



LARGEST REAL-WORLD STUDY OF BIOABSORBABLE TESTOSTERONE PELLETS IN MEN AND WOMEN SHOWS LOW COMPLICATION RATES OVER 7 YEARS AND 1.2 MILLION IMPLANTS

June 1, 2021

BIOTE REPORTS COMPLICATION RATES UNDER 1% IN STUDY EVALUATING THERAPY COMPLICATIONS AND CONTINUATION

IRVING, Texas—([BUSINESS WIRE](#))—Delivering testosterone via bioabsorbable pellets inserted under the skin is a low-risk approach to long-term hormone therapy for women and men, according to peer-reviewed data [published](#) in the journal "Therapeutic Advances in Endocrinology and Metabolism" (TAEM).

Practitioners from multiple clinical specialties reported an overall complication rate of less than 1% in 1,204,012 subcutaneous implants performed over a period of seven years. Each of the 376,254 patients treated for testosterone deficiency received implants of bioidentical hormones, either testosterone alone or combined with estradiol, with 85% of study participants being women, ages 25 to 92, and 15% men, ages 35 to 85.

"Clinical experience and research continue to demonstrate the significant negative impact of testosterone deficiency in both women and men on health and wellbeing, but most delivery methods have been inadequate for long-term therapy: Creams are absorbed inconsistently, injections cause hormone spikes, and previous attempts at patches failed to advance into standard of care because of high rates of side effects," said study author Dr. Gary Donovan, who has been a practicing OB/GYN for 30 years and founded hormone optimization company Biote. "This study adds to our understanding of one low-risk modality of long-term delivery."

Of the patients who received treatment at least twice, 93% chose to continue hormone pellet therapy.

"The high rate of voluntary continuation in this real-world retrospective analysis speaks to patient satisfaction with the therapy," Donovan said. Hypogonadism in men negatively affects general health and numerous conditions, including diabetes. The use of testosterone therapy in men has been increasing progressively year over year since the 1990s. As the most abundant biologically active gonadal hormone throughout the female lifespan, testosterone is also gaining recognition for its role as a vital hormone in women.

Pellets are inserted under the skin, where they are absorbed by the body over time. They have been studied since the 1930s. Practitioners reported complications in 0.785% of the procedures studied, the most common being implant extrusions, cellulitis/infection, and bleeding at the delivery site. Pellet extrusion was more common in men (<3%) than women (<1%).

The study is the largest reported retrospective study to evaluate the continuation and complication rates of testosterone pellet implants. Practitioners self-reported procedure data, a limitation of the study mitigated by its large sample size as well as the fact common secondary procedures usually required office follow-up. As the study examined the risk of pellet delivery procedure, it did not analyze secondary reactions that can occur in women, such as acne or body hair.

"The safety of hormone pellet implants in men and women over the long term appears to be better than other routes of administration," said Terry S. Weber, CEO of Biote. "We are hopeful that this study motivates further inquiry so that women and men managing hormone-related conditions like menopause, diabetes, and hypogonadism benefit from a broader continuum of care options within standard clinical protocols."

About Biote

Biote is a hormone optimization company that has translated over 80 years of scientific insight into clinically-validated medical approaches that identify and treat imbalances in the production of hormones. By partnering with over 5,500 medical providers across the United States, Biote is educating practitioners on the scientific evidence of the roles of hormones and supplements to support improved health, and on responsible treatment of patients. We are dedicated to helping patients live better, longer by changing the way healthcare is practiced on a global level.

Contacts

Liz DeForest, The Bliss Group for Biote
Biote@blissintegrated.com