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

Gus Gazzard[1], Antonio Fea[2]; Philippe Denis[3]; Brian Flowers[4]; Inder Paul Singh[5]; Iqbal Ike K Ahmed[6]

1. Moorfields Eye Hospital, London, UK; 2. Dipartimento di Scienze Chirurgiche–Clinica Oculistica, Torino, Italy; 3. Department of Ophthalmology, Hôpital de la Croix-Rousse, Lyon, France; 4. Ophthalmology Associates, Fort Worth, TX, USA ; 5. The Eye Centers of Racine and Kenosha, Wisconsin, USA; 6. John Moran Eye Center, University of Utah, Salt Lake City, Utah, USA.

PURPOSE

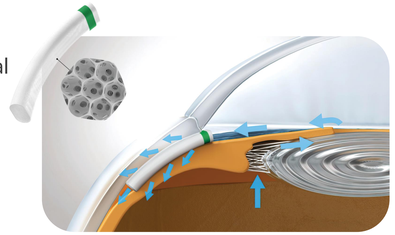
- Describe the 3-year safety and efficacy profile of a minimally-invasive glaucoma surgery (MIGS) device
  - MINIject® supraciliary device (iSTAR Medical, Wavre, Belgium)
- Patients with medically-uncontrolled open-angle glaucoma (OAG)

METHODS

- The device was implanted ab interno in a standalone procedure in phakic and pseudophakic eyes with no medication washout in 3 prospective trials (STAR-I,II,III).
- Trials were completed at 2 years in 66 patients in 11 sites in Europe, 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 48 patients who completed 3-year follow-up (72.7% of patients who completed the prior studies) are reported here.

MINIJECT®

- Made of proprietary STAR® material
- Soft, flexible with anti-fibrotic properties
- Micro-pores enable a natural flow speed of fluid and allow bio-integration of surrounding tissues



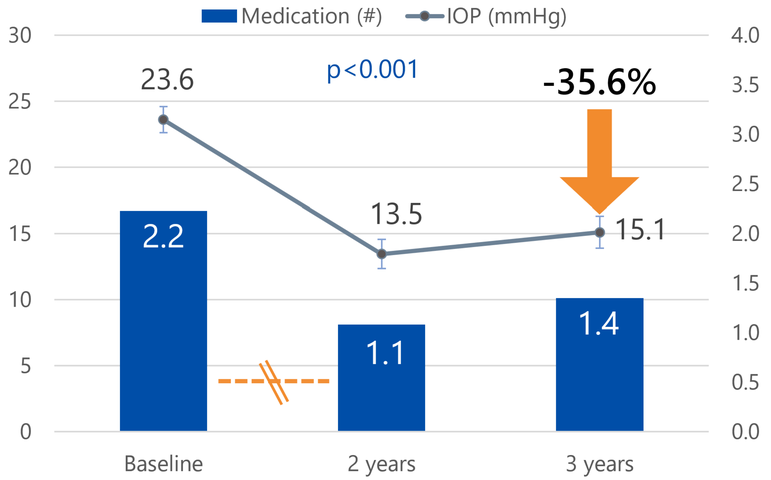
MINIject in the supraciliary space

SURGICAL PROCEDURE

- Stand-alone, implanted into supraciliary space
- Ab interno approach, ≤2.2mm corneal incision
- Bleb-free surgery, no MMC or 5-FU required

RESULTS

MEAN DIURNAL IOP AND MEDICATION REDUCTION



Results at 3 years	
Patients with ≥20% IOP reduction from baseline	90%
Patients with IOP ≤18mmHg	85%
Medication-free patients	42%

NOTE: No washout at any time point

Error bars represent 95% confidence interval. n=48 for all time points. Patients initially treated in the STAR-I,II,III studies. Provisional, interim results up to 3 years. P-value valid for IOP and medication reduction at both 2 and 3 years. Data on file.

- Adverse events since STAR-GLOBAL enrolment were: 1 case of ECD loss and 1 cataract progression.
- Mean central ECD loss in the per-protocol analysis (n=21) was 4.7% at 3 years, with one patient with ≥30% loss.

CONCLUSION

In an ethnically diverse cohort of patients, meaningful efficacy and a sustained reduction of hypotensive medications up to 3-years post-implantation was achieved. This supraciliary MIGS procedure offers a valuable bleb-free treatment option for patients with glaucoma requiring low target IOPs.

Clinicaltrials.gov IDs –
STAR-I: NCT03193736,
STAR-II: NCT03624361,
STAR-III: NCT03996200,
STAR-GLOBAL: NCT04524416

Disclosures: GG: Alcon Laboratories/Ivantis (C,L); Allergan/Abbvie (C,L); Bausch & Lomb (L); Belkin Vision (C); Elios Vision (C); Genentech/Roche (C); Glaukos Corporation (C,L); Haag-Streit Group (L); Lumenis (L); Lumibird/Quantel/Ellex (L); McKinsey Consulting (C); Merck & Co, Inc. (L); Reichert (C,L); Ripple Therapeutics (C); Santen, Inc. (C); Sight Sciences, Inc. (C); Thea (C,L); Vialase (C); Visufarma (C,L); **AF:** AbbVie, Santen, Johnson and Johnson, Oculus, Glaukos, EyeD, Elios Vision, iSTAR Medical; **PD:** Santen (C, L), AbbVie (C, L), Horus Pharma (C, L), Nicox (C), Théa Pharma (C, L), iSTAR Medical (C), Alcon (C, L); **BF:** Alcon (C), Glaukos (C), iSTAR Medical (C), New World Medical (C), NiCox (C), Sanoculis (C), Sight Sciences (C); **IPS:** iSTAR Medical, Allergan, Alcon, Quantel – Ellex, Sight Sciences, New World Medical, Glaukos, Zeiss, Rayner, Ocular Therapeutix, Alchemy, B+L, Visiox, Radius, Nova Eye; **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), MicroOptix (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).
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