THE EFFECTS OF A NOVEL PROCESSING TECHNIQUE ON DONOR CORNEA CLARITY FOLLOWING HYPOTHERMIC STORAGE

LIONS VISION GIFT™

OREGON HEALTH & SCIENCE UNIVERSITY

5134-10355

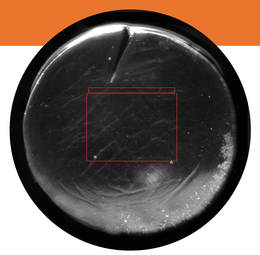

Figure 1
Tissue No. 5 before Treatment

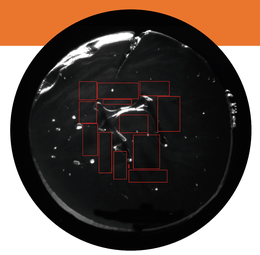

Figure 2
Tissue No. 5 after Treatment

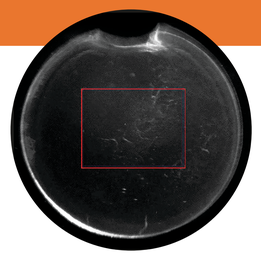

Figure 3
Tissue No. 18 before Treatment Submerged

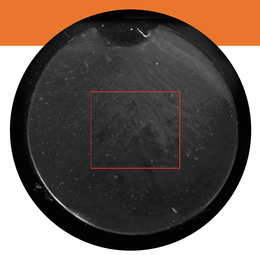

Figure 4
Tissue No. 18 after Treatment Submerged

Figure 5
Imaging Set-up

JEFFREY HOLIMAN, CEBT
CHRISTOPHER STOEGER, MBA, CEBT
Lions VisionGift, Portland, Oregon

YAN LI, PHD
DAVID HUANG, MD, PHD
Oregon Health Sciences University , Portland, Oregon

TABLE 1 : CLARITY MEASUREMENTS

TISSUE NO.	%TRANSPARENCY BEFORE TX	% TRANSPARENCY AFTER TX
TISSUE 01	92.7%	90.5%
TISSUE 02	90.5%	88.6%
TISSUE 03	88.0%	92.1%
TISSUE 04	96.0%	92.1%
TISSUE 05	86.8%	90.9%
TISSUE 06	92.9%	92.2%
TISSUE 07	92.1%	89.3%
TISSUE 08	91.7%	88.9%
TISSUE 09	94.9%	87.0%
TISSUE 10	93.3%	90.3%
TISSUE 11	95.3%	88.1%
TISSUE 12	96.6%	94.5%
TISSUE 13	90.1%	86.6%
TISSUE 14	96.7%	92.1%
TISSUE 15	95.0%	91.7%
TISSUE 16	94.2%	91.2%
TISSUE 17	97.7%	94.4%
TISSUE 18	95.9%	94.3%

PURPOSE: A new process involving 4°C storage, transfer to recombinant human serum albumin (rHSA) and subsequent terminal sterilization by electron beam irradiation was developed for long term storage of donor corneas at 20°C. This study is to objectively assess the change in clarity in corneas that have undergone this processing.

METHODS: Corneas suitable for anterior lamellar keratoplasty were selected in an eye bank (n=18). The corneas were first stored at 4°C for 11 to 13 days. The tissues were warmed to 20°C; epithelium and endothelium were removed. Next, tissue was trephined to 8.0 mm diameter and placed on a glass slide for dark field photomicroscopy. After photography, the corneas were placed in 20% rHSA and irradiated by electron beam. The tissue was allowed to reach -60°C before irradiation. Following a minimum of 72 hours after irradiation, the corneas were re-imaged for post processing comparison. Dark field photos were obtained under the same light condition and photomicroscopy settings. Tissues 1-6 were imaged in air, while tissues 7-18 were submerged in their respective media during imaging. Customized software coded with Matlab (software version R2012a) was designed to assess the corneal clarity change in dark field photos. The photos were converted into grayscale images with a normalized brightness range of 0 to 1. The brightness of a clear slide equaled 0, the brightness of an opaque frosted slide equaled 1. The brightness of the central cornea (range 9.5 - 10.5 mm^2) area was averaged for each dark field photo. Hyper-reflective regions due to air bubbles captured in the photos were excluded from brightness calculation. The transparency of the tissue was defined as (1 – averaged brightness) and converted to a percentage. Statistical analysis was performed with a two-sample t-test.

RESULTS: Eighteen corneas were included in this study (donor age 57-75 years). There were limitations in the initial analysis technique (n=6) due to variability in mechanical removal of cellular debris and subtle wrinkles due to natural curvature of each tissue. These artifacts were diminished in the final 12 grafts due to submersion in storage solution during imaging. The average corneal transparency was 93.4% ± 3.1% (range 86.8% - 97.7%) before processing and 90.8% ± 2.4% (range 86.6% - 94.5%) after processing. The average difference between the two groups is -2.6% change in clarity. P=0.009

CONCLUSIONS: Only small changes in clarity were detected in corneas that had undergone this novel processing technique intended for long term ambient temperature storage. In the future, clinical studies may be necessary to determine if this slight but significant decrease in transparency is relevant to patient outcomes.

DISCLOSURES: Jeffrey Holiman, LVG Employee; Yan Li, Carl Zeiss Meditec, Inc. (P), Optovue, Inc. (F, P); Christopher Stoeger, LVG Employee, David Huang, Carl Zeiss Meditec, Inc. (P), Optovue, Inc. (F, I, P)