Five-year Safety and Efficacy Results of a Supraciliary Drainage Device in Open Angle Glaucoma Patients (STAR-GLOBAL)

Keith Barton[1], Philippe Denis[2]; Christoph Hirneiss[3]; Iqbal Ike K Ahmed[4]

1. Moorfields Eye Hospital, London, UK; 2. Department of Ophthalmology, Hôpital de la Croix-Rousse, Lyon, France; 3. Klinikum der Universität München, Ludwig-Maximilians-Universität, Munich, Germany; 4. John Moran Eye Center, University of Utah, Salt Lake City, Utah, USA.

PURPOSE

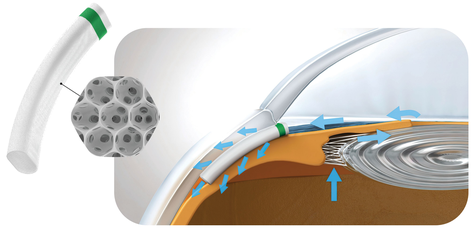
- Describe the 5-year safety and efficacy profile of a minimally-invasive glaucoma surgery (MIGS) device
  - MINIject® supraciliary device (iSTAR Medical, Wavre, Belgium)
- Patients with medically-uncontrolled open-angle glaucoma (OAG)

METHODS

- In the STAR-I trial, the device was implanted ab interno in a standalone procedure in phakic and pseudophakic eyes with no medication washout.
- The trial was completed at 2 years in 20 patients in 2 sites in Asia and Central America.
- Upon study completion, patients were invited to enrol in the STAR-GLOBAL study to continue follow-up annually until 5 years.
- Intraocular pressure (IOP) and IOP-lowering medication use were recorded annually, as well as a safety evaluation including adverse events and measurements of corneal endothelial cell density (ECD).
- Results from 14 patients who completed 5-year follow-up (70% of patients who completed the STAR-I trial) are reported here.

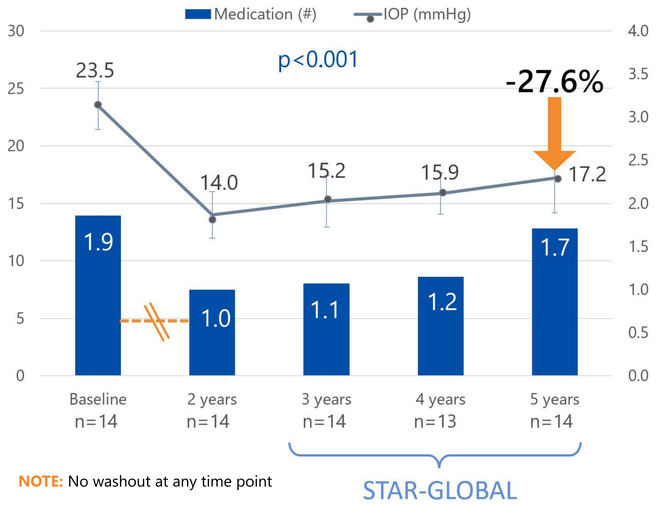
MINIJECT®

- Made of proprietary STAR® material
- Soft, flexible with anti-fibrotic properties
- Micro-pores allow bio-integration of tissues
- Implanted ab interno into the suprachoroidal space



RESULTS

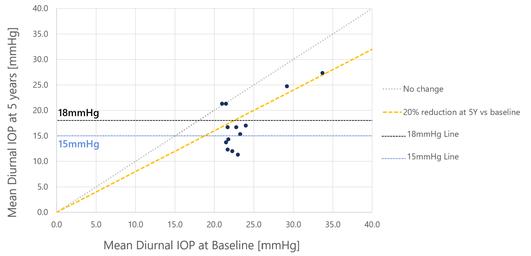
MEAN DIURNAL IOP AND MEDICATION REDUCTION



NOTE: No washout at any time point

Results	4Y	5Y
Patients with ≥20% IOP reduction from baseline	92%	69%
Patients with IOP ≤18mmHg	77%	69%
Medication-free patients	46%	21%

SCATTERPLOT FOR IOP AT 5 YEARS VS BASELINE (n=14)



Error bars represent 95% confidence interval. Patients initially treated in the STAR-I trial and followed for 5 years in STAR-GLOBAL. Provisional, interim results. P-value <0.001 for IOP at all time points. Medication reduction p<0.05 for both 2 and 3 years. P=0.17 and p=0.63 for medication reduction at 4Y and 5Y respectively. Data on file.

- Adverse events since STAR-GLOBAL enrolment: 1 case of ECD loss requiring implant trimming.
- Mean central ECD loss in the per-protocol analysis was 9.3% at 5 years, with no patients with ≥30% loss.

CONCLUSION

This suprachoroidal implant demonstrated 69% of patients maintained an IOP reduction >=20%, and 69% maintained IOP<=18mmHg at 5-year follow-up, without any safety concerns.

Clinicaltrials.gov IDs –
STAR-I: NCT03193736,
STAR-GLOBAL: NCT04524416

Disclosures: KB: AbbVie Ltd (C), Alcon (C), Advanced Ophthalmic Innovations (C), Allergan (C), Aquesys (S), Calilia (C), C-Mer Holdings (S), Elios Vision (C,S), EyeD Pharma (C), International Glaucoma Surgery Registry Ltd (S), iStar Medical (C), Ivantis (C,S), JamJoom Pharmaceuticals (C), Laboratoires Théa (C), Liquid Medical (C), MedEther Ophthalmology (Hong Kong) Ltd (S), Myra Vision (C,S), Nova Eye Medical (C), Ph Pharma (C), Radiance Therapeutics (C), Roche (C), Santen Pharmaceutical Co. Ltd (C), Sight Sciences (C), Vision Futures Ltd (S), Vision Medical Events Ltd (S); **PD:** Alcon (C, L), Glaukos (C, L), Santen (C); **CH:** AbbVie (S), Glaukos (L), iSTAR Medical, Novartis (S), Santen (C); **IIKA:** Aequus (C), Ace Vision (C), Aerie Pharmaceuticals (C, R), Akorn (C), Alcon (C,L,R), Allergan (C,L,R), Aquea Health, Inc (C), ArcScan (C), Avellino Lab USA, Inc (C), Avisi (C), Bausch Health (C), Beaver Visitec (C), Belkin Vision (C), Beyeonics (C), Bionode (C, R), Carl Zeiss Meditec (C, L), Centricity Vision, Inc (C), CorNeat Vision (C), Custom Surgical (C), Elios Vision (C), ElutiMed (C), Equinox (C), eyeFlow, Inc (C), EyedMed (C), EyeQ Technologies (C), Exhaura Limited (C), Genentech (C), Glaukos (C, R), Gore (C), Heine (C, L), Heru (C), Hexiris Pharma (C), Iantrek (C), InjectSense (C), Iridex (C), iCare (R), iSTAR Medical (C), Ivantis (C, R), Johnson & Johnson Vision (C, L, R), Labtician Thea (C), LayerBio (C), Leica Microsystems (C), Life Long Vision (C), Long Bridge Medical, Inc (C), MicroOptx (C), MST Surgical (C, L), Myra Vision/Shifamed LLC (C), New World Medical (C, R), NovaEye (C), Ocular Instruments (C), Ocular Therapeutix (C), Oculo (C), Oculus Surgical (C), Omega Ophthalmics (C), PolyActiva (C), PulseMedica (C), Radiance Therapeutics, Inc (C), Radius XR (C), Rheon Medical SA (C), Ripple Therapeutics (C), Samsara Vision (C), Sanoculis (C), Santen (C, R), Singapore Biodesign Programme Office (C), Sight Sciences (C), Smartlens, Inc (C), Stroma (C), Thea Pharma (C), TFS Health Science (C), ViaLase (C), Visus Therapeutics (C), Vizzario (C), VSY Biotechnology (C), Zilia, Inc (C). **C:** Consulting fees, **L:** Lectures, **R:** Grant, **S:** Stock or options.

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