

# Real-world efficacy of the Hydrus microstent in Black and Afro-Latinx patients with glaucoma: a retrospective study

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## Abstract

**Purpose:** The purpose was to determine the real-world efficacy of phacoemulsification cataract surgery and Hydrus microstent in Black and Afro-Latinx patients with glaucoma.

**Methods:** A retrospective noncomparative single-center study of 76 Black and Afro-Latinx patients with glaucoma who underwent phacoemulsification cataract surgery and Hydrus microstent placement for treatment of glaucoma at single practice. Investigated parameters were intraocular pressure (IOP), number of medications, mean deviation on visual field test, and visual acuity. Patients were also subgrouped into mild, moderate, and advance glaucoma for further analysis.

**Results:** We reviewed a total of 76 patients who had 6 months of follow up in the study. The mean number of medications decreased significantly from  $2.6 \pm 1.5$  preoperatively to  $0.72 \pm 1.4$  in 6 months ( $p < 0.0010$ ), while IOP decreased from  $14.7 \pm 3.7$  to  $13.9 \pm 4.3$  ( $p = 0.25$ ). At 6 months, 55 patients (74%) of all patients were medication free ( $n = 27$ , 84.4% mild glaucoma;  $n = 17$ , 70.8% moderate glaucoma;  $n = 10$ , 50% advance glaucoma). There was significant improvement in visual acuity ( $p < 0.00010$ ) and stabilization of mean deviation on visual field test (baseline  $-9.2$ ; 6 months  $-9.1$ ;  $p = 0.22$ ). The most common adverse effect was a transient IOP spike and transient corneal edema ( $n = 6$ , 7.9%;  $n = 6$ , 7.9%, respectively) with spontaneous resolution in all cases. No sight-threatening complications were reported at 6 months.

**Conclusion/clinical relevance:** This 6-month retrospective study demonstrated the efficacy of phacoemulsification cataract surgery and Hydrus microstent in reducing the medication burden while maintaining lower IOP in Black and Afro-Latinx patients with glaucoma.

**Keywords:** Black patients, cataract surgery, glaucoma, Hydrus microstent, microinvasive glaucoma surgery

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## Introduction

Age-related cataract is the most prevalent and leading cause of blindness in the world.<sup>1</sup> Glaucoma is the second most prevalent eye condition worldwide with projected 111.8 million people between the ages of 40 and 80 years affected in 2040.<sup>2</sup> Cataract surgery continues to be the most frequently performed procedure among Medicare beneficiaries; however, Schein and colleagues<sup>3</sup> reported a 30% lower rate of cataract surgery among Black patients compared

with their White counterparts when adjusted for age and sex. The prevalence of glaucoma is higher in Black and Afro-Latinx communities compared with Whites.<sup>4</sup> The intraocular pressure (IOP)-lowering effects of phacoemulsification cataract surgery has been well documented.<sup>5</sup>

There is a progressive increase in lens mass,<sup>6</sup> and anterior movement of the lens zonules adjacent to the posterior iris with aging. The increase in lens size results in compression of the trabecular

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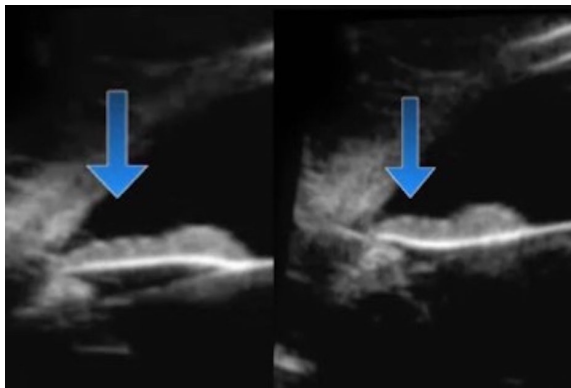
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**Figure 1.** Increased irido-zonular contact during accommodation.

meshwork (TM) and the Schlemm canal which leads to elevation in IOP.<sup>7</sup> In addition, there is increasing pigment liberation from lens zonules-iris rubbing against iris pigment epithelium contact due to iridolenticular contact exacerbated during accommodation (Figure 1).<sup>8</sup> The pigment liberation leads to obstruction of the TM and further contributes to elevating IOPs (Figure 2).<sup>8</sup> There is an association between elevated IOP and the development of glaucoma. Cataract surgery lowers IOP and prevents against lens-induced glaucoma.<sup>9</sup>

Currently, management of glaucoma includes ocular hypotensive medications, laser, and incisional surgery. Initial management of glaucoma with ocular hypotensive medications has only been partially successful to lower IOP because of poor patient compliance and ocular side effects; unfortunately, many patients with glaucoma still progress with medical therapy.<sup>10,11</sup> The IOP-lowering effect of laser surgery decreases in efficacy with time, and patients will often require additional medical therapy. Patients treated with laser are also predisposed to adverse effects of iritis and pressure spikes.<sup>12</sup>

The gold standard incisional surgery, trabeculectomy, and aqueous shunt surgery, although very effective in reducing IOP, have a higher risk of complications compared with the current medical and laser therapy. The *ab externo* approach used to create a filtration bleb in these procedures predisposes patients to a lifelong risk of endophthalmitis and bleb-related ocular surface issues.<sup>13</sup> There has recently been a paradigm shift toward earlier cataract surgery and microinvasive glaucoma surgery (MIGS) to safely lower IOP and reduce medication burden in patients with



**Figure 2.** Hydrus inserter in front of the heavily pigmented trabecular meshwork.

glaucoma. This is due to the enhanced safety profile of cataract surgery and MIGS. Cataract surgery alone can lower IOP up to 2.22 mmHg [95% confidence interval (CI): 1.93–2.52 mmHg;  $p < 2 \times 10^{-16}$ ] in early glaucoma patients.<sup>14</sup> In addition, in glaucoma patients, IOP can be lowered further when combined with trabecular bypass surgery.<sup>15–18</sup> These new surgical techniques and devices enhance aqueous outflow effectively and safely without the formation of blebs. Among them are iStent (Glaukos), iStent inject (Glaukos), OMNI (Sight Sciences), Kahook Dual Blade (New World Medical), and Hydrus (Ivantis, Inc, Irvine, CA).

Combination cataract surgery and MIGS devices dramatically lower IOP levels and reduced the number of medications used in recent studies and are increasingly becoming the mainstay treatment for mild to moderate glaucoma.<sup>19</sup> The HORIZON study showed excellent IOP lowering in the cataract surgery-alone group from  $25.3 \pm 2.9$  to  $19.3 \pm 4.2$  mmHg. This was significantly enhanced in the combined cataract surgery and Hydrus microstent implantation group to  $17.5 \pm 3.9$  mmHg.<sup>20</sup> The COMPARE study showed that patients with Hydrus microstent used fewer medications with a high surgical success rate compared with the 2-iStent device group (preoperative IOP 2-iStent  $19.1 \pm 3.6$  mmHg, Hydrus  $19.0 \pm 2.5$  mmHg; 12-month 2-iStent IOP  $18.1 \pm 3.7$  mmHg, Hydrus  $17.3 \pm 3.7$  mmHg).<sup>21</sup>

Although clinical trials with a 2-year follow-up period showed efficacy of Hydrus microstent, the real-world efficacy of Hydrus microstent has not been studied in a predominately Black and Afro-Latinx population. Hydrus is currently Food and Drug Administration (FDA) approved in the United States for use together with cataract surgery for patients with mild to moderate open-angle

glaucoma. Here, we report the real-world efficacy of cataract extraction and Hydrus microstent placement in Black and Afro-Latinx patients.

## Methods

This is a retrospective noncomparative study of 76 consecutive Black and Afro-Latinx patients with glaucoma who underwent phacoemulsification cataract surgery and Hydrus microstent placement for treatment of glaucoma at single practice in New York, USA, between December 2018 and December 2019. The ethnic makeup of the patients was reflective of the local community. The study was approved by the Institutional Review Board at the New York Eye and Ear Infirmary of Mount Sinai, New York, USA (IRB-19-02948); in addition, the study adhered to the tenets of the Declarations of Helsinki. All the patients provided written informed consent for evaluation and surgery.

All patients had a full ophthalmological assessment that included visual acuity (VA), Goldmann applanation tonometry, slit-lamp examination, gonioscopy, optic nerve assessment with Zeiss Cirrus 5000 HD-OCT, and visual field (VF) examination with Zeiss Humphrey Visual Field Analyzer 3 (Dublin, California, USA). The indications for Hydrus microstent glaucoma surgery were to reduce IOP and to reduce reliance on IOP-lowering medications at the time of cataract surgery in eyes with significant cataract (cortical and nuclear sclerosis grades 1–4) and medically treated glaucoma while avoiding the formation of a filtering bleb and its associated risk profile. We included consecutive cases that were done with open angles or partially open angles with indentation gonioscopy in the nasal quadrant. We excluded patients who had uveitic, neovascular glaucoma, and angle closure without the TM visible on indentation gonioscopy.

The main outcome measures were IOP reduction and decrease in ocular hypotensive medications after the surgery. Safety was evaluated by tabulating both solicited and unsolicited adverse events from the intraoperative period through the last follow-up. The patients were stratified into subgroups: mild, moderate, and advance based on the Hodapp–Parrish–Anderson criteria to assess the efficacy of phacoemulsification and Hydrus microstent.

All glaucoma medications were stopped in the operative eye on the day of surgery. After the procedure, patients were prescribed prednisolone

acetate 1% (Allergan, Dublin, Ireland) ophthalmic solution one drop every 6 h, ofloxacin 0.3% (Rising, Saddle Brook, New Jersey, USA) one drop every 6 h, and ketorolac 0.5% (Allergan, Dublin, Ireland) one drop every 8 h. Baseline and operative data were reviewed prior to the day of surgery, and the clinical course was assessed at day 1, 1, 3, and 6 months, postoperatively. Individual IOP goals were tailored to each individual patient postoperatively, and IOP-lowering medications were withdrawn or added as deemed necessary.

## Statistics

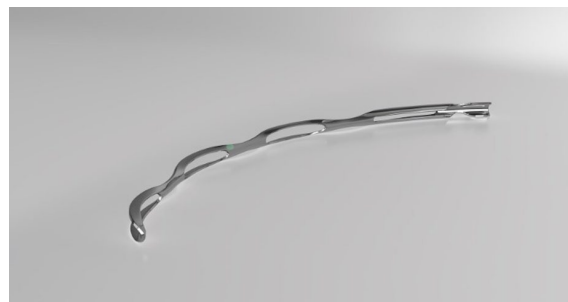
The hypothesis is that cataract surgery combined with the Hydrus microstent implant would reduce glaucoma medicine burden and maintain lower IOP. Data analysis was done with Microsoft excel (Microsoft, Redmond, Washington, USA) and Prism GraphPad (GraphPad, Seattle, Washington, USA). We used a paired *t* test for analysis. In this study, the significance threshold was set at  $p \leq 0.05$ .

## Instrument

The Hydrus microstent (Figure 3) is a biocompatible material made of nickel–titanium alloy and thermally set to fit the curvature of the Schlemm canal. It is made to be placed *ab interno* through the TM into the Schlemm canal (Figure 4) with the inlet residing in the anterior chamber (AC). The Hydrus microstent is able to dilate and scaffold a quadrant of the Schlemm canal upon placement. The device is able to drain aqueous through the resistant TM into the collecting channels via the Schlemm canal.<sup>19</sup>

## Procedure

Patients were administered preoperative prednisolone acetate 1% (Allergan, Dublin, Ireland) QID and ofloxacin (Rising, Saddle Brook, NJ,



**Figure 3.** Hydrus stent.



**Figure 4.** Hydrus microstent bypassing obstructed trabecular meshwork.

USA) QID starting 3 days prior to surgery. After the eye was prepped with betadine and draped, topical anesthesia was applied, and a clear corneal phacoemulsification was performed with implantation of an intraocular lens. Endocot (Abbott, Chicago, Illinois, USA) was placed in the eye to deepen the angle. A paracentesis was made 2.5 clock hours to the right of the corneal incision and Endocot was placed on the cornea. The patient's head was tilted away from the surgeon about 45°, and the microscope was tilted toward the surgeon about 45°. A direct gonio lens (Katena, Troy Hills, New Jersey, USA) was placed on the eye, and the microscope was focused down to obtain a direct view of the nasal angle structures. If peripheral anterior synechiae partially obstructed the view of the TM, a cyclodialysis spatula was used to gently perform goniosynechialysis for 1–2 clock hours to expose the TM. The presence of viscoelastic served as a tamponade for any heme and preserved visibility. The Hydrus microstent was passed into the AC through the paracentesis. Using the device injector, the TM was incised with the tip of the delivery cannula and the microstent was threaded into the Schlemm's canal (SC) over a span of approximately 90°. Upon visual confirmation of proper device positioning in the canal, the delivery system was withdrawn and the ophthalmic viscosurgical device removed and replaced with a balanced salt solution. Intracameral injection of diluted Vigamox (Alcon, Geneva, Switzerland) with the balanced saline solution 50/50 1cc was given via the paracentesis at the end of the procedure. In all patients, we noticed the angle was open nasally after cataract surgery or was opened partially with synechialysis with a cyclodialysis spatula 1–2 clock hours for Hydrus insertion.

## Results

A total of 76 patients were included in the study. Baseline characteristics of study patients are presented in Table 1. The mean age for the study participants was  $70.7 \pm 9.4$  years. Women outnumbered men in the ratio of 1.17:1.0, and the left eye-to-right eye procedure ratio was 1.05:1.0. The mean baseline preoperative IOP was  $14.7 \pm 3.7$  mmHg with a mean use of  $2.6 \pm 1.5$  ocular hypotensive medications. Of all the patients, 98% were using one or more ocular hypotensive medication and 31.6% were using four or more medications (Table 1).

At each postoperative visit, there was a significant drop in the number of medications compared with preoperative values. There was significant decrease in IOP at postoperative day 1 and 3 months only ( $p < 0.00010$ ;  $p = 0.0022$ , respectively; Table 2). The mean IOP and number of medications at postoperative day 1 were  $11.2 \pm 4.1$  mmHg and zero medication, representing a 23.8% drop in IOP and 100% drop in medication use, respectively. At 1 month, the IOP was at baseline values with 93.5% reduction in the number of medications. The IOP trended down at 3 months postoperatively with a mean IOP at  $13.3 \pm 3.2$  (9.5% drop from the baseline) on  $0.63 \pm 1.2$  (75.8% decrease from the baseline) number of medications. At 6 months, the trend continues with a 5.4% drop in the mean IOP (mean IOP at 6 months =  $13.9 \pm 4$ ,  $p = 0.25$ ) and 72% decrease in the number of medications (mean medication at 6 months =  $0.72 \pm 1.4$ ,  $p < 0.00010$ ).

The subgroup analysis is presented in Table 3. Patients were stratified into mild, moderate, or advance glaucoma according to the Hodapp–Parrish–Anderson criteria. The mild glaucoma group ( $n = 32$ ) had a baseline mean IOP of  $15.8 \pm 3.9$  mmHg on  $2.3 \pm 1.4$  medications. The average mean deviation on VF was  $-3.1 \pm 1.6$  dB. The moderate glaucoma group ( $n = 24$ ) had a mean IOP of  $13.8 \pm 2.7$  mmHg on  $2.6 \pm 1.5$  medications. The average mean deviation on VF was  $-9.2 \pm 2.1$  dB. There were a total of 20 patients with advanced glaucoma. The average mean deviation on VF for this group was  $-20.3 \pm 5.5$  dB with a mean IOP of  $14.4 \pm 3.8$  mmHg on  $3.1 \pm 1.6$  medications.

Patients with mild glaucoma had the most reduction in the number of medications (1 month 94.3%, 3 months 90%, and 6 months 80.9%). The mean IOP decreased by 27.8% at postoperative day 1, 3.2% at 1 month, 13.9% at 3 months,

**Table 1.** Baseline characteristics of study participants who underwent phacoemulsification cataract surgery and Hydrus microstent.

Variable	Category	Statistics
Age (years)	Mean (SD)	70.7 ± 9.4
Sex, <i>n</i> (%)	Male	35 (46%)
	Female	41 (54%)
Eye, <i>n</i> (%)	Right	37 (48.7%)
	Left	39 (51.3%)
Baseline IOP (mmHg)	Mean (SD)	14.7 ± 3.7
Ocular hypotensive medications	Mean (SD)	2.6 ± 1.5
Patients using ocular hypotensive medications, <i>n</i> (%)	0	2 (2.6%)
	1	24 (31.6%)
	2	10 (13.2%)
	3	16 (21.1%)
	≥4	24 (31.6%)
Visual acuity (logMAR)	Mean ± SD	0.36 ± 0.12
MD on VFT (dB)	Mean ± SD	-9.2 ± 7.7
Type of glaucoma	POAG	44 (57.9%)
	ACG	30 (39.5%)
	Pigmentary	1 (1.3%)
	Mixed	1 (1.3%)

ACG, angle-closure glaucoma; IOP, intraocular pressure; MD, mean deviation; *n*, number of patients; POAG, primary open-angle glaucoma; SD, standard deviation; VFT, visual field test.

**Table 2.** Main outcome measures, IOP, BCVA, number of ocular hypotensive medications, and mean deviation on visual field at preoperative and follow-up visits for all patients.

Timepoint	IOP (mmHg)			Ocular hypotensive medications			BCVA		Visual field test
	<i>N</i>	Mean ± SD	<i>p</i> value	<i>N</i>	Mean ± SD	<i>p</i> value	LogMAR (mean ± SD)	<i>p</i> value	Mean deviation ± SD (dB)
Preoperative	76	14.7 ± 3.7	-	76	2.6 ± 1.5	-	0.36 ± 0.12	-	-9.21 ± 7.71
Postoperative day 1	76	11.2 ± 4.1	<0.00010	76	0	-	-	-	-
1 month	74	14.9 ± 5.0 (range:6-36)	0.83	74	0.17 ± 0.74	<0.00010	0.21 ± 0.33	<0.00010	-
3 months	71	13.3 ± 3.2	0.0022	71	0.63 ± 1.2	<0.00010	0.18 ± 0.39	<0.00010	-
6 months	76	13.9 ± 4.3	0.25	76	0.72 ± 1.4	<0.00010	0.17 ± 0.38	<0.00010	-9.11 ± 8.16 ( <i>p</i> = 0.22)

BCVA, best-corrected visual acuity; IOP, intraocular pressure; *n*, number of patients; SD, standard deviation.



**Table 3.** Intraocular pressure and number of medications at preoperative visit and follow-up times for patients with mild, moderate, and advance glaucoma who underwent phacoemulsification cataract surgery and Hydrus microstent.

	Mild/early glaucoma			Moderate glaucoma			Advance glaucoma		
	N	IOP (mean ± SD; mmHg)	Number of Medications (mean ± SD)	N	IOP (mean ± SD; mmHg)	Number of Medications (mean ± SD)	N	IOP (mean ± SD; mmHg)	MEDS (mean ± SD)
Preoperative	32	15.8 ± 3.9	2.3 ± 1.4	24	13.8 ± 2.7	2.6 ± 1.5	20	14.4 ± 3.8	3.1 ± 1.6
Postoperative day 1	32	11.4 ± 4.0	0	24	11.5 ± 5.1	0	20	10.6 ± 3.1	0
1 month	32	15.3 ± 5.7	0.13 ± 0.71	22	13.8 ± 3.5	0.13 ± 0.61	18	15.2 ± 5.5	0.15 ± 0.67
3 months	30	13.6 ± 3.6	0.23 ± 0.77	23	13.0 ± 2.6	0.74 ± 1.1	18	12.7 ± 2.7	1.0 ± 1.3
6 months	32	14.0 ± 2.9	0.44 ± 1.1	24	12.9 ± 2.8	0.58 ± 0.97	20	13.9 ± 3.9	1.1 ± 1.4

IOP, intraocular pressure; SD, standard deviation.

**Table 4.** Number of patients medication free at preoperative visit and follow-up times after phacoemulsification cataract surgery and Hydrus stent.

	Baseline	1 month	3 months	6 months
All patients	2 (2.6%)	73 (96.1%)	54 (76.1%)	55 (72.4%)
Mild glaucoma	2 (5.0%)	31 (96.9%)	27 (90.0%)	27 (84.4%)
Moderate glaucoma	0 (0%)	21 (95.5%)	15 (65.2%)	17 (70.8%)
Advance glaucoma	0 (0%)	19 (95.0%)	10 (55.6%)	10 (50.0%)

and 11.4% at 6 months. The moderate group saw a reduction in the number of medications: 95% at 1 month, 71.5% at 3 months, and 77.7% at 6 months. Patients in this group saw a 16.7% reduction in IOP at postoperative day 1 with a return to baseline mean IOP at 1 month, 5.8% drop at 3 months, and 6.5% drop at 6 months. The advance glaucoma group had the least reduction in number of medications at 3 months (67.7%) and 6 months (64.5%). The mean IOP saw a 26.4% reduction at postoperative day 1, a decrease of 11.8% at 3 months, and 3.5% at 6 months (Table 3).

The number of all patients on no medications increased from 2.6% at baseline to 72.4% at 6 months (mild 79.4%, moderate 70.8%, and advance 50.0%; Table 4).

Adverse events were non-sight threatening and self-limited. Generally, only trace blood refluxed into the AC upon insertion of the Hydrus microstent and resolved spontaneously in all

cases typically within the first postoperative week. Postoperatively, IOP spikes (IOP increase greater than 10 mmHg or IOP ≥ 30 mmHg), mild posterior capsule opacification, hyphema, iris adhesion/block, peripheral anterior synechiae, transient corneal edema, cystoid macular edema (CME), device malposition, and obstruction were noted. No adverse events required secondary interventions (Table 5).

### Discussion

Elevation in IOP is often associated with the progression of glaucoma. Aggressive control of IOP has been suggested for the control of VF progression.<sup>22</sup> The increasing costs of medications, lack of access globally, nonadherence to ocular medications, and the emergence of MIGS make Hydrus microstent study particularly important. Our study patients, Blacks and Afro-Latinx, have a higher rate of blindness from glaucoma compared with White Latinx and White persons.<sup>23</sup> In addition, the literature on MIGS in predominantly Black

population is limited with major studies like the COMPARE trial and the HORIZON including only 1.3% and 8%–12.2%, respectively (participant of European descent 65.3% and 78.9%–81.8%, respectively).<sup>19,21</sup> Our study looks at a reported efficacious MIGS in a population with the highest prevalence of glaucoma and blindness.

This retrospective noncomparative study demonstrated the efficacy of Hydrus microstent in significantly reducing medication burden while maintaining lower IOP during a 6-month period in Blacks and Afro-Latinx with glaucoma. The greatest reduction in medication burden was seen in mild glaucoma patients, with 79.4% of patients medication free. The advance glaucoma patients were able to maintain lower IOPs (8–14 mmHg) on less medication at 6 months (64.5% decrease in the number of medications, 50% medication free) without any sight-threatening complications. The Hydrus microstent facilitates aqueous outflow through a dilated Schlemm canal and open unobstructed collecting channels without damaging the TM.<sup>24,25</sup> The Hydrus is 8 mm in length and spans 3 clock hours. Schlemm canal MIGS like Hydrus is subject to the IOP floor created by resistance distal to the Schlemm canal. Although the presence of the IOP floor prevents hypotony, it creates a threshold for IOP reduction after intervention.<sup>26</sup> In our study, the mean preoperative IOP was  $14.7 \pm 3.7$  mmHg. After 6 months of follow-up, the mean was  $13.9 \pm 4.3$  mmHg ( $p = 0.25$ ). In this real-world retrospective study, we noticed an insignificantly lesser change in IOP (in all subgroups) compared with the HORIZON study because we did not do a medication wash-out. However, the number of medications decreased significantly ( $p < 0.0010$ ). Fea and colleagues demonstrated similar efficacy in a multicenter study of 67 patients with primary open-angle glaucoma patients who underwent phacoemulsification and Hydrus microstent insertion. At the 2-year follow-up, 64% of the patients were medication free with a mean IOP of 15.5 mmHg (–19% change from the baseline).<sup>27</sup>

Recently, Rhee and colleagues presented a 4-year follow-up data from the HORIZON study. They showed that 65% of the Hydrus patients were medication free at 4 years compared with 41% in the control group ( $p < 0.001$ ). Mean unmedicated IOP in the Hydrus group was 16.7 mmHg (baseline medicated IOP = 17.9 mmHg) and 17.2 mmHg in the control group (baseline medicated IOP = 18.1 mmHg). There was a significant

**Table 5.** Complications/adverse effects of Hydrus microstent MIGS.

Adverse effect	Number	Percent
Intraocular pressure spike	6	7.9
Corneal edema	6	7.9
Hyphema	1	1.3
Device obstruction	1	1.3
Iris adhesion/block	2	2.6
Grade 1 cells in AC	1	1.3
Cystoid macular edema	2	2.6
Device malposition	1	1.3
Secondary cataract	1	1.3
Iridodialysis	1	1.3
Residual Healon	1	1.3
Device in supraciliary space	1	1.3
PAS, others	0	0

AC, anterior chamber; MIGS, microinvasive glaucoma surgery; PAS, peripheral anterior synechiae.

reduction in risk of surgical events in the Hydrus group (log rank  $p = 0.015$ ) and lower probability of event (2.1% in the Hydrus group, 6% in controls, hazard ratio = 0.289, 95% CI: 0.106–0.836,  $p = 0.022$ ). They did not notice any significant increase in endothelial cell loss after the 3-month follow-up. Hydrus microstent has long-term efficacy without sight-threatening effects.

Our study shows the efficacy of cataract surgery and Hydrus microstent in Black and Afro-Latinx patients with mild, moderate, and advance glaucoma. The effect was greatest among mild glaucoma patients compared with advance glaucoma patients. All the patients were able to achieve their IOP target goals on either no medication or less medication. No additional surgeries were required. In patients with angle closure, cataract surgery can allow greater access to the TM with removal of the massive natural lens. Residual peripheral anterior synechia can be gently removed with a cyclodialysis spatula for 1–2 clock hours to allow insertion of the Hydrus stent. Also, in chronic angle-closure patients, we hypothesize that cataract surgery contributes to the reduction in medication burden. In patients with advance glaucoma, there could be preexisting distal

damage to collector channels and aqueous veins that lead to the requirement of additional medical therapy.

The complications of Hydrus microstent insertion in this study included transient hyphema, peripheral anterior synechiae, device malposition, device obstruction, transient IOP spike, and secondary surgical interventions.<sup>19,21,24,28,29</sup> In this study, the most reported complications of the Hydrus microstent were transient IOP spikes and transient corneal edema (Table 5). The corneal edema was as a result of phacoemulsification of hard cataract lenses and they all resolved.

#### Study limitations

Limitations of the study include its nonrandomized nature, small sample size, and limited follow-up period. Nonetheless, the study provides real-world evidence of the efficacy and complications of the Hydrus microstent in Black and Afro-Latinx patients with glaucoma.

#### Conclusion

The Hydrus microstent implantation and phacoemulsification cataract surgery demonstrated a significant decrease in ocular hypotension medication in Black and Afro-Latinx patients with mild, moderate, and advanced glaucoma. The procedure has an excellent safety profile similar to other MIGS devices. Further long-term studies are needed to confirm the efficacy and safety seen in our study.

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#### Authorship

All named authors meet the International Committee of Medical Journal Editors (ICMJE) criteria for authorship for this article, take responsibility for the integrity of the work as a whole, and have given their approval for this version to be published.

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#### Conflict of interest statement

The authors declared the following potential conflicts of interest with respect to the research, authorship, and/or publication of this article: D.L. declares being a consultant to Aerie, Bausch Health and Ivantis. G.N. and C.N. report no disclosure.

#### Data availability

The data sets during and/or analyzed during the current study are available from the corresponding author on reasonable request.

#### Ethical approval

All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki Declaration and its later amendments or comparable ethical standards.

#### Informed consent

Informed consent was obtained from all individual participants included in the study.

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#### References

1. Klein R and Klein BE. The prevalence of age-related eye diseases and visual impairment in aging: current estimates. *Invest Ophthalmol Vis Sci* 2013; 54: ORSF5–ORSF13.
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. Schein OD, Cassard SD, Tielsch JM, *et al.* Cataract surgery among Medicare beneficiaries. *Ophthalmic Epidemiol* 2012; 19: 257–264.
4. Racette L, Wilson MR, Zangwill LM, *et al.* Primary open-angle glaucoma in blacks: a review. *Surv Ophthalmol* 2003; 48: 295–313.
5. Mansberger SL, Gordon MO, Jampel H, *et al.* Reduction in intraocular pressure after cataract extraction: the Ocular Hypertension Treatment Study. *Ophthalmology* 2012; 119: 1826–1831.
6. Bron AJ, Vrensen GF, Koretz J, *et al.* The ageing lens. *Ophthalmologica* 2000; 214: 86–104.



7. Chen Z, Sun J, Li M, *et al.* Effect of age on the morphologies of the human Schlemm's canal and trabecular meshwork measured with swept-source optical coherence tomography. *Eye* 2018; 32: 1621–1628.
8. Moroi SE, Lark KK, Sieving PA, *et al.* Long anterior zonules and pigment dispersion. *Am J Ophthalmol* 2003; 136: 1176–1178.
9. Sitoula RP, Sarkar I, Nayak D, *et al.* Lens induced glaucoma: an experience in tertiary eye care center in eastern Nepal. *Nepal J Ophthalmol* 2016; 8: 161–166.
10. Tsai T, Robin AL and Smith JP 3rd. An evaluation of how glaucoma patients use topical medications: a pilot study. *Trans Am Ophthalmol Soc* 2007; 105: 29–33; discussion 33–35.
11. Okeke CO, Quigley HA, Jampel HD, *et al.* Adherence with topical glaucoma medication monitored electronically the Travatan Dosing Aid study. *Ophthalmology* 2009; 116: 191–199.
12. Leahy KE and White AJ. Selective laser trabeculoplasty: current perspectives. *Clin Ophthalmol* 2015; 9: 833–841.
13. Gedde SJ, Heuer DK, Parrish RK 2nd, *et al.* Review of results from the Tube Versus Trabeculectomy Study. *Curr Opin Ophthalmol* 2010; 21: 123–128.
14. Qassim A, Walland MJ, Landers J, *et al.* Effect of phacoemulsification cataract surgery on intraocular pressure in early glaucoma: a prospective multi-site study. *Clin Exp Ophthalmol* 2020; 48: 442–449.
15. Salinas L, Chaudhary A, Berdahl JP, *et al.* Goniotomy using the Kahook Dual Blade in severe and refractory glaucoma: 6-month outcomes. *J Glaucoma* 2018; 27: 849–855.
16. Le JT, Bicket AK, Wang L, *et al.* Ab interno trabecular bypass surgery with iStent for open-angle glaucoma. *Cochrane Database Syst Rev* 2019; 3: CD012743.
17. Malvankar-Mehta MS, Iordanous Y, Chen YN, *et al.* iStent with phacoemulsification versus phacoemulsification alone for patients with glaucoma and cataract: a meta-analysis. *PLoS ONE* 2015; 10: e0131770.
18. Samet S, Ong JA and Ahmed IIK. Hydrus microstent implantation for surgical management of glaucoma: a review of design, efficacy and safety. *Eye Vis* 2019; 6: 32.
19. Samuelson TW, Chang DF, Marquis R, *et al.* A Schlemm canal microstent for intraocular pressure reduction in primary open-angle glaucoma and cataract: the HORIZON study. *Ophthalmology* 2019; 126: 29–37.
20. Jones J, Koch DD, Vold S, *et al.* Results from the United States cohort of the HORIZON trial of a Schlemm canal microstent to reduce intraocular pressure in primary open-angle glaucoma. *J Cataract Refract Surg* 2019; 45: 1305–1315.
21. Ahmed IIK, Fea A, Au L, *et al.* A prospective randomized trial comparing Hydrus and iStent microinvasive glaucoma surgery implants for standalone treatment of open-angle glaucoma: the COMPARE study. *Ophthalmology* 2020; 127: 52–61.
22. Musch DC, Gillespie BW, Niziol LM, *et al.* Intraocular pressure control and long-term visual field loss in the Collaborative Initial Glaucoma Treatment Study. *Ophthalmology* 2011; 118: 1766–1773.
23. Ophthalmology AAO. US eye disease statistics. AAO, <https://www.aao.org/eye-disease-statistics> (accessed 16 February 2020).
24. Fea AM, Ahmed II, Lavia C, *et al.* Hydrus microstent compared to selective laser trabeculoplasty in primary open angle glaucoma: one year results. *Clin Exp Ophthalmol* 2017; 45: 120–127.
25. Camras LJ, Yuan F, Fan S, *et al.* A novel Schlemm's canal scaffold increases outflow facility in a human anterior segment perfusion model. *Invest Ophthalmol Vis Sci* 2012; 53: 6115–6121.
26. Shah M. Micro-invasive glaucoma surgery – an interventional glaucoma revolution. *Eye Vis* 2019; 6: 29.
27. Fea AM, Rekas M and Au L. Evaluation of a Schlemm canal scaffold microstent combined with phacoemulsification in routine clinical practice: two-year multicenter study. *J Cataract Refract Surg* 2017; 43: 886–891.
28. Gandolfi SA, Ungaro N, Ghirardini S, *et al.* Comparison of surgical outcomes between canaloplasty and Schlemm's canal scaffold at 24 months' follow-up. *J Ophthalmol* 2016; 2016: 3410469.
29. Pfeiffer N, Garcia-Feijoo J, Martinez-de-la-Casa JM, *et al.* A randomized trial of a Schlemm's canal microstent with phacoemulsification for reducing intraocular pressure in open-angle glaucoma. *Ophthalmology* 2015; 122: 1283–1293.