling the number of qualified ocular donors as compared to surgical schedules. Utilization of corneas with extended preservation times of up to 11 days can help eye banks maximize placement of locally recovered tissues. Results from the Cornea Preservation Time Study (CPTS) released in November 2017 suggest that utilization of corneas for endothelial keratoplasty (EK) surgeries with preservation times of up to 11 days does not compromise patient outcomes. This study examines a method for implementing this data into the routine practice of corneal transplant surgeons in a manner that benefits the eye bank, donor families, surgeons and recipients.

The CPTS was a multicenter, randomized, masked, non-inferiority clinical trial designed to determine the effect of preservation time on graft success and endothelial cell loss in eyes undergoing DSAEK. The study included 1,330 corneal transplants in 1,090 patients with corneas transplanted by 70 surgeons at 40 clinical sites. The corneas were provided by 23 US eye banks and had preservation times of 0-7 days or 8-14 days. Patients were followed for three years and graft success and endothelial cell loss were compared from the two preservation time groups (0-7, 8-14 days). The study findings suggest that donor tissue with preservation times up to 11 days is suitable for DSAEK, in terms of both graft success and endothelial cell loss^{1,2}. Based on these findings, a protocol was devised to ensure that local surgeons, both university-based and in private practice, were aware of the study results and to encourage them to utilize corneal tissues with preservation times exceeding seven days as a standard of practice.

METHODS

All surgeons performing EK utilizing tissue provided by the eye bank were contacted via e-mail, phone, and/or personal visits. The CPTS results were reviewed and the benefits of utilizing tissue with extended preservation times were presented. Twelve surgeons agreed to utilize corneas with extended preservation times on a trial basis. All tissues offered for surgery met the Eye Bank Association of America's Medical Standards, Food and Drug Administration regulations and the policies of the eye bank. Over a five-month period (January-May 2018), 178 corneas were placed with these 12 surgeons for both DSAEK and DMEK procedures. Corneas with preservation times over 7 days were randomly offered among the 12 surgeons.

Results: Comparison of preservation times for EK surgeries performed in January-May 2018 (post-CPTS results) as compared to EK surgeries performed during July-November 2017 (pre-CPTS results) showed a definite increase in utilization of tissues preserved for greater than 7 days. The days to surgery range in the post-CPTS time period increased from 2-9 days to 3-11 days; the average days to surgery increased from 4.90 days to 6.71 days; and the number of surgeries performed on days 8-11 increased from 1.6% to 37.6% (Figure 1). Reported complications or primary graft failures (PGF) did not increase; one PGF was reported in each period. The PGF in the pre-CPTS period was clearly attributable to damage caused by tissue handling. The PGF reported in the post-CPTS period did have an extended preservation time (8 days), but the cause of the failure remains undetermined.

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	July – November 2017 Pre-CPTS results	January – May 2018 Post-CPTS results
# of surgeons routinely willing to accept tissue older than 7 days	2	12
Days to Surgery Range	2-9	3-11
Average days to surgery	4.90	6.71
% of surgeries performed on days 8-11	1.6%	37.6%

Figure 1

DISCUSSION

Utilization of corneas with extended preservation times of up to 11 days benefits the eye bank, donor families, corneal surgeons and recipients. The benefits to corneal surgeons include an increased pool of suitable corneas for scheduled surgeries without compromising patient outcomes. This is especially helpful for DMEK surgeries where the pool of suitable tissues is limited by the need for older, non-diabetic donors with high endothelial cell counts and there is a need to have back-up tissue available due to the unpredictable nature of DMEK corneal preparation. In addition, it helps the eye bank maintain lower service fees by maximizing full service fee placements of locally recovered tissues. The benefit to the donor family must not be overlooked; many families have reported that knowing that their loved one is continuing to help others through restoration of sight helped ease their grief. Education to the surgeons on the CPTS findings, explanation of the benefits and continued communication between the eye bank and the surgeon are critical components to the success of extending preservation times as a standard of practice.

CONCLUSION

The utilization of corneas for EK surgeries with extended preservation times of 8 to 11 days can improve the work

flow for the eye bank and increase the utilization of locally recovered tissue without negatively affecting patient outcomes. Increased utilization should equate to a stabilization of some of the associated costs of tissue acquisition and distribution by reduction of corneas lost to domestic placement and time spent locating placement outlets if local placements are not available. A concerted effort by the eye bank to provide education of CPTS study results to surgeons is critical to establish consensus on a new standard of practice of routinely utilizing corneas with preservation times of up to 11 days for EK surgeries.

REFERENCES

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