White Paper

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Technical Advancements of Surgical Vitrectomy Probes

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Main Takeaway Points:

- Vitroretinal surgery is a relatively "new" specialty that has advanced as technology has evolved
- Decreased Vitrectomy cutter gauge size and faster guillotine cut rates can reduce tractional forces and pulsatile motion in the cutter's sphere of influence
- Bevel-tip vitrectomy cutters allow dissection closer to the retinal surface as well as reduce the sphere of influence near the cutter tip when compared to flat-tip cutters
- Dual-blade vitrectomy cutters provide much faster cut rates and provide a nearly 100% duty cycle, approaching an "ideal" vitrectomy cutter profile that can help increase efficiency and safety

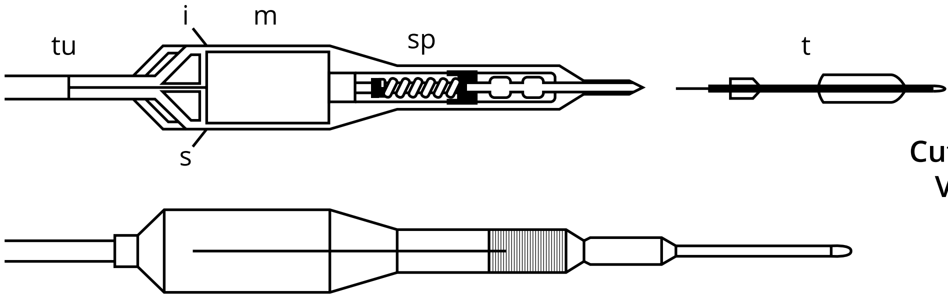
Vitrectomy - From Complication to Therapy

Much has changed since the advent of vitrectomy back in the late 1960s when David Kasner excised prolapsed vitreous as a complication of cataract surgery; he was surprised that a considerable loss of vitreous was well-tolerated, and his colleagues at the time questioned his assertion. He subsequently treated a patient with vitreous opacification caused by amyloidosis, which further surprised his colleagues. He initially removed the vitreous with forceps and scissors, but later found that vitreous adheres well to cellulose sponges to allow it to be pulled out of the eye and cut. Access was based on an enlarged cataract incisional approach, or by temporarily removing the cornea and then performing an intracapsular lens extraction to gain access to the vitreous cavity (open-sky vitrectomy).[1] This procedure required lens removal, with possible corneal complications from a large section or corneal graft combined with a cataract extraction, and vitreous removal always resulted in a severe iris inflammation, often followed by the formation of iridocorneal adhesions.[2]

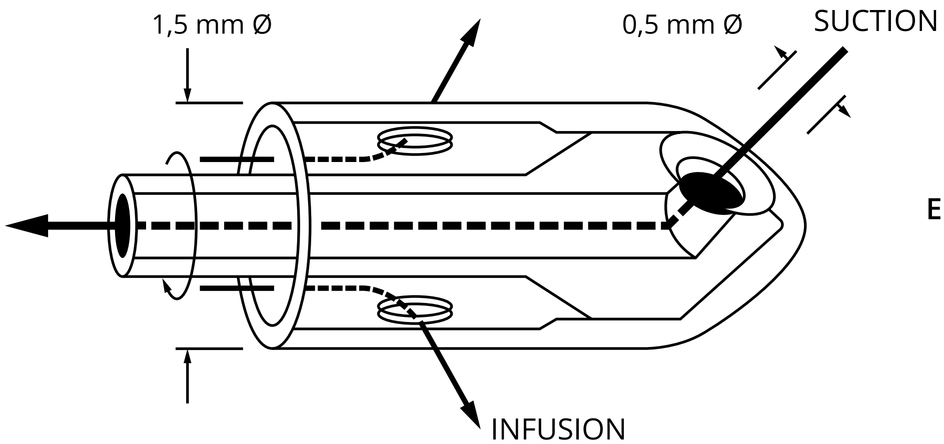
Based on the work of Kasner, Robert Machemer eventually developed a concept that would minimize trauma from vitreous extraction. The concept included a drill bit tightly encircled by a cylinder, which he tested through a small hole in an eggshell and successfully extracted egg whites. After extensive animal experiments, he performed a vitrectomy in January 1970 on a patient with poor visual acuity resulting from a non-clearing, dense, vitreous opacity after cataract extraction. After a penetrating keratoplasty was performed, the up-drawn iris was incised and the instrument was guided into the vitreous cavity. The central vitreous was removed and the cornea was repositioned without difficulty. This surgical approach had significantly less inflammation than eyes subjected to the original open-sky vitrectomy technique.[3]

Early Developments

Machemer's earlier work with animal experiments on retinal detachment provided him experience to access the vitreous cavity using a pars plana approach, which avoided damage to the lens and the retina. Addition of an infusion tube soldered to the outside of the vitreous cutter addressed the problem of collapse of the globe.[3] Further refinements resulted in a smaller instrument with a diameter of 1.5mm.[2] On April 20, 1970, he performed a landmark procedure on a diabetic patient with a persistent non-clearing vitreous hemorrhage. The vitrectomy was successfully performed with the Vitreous Infusion Suction Cutter (VISC) using a pars plana approach without complications.[3] [Figure 1]



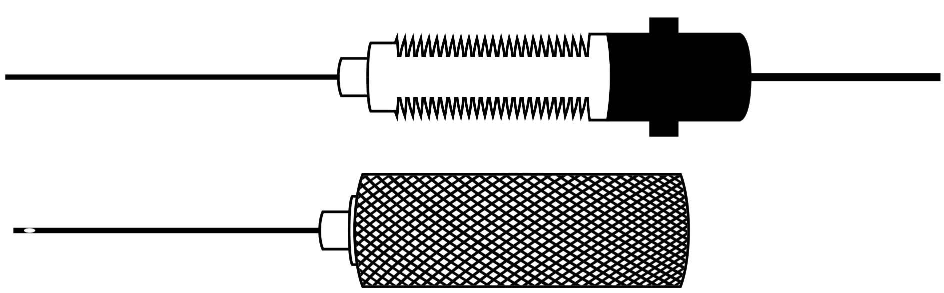
Cutaway and Overall Views of the VISC



Enlarged View of the Rotating Tip

Figure 1: Design drawings of Machemer's Vitreous Infusion Suction Cutter (VISC). Adapted from Machemer R, Parel JM, Buettner H. A new concept for vitreous surgery. 1. Instrumentation. Am J Ophthalmol. 1972;73(1):1-7.

In 1974, Connor O'Malley and engineer, Ralph Heintz, developed a cutter design with reciprocating movements driven by air pressure to cut and aspirate vitreous, inspiring iteration and improvements of today's vitreous cutters. O'Malley used a separate entry port for infusion and another one for illumination, with the final "Vitritome" design having a 0.88mm diameter (20-gauge).[4] [Figure 2] Cutting rates could be adjusted between 60 to 300 cuts per minute (cpm) and active suction/aspiration could be varied from 40 to 420 mm Hg. The success of this new approach, highlighted by its smaller gauge and enhanced cut and aspiration rates, led to its broad adoption. Over time, additional advancements such as fiber optic lighting, microinstrument development and improved reliability were realized.



Exploded view of the cutting unit with mobile cutter segment on top and fixed, hollow segment with cutter port on bottom.

Figure 2: The "Vitritome" by O'Malley and Heintz. Adapted from O'Malley C, Heintz RM Sr. Vitrectomy with an alternative instrument system. Ann Ophthalmol. 1975;7(4):585-594.

Steve Charles was another pioneer who worked with several companies to make further technical advancements to both the vitreous cutters and the control units, as well as including fluid-air exchange. Charles worked with Carl Wang to develop the disposable 20-gauge pneumatic axial cutter with higher cutting rates and faster aspiration fluidics;[5] these innovations in vitrectomy cutters with their corresponding surgical control units paved the way towards smaller-gauge cutters, as well.

With an increasing number of successful vitrectomy procedures performed, a better understanding of disease states was achieved and further developments and refinements were made. Additional indications for vitrectomy began to surface, such as the treatment of giant retinal tears, proliferative vitreoretinopathy, complications of diabetic retinopathy, penetrating and perforating injuries, macular puckers and holes, and age-related macular degeneration (AMD).[3]

Some of the early cases using vitrectomy cutters were learning experiences for these pioneers, and some of the complications described in these early experiences included evulsion of the vitreous base with retinal dialysis or retinal tears, retinal hole formation when working near the retinal surface, secondary cataract development after touching the posterior lens or after intraocular air tamponade, hemorrhages caused by retinal vessel traction and development of pre-retinal proliferation that could negate an originally good result.[6] As experience was gained over time, limitations of the vitrectomy cutters were better established and treatment pathways were better understood. This experience also led to further innovation and development that led to current microincisional vitrectomy surgery (MIVS). The years following resulted in significant advancements in vitreous cutter speeds and smaller instrument sizes.

The Path to Smaller, More Effective Vitrectomy Cutters

In 2001, a 25-gauge vitrectomy cutter was developed and described by Fujii et al that allowed for a transconjunctival sutureless technique. Despite reduced infusion and aspiration rates of this 25-gauge system, the total operative time compared to the 20-gauge system was significantly less (26 minutes, 7 seconds for the 20-gauge versus 17 minutes, 17 seconds for the 25-gauge, $p=0.011$).[7] Of note, sutureless canula development was also a novel aspect of the system, which enabled transconjunctival approaches with enhanced healing and reduced operating times. However, because this was a study reporting the initial experience using this new 25-gauge technology with only a short follow-up period for most patients, the limited efficacy and safety results obtained with this 25-gauge system could not be proven to actually exceed those ultimately obtained with large-gauge conventional systems. Furthermore, some surgical technique modifications were required secondary to the smaller gauge size, including the need for maximum aspiration vacuum (500 mmHg) due to significantly decreased aspiration flow compared to conventional 20-gauge vitrectomy systems as well as the need to set the cutting rate at a maximal level to promote smaller vitreous or fibrous tissue partition to better facilitate aspiration. Notably, the 25-gauge infusion cannula could not be used in conjunction with a standard 20-gauge vitreous cutter because of functional discrepancy between the infusion and aspiration rates of these 2 different systems, which could lead to hypotony. A significant early drawback of the 25-gauge instruments was their increased flexibility which could lead to significant instrument bending and possibly breaking when manipulating the eye.[8]

As a result of this limitation of decreased rigidity, Eckhardt described the development of a sutureless 23-gauge vitrectomy system in 2005 that offered the advantages of the 25-gauge transconjunctival sutureless vitrectomy system but included the benefits of sturdier, larger instrumentation. The introduction of 23-gauge after 25-gauge vitrectomy cutters implied to many surgeons that the 23-gauge vitrectomy cutter combined the best attributes of both systems.[5] With adoption of the 23-gauge vitrectomy system, there was significant attention brought to wound management. Rather than a straight in approach with the trocar insertion, a tangential tunnel incision was needed to decrease post-operative wound leakage with hypotony. This required an additional tool and a modified technique by making the tunnel incision with a stiletto blade and finally insertion of the cannula using a blunt inserter.[9] According to Eckhardt, the sutureless 23-gauge sutureless vitrectomy system appeared to be a viable alternative to 25-gauge system, however, he did mention that utilizing the 23-gauge vitreous cutter was slower at performing an extensive vitrectomy than the historical times achieved using the larger 20-gauge cutter, but the 20- and 23-gauge cutters were not directly compared in his report.

In 2010, Oshima and colleagues described initial results with a 27-gauge vitrectomy cutter.10 Vitrectomy with the 27-gauge vitrectomy cutter was performed without use of a trocar-cannula system for patients being treatment for simple vitreous hemorrhage or a diagnostic vitrectomy, situations which had less chance for instrument exchanges during surgery. After simply removing all instruments, surgery can be concluded at once with all sclerotomies self-sealed without suture placement. By making the vitrectomy cutter shorter, it had similar stiffness to the 25-gauge vitrectomy cutter, but had a larger port surface area compared to the 25-gauge cutter. The duty cycle of the 27-gauge cutter was equivalent or better when compared to a 25-gauge vitrectomy cutter at cut rates of 1000 - 1500 cuts per minute (CPM), however, it decreased to 21% or less when the cut rate exceeded 2000 CPM. The 27-gauge vitreous cutter also experienced a gradual reduction in aspiration rate with increasing cut rates.[10]

When Described	Individual	Development
1970	Robert Machemer	1.5mm Rotary Vitreous Infusion Suction Cutter (VISC)
1974	Connor O'Malley	Vitritome 20-Gauge Guillotine Cutter
2001	Gildo Fujii	25-Gauge Transconjunctival Sutureless Vitrectomy System
2005	Claus Eckhardt	Sutureless 23-Gauge Vitrectomy System
2010	Yusuke Oshima	Trocarless 27-Gauge Vitrectomy Cutter
2011	Stanislao Rizzo	Modified "Hole Vitrectomy Cutter"
2014	Tommaso Rossi	Modified "Slit Blade Vitrectomy Cutter"

Table 1: Historical Evolution of Vitrectomy Cutters

Insightful bench research has generated a greater understanding of the fluid dynamics for vitrectomy cutters with regards to cut rate, duty cycle and vacuum pressures. An overemphasis on higher flow rates found with larger-gauge vitrectomy cutters, incorrectly referred to as efficiency, may contribute to the unintended consequence of increased iatrogenic retinal breaks from vitreoretinal traction. Instead, efficiency may be better defined as the volume of vitreous removed per volume of infusion fluid. Furthermore, emphasis on faster surgical times and operating room efficiency can alter surgical technique that can increase the risk of producing vitreoretinal traction including pulling the cutter away from retina while aspirating, and rapid cutter repositioning.[11] According to the work by Hubschman et al in evaluating different-gauge contemporary vitrectomy cutters and surgical consoles in water and egg whites, the flow rate of an ideal vitreous cutter should possess the highest duty cycle, the largest internal diameter and a sharp guillotine. Additionally, higher flow rates can also be seen with the use of higher cut rates and may be explained by better vitreous fragmentation.[12]

Magalhaes et al. confirmed this latter point in porcine vitreous in that his group found that during cutting, vitreous fragments are attached to the main block of the vitreous and sometimes to the retina. When the port opens, the cutter aspirates a portion of this vitreous block, creating tractional force on the surrounding tissue. An ideal cutter produces a less traumatic vitreous removal, leading to decreased force on the vitreous block surface. As the vitrectomy cut rate increases (at a constant flow rate), the quantity of vitreous withdrawn into the cutter with each cut is reduced and the chunks of vitreous become smaller. These smaller chunks are pulled into the cutter port continuously, which allows smoother cutting without surging from intermittent obstruction within the lumen of the vitrectomy cutter. Lowering the vacuum of the vitrectomy cutter can also reduce the tractional force of the vitreous as it is withdrawn into the cutter.[13] The work of Teixeira et al in fresh porcine eyes independently confirmed that the factors contributing to retinal traction during vitrectomy included vacuum level, cut velocity (cut rate), distance from the retina, and gauge of the cutter. In other words, retinal traction increased with a larger gauge cutter, increasing aspiration vacuum and proximity to the retina, while retinal traction decreased with increasing cut rate.[14]

There are several other critical aspects of vitreous cutters that are important to describe. Vitreous cutter probes are designed using one of two different modes and one of two different actuating principles: “electric” and “pneumatic” modes, as well as “single actuation” or “dual actuation” cutting. The electric system has a sinusoidal shape cutter movement (typically with a constant duty cycle at varying cut rates), whereas the pneumatic system can vary the duty cycle.[12] Duty cycle is defined as the percentage of port open time versus total cycle time. The duty cycle can also be affected by whether it is a single or dual actuating cutter. A single actuation cutter relies on spring pressure to open the guillotine, and a dual actuation cutter relies entirely on air pressure to both open and close the guillotine, which can result in much more rapid closing and variable duty cycle control. In essence, elimination of the spring increases cutting rates as well as cutter velocity at the time of guillotine closure.[11] A lower duty cycle can limit port-based flow and provide better fluidic stability and less pulsatile vitreoretinal traction (as is the case in Shave Vitrectomy mode on the Alcon Constellation platform). A higher duty cycle produces greater flow suitable for core vitrectomy. Variable duty cycle control can enable control of flow at the port even at relatively high cutting rates. As stated previously, higher cutting rates have been shown to be safer.[11] From a practical standpoint, pneumatic cutters are also much lighter and more compact than electric cutters, which can be a significant advantage as it allows better dexterity with decreased hand fatigue.[11]

In 2014, Rossi and colleagues described a revised “slit blade” vitrectomy cutter design[15] based on a “hole blade” vitrectomy cutter modification first described by Rizzo in 2011.[16] A 23-gauge vitrectomy cutter was modified by creating a 0.1-mm wide slit with cutting edges cut across the inner cylinder, projecting in the center of the port with the blade closed. When testing with both Balanced Salt Solution (BSS) or egg albumen, the slit blade design compared to the hole blade or the unmodified guillotine blade designs consistently generated the least amount of acceleration with minimal dependence on blade motion, which approached an ideal “constant-flow” condition during vitrectomy.[15] (Figure 3)

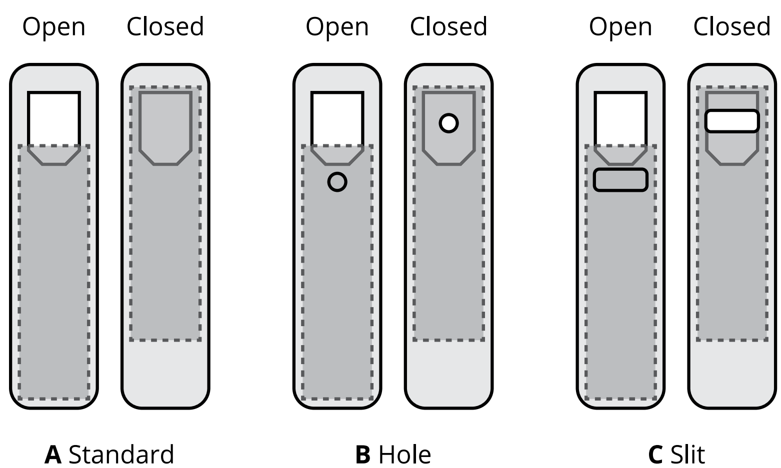


Figure 3: A comparison of standard and modified guillotine vitrectomy cutters. Adapted from Rossi T, Querzoli G, Angelini G, et al. Introducing new vitreous cutter blade shapes: a fluid dynamics study. Retina. 2014;34(9):1896-1904.

The Alcon Vitrectomy Probe Portfolio

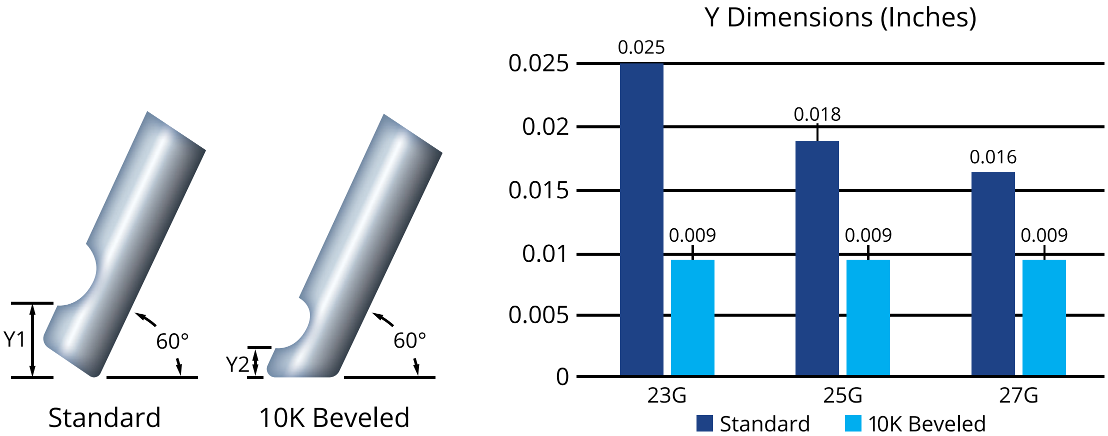
ULTRAVIT

Many of these previously described features have been incorporated into the Alcon Constellation Vision System coupled with the Alcon ULTRAVIT vitrectomy probes. Higher cutting rates can produce higher flow rates with the ULTRAVIT dual-pneumatic actuation scheme because the pulse flow remains constant;[17] single actuation cutters used by other manufacturers produce a decreased duty cycle and, as stated above for the 27+ gauge vitrectomy cutters, decreased flow rates when used at higher cutting rates.[10, 11] Bench research by Dugel et al evaluated two important factors to consider when working near a detached retina: the tissue attraction distance (the distance at which a test membrane is first attracted to the probe port) and sphere of influence (the region around the probe influenced by fluid dynamics) of various gauges of ULTRAVIT probes (Figure 4). This study confirmed, as in previous studies, that vitrectomy with the smaller, enhanced 27+ gauge probe had the shortest attraction distance across all cutting speeds (up to 7500 CPM) and duty cycles. To attract a membrane at a fixed distance, an increased vacuum pressure was necessary with higher cutting rates and smaller probe gauges, however, the flow rate remained relatively constant. They also found that a higher, more 'open', duty cycle was associated with a longer attraction distance than 50/50 or lower, more 'closed' duty cycles. Indeed, selection of duty cycle may improve intraoperative fluid control and expand the cutter's utility to include its use as forceps or as horizontal or vertical scissors for membrane dissection. In essence, this bench study seemed to indicate that the enhanced 27+ gauge probe can function similar to and as efficiently as the enhanced 25+ gauge and 23-gauge probes.[18]

ADVANCED ULTRAVIT

The Advanced ULTRAVIT probe was an evolution in design in that the cutter rate was increased to 10,000 CPM, a larger port opening was introduced and a beveled tip became available. The beveled tip places the cutting port closer to the retina (Figure 4), and coupled with a higher cut rate of 10,000 CPM, computer modeling indicates that retinal traction and backflow through the port as the cutter closes is reduced.[19] González-Saldivar and colleagues recently reported the use of a beveled-tip vitrectomy cutter to perform a 'shovel and cut' technique to address broad diabetic plaques, possibly the most difficult portion of diabetic membrane dissections. Initially, the edges of these plaque can be segmented from the surrounding vitreous and then the beveled tip of the cutter can be used as a 'shovel' to create a tissue plane between the plaque and underlying retina. As a tissue plane is created, the plaque tissue feeds into the cutting port where it is cut at controlled lower flow rates.[20]

Standard Tip vs Bevel Tip — Port-to-Retina Distance



Alcon Data on File, 2017

Figure 4: Distance from port to tip in beveled tip vs standard tip vitrectomy probes.

HYPERVIT

The latest development in the Alcon profile of vitrectomy cutters, HYPERVIT, adds the beneficial effects of a dual blade as described by Rossi and colleagues, above.[15] HYPERVIT is available in both 25+ and 27+ gauges, and embodies all of the technological advancements within a single cutter. With its dual-blade technology, a bevel-tip, dual pneumatic actuation design using the Constellation Vision System and a nearly 100% duty cycle, cutter rates of 20,000 CPM are achievable, which can actually provide increased flow rates compared to their single blade predecessors[21,22] while reducing acceleration of vitreous contents into the cutter lumen,[15] that can provide both efficiency and safety.

Further testing was performed to demonstrate these benefits. In a bench test using a cadaveric porcine vitreous at 650mm Hg vacuum, the 25+ and 27+ gauge HYPERVIT probes result in a 44% and 26% greater maximum flowrate, respectively, as compared to the single-cutter Advance ULTRAVIT 10,000 CPM probes (Figure 5).[21,22] In addition, there was a 28% and 31% reduction in peak traction force in porcine vitreous for the 25+ and 27+ gauge HYPERVIT probes, respectively, compared to the single-cutter Advanced ULTRAVIT 10,000 CPM probes in core duty cycle mode (Figure 6).[23,24] Furthermore, the 25+ gauge HYPERVIT, when compared to the 25+ gauge Advanced ULTRAVIT 10,000 CPM probes, has an 82% decreased pulsatile motion intensity and 46% decreased sphere of influence based on a computer flow model at matched flow rates in a balanced saline solution (Figure 7),[25] which is clinically relevant, as it may be representative of the environment in the eye after the performance of a core vitrectomy.[18] When the maximum vitreous flowrates of the 27+ gauge HYPERVIT is compared to the previous generation 25+ gauge ADVANCED ULTRAVIT as seen in Figure 5 (2.15 vs 2.78 cc/min), they are much more comparable than the corresponding values when comparing the previous generation 27+ and 25+ gauge ADVANCED ULTRAVIT vitreous flowrates (1.71 vs 2.78 cc/min).

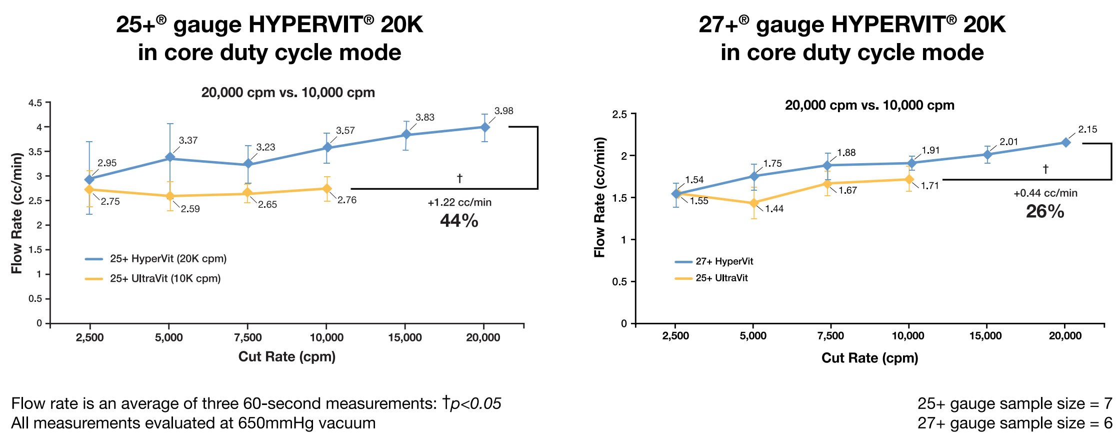


Figure 5: Vitreous Flowrate Comparison of HyperVit 20,000 CPM vs Advanced UltraVit 10,000 CPM Probes.[21,22]

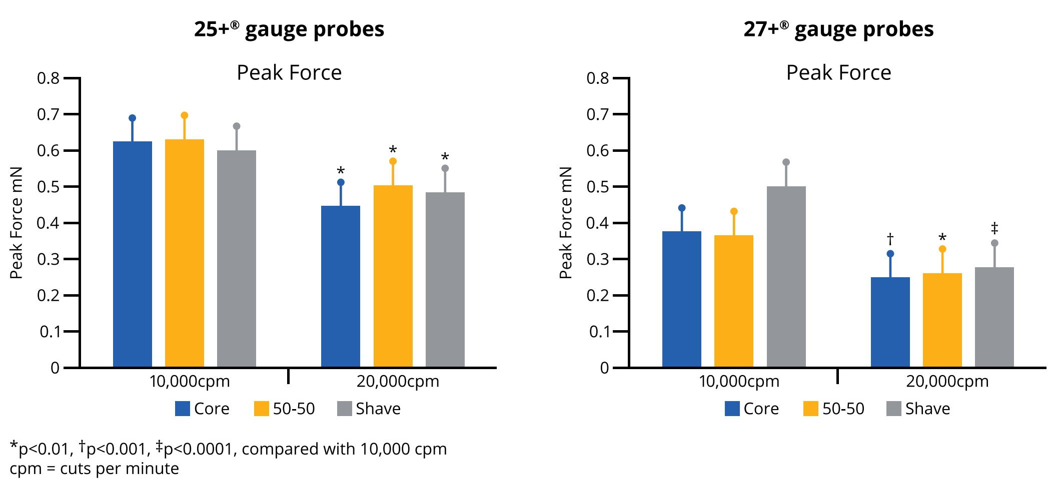


Figure 6: Vitreous Peak Traction Force Comparison of HyperVit 20,000 CPM vs Advanced UltraVit 10,000 CPM Probes at Various Duty Cycles.[23,24]

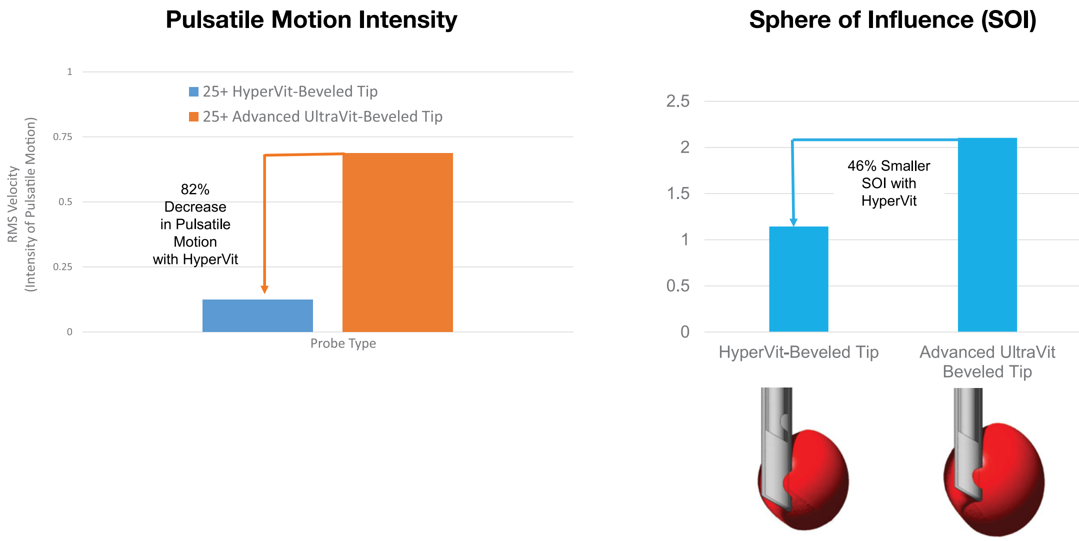


Figure 7: Pulsatile motion and sphere of influence of 25+ gauge HyperVit compared to 25+ gauge Advanced UltraVit.[25] ***Sphere of Influence denoted by red area around the port.***

HYPERVIT, with its dual-blade cutter and 20k cut rate, has the potential to enhance surgical safety and precision. After our initial surgical experience with a handful of cases over the past year at Florida Retina Institute, there are several surgical cases and scenarios that we feel HYPERVIT excels. First, I have been a 25+ gauge user that has been reluctant to switch to smaller 27+ gauge instruments. The time efficiency upon switching was a major impediment to me, as the 27+ gauge ULTRAVIT with 10k cut rates resulted in my vitrectomy times to increase compared to 25+ gauge. However, in similar cases (vitrectomy for floaters, macular holes/puckers), I found that the time efficiency of the 27+ gauge HYPERVIT was on par with the 25+ gauge ADVANCED ULTRAVIT. As a result, the improved efficiency of the HYPERVIT will allow me to incorporate 27+ gauge instrumentation into my armamentarium. In both 25+ and 27+ gauge HYPERVIT, the increased cut rate results in less pulsatile traction, with the potential for less risk of iatrogenic retinal breaks.[11] The sphere of influence is also smaller, thus allowing for removal of vitreous with enhanced precision. Combined with higher cut rates, there is also the potential for enhanced safety with high precision vitreous removal around detached, highly mobile retina.

Another added benefit of the 27+ gauge beveled-tip HYPERVIT is in the setting of diabetic patients with complex tractional retinal detachments. The small gauge instrument with the addition of the beveled tip allows the vitrector to be used as a multi-purpose instrument to segment and delaminate fibrovascular membranes. Whereas, in the past, we often used a combination of the vitrector, scissors, forceps, picks, as well as other advanced techniques (visco-dissection, bi-manual techniques), the large majority of cases can now be successfully managed with just the vitrector and a forcep. The beveled 27+ gauge vitrector functions as a pick, forcep, and scissors all in one. In my experience, the HYPERVIT effectively removes dense fibrous tissue in these cases with ease, notably faster and more precisely compared to the ADVANCED ULTRAVIT.[21-25] As a result, I anticipate that many surgeons will consider incorporating more 27+ gauge surgeries for complex diabetic patients.

Conclusion

Advances in vitrectomy probe technology over the years has been largely influenced by the needs defined by the relatively "new" specialty of vitreoretinal surgery. Knowledge of the history and drivers of technical advancements allow continued collaboration between surgical pioneers and industry to develop the much-needed technological advancements. Research regarding fluidics, cut rates, actuation modes and other functional characteristics of vitrectomy probes has allowed their miniaturization, thereby improving safety, yet has also allowed the ability to create efficiencies with smaller gauge vitrectomy probes.

HYPERVIT encompasses optimal characteristics that allow vitrectomy to be performed in procedures ranging from straightforward core vitrectomies to more advanced diabetic patients with complex tractional retinal detachments. The 27+ gauge HYPERVIT with the beveled tip can be used as a multi-purpose instrument to segment and delaminate fibrovascular membranes in difficult diabetic cases. Overall, precision and speed coupled with improved safety are attractive characteristics of this latest-generation HYPERVIT probe.

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MIVS Important Product Information

Caution: Federal law restricts this device to sale by, or on the order of, a physician.

Indications for Use: The CONSTELLATION® Vision System is an ophthalmic microsurgical system that is indicated for both anterior segment (i.e., phacoemulsification and removal of cataracts) and posterior segment (i.e., vitreoretinal) ophthalmic surgery.

The ULTRAVIT® Vitrectomy Probe is indicated for vitreous cutting and aspiration, membrane cutting and aspiration, dissection of tissue and lens removal. The valved entry system is indicated for scleral incision, canulae for posterior instrument access and venting of valved cannulae. The infusion cannula is indicated for posterior segment infusion of liquid or gas.

Warnings and Precautions:

- The infusion cannula is contraindicated for use of oil infusion.
- Attach only Alcon supplied products to console and cassette luer fittings. Improper usage or assembly could result in a potentially hazardous condition for the patient. Mismatch of surgical components and use of settings not specifically adjusted for a particular combination of surgical components may affect system performance and create a patient hazard. Do not connect surgical components to the patient's intravenous connections.
- Each surgical equipment/component combination may require specific surgical setting adjustments. Ensure that appropriate system settings are used with each product combination. Prior to initial use, contact your Alcon sales representative for in-service information.
- Care should be taken when inserting sharp instruments through the valve of the Valved Trocar Cannula. Cutting instrument such as vitreous cutters should not be actuated during insertion or removal to avoid cutting the valve membrane. Use the Valved Cannula Vent to vent fluids or gases as needed during injection of viscous oils or heavy liquids.
- Visually confirm that adequate air and liquid infusion flow occurs prior to attachment of infusion cannula to the eye.
- Ensure proper placement of trocar cannulas to prevent sub-retinal infusion.
- Leaking sclerotomies may lead to post operative hypotony.
- Vitreous traction has been known to create retinal tears and retinal detachments.
- Minimize light intensity and duration of exposure to the retina to reduce the risk of retinal photic injury.

ATTENTION: Please refer to the CONSTELLATION® Vision System Operators Manual for a complete listing of indications, warnings and precautions.

Alcon Medical Affairs