Hypersonic vitrector holds potential for multiple benefits

Technology liquefies tissue at edge of port prior to aspiration using high-speed flow field

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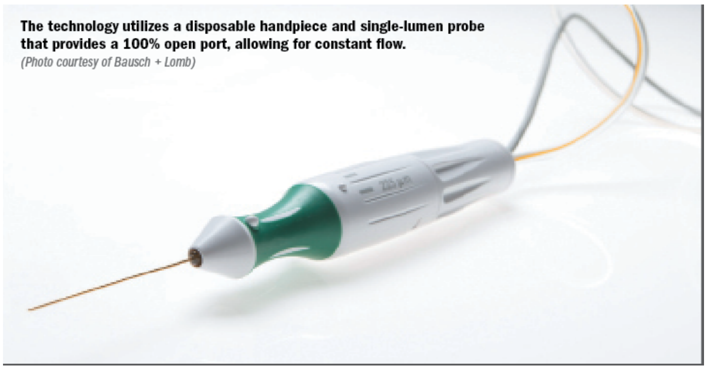
A new hypersonic vitrectomy system (Vitesse, Bausch + Lomb) is novel technology that is expected to provide a number of advantages compared with conventional pneumatic guillotine vitrectors because of its unique design features and mechanism of action.

The technology utilizes a disposable handpiece and single-lumen probe that provides a 100% open port, allowing for constant flow. Instead of cutting vitreous, it liquefies tissue at the edge of the port prior to aspiration using the principle of a high-speed flow field.



The technology utilizes a disposable handpiece and single-lumen probe that provides a 100% open port, allowing for constant flow. *(Photo courtesy of Bausch + Lomb)*

In theory, these features may offer specific advantages compared with guillotine vitrectors, and early experience using the device in practice is encouraging, said Paulo E. Stanga, MD, professor of ophthalmology and retinal regeneration, Manchester Royal Eye Hospital and University of Manchester, Manchester, England.

Dr. Stanga was involved in the development of the hypersonic vitrector from the bench prototype stage through FDA approval. He conducted studies investigating its performance in cadaver eyes and live animals, and he performed the first clinical cases of hypersonic vitrectomies in patients.

“Hypersonic vitrectomy is a new technology that allows for smaller-gauge vitrectors with efficiency similar to that of a guillotine-based device,” Dr. Stanga said. “This new technology also allows for the removal of vitreous, dense hemorrhage, soft lens material, and silicone oil as well as the execution of a retinectomy using the same probe.

“Our first in-human experience suggests that this new hypersonic vitrector is a promising alternative to the currently commercially available guillotine vitrectors,” he said. “With hypersonic vitrectomy, vitreous was removed effectively in all cases. Now, larger scale studies are required to confirm our initial findings.”

Brief history

Initial interest in the ultrasound-powered, single-needle device was sparked by the fact that it seemed to be effective at disrupting vitreous while operating at a very high speed with a constant open-duty cycle, noted Brian McCary, MBA, director, innovation and design, Bausch + Lomb, Bridgewater, NJ.

“There was long-standing interest in the industry for developing a vitrector with a faster cut rate and longer open-duty-cycle time to maintain constant flow,” McCary explained. “While there is an inherent trade-off between achieving those two goals with a guillotine vitrector, this system overcame the conflict and showed the potential to fulfill customer desires for both features.

“Over a period of about 6 years, we worked to refine and improve the device and understand how it works,” he added.

This video features the induction of a PVD (Posterior Vitreous Detachment) and removal of vitreous base with the Vitesse system. (Video courtesy of Bausch + Lomb)

Liquefaction at the tip

Whereas with a guillotine vitrector, vitreous is pulled into the port where it is trapped and sheared by the action of the inner needle, with the hypersonic vitrector, vitreous is disrupted in front of the port by a field of high-speed fluid flow. Then, the liquified material enters the port.

“The limited movement of the single needle is moving fluid through the port at a very high velocity, exceeding 5 meters per second,” McCary said. “It is this controlled hypersonic fluid movement that is primarily responsible for breaking up the vitreous.

“Although the needle tip itself is moving at a low velocity, the maximum instantaneous velocity at which fluid or vitreous moves out of the port is much higher because of hydraulic gain, which occurs because the surface area inside the end of the needle is much larger than that of the port,” he added.

Electron microscopy studies done by Dr. Stanga confirm the liquefying action of the hypersonic vitrector. The images showed that the collagen fibrils in the vitreous were cut into lengths <5 µm when using the hypersonic device compared with lengths of 100 to 300 μm when operating with a guillotine cutter. Integrity of the collagen fibrils in vitreous is key to why the gel sticks together and to how much traction it can exert on the retina.

"Most efforts to date toward removing the vitreous more efficiently have been directed towards increasing cut rate," Dr. Stanga said. "However, there are limitations that include speed of the cutter blade, duty cycle, and turbulence within the probe.

"Carrying out what we believe is the first ever histopathology study of vitreous fibers after vitrectomy, we observed that the fragmentation of collagen fibers is significantly greater with hypersonic vitrectomy than with the guillotine vitrector," he said.

By ultra-fragmenting the collagen fibers, hypersonic vitrectomy modifies the viscosity of the vitreous before it passes through the port. Thereby, we are introducing the concept of "vitreous liquefaction" in which the aspiration of vitreous though a small gauge is facilitated by altering its rheological characteristics, he noted.

Host of potential benefits

Notably as well, the cutting effect of the vitrector is limited to the region immediately in front of the port because the speed at which the fluid away from the port is moving drops off rapidly with increasing distance. The latter phenomenon is explained by a combination of flow dynamics and the inverse-square law of physics. This results in surgeons having very precise control over the region of vitreous liquefaction, through their visualization of the region in front of the port on the tip.

"The fact that the cutting occurs in front of the port when using the hypersonic vitrector rather than inside also means surgeons should find better accessibility to tissue," McCary said. "Therefore, it is expected that some steps of the procedure may be done more easily."

Compared with guillotine vitrectors, the hypersonic vitrector is also able to operate with a smaller port opening. Its port diameter is just 200 to 250 μm, compared with 500 to 600 μm for guillotine vitrectors. Thus, because force is the product of vacuum and area, the hypersonic cutter may exert less traction. In addition, it can work at a lower vacuum level than guillotine vitrectors because it has a small, fixed open port and is drawing in liquefied vitreous. Lower vacuum can translate to less traction.

"With our system, vitrectomy can be done at vacuum levels of just 50 to 100 mm Hg, and it is even possible to use almost no vacuum when working very close to the retina," McCary said.

There is also much less turbulence created using the hypersonic cutter compared with a guillotine cutter. The explanation for this difference is twofold. The periodic opening and closing of the port in a guillotine cutter creates both a mechanical disturbance by pulling the vitreous back and forth across the port, and the need for higher peak flow rates into the port to compensate for the time during the duty cycle when flow through the port is blocked.

"Because it has a single moving part, we also expect the hypersonic vitrector will have an advantage over guillotine vitrectors when it comes to mechanical reliability," McCary said.

Future innovations

The hypersonic vitrector is currently available only as a 23-gauge system, and it is driven exclusively by a surgical platform (Stellaris Elite, Bausch + Lomb). The opportunity exists to create higher-gauge versions, however, because with cutting occurring in front of the tip and the lack of an inner needle, smaller lumen size should neither compromise flow nor risk internal clogging that that can create traction.

"As we have seen with the history of guillotine vitrectomy over the last 40 years, the Vitesse technology will also continue to evolve in both form and application," said Rob Niemietz, MBA, director of marketing, Surgical Retina, Bausch + Lomb. "We see [this] as a truly disruptive technology potentially changing how and where vitrectomy surgeries, and even other ophthalmic surgeries, are performed in the future.

“For instance, because the inner lumen of the hypersonic vitrector is open, there is also the potential for developing a bent shape design that is common in other vitreoretinal instruments, but that has not yet been realized with guillotine cutters,” he said.

Paulo E. Stanga, MD

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Dr. Stanga is a consultant to Bausch + Lomb and receives research funding, lecture fees, and travel expenses.