

'Restorative' treatments for erectile dysfunction aren't proven to work. Men pay thousands anyway

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Three years ago, Stephen Borgese left the stress of emergency medicine to form a new practice in Bryn Mawr, Pennsylvania, that uses shockwave

therapy to help men with erectile dysfunction (ED). This relatively new and still largely unproven treatment aims to repair damaged tissue, not just increase blood flow with pills or prop up penises with prostheses.

At Forge Medical Group, Borgese, who charges \$3,000 for 12 sessions, has treated more than 700 men. Four in 10 of them can have sex without medication after having shockwaves, he said. Another four can achieve success with pills, which had stopped working before [shockwave](#).

Borgese sees it as a win-win. "It's a fun job. It's much less stressful, and I help people."

The Sexual Medicine Society of North America begs to differ.

In a recently published position statement, it said that low-intensity shock wave therapy, aka shockwave, and other "restorative" treatments are "promising" but are not yet ready for widespread clinical use. There's not enough information from placebo-controlled trials about how well different devices and treatment protocols work or how long any benefits last, the group said. The treatments, it added, should be offered only to patients enrolled in clinical trials. The organization said it is not "appropriate or ethical" to "advertise or otherwise make implicit or explicit claims of efficacy for these therapies pending further data."

"None of these things that are being touted in the community and by some doctors are FDA approved," said Trinity Bivalacqua, a Penn Medicine urologic oncologist who co-wrote the society's position statement. "None of them have been proved effective in an appropriately designed, randomized, controlled trial."

Doctors use a variety of devices to deliver the shockwaves—these are pressure waves, not electricity—and it can be hard for patients to know which a community doctor offers. The shockwaves fall into two main

categories: focal and radial. Radial waves—what Borgese uses—cover a broader area, but do not penetrate as deeply. There is more evidence from basic science and clinical trials that focal waves may trigger healing in tissue and improve erections.

Bivalacqua was especially critical of radial-wave machines, which are far more common in community practices because they are cheaper than focal devices. Radial waves, he said, are not powerful enough to induce the tissue healing, such as creation of new blood vessels, needed to restore natural function. "It's not going to work," he said.

Other restorative treatments include injections of platelet-rich plasma (PRP or P-shots) and stem cell therapy. Both are made from patients' own blood. Bivalacqua will soon be involved in a trial that will test whether injected cytokines, which are immune substances, can mobilize stem cells in the penis to repair tissue.

He said some people who offer radial shockwaves are not urologists or sexual medicine experts. Many of these physicians, he said, are not treating the underlying disease but are "more interested in financial rewards." Insurance, which offers spotty coverage for approved [erectile dysfunction](#) treatments, doesn't cover restorative therapy at all.

Gregory Broderick, a urologist at Mayo Clinic Florida who was also involved in crafting the position statement, was less harsh about community shockwave practitioners. There is a "signal" that shockwave may help some men with ED, he said, although "there's evidence that the energy required is much higher than in radial machines."

"... The doctors who are offering therapy are not charlatans," he added "They're not selling you snake oil, but, as a medical consumer, you have to be a little bit savvy."

Broderick said a more powerful version of shockwave has long been used to break up kidney stones. Low-intensity shockwaves are approved for treatment of plantar fasciitis, Achilles tendon and tennis elbow, and the technology is being studied in patients with coronary artery disease.

Because men have to pay cash, price is an issue. "Men are being charged excessive amounts of money for something the FDA has not approved," Broderick said.

Thomas Masterson III, a University of Miami urologist who has been involved in restorative therapy clinical trials, said he thinks it's "fine" for men who adamantly want shockwave to choose the treatment if it's in their budget. But, he said, he has seen "grandiose claims" that should give men pause. "If you're being told this is going to change your life forever, I would not trust that person," he said.

According to the clinical trials registry, clinicaltrials.gov, there are no trials of shockwave, the most widely used restorative therapy, within 300 miles of Pennsylvania or New Jersey.

Some say shockwave soon will be widely used

There are, however, multiple doctors who, like Borgese, offer shockwave and other treatments to men with ED. Some said they're offering a valuable service to men who are dissatisfied with standard medical alternatives. Some point out that European medical societies are friendlier to these treatments than are those in the United States.

The American Urological Association (AUA), which estimates that as many as 30 million American men have erectile dysfunction, classifies shockwave and stem cell therapy as "investigational" with low-quality evidence of benefit and risk. It says PRP is "experimental" and should only be used in clinical trials.

Borgese, who is not a member of the sexual medicine society, said he thinks the group is "absolutely correct, and I think they're absolutely wrong."

They are correct that there are not enough data from high-quality clinical trials, he said. But, he added, "there will never be good clinical trials on this." Such trials are too expensive for device makers, and their placebo arms are not attractive to men with ED, he said.

Borgese thinks it makes sense to offer something that might work to men who are suffering while they can still benefit. Many are old enough that they'll have no hope of resuming their sex lives if they have to wait years for the results of [clinical trials](#). Shockwave treatment does not have serious side effects, he said.

He tells patients the treatment might not work for them and warns that they're not going to feel like they're 18 again. They'll be doing well if they can have sex once a week. For him, the evidence is in his patient feedback. "It works," he said.

Paul Gittens, a urologist who is a member of the sexual medicine society, has been offering focal shockwave treatments at his Centers for Sexual Medicine in Bala Cynwyd and Manhattan for five years. He also uses PRP.

He says there is "mounting evidence" that shockwave is beneficial. "Eventually, every urologist will have it in their office," he said.

Gittens said he is "transparent" with patients that the treatment is not FDA approved for ED, is considered experimental, and may not work.

Bruce Sloane, a Philadelphia urologist who charges \$5,000 for 12 radial shockwave treatments and \$1,500 for PRP, said new treatments often

are met with establishment resistance. He pointed to laparoscopic kidney removal and robotic prostate removal, which he said are now standard of care.

While he agrees that scientific support for restorative treatments could be better, he also said there's solid evidence that shockwave treatment is safe. The fact that patients keep coming and thank him for the results, he said, shows him his treatments are working.

Erectile dysfunction often stems from systemic cardiovascular problems or nerve and vessel damage caused by diabetes. It can be an early warning of bigger health issues that need to be addressed, doctors said. "Penile issues tend to precede cardiac or heart issues by about five to 10 years," said Matthew Sterling, a Bryn Mawr urologist who does not use restorative therapies because he thinks there's insufficient proof of their value. If a patient with heart disease doesn't eat healthier food, lose weight, exercise and stop smoking, his erectile dysfunction is likely to progress.

Broderick said a man needs five things to get an erection: blood flow, functioning nerves, hormones, stimulation and relaxation. Restorative therapies might address the first two.

Of course, a fair amount of sexual response also happens in the brain. The placebo effect for erectile dysfunction is 30% to 40%, Broderick said. Borgese said he always talks with patients about the emotional issues that affect performance.

Current treatments all have drawbacks. What they have in common is that they do not lead to the spontaneous erections that younger men take for granted. Pills must be taken at various times before sex, which requires planning. Viagra is to be taken on an empty stomach, which is tough to accomplish on a dinner-date night. If pills fail, the next step is

for men to inject a medicine into a specific part of their penis a few minutes before sex. This is a bridge too far for some of them. Implants are not a popular idea, either, although urologists said some men with serious impotence learn to like them.

Dissatisfaction with these options, along with the emotional impact of ED, leads many to hunt for alternatives and makes some willing to try everything from shady supplements to stem cells.

"Men tend to measure their entire self-worth on the functioning of their penis," Masterson said. That, he said, is "why men are so willing to seek out these treatments and do whatever they can to get that function back."

Gitten said that's too simplistic a view of erectile dysfunction treatment. "It's about self-confidence. It's about relationships," he said. "It's about not having your body betray you."

William Marsh, a 53-year-old licensed massage therapist in Germantown, said he started experiencing erectile dysfunction in his mid-40s. It ate away at his self-confidence. "It very slowly strips away your identity as a man. It strips away your identity as a strong man," said Marsh. He is a big, physically fit guy and does not have chronic medical illnesses. "I was slowly losing who I was."

Even though Marsh's wife of 22 years was understanding, he was upset about this new unpredictability and began to withdraw. "The hardest part was the frustration of letting your partner down," he said.

He tried Viagra, Cialis and several supplements. They didn't work. Marsh suspected that he had scar tissue from a softball injury in his 30s. A line drive hit his crotch so hard that the protective cup he wore cracked.

One day his wife handed him an advertisement for Borgese's practice. He said he did the research and knew the treatment might not work. He figured the price tag would motivate him to follow the doctor's instructions. "What did I have to lose?" he thought.

He began treatment in June. Although he described the shockwave itself as painful, Marsh almost immediately felt that he and his wife were coming closer. She appreciated how much effort he was putting in to trying to solve the problem. As Borgese suggested, they worked on their relationship. Marsh said his physical responses became more dependable and he'd now say his function is normal. He attributes about three-quarters of the improvement to the [treatment](#) and a quarter to his emotional response.

Marsh said that the impact of having more normal sexual function goes well beyond what happens in bed. "I started to see the old person that I was come out," he said.

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