

News

Treatment found effective up to 4 months

Implantable T pellets show advantages in men with low T

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San Diego—A form of testosterone replacement therapy that uses implantable testosterone pellets (Testopel) is a viable alternative to existing treatments for hypogonadism, with a number of practical advantages for patients, investigators reported at the Sexual Medicine Society of North America 2009 annual meeting.

Sexual Dysfunction

The pellets have been found to provide sustained levels of testosterone for at least 4 months, decrease gonadotropin levels, and are well tolerated. But for Andrew McCullough, MD, their real attraction is pragmatic.

“It came to me as I was flossing my teeth in preparation for my dental appointment,” said Dr. McCullough, associate professor of urology at the New York University School of Medicine. “Had I been flossing as I was supposed to for the last 3 months, or was I doing what everyone else does and flossing before the appointment so I could tell him that I floss regularly?”

Men, he surmized, are notoriously noncompliant with their medications, and may not want to apply a daily gel “reminding them that their ‘testosterone factories’ are defective.”

Compliance levels in testosterone gel studies tend to be artificially high, Dr. McCullough noted. In real life, men are much less likely to comply with the daily application of gel needed to maintain testosterone levels.

Thus, implantable pellets may be

more feasible for large numbers of men, according to Dr. McCullough. He and colleagues reviewed data on 172 patients with 240 implantations of Testopel pellets. Sixty of those patients had two or more implantations.

The researchers obtained 354 follow-up levels an average of 77 days following implantation. Mean age in the cohort was 60 years. About 16% of subjects received six or seven pellets, 43% received eight or nine pellets, and 41% received 10 to 12 pellets.

Pellets effective up to 4 months

The pellets were found to raise testosterone levels for at least 4 months, with those receiving 10 to 12 pellets enjoying the best results.

“We’re trying to refine the number of pellets based on patients’ body mass index and aromatase activity,” said Dr. McCullough. “For now, the standard I use is 10 pellets.”

In a separate, 32-patient retrospective study, Dr. McCullough’s team observed gonadotropin levels decreasing as testosterone levels rose following pellet implantation. The researchers also suggested that serum gonadotropin levels may be combined with serum testosterone levels to determine optimal timing for re-implantation.

When Dr. McCullough first presented his data at an AUA section meeting, he was asked whether he starts his patients on testosterone gels first.

“I told them, no, I don’t,” he said. “I want the man to know how it feels to have

a normal testosterone level. When he comes back in 3 months, he can then tell me which therapeutic option, if any, he wants. What we’ll know at that point is if low testosterone

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ANDREW McCULLOUGH, MD

was the cause of his symptoms. If he has not symptomatically improved, replacing his testosterone is not the solution.

“Testosterone replacement is a lifetime thing, so it makes sense to know definitively at the outset whether replacement is the right thing for him.”

Sterile technique key

SMSNA meeting attendees also heard results of a retrospective safety analysis of Testopel therapy for men and women with testosterone deficiency syndrome. The key to avoiding infections and other

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The pellets were found to raise testosterone levels for at least 4 months in one study.

complications, said study author Irwin Goldstein, MD, is strict attention to detail when implanting the pellets and improved design of the pellets themselves.

“We’re very obsessive and compulsive about sterile technique,” said Dr. Goldstein, director of sexual medicine at Alvarado Hospital, San Diego. “We use surgical facemasks, we wash the [implantation] site for 5 minutes with chlorhexidine topical and clean it with 99% alcohol, and we prep the area with Betadine and a sterile drape.

“We use two sets of sterile gloves and identify one sterile gloved hand that contacts and grasps the pellet. It never touches the prepared skin area.”

Dr. Goldstein added that a newer manufacturing process now produces a smaller, more compact pellet, which also helps improve outcomes.


After preoperative washing and preparation, Dr. Goldstein’s team applies anesthetic and makes the appropriate incision. They introduce a trocar with sharp stylet surrounded by a backdrop of sterile gauze. Pellets are loaded individually into the trocar and advanced with a blunt stylet.

The Alvarado group’s safety analysis showed that of 64 implant procedures (28 men, 36 women) over 19 months, there were no implantation site infections or

spontaneous pellet extrusions.

“It was important for us to develop these techniques because long-acting testosterone treatment, such as that provided by pellets, is extremely useful for patients,” Dr. Goldstein said.

Dr. McCullough uses a simpler implantation technique with similar success in terms of site infections and pellet extrusions. Early versions of the testosterone pellet carried a 6% to 8% infection rate, but he said that has not been an issue with Testopel.

Dr. McCullough has served as a speaker/consultant for Plethora Solutions, Spectrum Pharmaceuticals, and VIVUS. 

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