Conversion of Flow-restrictive Ahmed Glaucoma Valve to a Non-restrictive Drainage Implant by Slicing the Valve Leaflets: An In Vitro Study

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Precis: With a newly designed blade, slicing of the Ahmed glaucoma valve (AGV) leaflets helped to convert the flow-restrictive AGV into a non-flow-restrictive device. Flow characteristics by our in-vitro study confirmed the loss of resistance of AGV valve leaflets.

Purpose: To describe a new blade to destroy the valve leaflets of AGV and to report the in-vitro flow characteristics of AGV after valve destruction.

Methods: All the newly opened AGV implants and the Aurolap aqueous drainage implants (AADI, used as controls) were tested by connecting to a 27-G cannula, open manometer, digital manometer, and automated infusion pump. Data logging was done using a digital manometer at 4 Hz using computerized software. When the AGV’s flow characterization reached the steady phase, their valve functionality was destroyed by disrupting the valve leaflets, using a specially designed blade. The flow characteristics after valve slicing were compared with that of AADI.

Results: A total of 5 FP7 AGVs and 2 AADIs were tested. After initial resistance to flow (5, 8 mm Hg) observed in the case of AADI for 1 to 3 hours, it dropped to 1 mm Hg in both the implants. The flow-restrictive AGV showed 3 distinct phases in the flow characterization. The first phase included the transient phase followed by the steady phase wherein the pressure was 11.2 ± 2.6 (min 7, max 14) mm Hg. The pressure resistance of the AGV dropped significantly (P < 0.001) to a mean of 0.4 ± 0.54 mm Hg (1 mm Hg in 2 devices and 0 mm Hg in 3 devices) after the valve functionality was destroyed. The average time taken for this drop in pressure resistance after valve slicing was 10.2 ± 3.0 minutes (min 7, max 15).

Conclusions: It was possible to convert the flow-restrictive AGV into a non-flow-restrictive device by destroying the functionality of the valve leaflets. The pressure of the AGVs was similar to AADI after valve destruction.

Key Words: AGV valve destruction, failed AGV, AGV flow characteristics

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Flow-restrictive [Ahmed glaucoma valve (AGV)] and non-flow-restrictive [Baerveldt/Aurolap aqueous drainage implant (AADI)] glaucoma drainage devices are excellent options in the management of refractory glaucomas when conventional trabeculectomy fails or has a high risk of failure.1,2 Although drainage implants can help overcome failure related to the blockage of the drainage ostium with a permanent drainage tube, bleb encapsulation and fibrosis remain the most common cause of long-term failure with flow-restrictive implants.3–5 The other rare causes being the fusion of the valve membranes6 or the valve outlet block by fibrovascular tissue.7 The options available in the management of elevated intraocular pressure after a failed glaucoma implant surgery are as follows: the transscleral cyclophotocoagulation (TSCPC),8,9 trabeculectomy, bleb wall excision,5,6 shunt revision,10 second drainage implant,11–13 or exchange of flow-restrictive AGV with a non-flow-restrictive implant like Baerveldt.14 TSCPC is a destructive procedure with unpredictable results and complications.15 Repeat trabeculectomy is a challenge; however, it has been tried in selected cases after the failure of the drainage implant.16 Repeat implant is a possibility, however, this would involve using another site for surgery and complex eyes with scarred conjunctiva it may a difficult option. Implant exchange is difficult but still a viable option. However, the surgical challenges and cost of a second implant are to be weighed. If we can revive the drainage through the same implant, by converting the flow-restrictive implant into a non-flow-restrictive device, then we could avoid the second implant and its economic and surgical implications.

With this hypothesis, we chose to perform an in-vitro study to convert the flow-restrictive implant into a non-flow-restrictive implant by slicing the bi-membrane valve leaflets of the AGV without affecting the tube stability.

METHODS

In an experimental setup at the L V Prasad Eye institutes’ engineering and innovation center, we studied the flow characteristics of 5 AGVs and 2 AADIs (used as controls). The description of the experimental setup, priming, and flow characterization methods, data capture, and plotting are described in our previous study.17 Briefly, the experimental setup consisted of a 5-mL syringe, a digital manometer, and an implant, all were connected using a 27-G, 3-way cannula. An automated infusion pump and the open manometer were connected to the setup. The AGV or AADI were connected to a 5-mL syringe through a 27-G cannula and the implant was submerged into a saline bath at a depth of 3 cm. After priming, the saline was infused into the system at the rate of 3 µL/min (to simulate the aqueous humor production rate in the eye) for 24 hours. The pressure changes were recorded.
by the digital manometer using computerized data logging and the pressure curves were plotted against time using MATLAB software. This experimental study did not require ethics committee approval.

Procedure

Five new AGVs were used for the experiment. After priming and assessing the flow characteristics of the AGV, the bi-membrane valve leaflets of the AGV were destroyed by slicing the leaflets. After slicing, the flow characterization was repeated and compared with that of AADI. The technique of valve slicing to disrupt valve function was designed so as to be replicated in vivo. The leaflets were vertically sliced using a specially designed blade (Fig. 1) as a toothed forceps held the outer casing of the valve compartment for stability. The blade tip was passed through the posterior outlet of the trapezoidal chamber through the gap between the casing and the membranous valve leaflets (Fig. 2).

The blade was designed in such a way that it can be held either by the right hand or the left hand as per the eye to be operated. In the case of a right-handed user, the blade can be passed through the casing outlet, with the sharp edge facing downwards and the leaflets are cut by applying certain pressure and dragging the blade downwards (see video, supplemental digital content 1, http://links.lww.com/IJG/A457, which demonstrates slicing of the valve membranes). For a left-hand user, the blade is passed through the separation between the casing with the sharp edge facing upwards. The leaflets are cut by dragging the blade upwards toward the casing walls and the implant was primed to evaluate resistance. When the flow characteristics were evaluated after valve slicing, there was an initial lag followed by loss of complete resistance with free flow of fluid (see video, supplemental digital content 2, http://links.lww.com/IJG/A458, which demonstrates loss of resistance noted as the free flow of dye instead of the fluid jet that is typically seen while priming with intact resistance). Data logging continued during and post the destruction of the leaflets for several hours.

The detailed methods of testing both types of implants are described below.

Testing of AGV

Priming

We used diluted trypan blue (with normal saline) to prime the device as per the protocol described in our earlier publication.1

Flow Characterization

After priming, the device was placed in the saline bath and was connected to a digital manometer (Lutron PM-9100, Taiwan). An open manometer and an automated infusion pump were used to infuse saline at the rate of 3 µL/min (to simulate the aqueous humor production rate in the eye). Readings were recorded at 4 Hz using computerized RS232 data logging software and data logging was carried out for a minimum of 24 hours ensuring achievement of the steady phase for the device.

Breaking

After flow characterization, the valve function of the AGV was destroyed by slicing the leaflets. The supplementary video shows the process of this experiment.

Testing of the AADI

Testing the Patency

In the case of the AADI, the implants are tested for patency using a similar protocol established in the previous study,1 using a 5-mL syringe with a 27-G cannula, diluted trypan blue (for better visibility) was injected till a jet of fluid exits through the outlet.

Flow Characterization

Once the patency test was completed, the implant was then placed inside a saline bath by connecting it to the digital manometer (Lutron PM-9100, Taiwan), an open manometer, and an automated infusion pump to infuse saline at the rate of 3 µL/min. All the readings from the digital manometer were...
recorded using a computerized data logging software similar to the procedure used for the AGVs.

**RESULTS**

In this study, a total of 5 AGVs and 2 AADI implants were tested. All the AGVs used were of the model FP7 single-plate type with a drainage area/implant surface area of 184 mm² and the AADI was 350 mm². Data obtained from the 5 AGVs and 2 AADIs were analyzed. The data collection was done at a rate of 4 Hz. Pressure versus time curves was plotted at each stage without discontinuation until the valve function of the AGV was destroyed. The pressure versus time plots of the AADI was plotted after flow characterization. The graphs obtained after the destruction of the AGV leaflets were compared with that of the graphs of AADI. Table 1 shows the details of parameters and flow characteristics at various phases in all the 7 implants.

**Flow Characterization of AGV**

Figure 3 shows the graph demonstrating the flow characteristics of AGV during the experiment. This has 2 distinct phases. The implant initially experienced the phase of gradual increase in pressure wherein the leaflets open and the nozzle widens as demonstrated in our previous experiment (A) after which the bi-membrane leaflets reach a stable opening and closing pressure termed the steady phase (B). After the disruption of the valve function (C), a significant drop in pressure (D) (within 10 min) was identified from the graphs, which indicate that the functionality of the AGV flow restriction was lost. The mean (SD) of steady phase opening pressures for the AGVs was 11.2 ± 2.6 mm Hg (min 7, max 14). Once the valve leaflets were destroyed, the pressure in the AGVs dropped to a mean of 0.4 ± 0.54 mm Hg (1 mm Hg in 2 devices and 0 mm Hg in 3 devices). The mean opening pressure for the AGV implant decreased significantly ($P < 0.0001$; t test). The average time taken for this drop in pressure resistance after valve slicing was 10.2 ± 3.0 minutes (min 7, max 15). The AGV 4 and 5 showed a longer transient phase when compared with all other AGVs.

**Flow Characterization of AADI**

The average pressures while testing patency for the AADI implants were 503 mm Hg (min 460, max 545 mm Hg). Figure 4 shows the graph demonstrating flow characterization of AADI, a non-flow-restrictive device: we noted a short period of resistance (A) after the tube patency was checked followed by a drop in the pressure (B). The initial resistance observed in the AADI lasted for around 2.36 ± 1.6 hours. Post this resistance, the pressure in the AADIs dropped to 1 mm Hg and continued to be in this range. To understand if this drop was permanent, the data logging continued for 2 to 8 hours until no significant change in the pressure was noted.

![Graph showing flow characteristics of AGV and AADI](https://www.glaucomajournal.com)

**TABLE 1. Table Showing the Parameters and Flow Characteristics all 7 Implants at Various Phases**

| Serial No. of Implant | Type of Implant | Priming Pressure (mm Hg) | Transient State Maximum Opening Pressure (mm Hg) | Transient State Duration (h) | Steady State Opening Pressure (mm Hg) | Steady State Closing Pressure (mm Hg) | Pressure After Valve Destruction (mm Hg) |
|-----------------------|----------------|--------------------------|-----------------------------------------------|----------------------------|----------------------------------|----------------------------------|----------------------------------------|
| 1                     | FP7            | 1145                     | 14                                            | 01:40                       | 14                               | 12                               | 0                                      |
| 2                     | FP7            | 1130                     | 11                                            | 04:17                       | 11                               | 8                                | 0                                      |
| 3                     | FP7            | 1625                     | 12                                            | 03:27                       | 13                               | 10                               | 0                                      |
| 4                     | FP7            | 635                      | 15                                            | 28:20                       | 11                               | 9                                | 1                                      |
| 5                     | FP7            | 660                      | 30                                            | 29:98                       | 7                                | 5                                | 1                                      |
| 6                     | AADI           | 460                      | 5                                             | 01:21                       | 2                                | 1                                | NA                                     |
| 7                     | AADI           | 545                      | 8                                             | 03:35                       | 1                                | 0                                | NA                                     |

AADI indicates Aurolab aqueous drainage device; NA, not applicable.

![Graph showing flow characteristics of AGV](https://www.glaucomajournal.com)

FIGURE 3. The graph showing the flow characteristics of the Ahmed glaucoma valve (AGV). This has 2 distinct phases. The implant initially experiences a gradual increase in pressure, opening the silicone leaflets and widening the nozzle in the transient phase (A) after which the bi-membrane leaflets reach a stable opening and closing pressure termed the steady phase (B). After the disruption of the valve function (C), a significant drop in pressure (D) (within 10 min) was identified from the graphs, which indicate that the functionality of the AGV flow restriction was lost. The x-axis shows time in seconds and the y-axis shows pressure in mm Hg. Figure 3 can be viewed in color online at www.glaucomajournal.com.
DISCUSSION

In an in-vitro laboratory study, we investigated the outcomes of AGV valve slicing to convert a flow-restrictive AGV to a non-flow-restrictive AADI. The destruction of the valve mechanism was achieved by slicing the valve leaflets using a specially designed blade. After valve destruction, the valve property of AGV was lost and behaved similarly to a non-flow-restrictive AADI. This technique would benefit us in possibly treating eyes with AGV failure when combined with bleb wall excision and tube ligature. A patent application for the blade has been filed.

Although all the 5 AGV implants used in this study were of the FP7 model from the same batch, there was a significant variation in the flow characteristics of each implant. The flow characteristic of AGV had 2 distinct phases before the valve destruction. The transient phase and the steady phase. Once the leaflets of the AGVs were destroyed, the capability of the valve to restrict the outflow was lost. After an average of 10 minutes after valve destruction, flow characterization showed a significant drop in pressure to 1 and 0 mm Hg indicating loss of functionality of the valve for flow restriction. This significant pressure drop was maintained and was comparable with that of AADI. We noted a time delay for loss of resistance by ~10 minutes after slicing the valve leaflets. The probable reason behind the time delay in loss of resistance even after the membrane slicing is as follows: the initial high resistance between the 2 membranous valve leaflets is reduced during the priming and flow characterization process, however, the resistance is not eliminated that is why it functions as a “valve.” The resistance is offered by the leaflets of the valves that are prestressed to maintain apposition against each other. During the process of slicing the membranous valve, the pressure is applied by the blade on the leaflets that are pressed toward the casing and are sliced. This process may appose the 2-valve leaflets that possibly offers the initial resistance. With the initiation of fluid flow after slicing, there is a slow buildup of fluid and the leaflets may get separated by the fluid pressure after a few minutes. Because of the lack of tension on the bi-membrane valve leaflets that are disrupted, they do not offer any resistance after the initial separation. One can verify this proposed mechanism by applying high inlet fluid pressure and disrupting the valve function during the high flow. Once the valve is disrupted, the fluid pressure can be lowered to the physiological range and the resistance to flow can be rechecked. As the study was aimed at developing a mechanism of valve disruption that can be translated to clinical use, we wanted to simulate in-vivo conditions, hence, the described test was not performed. Interestingly, even with AADI, initial flow resistance was noted that later dropped to 0 and 1. AADI being a “nonvalved” implant does not offer resistance. The possible reason for this transient resistance could be because of the surface resistance offered by the tube. Once the fluid pressure overcomes the resistance in the AADI tube, continuous flow is ensured by the fluid flow velocity.

AADI being a non-flow-restrictive device is not expected to offer any resistance to fluid flow. However, in our experiment, we noted 460, 545 mm Hg pressure during AADI flow characterization when checking the tube patency. There could be 2 reasons for this high pressure. First, because of the resistance between the tube wall and the fluid because of the friction and viscosity of the fluid. Second, during the manufacturing process of the AADI, an air column fills the tube that could offer resistance. We could actually infer that in AADI, although priming may not be required (as there is no valve), checking the tube patency may be helpful to overcome the transient resistance by replacing the air column with fluid.

The 2 levels of resistance offered by the AGV are the bi-membrane valve and the thick fibrous capsule around the implant plate and rarely, a fibrovascular proliferation blocking the outlet. By destroying the leaflets of the valve, 1 level of resistance is lost as is shown in our experiment. The second level of resistance is the thick fibrous capsule around the plate that prevents diffusion of fluid out of the encapsulated bleb. We propose a technique of destruction of valve leaflets and bleb wall excision to remove both the levels of resistance, this is combined with a tube ligature to prevent early hypotony. The technique we followed was tube ligature followed by the excision of thick bleb capsule and slicing of the membranous valve. Opening and excising the thick bleb capsule may result in a sudden intraocular pressure drop, this could be prevented by filling the anterior chamber with viscoelastic or by ligating the tube with 6-0 vicryl before the bleb wall excision. This is followed by slicing of the valve leaflets followed by a watertight conjunctival closure. In-vivo testing of this hypothesis in eyes with encapsulated thick blebs with AGV failure is necessary...
to prove the clinical usefulness. A prospective study is ongoing and results are awaited.

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