

Growing Cheaper Embryos for IVF Inside the Vagina

A new vaginal incubator is half the price of traditional IVF and could be more acceptable to Catholics. Will it revolutionize access to fertility medicine?



Doctor Katarzyna Koziol injects sperm directly into an egg during an in-vitro fertilization procedure.

Kacper Pempel / Reuters

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As the number of U.S. babies born as a result of fertility treatment tops **1 million**—an all-time high—clinics are under pressure to keep up to date with pricey lab equipment that can create, develop, and test embryos. But some fertility doctors have started to offer a new low-tech device that enables a woman to incubate them in her own body.

The catch: She grows them inside her vagina.

A doctor places a mixture of surgically extracted eggs and sperm inside a device that looks like a tiny acrylic saltshaker and inserts it deep into a patient's vaginal canal near her cervix. That's where it will hover, like a thimble-sized satellite, for up to five days until the doctor retrieves it, removes the resulting embryos and transfers one or more to her uterus in the hopes of creating a pregnancy. "It's like having a tampon in the vagina," explains Kevin Doody, a Dallas reproductive endocrinologist who's led studies on the device, called INVOcell, which [was approved](#) by the U.S. Food and Drug Administration in 2015. "It's not going to come out."

It's a concept designed to appeal to patients who prefer a less tech-heavy approach to scientific baby-making. That could include Catholics who've rejected traditional in-vitro fertilization (IVF) treatment because it facilitates conception outside the body.

But INVOcell could be a game-changer for the \$2 billion assisted reproductive technology market. The protocol calls for fewer eggs (and less hormonal medication) than traditional IVF, and only requires about one-third as many office visits. The vaginal incubator also costs one-third to half the price of regular IVF treatment.

That's no small matter for the estimated [1 in 8 couples](#) in the United States who have trouble getting pregnant or carrying a baby to term—three-fourths of whom don't receive the care they need because they [can't afford it](#), according to the American Society for Reproductive Medicine. Although the average price range of regular IVF [is quoted as](#) between \$10,000 and \$15,000, the real-life costs are [closer to \\$20,000](#) by the time medications, sperm injection, and genetic testing services are factored in, according to [data](#) from 3,200 IVF patients that was analyzed by the fertility doctor review site FertilityIQ for the personal finance website NerdWallet.

Insurance coverage for traditional IVF is sparse: [About 26 percent](#) of workplaces offer infertility benefits, according to the Society for Human Resource Management. Just 15 [states mandate](#) that employers provide any kind of infertility

coverage, and only eight states require that to include IVF treatment. (Insurers have yet to start paying for INVOcell.) As a result, many patients blow through their savings, load up their credit cards—one survey of more than 200 women who'd gone through IVF found that 44 percent racked up at least \$10,000 in debt—or beg for financial help on crowdfunding sites. More than 8,500 GoFundMe campaigns created to raise money for fertility treatments have collected \$13.5 million in the last six years, according to figures provided by the company.

By contrast, INVOcell, which is manufactured by INVO Bioscience in Medford, Mass., costs about \$6,800, including medication. “We can pay for this without going into debt,” says Katie Whited, 28, a nurse from Durham, N.C., who's tried nearly every fertility treatment short of IVF, including ovulation induction drugs with timed intercourse, acupuncture, and intrauterine insemination in which a doctor injects sperm directly into a patient's uterus. “We wouldn't have been able to find \$18,000 for IVF.”

Early numbers are promising: One randomized clinical trial of 40 women under 38 found no significant difference in success rates between traditional IVF and INVOcell. Although IVF produced more quality embryos overall, the birth rates were similar: Of the 20 women undergoing IVF, 12 got pregnant and delivered 15 babies, including three sets of twins. In the INVOcell group, 11 of 20 women gave birth to 16 babies, including five sets of twins.

“I see so many patients who can't have kids because they can't afford IVF. We've got to do better. It's a matter of medical ethics,” says Doody, who has trained a couple dozen doctors on using the vaginal incubator for INVO Bioscience. “Now a greater number of people will be able to access care, and it's going to open up the market.”

According to Doody, doctors who offer INVOcell can cut the number of office visits for one round of treatment from eight (for traditional IVF) to two or three, which is a big deal for patients in underserved areas, especially in the southeastern and southwestern United States, who often must drive several hours to reach fertility clinics. That means there's less work for staff who administer blood draws and

ultrasounds and play phone tag with patients with updates after each visit.

“Patients take less medication, and we’ve gotten better at dosing and predicting how they will respond so we can do less monitoring,” says Doody, who is also the president of the Society for Assisted Reproductive Technology, the organization that reports fertility clinics’ data to the government. “We’re not trying to get 10 to 15 eggs like with regular IVF. We just need six to eight eggs to get one or two good embryos to transfer.” His rationale: More eggs aren’t always better, and doctors should aim for a handful of quality eggs, rather than the larger quantity typically generated during regular IVF.

And because the embryos are grown in the mother’s body, there’s no need for lab staff to run costly incubators with extensive security systems around the clock, which also brings down the price.

The fact that INVOcell preserves some of the mystery of baby-making was a big selling point for Brittney Koch-Dowell, since she and her wife are depending on help from science to conceive. (They each plan to take a turn carrying a baby.) “We’re already using donor sperm, so this helped it feel more real and natural,” says Koch-Dowell, 37, a restaurant manager from Elsberry, Mo., who’s scheduled to undergo the procedure this month. “I get to be the incubator. My body and my heat are producing the child.”

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In some ways, the rationale behind INVOcell sounds so obvious. (“It’s like what’s old is new again,” quipped John Couvaras, a fertility doctor in Phoenix who’s helped four women conceive with the device.) Yet it took French embryologist Claude Ranoux nearly 30 years to fine-tune his invention, which has been available in Europe since 2008. Since the birth of the first “test-tube baby” in 1978, Ranoux had been fascinated by the idea of growing embryos inside the human body rather than in a petri dish. And he wasn’t impressed with the unreliable incubator at his workplace, the Cochin Hospital at Paris Descartes University. “I was forced to be an innovator because I had a bad machine,” says Ranoux.

So Ranoux rigged up a little portable incubator from plastic tubing. At first, he considered sewing it under the abdominal skin, but that would require two surgeries to implant and extract the device and risked causing an infection. Taping it under an armpit would provide a nice warm place, but he thought it would feel too uncomfortable over several days. He also considered securing it in the back of a patient's mouth, but he didn't want to risk shocking the embryos if she drank cold water or hot coffee. Besides, there was the chance she could accidentally swallow it.

Next he considered having a patient swallow the capsule and letting the embryos grow over the two to three days it would take the device to wind its way through the digestive tract. But he feared the intestinal environment would be too toxic. "Also, it would be a nightmare for the embryologist to retrieve the device later," he says.

He came to the most logical place last. "I didn't think about it initially because I worried the capsule could lead to infections or irritate the cervix and interfere with embryo transfers," he says. Those concerns were unfounded; instead, he found that the vagina provided the best consistent temperature, pH, and oxygen balance and enabled easy insertion and removal of a device. He also believed that embryos would benefit from the slight temperature variations that women undergo throughout the day, which embryos that are created during natural conception experience as they grow in the uterus.

Although INVOcell is designed to stay in the vaginal canal on its own, doctors have the option of adding a diaphragm net to catch it, just in case. If it somehow works its way out completely, patients are advised to wash it off and push it back up.

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In the meantime, patients still have to get used to the idea.

Anne Swart, 38, of Berkeley, California says she and her husband decided against using INVOcell to help them conceive their second child after enduring two miscarriages, even if it meant paying close to \$25,000 out of pocket for IVF, including sperm injection and genetic testing. "It hasn't been around in the U.S. for

a long time and just felt riskier,” she says. “We didn’t want to go through more heartbreak. We just wanted to do everything to give us the best chance.”

The main challenge with marketing INVOcell is that it’s recommended mostly for younger women with uncomplicated fertility issues and partners with normal sperm counts, says Fady Sharara, a fertility doctor from Reston, Va., who’s only treated one patient with INVOcell after advertising it for a year. “My patients are older, and they want to get the maximum amount of eggs with IVF, so they can do genetic testing to make sure they have a normal embryo to transfer,” he says.

“They have a small pot of money. They say, ‘I can’t afford to try INVOcell and then IVF later.’”

The lab also provides important feedback on growing embryos that’s impossible with INVOcell’s “in the dark” approach, adds Michael Tucker, the director of IVF and embryology labs at Shady Grove Fertility, the largest fertility center in the U.S. He argues that modern lab technology, including time-lapse imaging of developing embryos, helps embryologists pick the best ones to transfer to the uterus. “The idea of INVOcell is clever, but in a diagnostic sense, you lose so much,” he says. “You have no idea what’s happening inside the body. You don’t know if fertilization was normal. There’s something to be said [for] following the entire process.”

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It’s also unknown whether mainstream fertility medicine is ready to embrace an IVF alternative that might cut into clinic bottom lines. “When clinics don’t offer lab services, they strip out a major profit center,” says Jake Anderson-Bialis, co-founder of FertilityIQ.

Yet most clinics can afford to add INVOcell to their menu of treatment options, says Richard Paulson, a reproductive endocrinologist at University of Southern California Fertility and president of the American Society for Reproductive Medicine. “We have a very expensive heavy-handed approach to IVF in the U. S.

There's definitely room to bring the cost down," says Paulson, who wrote a paper on [ways to broaden access](#) to reproductive care, such as offering minimal stimulation of eggs, retrieving immature eggs or embracing vaginal incubation, like INVOcell's device. He says the pressure to report the best clinic pregnancy rates to attract patients has caused doctors to shy away from trying more cost-effective alternatives that have smaller chances of success.

The acceptance of INVOcell could make doctors more open to other innovative technologies that might bring down the cost of fertility medicine, adds Alan Penzias, a fertility doctor at Boston IVF and a professor at Harvard Medical School. Other inventions in the works include a portable ultrasound that IVF patients could use with their electronic tablets, a [spit test](#) to measure hormone levels that would replace blood draws, and an at-home [semen analysis test](#) that uses a smartphone app.

Or doctors could use INVOcell to extend the reach of clinics to underserved areas. "I might be able to put some equipment in a van and set up a temporary shop in a hospital a few times a year," suggests Penzias. "It could provide another outlet to expand access to fertility care."

So could a Catholic endorsement. The Vatican has long opposed IVF on the grounds that it enables creating babies outside the bounds of marital intercourse. "The rule of thumb is that you can assist reproduction but not replace reproduction," explains Father Kevin FitzGerald, an oncologist who specializes in Catholic health-care ethics at Georgetown University. So reproductive scientists have tried to find creative solutions, such as a procedure invented in the late 1980s called gamete intrafallopian transfer (GIFT) involving shooting a mixture of sperm and egg directly into the fallopian tubes through a catheter. But multiple births were common with that procedure, and doctors eventually stopped using it as IVF success rates improved.

While the Church has yet to issue an opinion on INVOcell, experts say it's a potentially Catholic-friendly alternative to traditional IVF because the device technically helps fertilization occur inside the body. By the time doctors insert the

incubator containing the egg and sperm soup inside the vagina—about 15 to 30 minutes following egg retrieval—the sperm have just started to attach to the eggs' outer layer and haven't yet started to burrow inside. It takes at least 18 hours for the chromosomes to join together and fertilization to finish.

“INVOcell is a move in the right direction to a more natural assisted method,” explains FitzGerald. His ideas for making it even more acceptable to Catholics: Collecting the sperm during sex in a condom, rather than asking men to masturbate into a cup in a fertility clinic closet. It would also help if doctors only inserted the number of eggs they estimated might turn into embryos. “You must use what's fertilized so you don't discard embryos and destroy human life,” he says.

What's appealing for some Catholic patients of Julie Rhee, a fertility doctor in St. Louis, is that INVOcell eliminates the role of the embryologist tinkering with sperm. “The part that makes them feel comfortable is that you're not determining which sperm will be injected inside the egg or whether fertilization will even happen at all,” says Rhee, who just started offering the vaginal incubator in May and has 10 patients lined up for treatment.

Ranoux, the founder of INVO Bioscience, didn't set out to appease the Vatican at first, yet he's found a way to accommodate his Catholic patients. In addition to collecting the semen in a condom (there's a special coitus room at his clinics), Ranoux also pricks the bottom of the condom, to leave open the possibility of a natural conception.

But still, unlike GIFT, which enabled embryos to travel to the womb on their own, INVOcell requires a doctor to take the embryos out of the device and manually insert them into the uterus. That interference in the baby-making process—plus the act of selecting embryos and potentially freezing the extras, which could later be destroyed—makes a Catholic endorsement less likely. “You're interrupting the natural chain of events,” says Daniel Sulmasy, who studies clinical bioethics at Georgetown University.

What could be acceptable, he argues, is if someone invents an incubator that is placed directly in the uterus, and then dissolves. But it's a tricky timing gamble. The device would have to self-destruct at the exact moment the embryos have developed and were capable of attaching to the uterine lining. Still, it might not be impossible. "I have some ideas," says Ranoux.

ABOUT THE AUTHOR

SARAH ELIZABETH RICHARDS is a writer based in San Diego and the author of *Motherhood, Rescheduled: The New Frontier of Egg Freezing and the Women Who Tried It*. Her work has appeared in *The New York Times*, *The Wall Street Journal*, and *Time*.
