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Early to late explantation of Hydrus microstent MIGS device: A case series

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ABSTRACT

Purpose: The Hydrus microstent was approved by the FDA in August 2018 for use with cataract surgery to reduce IOP in patients with mild to moderate primary open angle glaucoma (POAG). Pivotal clinical trials demonstrated its overall safety and efficacy in lowering IOP. However, malpositioning of the implant can result in uveitis-glaucoma-hyphema (UGH) syndrome necessitating device explantation. Here we report four such cases and their associated challenges. We also highlight the importance of early recognition of post-operative complications for ease of implant removal.

Observations: Case 1: A 75-year-old female patient was referred for chronic granulomatous anterior uveitis with cystoid macular edema (CME) and uncontrolled IOP in the left eye after cataract extraction with Hydrus implantation. On gonioscopy, the implant was occluded and embedded in the iris. The patient underwent removal of the Hydrus implant 10 months after the initial surgery with canaloplasty to control IOP.

Case 2: A 71-year-old male patient on dual anti-platelet developed intraoperative hyphema during cataract extraction with Hydrus microstent in the right eye. Post-operatively, clopidogrel was stopped, but hyphema persisted with uncontrolled IOP. The Hydrus was noted to be synched against the iris face. The patient underwent anterior chamber washout with Hydrus explantation and Ahmed glaucoma valve implantation 16 days after the first surgery.

Case 3: A 76-year-old patient developed persistent granulomatous anterior uveitis in the left eye after cataract extraction with Hydrus microstent. On gonioscopy, the Hydrus ostium was seen resting on the iris without occlusion, and the patient underwent Hydrus removal with nasal goniotomy 3 months after initial surgery.

Case 4: A 63-year-old patient underwent cataract extraction with endoscopic cyclophotocoagulation and a complex Hydrus microstent implantation requiring multiple attempts. Eleven months later, the patient was found to have uveitis-glaucoma-hyphema syndrome and macular edema, and the Hydrus was noted to be insufficiently inserted and posteriorly rotated with contact against the iris. The Hydrus was explanted, and nasal goniotomy was performed.

Conclusions and importance: Hydrus microstents that are malpositioned can result in persistent uveitis-glaucoma-hyphema syndrome. Explantation between 2 weeks and 11 months successfully resolved post-operative uveitis and hyphema, but all cases required additional glaucoma-hyphema syndrome. Early recognition is important since late removal was more challenging due to the implant becoming embedded in the iris.

1. Introduction

Minimally invasive glaucoma surgeries (MIGS) have revolutionized glaucoma management since their introduction in 2007. Despite their favorable safety profile, these devices can still be associated with post-operative complications. The Hydrus microstent (Ivantis, Irvine, CA) is an 8 mm long intracanalicular scaffold made of nitinol (nickel-titanium alloy) designed to increase outflow facility by bypassing the trabecular meshwork and dilating the Schlemm's canal along one quadrant.[1] The overall safety profile is excellent for the Hydrus microstent. The HORIZON trial reports no significant increase in adverse events for Hydrus, which includes intraoperative device malposition (1.6 % phaco-Hydrus vs 0 % phaco-only), uveitis/iritis requiring steroids (5.6 % vs 3.7 %), cystoid macular edema (2.2 % vs 2.1 %), and focal peripheral anterior synechiae (obstructive 3.8 %, non-obstructive 14.9 %, vs 2.1 % phaco-only).[2] While the study was not powered to detect differences in rates

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of rare events, no complications in the 5-year follow-up report of the HORIZON trial necessitated implant removal. However, since its approval the Hydrus has anecdotally been linked to rare post-operative complications necessitating its removal. Here we report four cases of rare Hydrus-associated post-operative complications due to uveitis-glaucoma-hyphema (UGH) syndrome resulting from malposition that required surgical removal.

2. Findings

Case 1: A 75-year-old female with a history of bilateral chronic angle closure glaucoma and age-related macular degeneration was referred for chronic granulomatous uveitis with elevated IOP after cataract surgery with Hydrus microstent implantation in the left eye 8 months prior. The patient complained of no improvement in vision after the surgery and had a history of recurrent inflammation on tapering topical steroids. On examination, the patient had a visual acuity of 20/20-3 in the right and 20/250 in the left eye. The IOP was 14 mmHg in the right eye on latanoprost once daily and 19 mmHg in the left eye on maximal glaucoma topical therapy, prednisolone acetate, and ketorolac four times daily. A slit lamp examination revealed no signs of uveitis in the right eye. The left eye had granulomatous keratic precipitates with 1+ anterior chamber cells, patent peripheral iridotomy nasally, PC-IOL, and anterior vitreous cells. On gonioscopy, the left eye angle was open with an occluded Hydrus deeply embedded in the iris (Fig. 1). OCT in the left eye showed CME with a central macular thickness of 405 μm. No operative report from the referring office was available for the surgical approach. Uveitis workup for infectious and non-infectious causes was negative.

Intraoperatively, disposable micro forceps (Alcon Grieshaber Max-Grip, 23G) were used to remove the Hydrus microstent. The distal end of the microstent was noted to be adherent to the iris and was carefully peeled off using micro-forceps. Additionally, *ab interno* canaloplasty of the superior and inferior 180° was done for IOP control using the OMNI device (Sight Science, Menlo Park, CA). On the first postoperative day (POD), IOP was 25.5 mmHg with a 1 mm hyphema. Prednisolone acetate was increased to 6 times/day. At postoperative month (POM) 1, the patient had no KP or anterior chamber cells but had persistent CME with a central macular thickness of 644 μm and visual acuity of 20/200 and IOP 20 mmHg. Gonioscopy showed residual peripheral anterior synechiae of the nasal angle (Fig. 2). The steroids were changed to difluprednate 4 times daily. At POM 5, the patient had a visual acuity of 20/30-1 with no signs of uveitis, IOP of 11 mmHg on maximally tolerated medical therapy, and improved CME with a central macular thickness of 352 μm. This case highlights that Hydrus implants, which are not FDA-approved in angle closure glaucoma, can be malpositioned in such eyes. Late removal of the implant can be difficult due to iris adhesions.

Case 2: A 71-year-old man with POAG on dual anti-platelet therapy (aspirin and clopidogrel) presented with persistent hyphema and uncontrolled IOP after the Hydrus implant. During his cataract and Hydrus implant surgery, significant bleeding was noted from the initial goniotomy site for Hydrus insertion, and additional viscoelastic was able to tamponade the bleed intraoperatively. In the post-operative period, the patient developed a large hyphema and nasal clot with an IOP of 64 mmHg and was started on oral acetazolamide. Clopidogrel was stopped after consulting the cardiologist, but aspirin 81 mg was continued. The patient continued to have hyphema with uncontrolled IOP on maximal medical therapy. B-scan was negative for posterior segment hemorrhage. The patient underwent anterior chamber washout with Hydrus explantation and Ahmed glaucoma valve implantation 16 days after the first surgery. Intraoperatively, the proximal end of the implant was surrounded by peripheral anterior synechiae and iris tissues. It was pulled free using a Sinsky hook, and a Hydrus deployer was used to retract the implant into the anterior chamber and out of the eye. On POD 1, IOP was 11 mmHg with visual acuity of hand motion and no hyphema, but vitreous hemorrhage was noted. The patient was started on prednisolone acetate four times daily with a gradual taper. By 5 months, the vitreous hemorrhage had cleared with improvement in visual acuity to 20/40, and IOP was 15 mmHg on medication. This case highlights that patients with Hydrus implants treated with anti-platelet therapy may be at higher risk for persistent hyphema in cases of implant malposition.

Case 3: A 76-year-old man with POAG presented with chronic granulomatous iritis after uncomplicated cataract and Hydrus implant surgery. The proximal end of the hydrus was malpositioned, being noted to protrude further into the anterior chamber than desired rather than lying close to the TM. Still, it was judged to be in acceptable position given that there was no contact with the iris and more than 2/3 of the

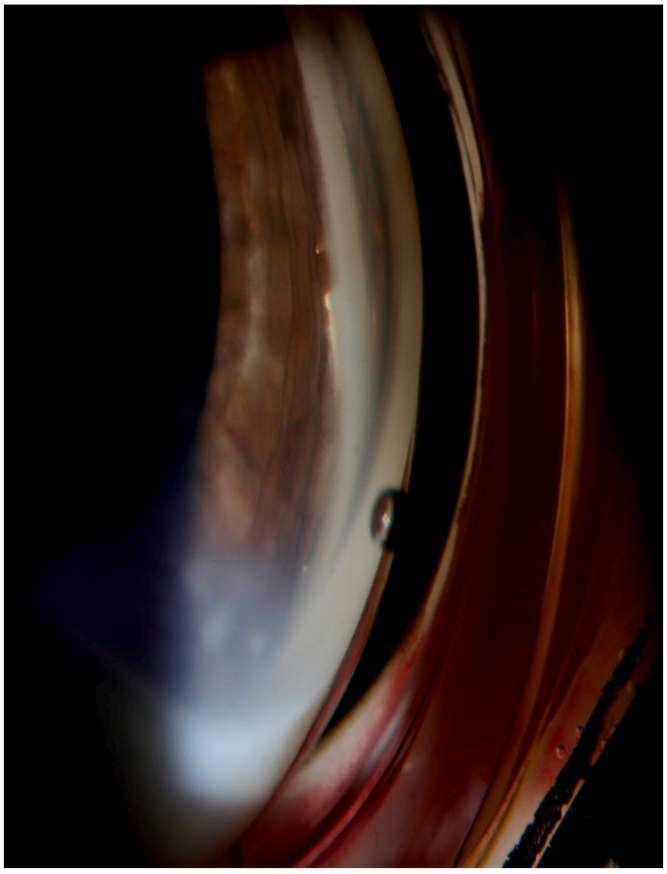

Fig. 1. Gonioscopic photo of Case 1 showing Hydrus microstent embedded in the iris.

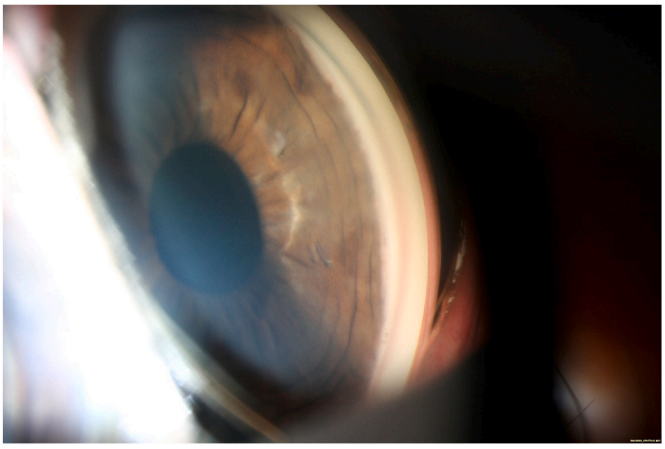

Fig. 2. Case 1 after Hydrus removal showing residual peripheral anterior synechiae at the nasal angle.

transition zone was covered. At the POM 1, visual acuity was 20/25 + 1 with an IOP of 12 mmHg, 1+ anterior chamber mixed cell. The patient had persistent inflammation at subsequent visits with 2+ anterior chamber granulomatous cells despite increasing steroids, and his IOP was 22 mmHg at a 3-month follow-up. There was no known history of metal allergy. On gonioscopy, the proximal end of the Hydrus, which was extending further into the AC than usual, was noted to be seated slightly above the iris with no contact, synechiae or occlusion (Fig. 3). However, it is suspected that given the proximity, the iris could still be in contact with the implant during blinking, lid squeezing, or prone position. Hydrus removal was performed at 3 months after the first surgery. Intraoperatively, MST forceps were used to remove the Hydrus. An intentional 2-clock-hour nasal goniotomy was created using the Hydrus microstent upon removal. Post-operatively, the patient was on slow prednisolone taper, and IOP increased up to 21 mmHg. POM6, his visual acuity was 20/25 with an IOP of 9.5 mmHg on latanoprostene bunod and brinzolamide without AC inflammation. However, at POM 8, the patient was noted to have visual field progression and was scheduled for trabeculectomy. This case highlights chronic granulomatous iritis despite no overt implant-iris touch should prompt one to suspect an adverse event related to the implant. Early recognition allows for easy explant and resolution of inflammation.

Case 4: A 62-year-old male patient with POAG and a possible traumatic component presented with cystic macular edema after phacoemulsification, endoscopic cyclophotocoagulation, and Hydrus implantation. During the initial surgery, the implantation was noted to be difficult, requiring multiple attempts, possibly due to occult damage to angle structures. Although the visible area of angle recession was distant from the implantation area, the Hydrus could not be seated fully within Schlemm's canal. The inlet and most of the first window remained in the anterior chamber, leading to its malposition. Over the 11 months after surgery, IOP fluctuated in the 15–28 mmHg range and required increasing medications. The Hydrus was also noted to rotate posteriorly with the proximal end opposing the iris face and peripheral anterior synechiae along the course of the implant. At POM 11, vision declined from 20/20 to 20/40, with CME and trace cells noted in the anterior chamber. The decision was made to remove the Hydrus. Intraoperatively, the distal end of the Hydrus was firmly synechied in place, the proximal end was embedded against the iris face, and peripheral anterior synechiae was again noted along the length of the implant. MST forceps were used to remove the Hydrus by carefully maneuvering it out of the iris and drawing it backward following the curvature of the implant. A 3-clock hour goniotomy was performed following explantation. During the post-operative period, IOP spiked as high as 51 mmHg due to hyphema. At POM 3, the patient had VA 20/50 and IOP 30 mmHg on maximal tolerated medication. He subsequently underwent a Clearpath Ahmed implant for IOP control.

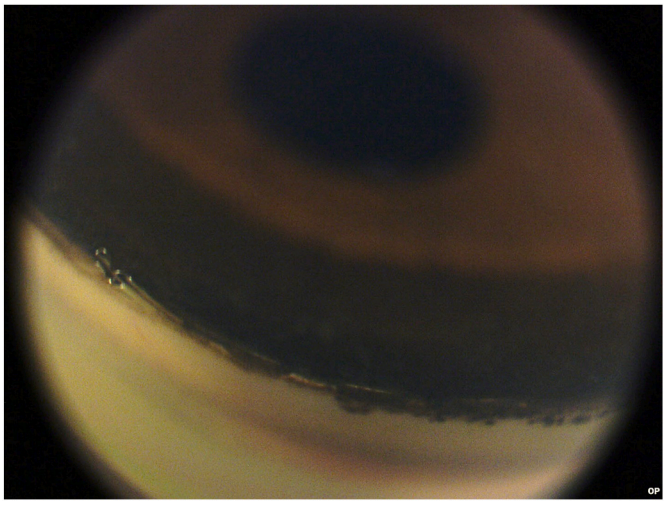

Fig. 3. Gonioscopic photo of Case 3 showing the proximal Hydrus inlet protruding into the anterior chamber but without synechiae or iris occlusion.

3. Discussion

This collection of cases highlights post-operative complications related to Hydrus malpositioning ultimately requiring explantation. All cases presented with components of the uveitis-glaucoma-hyphema (UGH) syndrome. Findings noted in our patients included iritis (3 cases), CME (2), non-clearing hyphema (1), and high IOP (4). Complications may be due to malposition with chafing against uveal tissue and/or subsequent formation of iris adhesions around the device. No common risk factors were observed among these 4 cases by examining axial length (mean 23.86 mm), anterior chamber depth (mean 3.19 mm), or TM pigmentation, and no cases used trypan blue. Hydrus removals were performed 2 weeks to 11 months after the initial surgery. In Cases 1 and 4 in which the Hydrus had been left in place for longer than 6 months, angle tissues were noted to be strongly adherent to the implant, which made the explantation more difficult. All patients had resolution or improvement of UGH syndrome after the Hydrus explantation. All patients underwent concurrent glaucoma surgery (3 nasal goniotomies, 1 Ahmed valve) with the Hydrus explantation, but 2 cases required subsequent filtering procedures for glaucoma control within 1 year from the initial surgery.

In previous randomized controlled trials with the Hydrus microstent, the most common device-related adverse events were focal adhesions, and the degree of obstruction was unrelated to an increase in IOP. Although other adverse events were reported (device malposition, hyphema, uveitis requiring steroids, cystoid macular edema), there were no reports of device explantation.[2] There are only a few case reports on removing the Hydrus microstent. Young et al.[3] reported a case of malposition causing UGH syndrome, which resolved upon implant removal. Other reported cases of Hydrus removal include one case of malposition, one of iris-stent touch, and one of uveitis and macular edema in a patient with a known skin allergy to nickel.[4–6] Conservative medical therapy has been reported to successfully treat complications related to Hydrus and should be tried first. Karaca et al.[7] reported a case of acute iridocyclitis and cystoid macular edema due to a kinked Hydrus microstent causing iris chafing 2 years following combined cataract surgery and Hydrus microstent implantation. The patient responded well to medical treatment with topical NSAIDs and steroids. In addition, not all cases with mispositioned Hydrus develop complications. In a case series of five patients with mispositioned Hydrus microstents imaged using NIDEK GS-1 gonioscope, none developed any adverse events such as macular edema or chronic inflammation.[8]

Our case series reported one case of persistent hyphema resulting in uncontrolled IOP from a patient on dual anti-thrombotic therapy. There are no general guidelines on perioperative management of anti-thrombotic agents in MIGS. The survey showed that 15 % of glaucoma surgeons would likely stop anti-thrombotic for MIGS compared to 78 % for trabeculectomies and 7 % for glaucoma drainage implantations.[9] Transient hyphema was significantly more common with Hydrus microstent (36.4 %) than with iStent (19.9 %) and iStent inject (8.5 %), and one eye with Hydrus implant required anterior chamber washout.[10]

Additionally, cases 1 and 4 highlight the importance of careful case selection. Hydrus microstent is approved for use in POAG. Randomized control trials on Hydrus have excluded angle closure and all secondary glaucoma except pigmentary and pseudoexfoliative glaucoma.[2] Hydrus use in other types of glaucoma besides POAG could predispose to an increased risk of adverse outcomes.

4. Conclusions

To our knowledge, this manuscript represents the largest case series to date of Hydrus explantations. Although an effective device for

treating open angle glaucoma, a malpositioned Hydrus microstent may be associated with UGH syndrome that may ultimately require explantation. In Case 1, the Hydrus was embedded deeply in the iris; in Case 2, the proximal end was insufficiently buried and became surrounded by iris tissues; in Case 3, the Hydrus was protruding into the anterior chamber and was seated in close enough proximity to the iris face that it was likely abrading during normal movements of the iris; and in Case 4, the Hydrus was rotated posteriorly. While all four cases involved some degree of malposition, some were more subtle than others. In some cases, the malpositioning was noted only postoperatively. Because delays in recognizing complications can lead to more challenging removals due to adherent iris tissues, it is important to remain vigilant for signs and symptoms associated with malposition, including refractory iritis, elevated IOP, and non-clearing hyphema. While Hydrus explantation led to the resolution of iritis and hyphema in all cases presented, additional glaucoma surgeries may be needed to maintain IOP control in these situations.

Patient consent

This study was approved through the institutional IRB. Written consents were obtained using the forms provided by the IRB.

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CRediT authorship contribution statement

Neha Sachdeva: Writing – review & editing, Writing – original draft, Project administration, Methodology, Investigation, Formal analysis, Data curation, Conceptualization. **Lynn W. Sun:** Writing – review & editing, Writing – original draft, Methodology, Investigation, Data curation. **Jonathan Young:** Writing – review & editing, Investigation, Data curation. **Aiyin Chen:** Writing – review & editing, Writing – original draft, Supervision, Project administration, Methodology, Investigation, Formal analysis, Data curation, Conceptualization.

Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

The authors have no conflict of interest.

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