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PO115: Endothelial Safety Profile of Minimally Invasive Glaucoma Surgery Stents

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Background and Objective

- Corneal endothelial cells maintain corneal transparency by regulating stromal hydration via ion pump channels.[1]
- Endothelial cell density (ECD) loss to below 400 to 500 cells/mm^2 can lead to corneal edema, corneal decompensation, and vision loss.[2]
- The glaucoma patient is subjected to risk factors for ECD loss from the disease, surgical treatment, and implants.[3,4]
- Given the chronicity of glaucoma, the preservation of endothelial cells, which are non-regenerative, is another dimension that surgeons must consider, in addition to ocular co-morbidities requiring surgery and natural loss of 0.6% per year.[1,3]
- This study examined the additional impact of CyPass® Micro-Stent, Hydrus® Microstent, and iStent *inject*® + cataract surgery (CS) vs. CS alone on ECD up to 5 years postoperative from extension studies of or respective pivotal randomized clinical trials (RCTs).

Methods

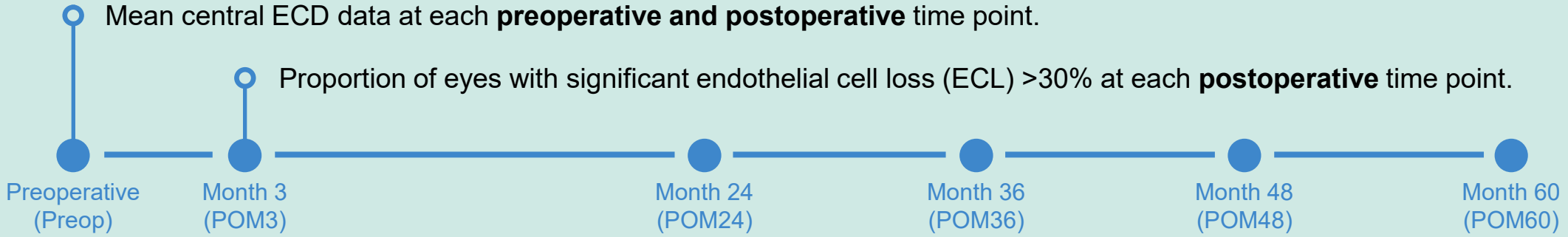
- The 3-year iStent *inject* + CS vs. CS only **extension study** was initiated after the 2-year pivotal trial[5] and used the same central image analysis reading center, Cornea Image Analysis Reading Center (CIARC), and methods[5,9] to measure ECD.
- Published ECD outcomes from the 5-year RCT on the Hydrus + CS vs. CS only[6,7,8] and 3-year extension study on the CyPass + CS vs. CS only[9] were included in this study.

	iStent *inject*		Hydrus		CyPass	
	Cataract and mild to moderate POAG					
Pivotal RCT inclusion criteria	• MDIOP of 21–36mmHg • On 1–3 medications		• MDIOP of 22–34mmHg • On 1–4 medications		• MDIOP of 21–33mmHg • On 0–3 medications	
Extension study among patients willing to undergo follow-up	Had arithmetically similar mean ECD & ECL >30% at POM24 vs RCT cohort		N/A		Had arithmetically similar mean ECD & ECL >30% at POM24 vs RCT cohort	
Sample size						
Implant + CS	178		369		215	
CS only	49		187		67	
Preop ECD, cells/mm² (SD)						
Implant + CS	2450 (355)	P=0.8745	2417 (390)	P=0.7949	2433 (370)	P=0.9698
CS only	2441 (344)		2426 (371)		2435 (320)	

ECL, endothelial cell loss

Methods

- Outcomes included:



Study endpoints were:

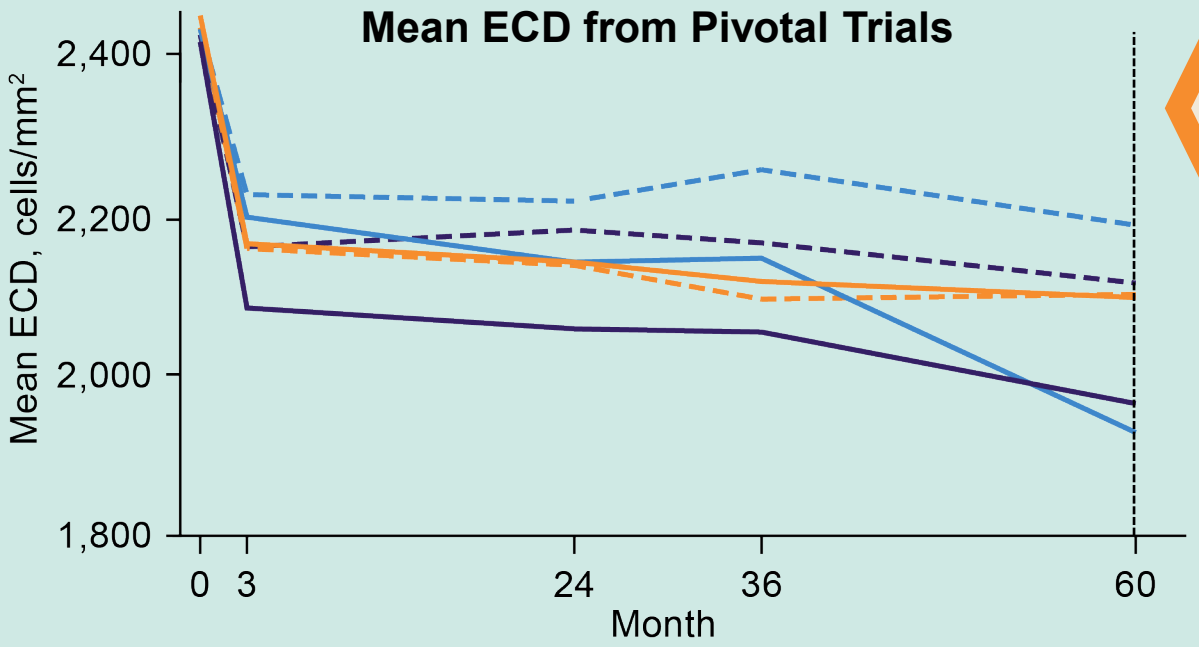
1. **differences in mean ECD**
2. **differences in proportion of eyes with ECL >30%**

at POM60 within each implants' respective study

Statistical analyses were two-sample t-test for population means and Pearson's chi-square test or Fisher's exact test for categorical variables; two-tailed P value <0.05 indicated statistical significance.

Results

- Post POM3, CyPass had exhibited increased rate of mean ECD loss vs. its control group at POM36; whereas iStent *inject* and Hydrus appeared to have similar trends vs. their respective control groups
- At POM60, the differences in **mean ECD** (implant + CS vs. CS only) were statistically significantly different for CyPass & Hydrus, but not for iStent *inject*.



At POM60:

iStent *inject* (n=170)		iStent *inject* control (n=48)	P=0.954
Hydrus (n=298)		Hydrus control (n=132)	P=0.004
CyPass (n=163)		CyPass control (n=40)	P=0.014

Timepoints statistically significant* between groups

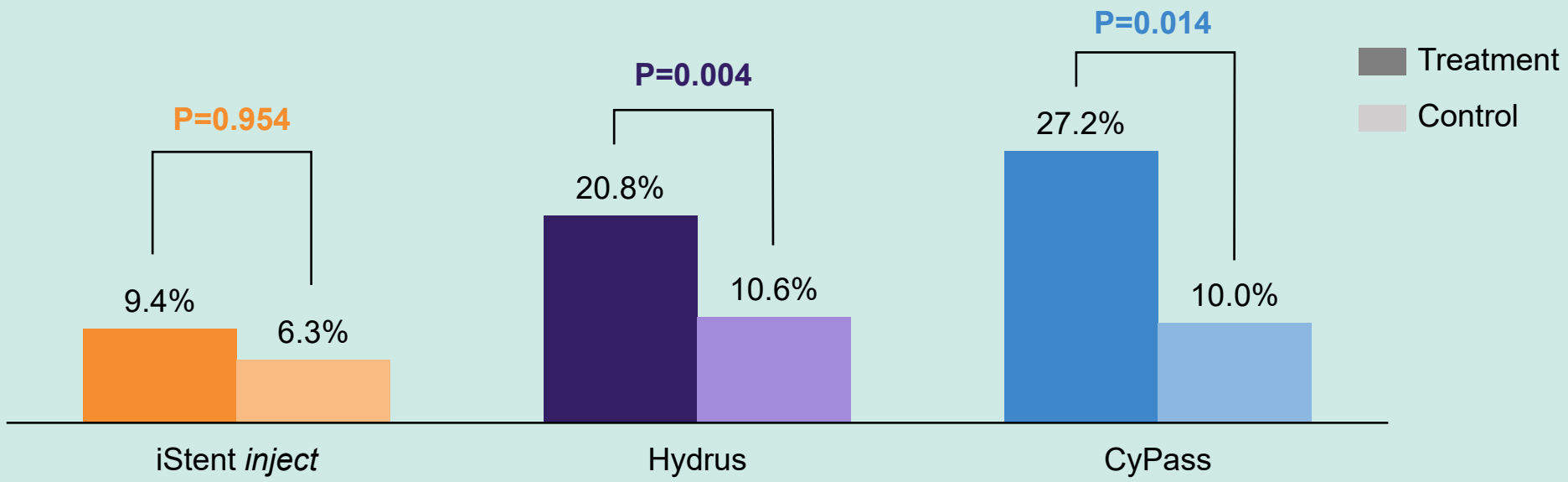
iStent *inject*: none

Hydrus: POM24, POM36, & POM60

CyPass: POM48 & POM60

Results

- Eyes treated with Hydrus or CyPass + CS had greater risks of developing **>30% ECL** at POM60 vs. their respective control group; whereas no significant differences were observed with iStent *inject*.



Conclusions

- The uniformity of the pivotal MIGS trials in terms of demographics, disease severity, and study design afford valuable comparative data on the effect of the three implantable MIGS devices on the health of the corneal endothelium.
- Among the micro-invasive glaucoma surgical (MIGS) implants with 5-year follow-up data, only iStent *inject* had no statistically significant additional effects on mean central ECD and clinically significant ECL vs. CS implantation.
- Surgeons should consider the health of the corneal endothelium when selecting a MIGS procedure for individuals with glaucoma, especially those with compromised endothelium or other conditions that may subject them to increased corneal risk.
- A limitation of this study is potential selection bias in the extension studies; however, patient baseline characteristics were arithmetically similar, and ECD results were similar in the respective RCT and extension study cohorts for iStent *inject* and CyPass.
- Comparative effectiveness studies or network meta-analysis studies of MIGS should include long-term ECD parameters to provide more insight into patient safety when considering risks vs. benefits.

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