

MINIject supraciliary glaucoma implant

A Retrospective Cohort Study of Real World Data at **6 Months**

Luke Tanner, Caroline Wong, Mohammad Ihsan Fazal, Rynda Nitiahpapand, Georgios Chatzithanasis, Mohammed Elghobaier, Spyros Pipis, Minas Aslanides and Chrysostomos Dimitriou at **The Colchester Eye Centre of Excellence, United Kingdom**

East Suffolk and North Essex NHS Foundation Trust

Introduction

Glaucoma is a sight-threatening multifactorial disease of the optic nerve, which can cause permanent loss of vision. It is the leading cause of irreversible blindness worldwide. Intra-ocular pressure reduction remains the main therapeutic intervention currently available to the treating clinician. (1,2)

Minimally invasive glaucoma surgery (MIGS) devices are at the forefront of glaucoma research for their potential to lower intraocular pressure and reduce drop dependence without more invasive surgery. MINIject is a novel ab-interno MIGS implant, enhancing physiological uveoscleral outflow from the anterior chamber to the supraciliary space, lowering IOP. The MINIject implant is a flexible, porous, silicone micro-sponge, bio-integrating with surrounding tissue to provide long-term stability and drainage efficacy. It is currently the only available MIGS device which targets the supracilliary space. (3)

The MINIject implant can be inserted as a stand-alone procedure or in combination with cataract surgery, and is approved for use in patients with open angle glaucoma.

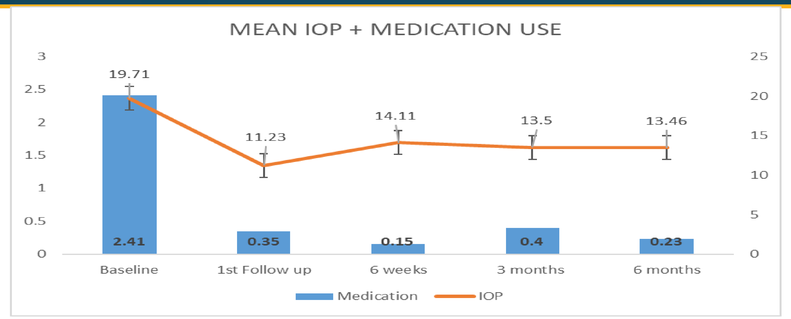
Methods

Between March 2022 to December 2022, 39 eyes of 32 patients with progressive glaucoma received a MINIject implant, either as a stand-alone procedure or combined with phacoemulsification. These cases were reviewed retrospectively to determine:

- Primary outcome: IOP reduction from baseline, with a target of ≥20%.
- Secondary outcomes: reduction of IOP-lowering drops; incidence of adverse events.

Results

39 eyes of 32 patients received the MINIject. 56% (n=22) were female, 44% (n=17) were male and the mean age was 78.6 years (62 to 93 years). Two eyes were excluded from 6 month data analysis as one implant required explantation and the other patient died. The majority, 71.8% (n=28) of procedures were combined with phacoemulsification and the remaining, stand alone MINIject implants. Our cohort had a mean baseline IOP of 19.71 mmHg and required an average of 2.41 IOP lowering agents. At 6 months, 64.1% (n=25) achieved ≥20% IOP reduction from baseline with 87.18% (n=34) of patients being drop independent. The mean IOP reduced to 13.46mmHg with the average percentage decrease in IOP being 20%. Furthermore 64.1% (n=25) achieved an IOP of <15mmHg. The average IOP at 6 months in the phacoemulsification-combo eyes was 13.92 mmHg and 13.11mmHg in the standalone group.



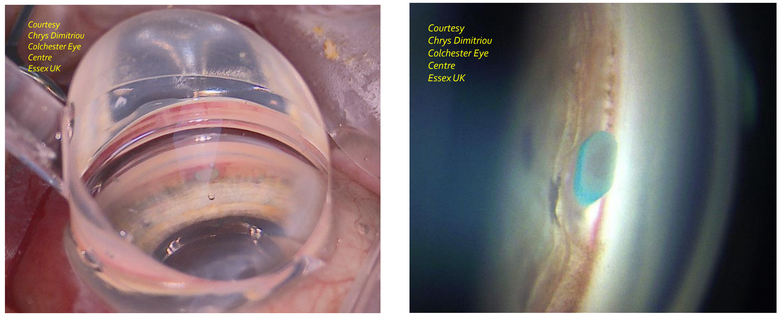
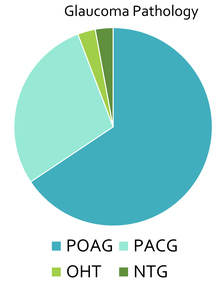


Figure: (Right) insertion of MINIject intraoperatively, (Left) Gonio view from clinic showing MINIect in situ



Adverse events were observed in 12.8% (n=5) of cases, the most frequent being post-operative hyphaema (3), aqueous misdirection (1) and vitreous haemorrhage (1). No cases of sight-threatening hypotony, choroidal effusion, choroidal or retinal detachment, or suprachoroidal haemorrhage were observed. One case of post-operative hyphaema required an anterior chamber washout one week following initial surgery. Other cases of micro-hyphaema resolved spontaneously over the first month postop. The aqueous misdirection was managed intraoperatively with viscoelastic fluid exchange with no further untoward events.

Discussion

The MINIject implant was shown in this study to be effective at lowering IOP at 6 months. The mean reduction of 31.70% (6.25 mmHg) at 6 months from an already low baseline in patients who have had their IOP well managed with conventional treatment, highlights it's powerful pressure lowering effect. One key finding was 87.18% of patient were on no drops from previously having progressing glaucoma. This is based on a population of patients who have not had a washout period from medication. Drops are known to have many side effects and can impact a patients quality of life. Not only does drop independence improve patients lives it also optimises the ocular surface should further glaucoma surgery be necessary as well as provide a potential cost saving. The MINIject has been shown to be relatively safe with 12.8% of our cohort experiencing adverse events with only one requiring further intervention and others were managed medically or resolved spontaneously. There were no observed cases of raised intraocular pressure secondary to fibrosis of the MINIject, neither haemorrhagic or hypotonous adverse events, as would be of concern with any supraciliary implant.

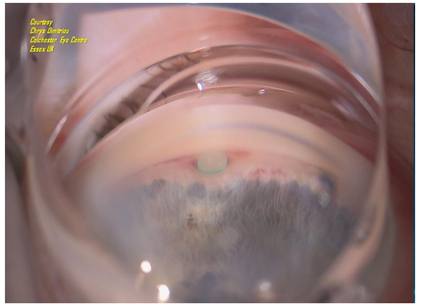


Figure: MINIject implant green demarcation line at the level of scleral spur with minimal surrounding cleft.

Conclusion

The MINIject implant was found to only require a shallow learning curve, which is minimal for a surgeon experienced in MIGS procedures. Ease and speed of injection are major advantages to consider in addition to its impressive IOP lowering ability. One salient finding from the study was the vast majority of patients achieving IOP within target off glaucoma medication. While our preliminary data is limited by a small sample size and a short 6 month follow up, they demonstrate that the MINIject implant achieves a powerful reduction in IOP with few adverse events, and this is supported by other longer term studies in the literature.[3]

References

(1) Jonas, J.B., Aung, T., Bourne. R.R., et al. (2017) Glaucoma. Lancet 390(10108), 2183-2193. (2) Tham YC, Li X, Wong TY, et al. Global prevalence of glaucoma and projections of glaucoma burden through 2040: a systematic review and meta-analysis. Ophthalmology 2014; 121: 2081–2090. (3) Denis P, Hirneiß C, Durr GM, et al. "Two-year outcomes of MINIject drainage system for uncontrolled glaucoma from STAR-I first-in-human trial". Br J Ophthalmol 2022; 106(1): 65-70.