Vitreous hemorrhage following CyPass® glaucoma stent surgery

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ABSTRACT

Objective: To report a previously unpublished complication of CyPass® glaucoma stent placement in a patient undergoing combined cataract and glaucoma surgeries. This case occurred prior to voluntary withdrawal of the CyPass® device from the market.

Case Description: A 70-year-old Hispanic male with a history of advanced pseudoexfoliation glaucoma left eye (OS) > right eye (OD) presented to the North Texas Veterans Affairs Medical Center with disease progression despite escalation to maximum medical therapy. His maximum intra-ocular pressure (IOP) prior to treatment was 29 mm Hg in OD and 60 mm Hg in OS. Given the presence of a visually significant cataract in OS with advanced glaucoma that was progressing despite maximum medical therapy, a decision was made to pursue cataract phacoemulsification in conjunction with insertion of a CyPass® stent device in OS. The patient was consented prior to surgery. Postoperatively, his IOP dropped to as low as 4 mm Hg, followed by hyphema as well as a dense vitreous hemorrhage. Appropriate placement of the stent was confirmed by ultrasound biomicroscopy, gonioscopy, and anterior segment optical coherence tomography (OCT). The hypotony, hyphema and vitreous hemorrhage all resolved with conservative medical management by the time the patient was seen again one month later.

Conclusions: It is important for surgeons to be aware of even less common complications of micro invasive glaucoma surgery (MIGS) procedures. In our case, the patient developed a complication that had previously not been described. While this case resolved with conservative medical management, this case illustrates that it is important to appropriately assess pre-operative risk factors and confirm appropriate placement of a MIGS device postoperatively.

Keywords: CyPass®, vitreous hemorrhage, minimally invasive glaucoma surgery.

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Introduction

Previously, when advanced glaucoma necessitated the use of incisional surgery to achieve better IOP control, fewer options were available, which included filtering and tube shunt procedures [(1)]. However, over the past several years, a new class of surgeries – termed minimally invasive glaucoma surgery (MIGS) – have emerged which share five common advantageous

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Qualities, as described by Saheb and Ahmed [2]: minimal trauma to the target tissue, ab interno clear corneal approach, IOP lowering ability, high safety profile, and rapid recovery time. Some of the primary stent technologies currently approved for use in the US are the iStent® (Glaukos, Laguna Hills, CA, USA), and XEN® stent (Allergan plc, Dublin, Ireland). The iStent® bypasses the trabecular meshwork and is inserted directly into Schlemm's canal. Finally, the XEN® stent drains aqueous humor into the subconjunctival space. [2].

Of particular interest to us in this case study is the CyPass® device (Figure 1) [3], which was used in conjunction with cataract surgery. The CyPass® created a conduit for outflow into the suprachoroidal space. The stent was made of flexible polyimide material containing 64 fenestrations and is injected just below the junction of the scleral spur and the ciliary body. There is currently a large, multi-center, randomized controlled trial – the COMPASS trial – studying the safety and efficacy of this device [3]. The published two-year results detailed multiple adverse side effects, including subconjunctival hemorrhage and hyphema [3]. More recently, the device was voluntarily withdrawn by the manufacturer due to the five-year data demonstrating a significantly higher rate of endothelial cell loss [4]. However, previously there had been no reports of vitreous hemorrhage following CyPass® stent implantation. In this report, we aim to detail perioperative factors which may have contributed to the patient's postoperative course.

Figure 1: Gonioscopic view of CyPass Stent device.

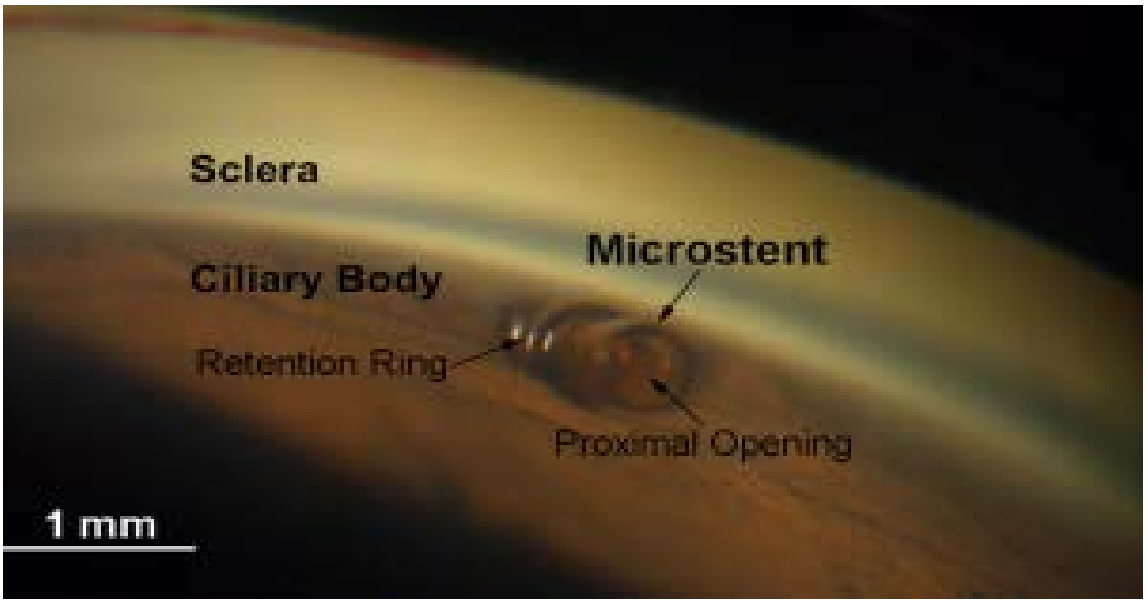

Figure 1

Case Report

Our patient was a 70-year-old Hispanic male who presented to the North Texas Veterans Affairs Medical Center in August 2017, with a history of advanced pseudoexfoliation glaucoma (OS > OD). His glaucoma progressed despite adherence to maximum medical therapy. Maximum pre-treatment IOP was 29 mm Hg OD and 60 mm Hg OS. Gonioscopy confirmed open angles in both eyes (OU). At the time of presentation, he was already on a regimen of latanoprost 0.005% (Xalatan®) at bedtime (qhs)-OU, dorzolamide-timolol 2%,0.5% (Cosopt®) twice a day (BID) OU, and brimonidine 0.2% (Alphagan®) three times a day (TID) OU, and acetazolamide (Diamox®) 250 mg four times a day orally (QID). The only other intervention prior to incisional surgery was selective laser trabeculoplasty (SLT) of the left eye in December 2016.

Visual fields by Humphrey Field Analyzer 3 (Humphrey Instruments, CA, USA) were unremarkable in the right eye (central 24-2 threshold test) and showed significant global depression in the left eye (central 10-2 threshold test), revealed significant progression from central island (Figure 2A).

OCT of the retinal nerve fiber layer performed in June 2017 was borderline (average of 86 µm) in the right eye and showed significant diffuse thinning in the left eye (average of 27 µm) (Figure 2B).

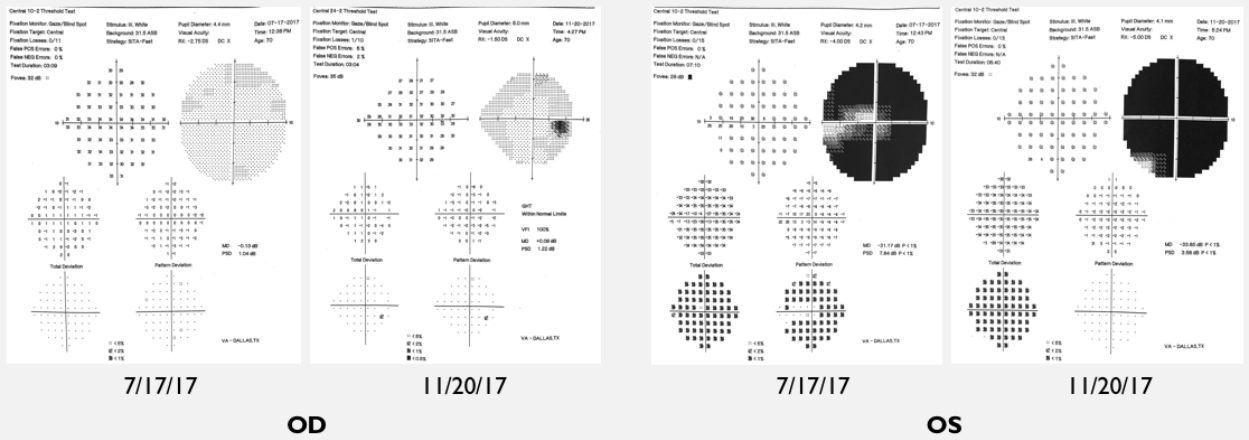

Figure 2A

Figure 2B

Figure 2. Pre-operative glaucoma testing.

(A) Humphrey Visual Field testing from 7/2017 and 11/2017. (B) OCT retinal nerve fiber layer images from 4/2016 and 6/2017.

In November 2017, patient's right eye visual acuity with spectacle correction was 6/9.5 (20/30) with evidence of 2+ nuclear sclerotic and 2+ cortical cataract. In his left eye, the visual acuity with spectacle correction was 6/24 (20/80) pinhole to 6/19 (20/70) with evidence of 2+ relative afferent pupillary defect and 2+ nuclear sclerotic and cortical cataract. Additionally, the left optic nerve was noted to have a cup to disc ratio of 0.9, compared to 0.3 in the right eye. IOPs in the right and left eyes had stabilized to 14 mm Hg and 15 mm Hg, respectively. Given the presence of a visually significant cataract in the left eye with advanced progressive glaucoma, a decision was made to pursue cataract phacoemulsification in conjunction with insertion of a CyPass® stent device.

In January 2018, the patient was consented prior to surgery and underwent an uncomplicated cataract phacoemulsification with insertion of an Alcon SN60WF 12.5D single piece intra-ocular lens into the capsular bag as well as successful implantation of a CyPass® stent device into the nasal angle. On postoperative day 1, the patient's left eye vision was 6/60 (20/200) and his IOP was 6 mm Hg. The corneal exam was significant for 2+ stromal edema with 2+ Descemet's folds, and the anterior chamber was noted to have trace white blood cells as well as 4+ red blood cells with a layering 0.33 mm hyphema. He was started on routine postoperative therapy which included 1% prednisolone acetate (Pred-Forte®) four times a day, moxifloxacin (Vigamox®) four time a day, and bacitracin zinc and polymyxin B sulfate ophthalmic ointment (Polysporin®) at night. On postoperative day 4, visual acuity had worsened to light perception, and IOP had decreased to 4 mm Hg. Corneal edema was stable and the layered hyphema had worsened to 1.5 mm. There was no

view by funduscopic exam, and so a B-scan was performed which did not reveal any choroidal effusions. On postoperative day 11, visual acuity remained stable at light perception and IOP had increased slightly to 5 mm Hg. Corneal and anterior chamber exams were stable. There was still no view for a funduscopic exam, and a repeat B-scan revealed a small new choroidal effusion with vitreous hemorrhage. Atropine 1% twice a day was initiated in the left eye, prednisolone was maintained at QID, and antibiotics were stopped. At his postoperative week 3 appointment, his visual acuity remained stable at light perception and IOP had increased to 10 mm Hg. A repeat B-scan showed that the choroidal effusion had resolved but the vitreous hemorrhage persisted. Gonioscopy showed that the CyPass stent was appropriately positioned at the ciliary body band. At his postoperative week 4 appointment, the exam B-scan were stable for resolved hyphema and IOP increased to 16 mm Hg. Latanoprost qhs was restarted for the left eye. At his postoperative week 6 appointment visual acuity had improved to hand motion and IOP was slightly increased at 18 mm Hg. Ultrasound biomicroscopy and anterior segment OCT confirmed appropriate placement of the CyPass stent in the suprachoroidal space (Figures 3A and 3B). A decision was made to slowly taper the prednisolone acetate by 1 drop every week and tentatively plan for a pars plana vitrectomy of the left eye for non-clearing vitreous hemorrhage. However, the hemorrhage subsequently resolved by the time he was seen one month later and visual acuity improved to 20/50.

Figure 3A

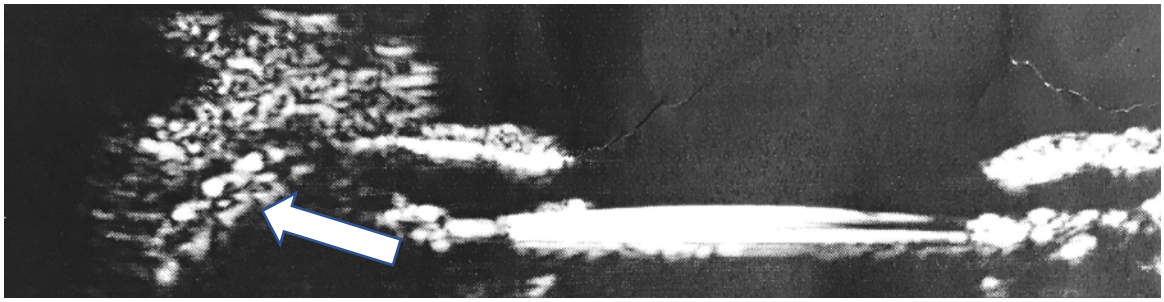

Figure 3B

Figure 3: Post-operative anterior segment imaging.
(A) Anterior segment OCT and (B) Ultrasound biomicroscopy of the iridocorneal angle showing appropriate placement of the CyPass stent (white arrow) in the supraciliary space.

Discussion

To our knowledge, this is the first reported case of a phacoemulsification/CyPass® stent implantation surgery being complicated by post-operative vitreous hemorrhage in the setting of hypotony. While suprachoroidal hemorrhage have been known to occur with intraocular surgical procedures [5], there were no clinical findings concerning for suprachoroidal hemorrhage in our patient. Additionally, we would expect such a hemorrhage to be limited to the suprachoroidal space and not spill over into the vitreous cavity. A communication between the two spaces could have been created by inaccurate placement of the CyPass device, but appropriate placement was confirmed by multiple methods including gonioscopy, anterior segment OCT (Figure 2A), and ultrasound biomicroscopy (Figure 2B).

One possible alternative mechanism that we considered was spill-over hemorrhage from the anterior chamber hyphema. As was noted previously, the COMPASS trial has shown that hyphema is a known complication of CyPass implantation [3]. Furthermore, pseudoexfoliation has been associated with zonular instability, including zonular dialysis [6], which would allow for communication between the anterior and posterior segments. We therefore posit the possibility that a post-operative hyphema carried over into the posterior segment through such an opening. However, the vitreous hemorrhage that we observed was dense, causing light projection vision and likely cannot be fully explained by spill-over hemorrhage alone.

Another possibility is occult retinal neovascularization that was unmasked in the setting of hypotony and manifested as hemorrhage. However, the patient's only risk factor prior to surgery was hypertension and pre-operative funduscopic exam did not note any evidence of hypertensive retinopathy. In a similar vein, alternative mechanisms for hypotony-mediated hemorrhage have been proposed. One mechanism is a mechanically induced retinal vein occlusion caused by anterior shifting of the lamina cribrosa and blockage of axonal transport, leading to retinal vein compression [7,8]. An additional mechanism is a hemorrhagic posterior vitreous detachment caused by the vitreous body being suddenly pulled forward [9,10].

Finally, although less likely, a phenomenon known as acute ocular decompressive retinopathy has been described. This condition is characterized by retinal hemorrhages which can include vitreous and subhyaloid hemorrhages that occur shortly following a rapid drop in IOP–such as that associated with tube shunt and filtering surgeries [101. This is thought to occur when a sudden drop in IOP leads to a sudden increase in blood flow through retinal vessels with impaired autoregulation, thereby overwhelming the normal capacitance of these vessels [10]. One review of 32 studies found that the average IOP drop associated with this condition was 33 mm Hg but ranged from 4-57 mm Hg. Given that the patient's pre-operative intraocular pressure was 15 mm Hg and dropped to as low as 4 mm Hg postoperatively, this is certainly a consideration.

While it is unclear what caused the dense post-operative vitreous hemorrhage observed in our patient, it is likely related to the post-operative hypotony. Per the COMPASS trial, hypotony was one of the more common adverse events encountered after CyPass stent placement [3]. As such, our case shows that it is important to be prepared for the possible sequela of prolonged hypotony. The differential diagnosis for hemorrhage triggered by hypotony is diverse, and the various possibilities should be prioritized and investigated based using an individualized approach that considers a patient's unique perioperative risk factors.

Conclusions

In summary, this case illustrates a complication of CyPass® stent placement that had not been previously published. There were no pre-operative findings on exam that would have suggested this patient would have been at risk for developing a post-operative vitreous hemorrhage. This complication was therefore most likely due to post-operative hypotony created by stent placement or by spillover of blood from the anterior chamber to the vitreous cavity through zonular defects commonly seen in pseudoexfoliation. As hypotony is not an uncommon complication after incisional glaucoma surgery, it is important to be prepared for it as well as any associated sequela. Furthermore, while this patient did not have pre-operative risk factors for developing vitreous hemorrhage, such as retinopathy, it is important to conduct a thorough pre-operative examination and be cognizant of such risks factors if they are present.

Patient Consent

As no identifying information is disclosed, patient consent was not obtained.

Acknowledgements and Disclosures

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