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Section Editor

PART 3 IN A SERIES

How Will Hypersonic Vitrectomy Affect the Surgical Landscape?

Rarely do technologies appear that may shift not only our behavior, but our thought process—and all developments to come. If such disruptive technology causes a paradigm shift, we can often point to a seminal period of time, one usually filled with criticism and obstacles.

We witnessed such a time during a paradigm shift from extracapsular cataract surgery to phacoemulsification. Many have since tried to recreate this seismic shift. In part 3 of our surgical innovation series, 3 world-renowned surgeons discuss the potential for hypersonic vitrectomy to be either a "game changer" or another "try."

Panelists:

Carl C. Awh, MD
Tennessee Retina
Nashville, Tennessee

Kourous A. Rezaei, MD
Illinois Retina Associates
Rush University Medical Center
Chicago, Illinois

Tarek S. Hassan, MD
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'Hypersonic vitrectomy is a new method of vitreous removal in which ultrasonic power is used to drive the vitrectomy cutter tip.'

—Carl C. Awh, MD

Pravin Dugel: In the first part of the series, we talked about how far we have come—essentially, all the advances we've made. In the second part, we talked about the gap between countries with resources and those that may have resource challenges related to our future technology. Now I'd like to talk about what you see as the most consequential things in the pipeline, and I'd like to focus on vitreous cutting, and on visualization.

Let me start with vitreous cutting. Carl, for many decades, we have talked about cutting the vitreous faster because we want to reduce traction, but you have been working on something that may change our entire paradigm, and that's hypersonic vitrectomy. Can you describe what that is, and what its significance may be in terms of the way we look at removing vitreous?

Carl Awh: *Hypersonic vitrectomy* is a new method of vitreous removal in which ultrasonic power is used to drive the vitrectomy cutter tip. Rather than the conventional guillotine-type cutter, which has an outer tube with a port in it and an inner tube that moves up and down—thereby cutting tissue pulled into the port like a guillotine blade—the hypersonic vitrector utilizes a single lumen tube, sealed at the end and with a port cut into the side.

The hypersonic vitrector tip oscillates at a frequency of around 1.7 million "cuts" per minute. This creates an effect that causes tissues to be emulsified at the port, a phenomenon we refer to as *hypersonic liquefaction*. The emulsified material is drawn up through the vitrector by traditional vacuum and removed from the eye. The manner in which the hypersonic vitrector disrupts and liquefies the vitreous is fundamentally different from the mechanism of conventional guillotine-style vitrectomy cutters.

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Another important difference: This disruptive effect seems to occur at the *surface* of the instrument, meaning that tissue does not have to be pulled into the port (as with guillotine cutters) before being cut. In theory, this will provide additional reduction in vitreous traction. Also, the hypersonic vitrector's port size and location can be altered with much more freedom than with a guillotine cutter, which will allow us more freedom to design probes with novel geometries.

The first human trials were just completed, a series of around 20 cases performed by 3 surgeons in India. The initial results were positive, and I hope to be using the hypersonic vitrector for the first cases in the United States by October 2017. Our goal will be to explore the safety, efficacy, and any limitations of this new technology. Because we now have a new set of variables—such as ultrasound stroke length, power cycle, port geometry—much work will be needed to understand how to harness the potential of hypersonic vitrectomy.

Pravin Dugel: Carl, it sounds like a fascinating new paradigm. For those of us who are not engineers, what does that mean? If everything goes according to plan, what are the potential advantages of this new type of cutting—and I'm not even sure if *cutting* is the right word—maybe the right term is *new paradigm*—for removing the vitreous? What are the potential advantages and disadvantages?

Carl Awh: One of the principal advantages of current high-speed vitrectomy cutters is that the faster we're able to move the cutting element, the smaller the bits of vitreous we can remove. This reduces the friction with which cut material moves up the cutter shaft, up the tubing, and into the machine—and that's what has made small-gauge vitrectomy increasingly effective, even at 27 gauge.

With the hypersonic vitrectomy cutter, which creates *hypersonic liquefaction,* the disruptive effect on the vitreous is an order of magnitude of improvement, creating even tinier bits of collagen and material for aspiration, so it behaves like liquid as it is aspirated. This effect has been elegantly demonstrated in electron micrographs of vitreous after removal by hypersonic vitrectomy and compared to that removed by conventional high-speed cutters.

With conventional cutters, short strands of collagen are present throughout the aspirated material, but with the hypersonic vitrector there are virtually no recognizable collagen strands—only tiny "dots" of material. This effect may allow more improvements in flow through even the tiniest-gauge devices.

Also, because the liquefaction occurs at the surface of the port, this device may provide a better way of membrane dissection near the retina. If we can effectively cut tissue without having to first draw it into the port, as with guillotine-type cutters, this should reduce unwanted retinal traction. This may also provide benefit during simple vitrectomy, because of the incremental decrease in the distance vitreous need to travel into the port before being cut or emulsified.

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>
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I don't know whether that theoretical advantage will translate into anything of practical value, because even in an eye devoid of vitreous and filled only with fluid, we must always create some amount of pull, or traction, toward the port in order to engage the target tissue. However, the evolution of vitreous cutters has been driven in part by a desire to reduce vitreoretinal traction, and I think that hypersonic vitrectomy has the potential to do so.

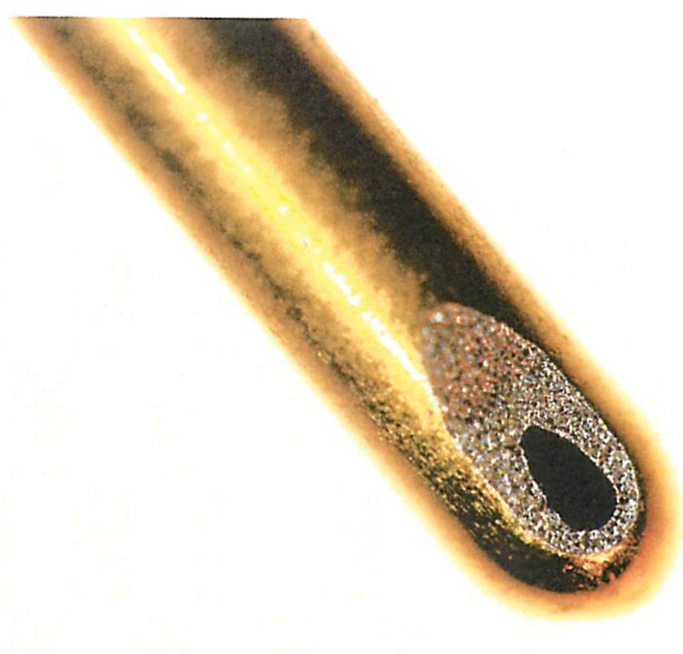
Pravin Dugel: Carl, I think this is extremely exciting. I can't wait to try it myself. I know Bausch + Lomb has this technology, and I know you're familiar with it. Let me ask you the flip side: What potential disadvantages do you see?

Carl Awh: The biggest potential disadvantage is that the hypersonic vitrector may not work as well as conventional vitrectomy cutters in certain settings. For example, there's not a good laboratory model for the dense, fibrovascular membranes we encounter in a difficult diabetic traction detachment. We know that pneumatic cutters can deal with most of these effectively, but we have yet to use the hypersonic vitrector in these types of cases.

I think the hypersonic vitreous cutter will also work to cut thick membranes, but until we actually try it in a human, we won't know. As I mentioned, we plan to try the device in a wider range of pathologies and hope to have more to report soon. We may also find that the tip design that we are using for our initial cases, as well as the hypersonic drive settings, need modification or refinement to allow us to realize the full benefits of the technology. There's a lot to learn!

Pravin Dugel: Yes, and I asked you about potential disadvantages, and certainly, none of these things are realized, but thank you for that.

Tarek, when you hear Carl talking about this—and I know you're also familiar with this technology—are you as excited as he is and I am in terms of possibly having a new paradigm for removing vitreous?



This Bausch + Lomb Vitesse™ hypersonic vitrector tip is one of several tip and port designs being evaluated. Image is provided compliments of Bausch + Lomb—no endorsement or affiliation with the Publisher and/or Authors is implied.

Tarek Hassan: I'm certainly excited anytime anyone talks about a new paradigm for anything we do. Maybe I'm taking a bit more of a wait-and-see attitude as far as its clinical applicability. I'll be excited about the hypersonic vitreous cutter if the direction taken is somewhat different than that which we follow now. But if this is a new device that we are going to use in the same way that we use our existing vitreous cutting systems, then I'm not sure how much additional value it will provide.

I hope I'm wrong because I love new things and I love the concept of potentially doing things more safely with higher vitreous cut speeds but I'm not convinced that we have a significant problem with traction at cut speeds of 7500 or 10,000 cuts per minute with our current devices. Where I do think…

Pravin Dugel: So, let me stop you there because that's an interesting statement. You said, "I don't think we have a big problem with traction cutting at our current cut speed, which is 7500, maybe even 10,000 cuts per minute." So do you think we've reached the ceiling for how fast we need to cut with a guillotine-type system? And is traction no longer much of an issue of concern?

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> —Tarek S. Hassan, MD

Tarek Hassan: I think that's a complicated question. I would love a machine that cuts at a million cuts per minute because it's not for me to make the machine, right? So, if a company wants to spend its development money on making a machine that cuts 20,000 or 30,000 cuts per minute, all the better, because we do things because they are theoretically, or actually, safer. If someone's going to give us a machine that meets even the theoretical standards of improved safety, I'm going to use it.

Pravin Dugel: But are you going to pay more money for it?

Tarek Hassan: That's a good question. I don't know if I would pay more. Given current skill levels and training methods and the ubiquitous nature of good vitreous technique, do I believe there has been an incremental improvement in safety because of decreased traction as we increased our cut rates from, say, 7500 to 10,000? I'm skeptical.

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Pravin Dugel: So, if you had a dollar to spend, would you not spend that dollar on reducing traction? Would you say, "I'd rather spend the dollar somewhere else" because this comes with a price?

Tarek Hassan: I would absolutely spend a dollar for it; the key question is how much more money I would spend for it. We would likely all pay to reduce traction. But, A) would it reduce traction beyond theory? and, B) would it reduce traction to a point where it's clinically significant, where it makes a difference in what I'm doing? Would I be a better, safer surgeon if I were cutting at 12,500 rather than 10,000? That stuff is theory. I will pay for theoretical safety. But the question is, how much will I pay for theoretical safety and what will we do as a specialty to demonstrate that we are actually getting reduced traction and increased safety?

I think this is really an exciting new technology if we change the paradigm of how we work. Something that could actually liquefy vitreous could be applied to solve issues of vitreous removal, maybe not even in the operating room. Perhaps we can do things at 35 gauge or 40 gauge, tiny little incisions, because we can safely liquefy vitreous.

I think it's exciting to hear about the applicability of such amazing technology to a different paradigm that includes new ways of approaching cases surgically and from a procedural perspective. Everything is incremental and you've got to take baby steps, so I'm completely on board and supportive of the direction that this new technology is going, but I don't see it as a breakthrough until we actually do something different with that device—particularly if it doesn't cut tissue as well as the standard guillotine cutter.

Pravin Dugel: Tarek, you make some excellent points; Kourous, let me turn to you and try to extrapolate on Tarek's points. He's told us there are 2 things you've got to look at—one is the cut rate, and the other is an entirely different paradigm for vitreous liquefaction, and these are 2 essentially separate discussions. I know they are intertwined in this device, but they are distinct discussions, so let me take them separately.

Let me talk about a cut rate first. Do you feel that we've hit a ceiling as far as the cut rate is concerned, and whether you cut at 7500 or 10,000 or 20,000 may not make that much of a difference because traction is not that much of a problem? When you think about our resource dollars, there are only certain things that we can spend those dollars on. Would you rather like to see dollars spent somewhere else than to simply increase the cut rate to decrease traction, Kourous?

Kourus Rezaei: I don't think the technology and its advancement work that way, because during the time when ophthalmologists were performing extracapsular cataract surgery, if you were to ask them whether they would like to switch to phacoemulsification, they would have said no—that they were comfortable with extracapsular cataract surgery and did not see any need for change.

It was the same with 25 gauge when it was introduced. Retina surgeons were comfortable with 20 gauge; and did not have any problems. I think at this stage, it's difficult to judge because we don't know much about hypersonic technology. However, I agree that retina specialists are always excited when new technology arrives and they like to embrace it because retina is a technology-driven field.

The 2 key points are whether one can use smaller-gauge instruments with the hypersonic probe without sacrificing performance, and whether the use of these smaller instruments with hypersonic technology would allow us to operate in our offices or would induce a paradigm shift on how we operate, which is very exciting.

Further, if this technology allows you to save time during surgery and spend less time in the eye, which indirectly translates to a safer surgery, it would be advantageous. But I think you would know more when you try the new instrument and compare it with your current technology to see whether it provides enough advantage to you to change, purchase, and invest. Does that answer your question?

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> —Kourous A. Rezaei, MD

Pravin Dugel: Yes, it does. I'm excited about this technology; this is a really interesting discussion because I think Tarek is right. If this hypersonic technology is such that you simply increase the cut rate, it may not quite be as exciting, but on the other hand, Carl has taught us it's not just about increasing the cut rate. You can have a million cuts a minute. It's an entirely different paradigm in terms of talking about how the vitreous is removed.

The fact that you can then use that as the first step toward having the port in many places, anywhere you wish, cutting the vitreous in an entirely novel manner, tells me there's the potential for a seismic shift, much like we made from extracapsular surgery to phacoemulsification.

If I had a dollar, I'm not sure I would spend it on simply increasing my cut rate, because I think Tarek is correct. I think we've done things in a very safe way, but I sure as heck would invest that dollar in the potential of an entirely new way of removing the vitreous. *That's* a worthwhile investment.

Carl, let me give you the last word. What are your thoughts?

Carl Awh: I think all of the points Tarek and Kourous have made are appropriate, and I also agree that with virtually all new technology, we are incapable of predicting all future benefits and value.

When 25-gauge vitrectomy was new, it was met with quite a bit of resistance. Many thought of this as simply a modification in technique in order to avoid sutures. However, with increased experience and continual refinement of techniques and technology, sutureless small-gauge vitrectomy, which is now the accepted standard of care, provides so many more benefits than we predicted at its advent.

This new ultrasonic technology, removes tissue in a fundamentally different way. That's easy to grasp, but as this discussion show us, even this group of experienced vitreoretinal surgeons is unable to know whether this new technology will represent just minor modification or whether it may allow us to perform fundamentally different procedures one day.

To summarize, we must first determine that hypersonic vitrectomy allows us to perform the range of procedures currently possible with guillotine cutters. If so, we'll begin to explore the advantages afforded by a device that seems to emulsify tissue at its surface. Imagine if we could one day simply touch or stroke a membrane or other unwanted material and, in a sense, erase it. This could open up a host of new procedures and indications. But, as we've discussed, first things, first. I hope that when we next speak we will have much more knowledge about and experience with hypersonic vitrectomy.

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>
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Pravin Dugel: Well, I look forward to the development, and I think this is very exciting. Author Douglas Adams famously stated, "We are stuck with technology when what we really want is just stuff that works." This is a profound statement. As our experts indicated, disruptive technology is wonderful, but it must do more than we can do today. Therein lies the test.

The bar today with surgical instrumentation is high, but a paradigm change in removing the vitreous (and fibrous tissue) would not only change our behavior, but open doors to new possibilities that we have not yet imagined. Such was the case with the introduction of phacoemulsification ... but that is exceedingly rare.

Perhaps the best advice of all was given by Thomas Watson, the founder of IBM: "The way to succeed is to double your failure rate."

I look forward to the development of this potentially disruptive technology and congratulate the researchers and investors for their willingness to disrupt the status quo.

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