Four-arm comparative study of outcomes for Hydrus, iStent, and OMNI MIGS devices with standalone phacoemulsification in glaucoma: 6-month follow-up preliminary results

Jeremy Chan[1], Shaheryar Ahmed Khan[1], Panagiotis Dervenis[1], Saad Mahmud Khan[2], Mohammad Ihsan Fazal[1], Chrysostomos Dimitriou[1]

1. Colchester Hospital, East Suffolk and North Essex NHS Foundation Trust. 2. West Suffolk Hospital, West Suffolk NHS Foundation Trust.

East Suffolk and North Essex NHS Foundation Trust

Background

Microinvasive glaucoma surgery (MIGS) has a lower rate of complications and shortens recovery time compared to traditional glaucoma surgery.[1]

A variety of glaucoma drainage devices have been developed and used to decrease intra-ocular pressure (IOP) by increasing aqueous drainage from the globe in primary open-angle glaucoma (POAG).[2]

The aim of this study is to detect any difference in pre-operative and post-operative IOP, glaucoma progression, safety profile, and success rate of POAG patients who were treated with three different Schlemms' canal based MIGS devices:

- Hydrus Microstent
- iStent inject trabecular micro-bpass system,
- OMNI surgical system

with or without phacoemulsification with intra-ocular lens (phaco).

Methods

A single-centre retrospective analysis of POAG patients between 2nd August 2021 to 31st August 2023 being treated with MIGS devices ± phaco: iStent, Hydrus, OMNI, and with a control group of standalone phaco was conducted.

Demographic factors such as gender, age, operated eye were collected. Intergroup differences in IOP, visual acuity (VA), and number of eye drops were compared pre-operative, post-operatively at the first follow-up (FU) appointment, second FU appointment at 3 months, and third FU appointment at 6 months. Differences in pre-operative IOP, VA, and number of eye drops were also compared with within each treatment arm.

Qualified success is defined as reduction of 20% IOP from pre-operative levels regardless of being on drops. Complete success is defined as as reduction of 20% IOP from pre-operative levels wihtout being on drops.

Microsoft Excel & SPSS 2024 were used for statistical and data analysis.

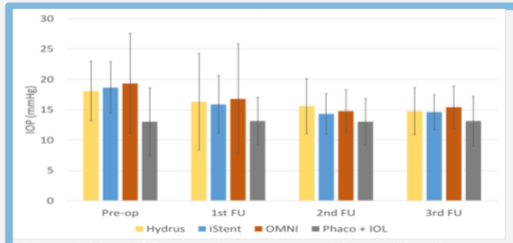


Figure 1: Mean IOP pre and post-op at each interval for all groups

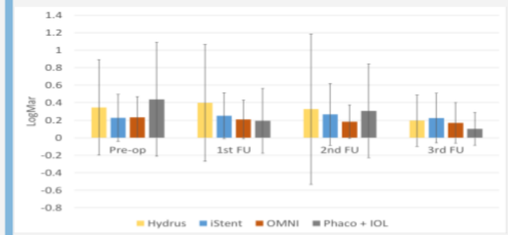


Figure 2: Mean VA pre and post-op at each interval for all groups

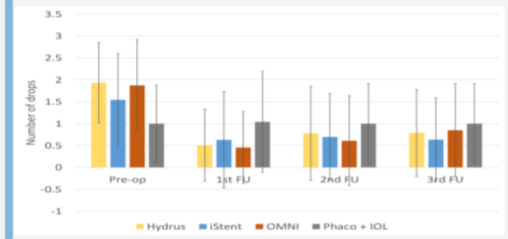


Figure 3: Mean number of drops pre and post-op at each interval for all groups

Results

143 cases were identified and eligible for analysis (50 Hydrus, 31 iStent, 36 OMNI, and 26 standalone phaco).

There were no significant intergroup differences observed in demographic outcomes, IOP, VA, and drops amongst the groups at the specified intervals (p>0.05), except for pre-operative IOP (p<0.001) and pre-operative drops (p=0.001).

There was no significant change in IOP, VA and number of drops pre-operatively and post-operatively at all intervals for all arms (p>0.05) (Figures 1-3).

When comparing IOP difference between the 4 arms pre-operatively and at the 6 months (Table 1):
Hydrus had a significantly larger IOP difference than standalone phaco (Hydrus=3.0, phaco=-0.9, MD=3.8, p=0.02).
iStent had a significantly larger IOP difference than standalone phaco (iStent=4.2, phaco=-0.9, MD=5.1, p=0.01).

When comparing difference in drops between the 4 arms pre-operatively and at 6 months (Table 2):
All MIGS arms had a significantly larger IOP difference than standalone phaco (Hydrus=1.23, phaco=0.06, MD=1.17, p<0.001; iStent=1.07, phaco=0.06, MD=1.01, p=0.03; OMNI=1.22, phaco=0.06, MD=1.16, p=0.001).

When comparing success rates between the 4 arms pre-operatively and at 6 months (Table 3):
iStent had a significantly higher qualified success rate than standalone phaco (iStent=59%, phaco=15%, MD=44%, p=0.04).
iStent had a significantly higher complete success rate than standalone phaco (iStent=29%, phaco=0%, MD=29%, p<0.001).
Hydrus had a significantly higher complete success rate than standalone phaco (Hydrus=22%, phaco=0%, MD=22%, p=0.01).
iStent had a significantly higher complete success rate that OMNI (iStent=29%, OMNI=11%, MD=18%, p=0.01).

4 (11%) OMNI and 1 (4%) standalone phaco cases had an intra-operative complication, all of which were hyphaema.

The most common post-operative complication was raised IOP in 1st FU: 9 (18%) Hydrus, 4 (13%) iStent, 5 (14%) OMNI, and 3 (12%) standalone phaco cases. 1 (2%) Hydrus case had anterior uveitis. 1 (3.8%) standalone phaco case had cystoid macular oedema.

MIGS	Mean pre-op IOP	Mean post-op IOP at 6 months	Mean IOP reduction
Hydrus	18.0	14.7	3.0 mmHg
iStent	18.7	14.6	4.2 mmHg
OMNI	19.3	15.4	3.9 mmHg
Standalone phaco	13.0	13.1	-0.9 mmHg
	OMNI vs Hydrus	Hydrus vs iStent	OMNI vs iStent
p-value:	p=0.66	p=0.46	p=0.87
	OMNI vs Phaco	Hydrus vs Phaco	iStent vs Phaco
p-value:	p=0.06	**p=0.02**	**p=0.01**

Table 1: Comparison of mean difference in IOP for all groups

MIGS	Mean no of pre-op drops	Mean no of post-op drops at 6 months	Mean drop reduction
Hydrus	1.93	0.99	1.23
iStent	1.54	0.95	1.07
OMNI	1.87	1.06	1.22
Standalone phaco	1	0.91	0.06
	OMNI vs Hydrus	Hydrus vs iStent	OMNI vs iStent
p-value:	p=0.96	p=0.61	p=0.66
	OMNI vs Phaco	Hydrus vs Phaco	iStent vs Phaco
p-value:	**p=0.001**	**p<0.001**	**p=0.03**

Table 2: Comparison of mean difference in number of drops for all groups

MIGS	Qualified success	Complete success
Hydrus	45%	22%
iStent	59%	29%
OMNI	46%	11%
Standalone phaco	15%	0%
Qualified success	OMNI vs Hydrus	Hydrus vs iStent	OMNI vs iStent
p-value:	p=0.93	p=0.33	p=0.41
Qualified success	OMNI vs Phaco	Hydrus vs Phaco	iStent vs Phaco
p-value:	p=0.41	p=0.14	**p=0.04**
Complete success	OMNI vs Hydrus	Hydrus vs iStent	OMNI vs iStent
p-value:	p=0.27	p=0.09	**p=0.01**
Complete success	OMNI vs Phaco	Hydrus vs Phaco	iStent vs Phaco
p-value:	p=0.14	**p=0.01**	**p<0.001**

Table 3: Comparison of success rates for all groups

References

1. Management of Angle Closure Glaucoma Guideline. (2022). Retrieved February 19, 2024, from The Royal College of Ophthalmologists website: https://www.rcophth.ac.uk/wp-content/uploads/2022/06/Management-of-Open-Angle-Closure-Glaucoma-1.pdf
2. Balas, M., & Mathew, D. J. (2023). Minimally Invasive Glaucoma Surgery: A Review of the Literature. Vision (Basel, Switzerland), 7(3), 54. https://doi.org/10.3390/vision7030054

Conclusion

- Hydrus, iStent, and OMNI had similar outcomes post-op for IOP reduction (p>0.05) with good sustained IOP reduction & good safety profile.
- Mean medication reduction was also similar in the 3 groups (Hydrus, iStent, and OMNI)- (p>0.05).
- iStent had the consistently highest qualified and complete success rates.
- Standalone phaco did not reduce mean IOP or mean number of drops.
- Further 12 months results to follow.