



# A Prospective Randomized Trial Comparing Hydrus and iStent Microinvasive Glaucoma Surgery Implants for Standalone Treatment of Open-Angle Glaucoma

## The COMPARE Study

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**Purpose:** To compare the efficacy of different microinvasive glaucoma surgery (MIGS) devices for reducing intraocular pressure (IOP) and medications in open-angle glaucoma (OAG).

**Design:** Prospective, multicenter, randomized clinical trial.

**Participants:** One hundred fifty-two eyes from 152 patients aged 45 to 84 years with OAG, Shaffer angle grade III–IV, best-corrected visual acuity (BCVA) 20/30 or better, and IOP 23 to 39 mmHg after washout of all hypotensive medications. Eyes with secondary glaucoma other than pseudoexfoliative or pigmentary glaucoma, angle closure, previous incisional glaucoma surgery, or any significant ocular pathology other than glaucoma were excluded.

**Intervention:** Study eyes were randomized 1:1 to standalone MIGS consisting of either 1 Hydrus Microstent (Ivantis, Inc, Irvine, CA) or 2 iStent Trabecular Micro Bypass devices (Glaukos Inc, San Clemente, CA). Follow-up was performed 1 day, 1 week, and 1, 3, 6, and 12 months postoperatively.

**Main Outcome Measures:** Within-group and between-group differences in IOP and medications at 12 months and complete surgical success defined as freedom from repeat glaucoma surgery, IOP 18 mmHg or less, and no glaucoma medications. Safety measures included the frequency of surgical complications, changes in visual acuity, slit-lamp findings, and adverse events.

**Results:** Study groups were well matched for baseline demographics, glaucoma status, medication use, and baseline IOP. Twelve-month follow-up was completed in 148 of 152 randomized subjects (97.3%). At 12 months, the Hydrus had a greater rate of complete surgical success ( $P < 0.001$ ) and reduced medication use (difference =  $-0.6$  medications,  $P = 0.004$ ). More Hydrus subjects were medication free at 12 months (difference = 22.6%  $P = 0.0057$ ). Secondary glaucoma surgery was performed in 2 eyes in the 2-iStent group (3.9%) and in none of the Hydrus eyes. Two eyes in the Hydrus group and 1 in the 2-iStent group had BCVA loss of  $\geq 2$  lines.

**Conclusion:** Standalone MIGS in OAG with the Hydrus resulted in a higher surgical success rate and fewer medications compared with the 2-iStent procedure. The 2 MIGS devices have similar safety profiles. *Ophthalmology* 2020;127:52-61 © 2019 by the American Academy of Ophthalmology



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Glaucoma is the second-leading cause of blindness worldwide.<sup>1</sup> Although intraocular pressure (IOP) is not a direct measure of structural or functional optic neuropathy, it is the only risk factor that can be modified, and reduction of IOP has been shown to reduce glaucoma progression and visual field loss.<sup>2</sup> IOP can be lowered medically or surgically, and the treatment modality is usually based on the severity of visual field impairment and rate of progression.<sup>3–5</sup>

Topical medications have a proven record of efficacy and are used as first-line therapy at all stages of glaucoma and ocular hypertension. Though chronic medication use is generally safe, efficacy is frequently undermined by high rates of patient noncompliance,<sup>6–8</sup> which increase when multiple medications are concurrently prescribed. Medications are also associated with side effects and may exacerbate dry eye and ocular surface disease.<sup>9</sup> Furthermore, chronic medication use may reduce the success rate of subsequent

glaucoma filtration surgery.<sup>10</sup> Surgical management lowers IOP more than medical management but is typically reserved for more advanced disease because of the potential for sight-threatening complications.<sup>11</sup>

A new class of microinvasive glaucoma surgery (MIGS) devices<sup>12</sup> has been developed that shunt aqueous into the Schlemm canal,<sup>13</sup> the suprachoroidal,<sup>14</sup> or subconjunctival<sup>15</sup> space. MIGS devices may be safer than conventional filtering surgery, can eliminate or reduce adjunctive topical medication therapy, and do not impede or preclude subsequent filtration surgery.<sup>16</sup> In randomized clinical trials, 3 different MIGS devices implanted in combination with phacoemulsification were shown to be effective in reducing IOP and medication use.<sup>17–20</sup>

The purpose of this study was to compare 2 different Schlemm canal–based MIGS devices for standalone use in phakic or pseudophakic patients with OAG. The Hydrus Microstent (Ivantis, Inc, Irvine, CA) and the iStent Trabecular Micro-Bypass Stent System (Glaukos Corporation, San Clemente, CA) both provide a conduit for aqueous fluid into the Schlemm canal through the trabecular meshwork (TM), which is thought to be the primary location of outflow obstruction in open-angle glaucoma (OAG).<sup>21–23</sup> The iStent provides a trabecular bypass and penetrates approximately 1 mm into the Schlemm canal, and the Hydrus device provides a trabecular bypass and dilates approximately 3 clock hours of the Schlemm canal, thereby providing direct aqueous access to a quadrant of collector channels.

Previous laboratory experiments have shown mechanistic differences in the 2 approaches; in paired cadaveric eyes, the Hydrus Microstent increased outflow facility by a factor of 2 to 2.5 when compared with eyes implanted with 2 iStent devices.<sup>24</sup> Based on the mechanistic differences and laboratory results, we hypothesized that a single Hydrus Microstent lowers IOP and decreases number of medications more than 2 iStent devices.

## Methods

### Study Design

The COMPARE study was a prospective, multicenter, randomized, single-masked clinical trial. The efficacy measures were chosen to evaluate the ability of each device to lower IOP while reducing or eliminating hypotensive medications. The study was conducted at 12 investigational sites in 9 countries (see listing in [online Appendix; supplementary materials](#) available at [www.aojournal.org](http://www.aojournal.org)). Follow-up was completed at 1 year, at which time the outcomes were assessed.

Because this study compares 2 types of surgically implanted devices, prior experience with both devices was required of the investigators. The iStent had been in commercial distribution internationally for at least 3 years before the start of the study, and so the investigators began this study with comparatively more experience with the iStent device.

The study protocol was designed to minimize the potential for bias in determining the efficacy end points. Baseline washout of medications was required to ensure inclusion of subjects within a known range of IOP. Randomization was performed in the operating room by opening a sequentially numbered envelope. The allocation was determined by a computer-generated sequence

stratified by site and prepared in advance by the study statistician so as to provide balanced study groups. Baseline and postoperative tonometry was performed according to the 2-operator method to provide masking as described in the Ocular Hypertension Treatment Study.<sup>25</sup> All medications were discontinued before surgery, and reintroduction at IOP <19 mmHg required clinical justification. Additionally, study subjects were masked to their treatment assignment.

The study protocol was approved by the Medical Ethics Committees at each site. The study was conducted according to the principles described in the Declaration of Helsinki and all study subjects provided written informed consent before participation in the trial. The study was registered in the National Library of Medicine database ([clinicaltrials.gov](http://clinicaltrials.gov) NCT02023242). The study data were 100% source document verified by independent clinical monitors with funding provided by the study sponsor. The data set was audited and the final statistical analyses were conducted using SAS (software version 9.3; SAS Institute Inc, Cary, NC).

### Study Patients

The risks and benefits of the 2 procedures were described to potential subjects, and signed informed consent was required for inclusion in the study. Only 1 eye per patient was eligible for treatment, although both eyes could be screened for inclusion. Entry criteria included phakic and pseudophakic eyes with a diagnosis of mild-to-moderate OAG (primary OAG, pseudoexfoliative glaucoma, or pigmentary glaucoma) confirmed by optic nerve examination, characteristic visual field deficits on automated perimetry, and a history of hypotensive medication use. Study candidates had to be capable of safely undergoing medication washout, in the opinion of the investigator.

Clinical exclusion criteria included angle closure glaucoma, secondary glaucoma (except for pseudoexfoliative and pigmentary glaucoma), exudative age-related macular degeneration, proliferative diabetic retinopathy, or significant risk of glaucomatous vision loss owing to washout of IOP-lowering medications. Anatomic exclusion criteria were narrow anterior chamber angle (Shaffer grade I–II) or other angle abnormality visible upon gonioscopy, clinically significant corneal dystrophy, and central corneal thickness of less than 480 or more than 620  $\mu\text{m}$ . Patients with prior corneal surgery, cycloablation, or any incisional glaucoma procedure such as trabeculectomy, tube shunts, deep sclerectomy, or canaloplasty were also excluded. Prior selective laser trabeculoplasty (SLT) was allowed, but not argon laser trabeculoplasty.

Subjects who met eligibility criteria had to have a diurnal IOP (DIOP) of 23 to 39 mmHg after washout of ocular hypotensive medications. The duration of washout was a minimum of 4 weeks for prostaglandin analogues or  $\beta$ -blockers and 2 weeks for carbonic anhydrase inhibitors or  $\alpha$  adrenergic agonists. The DIOP value was obtained by averaging 3 Goldmann tonometry measurements taken 4 hours apart between 8AM and 4PM. Two readings were taken at each time point. If the difference in the 2 measurements was more than 2 mmHg, a third measurement was taken. The average of 2 measurements (or the median value of 3) was used for the time point, and the DIOP was the average of all 3 time points on the visit day. Subjects whose DIOP met entry criteria were scheduled for surgery.

### Study Devices

The Hydrus Microstent is a metallic microstent designed to bypass the TM and dilate approximately 3 clock hours of the Schlemm canal. The details of the device construction and preclinical testing have been described previously.<sup>20</sup> The Hydrus was first

approved for international use in 2011 and is currently approved in the United States for use in combination with cataract surgery. The iStent is an “L”-shaped titanium device, with a single fluid inlet port and extension that is designed to extend approximately 1 mm into the Schlemm canal.<sup>26</sup> Like the Hydrus, iStent is approved internationally for general use but in the United States in combination with cataract surgery only.

Prior comparative studies suggest the Hydrus may be superior to SLT<sup>27</sup> and canaloplasty.<sup>28</sup> The effectiveness of 1 or more iStents for reduction of IOP has been reported in cadaveric outflow studies,<sup>29</sup> in single-center clinical studies in combination with cataract surgery,<sup>30</sup> and as a standalone procedure with and without adjunctive hypotensive medication.<sup>31,32</sup> Published data indicate that placement of 2 iStents may increase IOP-lowering effectiveness compared with a single iStent implant in standalone procedures.<sup>33</sup>

## Surgical Technique

The surgical microscope was positioned and the head tilted to allow a clear view of the angle structures with a surgical gonioscope. Subjects were randomized for treatment with a single Hydrus Microstent or 2 iStent devices after intraoperative gonioscopy confirmed the angle structures could be adequately visualized. Viscoelastic was injected through a 1- to 1.5-mm clear corneal incision for chamber maintenance and better angle visualization. The assigned device(s) was introduced into the anterior chamber through the incision and implanted through the TM in the nasal hemisphere of the Schlemm canal. The iStents were implanted in the nasal hemisphere approximately 2 clock hours apart, facing opposite directions, according to the technique described by Ahmed.<sup>34</sup> iStent placement was targeted to areas with reflux of blood or greater TM pigmentation where apparent, as these are thought to represent a locus of collector channel outflow. Hydrus implantation was done as described previously by Pfeiffer et al.<sup>18</sup> Upon visual confirmation of device(s) position in the canal, the delivery system was withdrawn, viscoelastic removed, and the anterior chamber was inflated with balanced salt solution to achieve physiologic IOP. Patients were administered antibiotics (moxifloxacin 0.5% or equivalent, 1 drop 4 times per day, commencing the day of the procedure and continued for approximately 1 week postoperatively) and anti-inflammatory medications (prednisolone acetate 1.0% or equivalent) with initial frequency of 1 drop 4 times per day, tapered over 4 weeks postoperatively.

## Follow-up Examinations

Follow-up examinations were conducted at 1 day, 1 week, 1 month, 3 months, 6 months, and 12 months postoperatively. At each scheduled visit, examinations included slit-lamp biomicroscopy, ophthalmoscopy, manifest refraction, visual acuity using the Early Treatment of Diabetic Retinopathy Study (ETDRS) system, and measurement of IOP using Goldmann applanation tonometry. Automated achromatic visual field testing using the 24-2 SITA standard strategy using a Humphrey Visual Field Analyzer (Carl Zeiss Meditec, Jena, Germany) at 3 and 12 months. Ocular hypotensive medications could be added during follow-up at the investigator's discretion. At 12 months, DIOP was measured using the same tonometry techniques as the baseline visit.

## End Points

Clinical outcome measures included changes in mean IOP and medications. Surgical success was defined as freedom from secondary surgery, IOP 18 mmHg or less, and discontinuation of all ocular hypotensive medications. Safety end points included

intraoperative complications and the prevalence of ocular adverse events.

The study was originally designed to include washout at the 12-month follow-up visit, thereby allowing for direct comparison of IOP reduction associated with each device without the confounding effect of concomitant medications. However, among the first 40 randomized study subjects to reach 12 months follow-up, investigators were unwilling to wash out approximately 20% of eyes in the 2-iStent group owing to persistent IOP elevation despite application of maximum tolerated medical therapy. Therefore, in the interest of patient safety, the study protocol was modified to eliminate the 12-month washout requirement. The modified study plan was fully implemented across study sites by the time the 64th subject reached the 12-month visit. As a result of this change, the ability to directly compare washed-out IOP was lost, but comparisons associated with medicated IOP and medication reduction were preserved. As a surrogate for washout, categorical end points evaluating unmedicated eyes with a 20% or more reduction in IOP, or an IOP of  $\leq 18$  mmHg, were added to the protocol.

## Statistical Analysis

The study was originally designed to detect a 2 mm difference in 12-month washed-out IOP with  $>80\%$  power and 0.05 significance level; approximately 60 subjects per study arm were required. After elimination of the follow-up washout, an additional 15 subjects per arm were added to provide  $>80\%$  power to detect a 25% difference in the proportion of eyes that were medication free with IOP 18 mmHg or less at 12 months with 0.05 significance level. Analyses of the efficacy outcomes were performed using the intention-to-treat principle. Patients who underwent glaucoma surgery or IOP-lowering procedures of any kind (including trabeculectomy or cataract surgery) after the index procedure were counted as failures in categorical efficacy measures and assigned last observed IOP and medication values for subsequent IOP and medication averages. Categorical variables were reported as counts and percentages and differences were tested using Fisher exact test for binary variables. Means and standard deviations of continuous variables are presented according to treatment group. Within-group and between-group differences were tested using unpaired 2-sided *t* tests.

## Results

### Preoperative Characteristics

A total of 152 eyes from 152 patients were randomized from March 2013 to May 2015. The study population included 75 Hydrus eyes and 77 2-iStent eyes. The 12-month IOP assessment was completed in 73 of 75 (97.3%) Hydrus and 75 of 77 (97.4%) 2-iStent eyes; 1 subject in each group was lost to follow-up and 1 subject from each group missed the 12-month visit and were excluded from the analyses.

The 2 randomized study arms were well balanced for demographic and baseline characteristics (Table 1). In the intention-to-treat population, the mean age was 66 years and 55% of study subjects were women; 65.3% and 62.3% were phakic in the Hydrus and 2 iStent groups, respectively. Primary OAG was the predominant diagnosis. At the screening visit, mean IOP was  $19.0 \pm 3.9$  mmHg and  $19.1 \pm 3.6$  mmHg on  $2.5 \pm 0.7$  and  $2.7 \pm 0.8$  medications in the Hydrus and 2-iStent groups, respectively. Almost all patients were on multiple medications at baseline. The most frequently used medications were prostaglandin analogues and  $\beta$ -blockers, or a combination of both. After medication washout, baseline DIOP was  $27.5 \pm 4.4$  mmHg and  $27.3 \pm 4.2$  mmHg in the Hydrus and 2-iStent groups, respectively.

Table 1. Baseline Demographics and Ocular Characteristics

Parameter	Hydrus N = 75	2 iStents N = 77	P Value
Age (years)	66.9±10.0	66.5±9.5	0.9
Female	54.7%	58.4%	1.0
European	65.3%	63.6%	0.9
Latin American	18.7%	16.9%	0.8
Asian	14.7%	14.3%	1.0
African ancestry	1.3%	3.9%	0.6
Glaucoma status			
POAG	96.0%	92.2%	0.5
PXG/PDG	4.0%	7.8%	0.5
MD, dB	-6.2±5.4	-6.2±6.5	1.0
PSD, dB	5.5±3.5	5.1±3.3	0.9
Ocular status			
Phakic	65.3%	62.3%	0.7
Pseudophakic	34.7%	37.7%	0.7
BCVA (Snellen)	20/25	20/24	0.9
Pachymetry (µm)	542±36	541±34	1.0
Mean vertical C:D	0.65±0.16	0.67±0.18	0.9
Previous SLT	14.7%	15.6%	1.0
Preoperative IOP and medication			
Mean IOP, mm Hg	19.0±3.9	19.1±3.6	0.8
Mean medications	2.5±0.7	2.7±0.8	0.2
WO DIOP (mmHg)	27.5±4.4	27.3±4.2	0.8
Medication distribution class			
PGA	68%	68%	0.9
BB	23%	31%	0.3
CAI	44%	45%	0.9
AA	15%	17%	0.8
BB + PGA*	19%	23%	0.6
BB + CAI*	21%	23%	0.8
BB + AA*	13%	12%	0.8

AA =  $\alpha$  adrenergic agonist; BB =  $\beta$ -blocker; BCVA = best-corrected visual acuity; CAI = carbonic anhydrase inhibitor; C:D = cup-to-disc ratio; DIOP = diurnal intraocular pressure; IOP = intraocular pressure; MD = mean deviation; PDG = Pigmentary Glaucoma; PGA = prostaglandin analogue; POAG = primary open-angle glaucoma; PSD = pattern standard deviation; PXG = pseudoexfoliative glaucoma; SLT = selective laser trabeculoplasty; WO = Washed Out.

\*Combination medication.

## Procedure Outcomes

Implantation was successful in 100% of Hydrus eyes and 97.4% of 2-iStent eyes; in 2 cases only 1 iStent could be implanted. These subjects were included in the intent-to-treat analysis. All subjects underwent the assigned procedure. There were no instances of lost or migrating devices or corneal touch in either group, and there were no surgical complications associated with either device.

## Efficacy Measures

Mean IOP and medication use at each follow up visit are shown in Figure 1A-B. IOP was uniformly lower throughout the 12 month follow up, and although there were no significant between-group differences in IOP at any time point, medication use was significantly lower in the Hydrus group at all visits after 1 month. The results of the analysis for change in IOP and medications from preoperative to 12 months are presented in Figure 2A-B. Although the mean IOP in the Hydrus group was lower compared with preoperative IOP, the between-group difference was not significant (difference in change =  $-0.7$  mmHg,  $P = 0.3$ ). Both groups

significantly reduced medication use at 12 months compared with preoperative; however, the reduction in the Hydrus group was significantly greater (difference in change =  $-0.6$  medications; 95% confidence interval [CI],  $-0.9$  to  $-0.2$ ;  $P = 0.004$ ). IOP distribution stratified by IOP interval are shown in Table 2. Even with fewer medications, there were significant reductions in the number of eyes at IOP  $\leq 21$ , 18, and 15 mmHg at 12 months compared to preoperative in the Hydrus group and no significant changes in the 2 iStent group.

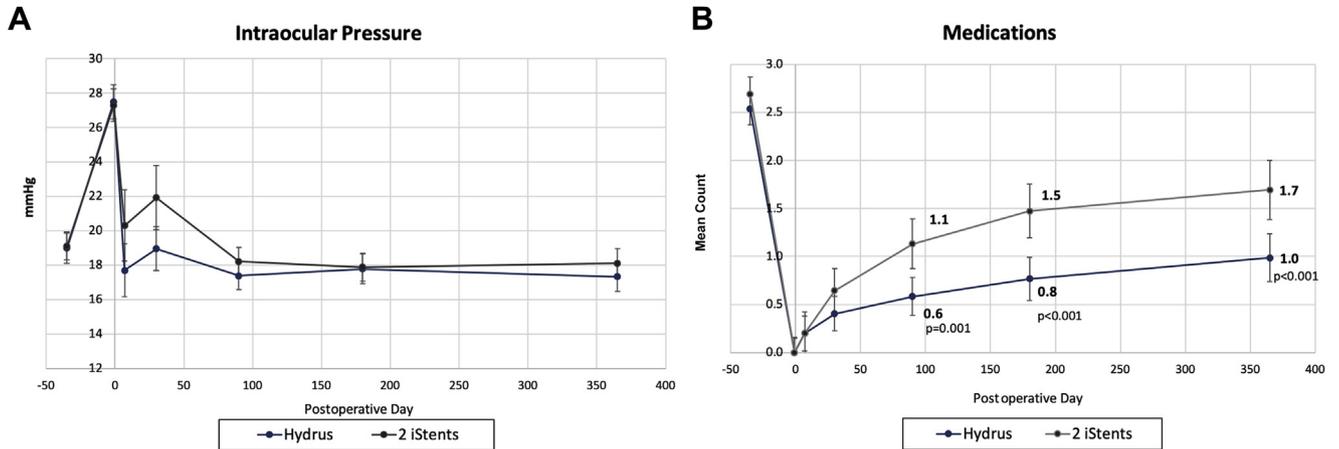
At 12 months 46.6% of Hydrus patients and 24.0% of 2-iStent patients were medication free ( $P = 0.006$ ) (Table 3 and Figure 3). The percentage of eyes reaching  $\leq 18$  mmHg without medications was greater in the Hydrus group (30.1% vs. 9.3%,  $P = 0.002$ ), as was the percentage of eyes reaching a 20% or more reduction in IOP from washed-out baseline without medications (39.7% vs. 13.3%,  $P < 0.001$ ). The mean IOP for eyes without medications was  $17.3 \pm 3.3$  in the Hydrus group and  $19.2 \pm 2.4$  in the 2-iStent group (mean change  $-8.2$  mmHg vs.  $-5.1$  mmHg, difference in change,  $-3.1$  mmHg; 95% CI,  $-5.4$  to  $-0.8$  mmHg;  $P = 0.003$ ).

Before surgery, 50.7% of Hydrus eyes and 58.5% of 2 iStent eyes were on 3 or more medications. At 12 months, the percentage of eyes on  $\geq 3$  medications was lower in the Hydrus vs. 2-iStent group (8.2% vs. 29.3%,  $P = 0.001$ ). Conversely, the number of subjects with no change or an increase in medication use was lower in the Hydrus group (17.8% vs. 38.7%,  $P = 0.006$ ), and the number of patients with a  $\geq 3$ -medication reduction was higher (23.3% vs. 5.3%,  $P = 0.002$ ) in the Hydrus group. (Changes in medication use from baseline to follow-up are presented in Table S1, available at [www.aaojournal.org](http://www.aaojournal.org)).

Because the follow-up washout was eliminated from the protocol after approximately 42% of subjects completed the 12-month visit, the medication-prescribing behavior of study investigators was assessed to determine if the study groups were treated uniformly. During the first year of follow-up, there were more than 600 IOP assessments. The mean IOP for a medication increase decision was  $21.3 \pm 4.9$  mmHg in the Hydrus group and  $21.8 \pm 5.9$  mmHg in the 2-iStent group ( $P = 0.61$ ). The mean IOP for all decisions to leave medications unchanged or to decrease by 1 or more was  $16.9 \pm 3.4$  mmHg in the Hydrus group and  $17.5 \pm 3.8$  mmHg in the 2-iStent group ( $P = 0.09$ ). The intent of the protocol was to leave eyes unmedicated if IOP was  $< 19$  mmHg. The frequency at which medication was added at this IOP range as a percentage of all medication change decisions was evenly distributed between groups at 28.6% in the Hydrus group and 28.8% in the 2-iStent group. The medication change decisions were also evenly distributed at various IOP intervals above 19 mmHg (Fig S1, available at [www.aaojournal.org](http://www.aaojournal.org)).

Surgical success through 12 months was assessed using Kaplan–Meier event-free survival analysis. Failure was defined as repeat glaucoma surgery or any IOP-lowering procedure (including cataract surgery) at any postoperative time, IOP  $> 18$  mmHg, or use of glaucoma medications for 2 consecutive visits after 1 month. As shown in Figure 4, the 12-month cumulative event-free survival rate was 35.6% in the Hydrus group and 10.5% in the 2-iStent group ( $P = 0.001$ , log-rank test).

This study included both phakic and pseudophakic eyes. Compared with phakic eyes, there were more eyes on 0 medications in the Hydrus pseudophakic subgroup (56% vs. 42%) but fewer in the 2-iStent group (14% vs. 30%), although the differences were not significant. The proportion of eyes with 0 medications and IOP  $\leq 18$  mmHg was also higher in the Hydrus pseudophakic eyes compared with phakic eyes (40% vs. 25%), as was the proportion of eyes with 0 medications and a 20% IOP reduction (56% vs. 31%). In the 2-iStent group, the proportion of eyes with 0 medications and IOP  $\leq 18$  mmHg was similar in the



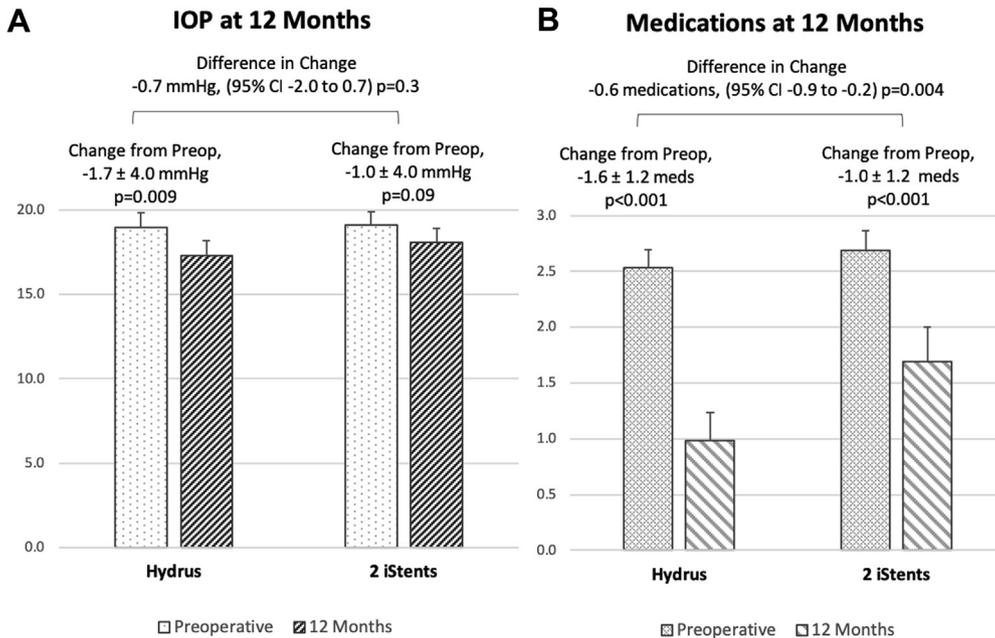
**Figure 1.** A, Intraocular pressure (IOP). B, Medications. There were no significant differences in IOP between groups at any time point. There was a significant differences in mean medication count at all time points  $\geq 90$  days. The error bars are 95% confidence intervals.

pseudophakic and phakic subgroups (11% pseudophakic vs. 9% phakic), as was the proportion of eyes with 0 medications and 20% IOP reduction (11% pseudophakic vs. 15% phakic).

Before the washout requirement was removed, 64 subjects reached the 12-month end point, 32 in each study arm. The number of washout exceptions was proportionally higher in the 2-iStent group (7 vs. 1), and so the number of eyes available for analysis was not evenly distributed between groups. In the Hydrus group, 30 of 32 eyes were available (94%); 1 eye was not washed out for safety reasons and 1 was lost to follow-up. In the 2-iStent group, 24 of 32 eyes were available (75%); 1 eye had trabeculectomy at month 4 and 7 eyes were not washed out for safety reasons. For eyes completing washout, the mean change in washed-out IOP

from baseline to 12 months was  $-6.0 \pm 5.4$  mmHg in the Hydrus group ( $n = 30$ ) and  $-4.0 \pm 5.6$  in the 2-iStent group ( $n = 24$ ).

The influence of key demographic and preoperative factors on the probability that the subject would be medication free at 12 months was assessed using logistic regression. The model included the subject's treatment group, ethnicity, age, number of baseline medications ( $\leq 2$  or  $\geq 3$ ), visual field mean deviation ( $\leq -6$  dB or  $> -6$  dB), baseline washed-out DIOP, and surgeon experience (more than or fewer than 100 cases before initiation of the study). The analysis showed that age, ethnicity, number of baseline medications, and surgeon experience did not significantly affect the end point. The strongest predictor of freedom from medication was treatment with the Hydrus device (odds ratio [OR], 4.08; 95% CI, 1.7–9.90;



**Figure 2.** A, Intraocular pressure (IOP). B, Assessment of IOP and medication at 12 months. Compared with preoperative IOP, there was a significant reduction in IOP in the Hydrus group but not in the 2-iStent group. A, The difference in change between groups was not significant. Both groups significantly reduced medication use compared with preoperative values. B, The difference in change was significantly greater in the Hydrus group. Note: within-group P value is calculated for the 12-month vs. medicated preoperative IOP. The error bars are 95% confidence intervals.

Table 2. Medicated Mean Intraocular Pressure and Stratified Distribution

	Preoperative	12 Months	P Value*
<b>Hydrus</b>			
N	75	73	—
Mean (SD) IOP, mmHg	19.0±2.5	17.3±3.7	0.009
% ≥21 mmHg	25.3	8.2	0.008
% ≤21 mmHg	74.7	91.8	0.008
% ≤18 mmHg	41.3	64.4	0.006
% ≤15 mmHg	17.3	24.7	0.31
<b>2 iStents</b>			
N	77	75	—
Mean (SD) IOP, mmHg	19.1±3.6	18.1±3.7	0.10
% ≥21 mmHg	27.3	16.0	0.12
% ≤21 mmHg	72.7	84.0	0.12
% ≤18 mmHg	44.2	57.3	0.11
% ≤15 mmHg	14.3	20.0	0.31

IOP = intraocular pressure; SD = standard deviation.  
\*P value: within-group preoperative vs. 12 months.

$P = 0.001$ ). The model also showed that lower baseline DIOP (OR, 0.73; 95% CI, 0.63–0.84;  $P < 0.0001$ ) and milder visual field severity (OR, 1.16; 95% CI, 1.04–1.29;  $P = 0.0065$ ) were significant predictors of 0 medication count. (A summary of the analysis is provided in Table S2, available at [www.aajournal.org](http://www.aajournal.org).)

### Safety

Slit-lamp findings were limited to mild anterior chamber cell and flare and mild corneal edema, apparent in a minority of patients in the first postoperative month. New cataracts were reported in 2 Hydrus eyes and 1 2-iStent eye by 12 months, and cataract surgery combined with trabeculectomy was performed in 1 eye in the 2-iStent group. Mild posterior capsular opacification was reported in approximately 5% of pseudophakic patients in both groups at screening and remained stable throughout follow-up. There were no significant changes in fundus appearance and cup-to-disc assessments.

There were few adverse events in study eyes from either group within the 12-month follow-up period, and there were no significant differences between groups (Table 4). In the 2-iStent group, there was 1 case of best-corrected visual acuity (BCVA) loss >2 lines and 4 cases of IOP elevation >10 mmHg over baseline. In the Hydrus group, there were 2 cases of BCVA loss >2 lines and 3 cases of IOP elevation >10 mmHg. Device obstructions occurred at similar rates between groups, although obstructions related to iris

Table 3. Effectiveness Assessment

	Hydrus N = 73	2 iStents N = 75	P Value
<b>Patients on 0 medications at 12 months</b>			
N (%)	34 (46.6%)	18 (24.0%)	0.006
Mean (SD) IOP, mmHg	17.3±3.7	19.2±2.4	0.037
Mean (SD) ΔIOP, mmHg	-8.2±3.7	-5.1±2.9	0.003
≥ 20% IOP reduction*	39.7%	13.3%	<0.001
IOP ≤18 mmHg	30.1%	9.3%	0.002

IOP = intraocular pressure; SD = standard deviation.  
\*Compared with washed-out baseline diurnal IOP.

### Medication Distribution at 12 Months

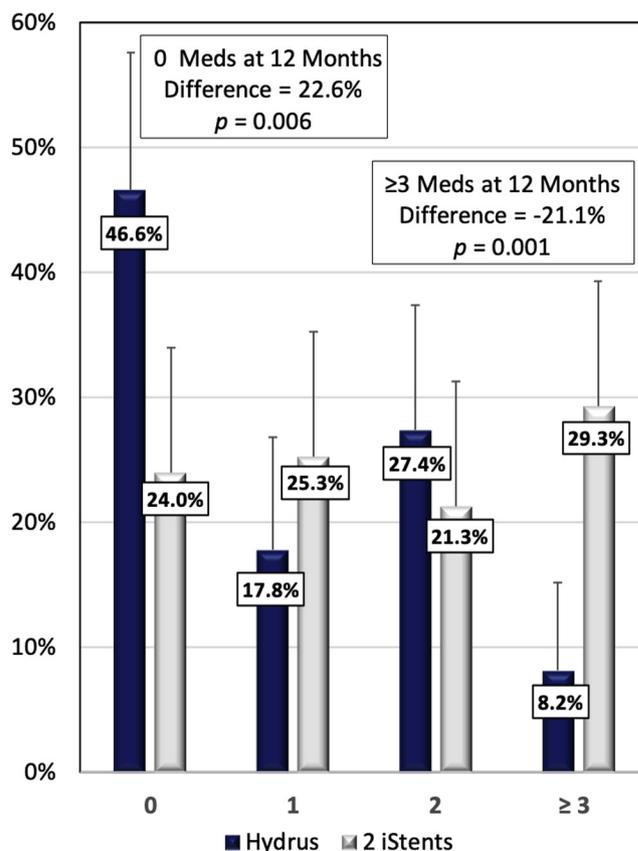
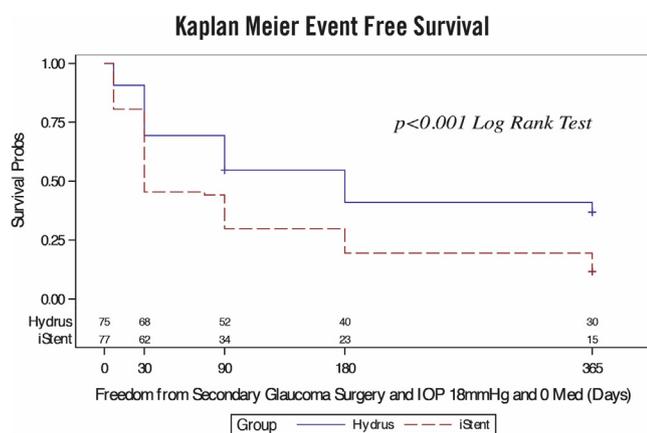


Figure 3. The percentage of eyes using 0, 1, 2, or ≥3 medications at 12 months in Hydrus and 2-iStent groups.

or other tissue adhesions were more common in the 2-iStent group and obstructions owing to peripheral anterior synechiae (PAS) were more common in the Hydrus group. There were no reports of hypotony, device migration, or dislocation in either group. In the 2-iStent group, 2 subjects required subsequent glaucoma surgery owing to uncontrolled IOP despite maximum medical therapy; there were no instances of incisional glaucoma surgery in the Hydrus group, although there was 1 yttrium–aluminum–garnet laser treatment for tissue adhesion near the device inlet.

### Discussion

This prospective, multicenter, randomized, single-masked trial demonstrated an advantage in favor of the Hydrus Microstent over 2-iStent Trabecular Bypass devices in reducing medication use and surgical success in OAG patients at 1 year postoperatively. Medication use was reduced by a greater margin (difference = -0.6 medications/eye,  $P = 0.004$ ) or eliminated completely more frequently in the Hydrus group (46.6% vs. 24.0%,  $P = 0.006$ ) than in the 2-iStent group. Among eyes without medications, Hydrus achieved an IOP ≤18 mmHg more often (30.1% vs. 9.3%,  $P < 0.001$ ). At 12 months, mean IOP was reduced in the Hydrus group concurrently with elimination of 1.6 medications; in the 2-iStent group IOP was maintained at



**Figure 4.** Twelve-month Kaplan–Meier event-free survival: complete success. Failure was defined as any secondary glaucoma surgery, intraocular pressure (IOP) >18 mmHg, or use of hypotensive medications on 2 consecutive visits after the 1-month follow-up visit. Patients lost to follow-up were censored.

preoperative levels concurrently with reduction of 1.0 medication.

This is the first study to directly compare the efficacy of different MIGS devices for use in glaucoma management without concurrent cataract surgery. Multiple surgeons with significant prior experience with both devices participated in the study. The study population was ethnically heterogeneous, had moderate disease severity, and was using multiple medications to control IOP preoperatively. The study groups were well matched for age, demographics, and key baseline ocular characteristics such as IOP, medication use, BCVA, cup-to-disc ratio, and visual field defect.

This study suggests that trabecular MIGS devices may play an important role in managing IOP and reducing the need for hypotensive medications. In the 40% to 50% of glaucoma patients dependent on multiple medications to control IOP, a procedure that reliably reduces medication number to 1 or 0 is desirable because patient adherence drops to 44% when more than 1 medication is prescribed.<sup>35</sup> Poor adherence increases the risk of visual loss in glaucoma patients.<sup>36</sup>

Table 4. Safety Findings

	Hydrus N = 74	2 iStents N = 76
BCVA loss >2 lines at 12 months, n (%)	2 (2.7)	1 (1.3)
IOP spike >10 mmHg, n (%)	3 (4.1)	4 (5.2)
New cataract, n (%)	2 (2.6)	1 (1.3)
Device obstruction, n (%)		
Iris/other tissue	4 (5.4)	10 (13.2)
PAS	5 (6.8)	0 (0)
Secondary surgical intervention, n (%)		
Glaucoma surgery (trabeculectomy/GDD)	0 (0)	2 (2.6)
Stent migration/repositioning/removal	0 (0)	0 (0)
Cataract surgery	0 (0)	1 (1.3)

BCVA = best-corrected visual acuity; GDD = glaucoma drainage device; IOP = intraocular pressure; PAS = peripheral anterior synechiae.

We observed substantially lower levels of IOP reduction for the standalone 2-iStent procedure compared with a previously published series of single-center studies for the same procedure<sup>33,35,36</sup> These studies report 12-month mean IOPs in the range of 13 to 14 mmHg, with and without medications at 12 months. Of these previous studies, 1 reported an IOP of 17.1±2.2 mmHg after medication washout at 12 months for standalone treatment of OAG with 2 iStents.<sup>36</sup> Treatment efficacy rates >90% at 12 months were consistently reported among these studies, whether defined as 20% decrease in IOP or IOP ≤18 mmHg with or without medications. Although MIGS devices are thought to lower IOP more when combined with cataract surgery,<sup>37</sup> the previously reported standalone findings are superior to the results for any published combined study using 1 or more iStent devices. The 12-month IOP and medication counts reported in these studies are consistent with published outcomes for filtration surgery.<sup>38</sup>

The differences in outcome between our study and previously published results do not appear to be related to demographics or inclusion criteria. Although our study was ethnically heterogeneous and multicenter, whereas the aforementioned studies were conducted in a primarily white population at a single center located in Armenia, multivariate analysis of the COMPARE study data showed ethnicity and site location did not affect our outcomes. Although preoperative visual fields were not reported in the previous studies, the average patient in the current study was using more medications compared with prior iStent studies, which were grouped by 0, 1, or 2 preoperative medications. Nonetheless, the mean washout IOPs were similar, and multivariate analysis showed that the Hydrus group reached 0 medications more frequently than the 2-iStent group. Factors associated with reaching 0 medications included lower baseline IOP and medication counts and for mild disease severity as assessed by visual field. In addition, multivariate analysis did not show surgeon experience to be a significant factor in the outcome.

The only published report of double iStent standalone surgery performed outside of the MIGS Study Group was a 10-patient pilot study conducted at a single center in Japan.<sup>39</sup> In that study, the mean preoperative IOP was 22.2±3.0 mmHg and each patient was on 3 medications (prostaglandin analogues, β-blockers, and carbonic anhydrase inhibitors) per protocol throughout the 6-month course of the study. At 6 months follow-up, mean IOP was 16.9±3.6 mmHg on 3 medications, and the response rate, defined as the percentage of eyes reaching ≤18 mmHg, was 44%. (We observed that 57.3% of 2-iStent eyes reached this level on 1.6 medications.) Although this was a small series with limited follow-up, these results are more similar to the 2-iStent results in our study than the response rates of 90% or more reported in the other cited studies.

The clinical results of this study were predicted in pre-clinical human cadaveric anterior segment perfusion models, which compared 2 iStents vs. the Hydrus device. Hays et al<sup>24</sup> showed that aqueous outflow facility (i.e., drainage) was increased by 74% by the Hydrus device compared with 34% by 2 iStents. In prior cadaveric laboratory studies, the Hydrus device improved outflow

facility and corresponded histologically to a dilated Schlemm canal and open and unobstructed collecting channels.<sup>26,30</sup> It is possible that stretching the TM by the Hydrus scaffold may be the basis of the improved aqueous drainage, which was also seen with the 1-year results for canaloplasty as a standalone procedure; the eyes that had greater trabecular distension, as measured by high-resolution ultrasound biomicroscopy, had greater IOP reduction compared with eyes that had minimal or no trabecular distension (40% vs. 24%, respectively), even if there had been successful intracanalicular suture placement.<sup>40</sup> TM stretch is one of the mechanisms of action of pilocarpine.<sup>41,42</sup> In live mice, which are the most robust models aside from certain monkey species to study outflow, pilocarpine-induced stretch prevents the collapse of the Schlemm canal in situations of elevated IOP.<sup>43</sup> It is possible that it is the TM stretch, induced by the Hydrus and in those cases of canaloplasty, that is preventing collapse of the Schlemm canal, leading to the observed superiority of outflow facility in experimental studies and the clinical results of this investigation.

The safety observations in this study are of particular importance given the generally moderate disease severity in the study cohort. There was no difference in visual acuity between the 2 study groups throughout the 12-month post-operative follow-up period. We observed 2 cases of secondary glaucoma surgery in the 2-iStent group, 1 of which was combined with cataract surgery; otherwise, ocular adverse findings in both groups were similar in frequency to those reported for cataract surgery and were mild and transient. Typical safety risks for traditional transscleral glaucoma surgery, such as hypotony, significant vision loss, infections, and bleb-related complications, were absent from both treatment groups, as expected for a MIGS procedure. We did observe new cataracts in 3 subjects (2 in the Hydrus group and 1 in the 2-iStent group), which may or may not have been related to the study procedure. Additional follow-up is ongoing.

### Limitations

This study was powered to detect differences in efficacy and although safety outcomes were carefully recorded, the sample size is too small to fully evaluate safety differences. The reluctance of investigators to conduct 12-month washout in a high proportion of 2-iStent eyes was a deviation from the original study design, and it led to a protocol change that eliminated the ability to directly compare device-related IOP reductions and limits our ability to reach definitive conclusions about the efficacy of the 2 devices. Patient follow-up is limited to 12 months, although extended follow-up is ongoing. The study population was limited to subjects with elevated washed-out IOP. Although the study incorporated design elements intended to minimize bias, the investigator at each study site was not masked to treatment randomization during follow-up examinations. Finally, although balanced evenly between groups by randomization, the study was not large enough to determine the influence of lens status or prior SLT on study outcomes.

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## Footnotes and Financial Disclosures

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**HUMAN SUBJECTS:** Human subjects were included in this study. The study protocol was approved by the Medical Ethics Committees at each site. The study was conducted according to the principles described in the Declaration of Helsinki and all study subjects provided written informed consent before participation in the trial. The study was registered in the National Library of Medicine database ([clinicaltrials.gov](http://clinicaltrials.gov) NCT02023242).

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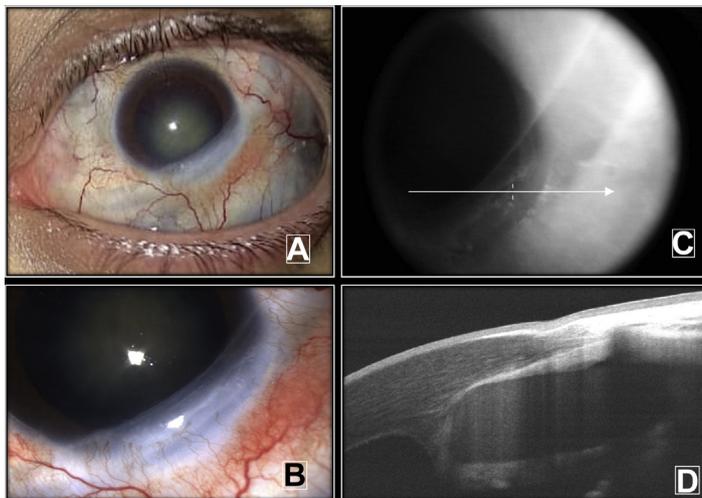
**Abbreviations and Acronyms:**

**BCVA** = best-corrected visual acuity; **CI** = confidence interval; **DIOP** = diurnal intraocular pressure; **IOP** = intraocular pressure; **MIGS** = microinvasive glaucoma surgery; **OAG** = open-angle glaucoma; **OR** = odds ratio; **SLT** = selective laser trabeculoplasty; **TM** = trabecular meshwork.

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## Pictures & Perspectives



### Intracorneal Migration of Silicone Band

A 40-year-old man presented with a large ciliary staphyloma due to secondary glaucoma in his left eye. The patient had undergone scleral buckling surgery with intravitreal perfluoropropane gas injection for rhegmatogenous retinal detachment 6 years previously. Anterior-segment slit-lamp (Fig A and B) examination showed intracorneal migration of silicone band (Fig A and B). Infrared imaging (Fig C) showing the linear area through which anterior-segment OCT (AS-OCT) is captured. The AS-OCT imaging (Fig D) showed extension of the band into the cornea. Intracorneal migration of silicone band may be attributed to ciliary staphyloma resulting from raised intraocular pressure leading to enlargement of eyeball along with scleral thinning. (Magnified version of Fig 1A-D is available online at [www.aaojournal.org](http://www.aaojournal.org)).

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