Retrospective Analysis and Outcome Characterisation of Preliminary Post-Operative Results from 3 Schlemm's Canaloplasty Devices Combined with Cataract Surgery

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Introduction

Minimally Invasive Glaucoma Surgery (MIGS) is at the cutting edge of modern glaucoma management. MIGS aims to reduce the burden of drops and deliver lower IOPs without more invasive surgery such as trabeculectomy. A wide variety of devices are available and of these, we evaluated three that increase aqueous outflow via Schlemm's canaloplasty:

OMNI SURGICAL SYSTEM

The Omni device uses a microcatheter in 180° of Schlemm's canal to deliver viscoelastic and dilate the canal and collector channels. It has a "Triple approach": Schlemm Canaloplasty, Collector Channel Canaloplasty and an Optional Trabeculotomy the extent of which is surgeon controlled.

HYDRUS® MICROSTENT

The Hydrus Microstent is an 8mm long fenestrated stent inserted into Schlemm's canal to dilate the canal up to 5 times its natural size preventing the collapse of Schlemm's in high IOP while the fenestrations facilitate aqueous outflow to collector channels.

iTrack™

The iTrack device uses a microcatheter in 360° of Schlemm's canal to deliver viscoelastic and dilate the canal and collector channels. The iTrack incorporates a fibre optic light pipe to visualise the tip of the catheter as it is advanced.

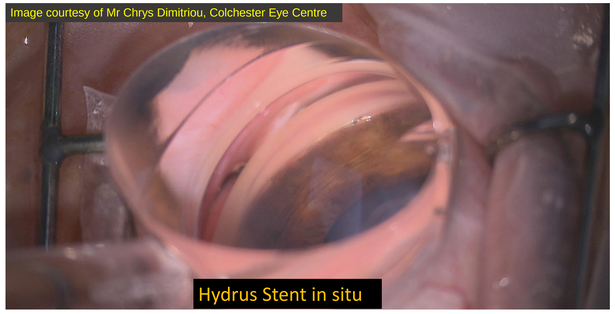
Methods

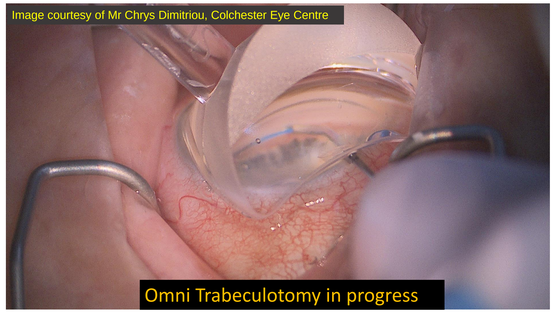
We conducted a retrospective analysis to identify all cataract surgery cases where Hydrus, Omni and iTrack devices were used by a single surgeon between 1st March 2021 and 30 November 2022. Data was collected on: Number of IOP lowering drops, IOP and Visual acuity at pre-op and subsequent follow up at 1 week, 6 weeks, 3 months and 6 months.

Results

43 Omni, 43 Hydrus and 14 iTrack surgeries were performed. Of these, 19 Omni, 21 Hydrus and 3 iTrack cases had 6 month follow up data. The mean number of drops at baseline vs 6 months were 1.32 to 0.58 (Omni), 1.45 to 0.61 (Hydrus)and 1.00 to 0.33 (iTrack). There were no intra-operative complications. Post-operatively, there was CMO in the iTrack (n=1, 33%) and Omni (n=1, 5.26%) cohorts. The Omni cohort also encountered uveitis (n=1, 5.26%) , hyphaema (n=1, 5.26%) and choroidal folds (n=1, 5.26%) which all resolved. The Hydrus cohort had uveitis (n=2, 9.52%). IOP was reduced at 6 months in Omni (19.4%), Hydrus (26%) and iTrack (12.1%). There was no significant difference in IOP reduction amongst the cohorts. Visual acuity improved with Omni and Hydrus but was slightly worse in the iTrack cohort.

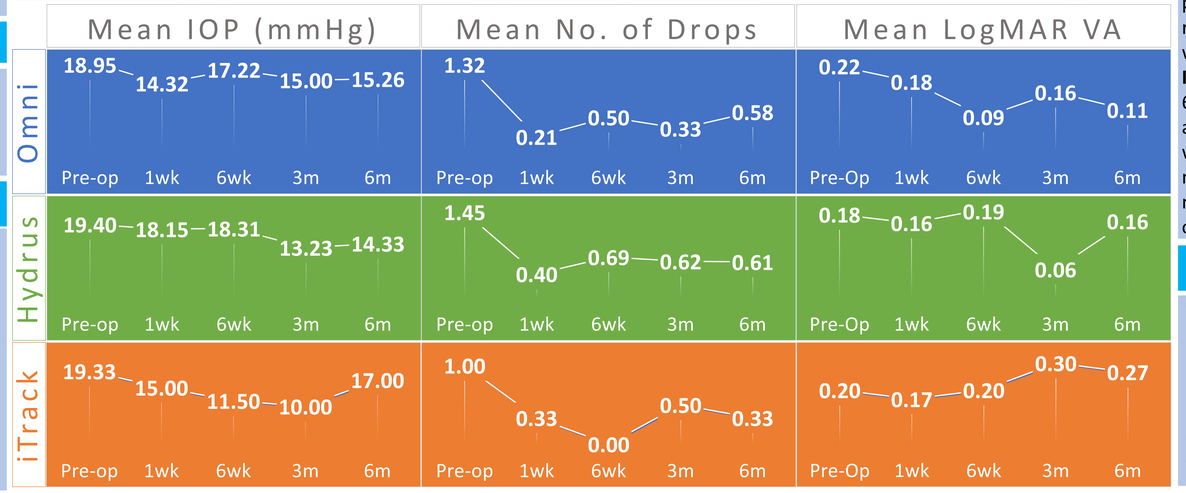






Demographics

	n	Mean age at surgery (SD)	Male : Female	Significant Comorbidity
Omni	19	74 (10.9)	9:10	1
Hydrus	21	89 (5.1)	12:9	2
iTrack	3	78 (2.1)	3:0	1



Discussion

All 3 devices resulted in a clinically significant reduction in mean IOP. This reduction was coupled with a decrease in the mean number of drops. Changes in visual acuity were variable but largely attributed to the combined cataract surgery and ocular comorbidities. Complications were minor and all resolved without the need for any further surgical intervention.

In the Omni cohort, 73% of patients had a reduction in drops or experienced lower IOP while remaining on 0 drops at 6 months compared to baseline. 47% of patients were drop free at 6 months. 47% of patients had a drop in IOP ≥ 20% at 6 months compared to baseline. This is at odds with the 6 months results of the Gemini study, however, in our cohort the extent of trabeculotomy varied whereas in the Gemini study all patients had 180 degrees of trabeculotomy (1).

In the Hydrus cohort, 71.4% had a reduction in drops or experienced lower IOP while remaining on 0 drops at 6 months compared to baseline. 61.9% of patients were drop free at 6 months. 61.9% of patients had a drop in IOP ≥ 20% at 6 months compared to baseline. Which differs with the HORIZON study, which at 6 months >80% of patients were drop free while 85.9% of patients had an IOP reduction ≥ 20% at 12 months (2). This can be attributed to no washout period at baseline in our study.

In the iTrack cohort, 66.7% had a reduction in drops at 6 months. 66.7% of patients were drop free at 6 months. 33.3% of patients had a drop in IOP ≥ 20% at 6 months compared to baseline. This differs with reported outcomes where 80% of patients were drop free at 12 months and 84.9% of patients experienced a drop in IOP ≥ 20% at 12 months (3). However, this is largely attributed to the sample size of our cohort.

Conclusion

The results of this retrospective audit demonstrate that the Omni, Hydrus and iTrack safely deliver a clinically significant reduction of IOP and decrease the burden of drops for uncontrolled glaucoma patients. Differences in our data compared to published literature can be attributed to no medication washout periods, variation in the extent of trabeculotomy in Omni and small iTrack sample size. The safety profile and efficacy is similar between the 3 devices.

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(2) Samuelson, T. W., Chang, D. F., Marquis, R., Flowers, B., Lim, K. S., Ahmed, I. I. K., Jampel, H. D., Aung, T., Crandall, A. S., Singh, K., & HORIZON Investigators (2019). A Schlemm Canal Microstent for IOP Reduction in Primary Open-Angle Glaucoma and Cataract: The HORIZON Study. Ophthalmology, 126(1), 29–37. https://doi.org/10.1016/j.ophtha.2018.05.012
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