IN VITRO FLOW ANALYSIS OF NOVEL DOUBLE-CUTTING, OPEN-PORT, ULTRAHIGH-SPEED VITRECTOMY SYSTEMS

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Purpose: To analyze the performance and flow characteristics of novel double-cutting, open-port, 23-, 25-, and 27-gauge ultrahigh-speed vitrectomy systems.

Methods: In vitro fluidic measurements were performed to assess the volumetric aspiration profiles of several vitrectomy systems in basic salt solution and egg white.

Results: Double-cutting open-port vitrectomy probes delivered stable aspiration flow rates that were less prone to flow variation affected by the cutting speed. Increase in cutting frequency to the maximum level resulted in flow reduction of less than 10% (0.0%–9.5%). Commercially available 23-, 25-, and 27-G double-cutting probes exhibited higher egg-white and basic salt solution flow rates at all evaluated cut rates, with aspirational efficiencies being 1.1 to 2.9 times the flow rates of standard single-blade vitrectomy probes of the same caliber at the maximum preset vacuum. The highest relative differences were observed at faster cut rates.

Conclusion: The newly introduced double-cutting open-port vitrectomy probes delivered stable aspiration flow rates that were less prone to flow variation affected by the cutting speed. The fluidic principle of constant flow even at the highest cut rates and low vacuum levels might impact surgical strategies, especially when performing manipulations close to the retina.

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The invention of the vitreous infusion suction cutter by Machemer pioneered the development of the closed-system pars plana approach for removal of the vitreous.[1] Since then, continued surgical and engineering advancements have focused on two main physical principles—first, port miniaturization allowing for transconjunctival smaller-gauge vitreoretinal instrumentation to make vitrectomy surgery less invasive and minimize patient discomfort[2–4] and second, constant increase of available cutting speeds along with duty-cycle improvement, resulting in more efficient vitreous removal and greater fluidic stability with less tractional forces, especially when shaving close to the retina.[5] Fluidic stability is a key surgical prerequisite for the controlled and safe removal of different media of alternating viscosity during pars plana vitrectomy.

The flow rate of a Newtonian fluid through a vitrectomy probe can be described by Poiseuille law, but the flow of aspirated material during vitrectomy is more complex to characterize. Viscous materials offer increased resistance to flow through the vitrectomy probe, and because of the constantly changing outflow, the inflow of basic salt solution (BSS) must be permanently adjusted. The vitreous is a heterogeneous substance composed of water, collagen fibers, and hyaluronic acid, which exhibits dynamic viscoelastic properties. During senescence, the vitreous morphology is progressively reorganized, and changes in the composition of hyaluronic acid, water, and the molecular collagen network result in liquefaction and possible detachment of the vitreous base.[6] Furthermore, a dynamic

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23-, 25-, 27-G vitrectomy probes were provided by the respective manufacturers (Alcon Laboratories, Fort Worth, TX; DORC Dutch Ophthalmics, Zuidland, The Netherlands; and Oertli Instrumente AG, Berneck, Switzerland) for in vitro analysis.

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viscosity profile of vitreous and reinfused BSS is encountered during aspiration throughout the surgical procedure.

It has been demonstrated that the viscosity of heterogeneous non-Newtonian fluids such as the vitreous can be effectively reduced by using high cutting frequencies. A faster cut rate of the vitrectomy probe results in smaller vitreous bites during an individual cut, thereby actively reducing the viscosity of the aspirated vitreous frill.[7,8] This results in smoother flow and fewer surge effects; however, in a standard vitrectomy cutter, the increased cut rate reduces the proportion of time for which the cutter is open relative to that for which it is closed during a surgical cutting cycle. This reduction of active aspiration phase during a complete cutting cycle, therefore, correlates with lower BSS and vitreous flow rates with increase in speed.[9] With the introduction of dual pneumatic cutter guillotine-drive systems, efforts have been made to optimize and extend the active open time (i.e., duty cycle) of the port during the opening and closing movements of the blade in the cutter. Nevertheless, complete closure still results in reduced efficiency because of the pulsatile flow of aspiration and the potential for tractional damage to the retina.[5]

Interestingly, vitrectomy probe designs with a single guillotine-shaped cutter blade remained basically unchanged for the past 40 years since the introduction of vitreous infusion suction cutter by Machemer. To improve fluidic control and aspiration efficiency, Hayafuji et al engineered and patented the concept of a double-cutting vitrectome with a constantly open port.[10] A guillotine with two blades cuts the vitreous as it enters the cutter port with a forward stroke of the distal blade and then again during the backward stroke with the proximal blade of the shaft. Thus, during a complete cycle in which the pneumatically driven cutter performs a back-and-forth movement, vitreous cutting occurs twice. This doubles the cut rate and technically allows for cutting frequencies up to 16,000 cuts per minute (cpm). A further particularly important characteristic of the double-cutting geometry is that the cutter port is never completely occluded, which supports constant aspirational flow (Figure 1).[11–14]

This novel blade design has now been incorporated into commercially available vitrectomy probes (EVA ophthalmic surgical system—TDC probes; two-dimensional cutting vitrectomes, DORC Dutch Ophthalmic, Zuidland, The Netherlands; OS4—continuous-flow vitrectomy, Oertli Instrumente AG, Berneck, Switzerland). The theoretical advantages of this guillotine design include more efficient aspiration of the vitreous and more stable flow characteristics, which potentially results in less tractional forces, especially during vitreous shaving with a mobile detached retina.

The objective of this in vitro study was to comparatively analyze the performance and pivotal parameters related to vitreous surgery using commercially available high-speed standard single-blade and double-cutting open-port 23-, 25-, and 27-gauge (G) vitrectomy probes. These results will provide information to vitreoretinal surgeons regarding the aspirational efficiency of new small-gauge double-cutting vitrectomy probe designs and how constant flow characteristics might influence the surgical approach when working close to delicate retinal structures.

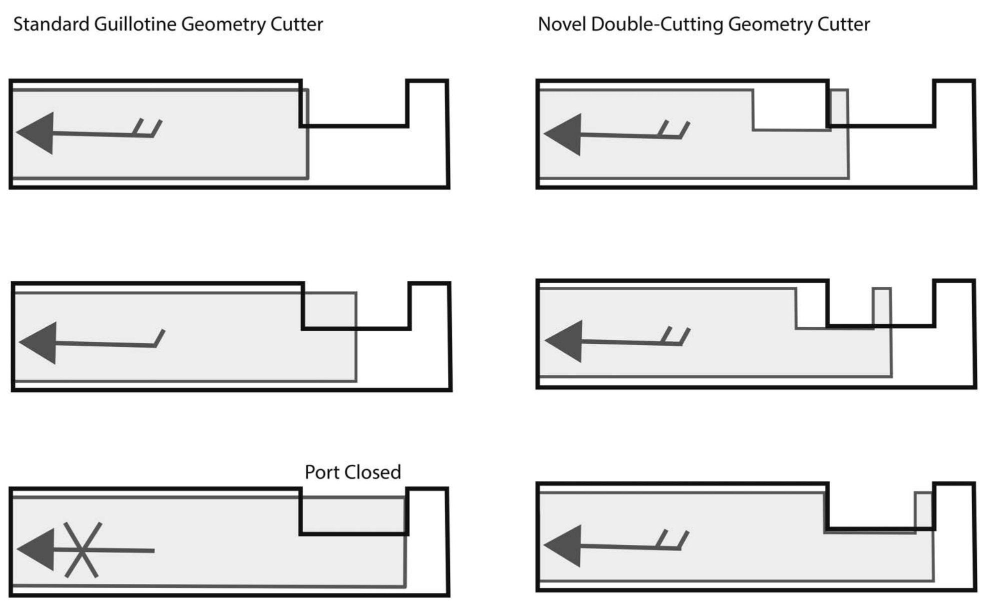

Fig. 1. Schematic diagrams of cutter geometries. In double-cutting open-port vitrectomy probes, a guillotine with two blades cuts the vitreous as it enters the port with a forward stroke of the distal blade and then again during the backward stroke with the proximal blade of the shaft. Thus, during a complete cycle in which the pneumatically driven cutter performs a back-and-forth movement, vitreous cutting occurs twice. This technically doubles the cut rate relative to that of a standard single-cut vitrectomy probe. Moreover, owing to the blade geometry, the cutter port is never completely occluded.

Table 1. Summary of Vitreous-Cutter Geometry, Models, Make, Specifications, and Consoles

Probe Denomination	Vitreous-Cutter Geometry	Vitreous Cutter Product Name	Analyzed Settings: Vacuum Range (mmHg)	Analyzed Settings: Cut Rate Range (cpm)	Vitrectomy Console
23-gauge probes					
23-G	Double-cutting	DORC two-dimensional cutting (TDC) vitreous cutter*	100–650	500–16,000	EVA ophthalmic surgical system*
23-G	Double-cutting	Oertli continuous-flow Twinac cutter†	100–650	500–10,000	OS4†
23-G	Single blade	Alcon ULTRAVIT cutter‡	100–650	500–7,500	CONSTELLATION Vision System‡
25-gauge probes					
25-G	Double-cutting	DORC two-dimensional cutting (TDC) vitreous cutter*	100–650	500–16,000	EVA ophthalmic surgical system*
25-G	Double-cutting	Oertli continuous-flow Twinac cutter†	100–650	500–10,000	OS4†
25-G	Single blade	Alcon ULTRAVIT cutter‡	100–650	500–7,500	CONSTELLATION Vision System‡
27-gauge probes					
27-G	Double-cutting	DORC two-dimensional cutting (TDC) vitreous cutter*	100–650	500–16,000	EVA ophthalmic surgical system*
27-G	Double-cutting	Oertli continuous-flow Twinac cutter†	100–650	500–10,000	OS4†
27-G	Single blade	Alcon ULTRAVIT cutter‡	100–650	500–7,500	CONSTELLATION Vision System‡

*DORC, Dutch Ophthalmic, Netherlands.
†Oertli Instrumente AG, Switzerland.
‡Alcon Laboratories, Fort Worth, TX.

Methods

The performances of 23-, 25-, and 27-G vitrectomy probes were tested using appropriate vitrectomy consoles (Table 1). Commercially available double-cutting probes were tested using the EVA ophthalmic surgical system (23-, 25-, and 27-G TDC probes—two-dimensional vitrectomes, DORC Dutch Ophthalmic) and the OS4 system (23- and 25-G continuous-flow Twinac cutter; Oertli Instrumente AG). The Oertli 27-G continuous-flow Twinac cutter is not yet commercially available, and prototypes were provided by the manufacturer.

The referential performances of standard single-blade small-gauge vitrectomy probes were analyzed using the CONSTELLATION Vision System (23-, 25+-, and 27+-G ULTRAVIT probes; Alcon Laboratories, Fort Worth, TX). On the CONSTELLATION console, the duty cycle was preset to the core mode to allow for higher proportional flow rates.[15]

In vitro fluidic measurements were performed to assess the volumetric aspiration profiles of the probes in BSS and egg white. Vials containing the respective liquids were placed on a high precision balance (Sartorius Analytical Balance A2005; Sartorius Lab Instruments, Goettingen, Germany; resolution, 0.0001 g). The vitrectomy probe was connected to the vitrectomy machine, and a priming procedure was performed in accordance with the manufacturer's recommendations. The vitreous cutter was completely inserted into the vial. On activation of the vitreous cutter with the preset parameters, the vacuum levels stabilized. When the flow became constant, the weight reduction of the fluid in the vial was measured for 60 seconds for each individual analysis. The aspiration flow rate, defined as volume of fluid per unit time, was calculated using the following equation: Flow rate (mL/second) = {(initial fluid weight [g] − final fluid weight [g]) × time [seconds]}/fluid mass density (g/mL). The measured mass density was 0.98 mg/mL for egg white and 1.0 mg/mL for BSS. For each analysis, at least two successive new identical probes were tested. Five measurements were performed for each prespecified measurement point in each medium, and the average aspiration flow was calculated. Tabular measurement end points were defined by the highest performance settings (vacuum and cutting rates), as specified by the vitrectomy probe manufacturer and the limits of the vitrectomy console. Matching scalar vacuum and cpm measurement points were defined on all vitrectomy systems to allow for cross-platform analysis in tabular and graphical representations.

Data were analyzed using SPSS Statistics 22 (IBM Analytics, Armonk, NY). Assuming normal distribution for flow-rate values, primary two-way analysis of variance was performed with factors including the cutter type, cut rate, vacuum rate, and gauge size, once each using the flow rates recorded in BSS and egg white. Furthermore, one-way analysis of variance was performed for every experimental setting—each cutter type, gauge size, and medium was evaluated to obtain detailed results regarding differences in flow rates between cut rate settings. In an experimental setting involving 5 different cut rates, the flow rates of the 23-, 25-, and 27-G vitrectomy probes of different manufacturers were compared as dependent variables. Post hoc analysis results were corrected by the Bonferroni method. We considered $P < 0.05$ as statistically significant.

Results

Basic Salt Solution Flow Rates for 23-, 25-, and 27-G Cutters

The BSS flow rates for the 23-, 25-, and 27-G cutters at incremental cut rates and vacuum levels are presented in Figure 2. Among the evaluated gauge sizes, the highest flow rates were obtained with double-cutting DORC TDC probes. The maximum flow rates of the 23-, 25-, and 27-G probes were 32.8, 23.3, and 9.5 mL/minute, respectively. The highest aspiration efficiencies of standard single-blade 23-, 25-, and 27-G ULTRAVIT probes were determined to be 21.7, 12.4, and 7.0 mL/minute. These peak BSS flow measurements of the ULTRAVIT probes were obtained with the lowest preset cut rate of 500 cpm in a biased open mode at the maximum vacuum level of 650 mmHg for all gauge sizes. In single-blade ULTRAVIT probes, despite maximum vacuum presets, the aspiration flow gradually declined with increasing cut rates. Relative to the aspiration efficiencies at 500 cpm, those at 7,500 cpm were reduced by 34.6% in 23-G, 30.6% in 25-G, and 32.9% in 27-G ULTRAVIT probes ($P < 0.0001$, all).

However, in case of the 23-, 25-, and 27-G double-cutting DORC TDC probes, this tendency of reduction in aspiration flow efficiency was not observed, and the BSS flow remained stable despite an increase in cut rates. At increasing cut rates, the BSS flow rates of the 23-, 25-, and 27-G DORC double-cutting TDC probes were between 1.5 and 2.3 times, 1.8 and 2.7 times, and 1.3 and 2.0 times those of the corresponding reference Alcon ULTRAVIT probes, respectively.

Similar to the double-cutting DORC TDC probes, the Oertli 23-G double-cutting continuous-flow Twinac probe exhibited stable flow properties with increasing cut rates. However, relative to the corresponding flow rates at lower cutting frequency settings of the vitrectomy console, probes with smaller gauge sizes—that is, 25- and 27-G—exhibited flow reductions of 7.7% and 15.2%, respectively, at higher frequencies. The BSS flow rates of the 23- and 25-G Oertli double-cutting probes were 1.1 to 1.8 times those of the corresponding Alcon ULTRAVIT vitrectomes. The premarket prototype 27-G Oertli continuous-flow Twinac probe exhibited lower flow rates (0.5–0.6 times) than the reference 27-G Alcon standard single-blade vitrectomy probe.

Egg-White Flow Rates for 23-, 25-, and 27-G Cutters

The egg-white flow rates for the 23-, 25-, and 27-G cutters are summarized in Figure 3. Similar to the BSS flow rates, the highest aspiration rates of egg white were obtained with double-cutting DORC TDC probes across all gauge sizes. The maximum egg-white flow rates of the 23-, 25-, and 27-G probes were 16.8, 7.8, and 2.8 mL/minute, respectively. Relative to the corresponding maximum aspiration flow rates of BSS, those of egg white were 51.2%, 31.8%, and 29.8%, respectively, with the 23-, 25-, and 27-G DORC TDC probes. At increasing cut rates, the aspiration rates of egg white with the 23-, 25-, and 27-G DORC double-cutting TDC probes were between 1.6 and 2.9 times, 1.3 and 2.0 times, and 1.5 and 1.7 times those of the corresponding reference Alcon ULTRAVIT probes, respectively.

The highest aspiration efficiencies of standard single-blade 23-, 25-, and 27-G Alcon ULTRAVIT probes were determined to be 10.3, 5.7, and 1.9 mL/minute, respectively. These peak egg-white flow rates of the ULTRAVIT probes were obtained at a cut rate of 500 cpm in a biased open mode at the maximum vacuum level of 650 mmHg for all gauge sizes. In standard-geometry ULTRAVIT probes, despite maximum vacuum presets, the aspiration flow of egg white gradually declined with increasing cut rates. Relative to the aspiration efficiencies at 500 cpm, those at 7500 cpm were reduced by 34.6% in 23-G, 30.6% in 25-G, and 32.9% in 27-G ULTRAVIT probes ($P < 0.0001$; $P < 0.001$; $P = 0.0326$, respectively).

In case of the double-cutting 23-, 25-, and 27-G DORC probes and 23- and 25-G Oertli probes,

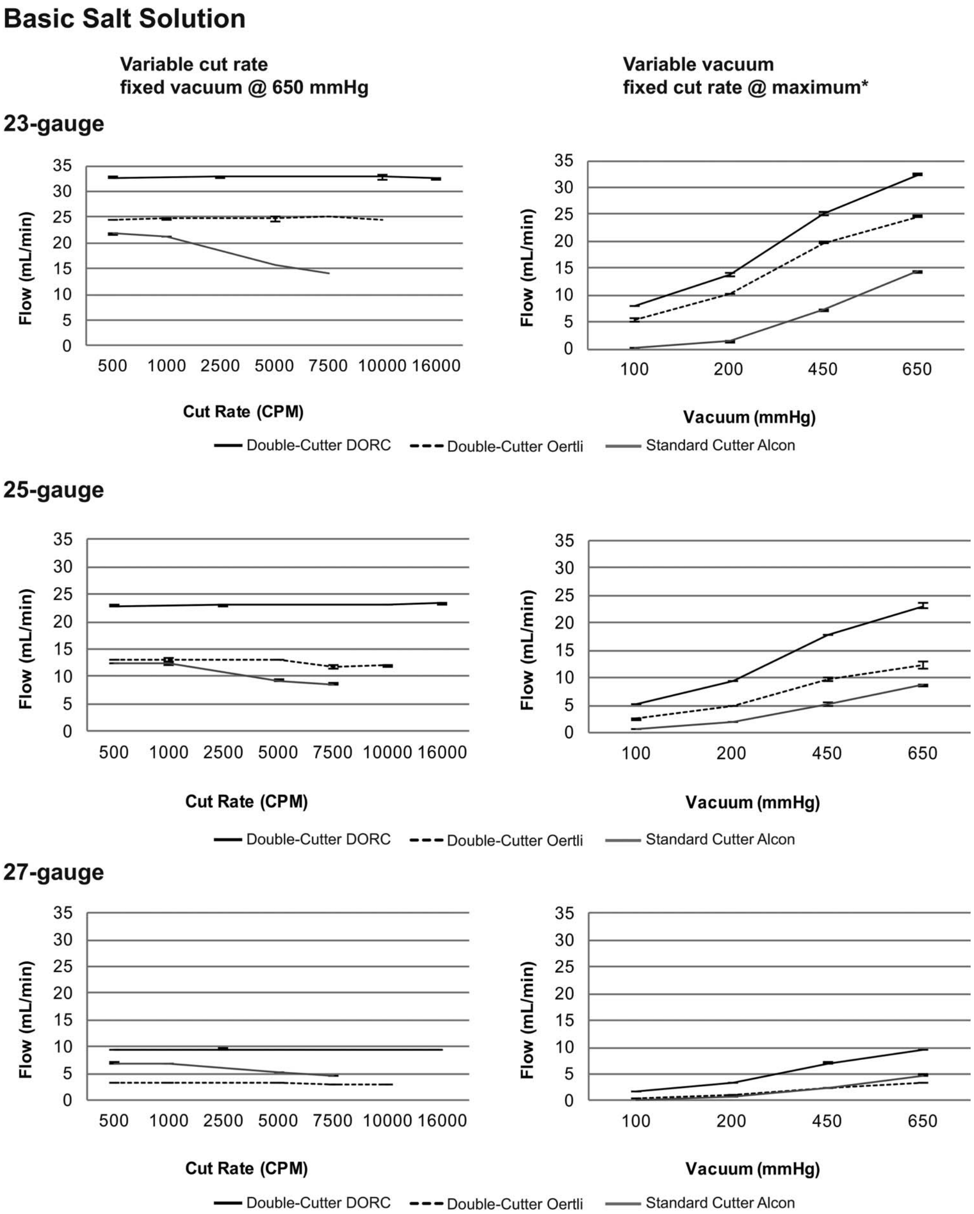

Fig. 2. BSS flow rates of 23-, 25-, 27-gauge (G) vitrectomy probes. For double-cutting probes, in vitro measurements were performed with the EVA ophthalmic surgical system (23-, 25-, and 27-G TDC probes, 2-dimensional vitrectomes, DORC Dutch Ophthalmic; *maximum 16,000 cpm) and the OS4 system. The Oertli 27-G continuous-flow Twinac cutter is a double-cutting probe prototype and is not commercially available yet (23-, 25-G, and 27-G continuous-flow Twinac cutter; Oertli Instrumente AG; *maximum 10,000 cpm). The referential performances of standard single-blade small-gauge vitrectomy probes were analyzed using the Constellation Vision System (23-, 25+-, and 27+-G ULTRAVIT probes; Alcon Laboratories; *maximum 7,500 cpm).

increase in cpm to the maximum frequency resulted in flow reduction of less than 10% (0.0%–9.5%; DORC: $P = 0.005$, 0.037, and 0.522, respectively; Oertli: $P = 0.523$ and 0.879, respectively). The premarket prototype Oertli 27-G continuous-flow Twinac double-cutting probe exhibited a 77.8% decrease in aspirational performance between 500 and 10,000 cpm at a maximum vacuum setting of 650 mmHg ($P < 0.0001$).

Discussion

For vitreoretinal surgeons, the fluidic demands for performing an efficient and safe vitreoretinal procedure are high. The vitreous has to be extracted quickly and efficiently while exerting as little traction as possible on the vitreoretinal interface. However, there is an ongoing trend favoring gauge-size miniaturization. In clinical practice, the use of 25- and 27-G vitrectomy instrumentation is expanding because of its advantages in terms of reduced intraoperative tissue manipulation and postoperative inflammation.[16]

Accommodating these technical demands of vitreoretinal surgeons poses a challenge to the physical principles of fluidics and the definition of Poiseuille law, shown in the following equation:

$$\text{Flow} = \frac{\Delta P \cdot \pi \cdot r^4}{\eta \cdot L \cdot 8}$$

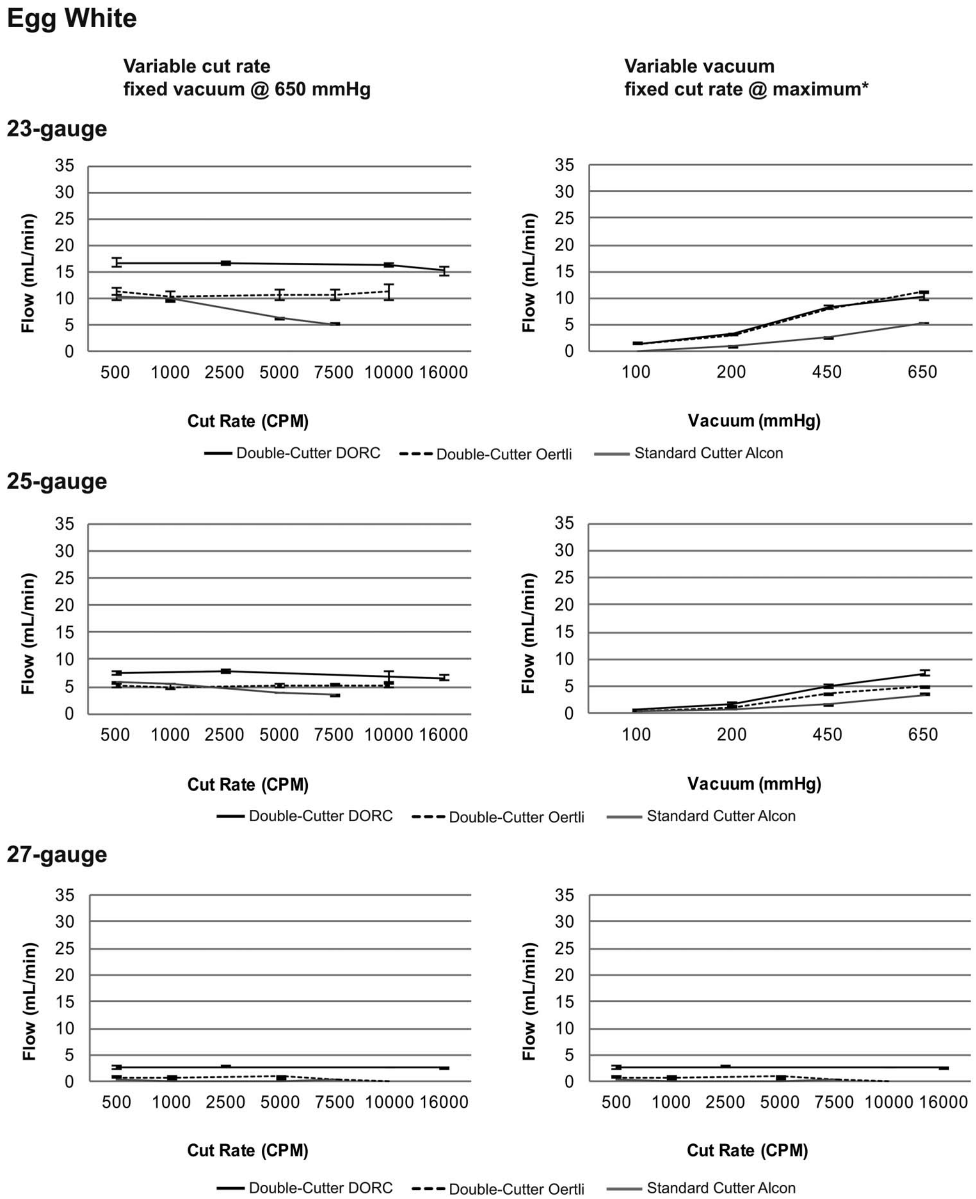

Fig. 3. Egg-white flow rates of 23-, 25-, 27-gauge (G) vitrectomy probes. For double-cutting probes, in vitro measurements were performed with the EVA ophthalmic surgical system (23-, 25-, and 27-G TDC probes, 2-dimensional vitrectomes; DORC Dutch Ophthalmics; *maximum 16,000 cpm) and the OS4 system. The Oertli 27-G continuous-flow Twinac cutter is a double-cutting probe prototype and is not commercially available yet (23-, 25-G, and 27-G continuous-flow Twinac cutter; Oertli instrumente AG; *maximum 10,000 cpm). The referential performances of standard single-blade small-gauge vitrectomy probes were analyzed using the CONSTELLATION Vision System (23-, 25+-, and 27+-G ULTRAVIT probes; Alcon Laboratories; *maximum 7,500 cpm).

In the equation, ΔP represents the pressure difference across the length L of the probe needle; r is the internal radius of the probe; and η is the viscosity of the aspirated liquid. With the reduction of gauge size, along with a smaller inner diameter of the probe, the aspiration flow is reduced exponentially by a factor of 4. Bearing Poiseuille law in mind, one technical approach for maintaining the flow rate for efficient vitreous removal despite gauge-size reduction is to increase the applied vacuum (ΔP). Modern vitrectomy consoles, therefore, provide upper vacuum limits of more than 600 mmHg. In this study, all consoles were tested up to a coordinated maximum vacuum setting of 650 mmHg. As expected, the highest flow measurements with all three evaluated probe diameters (i.e., 23-, 25-, and 27-G) were observed at maximum vacuum presets on all three vitrectomy consoles.

Another method for optimizing fluidic characteristics is to increase the cut rate. The vitreous is a highly viscous substance, and the aspirated material offers increased flow resistance through the probe. Increasing the cut rate allows for efficient reduction of viscosity (η) in the fluidics equation. Aspiration of smaller vitreous bites during individual cuts reduces the viscosity of the aspirated material and allows for homogenization of the nonperfectly Newtonian media encountered during vitreoretinal surgery.[7,8]

In standard single-blade cutters, ultrahigh-speed cutting at rates up to 7,500 cpm is technically demanding, and the high cutting frequency directly affects the ratio of time for which the aspirational port of the vitrectomy probe is open and closed (i.e., duty cycle). Dual pneumatically controlled cutting cycles can extend the open time and shorten the relative time of complete port closure of the guillotine during a complete open–close cycle. Duty cycle–based technical refinements of blade-movement timing during a cutting cycle cannot overcome the fact that an active cut needs complete port closure in standard single-blade vitrectomes. In other words, the standard cutter mechanics implies a direct correlation—greater cpm results in more complete port closure time per minute, and this physical principle can only be partly mitigated by duty cycle management. This complete occlusion and reopening of the port potentially results in pulsatile flow and potentially less predictable surgical characteristics.[17,18]

The Alcon ULTRAVIT probes used in this study feature the classical single-blade cutter design, and blade movement is controlled by a dual pneumatic mechanism. The preset was in the core mode, biased open to assure maximum open port time. With increasing cut rates, probes of all three gauge sizes exhibited significant decreases in aspiration flow rates of BSS and egg white, as depicted by the downward sloping curve in the diagram representing the results of analysis with variable cut rates. This trend might be attributable to the decline of the duty cycle at higher cut rates.[5,7]

Double-cutting vitrectomes essentially provide two cuts per cycle; accordingly, a cut rate of 5,000 cpm is equivalent to 10,000 effective cpm. In the device specifications, manufactures of the new double-cutting vitrectomes present the effective cut rates of their systems differently. Although DORC displays the cut frequency setting on the console at a maximum of 8,000 cpm, it refers to the number of complete cutter cycles per minute, which is equivalent to 16,000 effective cpm of the double-cutting blade.[14] By contrast, Oertli states the maximum frequency to be 10,000, referring to the number of effective cpm of the double-cutting blade, which is equivalent to 5,000 movement cycles of a standard single-blade guillotine vitrectome.

In this in vitro study, relative to the corresponding classic single-blade probes, the 23-, 25-, and 27-G DORC double-cutting guillotine blades were less prone to flow-rate reduction at higher cut rates in egg white and BSS. The Oertli 23- and 25-G continuous-flow Twinac double-cutting probes exhibited a similarly stable flow-rate profile across different cut rates (Figure 2). The premarket Oertli 27-G probes, which were provided by the manufacturer for in vitro analysis in this study, exhibited low flow rates across all vacuum and cpm levels. Owing to the premarket status of the Oertli 27-G probe design, these results are only conditionally comparable.

The newly introduced 23-, 25-, and 27-G double-cutting open-port vitrectomy probes delivered stable aspiration flow rates that were less prone to flow variation affected by the cutting speed. The commercially available double-cutting probes exhibited higher flow rates at all evaluated cut rates, and, at the maximum preset vacuum, the aspirational efficiency of BSS was 1.1 to 2.7 times that observed with standard single-blade vitrectomy probes of the same caliber. The highest relative differences were observed at higher cut rates. At the lowest evaluated vacuum levels and maximum preset cut rates, the BSS flow rates of the new probes were even more striking, with aspiration rates of up to 79 times those observed with the classic cutters. Similar differences were observed in the viscous egg-white in vitro model.

Limitations of this study include the use of egg white to simulate human vitreous, and thus, our conclusions must be interpreted with caution. Egg white is frequently used as a stable and more consistent fibril-structured medium than porcine or cadaver vitreous that are prone to liquefaction.[13,19,20] Comparison and multiple testing of the various probes were performed under consistent laboratory conditions, and the measurements were reproducible with low standard deviation for each prespecified measurement point in BSS and egg white. The study was designed and conducted at an academic research laboratory of the Medical University of Innsbruck as an investigator-initiated trial, independent of corporate interests.

The standard guillotine-shaped vitrectomy cutter has been used for many years. Because of its movement of cutting the vitreous with complete port closure, it possesses different aspirational characteristics relative to the new double-cutting vitreous cutting systems with a constantly open port. In standard single-blade vitrectomy probes, increasing the cut rate, modifying the duty cycle, and reducing the vacuum help limit the flow rate during shaving procedures close to the retina.[5,9,21] The present data show that, for double-cutting open-port designs, variation of the cut rate as a means of limiting the flow and tissue-attractive capabilities of the cutter tip might only play a subordinate role in the adjustment of settings for vitreoretinal shaving procedures.

Because of its simplicity and robustness, the technical design principle of standard guillotine-shaped vitrectomy probes has not changed substantially over the past decades. New blade shapes with stable aspirational flow at increasing cut rate frequencies could bring about a significant improvement in vitrectomy. It is important for vitreoretinal surgeons adopting the new open-port double-cutting geometries in their surgical practice to consider the marked differences in aspirational flow rates between the new double-cutting and conventional vitrectomy probes. The fluidic principle of constant flow even at highest cut rates and low vacuum levels might impact surgical strategies, especially when performing manipulations close to the retina.

Key words: cut rate, double-cutting vitrectomy probe, fluidics, open port, vitreous cutter, vitrectomy, 23-gauge, 25-gauge, 27-gauge.

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