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Evaluation of Endothelial Cell Density Following iTrack™ Ab-Interno Canal Based Surgery

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Purpose

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To evaluate stability of endothelial cell density over a five year period in patients who have undergone ab-interno canal-based surgery using the iTrack surgical system (Nova Eye Medical, Adelaide, Australia). The 1 year interim postoperative data is presented.

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Methods

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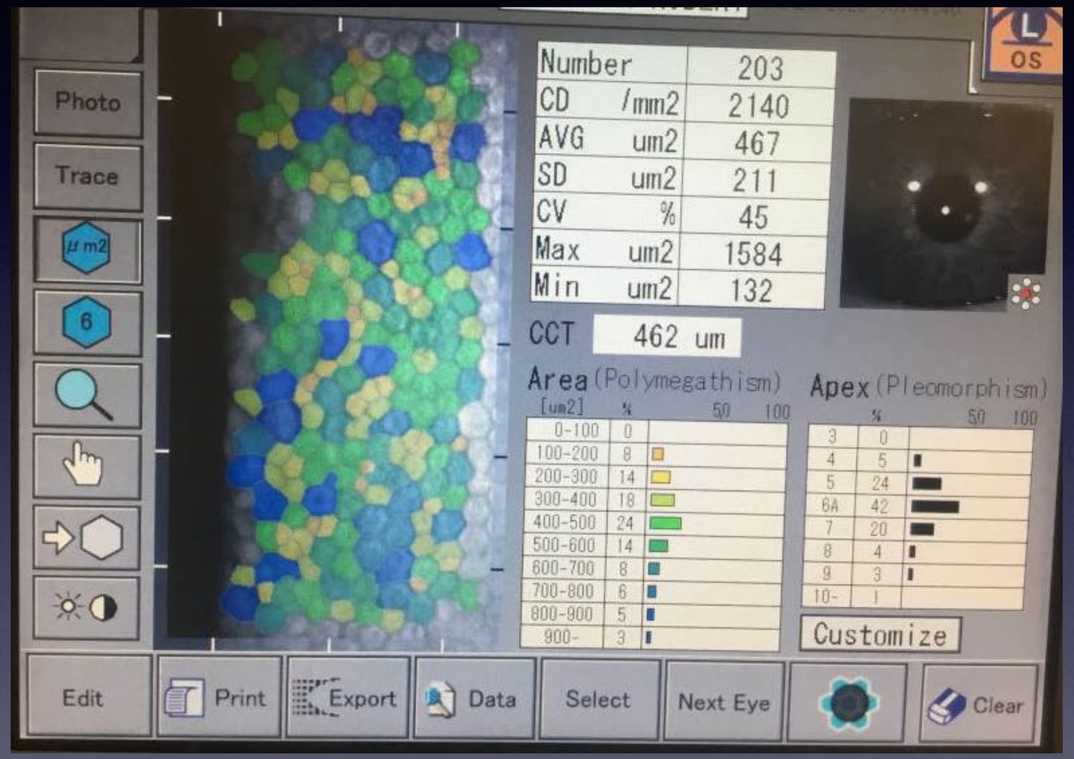
- Prospective, multi-center RWE study commenced in January 2019
- Patients to be followed for 60 months following ab-interno iTrack™ canal-based surgery combined with cataract surgery
- Standard metrics for MIGS follow-up to be performed include visual acuity, intraocular pressure, glaucoma medication use, visual fields, optic nerve/ganglion cell analysis and endothelial cell density
- Surgical parameters documented include degrees of microcatheter circumnavigation, type of OVD used for viscodilation and number of microboluses delivered
- Objectives of the study are to evaluate iTrack™ canal based surgery:
  - Effect on endothelial cell density
  - Efficacy
  - Safety
  - Dosimetry
  - ‘Ideal’ OVD

- Specular microscopy performed preoperatively and at 6, 12, 24, 36, 48 and 60 months postoperatively
- Endothelial cell density is analyzed at each time point.
- Results from analysis of endothelial cell density study patients are compared with control group i.e. patients undergoing cataract surgery alone



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Results

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77 eyes of 46 patients			
Age	Mean 74.7	SD 6.8	Range 61-88
Glaucoma Severity	Mild	10 (13%)	
	Moderate	42 (55.5%)	
	Severe	22 (28.6%)	
	Indeterminate	3 (3.9%)	
Pre-op IOP	Mean 17.7 mm/hg	SD 3.4	
Post-op IOP	Mean 14.8 mm/hg	SD 2.9	$P < 0.05$
Pre-op ECC	Mean 2304/mm^2	SD 362/mm^2	Range 1262-3351/mm^2
12 Month Post-op ECC	Mean 2230/mm^2	SD 356/mm^2	Range 1108-3284/mm^2
Endothelial Cell Loss	Mean 80/mm^2	SD 157/mm^2	$P = 0.21$

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Procedure	12 mo % EC loss	
iTrack combined with cataract surgery	-3.2%	SD:9.0%
Cataract Surgery Alone (1) [iStent FDA pivotal trial]	-12.3%	SD:12.7%,
Cataract Surgery Alone (2) [Hydrus FDA pivotal trial]	-10%	SD:11%

- Mean change in endothelial cell density at 12 months following iTrack canal based surgery combined with cataract surgery was -3.1% (SD: 9.0%).
- Endothelial cell density change in the control groups (cataract surgery alone) of FDA pivotal trials related to MIGS (as –12.3% (SD: 12.7%) and -10% (SD: 11%).[1,2]

1. Samuelson, T et al, Prospective, Randomized, Controlled Pivotal Trial of an *Ab Interno* Implanted Trabecular Micro-Bypass in Primary Open-Angle Glaucoma and Cataract, Ophthalmology June 2019, pages 811-821
2. Ahmed, Iqbal Ike K., et al. "Three-Year Findings of the HORIZON Trial: A Schlemm Canal Microstent for Pressure Reduction in Primary Open-Angle Glaucoma and Cataract." Ophthalmology 128.6 (2021): 857-865.

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Conclusion

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iTrack canal based surgery performed in conjunction with cataract surgery causes minimal change in endothelial cell density 12 months following surgery that is comparable to cataract surgery alone. Analyses of data at additional time points of this study will assess long-term stability of the endothelium.

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Discussion

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- Corneal endothelial cell density decreases significantly and continuously, 3-5%/year, following trabeculectomy[1]
- Corneal endothelial cell density decreases even more significantly and continuously, 5-8%/year, following tube shunt placement[2,3]
- Did withdrawal of Cypass set an unreasonable expectation of 0% cell loss from new glaucoma procedures?
- At what point does the risk of loss of ganglion cells outweigh the risk of loss of endothelial cells.
- Is the mechanism of continued endothelial cell loss following glaucoma surgery due to altered aqueous currents or the presence of a foreign body or both?

1. Hirooka K, Nitta E, Ukegawa K, et al Effect of trabeculectomy on corneal endothelial cell loss British Journal of Ophthalmology Published Online First: 14 June 2019. doi: 10.1136/bjophthalmol-2018-313417
2. Tan et al, Corneal endothelial cell loss after Baerveldt glaucoma drainage device implantation in the anterior chamber, Acta Ophthalmol. 2017 Feb; 95(1): 91–96.
3. KIm et al, Changes in corneal endothelial cell density and morphology after Ahmed glaucoma valve implantation during the first year of follow up, Clin Exp Ophthalmol. 2008 Mar;36(2):142-7

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- If maintenance of endothelial cell health is a key criteria for glaucoma procedures (MIGS) then iTrack canal based surgery would be highly recommended.

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Thank you!