



Experimental anterior chamber maintenance in active versus passive phacoemulsification fluidics systems

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PURPOSE: To evaluate the ability of phacoemulsifiers with active versus passive infusion fluidics control systems to maintain target intraocular pressures (IOPs) under varying flow conditions.

SETTING: Alcon Research, Ltd., Lake Forest, California, USA.

DESIGN: Experimental study.

METHODS: An acrylic test chamber was used to model the anterior chamber of the eye. Two passive (gravity-based) systems were tested using bottle heights yielding infusion pressures of 41, 75, and 109 cm of water under zero-flow conditions. One actively controlled system was tested using equivalent target IOPs of 30, 55, and 80 mm Hg. Test chamber IOPs were measured at aspiration flow rates of 15, 30, 45, and 60 cc/min.

RESULTS: The measured flow rates were similar between fluidics systems across the range of intended aspiration flow rates. All systems achieved the desired target IOPs under zero-flow conditions. After activation of aspiration flow, however, measured IOPs decreased from target IOPs for the 2 passive systems. Each 15 cc/min increase in the aspiration flow rate produced a pressure drop of 14.0 to 16.2 mm Hg or 9.3 to 14.2 mm Hg, depending on the system. Measured IOPs in the actively controlled system closely matched the targeted IOPs across all tested aspiration flow rates, deviating from targets by no more than 4.3 mm Hg.

CONCLUSIONS: All phacoemulsification aspiration infusion fluidics systems achieved target IOPs under zero-flow conditions. Only the actively controlled system maintained target IOPs across a range of aspiration flow rates. These experimental findings suggest that anterior chamber stability might be better in the clinical setting using an actively controlled system.

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Anterior chamber maintenance is one of the keys to successful outcomes in phacoemulsification cataract surgery.¹ One primary factor in maintaining a safe and stable anterior chamber is controlling intraocular pressure (IOP) to stay within or near the physiologic range.² However, large fluctuations in IOP can occur during cataract surgery.³ An IOP that is too high can cause ocular discomfort, decreased ocular perfusion, accelerated glaucomatous optic nerve damage, and postoperative corneal edema.^{4,5} An IOP that is too low or that fluctuates widely can lead to instability or collapse of the anterior chamber, ocular discomfort,

and trauma to anterior segment structures such as the cornea, iris, and lens capsule.⁶

In passive or gravity-based phacoemulsification aspiration devices, pressure and flow are inversely related; increased flow results in decreased pressure and vice versa, in particular when the source pressure is held constant.⁷ During phacoemulsification, inflow supplied by the irrigation line equals outflow under steady-state conditions. Total outflow is the sum of flow through the aspiration line and leakage through the incisions.⁸ If incision leakage is zero, the infusion flow rate equals the aspiration flow rate. Because

intraoperative IOP and the infusion flow or aspiration flow rate are inversely related, compensation for active fluid dynamics is critical if a surgeon desires to achieve and maintain a target IOP during phacoemulsification surgery.

Modern phacoemulsification aspiration systems use advanced aspiration fluidics technologies to control the fluid flow from the eye. As technological developments facilitate increasingly smaller corneal incisions and more efficient application of ultrasound (US) energy, infusion fluidics and anterior chamber stability are becoming increasingly important. Most phacoemulsification aspiration systems control the aspiration of fluid out of the eye using a venturi or a peristaltic pump.⁹ The passive force of gravity on the fluid column determines the infusion pressure. The higher the fluid reservoir is positioned above the eye, the higher the IOP, all other factors being equal. The primary limitation of passive or gravity-based fluidics is that IOP varies with the aspiration flow rate; increasing or decreasing the aspiration flow rate results in lower IOP or higher IOP, respectively. The IOP can drop quite low if a high aspiration flow rate (eg, 60 cc/min) is commanded, even if the irrigation bottle or bag is positioned relatively high above the eye.

Some phacoemulsification aspiration systems augment IOP by pressurizing the irrigation bottle with gas. Because the gas infusion pressure does not necessarily vary in response to changing the aspiration flow rate, the effect is the same as raising the irrigation bottle or bag height. One phacoemulsification aspiration system augments IOP control by dynamically squeezing a compliant bag of irrigating fluid in

response to the aspiration flow rate and estimated incision leakage. This system differs from traditional gravity-based systems in that it provides active control of infusion pressure to maintain a more stable target IOP level despite variations in the aspiration flow rate.

The objective of this laboratory study was to evaluate the ability of phacoemulsifiers with active and passive infusion fluidics systems to maintain target IOPs.

MATERIALS AND METHODS

Phacoemulsification Aspiration Systems and Fluidics Configurations

The following 2 phacoemulsification aspiration systems were evaluated in this study: the Infiniti Vision System (Alcon Laboratories, Inc.) and the Centurion Vision System (Alcon Laboratories, Inc.). Both use peristaltic pumps to control aspiration. Similar to other gravity-based phacoemulsification aspiration systems, the Infiniti uses a bottle of balanced salt solution suspended by an adjustable pole with gravity supplying the infusion pressure (Figure 1, A and B). The Centurion can operate in 1 of 2 infusion modes; that is, using gravity as a passive force or using an active system that compresses a compliant, balanced salt solution-filled bag between motorized plates (Figure 1, C). The actively controlled system applies or releases bag pressure in response to varying irrigation pressure at the cassette to maintain a target IOP during surgery despite varying aspiration flow rates.

Three phacoemulsification aspiration configurations were tested. The Infiniti was outfitted with an Infiniti Ozil handpiece, Infiniti Intrepid Plus Fluidics Management System (FMS) cassette and tubing, and an Alcon balanced salt solution bottle (configuration 1). The Centurion was tested with passive infusion fluidics (Centurion-gravity; configuration 2) and active infusion fluidics (Centurion-active; configuration 3). In the gravity configuration, the Centurion was outfitted with a Centurion Ozil handpiece, Centurion Gravity FMS, and an Alcon balanced salt solution bottle. In the active configuration, the Centurion was outfitted with a Centurion Ozil handpiece, a Centurion Active FMS, and a Centurion balanced salt solution bag. To minimize variations across experiments, a 45-degree mini-flared Kelman tip (Alcon Laboratories, Inc.) and an Ultra Sleeve (Alcon Laboratories, Inc.) were used for all experiments.

Experimental Setup

The anterior chamber of the eye was modeled using a noncompliant acrylic test chamber. Simulated IOP within the chamber was measured using an electronic pressure transducer (Foxboro, Honeywell), and the aspiration flow rate was measured using a flow probe (ME1PXN Flow-probe, Transonic Systems, Inc.) and a flow meter (TS410 Flowmeter, Transonic Systems, Inc.). The accuracy of the pressure transducer was checked against a separate factory-calibrated digital pressure meter (DPM4 Parameter Tester, Fluke Biomedical) before each experiment. The flow measurement system (flow meter and probe) was calibrated against a syringe pump (Pump 33, Harvard Apparatus) at discrete flow rates of 15 cc/min, 30 cc/min, 45 cc/min, and 60 cc/min. Pressure and flow-rate data were recorded

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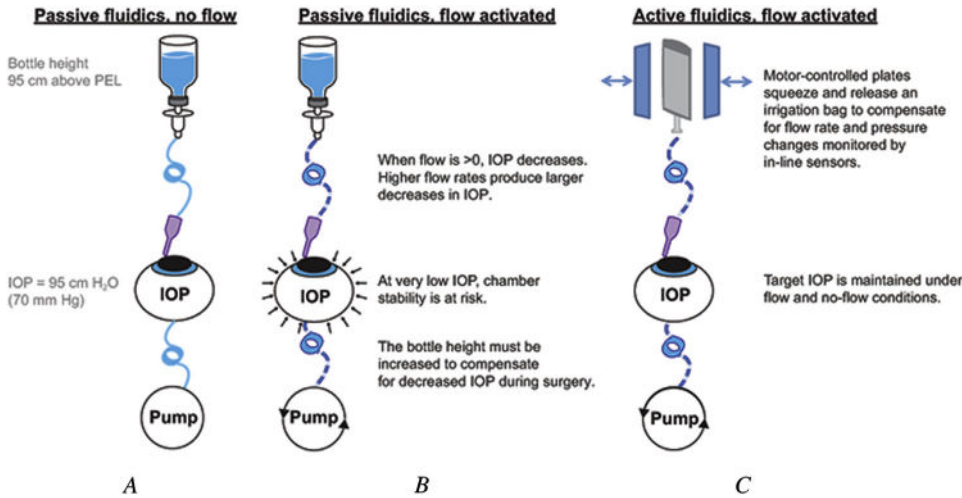


Figure 1. Passive and active fluidics. A: Fluid dynamics under zero-flow conditions. Passive fluidics are shown. B: Passive fluid dynamics with flow activated. C: Actively controlled fluid dynamics with flow activated; pressure plates are used to control fluid dynamics and maintain target IOP (H₂O = water; IOP = intraocular pressure; PEL = patient eye level).

as voltages on a digital oscilloscope (MSO7064A, Agilent Technologies).

Testing was performed with each US tip and sleeve inserted into an opening in the test chamber that matched the diameter of the proximal end of the sleeve to create a watertight seal; therefore, an incision with zero leakage was ensured. Figure 2 shows a schematic diagram of the test setup.

Simulated Patient Eye-Level Calibration

To ensure that IOP measurements were accurate and consistent across phacoemulsification aspiration platforms, the actual patient eye level was confirmed before each test for each phacoemulsification aspiration unit using the digital pressure meter. For the Infiniti (configuration 1), the patient eye level was at the 0 location indicated by the manufacturer's specifications; this was confirmed by measuring the pressure at the irrigation outlet of the fluidics cassette at different bottle heights. The handpiece, acrylic test chamber, and pressure transducer were then positioned at an equivalent patient eye-level elevation. The patient eye level for the Centurion (configurations 2 and 3) was set using a similar procedure. Because the patient eye level at the 0 location for the Centurion was approximately 5 cm higher than that

of the Infiniti, the patient eye level for the Centurion was set to -5.0 cm to avoid changing the elevation of the handpiece, acrylic test chamber, or pressure transducer. Equivalent pressures at the test chamber were confirmed using the digital pressure meter.

Experiments

Each phacoemulsification aspiration configuration was primed before each experiment according to the manufacturer's instructions. A patient eye-level calibration was then performed. With the tip and sleeve of the handpiece inserted into the acrylic test chamber, the desired bottle height or target IOP, aspiration flow rate, and vacuum level were set. The upstream connector of the flow probe was attached to the aspiration port on the handpiece; the downstream side was connected to the aspiration line on the cassette. All trapped air was removed from the system, test chamber, and measurement devices. Before the start of each test, continuous irrigation was activated and the aspiration flow rate was set to 0 cc/min to confirm maximum chamber pressure and ensure that each configuration achieved the expected initial IOP.

Phacoemulsification aspiration configurations with gravity fluidics (configurations 1 and 2) were tested at bottle

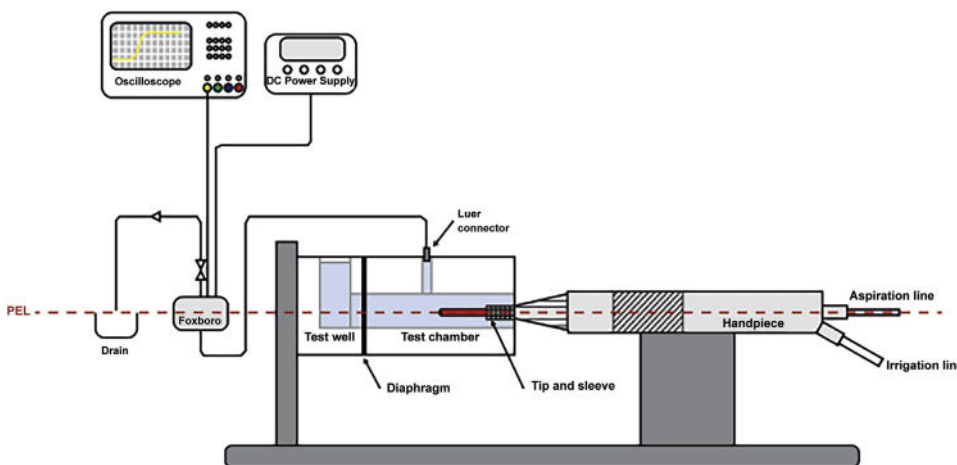


Figure 2. Test setup. The experimental setup of phacoemulsification equipment and data recording devices is shown (DC = direct current; Foxboro = Foxboro pressure transducer; PEL = patient eye level).

heights yielding infusion pressures of 41 cm of water (H₂O), 75 cm H₂O, and 109 cm H₂O. The actively controlled fluidics configuration (configuration 3) was tested using target IOP settings of 30 mm Hg, 55 mm Hg, and 80 mm Hg. These gravity and active fluidics settings (41 cm H₂O and 30 mm Hg; 75 cm H₂O and 55 mm Hg; 109 cm H₂O and 80 mm Hg) are equivalent at aspiration flow rate of 0 cc/min; the conversion from pressure produced by a given bottle height to the target IOP is 1.0 cm H₂O = 0.74 mm Hg.⁹ The experiments were performed at aspiration flow rate settings of 15 cc/min, 30 cc/min, 45 cc/min, and 60 cc/min and a fixed vacuum level of 600 mm Hg, which ensured that there were no vacuum limitations during unoccluded flows. With the exception of patient eye level, system default settings were used for all other phacoemulsification aspiration operating variables (eg, dynamic rise, irrigation factor). Bench testing was performed with longitudinal and torsional US powers set to 0%. The footpedal was fully depressed, and the system was allowed to reach steady-state aspiration flow before measurements were made.

Each phacoemulsification aspiration configuration was tested 3 times, and a new fluidics pack was opened for each test. When steady-state conditions were achieved as determined by oscilloscope tracings, the IOP and aspiration flow rate were measured as voltages by the oscilloscope at a sampling rate of 100 Hz. Data were sampled for at least 2 seconds and were recorded as average voltages.

Data Analysis

Intraocular pressure and flow-rate data were converted from voltages on the oscilloscope to the appropriate units using the following conversions: IOP, -5 mV = 1 mm Hg; flow rate, 1 V = 20 cc/min. Converted data were summarized descriptively and presented as the mean ± SD. The simulated IOP was plotted against the actual measured aspiration flow rate to enable accurate comparison of the relationship between the IOP and aspiration flow rate between the configurations tested.

RESULTS

The 3 configurations performed similarly across all intended aspiration flow rates with regard to actual measured flow rates. All 3 configurations achieved aspiration flow rates that were similar to those commanded at flow rates of 15 cc/min and 30 cc/min (Table 1). The measured aspiration flow rates were

Table 1. Intended versus measured aspiration flow rates.

Selected AFR Setting (cc/Min)	Mean Measured AFR* (cc/Min)		
	Infiniti	Centurion-Gravity	Centurion-Active
15	15.4	14.9	14.8
30	29.7	28.3	28.8
45	42.5	40.4	41.6
60	53.4	48.2	52.3

AFR = aspiration flow rate

*Data reflect the mean of triplicate tests; data for each test were collected over ≥2 seconds at a sampling rate of 100 Hz. The standard deviation was <0.7% for all configurations.

slightly lower than those commanded at the higher flow rates of 45 cc/min and 60 cc/min.

With the aspiration flow rate at 0 cc/min, the target IOP was achieved with all 3 configurations, showing the accuracy of bottle-height positioning for the gravity configurations and of the target IOP for the actively controlled configuration (Figure 3). When the aspiration flow was activated, the measured IOP decreased from the target IOP for both of the gravity-based

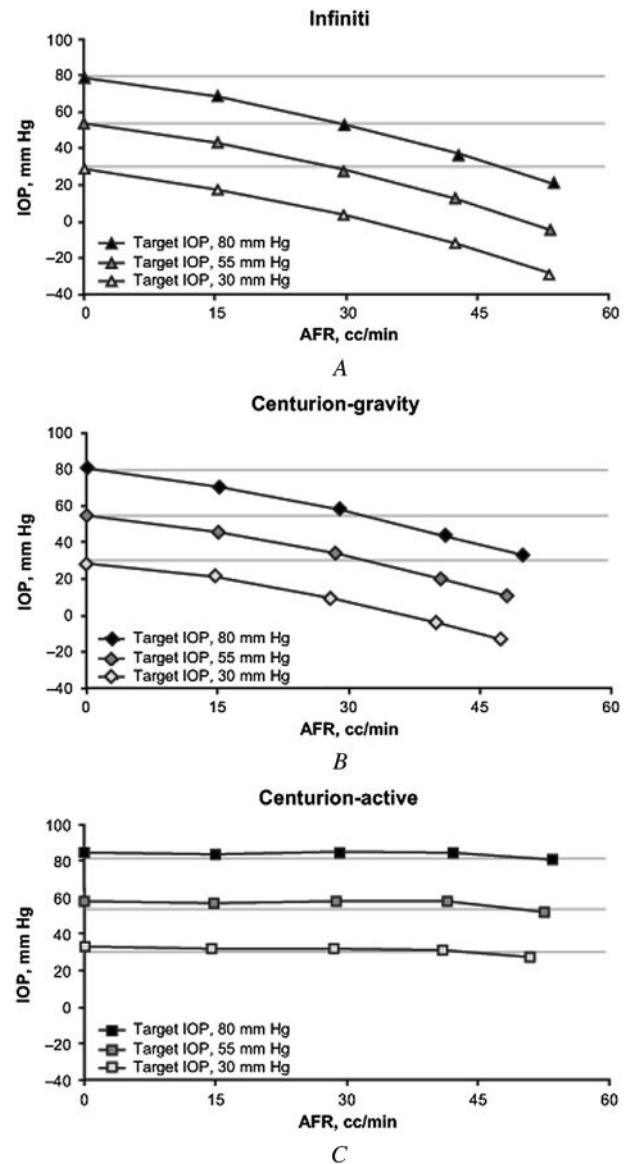


Figure 3. Relationship between IOP and aspiration flow rate. A: Infiniti with gravity fluidics. B: Centurion with gravity fluidics. C: Centurion with active fluidics. Target IOPs of 30 mm Hg, 55 mm Hg, and 80 mm Hg are indicated by gray lines. The IOP was plotted against actual measured aspiration flow rates. For gravity fluidics, target IOPs of 30 mm Hg, 55 mm Hg, and 80 mm Hg were equivalent to 41 cm H₂O, 75 cm H₂O, and 109 cm H₂O, respectively (AFR = aspiration flow rate; IOP = intraocular pressure).

configurations (Figure 3, A and B). The IOP was inversely related to the aspiration flow rate, with the lowest IOPs observed at the highest measured aspiration flow rates. With each 15 cc/min aspiration flow rate setting increase, the IOP decreased by 14.0 to 16.2 mm Hg with configuration 1 and by 9.3 to 14.2 mm Hg with configuration 2. The recorded pressure in the artificial anterior chamber using configuration 3 closely matched the target IOP at all tested aspiration flow rates (Figure 3, C). At the highest achieved aspiration flow rates of 51.0 to 53.4 cc/min, a small decrease in IOP was observed for all intended target IOPs; however, the measured IOP deviated from the target IOP by 4.3 mm Hg or less across all intended aspiration flow rates and target IOP levels.

DISCUSSION

Modern phacoemulsification systems use fundamental fluid dynamics to regulate IOP during cataract extraction. These experiments evaluated 2 passively controlled infusion systems and 1 actively controlled infusion system. All 3 systems achieved target IOPs under zero-flow conditions. Consistent with the known fluid dynamic behavior of passive systems, the IOP in the test chamber decreased with an increasing aspiration flow rate. In contrast, the actively controlled system maintained the target IOP regardless of the flow rate.

For all configurations tested, the actual aspiration flow rates for target flow rates of 15 cc/min and 30 cc/min were similar to the intended values. However, the actual aspiration flow rates at target flow rates of 45 cc/min and 60 cc/min were lower than intended. This disparity could be attributed to fluid mechanical behavior using compliant tubing. Under higher flow rates, a large enough pressure drop in the aspiration fluidics lines might restrict fluid flow.

Under zero-flow conditions, all fluidic configurations achieved the target IOPs. However, when outflow was activated, even at the lowest aspiration flow rate of 15 cc/min, the phacoemulsification aspiration configurations using gravity fluidics showed considerable drops in IOP, producing measured IOPs that were markedly lower than the target IOPs across the range of non-zero aspiration flow rates. For these configurations, the target IOP continued to decrease with each increase in aspiration flow rate. In contrast, the active fluidics configuration maintained the IOP at target levels across the aspiration flow-rate range tested, with only a slight decrease observed at the highest flow rates. This small drop in IOP likely reflects the effect of high flow through the annulus between the phacoemulsification tip and irrigation sleeve, the smallest area through which

flow travels. The default irrigation factor, 1.0, was used in the current study; the effect of the selected compensation factor was negligible at low flow rates but increased gradually with higher flow rates. Use of a higher irrigation factor would have compensated for increasing fluid dynamic effects that are more apparent at higher aspiration flow rates by applying even greater pressure to the irrigation bag to better maintain the target IOP at high flow rates.

Considering some of the potentially negative effects associated with high intraoperative IOP, ophthalmic surgeons might prefer to use lower target IOPs that can be safely maintained during surgery, including during zero-flow conditions when IOP is maximum. A study of porcine eyes¹⁰ found that lower bottle heights (ie, lower target IOPs) during simulated surgery caused less damage to the corneal endothelium. By maintaining a stable target IOP across the tested range of aspiration flow rates, actively controlled fluidics enable lower starting IOPs, whereas passive fluidics require higher starting IOPs in anticipation of the IOP drop that would occur with increasing outflow. Furthermore, actively controlled fluidics systems can adjust for intraoperative variations in flow conditions (eg, higher vacuum limits and aspiration flow rates) to maintain a target IOP.

Although not directly measured, the portion of the Centurion's fluidics management system that monitors and actively controls the target IOP would not be sufficiently responsive to compensate for rapid fluidic events (eg, the postocclusion break surge response). However, the Centurion has better surge protection than its predecessor, the Infiniti, because of its reduced overall system compliance, which is a significant contributor to anterior chamber stability during such events.¹¹

The experimental approach described in this report has strengths and weaknesses. The use of a rigid acrylic test chamber to simulate the anterior chamber of a compliant human eye is a limitation because the human eye is slightly compliant. However, minimizing compliance reduced the experimental variability between test configurations. In a clinical setting with a nonrigid system such as a human eye, a small degree of leakage would typically occur between the tip sleeve and the incision. Because the goal of this study was to evaluate simulated IOP in a controlled setting, the test setup used a watertight interface with no leakage. Comparative studies to evaluate the performance of these phacoemulsification aspiration and fluidics systems in a compliant chamber or a tissue globe environment (eg, porcine or cadaver eyes) are needed to define the potential advantage of actively controlled fluidics in a more clinically relevant setting.

In conclusion, phacoemulsification aspiration devices with passive, gravity-based fluidics performed as expected, with IOP decreasing predictably with increasing flow through the irrigation tubing. The phacoemulsification aspiration configuration with active fluidics maintained tight control over a clinically relevant range of target IOPs and aspiration flow rates. Given these experimental findings, we would expect anterior chamber stability in the clinical setting during phacoemulsification cataract surgery to be more tightly controlled using an active fluidics system. The potential clinical advantage of actively controlled fluidics is an area of future study.

WHAT WAS KNOWN

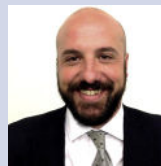
- Most modern phacoemulsification systems use passive or gravity fluidics to regulate IOP during surgery.
- Gravity-based fluidics systems are subject to principles of fluid dynamics that affect IOP control because pressure decreases as a function of an increasing flow rate.

WHAT THIS PAPER ADDS

- Two passive or gravity-based fluidics systems showed predictable decreases in IOP with increasing aspiration flow rates, whereas an active fluidics phacoemulsification system that regulated fluid flow by applying pressure to a compliant irrigation reservoir maintained target IOPs across zero-flow and active-flow conditions.
- Actively controlled fluidics systems should improve anterior chamber stability during phacoemulsification cataract surgery.

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