Real-life Safety and Efficacy Results of a Supraciliary Drainage Device at 12 months (STAR-LIFE)

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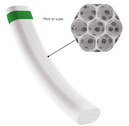
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PURPOSE

The safety and efficacy of a novel, minimally-invasive glaucoma surgery (MIGS) device (MINIject®; iSTAR Medical, Belgium) implanted ab interno into the supraciliary space in glaucoma patients is described in a real-life setting.

METHODS

- The STAR-LIFE study is a real-life, observational, multi-centre registry with follow-up until 2 years in up to 320 patients treated with the MINIject supraciliary MIGS.
- Included patients were adults diagnosed with open-angle glaucoma who were treated with commercially available MINIject devices, regardless of lens status.
- The patient was followed according to the treating surgeon's standard of care with no medication washout.
- The primary endpoint was the reporting of unexpected incidents and/or serious reportable incidents, and secondary endpoints included intraocular pressure (IOP) measurements and ocular hypotensive medication use compared with baseline.
- These are results from the first 145 patients who completed 12-month follow-up.

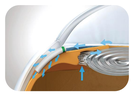


MINIJECT®

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

SURGICAL PROCEDURE

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



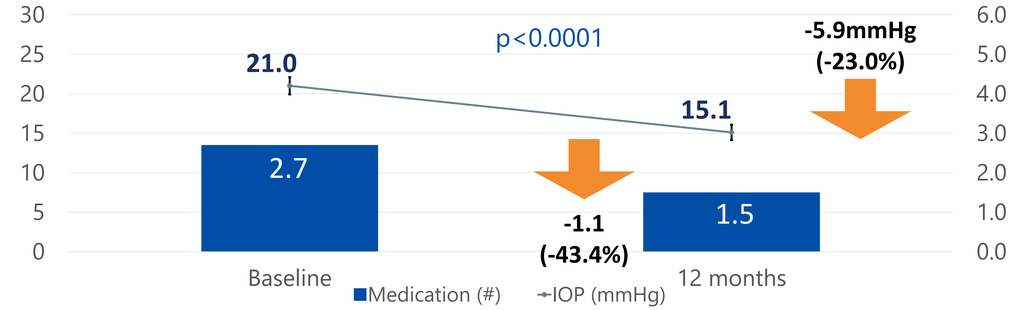
MINIject in the supraciliary space

RESULTS

- At the time of analysis, 145 patients had reached 12-month follow-up in 12 sites in Germany, Switzerland, UK and Austria.
- A standalone procedure was performed in 84.1% of cases (independent of cataract surgery) and investigators reported mild-to-moderate glaucoma in 63.5% patients, where reported. Apart from cataract surgery, 43.4% of patients had no prior surgery.
- There were 82.1% of patients who achieved either an IOP reduction of >=20% and/or a reduction in medication.
- Secondary surgical interventions were performed in 7.6% of patients.

STAR-LIFE Demographics		Standalone	Combo cataract	All
Population		122	23	145
Gender	Female	54.9%	52.2%	54.5%
Mean Age (years)		72.8±10.4 (range 34-89)	73.7±7.3 (range 58-87)	73.0±10.0 (range 34-89)
Ethnic origin	Caucasian	86.9%	87.0%	86.9%
	African	6.6%	4.4%	6.2%
	Asian	1.6%	4.4%	2.1%
	Hispanic	0.8%	4.4%	1.4%
	Arabic	0.8%	0.0%	0.7%
	Other	1.6%	0.0%	1.4%
	Unknown	1.6%	0.0%	1.4%
Study eye	OS	54.1%	47.8%	53.1%
Pseudophakic		79.5%	-	69.7%
Glaucoma Type	POAG	71.3%	73.9%	71.7%
	PXF	18.0%	17.4%	17.9%
	Pigmentary	3.3%	0.0%	2.8%
	Neovascular	0.8%	0.0%	0.7%
	Other	5.7%	8.7%	6.2%
	Unknown	0.8%	0.0%	0.7%
Severity of glaucoma	Mild	16.4%	30.4%	18.6%
	Moderate	43.4%	30.4%	41.4%
	Severe	35.3%	30.4%	34.5%
	Unknown	4.9%	8.7%	5.5%
Mean baseline medicated diurnal IOP (mmHg)		21.4±6.6 (range 11-51)	18.9±7.3 (range 11-45)	21.0±6.7 (range 11-51)
Mean baseline IOP lowering drugs		2.7±1.5 (range 0-8)	2.5±1.4 (range 0-5)	2.7±1.5 (range 0-8)

MEAN DIURNAL IOP AND MEDICATION REDUCTION



NOTE: No medication washout.

Error bars represent 95% confidence interval. First 145 patients with results on file up to 12-months. Provisional, interim results.

Results	Baseline	12M
Patients with IOP reduction ≥20% from Baseline	N/A	53%
Patients with IOP ≤18mmHg	40%	77%
Patients with IOP ≤15mmHg	19%	50%
Patients medication-free	10%	42%

- There were no unexpected nor serious reportable incidents. Serious incidents were: 6 IOP increase (4.1%), 5 hypotony (3.4%), 3 device migration (2.1%), 2 hyphema (1.4%), and 1 each of vitreous haemorrhage, anterior chamber (AC) inflammation and narrow AC (0.7%). All serious incidents were resolved at the time of analysis except 1 IOP increase treated only with medication.
- Outcomes at 12 months after standalone vs combined surgery were similar for IOP reduction (-24.2% vs -16.5%; p=0.308) and medication (-39.3% vs -66.3%; p=0.065) reduction respectively. Although not powered, results showed a trend towards more medication reduction after combined surgery.

CONCLUSION

In diverse centres in the STAR-LIFE study, a meaningful IOP reduction of 5.9mmHg was achieved 12-months after treatment with the MINIject implant, in addition to a mean 1.1 medication reduction. This supraciliary MIGS procedure offers a valuable bleb-free treatment option for patients with glaucoma, either as a standalone procedure or in combination with cataract surgery.

Clinicaltrials.gov ID: NCT05269680

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C: Consulting fees, **L:** Lectures, **R:** Grant, **S:** Stock or options, **T:** Travel.

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

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