Superiority of mature differentiated cultured human corneal endothelial cell injection therapy for corneal endothelial failure

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PURPOSE: To investigate the safety and efficacy of cultured human corneal endothelial cell (hCEC)-injection therapy with mature differentiated (mature) cell subpopulations (SPs) for corneal endothelial failure (CEF).

DESIGN: Comparative, interventional case series.

METHODS: This study involved 18 eyes with CEF that underwent cultured hCEC-injection therapy, categorized into two groups: 1) 11 eyes administered a relatively lower proportion (0.1 to 76.3%) of mature cell SPs [Group 1 (Gr1)], and 2) 7 eyes administered a relatively higher proportion (>90%) of mature cell SPs [Group 2 (Gr2)]. From 1-week to 3-years postoperative, corneal endothelial cell (CEC) density (CECD), central corneal thickness (CCT), and best-corrected visual acuity (BCVA) were recorded, and the CEC parameter's 'spring constant' was calculated. The proportion of mature SPs was evaluated by fluorescence-activated cell sorting analysis based on cell-surface markers.

RESULTS: At 3-years postoperative, corneal restoration with improved BCVA was attained in 10 of the 11 Gr1 eyes and all Gr2 eyes, the median CECD in Gr2 (3,083 cells/mm^2; range, 2,182-4,417 cells/mm^2) was higher than that in Gr1 (1,349 cells/mm^2; range, 746-2,104 cells/mm^2) (P < 0.001), and the spring constant in Gr2 53 × 10^-3 /µm^2 (range, 18 – 78 × 10^-3 /µm^2) was higher than that in Gr1 15 × 10^-3 /µm^2 (range, 7 – 34 × 10^-3 /µm^2) (P = 0.003). From 24-weeks through 3-years postoperative, the median percentage of CECD decrease was 3.2% in Gr2 and 23.6% in Gr1 (P < 0.005). CCT recovery was prompt and constant in Gr2, while diverse in Gr1. No adverse events were observed.

CONCLUSION: Our findings showed that mature cell SPs for hCEC-injection therapy provide rapid recovery of CCT, better CECD, and low CECD attrition over 3 years post surgery.