More Accurate Male Fertility Testing

Androvia Life Sciences licensed a new tool for diagnosing male infertility from Alexander Travis' lab. Soon it will help many infertile couples.

Featured

Alexander J. Travis
Biomedical Sciences/Baker Institute for Animal Health, College of Veterinary Medicine

by Caitlin Hayes

Infertility plagues roughly 10 percent of couples, often with high costs—financial, physical, and emotional. Male infertility accounts for about a half of these instances, but efforts to identify these men have fallen short.

"Most men who have fertility problems pass the traditional semen analysis," says Alexander J. Travis, Biomedical Sciences/Baker Institute for Animal Health, "and many men with low scores on the traditional tests wind up having success. So the traditional assessments track poorly with actual male fertility."

Travis' lab has developed a tool that lays the foundation for a diagnostic assay that more accurately measures sperm function. Cornell has licensed this technology to Androvia Life Sciences, a company that he helped cofound. "There's been a call for some time to develop this kind of test," Travis says. "Androvia has now developed that technology into a test of male fertility that can assess whether a sperm can fertilize an egg."

Androvia Life Sciences' Cap-Score™ Sperm Function Test

Historically, semen analyses have been descriptive, Travis explains. "The traditional tests ask: How many sperm are there? Do they look normal? Do they swim normally?"

The problem is that no matter what they look like and how well they swim, sperm have to go through a critical extra step in order to fertilize an egg. "When sperm enter the female tract, they look like mature sperm, but they can't fertilize yet," Travis says. "They mature within the female tract in a process we call capacitation. Put very simply, if sperm can't capacitate, they cannot fertilize."

Using a semen sample, Androvia's assay tests whether or not sperm can go through this process. In an early clinical trial, performed independently by Gianpiero D. Palermo, Embryology in Obstetrics and Gynecology at Weill Cornell Medicine, data showed that men scoring below a certain threshold of capacitation ability had only a 21 percent chance of success. Men scoring above the threshold had a 92 percent success rate. Further studies have strongly reinforced these results, showing that the assay, known as the Cap-Score™ Sperm Function Test, reflects sperm capacitation and has minimal relationship with the traditional descriptive parameters. These findings were published in *Molecular Reproduction & Development*. "What we've found is that this ability to capacitate tracks very well with actual performance in the fertility clinic," Travis says.

"We've contributed something that's functional and complementary to the normal semen analysis," he adds. "Androvia's test doesn't replace the old ones but adds another angle of analysis that identifies a much larger proportion of men having difficulty with fertility."

Help for Infertile Couples

The assay will be especially helpful to clinicians and infertile couples who are trying to decide among various treatment options. The least invasive of those options, intrauterine

insemination (IUI), gives sperm a head start; doctors inject semen farther into the female tract to help more sperm reach the fallopian tubes.

"This is lower cost and has a lower level of invasiveness, but if the sperm can't fertilize, then it's doomed to fail," Travis says. Without a good way to identify male infertility, however, couples may go through this process unnecessarily. In some states and under some insurance plans, it's even required that couples try IUI many times before they move on to more expensive and invasive procedures. On the other hand, some couples might be tempted to skip ahead to the more expensive procedure if they're older and don't have much time—without knowing whether IUI would be an equally effective, lower cost, and less invasive option for them.

In both circumstances, Androvia's assay can help couples determine whether IUI is likely to work. If the male's sperm can't capacitate, the couple can go straight to an advanced treatment. "Without a test of sperm function, there's really not a good way for the clinicians and couples to make these decisions," says Travis. "That's what the test is designed to do—to empower couples and clinicians to come up with the right strategy. Hopefully, this knowledge will help spare couples emotional, physical, and financial costs."

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Learning the Ropes of Commercialization

The Center for Technology Licensing at Cornell (CTL) licensed the assay to Androvia in 2015. Since then, the company has set up a laboratory in New Jersey, which has conducted broader clinical trials and performed the work needed to develop the assay into a commercially viable test.

While now on the verge of widespread distribution of the assay, Travis says that he and his lab initially "went through the valley of death" with the technology. Travis patented it in 2004 and struggled for years to get funding for clinical trials in humans. That changed after he attended a Pre-Seed workshop, hosted by the Cornell Institute of Biotechnology's Center for Advanced Technology and the McGovern Center for Venture Development in the Life Sciences.

"That's when I learned how to give a pitch," Travis says. "I learned how to start with a description of the market—the size and potential of it—and what pain the technology

relieves. Venture capitalists don't want to hear about the inner workings of the science first. It's a different mindset."

With these new skills, Travis applied for and won a BioAccelerate NYC Prize from the Partnership for New York City to fund the initial clinical trial in Palermo's lab. With those data and the help of Louis Walcer, director of the McGovern Center, Travis joined forces with cofounder and CEO, Michael V. Novinski, and Androvia was born.

"Switching gears to a business perspective is really hard for faculty. We don't know what we don't know, and that can make it hard to make decisions that are pretty important," Travis says. "Your brain just explodes because there's this whole new language—equity and preferred versus common stock and so many other terms and things to consider. It's like going to business school. But it's tremendously exciting because I'm learning something entirely new."

Doing Basic Science with an Eye on Practicality

While a newly minted entrepreneur, Travis is still doing a lot of basic research in his lab in Ithaca. "I'm a clinician-scientist, both a veterinarian and a PhD, so the idea of always keeping my eyes open for applications—that's part of who I am. I'm a practically-minded person who does basic science with goals to improve human and animal health."

This ethic is one that defines work at the Baker Institute for Animal Health, Travis says, adding that, "The environment facilitates this kind of approach."

Starting at the basic science level also lends itself to numerous possibilities for applications. "When you do basic science, you can use it in different ways; so knowledge of how sperm become able to fertilize can help promote fertility for humans, but potentially also for animals. In addition to diagnostics, it can help develop new, assisted reproductive technologies."

In 2015, Travis' lab successfully performed the first in vitro fertilization of dogs ever in the world (Travis has adopted two puppies of the first litter of seven). He's also studied how to preserve frozen dog embryos, and then thaw and transfer them with the successful birth of a puppy from one of the embryos. His lab was also the first to transplant sperm-making stem cells from one dog to another, so that the genes of one dog can be expressed via the sperm of another. These advances could play a role in keeping endangered species from extinction and in maintaining genetic diversity in captive animal populations. On the flip side, Travis' expertise can also be applied to developing contraceptives.

"I initially got into this field because of wildlife conservation. Along with helping people, that remains an underlying passion," says Travis, who recently served as Faculty Director for the Environment at Cornell's Atkinson Center for a Sustainable Future and who now directs

Cornell's new Master of Public Health program. "The overarching theme in my lab is to do good science that helps both humans and animals."

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