Combined phacoemulsification and iStent inject versus combined phacoemulsification and Hydrus microstent in South East Asian eyes

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Purpose

- **Minimally invasive glaucoma surgery (MIGS)** has been shown to be **effective** in reducing intraocular pressure and medication burden while providing a **safe** alternative to traditional glaucoma filtration surgeries
- **iStent** inject (Glaukos Corporation, San Clemente, CA, USA) and **Hydrus** microstent (Ivantis, Inc, Irvine, CA, USA) have the advantage of using the same **clear cornea incision** made during cataract surgery to implant these devices, augmenting the pressure-lowering effect of cataract surgery **without** the need for scleral or conjunctival manipulation

Purpose

- Previous study (COMPARE study[1]) has reported **superior** outcome with **Hydrus** compared with two iStent G1 at 1 year, but there is lacking evidence comparing the two in Asian eyes
- **Asian eyes** respond **differently** to glaucoma surgery as they have been associated with higher amount of **pigmentation** and **inflammation**[2] when undergoing glaucoma filtration surgery
- This study aims to compare the **efficacy** and **safety** of combined phacoemulsification with iStent inject (**Phaco-iStent**) and combined phacoemulsification with Hydrus microstent (**Phaco-Hydrus**) in **Asian** patients with **open angle glaucoma**

[1]Ahmed I, Fea A, Au L, Ang R, Harasymowycz P, Jampel H, et al. A prospective Randomized Trial Comparing Hydrus and iStent Microinvasive Implants for Standalone Treatment of Open-Angle Glaucoma- The COMPARE Study, Ophthalmology 2020;127:52-61Glaucoma Surgery
[2]Corbett MC, Hingorani M, Boulton JE, Shilling JS, Factors predisposing to postoperative intraocular inflammation Eur J Ophthalmol 1995;5(1):40-7

Method – Study design

- **Retrospective** case notes review of **consecutive** eyes which underwent Phaco-iStent between April 2019 to August 2020 and Phaco-Hydrus between August 2019 to December 2020 at a **tertiary** eye specialist centre in Singapore
- **Inclusion criteria**: Eyes with **open angle glaucoma** (including primary open angle glaucoma and normal tension glaucoma (NTG) of any severity)
- **Exclusion criteria**: Eyes with **previous ocular surgery** (such as cornea surgery or glaucoma filtration surgery), and **secondary glaucoma**; Patients **lost to follow up** at post-operative **month 12**

Method – Surgical procedure

- Standard or femto-second-assisted **phacoemulsification**
- **Viscoelastic** in anterior chamber
- Either **2 iStent injects** or **Hydrus microstent** implanted at the trabecular meshwork into Schlemm's canal at nasal quadrant using surgical goniolens and pre-loaded injector
- **Topical antibiotics** and **steroid** eye drops started post-operatively, which were **tapered** over **4 to 5 weeks**
- **Anti-glaucoma medications** were either **continued** or **stopped** immediately after surgery depending on severity of glaucoma and surgeon's discretion

Method – Outcome measures and analysis

- Data from post-operative **day** (POD) **1**, **week** (POW) **1**, **month** (POM) **1, 3, 6 and 12** were collected
- On each visit, **best corrected visual acuity**, **intraocular pressure** (IOP), **number of anti-glaucoma medications** and any **adverse events** were noted
- **Statistical analysis** was performed using **IBM SPSS 27.0** (IBM Corp, New York, USA) with significance level set at 5% level

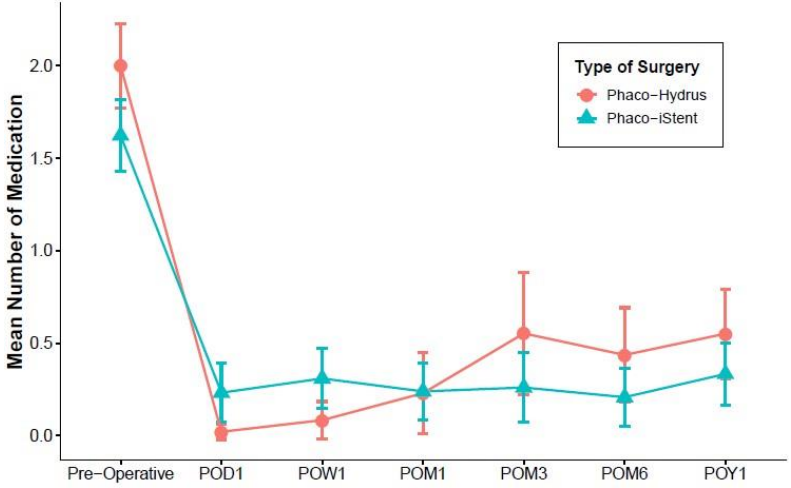
Results – Patient characteristics

- **69 eyes** had *Phaco-iStent* and **49 eyes** had *Phaco-Hydrus*
- Baseline characteristics were **similar**, except for:
  - Proportion of **NTG** being higher in *Phaco-iStent* arm (p=0.005)
  - **Pre-operative number of medications** being greater in the *Phaco-Hydrus* arm (p=0.006)

Parameters	Phaco- Hydrus (N = 49)	Phaco- Istent (N = 69)	p-value
Mean Age (SD), years	72.9 (8.4)	73.0 (8.8)	0.922[1]
Gender			
Male (%)	33 (67.3)	42 (60.9)	
Female (%)	16 (32.7)	27 (39.1)	0.471[2]
Race			
Chinese (%)	43 (87.8)	60 (87.0)	
Malay (%)	2 (4.1)	4 (5.8)	
Indian (%)	2 (4.1)	3 (4.3)	
Others (%)	2 (4.1)	2 (2.9)	1.000[3]
Previous SLT			
No (%)	48 (98.0)	67 (97.1)	
Yes (%)	1 (2.0)	2 (2.9)	1.000[3]
Glaucoma Type			
POAG (%)	41 (83.7)	41 (59.4)	
NTG (%)	8 (16.3)	28 (40.6)	0.005[2]
Median Vertical CDR (IQR)	0.80 (0.70 to 0.85)	0.80 (0.70 to 0.90)	0.410[4]
Glaucoma Severity			
Mild (%)	12 (25.0)	16 (24.6)	
Moderate (%)	13 (27.1)	13 (20.0)	
Severe (%)	23 (47.9)	36 (55.4)	0.638[2]
Mean HVF MD (SD)	-12.1 (7.6)	-13.4 (8.1)	0.390[1]
Mean HVF PSD (SD)	6.7 (3.4)	7.7 (3.7)	0.180[1]
Mean IOP (95% CI)	16.6 (15.3 to 17.9)	15.5 (14.7 to 16.4)	0.157[1]
Mean Number of Medication	2.0 (1.7 to 2.2)	1.62 (1.4 to 1.8)	0.006[4]

[1]Unpaired t-Test with equal variances, [2]Pearson Chi-square Test, [3]Fisher's Exact Test, [4]Mann-Whitney Test (Rank sum Test); SD= Standard deviation; SLT= selective laser trabeculoplasty; POAG= Primary open angle glaucoma; NTG= normal tension glaucoma; CDR= cup to disc ration; IQR= interquartile range; MD= mean deviation; PSD= pattern standard deviation

Results – Efficacy (Reduction in medications)

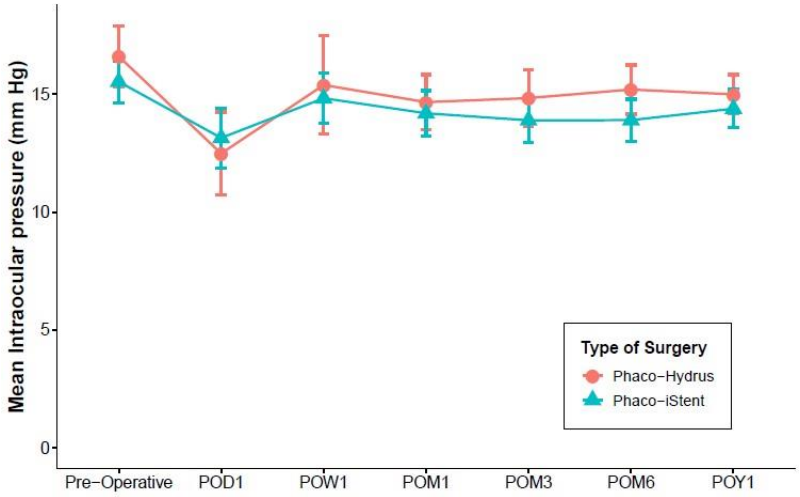


- Both arms had **reduction** of **anti-glaucoma medication** required post-operatively, which was sustained at POM12

- There was **no significant difference** in the mean number of medication reduction **between the two groups** at POM12
- There was reduction of **-1.3±0.1** eyedrops for *Phaco-iStent* group versus **-1.4±0.1** for *Phaco-Hydrus* group at POM12

Results – Efficacy (IOP lowering)

- At POM12, There was **no significant reduction** of mean IOP **from baseline** in both groups.
  - This is likely due to the lack of medication washout preoperatively. Hence, the IOP lowering effect was demonstrated in the reduction of anti-glaucoma medication instead
- Also, there was **no significant difference** in reduction **between** the 2 groups



- Mean IOP reduction was **-1.1 ± 0.5**mmHg (p= 0.149) in the *Phaco-iStent* arm and **-1.6 ± 0.9**mmHg (p= 0.384) in the *Phaco-Hydrus* arm

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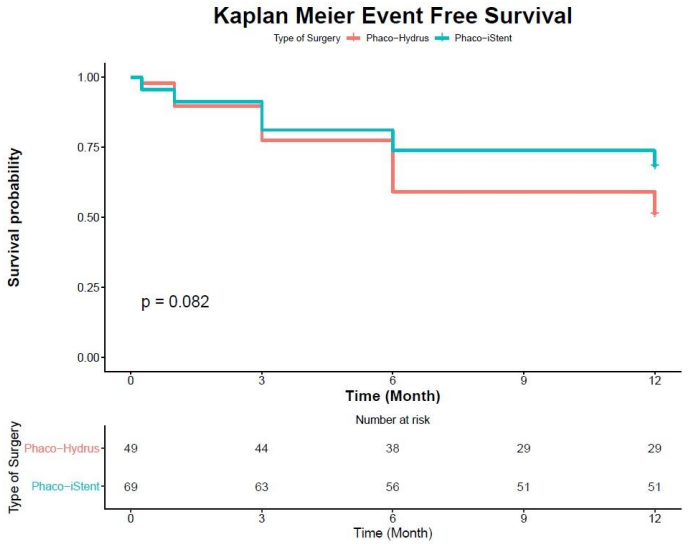
Results – Efficacy (Surgical success)

Parameters	Phaco- Hydrus (N = 49)	Phaco- Istent (N = 69)	p-value
Complete success rate[1] (%)	51.0	68.1	0.061
Qualified success rate[2] (%)	45.0	30.0	0.108
Surgical failure rate[3] (%)	4.1	1.4	0.569

[1]Complete surgical success = Freedom from second glaucoma surgery, IOP of 18mmHg or less and discontinuation of all anti-glaucoma medications
[2]Qualified success = Freedom from second glaucoma surgery and IOP of 18mmHg or less with the use of anti-glaucoma medication, irrespective of whether laser iridoplasty was performed
[3]Surgical failure = Any second glaucoma surgery at any post-operative time or IOP of more than 18mmHg for 2 consecutive visits despite use of anti-glaucoma medications



- There was **no significant difference** in the **success / failure rate rate** between the 2 groups
- **12 months event-free survival rate** was **68.1%** in the *Phaco-iStent* arm and **51.0%** in the *Phaco-Hydrus* arm (p= 0.082)
- Further analysis did **not** reveal any significant patient / ocular factors influencing the probability of complete success at POM12

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Results – Safety (Complications) / Blockage

- **No statistically significant difference** in the intra/ postoperative complications between the two groups **other than** rate of **hyphema**
  - **8.2%** in ***Phaco-Hydrus*** vs **0%** in *Phaco-iStent* arm, p=0.028
  - **3 of 4** hyphema cases **resolved** within a week, while **1** required **anterior chamber washout**
- **Device obstruction** was **more common** in the ***Phaco-Hydrus*** arm (**14%**) than in the *Phaco-iStent* arm (**4.3%**) (p= 0.04)
  - **Slightly higher rate** compared to reported rate of 8-13.9%[1,3,4], likely due to **thicker iris** in Asian eyes
  - **7 of the 8** blocked Hydrus underwent **iridoplasty**, of which **most** (5 eyes) did **not** require further eyedrops or surgical intervention

[3]Shaarawy T., Grehn F., Sherwood M., WGA Guidelines on Design and Reporting of Glaucoma Surgical Trials.The Hague: Kugler Publications, 2009
[4]Samuelson_TW, Chang_DF, Marquis_R, Flowers_B, Lim_KS, Ahmed_IIK, et al. A Schlemm canal microstent for intraocular pressure reduction in primary open-angle glaucoma and cataract: the HORIZON study. Ophthalmology 2018;126(1):29-37.

Conclusion

- *Phaco-Hydrus* and *Phaco-iStent* have **similar efficacy** rates (reduction in mean IOP and mean number of anti-glaucoma eyedrops + success rate) and **safety** profile for both **primary open angle glaucoma** and **normal tension glaucoma** in **Asian eyes.** *Phaco-Hydrus* had **slightly higher rate** of **device blockage** and **hyphema** which can generally be managed with iridoplasty or conservative measures, respectively.
- Further **large-scale** head-to-head **prospective** comparative studies are needed to evaluate if both devices are indeed equally effective.