

# No more pills: Male contraceptive takes new approach

May 12 2010

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The year: 2014. Imagine the scene: A man's wife doesn't feel good on the Pill. He'd like to have the "old her" back, and figures it's his turn to take responsibility for contraception. But they want another child, so vasectomy is not an option. So what does he do? While he drops his electric car off for a quick charge, he pops into the doctor's office for a recharge of his own: 15 minutes of ultrasound treatment, for 6 months of contraception.

Sound futuristic? It's not. The effect of ultrasound on sperm production has been known since the 1970's, but never pursued since then. But with Monday's announcement of a Bill & Melinda Gates Foundation Grand Challenges Explorations grant to a team at the University of North Carolina, this method may finally have its day.

The late Dr. Mostafa Fahim at the University of Missouri-Columbia was the first to have the idea to try ultrasound for contraception-- the same ultrasound used daily by physical therapists to treat injuries. He found that with 10-15 minutes of the painless warming waves to the testes, animals from rats to rabbits to monkeys, cats, and dogs would have 6 months of contraception-- and even tried it in 8 men. The men didn't find it uncomfortable. Applying it multiple times 48 hours apart in animals appeared to result in permanent sterilization, with no vasectomy needed.

"But it seemed too crazy to be true," explains Elaine Lissner, director of the nonprofit Male Contraception Information Project. "Nobody took

him seriously, especially after another researcher-- who happened to not have a foreign-sounding name-- published that he tried it and it didn't work. But that researcher used entirely different conditions. Dr. Fahim got pretty bitter about it, which didn't help." Dr. Fahim passed away in 1995 without ever being vindicated.

However, a small group believed in Dr. Fahim's work. Dr. Min Wang, a colleague of Dr. Fahim's, kept working along with Dr. Fahim's widow and daughter and a small group of investors to bring another of his ideas to market: a nonsurgical sterilization for dogs. This product made it to the U.S. market in 2002 as Neutersol, and is now on the market in Mexico as Esterilsol<sup>TM</sup>. "At that point it became harder to completely discount his work," says Lissner.

And men and advocates continued to push for more research. "We have more than 5,000 signatures on our petition calling for funders to move male methods forward," said Kirsten Thompson, director of MaleContraceptives.org, the most popular nonprofit source for information on new methods. "And every week we get more."

For many years, funders believed that men were not interested in contraception-- but that began to change with generational shifts and when advocates pointed out that between condoms and vasectomy, men were already covering a third of the contraception in the United States. In some countries, the numbers are even higher-- in New Zealand, a survey showed that more than half the men in their 40's had vasectomies.

But though attitudes began to change, funding was still a problem. "There's really been a trickle of funding compared to other research areas like heart disease or AIDS," said Lissner. "Most of it went to hormonal methods, and the rest was spread pretty thin."

Finally, a new foundation with advocacy roots, Parsemus Foundation,

got the opportunity to give ultrasound a chance. The foundation was not large enough to do all the studies necessary to get ultrasound through FDA approval for this use-- but at least it could try for proof of concept. In 2007, the foundation funded a study by a team of top researchers from Family Health International and the University of North Carolina at Chapel Hill. After significant effort, the researchers found a dose level and treatment protocol that was effective. Preliminary results from that study gave the UNC team confidence to apply for further funding from the Gates Foundation Grand Challenges Explorations.

Meanwhile, completely independently, researchers in Italy were exploring whether they could use repeated doses of ultrasound for permanent nonsurgical sterilization in dogs. They were successful, and published their work in a veterinary journal (*Reproduction in Domestic Animals*) in 2009. Their further results were presented as a poster presentation at the April 2010 Alliance for [Contraception](#) in Cats and Dogs conference in Dallas, Texas.

"It's pretty funny-- the dogs think it's a game," says Raffaella Leoci, chief author of the study. "They lie on their side, and we move the transducer around their testes for 5 minutes at a time, just like a physical therapist would do to treat an injury in your wrist or back. They like the attention-- for them it's a warm massage. But we do it 3 times in a row 2 days apart, and after that they're infertile." The team's next goal is to see whether 2 longer sessions would work as well as 3 short ones.

Encouraged by the preliminary FHI/UNC team results, a team at the University of California is also doing a pilot study exploring ultrasound in larger animals, with results expected next year.

Other researchers are supportive of the University of North Carolina team's grant win. "It's great that many people are working on ultrasound-- it will make it easier to get the answers we need," says Leoci. "We're working on our application for the next round right now,

and it's quite hard to convey all the issues and the excitement in only two pages. They must have managed to do that in their application-- so they've done a real service to science."

But men have been hearing that the hormonal "male Pill" is right around the corner for years. Could a new approach like this work out any better? Gary Gamerman, a regulatory consultant to contraceptive development programs, suggests cautious optimism: "There are a lot of questions to be answered still about ultrasound. How long does it act-- in men, as opposed to monkeys? How does it work? There's more human data on some of the new methods like RISUG for men or the new IUDs for women. But Gates is trying to do something new here-- give new ideas a chance."

Lissner agreed, and added a further question: Would fertility still bounce back after multiple uses over many years? "But the exciting thing is that we're getting started finding out. The smaller foundations don't have the money to get beyond proof of concept-- so Gates has really saved the day."

"With the Grand Challenges Explorations approach, they're taking a venture capital-style approach to funding new techniques. Not all the ideas will make it to market-- but if you never try, you'll never know. This day has been a long time coming."

Provided by Male Contraception Information Project

Citation: No more pills: Male contraceptive takes new approach (2010, May 12) retrieved 11 May 2024 from <https://medicalxpress.com/news/2010-05-pills-male-contraceptive-approach.html>

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