

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

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PURPOSE

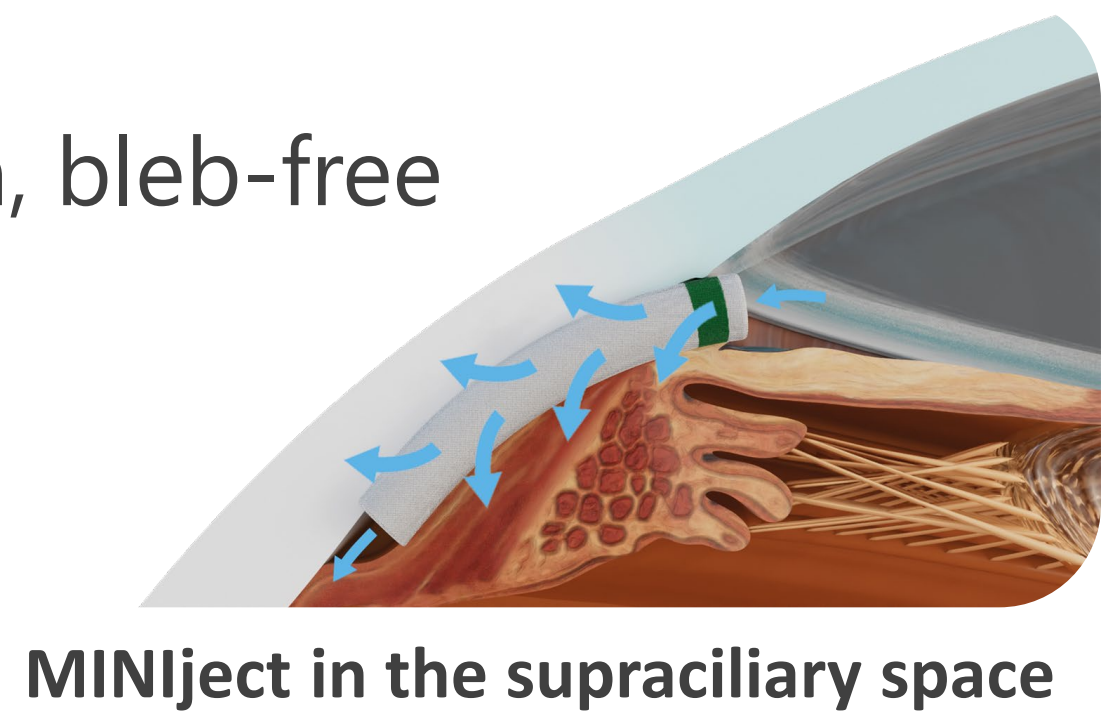
- Five-year safety and efficacy of a minimally invasive glaucoma surgery (MIGS) device, MINiject® (iSTAR Medical, Belgium).
- Implantation was ab interno into the supraciliary space in subjects with medically uncontrolled primary open-angle glaucoma.

METHODS

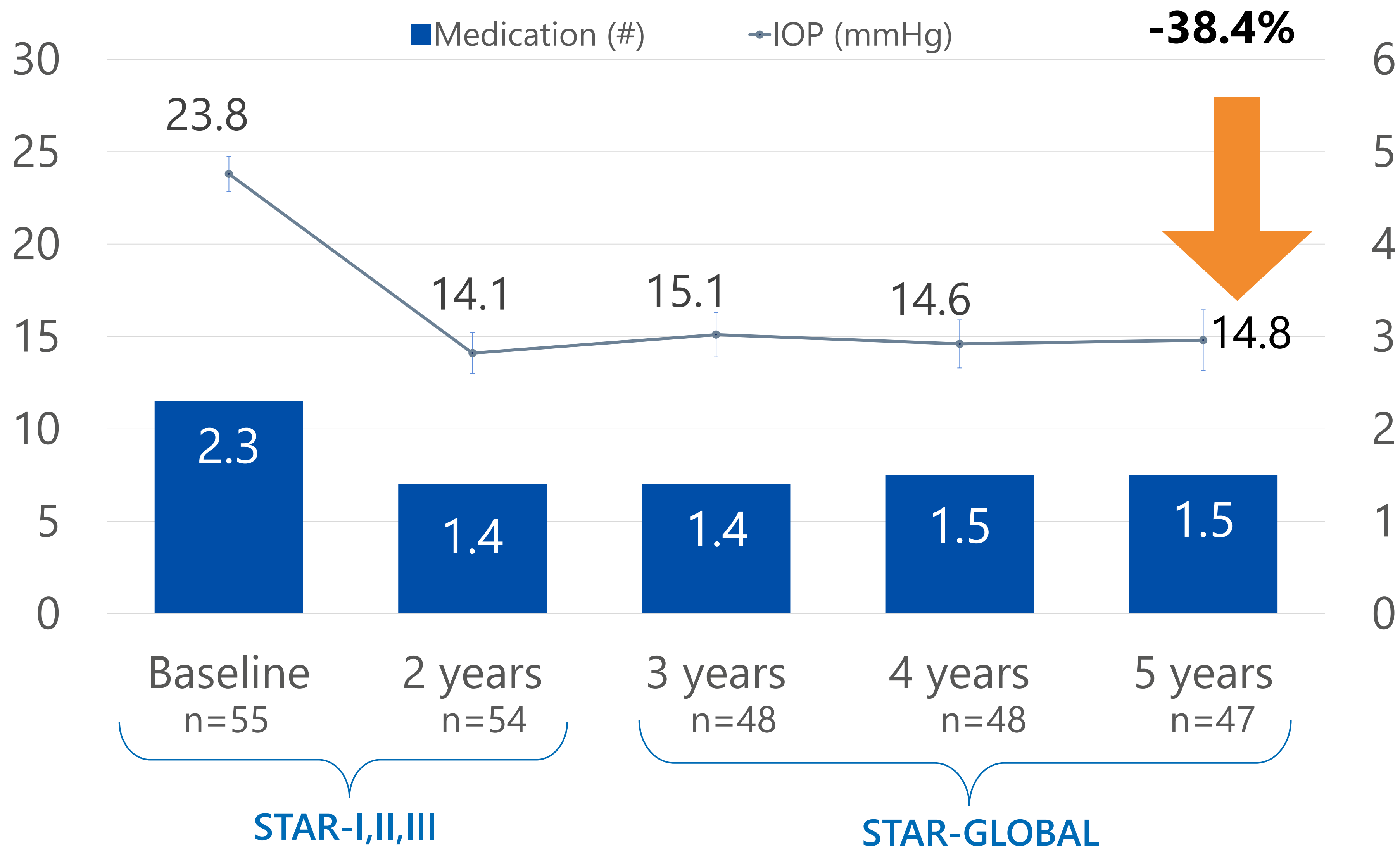
- The device was implanted in a standalone procedure in phakic and pseudophakic eyes in four prospective trials (STAR-I,II,III,IV).
- The trials were completed in 83 subjects in 11 sites in Europe, Asia and Central America with two-year follow-up.
- Upon study completion, subjects were invited to enrol into the STAR-GLOBAL study to continue follow-up annually until five years post implantation.
- Outcome measures were intraocular pressure (IOP), IOP-lowering medications (meds), adverse events and measurement of corneal endothelial cell density (ECD).
- Fifty-five subjects from the STAR-I,II,III trials were enrolled in the STAR-GLOBAL trial, with 47 completing 5-year post-implantation follow-up (85.4%).
- These are preliminary, interim results of subjects who have already completed the STAR-GLOBAL trial.

SURGICAL PROCEDURE

- Ab interno, ≤2.2mm corneal incision, bleb-free
- Controlled creation of supraciliary cleft with a spatula
- Only 0.5mm of the implant stays in the anterior chamber



MEAN DIURNAL IOP AND MEDICATION REDUCTION



NOTE: No washout at any time point

Error bars represent 95% confidence interval. P<0.0001 for IOP reduction at all timepoints. Patients initially treated in the STAR-I,II,III trials until 2 years and then followed from 3 until 5 years in the STAR-GLOBAL trial.

Results

	5Y
Patients with ≥20% IOP reduction from baseline	83%
Patients with IOP ≤18mmHg	79%
Medication-free patients	32%

RESULTS

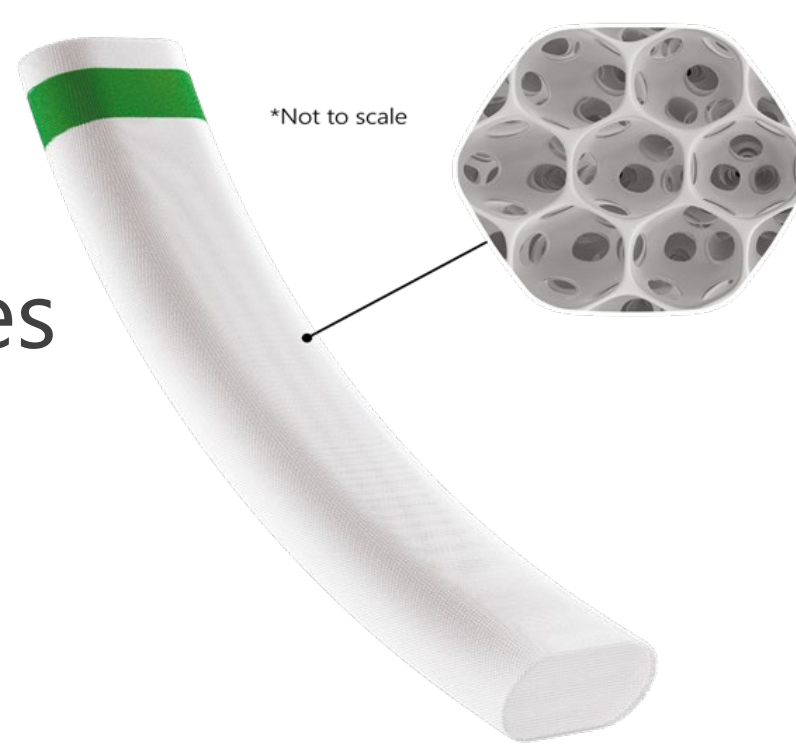
- In this STAR-GLOBAL population, mean baseline diurnal IOP was 23.8±3.5 mmHg with mean of 2.3±1.1 IOP-lowering meds (n=55).
- At 2-years post-implantation, mean diurnal IOP was 14.1±4.0 mmHg (-9.7mmHg, -40.0%; p<0.0001) on 1.4±1.3 meds (n=54).
- At 5-year post-implantation follow-up (n=47), mean diurnal IOP was 14.8±5.6mmHg (-9.1mmHg, -38.4%; p<0.0001) on 1.5±1.4 meds (p=0.001).
- Further, 83.0% of subjects achieved a ≥20% IOP reduction, 78.7% achieved IOP ≤18 mmHg, and 85.1% used the same or fewer medications compared with baseline at 5 years.
- Since STAR-GLOBAL enrolment, adverse events related to MINiject included one IOP increase, one cataract progression and one non-clinically significant iris neovascularization. Mean ECD loss at 5 years was 15.3%.

CONCLUSION

- Standalone MINiject implantation resulted in a clinically significant and sustained reduction in IOP and medication use up to five years post-implantation.
- This supraciliary MIGS device offers an effective, bleb-free treatment option for glaucoma patients requiring low and sustained target IOPs.

MINIJECT®

- Proprietary STAR® material
- Soft, flexible, with anti-fibrotic properties
- Micro-pores for a natural flow of fluid; allows bio-integration of surrounding tissues



Clinicaltrials.gov IDs:

STAR-I: NCT03193736

STAR-II: NCT03624361

STAR-III: NCT03996200

STAR-GLOBAL: NCT04524416

Disclosures: Andrew Tatham: Thea (C, I), Alcon (C, I), AbbVie (L, R), Sight Sciences (L), Heidelberg (L), SCOPE (L), Santen (C, I), Viartis (C), Regeneron (C, R), Ciliatch (C), iSTAR Medical (C, R), Nova Eye Medical (R). Antonio Fea: AbbVie (C, R, I), EyeD Pharma (C, M), Glaukos (M), Santen (C), Philippe Denis: Alcon (C, I), Glaukos (C, I), Santen (C), Christoph Hirneiss: AbbVie (S), Glaukos (I), iSTAR Medical, Novartis (S), Santen (C), Ike Ahmed: Aequus (C), Ace Vision (C), Aerle Pharmaceuticals (C, R), Akorn (C), Alcon (C, L, R), Allergan (C, L, R), American Academy of Ophthalmology Board (M), 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, I), 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, I), Heru (C), Hexins Pharma (C), Iantrek (C), InjectSense (C), Index (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), 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).

Provisional and interim results. Data on file at iSTAR Medical.

Study and analysis sponsored by:

