A case report of complete blockage of a Baerveldt glaucoma implant following insertion of a 3-0 Supramid suture

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Precis

We observed complete occlusion of a Baerveldt glaucoma implant with a 3-0 Supramid stent suture that highlights the importance of flow testing all devices before insertion due to variations in manufacturing conditions.

Abstract

Purpose: The aim of this study was to present a case of a Baerveldt glaucoma implant lumen being completely occluded with a 3-0 Supramid stent suture.

Patient and Methods: The patient underwent Baerveldt glaucoma implant surgery with placement of an intraluminal 3-0 Supramid stent suture that acts to restrict flow across the device and reduce the risk of post-operative hypotony. Following suturing of the implant to the sclera, the device was flow tested. No flow was observed through the device tube and a significant ballooning of the tube diameter occurred with increased pressure on the device. The device was explanted from the eye and replaced with a different implant without further post-operative complication. The explanted device was assessed using custom microfluidic equipment in an *in vitro* environment.

Results: This phenomenon occurred despite using several different batches of the 3-0 Supramid stent suture and the device had to be removed and replaced with another device without complication. *In vitro* microfluidic assessment of the device demonstrated no flow across the device tube despite over 150 mmHg of pressure being exerted on the device.

Conclusions: We hypothesize that the blockage occurred at the junction between the device tube and plate and that the ballooning phenomenon observed was due to a defect in the tube wall. This case highlights the importance of flow testing all glaucoma drainage devices before insertion given the variation in manufacturing conditions to avoid the risk of intra-operative complications.

Case Report

Glaucoma drainage devices (GDDs) are composed of a silicone tube (approximately 0.3 mm inner diameter) connected to a plate that drains aqueous humour from the anterior chamber to the subconjunctival space. GDDs can be valved to restrict flow below certain levels of IOP, such as the Ahmed glaucoma valve (AGV) (New World Medical, Rancho Cucamonga, CA), or non-valved such as the 350 mm^2 Baerveldt glaucoma implant (BGI) (Abbott Medical Optics, Santa Ana, CA). Studies have shown that the BGI has comparable outcomes to glaucoma filtration surgery (1).

The BGI requires the use of a stent suture inserted within or around the tube lumen to restrict flow initially following device insertion that is often removed several months later. It is our standard practice to place a 3-0 Supramid® Extra suture (0.2-0.249 mm diameter) (S. Jackson, Alexandria, VA, USA), a cable-type multi-filament suture co-extruded from nylon 6 and nylon 6.6, within the tube (2, 3). While we have demonstrated that the suture acts to reduce the risk of early hypotony (2), the suture diameter should be sufficiently small to allow some aqueous flow through the silicone tube to the subconjunctival plate. We report a case of intra-operative BGI device failure due to complete lumen occlusion with the Supramid stent suture that we validated using an *in vitro* microfluidic flow assessment setup following removal of the device.

Intraoperatively, the Supramid suture was inserted into the tube lumen and the plate subsequently sutured to the sclera. Before the tube was inserted into the anterior chamber, we assessed the patency of the device as per our standard practice by irrigation using balanced salt solution (BSS) through a

27G Rycroft cannula passed into the end of the tube lumen. Whereas we would expect BSS to flow from the tube to the plate (past the suture within the lumen), instead the silicone tube ballooned significantly (Figure 1A) and no flow was observed. The phenomenon repeatedly occurred despite three different batches of the suture being placed within the lumen. The device subsequently had to be removed from the sclera and replaced with another device that did not suffer from the same issue.

Subsequent *in vitro* microfluidic assessment of the non-functioning BGI, consisting of a reservoir of water connected to a microfluidic pressure pump/flow sensor (Fluigent, Villejuif, France), was performed. We were not able to generate flow through the BGI tube when any length of Supramid suture was placed in the tube up to connection with the plate despite the presence of more than 150mmHg of downward pressure. When excessive pressure was exerted on the non-functioning implant, the silicone tube ballooned as per Figure 1A without aqueous flow to the plate. Figure 1B shows the Supramid suture sitting within the tube lumen with thinning of the tube wall at the site of ballooning. Figure 1C shows the external orifice where the tube enters the plate and was measured as 300 μm wide. Figure 1D therefore demonstrates the location that we believe is where the manufacturing defect of the implant has occurred (the insertion of the tube into the plate) that prevented aqueous flow through the tube lumen following placement of the Supramid suture.

We report a case where the device failed flow-testing assessment before tube insertion into the anterior chamber and subsequently the whole device had to be removed and replaced. Repeated suturing of the sclera risks

complications such as scleral perforation. As far as the authors are aware, this is the first time that such BGI failure has been reported in the literature and we highlight a manufacturing defect of both the tube wall and connection between the tube and the plate in this case. We wish to increase the awareness of performing a flow testing assessment of BGI devices intra-operatively following placement of a stent suture in the tube lumen and before insertion into the eye to minimise the risk of intra- and/or post-operative complications.

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Image Legends

Figure 1: Device failure associated with the Baerveldt Glaucoma Implant (BGI) (Abbott Medical Optics, Santa Ana, CA) following insertion of a 3-0 Supramid® Extra suture (S. Jackson, Alexandria, VA, USA) in its tube lumen. (A) The BGI showing significant ballooning of the tube lumen when excessive pressure using balanced salt solution (BSS) was exerted on the end of the tube; (B) The Supramid suture can be seen to sit within the BGI tube lumen with no pressure exerted and space surrounding it that should allow for flow from the tube to the plate. Note also the thinning of the silicone tube wall inferiorly at the site of ballooning; (C) The exit of the BGI tube at the plate showing no obvious deformity and had an expected 300 μm inner diameter; (D) The insertion of the tube into the plate (arrowed) that is the likely point of device failure that prevented the aqueous outflow through the BGI following placement of a Supramid suture.