



## STUDY: TESTOSTERONE PELLETT THERAPY REDUCES BREAST CANCER INCIDENCE IN WOMEN

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*Real World Data of 2,337 Patients Over Nine Years Is Second Long-Term Study Showing Such Benefits*

IRVING, Texas--([BUSINESS WIRE](#))--Women who took testosterone via hormone pellets as part of bioidentical hormone replacement therapy (BHRT) had a 35.5% lower incidence of invasive breast cancer compared to expected age-adjusted Surveillance Epidemiology and End Results (SEER) rates, according to a new retrospective study. The results of "The Testosterone Therapy and Breast Cancer Incidence Study" were [published](#) in the peer-reviewed "European Journal of Breast Health."

Of the 2,337 women followed over nine years, only 14 developed invasive breast cancer, a marked reduction when compared to historical controls: Age-matched SEER data would have suggested 48 cases (incidence rate of 144/100,000 vs. 223/100,000), and 71 cases would be expected from the placebo arm of the Women's Health Initiative. The real-world data was collected from January 2010 through October 2020 and included women treated at least twice with hormone pellets consisting of either testosterone alone (640 patients) or testosterone and estrogen (1,737 patients). Ages ranged from 29 to 87 years.

"Given the way testosterone functions within the body, breast cancer prevention is an unsurprising but crucial addition to the corpus of research on hormone optimization, and this study adds to our knowledge of testosterone's vital importance to women's health," said Dr. Gary Donovitz, the OB/GYN founder of BioTE Medical, who administered and co-authored the study with Mandy Cotten, DNP, APRN, FNP-C. "This study reaffirms that hormone imbalances are an urgent medical condition for women, and that optimizing hormones responsibly can not just improve quality of life, but actually prevent disease."

Testosterone is a vital hormone in women but is often misunderstood. It promotes downstream physiological processes via functional androgen receptors that are located in almost all tissues, including the breast, heart, blood vessels, gastrointestinal tract, brain, bladder, uterus, vagina, ovaries, skin, bone, bone marrow, muscle, joints, and adipose tissue. Use of the validated Menopause Rating Scale questionnaire has yielded objective evidence that testosterone treatment significantly reduces symptoms in pre- and post-menopausal women.

This is the second, and largest, long-term study to demonstrate the relationship of testosterone pellet therapy to invasive breast cancer incidence in women. It follows the first breakthrough study on the subject, conducted by Dr. Rebecca Glaser and [published in "BMC Cancer"](#) in 2019, which showed a lower chance of invasive breast cancer compared to the expected age-adjusted SEER incidence rates.

"The preventive potential of hormone therapy, specifically testosterone for women, is one of the most understudied scientific hypotheses and may relate to numerous diseases. These two studies comprise some of the earliest and most insightful longitudinal data we have," co-author Cotten said. "Older studies are often limited in their scope or don't define well what is being evaluated: There are many hormone variations – natural, synthetic, bioidentical, and the body itself makes three different types of estrogen alone – and they function differently within the body."

"The broad-brush conclusions from limited studies are how we end up with the myth that 'estrogen causes cancer,' which just does such a disservice to the spectrum of hormones that could potentially be helping us prevent diabetes, cancer, brittle bones and other hormone-related conditions."

Twenty years ago, the Women's Health initiative, the largest long-term randomized clinical trial of combined equine estrogen therapy or estrogen/progestin therapy, found a significantly higher risk of developing invasive breast cancer among women using estrogen/progestin therapy, whereas a lower risk was observed in the equine estrogen alone arm. Testosterone was not studied.

Both the Glaser and the Donovitz-Cotten studies looked specifically at subcutaneous testosterone pellets. The rice-sized pellets are inserted under the skin and absorbed over time, and they have been used to treat hormone deficiencies in women since 1937. In the Donovitz-Cotten study, hormone dosing consistency was controlled through use of BioTE pellets, which use bioidentical estrogen and testosterone and are manufactured to potency standards of +/- 3%, stricter than the FDA's own requirement of +/- 10%. Neither study reviewed other delivery methods for testosterone, such as creams or shots, which are absorbed differently by the body and for which these preventive conclusions cannot yet be drawn.

All breast cancer incidences in the Donovitz-Cotten study were self-reported, a limitation of the study; the authors reviewed all patient charts and contacted each patient one year from their last insertion, and performed follow-up after obtaining suspicious mammogram results and surgical pathology reports to confirm diagnoses.

"This is really a drop in the bucket in terms of the research women deserve. The scientific world knows women have long been understudied in clinical trials, generally, but the gap in research about women's health, specifically, is even more vast," said Terry S. Weber, CEO of BioTE. "We're convening stakeholders across the care continuum to advance clinical research and educate providers on the benefits of hormone optimization, and we're calling on the academic community to step up in investigating the role of hormones in conditions like diabetes, age-related bone loss and other conditions, across women of all ages. The logical connections are all there. We need the scientific evidence to take these hypotheses to mainstream treatments that make a global impact on health."

### About BioTE Medical

BioTE Medical 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 Medical 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.

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