A Multi-Centre Study of a Supraciliary Glaucoma Drainage Device in Patients with Open Angle Glaucoma: 2-year Follow-Up Results (STAR-IV)

Gokulan Ratnarajan MD[1]; Antonio Fea MD PhD[2]; Iqbal Ike K Ahmed MD[3]

1. Queen Victoria Hospital, East Grinstead, UK; 2. Dipartimento di Scienze Chirurgiche–Clinica Oculistica, Torino, Italy; 3. John Moran Eye Center, University of Utah, Salt Lake City, Utah, USA.

PURPOSE

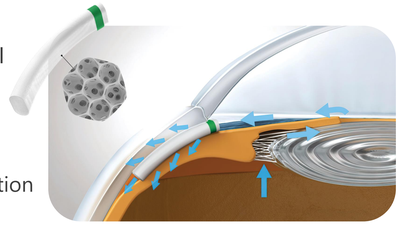
- Describe the safety and efficacy of a supraciliary, minimally-invasive glaucoma surgery (MIGS) system, **MINIject®** (iSTAR Medical, Wavre, Belgium).
- Patients with medically uncontrolled open angle glaucoma.

METHODS

- The **STAR-IV trial** is a prospective, multi-centre, interventional, single-arm study conducted at 2 sites in India and Panama.
- The implant is a 5-mm long network of hollow spheres made of soft, flexible silicone. The device was implanted into the supraciliary space of **21 eyes in a stand-alone procedure** using an ab-interno approach.
- Intraocular pressure (IOP), medication use, and other ocular parameters were evaluated preoperatively and postoperatively through **24 months**, at pre-specified timepoints.
- The **primary endpoint** of the study was **IOP reduction at 6 months** compared to baseline, analysed with a paired t-test. Safety evaluation includes the nature and frequency of adverse events. Preliminary study **results up to 24-months** 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



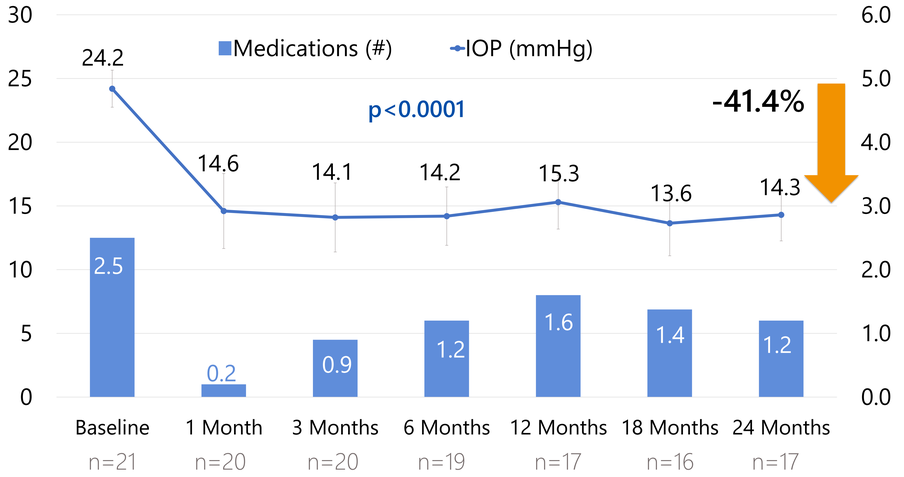
MINIject in the supraciliary space

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 IOP AND MEDICATION REDUCTION



88% of eyes had IOP < 18 mmHg at 24 months

94% of eyes had ≥20% reduction in IOP at 24 months

Error bars show 95% confidence intervals. Provisional results, data on file. P<0.0001 for IOP reduction at all time points. P<0.01 for medication reduction at all timepoints.

The most common adverse events were transient anterior chamber inflammation (n=11, 52%), pupillary deformity (n=4, 19%), transient blurred vision (n=4, 19%), visual acuity loss (n=3, 14%), cataract progression (n=3, 14%) and IOP decrease (n=3, 14%). No eye exceeded 30% loss in endothelial cell density from baseline.

CONCLUSION

MINIject effectively reduced IOP by 41.4% at 24 months, while decreasing the need for medication. This study confirms the sustained efficacy of standalone implantation of MINIject into the supraciliary space to reduce IOP and reduce dependency on glaucoma medications up to 24 months postoperatively.

MINIject® is available for sale and is a registered trademark in the EU, UK and Switzerland.

Clinicaltrials.gov
STAR-IV: NCT04517786

Disclosures: **GR**: Alcon (C), Glaukos (C), Santen (C), Elios (C), Zeiss (C), Allergan (C), Thea (L), BVI (L), Scope (L); **AF**: AbbVie, Santen, Johnson and Johnson, Oculus, Glaukos, EyeD, Elios Vision, iSTAR Medical; **IKA**: 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), EyeXMed (C), EyeQ Technologies (C), Exhaura Limited (C), Genentech (C), Glaukos (C, R), Gore (C), Heine (C, L), Heru (C), Hevvis 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/Shfamed 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.

Study sponsored by
iSTAR MEDICAL