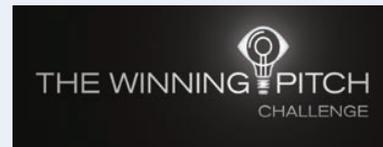


Jeffrey Gross, MD, Wins the 2019 Winning Pitch Challenge



The Winning Pitch Challenge, now in its third year, held its 2019 grand finale on Sunday, July 28 at the ASRS Annual Meeting in Chicago. This competition is retina's answer to the popular TV show, *Shark Tank** ... without the bite.



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The 2019 Winning Pitch Challenge had 16 submissions from which 3 finalists—Jeffrey Gross, MD; Jay Fleischman, MD; and Daniel Chao, MD, PhD—were selected to compete in the much-anticipated live event in Chicago. Finalists vied for a first prize of \$10,000, a second prize of \$5,000, a third prize of \$2,500, and an opportunity to engage in further discussions with the judges regarding a possible equity investment.

Four judges evaluated each of the pitches based on criteria including the magnitude of the problem, innovativeness of the proposed solution, market size, competitiveness, and business model.

After creative, informative pitches by the 3 finalists, the judges awarded the first prize to Jeffrey Gross, MD, for his simple yet ingenious device, the Speculet, described as the first major redesign of the eyelid speculum in over 60 years.

Second prize went to Jay Fleischman, MD, for his preferred retinal locus device, MD SIGHTeX; and third prize was awarded to Daniel Chao, MD, PhD, for his dry-AMD treatment, Visgenx.

The first-prize-winning Speculet is elegantly designed to provide a more comfortable patient experience, greater ease of insertion and removal, and improved physician work flow during the most commonly performed procedure in retina, intravitreal injections.

The Speculet is a disposable resin lid speculum with a unique design that maximizes patient comfort and physician use/access during intravitreal injections. The trademarked device even has a pediatric version for premature-infant exams.

What's News caught up with Dr. Jeffrey Gross to learn more about how the idea for the Speculet came about, and what the future holds for his device.

How did you first come up with your idea?

We brainstormed about how to make the speculum more comfortable. Initially we

looked at just making the blades, or lid scoops, of the traditional speculum out of a softer material. When I was not satisfied with the material, I started to think about which resin would work best.

As I studied materials used in corneal shields, I had an idea to fix the lid scoops on the surface of the shield, turn them outward away from the eye, and cut a notch in the shield or create a "C" opening for the injection. Then the shield could be placed on the eye and the scoops would hold the lids open from *inside* the plane of the lids.

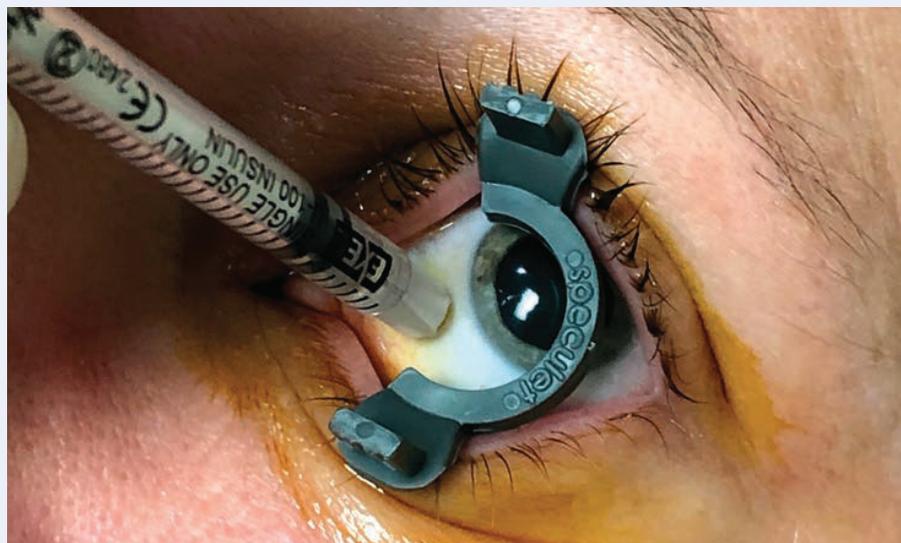
I was intrigued by this unconventional concept, which evolved to the design we have now. The Speculet has lid scoops attached to a C that hold the eyelids open at a comfortable distance and positions the speculum anterior to the eye so there is no corneal touch; the opening in the C provides a space for the injection.

The device is symmetrical to allow nasal or temporal injections in either eye. Unique finger tabs are strategically placed to hold the speculum and keep the portion that contacts

Continued on page 23



The Speculet significantly improves patient comfort as well as procedural workflow for intravitreal injections.



A patient receives an intravitreal injection with the Speculet in place.

*SHARK TANK is a registered trademark of Sony Pictures Television Inc and is not affiliated with these services.

the patient's eye sterile. A novel rotational insertion maneuver opens the lids in a comfortable and controlled fashion.

1. A scaled-down version can be used for pediatric and premature-infant exams and injections.
2. A stabilizing accessory can be attached to the C, allowing the physician to press on the eye to control it for aqueous paracentesis or corneal foreign-body removal (in the same manner we use a cotton tip to stabilize the eye).
3. The C portion is designed to hold a standard commercial vitrectomy macular lens for possible macular surgery or hands-free slit-lamp laser procedures.

What was involved with getting your product to the point it is at now?

I was fortunate to have a friend, John Lowsky, who is a mechanical engineer. He has a facility in our town that does computer-aided design (CAD), 3-D printing, tooling metal injection molds, and packaging and sales of speech therapy tools, all under one roof.

We came up with the concept, John drafted the CAD drawings and printed prototypes. To assess comfort, I was able to “test” them in some of my friends and patients who have had injections. Our union was so perfect that we could CAD a design and build a prototype in house very quickly, including any modifications. This really sped up the process, as most designers may not have that synergy available. We probably trialed 40 to 50 iterations until we achieved our final design.

Then we had to choose a resin material that would be medical grade, inexpensive, durable, and light. We created a start-up limited



Macular vitrectomy lens nested with the Speculet.

liability company (LLC) within a month of concept, trademarked the BioGenware name and created a logo, developed the website, came up with the name *Speculet*, and trademarked the name and logo.

Next, we commissioned a patent search followed by filing a provisional patent application using an attorney with biomedical engineering degrees, and commissioned an animation of the Speculet (narrated by my daughter, Amy), all within 3 months of concept!

We are now developing a plastic tray with individual cells to house the Speculet so the physician can easily grasp it by the finger tabs and remove it. The tray will have 16 perforated and separable cells and will be packaged in a box containing 2 trays for a total of 32 Speculets—an average number of injections per clinic day.

What's next for the product? Partners? Licensing?

We are in discussions with companies in the United States and other countries to form a

strategic partnership for distribution. My son, Joel, who is my part-time clinical research coordinator, is now working for John Lowsky's company to learn CAD, printing, and tooling for BioGenware.

Our early success has created interest; I have been contacted by other retina physicians to create CAD images and prototypes for their inventions. Perhaps this will develop into a rewarding offshoot.

For more information, including a Speculet demonstration and instructional video, please visit www.biogenware.com.

See Dr. Ratko Lazic's Updates From the Field video interview with Dr. Gross at asrs.org/AM2019videos

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