Performance of a Supraciliary Drainage Device in Glaucoma Patients with Various Stages of Disease Severity

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PURPOSE

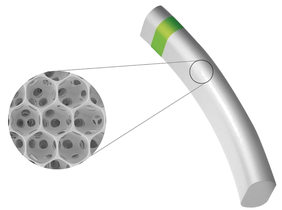
To investigate the **influence of disease severity at baseline** in patients with medically uncontrolled, primary open-angle glaucoma on **clinical outcomes 2 years** after implantation with a novel, supraciliary, minimally-invasive glaucoma surgery (MIGS) drainage device, MINIject® (iSTAR Medical, Belgium).

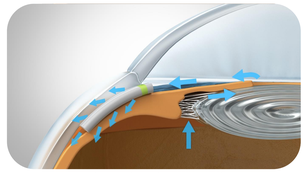
METHODS

- **Data pooled from 3 prospective, multi-centre, interventional, single-arm studies.**
- The implant is 5mm long and comprises a network of hollow spheres made of soft, flexible, medical-grade silicone.
- **Ab-interno implantation** into the supraciliary space was performed as a **standalone procedure** in each study.
- Patients were assessed at baseline and regular intervals until 2 years post-implantation.
- In this post-hoc analysis, glaucoma severity at baseline was defined by visual field mean deviation (MD) as mild (MD > -6dB), moderate (-6 ≥ MD ≥ -12dB) or severe (MD< -12dB). Patients were categorised and outcomes compared at 2 years (Kruskal-Wallis ANOVA test).

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 implanted in the supraciliary space

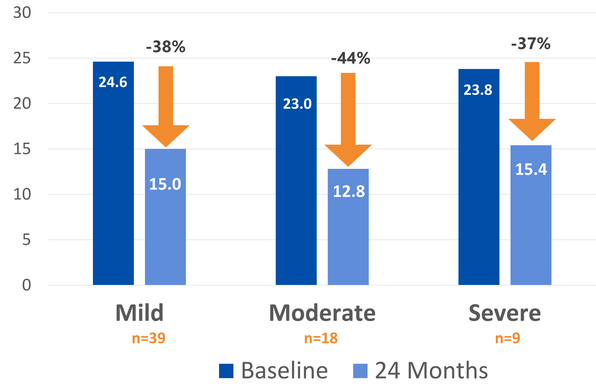
SURGICAL PROCEDURE

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

RESULTS

Disease severity (n)	Mean diurnal IOP at 2 Years (mmHg)	IOP reduction	Mean medications at 2 years (change from baseline)
Mild (n=39)	15.0 ± 4.4	38%	1.3±1.0 (-1.0)
Moderate (n=18)	12.8 ± 3.6	44%	1.1±1.0 (-1.2)
Severe (n=9)	15.4 ± 6.1	37%	1.9±2.0 (-0.7)
Total patients = 66		p=0.95	p=0.58

MEAN DIURNAL IOP REDUCTION BY DISEASE SEVERITY



CONCLUSION

This post-hoc analysis indicates that this supraciliary drainage device, implanted as a standalone procedure, may achieve similar levels of IOP and medication reduction regardless of the degree of glaucoma severity.

REFERENCES

- Clinicaltrials.gov - STAR-I: NCT03193736, STAR-II: NCT03624361, STAR-III: NCT03996200
- 6 months STAR-I: Denis P, Hirneiß C, Reddy KP et al. "A First-in-Human Study of the Efficacy and Safety of MINIject in Patients with Medically Uncontrolled Open-Angle Glaucoma (STAR-I)." Ophthalmol. Glaucoma 2019;2:290-297.
- 24 months STAR-I: Denis P, Hirneiß C, Durr GM, et al. "Two-year outcomes of the MINIject drainage system for uncontrolled glaucoma from the STAR-I first-in-human trial." Br J Ophthalmol. 2022;106:65-70.
- 6 months STAR-II: García Feijoó J, Denis P, Hirneiß C et al. "A European Study of the Performance and Safety of MINIject in Patients With Medically Uncontrolled Open-angle Glaucoma (STAR-II)", J Glaucoma: 2020 Oct; 29(10); 864-871.

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