Influence of pre-operative intraocular pressure or medication use on two-year outcomes of a supraciliary drainage device: A pooled analysis from the STAR-I,II,III studies

Ian Rodrigues MBBS FRCOphth[1]; Antonio Fea MD PhD[2]; Philippe Denis, MD PhD[3], Christoph Hirneiß MD PhD[4], Brian Flowers MD[5]; Inder Paul Singh MD[6]; Iqbal Ike K Ahmed MD[7]

1. Guy's & St Thomas' NHS Foundation Trust, London, UK; 2. Dipartimento di Scienze Chirurgiche–Clinica Oculistica, Torino, Italy; 3. Department of Ophthalmology, Hôpital de la Croix-Rousse, Lyon, France; 4. Klinikum der Universität München, Ludwig-Maximilians-Universität, Munich, Germany; 5. Ophthalmology Associates, Fort Worth, TX, USA; 6. The Eye Centers of Racine and Kenosha, Wisconsin, USA; 7. John Moran Eye Center, University of Utah, Salt Lake City, Utah, USA.

PURPOSE

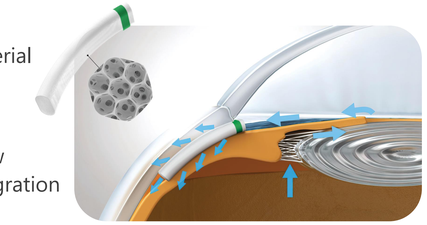
- Describe the influence of **baseline intraocular pressure ($_b$IOP) or number of medication classes ($_b$Med)** on outcomes at 2 years.
- Phakic and pseudophakic eyes with open-angle glaucoma (OAG).
- Standalone ab-interno implantation with no medication washout of a supraciliary, minimally-invasive glaucoma surgery (MIGS) device, **MINIject®** (iSTAR Medical, Belgium).

METHODS

- Data from **66 patients** who completed **2-year follow-up** from three trials (STAR-I,II,III) were pooled in a post-hoc meta-analysis.
- Outcomes of patients with **high $_b$IOP** (>24mmHg pre-surgery) were compared to those with **moderate $_b$IOP** (21-24mmHg).
- Outcomes were also compared between patients with **higher $_b$Med** (3-4 medication classes pre-operatively) and with **lower $_b$Med** (1-2 classes).
- Success was defined as IOP >5 and ≤21mmHg with ≥20% reduction in IOP from baseline, without (complete) or regardless of (qualified) glaucoma hypotensive medication use at follow-up.

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

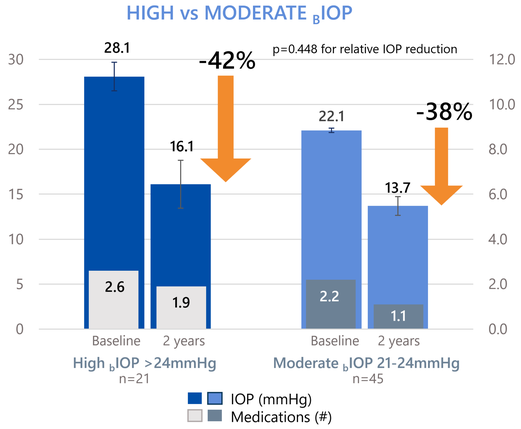


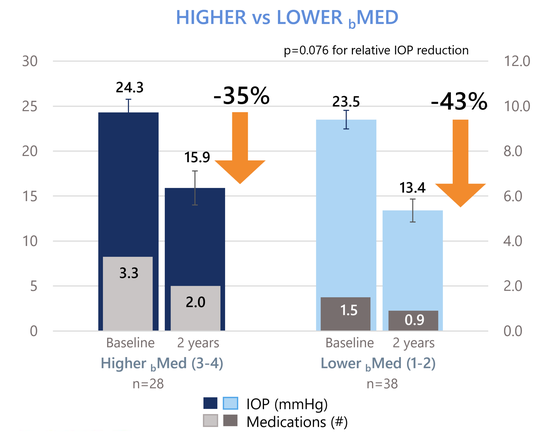
MINIject in the supraciliary space

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





Error bars represent 95% confidence intervals. Preliminary data on file.

	Higher $_b$Med Group	Lower $_b$Med Group	
Complete Success	18%	55%	p=0.003
Qualified Success	68%	84%	p=0.144

The likelihood of complete success was greater in the low $_b$Med group (55%,18%; p=0.003), but both groups had a similar qualified success rate (84%,68%; p=0.144).

CONCLUSION

Comparable levels of relative IOP reductions at 2 years were seen in patients regardless of a high (mean 28.1mmHg) or moderate (mean 22.1mmHg) baseline IOP prior to MINIject implantation. Likewise, a comparable reduction in relative IOP was achieved despite the number of medications used pre-operatively.

Clinicaltrials.gov:
STAR-I: NCT03193736
STAR-II: NCT03624361
STAR-III: NCT03996200

Disclosures: **IR**: Altacor ©, Apperta Foundation (C), iSTAR Medical (C), Santen (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); **CH**: iSTAR Medical, Santen, AbbVie, Novartis; **BF**: Alcon (C, R), Ivantis (C, R), Glaukos (C, R), Sight Sciences (C, R), New World Medical (C), iSTAR Medical (C, R), Santen (C, R), NiCox (R), EyeNovia (C), Iantrek (C, R); **IPS**: iSTAR Medical, Allergan, Alcon, Quantel – Ellex, Sight Sciences, New World Medical, Glaukos, Zeiss, Rayner, Ocular Therapeutix, Alchemy, B+L, Visiox, Radius, Nova Eye; **IKA**: Aequus (C), Ace Vision (C), Aerie Pharmaceuticals (C, R), Alcorn (C), Alcon (C,LR), Allergan (C,LR), Aquea Health, Inc (C), ArcScan (C), Avellino Lab USA, Inc (C), Avisi (C), Bausch Health (C), Beaver Visitec (C), Belkin Vision (C), Beyeonics (C), Bioncode (C, R), Carl Zeiss Meditec (C, L), Centricity Vision, Inc (C), CorNeat Vision (C), Custom Surgical (C), Elios Vision (C), EluMed (C), Equinox (C), eyeFlow, Inc (C), EyeMed (C), EyeO 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), MicroOpti (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)

Studies and meta-analysis sponsored by iSTAR MEDICAL