

Functionality and Priming Stream Patterns of the Ahmed Glaucoma Valve in a Laboratory Setting

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Purpose: To determine if there is a significant association between the steady state pressure of Ahmed Glaucoma Valves (AGVs) and the fluid pattern exhibited during the priming step of implantation.

Methods: In this experimental laboratory study, fifty AGVs were primed according to manufacturer guidelines by injecting balanced salt solution through a 27-gauge cannula. Group 1 consisted of 8 AGVs with a distinct stream priming pattern. Group 2 consisted of 7 AGVs without a distinct stream priming pattern (pooling). These valves were further tested using a perfusion system to measure steady-state pressure across the valve. A Student's *t*-test was used to assess the differences in mean steady-state pressures.

Results: 43/50 AGVs (86%) demonstrated a distinct stream of fluid during priming (group 1), while 7 (14%) showed a pooling of fluid only, without a focal stream (group 2). Steady-state pressure was achieved by 45 seconds for the 15 samples. The mean steady-state pressure (\pm standard deviation) at 60 seconds was 11.00 ± 1.90 mmHg for group 1 and 10.31 ± 2.53 mmHg for group 2 ($p = 0.56$), demonstrating no significant difference between groups.

Conclusion: The most common fluid pattern observed is a focal stream of fluid exiting the valve, with a minority exhibiting a slow pooling of fluid. The fluid pattern observed during AGV priming does not predict the valve's functionality, as both priming patterns resulted in similar steady-state pressures, which were consistently in line with manufacturer specifications.

Plain Language Summary: Glaucoma is a leading cause of irreversible blindness, and devices like the Ahmed Glaucoma Valve (AGV) are often used in surgery to control elevated eye pressure. Before implanting the AGV, surgeons flush the valve with a fluid (a process called "priming") to ensure it works correctly. However, the fluid pattern during priming—either a distinct jet or a slower pooling—has caused debate. Some surgeons believe a pooling pattern might indicate a faulty valve and may discard it, leading to waste and longer surgeries.

This study tested 50 AGVs in a lab to see if the priming pattern affects how well the valve controls pressure. Most valves (86%) showed a jet pattern, while a few (14%) had a pooling pattern. After further testing, we found no difference in how the valves performed, regardless of the priming pattern. Both types regulated pressure effectively, meeting the manufacturer's standards.

These results suggest that the priming pattern does not predict valve functionality. Discarding valves based on the priming pattern may not be necessary and could increase waste and costs. Future research is needed to confirm these findings in actual surgical settings and understand why priming patterns vary.

Keywords: Ahmed Glaucoma Valve, AGV, priming, intraocular pressure, glaucoma drainage device

Introduction

Glaucoma remains one of the leading causes of irreversible blindness worldwide, characterized by progressive optic nerve damage often associated with elevated intraocular pressure (IOP).¹ While several treatment modalities including laser and topical therapy aim to mitigate elevated IOP, surgical intervention remains a cornerstone in managing glaucoma, particularly in cases refractory to more conservative therapies. Among a growing number of surgical options, the Ahmed Glaucoma Valve (AGV, New World Medical, Rancho Cucamonga, CA) has remained a frequently utilized

glaucoma drainage device due to its immediate efficacy in controlling IOP and relatively low rates of complications compared to other drainage devices.² In a comparative study, the AGV group experienced fewer early postoperative complications (11.97%) compared to the Baerveldt implant group (23.40%), as well as lower rates of long-term vision threatening complications and those that require reoperation.^{3,4}

The AGV, first introduced in 1993, operates on the principle of aqueous shunting to regulate IOP.⁵ Similar to traditional trabeculectomy, the AGV creates a fistula for aqueous outflow from the anterior chamber to the subconjunctival space, bypassing the trabecular meshwork. In contrast, the AGV utilizes a tube and reservoir in an attempt to maintain the fistulous pathway despite any post-operative fibrosis. This mechanism reduces the risk of obstruction of the fistula secondary to the development of adhesions. Additionally, the valve provides flow restriction to allow immediate aqueous outflow while preventing hypotony, offering a predictable postoperative outcome. The clinical efficacy of the AGV in lowering IOP has been well established, with randomized, controlled trials demonstrating significant IOP and medication reductions with a low rate of complications.^{6,7}

Despite its long track record of clinical use, the optimal priming pattern for this device during implantation remains a subject of debate and uncertainty. Priming, referring to the initial flushing of the valve with balanced salt solution (BSS) prior to implantation, is a necessary step of the procedure.^{5,8} This ensures there is no adhesion between the valve leaflets that would otherwise prevent proper flow of aqueous humor from the anterior chamber, through the valve, to the subconjunctival space. During the priming step, BSS fluid exits the valve and can be observed in one of two broadly described patterns: a focal, jet stream of fluid, or a slow pooling of fluid without a distinct stream. There is concern among some surgeons regarding a potential correlation between the priming pattern observed and AGV integrity, with a pooling pattern indicating a faulty or malfunctioning valve that may lead to hypotony. Although we are not aware of published evidence, there are anecdotal reports of many surgeons discarding valves with a pooling priming pattern, opting to implant only those that exhibit a distinct stream. However, this would likely be unfeasible in settings around the world with limited resources. This practice has led to not only a significant increase in surgical waste but a decrease in surgical efficiency as procedures tend to take longer when the surgeon facilitates this “trial and error” process until the desired priming pattern is observed. Although literature on AGV priming patterns is limited, a study by Cheng et al demonstrated that a preimplantation flow test can help predict early postoperative complications, such as hypotony and the hypertensive phase, following Ahmed Glaucoma Valve (AGV) implantation.⁹

Understanding the relationship between priming pattern and AGV integrity is paramount in optimizing surgical outcomes, decreasing surgical waste, and enhancing efficient patient care. In this study, we aim to assess benchtop priming data of the AGV, and elucidate the influence, if any, that observed priming patterns may have on device functionality and eventual postoperative outcomes.

Materials and Methods

This experimental study included fifty Ahmed Glaucoma Valves (AGVs), model FP7, which were primed in a standardized fashion under microscope visualization. The priming of the valve was done manually by a fellowship trained glaucoma specialist who has extensive experience with Ahmed valve priming and implantation. All valves were primed using identical technique, and only one surgeon was responsible for priming all the valves to ensure consistency between force applied and technique. Balanced salt solution (BSS) was injected from a 3 mL syringe through a 27-gauge cannula placed into the distal tube end of each AGV, and the priming pattern was observed and recorded as one of the two groups. Group 1 included valves demonstrating a distinct jet or stream of fluid during priming, while group 2 included valves that demonstrated a broad pooling of fluid only without a focal stream. Subsequently, a subset of AGVs was selected for further perfusion testing, comprising approximately equal numbers of AGVs from each group.

To assess the steady-state pressure across the valves, a sophisticated perfusion system was employed (Figure 1). This system comprised a syringe pump, a pressure transducer, a water bath, and the test samples connected in a sequential manner via tubing. The setup ensured precise control and measurement of pressure dynamics. All AGVs were connected to the perfusion system, and the steady-state pressure across the valves was monitored every 0.5 seconds. It was observed that all AGVs reached a steady-state pressure within 60 seconds of perfusion, indicating the stability of the system and

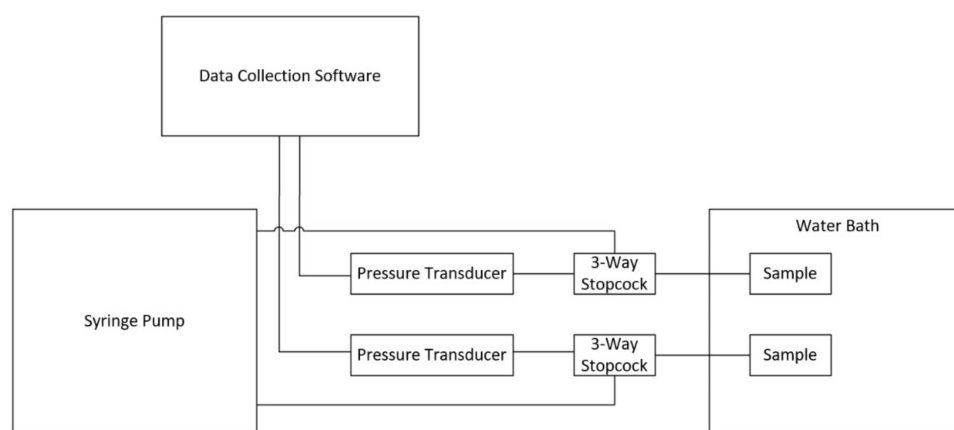


Figure 1 Diagram of the perfusion system setup.

the responsiveness of the valves to the imposed pressure gradients. The pressure data was continuously recorded for at least 5 minutes to ensure stability.

Basic frequencies and percentages of the two priming stream patterns were counted for all 50 valves. Pressure was recorded for 15 valves at each second for 5 minutes and plotted for the first 60 seconds by valve. Normality of the data was tested with the Shapiro–Wilk test. Since the data were normally distributed, Student’s *t*-tests were employed to assess statistically significant differences in the mean steady-state pressures between the two groups of AGVs. Statistical significance was set at a *p* value <0.05.

Results

Of the 50 AGVs subjected to testing, 86% (*n* = 43) exhibited a distinct jet/stream priming pattern (group 1), while 14% (*n* = 7) displayed a pooling pattern without a discernible fluid stream during priming (group 2). This observation underscores the preponderance of the jet/stream priming pattern among AGVs in this study sample.

For the subsequent perfusion study, 15 AGVs were tested, comprising 8 from group 1 and 7 from group 2. Steady-state pressure was attained within 45 seconds across all samples (Figure 2). There were no differences in mean steady-state pressure across the AGVs between the two groups throughout the duration of the study (Table 1). The mean (\pm SD) steady-state pressure for AGVs was 11.00 ± 1.90 mmHg for group 1 and 10.31 ± 2.53 mmHg for group 2 at 60 seconds of perfusion (*p* = 0.56).

Discussion

The findings of our study shed light on the priming patterns and functional performance of Ahmed Glaucoma Valves (AGVs), providing important insights into surgical practice and device optimization. We demonstrate that the predominant fluid pattern observed during priming is a distinct stream exiting the valve, with approximately 1 in 7 valves only exhibiting a pooling of fluid at the valve exit. However, the presence or absence of a distinct stream during priming does not influence the ability of AGVs to regulate pressure effectively under controlled perfusion conditions, underscoring the robustness and reliability of AGVs in maintaining consistent flow regulation.^{5,8}

These findings have important implications for clinical practice. The most notable aspect of our study is the revelation that the priming pattern observed during surgery does not reliably predict the functional performance of AGVs. This finding challenges anecdotal evidence and suggests that factors beyond visual cues during priming may influence valve functionality. Indeed, there are many anecdotal reports of surgeons discarding valves when they do not exhibit the hallmark stream priming pattern, which is falsely interpreted as a sign of valve dysfunction. This not only greatly contributes to surgical waste but plays a significant role in healthcare expenditures and surgical efficiency.

It is unclear how such misconceptions of valve integrity based on priming were generated, but likely resulted from the coincidental occurrence of hypotony that can occur with AGV implantation. It should be noted that while the AGV

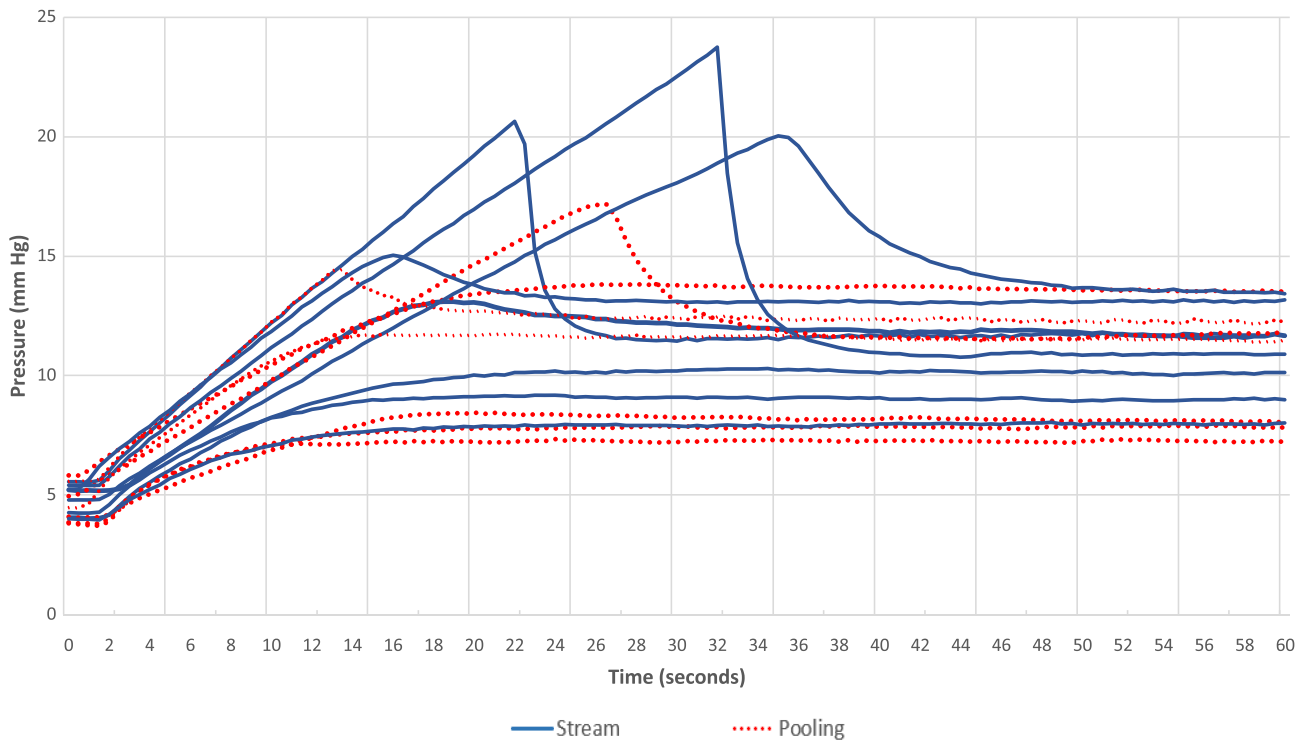


Figure 2 Steady-State Pressure Measured Across AGV With Respect to Observed Priming Pattern. The y-axis is pressure (mm Hg) and x-axis is time (seconds). Each of the 15 AGVs are graphed with blue lines for AGVs with a stream pattern and dotted red lines for AGVs with a pooling pattern.

guards against over-filtration, hypotony can still occur after implantation, and this is likely true for both fluid patterns. This is likely due to other surgical variables that contribute to its occurrence. These other sources of hypotony postoperatively include excess peri-tubular flow of aqueous around the tube through the sclerotomy tract, under-secretion of aqueous from ciliary body dysfunction, wound leak, and lack of capsule formation within the bleb cavity. Surgeons should ensure these more likely etiologies are considered before attributing low IOP to valve malfunction.

While our study provides valuable insights into the priming patterns and functional performance of Ahmed Glaucoma Valves (AGVs), several limitations should be acknowledged. Foremost among the limitations is the fact that our study was conducted in a laboratory setting rather than in vivo. While laboratory-based studies offer precise control over experimental variables and facilitate standardized testing procedures, they inherently lack the complexity and dynamic physiological interactions present in living organisms. While this approach provides valuable insights into device behavior, it may not fully capture the multifaceted dynamics of intraocular pressure regulation in vivo, which are influenced by factors such as aqueous humor production, outflow facility, and ocular biomechanics. Incorporating more

Table 1 Comparison of Mean Steady State Pressure for Stream and Pooling Patterns

| | Stream (N=8) Mean (standard Deviation) | Pooling (N=7) Mean (standard Deviation) | p-value* |
|-----------------------|---|--|----------|
| Time point 45 seconds | 11.09 (2.05) | 10.32 (2.52) | 0.52 |
| Time point 50 seconds | 11.04 (1.96) | 10.31 (2.52) | 0.54 |
| Time point 55 seconds | 11.00 (1.93) | 10.32 (2.49) | 0.56 |
| Time point 60 seconds | 11.00 (1.90) | 10.31 (2.53) | 0.56 |

Note: *Student's t-test.

comprehensive physiological assessments in future studies would offer a more nuanced understanding of the implications of priming patterns on AGV performance in clinical settings. As such, the extrapolation of our findings to clinical practice must be made cautiously, recognizing the potential differences in valve behavior and performance within the dynamic environment of the eye. Future studies incorporating in vivo experimentation are warranted to validate our findings and elucidate the clinical relevance of priming patterns on AGV functionality in real-world surgical scenarios.

One avenue for further investigation involves elucidating the underlying mechanisms contributing to the variability in priming patterns among AGVs. Factors such as device design, manufacturing processes, and individual priming techniques may influence the flow dynamics during priming, warranting detailed biomechanical analyses and computational fluid dynamics modeling studies. Future studies tracking consequent clinical outcomes of patients who received an AGV from each type of priming pattern will play a profound role in the ultimate elucidation of any potential differences in valve functionality with respect to intraoperative priming patterns. Lastly, studies that seek to both identify and characterize any additional variables or intraoperative techniques such as wound modulation, anatomic placement, and patient demographics or ocular characteristics may also play a significant role in the optimization of AGV implantation surgery.

Conclusion

The findings of this study demonstrate that the Ahmed Glaucoma Valve (AGV) is a reliable device for regulating intraocular pressure, regardless of the fluid pattern observed during the priming process. The majority of AGVs exhibited a focal stream priming pattern, while a minority displayed a slower pooling pattern. However, these differences in priming patterns did not correlate with variations in steady-state pressure, underscoring that both patterns reflect equivalent valve functionality.

This study challenges the common surgical practice of discarding valves based solely on priming patterns, a practice that contributes to surgical inefficiencies and increased waste. These results suggest that surgeons can confidently proceed with implantation of AGVs, even if the priming pattern does not present as a focal stream, as long as the valve has been primed according to manufacturer guidelines.

While the findings provide valuable insights for optimizing AGV use in clinical settings, further research, including in vivo studies, is necessary to confirm the clinical implications of these results. Investigating factors influencing priming variability and exploring their potential impact on long-term outcomes will be critical in enhancing surgical efficiency and reducing healthcare expenditures in glaucoma management.

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