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Research Article

Minimally Invasive Glaucoma Surgery: Preliminary Mid-Term Results of the Ghanaian Experience with the New Hydrus Microstent

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Abstract

Background: Minimally invasive glaucoma surgery has been shown to reduce intraocular pressure effectively and sustainably whilst avoiding the complications associated with conventional glaucoma filtration surgeries. The Hydrus® Microstent is a newly approved minimally invasive device for glaucoma surgery. It is implanted in Schlemm's Canal and dilates approximately 3 clock hours of the canal, increasing aqueous outflow and reducing intraocular pressure. There are currently no studies reporting on the results of Hydrus Microstent implantation in the West African sub region.

Objective: To report on the first experience with the Hydrus Microstent in Ghanaian glaucoma patients.

Method: Twenty-two Hydrus Microstents were implanted, as a standalone procedure or in combination with cataract surgery, and assessed for intraoperative and postoperative complications, reduction in intraocular pressure and reduction in medication use. Patients were followed for one year.

Results: After one year there was an average reduction of IOP of 23.92% and an average reduction in the number of medications by 39.02% with the Hydrus implant.

Conclusion: We found the procedure to have few complications and effective in reducing intraocular pressure as well as the number of glaucoma medication use among Ghanaian glaucoma patients, especially when implantation of the Microstent was combined with cataract surgery.

Keywords: Minimally invasive glaucoma surgery; Hydrus microstent; Glaucoma

Introduction

The development of Minimally Invasive Glaucoma Surgery or Micro Incisional Glaucoma Surgery (MIGS) procedures has arisen out of the need to develop a glaucoma surgical procedure that reduces intraocular pressure effectively and sustainably but avoids the complications and common failures associated with conventional glaucoma filtration procedures. These complications include hypotony, endophthalmitis and filtration failure [1]. Unfortunately, African and African-American race is one of the risk factors for filtration failure [1].

MIGS procedures avoid extensive conjunctival and Tenon's layer dissection. They employ small incisions (clear corneal or scleral) to insert devices into the trabecular meshwork. The devices open up parts of the trabecular meshwork and increase drainage or create an alternate pathway for aqueous to drain out of the anterior chamber to the eye's external drainage system. These procedures can be stand-alone or combined with other procedures e.g. phacoemulsification cataract surgery, result in modest reduction in intraocular pressure and are therefore targeted for cases of mild to moderate glaucoma [2]. They can also reduce the medication burden and prolong the need for conventional filtration surgery [3]. Current MIGS procedures include the iStent (Glaukos Corp., Laguna Hills, CA, USA), Hydrus Microstent (Ivantis Inc., Irvine, CA, USA), Xen Gel Stent (Allergan Plc, Dublin, Ireland), OMNI Surgical System (Sight Sciences, CA, and USA) and the iTrack Micro catheter (Ellex iScience Inc., CA, USA). The complications of these devices are minimal, usually resolve with conservative treatment and are not associated with vision-threatening sequelae [2].

The Hydrus Microstent developed by Ivantis Inc. (Irvine, CA, USA) is an 8mm long, crescent shaped open structure (tube with fenestrations), curved to match the shape of Schlemm's canal and able to mould its shape to conform to the shape of the Schlemm's Canal. It is made of Nitinol (Nickel-Titanium Alloy) which is an Inert, elastic, biocompatible material. It is pre-loaded on an Injector and inserted via a clear corneal incision into the trabecular meshwork where it sits within and dilates Schlemm's canal (about 3 clock hours, 4 to 5 times its natural width). Its scaffold design minimizes tissue contact and prevents it from blocking the collector channel ostia in the posterior part of Schlemm's canal [2]. Advantages and disadvantages of the Hydrus Microstent are similar to the other MIGS devices.

Numerous studies have been carried out on the Hydrus Microstent, also comparing it with other pressure lowering procedures [4-6] there are currently no studies reporting on the use and results of the Hydrus Microstents in the West African sub region. This population has the highest incidence of Primary Open-Angle Glaucoma (POAG) and the severest forms of post-operative failures after traditional

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trabeculectomy surgery. Early randomized control trials in other parts of the world [7] show greater washed out IOP reduction in Hydrus + Cataract Surgery combined group as compared to Hydrus alone [8]. This paper reports our experience with the Hydrus Microstent device in a West African setting.

Methodology

Our study was an Interventional study with no controls, conducted over a period of 1 year at the Komfo Anokye Teaching Hospital in Kumasi, Ghana. Other study sites involved in studying the effects of Hydrus Microstent implantation included Salt Lake City, Utah and Sacramento in the United States of America, Mainz in Germany, Manila in the Philippines, and Warsaw in Poland and Manchester in the United Kingdom.

Careful patient selection was done prior to implantation of the device. Patient demographic details and visual acuity were taken, and a comprehensive eye exam done with a Topcon® Slit Lamp Biomicroscope and with the aid of a Volk® 4-mirror Goniolens to examine the anterior chamber angle. Intraocular Pressure (IOP) was measured with a Goldmann Applanation Tonometer attached to the Slit Lamp Biomicroscope. Automated visual field analysis using the Zeiss 24-2 SITA Standard test was done for each patient in the study. The mean deviation and pattern standard deviations were noted.

The number of medications that the patients were using to maintain a satisfactory IOP pre-op and post-op were noted and the average reduction in the mean number of medications to maintain satisfactory IOP (<18 mmHg) was noted.

Our study procedure was in compliance with the tenets of the Helsinki Declaration. Informed consent was sought from the selected patients. All selected patients were Ghanaian. Inclusion criteria were glaucoma patients with open anterior chamber angles, glaucoma uncontrolled on maximum glaucoma medication (3 medications) or inability to afford or tolerate the glaucoma medications. Uncontrolled IOP was defined as that above 21 mmHg with maximum three medications. Exclusion criteria were glaucoma patients with narrow or closed angles, those with secondary glaucoma (e.g. neovascular glaucoma), active ocular inflammation, no consent or inability to give informed consent (e.g. patients less than 18 years of age).

The Hydrus Microstent was implanted over a 5-day period. Twenty-two devices were implanted in fifteen patients as a stand-alone procedure or in combination with phacoemulsification surgery for patients who had significant cataract in addition to the glaucoma. For patients who had the combined Hydrus Microstent &Phacoemulsification procedure, the Microstent was implanted first. Patients were followed up on first postoperative day and after 1 week, 1 month, 3 months, 6 months and 1 year. Data was entered into a portal provided by Ivantis Inc. for automated data analysis and report generation.

Main outcome measures were Intra- and post-op complications, percentage reduction in IOP compared to baseline and reduction in the number of glaucoma medications. A postoperative intraocular pressure persistently below 18 mmHg without medications was considered as a success and IOP above 21 mmHg with1 or more medications was considered as failure.

Results

Patient demographics and type of procedure performed are shown in Table 1. "Phakic + Hydrus" indicates those with their crystalline lens who had the Hydrus Microstent procedure only, "Pseudophakic + Hydrus" indicates those who had an artificial Posterior Chamber Intraocular lens in-situ already and had the Hydrus Microstent procedure only, whilst "Cataract Surgery + Hydrus" indicates those who underwent a combined Phacoemulsification and Hydrus Microstent procedure.

Intraoperative complications encountered were: Trabecular stripping (1 eye), Posterior capsule rent during phacoemulsification (1 eye) and Intraoperative corneal edema during phacoemulsification (2 eyes).

The only post-operative complication encountered was IOP increase of more than 10 mmHg above the subject's baseline IOP on glaucoma medications (4 eyes).

There was significant reduction in mean IOP as well as mean number of glaucoma medication use 1 year after implanting the Hydrus Microstent (Table 2). An intraocular pressure persistently below 18 mmHg was chosen as a well-controlled intraocular pressure. The number of eyes with an intraocular pressure below 18 mmHg increased from 19% to 69% (Table 3), whilst 4 eyes (18%) did not need glaucoma medications for the IOP to be maintained below 18 mmHg at 1-year post-op (Table 4). Although some eyes had to be on glaucoma medications for their IOPs to be controlled below 18 mmHg 38.1% of eyes had number of medications reduced by 1 or more for controlled IOP (Table 4).

Table 1: Patient Demographics.

Average age (years)	63.3(±15.76)
Female	10 eyes
Males	12 eyes
Number of devices implanted	22
Right eye	14
Left eye	8
Mean Initial IOP (mmHg)	28.8 (range 17-46)
Mean Initial number of glaucoma medications	2(1-3)
Standard Automated Perimetry Visual Field mean deviation	-10.3 (±6.39)
Standard Automated Perimetry Visual Standard deviation	6.5 (± 2.94)
Type of procedure:	
Phakic + Hydrus	n = 8 (36%)
Pseudophakic + Hydrus	n = 3 (14%)
Cataract Surgery + Hydrus	n= 11 (50%)

Discussion

We found that we could implant the Hydrus Microstent with minimal complications. Most intraoperative complications (1 case of posterior capsule rent, 2 cases of corneal edema) were encountered during the additional procedure (phacoemulsification). The only complication we encountered, which was related to implantation of the microstent was 1 case of trabecular meshwork stripping, out of the 22 cases. These complications are similar to those reported in other studies. The other intra-op complications reported by other studies include hyphema and corneal abrasions [6].

The only postoperative complication we encountered so far was a sharp increase (a spike) in IOP of more than 10 mmHg above the baseline, and this was observed in 4 out of the 22 eyes. For optimal IOP control, 2 out of these 4 eyes had further glaucoma surgery (trabeculectomy) whilst the other two were put on 2 glaucoma medications. Those with IOPs above 21 mmHg on 1 or more medications (considered as failures) were assessed for visual

Table 2: Reduction in Intraocular pressure and medications 1 year after Hydrus Microstent Implantation.

Mean of Parameters	Before Hydrus implantation (SD)	12 months after Hydrus implantation (SD)	Percentage Reduction (%)
Mean Intraocular pressure (mmHg)	28.8 (7.56)	20 (9.8)	23.82
Mean Number of medications	2 (0.67)	1.2 (0.87)	39.02

SD=Standard Deviation

Table 3:

Parameter	Before (Percentage %)	After (Percentage %)
Number of patients with IOP 21 mm Hg or below	5 (23.8)	15 (71.4)
Number of patients with an IOP of 18 mmHg or below	4 (19)	13 (61.9)
Number of patients on 0 medications & IOP less than 18 mmHg	0 (0)	5 (25)

Table 4:

Parameter	Number	Percentage %
Number of patients reduced by 1 or more medications	13	61.9
Number of patients with a post-op IOP of 21 mm or below AND medications reduced by 1 or more	10	47.6
Number of patients with a post-op IOP of 18mm or below AND meds reduced by 1 or more	8	38.1
Number of patients on no medications	5	22.7
Number of patients with a post-op IOP <18 mm AND on 0 meds	5	25

field progression and had further glaucoma surgery or additional medications if necessary. At 1-year post-op, none the eyes we implanted the microstent in have experienced additional complications reported by other studies: reduction in best corrected visual acuity by vision loss of greater than 2 lines and peripheral anterior synechiae [7].

Before the Hydrus implantation 95% of the patients had uncontrolled IOP (more than 21 mmHg on maximum medications). One year after Hydrus implants, 71% were controlled with either no medications or reduced number of medications. Some of the patients with a very high pre-op IOP had to be put on additional glaucoma medications post-op for their IOPs to fall below 18 mmHg. The patient with a pre-op IOP of 46 mmHg for example, was later put on 2 glaucoma medications.

The percentage reduction in IOP (23.82%) observed in our study is very encouraging: it is close to the International Council of Ophthalmology's suggested reduction in IOP for early Glaucoma (>25%) and moderate/advanced Glaucoma (>25% to 50%) [9]. Our study also found the eyes belonging to the "Cataract Surgery + Hydrus" group had a more sustained and steady reduction in IOP compared to the other groups and this is also similar to results reported by other studies [8]. This could suggest that the Hydrus Microstent may be more effective when used in combination with phacoemulsification, as compared to being used as a standalone procedure. The mean number of medications in our study reduced from 2 to 1.2 at 12 months. This is quite promising, compared with a reduction in number of medications from 1.7 to 0.3 at 24 months recorded by the HORIZON Study [6].

Our study is a short-term study, and a long-term study with a larger sample size is needed to make better informed decisions on the efficacy and sustainability of the device in the African population. We also had limited time to prepare for the study and a medication wash-out period was not included to determine baseline IOPs without medications. Results from this study can therefore not be compared to similar studies where washed-out IOPs were used. The target IOP was set to below 18 mmHg for all eyes and not individualized. Target pressures for each eye should have been used as a reference to make therapeutic decisions e.g. when to restart glaucoma medications. The non-uniform distribution of patients among the 3 surgical groups may have introduced some bias.

Conclusion

In our setting, implanting the Hydrus Microstent proceeded with few complications. The device may offer a minimally invasive way to reduce intraocular pressure in African glaucoma patients. It may also offer an alternative to glaucoma medication and could reduce medication burden in a condition whose management often requires long-term use of multiple medications.

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