Retrospective analysis of the safety and efficacy of the MINIject implant at 12 months

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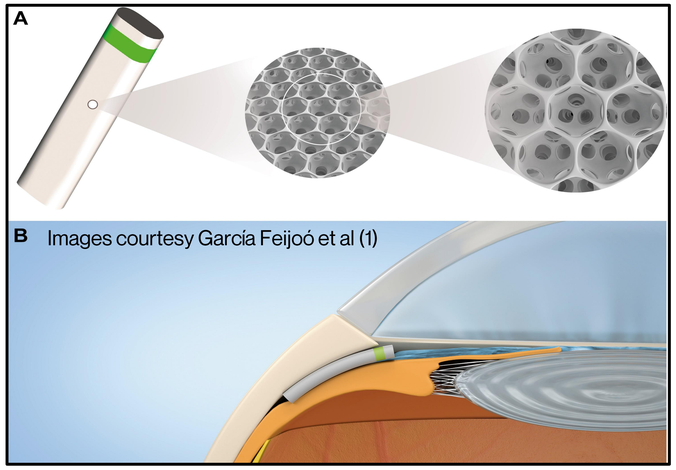
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Introduction

Minimally Invasive Glaucoma Surgery (MIGS) offers an attractive alternative to traditional procedures such as trabeculectomy. The MINIject is currently the only commercially available device targeting the supraciliary space. The MINIject is a 5mm long implant composed of interconnected hollow spheres made from a proprietary silicone material (Figure 1a). By inserting the device gonioscopically between the scleral spur and ciliary body, a communication is created between the anterior chamber and supraciliary space (Figure 1b). This ab interno supraciliary approach aims to enhance the alternate physiological drainage pathway.

Methods

A retrospective analysis of MINIject surgeries performed by a single surgeon at Colchester Hospital, UK, from March to November 2022, included stand-alone and combined procedures with phacoemulsification. The primary outcome was IOP reduction. Secondary outcomes included medication dependency, adverse events, and success rates. **Success was defined as complete (IOP ≤21 mmHg and >5 mmHg with ≥20% reduction without medication) or qualified (IOP ≤21 mmHg and >5 mmHg without medication).** There was no medicine washout. Statistical significance was determined by unpaired 2 tail T-test.



Objectives

With an ever-expanding variety of MIGS devices on the market promising increased drop independence and lower intraocular pressures it is important to assess how these products perform in the real world. This study aims to characterise intra- and post-operative efficacy and safety of the MINIject device to enrich discussion of device selection in MIGS.

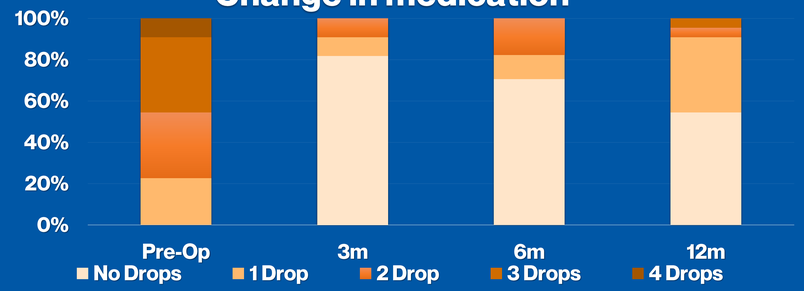
Results

Of 28 MINIject cases at Colchester Hospital, 22 had 12-month follow-up data. Primary open-angle glaucoma was the most common diagnosis, affecting 18 (82%) of these cases. The average age of patients was 75 years (range 55-88 years, SD 8.6). At 12 months, there was a significant reduction in the mean number of drops from 2.32 (SD 0.94) at baseline to 0.59 (SD 0.78) ($p < 0.0001$), with 54.5% of eyes becoming drop-free. Mean IOP decreased from 16.1 mmHg (SD 3.1) to 13.8 mmHg (SD 3.6), a 14.1% reduction ($p = 0.0169$). Of the eyes, 86.4% maintained an IOP <18 mmHg, with 90.9% achieving this with fewer drops. There were no intra-operative complications. Post-operative microhyphema occurred in 10.7% of cases and gross hyphaema in 7.1%. Complete success was reached in 27.3% (n=6) of eyes, and qualified success in 59.1% (n=13).

Conclusions

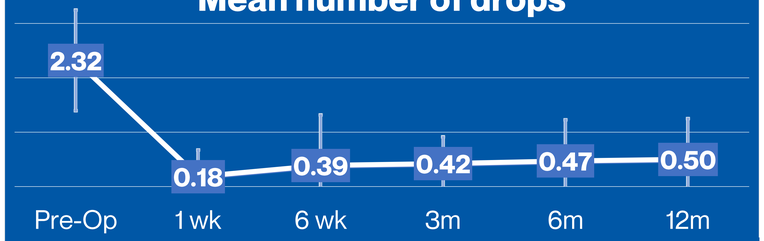
At 12 months, our study observed a mean IOP reduction of 19.6% to 13.0 mmHg with an average use of 0.4 IOP-lowering medications, compared to the STAR-I study's 30.83% reduction to 16.0 mmHg. Our baseline IOP was lower (16.14 mmHg vs 23.2 mmHg in STAR-I), potentially contributing to the lesser IOP reduction and subsequent reduced success rate. Despite this, both studies saw significant reductions in medication burden. Our complete and qualified success rates were lower than expected perhaps indicating patient selection favours those with higher baseline IOPs with targets in the mid-teens. Hyphaemia rates in our findings (11.5% to 22.6%) mirrored those reported in the literature and resolved in all cases, consistent with published outcomes. Our results affirm the MINIject device's effectiveness in significantly reducing IOP and medication use over 12 months, with transient hyphaemia observed in a minority of cases.

Change in medication



There was a significant reduction in drop burden at 3 months post MINIject ($p<0.0001$) which persisted to 12 months. This graph demonstrates most patients were medication free and no patients required more than 2 drops.

Mean number of drops



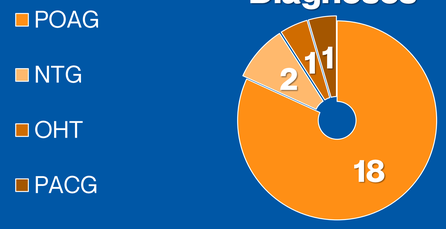
There was a significant reduction in drop burden post MINIject ($p<0.0001$). This graph demonstrates the mean number of drops reduced significantly and remained low at the 12-month point,

Mean IOP (mmHg)



There was a significant reduction in mean IOP post MINIject ($p=0.0039$). This graph demonstrates an initial reduction followed by a slight increase. There was a 14.1% reduction in mean IOP at 12 months with 86.4% of eyes <18mmHg.

Diagnoses



Primary Open Angle Glaucoma accounted for the most common diagnosis amongst patients (n=18 / 82%). Other diagnoses included normal tension glaucoma, ocular hypertension and primary angle closure glaucoma.

1) García Feijoó, J., Denis, P., Hirneiß, C., Aptel, F., Perucho González, L., Hussain, Z., Lorenz, K., Pfeiffer, N., & STAR-II Investigators (2020). A European Study of the Performance and Safety of MINIject in Patients With Medically Uncontrolled Open-angle Glaucoma (STAR-II). Journal of glaucoma, 29(10), 864–871. https://doi.org/10.1097/IJG.0000000000001632
2) Denis, P., Hirneiß, C., Reddy, K. P., Kamarthy, A., Calvo, E., Hussain, Z., & Ahmed, I. I. K. (2019). A First-in-Human Study of the Efficacy and Safety of MINIject in Patients with Medically Uncontrolled Open-Angle Glaucoma (STAR-I). Ophthalmology. Glaucoma, 2(5), 290–297. https://doi.org/10.1016/j.ogla.2019.06.001