

# **Millennium™ TSV25:**

**System Enhancements Bring Added Safety,  
Efficiency and Ease-of-Use to 25-gauge Vitrectomy**

**Brian D. McCary, BSEE; Daniel C. Splinter, BSEE;  
Keith H. Edwards, BSc FCOptomDip CLP FAAO, Bausch & Lomb**

## Overview

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The Millennium™ Transconjunctival Sutureless Vitrectomy System (TSV25) represented a revolutionary advance in posterior segment surgery when Bausch & Lomb introduced it in 2001. Several peer-review papers have confirmed that three-port, 25-gauge pars plana vitrectomy simplifies opening and closing the eye for the surgeon, minimizes surgical trauma for the patient and can be used for most posterior segment surgeries.<sup>1-6</sup>

During 2005, Bausch & Lomb is introducing a series of innovations for the TSV25 to enhance the system's precision performance and ease of use. Redesigned hand-pieces for all the components are smaller, lighter and more ergonomically shaped. In the Entry Site Alignment (ESA) system, a tighter trocar-cannula fit and a beveled microcannula tip reduce by 40% the force necessary to make incisions, as well as preventing tube buckling. Redesigned microcannula hubs and plugs are less reflective and easier to grasp. A larger hub opening facilitates insertion of the 25-gauge instruments.

Once inside the eye, surgeons will be able to accomplish the vitrectomy with tools that have been designed for superior control and maximum efficiency. The improved TSV25 light pipe produces a more even light field, 50% brighter and covering 30% more area. The light pipe has also been stiffened so that it can be used to position the eye during surgery. The redesigned Millennium high-speed electric vitrectomy cutter weighs 20% less and fits more comfortably in the hand. The aspiration line is recessed into the handle to lower the line's visual and tactile profile. A soft silicone tip on the aspiration cannula gives added safety when working near the retina.

These modifications are part of what will be a continuing stream of modular improvements to this system, and will enhance the value of tractionless 25 gauge vitrectomy and should improve surgical outcomes with the TSV25 for today's vitreoretinal surgeons.

## Background

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More than three decades ago, the pars plana approach began transforming vitrectomy from an "open sky" surgery, used for very few indications, to an essential procedure for treating a wide variety of vitreoretinal disorders. The first instrument for pars plana vitrectomy was a 17-gauge combination vitreous cutter, aspirator, irrigator and fiberoptic light described by Machemer et al. in 1971; it required a single, 2.3-mm scleral incision.<sup>7</sup> O'Malley and Heintz refined the instrumentation with a three-port system featuring a 0.9-mm diameter vitrector.<sup>8,9</sup> With various improvements since then, 19- and 20-gauge versions of this system remain in use today for the large majority of the vitrectomies performed worldwide.

Vitrectomies with 20-gauge instruments require a conjunctival peritomy, three 1-mm scleral incisions and multiple sutures. This procedure could cause more surgical trauma and necessitate a difficult rehabilitation course, including post-operative inflammation, surgically induced astigmatism, ocular irritation from the sutures, and an extended period before the patient's eye heals enough to recover visual acuity. Therefore vitreoretinal specialists have looked forward to a day when smaller, self-sealing incisions would make vitrectomy easier and better for doctor and patient alike.

In 1996, Chen reported success with using scleral tunnel incisions to eliminate the need for sutures after vitrectomy,<sup>10</sup> and modifications of this technique remain in use today.<sup>11-16</sup> However, there were reports that up to 20% of such sclerotomies failed to seal without suturing,<sup>17</sup> and that instruments were difficult to insert into the eye via the tunnels.<sup>16</sup>

After more than a decade of research on reducing vitrectomy instruments to 25-gauge size,<sup>18</sup> a group led by Eugene de Juan Jr., MD, and colleagues developed an alternative approach to self-sealing incisions: a three-port, 25-gauge (0.5 mm) microcannulated vitrectomy system. Their method of closed intraocular microsurgery used transconjunctival stab wounds, microcannulas for keeping the incisions open and providing ocular access, and a high-speed electric vitreous cutter for maximum efficiency. Bausch & Lomb introduced this system into the market in 2001 as the Millennium™ Transconjunctival Sutureless Vitrectomy System (TSV25).

Clinical experience has shown that, compared to standard 20-gauge surgery, the transconjunctival vitrectomy method using TSV25:

- Reduces the time it takes to open and close the eye, without significant changes in total surgical time and without increased complications.<sup>2,5-6,19-20</sup>
- Rarely requires any sutures in adults (7.1% incidence in the most recent published study<sup>6</sup>), and then usually at only one site through which extensive manipulation was done or a larger-gauge instrument had to be used.
- Produces less ocular trauma, leading to a normal-appearing eye soon after surgery<sup>2,5,6</sup> and faster healing. Independent research has shown the TSV25 trocar makes smoother incisions than a competitive 25-gauge system, and that the wounds heal in the first month to six weeks after surgery.<sup>21</sup>
- Causes less postoperative inflammation and surgically induced astigmatism.<sup>2,6</sup>
- Can be used for a wide variety of conditions, including macular holes, puckers, retinal detachments and moderate macular epiretinal membranes,<sup>1,6</sup> as well as for vitreous loss after cataract surgery.<sup>19,20</sup>
- Preserves an intact conjunctiva in patients who are at risk of needing glaucoma filtration surgery, or preserves filtering blebs in those who have already had such surgery.<sup>22,23</sup>

- Is especially suited to pediatric eyes (without dense fibrous proliferation) because the instruments are so small. Infants' eyes do require limbal peritomies, however.<sup>5,24</sup>
- Appears to pose no greater risk of endophthalmitis than conventional vitrectomy, though longer follow-up is necessary.<sup>1,5,20</sup>

TSV25 is a pioneering technique that many believe will become to 20-gauge vitrectomy what no-stitch cataract surgery already is to the cumbersome extracapsular cataract extraction (ECCE). Early clinical resistance to phacoemulsification through small, self-sealing incisions transformed into acceptance as instruments improved and the advantages for the patient became clear. Experienced 25-gauge vitreoretinal surgeons predict that, likewise, colleagues who try 25-gauge surgery eventually will find themselves doing almost all their vitrectomies in this way, because of the visible benefits it provides to patients.

## TSV25: The Entry Site Alignment (ESA) System

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The prerequisite for transconjunctival sutureless vitrectomy is the ability to enter the eye efficiently, through a 0.5-mm incision that stays open throughout the procedure but self-seals afterward. TSV25 accomplishes this with the Entry Site Alignment System (ESA), whose main function is to maintain a clear channel between offset conjunctival and scleral entry sites.

The heart of the ESA is a polyimide microcannula (inner/outer diameter of 0.57/0.62 mm) with a polymer hub, loaded onto a single-use trocar with a hollow, beveled needle. The ESA comes prepackaged with three trocars, 3 cannulas mounted on the trocars, 3 cannula plugs and an infusion line.

Immediately after inserting the trocar/microcannula tip through the eye wall, the surgeon holds the microcannula's external hub in place and withdraws the trocar. The cannula sits securely in the eye wall without suturing, and its orifice can be closed with a plug as needed. Typically, a 5-mm long infusion cannula (inner/outer diameter 0.37/0.56 mm) is inserted into a first microcannula, the TSV25's fiberoptic light pipe passes through a second microcannula and the Millennium high-speed electric vitreous cutter or other instruments are inserted through a third. In pediatric eyes, a two-port technique sometimes is used.

The average time for experienced surgeons to place three ESA microcannulas has been measured at 1 minute, 36 seconds (+/- 13 secs), about a third of the mean achieved in 20-gauge surgery ( $p < 0.001$ ).<sup>1</sup> In the same study, the mean time for closing the eye was measured at 17 minutes, 17 seconds (+/- 1 min, 48 secs), compared to 26 minutes, 7 seconds (+/- 2 minutes, 45 secs) for 20-gauge vitrectomy ( $p = 0.011$ ). Total procedure time was comparable between the two techniques.

## ESA enhancements

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As part of its continual efforts to improve the efficiency and ease of use of its products, Bausch & Lomb is introducing several enhancements to the ESA during 2005.

- **Easier cannula insertion**

Some surgeons have reported difficulty with inserting the first-generation ESA's trocar/microcannula assembly through the sclera.<sup>25</sup> This difficulty can be overcome with a slight rotation of the trocar during insertion.<sup>26</sup> However, the second-generation ESA has been revised to eliminate the need for this maneuver. These changes facilitate cannula insertion, and have been shown<sup>27</sup> to reduce the necessary insertion force by 40%:

**Beveled cannula** - The microcannula remains slightly larger than the trocar needle's 24½-gauge incision. This is necessary to prevent the cannula from dislodging during surgery. But a 30-degree bevel has been added to the cannula to help ease it into the smaller trocar needle's incision.

**Tighter fit between trocar and cannula** - The gap between the trocar and the cannula's inner surface has been reduced from 0.0025" to 0.0010". This smaller gap decreases the size of the "step" around the trocar needle that must be pushed through the incision to position the cannula securely.

**Less chance of buckling** - The smaller gap between trocar and microcannula creates a combination with more column strength than in the first-generation ESA. As a result, the trocar provides better support to the cannula when it is under load. This has reduced by 90% the chance that the cannula tubing will buckle during insertion.<sup>28</sup>

- **More ergonomic handle**

Gentle curves and strategically located ridges have been added to the trocar handle, providing better comfort and enhanced control when the surgeon grasps the trocar.

- **Integrated marker system**

The top of the ESA's redesigned trocar handle incorporates two posts that can be used to measure the distance of incisions from the limbus. This eliminates the need for a second marking instrument. The distance between post centers is 3.5 mm, between the inside of the posts is 3.0 mm, and between the outside of the posts is 4.0 mm.

- **Grasping grooves**

New grooves on the external portions of microcannula hubs and plugs make them easier to handle and remove, either with B&L's reusable, cross-action forceps or with the surgeon's existing 20-gauge scleral plug forceps.

- **Bigger hub opening**

A 33% larger opening in the cannula hub makes it easier to insert the delicate instruments designed for use in 25-gauge surgery. The hub opening also is funnel-shaped for this reason, as it was in the first-generation ESA.

- **Revised hub surface**

The color of the cannula hub in 25-gauge transconjunctival vitrectomy affects the ease of instrument insertion as the instrument designers at the Microsurgery Advanced Design Laboratory at the Doheny Retina Institute, University of Southern California found in their laboratory comparisons.<sup>28</sup> If the hub is black, the hole is difficult to see. If the hole is white, visualization of the hub portal is excellent. However, white coloring and a glossy finish on the hub can cause a flash of bright light into the microscope when the surgeon inserts the fiberoptic light pipe. Cannula hubs in the second-generation ESA have been given a slight texture and gray color to reduce the flash effects; plugs remain blue.

## Light Pipe Enhancements - Brighter, Wider Illumination

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Endoscopic illumination for 25-gauge intraocular surgery poses special challenges for biomedical engineers. Since the earliest days of pars plana vitrectomy, it has been known that the fiberoptic light needed to be filtered and modulated to avoid retinal phototoxicity from blue and ultraviolet light.<sup>29</sup> So, though vitreoretinal surgeons must have enough light over a large enough field to work inside the eye, the fiberoptic's spot cannot be too intense. Surgeons familiar with 25-gauge endoilluminators have said the light from the first generation of these light pipes is adequate, but needs to be better.<sup>6,31</sup>

The second-generation TSV25 light pipe has been designed to provide bright but safe illumination for excellent surgeon visualization. It uses the same metal halide light source as its predecessor, but an acrylic light fiber transmits more light and is more flexible than the glass fiber that previously was used.<sup>27</sup> The new TSV25 light pipe is 50% brighter and the light field is 30% bigger (measured at 2") than the earlier version.

In laboratory studies, the new light pipe produced a more evenly illuminated field of light, without noticeable shaded areas or spots, than two other 25-gauge light pipes tested. Its light output was up to 15% greater than that of a leading competitor.<sup>27</sup>

Additional revisions in the light pipe's design make it easier to use and more comfortable to handle during surgery. The new pipe attaches to the dual port illumination module via a precision-molded, modular connector with an integrated centering ring. The light pipe handle is smaller, increasing surgeon comfort. Using acrylic for the fiberoptic and polyethylene for the sheath makes it more flexible than its predecessor. This quality makes the light pipe easier to coil and uncoil, and reduces torque on the handle. The shorter length of the light-pipe's handle also reduces torque.

## Better Eye Positioning

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During 20-gauge vitrectomies, surgeons are accustomed to using the fiberoptic light pipe to position the eye, particularly when working in the retinal periphery. The increased flexibility of 25-gauge instrumentation heretofore has made this more difficult to accomplish.<sup>6,26,30,31</sup>

The new TSV25 light pipe addresses this problem by adding a stiffening sleeve between the pipe and the ESA microcannula. Mathematical modeling shows that, under equivalent conditions, this would increase the pipe's perceived stiffness by 118% from the previous version, and by 50% compared to a leading competitor.<sup>32</sup> This change will make it possible for the surgeon to rely on the light pipe to manipulate the eye during surgery. Vitreoretinal surgeons who have worked with the new light pipe confirm this characteristic.<sup>27</sup>

## Soft Tip Aspirator

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A new soft silicone tip for the aspiration cannula enhances extrusion of oil used for tamponade, and gives added safety when working near or on the retina.

## Millennium High Speed (HS) Electric Vitreous Cutter - A Lighter, Easier to Handle Vitreous Cutter

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The Millennium High-Speed Vitrectomy Cutter remains the only 25-gauge vitreous dissector that operates electrically, rather than pneumatically. The speed of this unique vitreous cutter not only makes 25-gauge vitrectomy take less time than it otherwise would, but also reduces traction on the retina by taking quick "bites" of tissue.

During the course of 2005, B&L is introducing a series of design improvements that will enhance the vitrector's ease-of-use.

**Redesigned handle** - After consulting vitreoretinal surgeons the handle's weight was reduced by 20%. It also was given a more ergonomic shape, with grooves in the grip area, for a better tactile feel and easier handling. It is also smaller, which reduces arm movement and lessens cord torque. Thus it is easier and more comfortable to use, and is less likely to interfere with the microscope or BIOM viewing system.

**Cord management** - The aspiration line is recessed into the handle surface, lowering its profile for the surgeon.

## Why an Electric Cutter?

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The pneumatic vitreous cutter first described by O'Malley and Heintz in 1975 proved to be the key piece of instrumentation behind more than a quarter-century of 19- and 20-gauge vitrectomies.



Air moved the vertical blade down, guillotine-like, with mechanical energy supplied by a remote unit.<sup>9</sup> This design, widely adopted, still makes it possible for a pneumatic cutter to be smaller and lighter than a cutter with an electric motor in the hand-piece, such as the Millennium TSV25's High Speed vitreous™ cutter. However, the smaller size of a pneumatic cutter comes at a cost, including:

**Flow rate:** In the lab, the average flow rate of the Millennium 25-gauge high speed cutter, set at 500 mmHg and 1,500 cuts per minute (cpm), is 40% greater than that of a 20-gauge pneumatic cutter operated at 250 mmHg and 750 cpm. At those same settings, if both cutters are 20 gauge, the high-speed electric cutter removes vitreous 88% faster than the pneumatic cutter.<sup>1</sup>

This wide difference in efficiency between an electric and a pneumatic cutter occurs when, because of inherent mechanical limitations, a pneumatic cutter cannot maintain a high duty cycle as the blade speed increases. This reduces the flow rate and thus the efficiency of cutting and aspiration. In contrast, as the Millennium HS vitreous cutter increases its speed to as high as 1,500 cpm, flow remains the same because the aspirator's open time (duty cycle) remains at 50%.

This difference between the two types of cutters takes on additional importance in 25-gauge surgery, because infusion and aspiration rates already are reduced by a factor of more than 6 compared to 20-gauge surgery.<sup>1</sup> The Millennium HS cutter enables the surgeon to take optimal advantage of state of the art Venturi fluidics for maximum efficiency.

In an independent study, vitreoretinal surgeon Philip J. Ferrone, MD, of Great Neck, N.Y., confirmed the better flow characteristics of the TSV25 system with the Millennium HS electric cutter. Dr. Ferrone tested TSV25 performance against that of a pneumatic 25-gauge system (Accurus, Alcon). In vitrectomy on rabbit eyes, Dr. Ferrone found the flow was 50% higher at 1,500 cuts per minute for the B&L unit than the Alcon (2.9 cc/min vs. 1.9 cc/min, p=0.023).<sup>21</sup>

**Vibration at the tip:** The same mechanical forces that limit flow rate for a pneumatic cutter also produce more vibration at the tip than occurs with an electric cutter. Although the Millennium HS cutter moves vertically at up to 1,500 cpm, vibration at the cutting tip is reduced 90% from that of a pneumatic cutter.<sup>26</sup> Less vibration equals less tissue motion, allowing safe, precise removal of vitreous even as the cutting tip approaches the retina.

## The Surgeons' Viewpoint

Vitreoretinal surgeons who have used the TSV25 praise the system for its efficiency, the precision control it gives inside the eye, and the post-operative comfort it provides patients. The TSV25 enhancements make the system easier and more comfortable to use, especially for those new to 25-gauge surgery, these experienced surgeons say.

David Chow, MD, FRCSC, of Chicago, said that in his clinical use the redesigned Entry Site Alignment (ESA) system has proved much easier to insert into the eye than the earlier version.<sup>33</sup> "With vitreoretinal surgeons who haven't adopted 25-gauge, one of their main concerns is difficulty working with the technology," Dr. Chow said. "This generation of microcannulas definitely gets rid of that problem. The new ESA will make people feel more at ease. It has a slicker, more even feel going into the eye."

Carl Awh, MD, of Nashville, Tenn., estimates that he has done 600 TSV25 over the last three years, and rarely had difficulty inserting the microcannulas.<sup>34</sup> However, he said he immediately noticed the improvements in the second-generation trocar/cannula assemblies.

"They definitely were easier to insert, yet they remained very secure in the eye, and the wounds were appropriately watertight on removal," Dr. Awh said. "I've used them with and without gas, and the incisions sealed fine in all cases."

Dr. Awh said he suspects that need for a stitch as a result of wound leakage is low with TSV25 (1.3% in a multi-center study he presented at the 2002 Combined Meeting of the Vitreous and Retina Societies,<sup>35</sup> and 7.1% in the most recent published study<sup>6</sup>). He attributes this to the very "clean" sclerotomies, without ragged edges, made by the ESA. He cited the study done in rabbit eyes by Philip J. Ferrone, MD, reported at the Vail Vitrectomy 2004 meeting.<sup>21</sup>

Dr. Ferrone, of Great Neck, N.Y., compared *in vivo* results with TSV25 and a competitor's 25-gauge vitrectomy system. In addition to having better flow (2.9 cc/min vs. 1.9 cc/min at 1,500 cpm), the TSV25 system produced wounds that healed better.<sup>21</sup> The Millennium HS cutter uses a hollow needle; whereas Accurus uses a solid needle.

### Wound Healing - Three Week Data Ferrone Rabbit Eyes



Vitrectomy using 20-gauge



Vitrectomy using 23-gauge



Vitrectomy using competitive 25-gauge



Vitrectomy using Millennium TSV25

"The wound healing is better with the B&L type entry," Dr. Ferrone said. "The other company's trocar went in more easily, but the wounds in general did not appear to heal as well."<sup>36</sup>

This year, Dr. Ferrone repeated his study using the second-generation ESA. His results are expected to be at the 2005 summer meeting of the American Society of Retinal Surgeons. Early indicators suggest that the wound-healing difference between the systems will persist, Dr. Ferrone said.

Dr. Awh said he performs about 75% of his vitrectomies using the 25-gauge technique - all of them with the TSV25 because he prefers the Millennium HS cutter's precise, tractionless and efficient performance.

"I have the other 25-gauge system available, but there is a real difference in the cutter," Dr. Awh said. "The Millennium HS cutter is the most efficient of the 25-gauge cutters, and it's far superior to a pneumatic cutter. With a pneumatic cutter, when you go up in the cut rate, the lumen is open a smaller percentage of the duty cycle. And therefore the flow drops, and so does the efficiency."

At the same time, the surgeon can choose to use the Millennium HS cutter at very low flow and gain even more precise control within the eye, Dr. Awh said. "With the high-speed cutter and the ability to effectively remove tissue at very low flow, it allows me to use the cutter to do a lot of delicate dissection close to the surface of the retina - in situations where I might have used scissors before," he said. "The delicacy of 25-gauge allows me to maneuver the cutter tip into areas inaccessible with the 20-gauge cutter."

Of course, a 25-gauge needle is so small that no vitrector of that size can ever perform vitreous removal as quickly as a 20-gauge system can, Dr. Chow noted. Nor will it be able to handle every case. "If you have a thick, thick scar, you are going to have a harder time getting that tissue removed. That's something physics can't overcome," he said. "But the reality is that most fibrous membranes aren't of a quality that a 25-gauge cutter can't handle them."

Better patient comfort and quick visual recovery after 25-gauge vitrectomy have convinced Dr. Awh that 25-gauge surgery represents the best option for most patients.

"Even if I know the case might take me a little bit longer, I feel that it is better for the patient," he said. "On average, my macular epiretinal patients achieve better-than-preoperative vision by one week after 25-gauge surgery, two weeks at the most. With 20-gauge, those same patients would have to wait eight or 10 weeks while their stitches dissolve and the induced astigmatism resolves."

Another advantage of 25-gauge surgery is preservation of the conjunctiva in patients with glaucoma filtering blebs or in those who might later require glaucoma filtration surgery, Dr. Awh said. He was co-author of a study presented by Brandon Busbee, MD, also of Nashville, demonstrating 100% preservation of functioning glaucoma blebs in a series of nine eyes operated on with the TSV25 system.<sup>37</sup> That's why, even when he thinks one sclerotomy might need enlarging to accommodate a larger instrument, such as submacular forceps, he begins with 25-gauge microcannulas.

Dr. Ferrone credits new instruments, like the enhanced TSV25 light pipe and specialized scrapers and scissors, for removing the main barrier to 25-gauge vitrectomy: the availability of adequate instrumentation. "In the past, you were looking for clinical cases that would fit within the 25-gauge realm. Now it's the opposite," he said. "Most cases are in the 25-gauge realm, and only a few cases require 20-gauge instrumentation."

To a surgeon feeling trepidation, Dr. Awh has this advice: "If you're not certain, spend some time with someone who is experienced and make a decision about 25-gauge after observing some cases.

"I've had many visitors to my operating room, and I don't think we've ever had a surgeon come and watch who didn't leave wanting to try this for his or her own patients. And people who have examined my patients with me postoperatively understand the benefits right away."

## Conclusion

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The second generation of the Millennium™ Transconjunctival Sutureless Vitrectomy System (TSV25) will give vitreoretinal surgeons enhanced levels of control, safety and efficiency in 25-gauge posterior segment surgery.

The Entry Site Alignment (ESA) system's redesigned trocar/microcannula assemblies reduce the force necessary to make incisions by 40%. Cannulas and their plugs are easier to grasp and to see. The light field produced by the new TSV25 light pipe is 50% brighter and covers 30% more area than the earlier version. The light pipe also can be used to position the eye in the same way as is customary in 20-gauge surgery. The weight of the Millennium high speed electric cutter has been trimmed 20%, reducing this highly efficient instrument to a size and shape that fits more comfortably in the hand.

These enhancements to the versatile Millennium platform eliminate many of the barriers to 25-gauge vitrectomy, giving surgeons a high-precision platform for minimally invasive posterior segment surgery with exceptional patient outcomes.

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