

Frequently Asked Questions for Physicians about Pellet Therapy

Q: How are hormones monitored during therapy?

A: Hormone levels testing needs to be ordered and evaluated before therapy is recommended.

In Women

- FSH
- Estradiol
- Testosterone
- Free Testosterone

Also consider:

- Thyroid Hormone Levels
- Monthly Self-Breast Exam
- Mammogram
- Pap

In Men

- Prostate Specific Antigen
- Sensitive Estradiol
- Testosterone Free & Total
- Liver Function Profile
- Lipid Profile
- CBC
- Estradiol
- TSH
- Fasting Blood Glucose (FBG)
- HbA_{1c}

Annual Rectal Exam

Levels will need to be reevaluated during hormone therapy prior to insertion of the next round of pellets, at or around 3 months. After the first year of therapy, hormones levels may be followed less frequently.

Q: Are there adverse reactions to pellet therapy?

A: The only regular adverse effect is extrusion (shown only to occur in 3 to 6% of patients), which may be related to mechanical factors such as habitual work activity but also possibly procedural factors. Other adverse effects such as bleeding (more prevalent in cases using increased number of pellets), infection (in 0.6%) and fibrosis are rare.

Q: Can a patient be allergic to the implants?

A: Very rarely, a patient will develop redness and itching at the site of the implant. There is generally minimal or no tenderness and no other sign of infection. Many pellet formulations include stearic acid and PVP (Povidone). Patients may react to the PVP.

Q: What training or certification is required to practice pellet therapy?

A: Training is a necessity, however certification is not generally required beyond that of state mandated physician licensing. ITRI has partnered with physicians experienced in pellet implant therapy to offer all of the training and support you will need to begin administering pellet therapy.

Q: Will pellet therapy be covered under my malpractice insurance or do I need to purchase additional coverage to perform these procedures?

A: Every insurance policy is subject to its own limits and exclusions. It is important to review your policy to be certain of your coverage. Wellness Medical Protection Group provides specialty insurance policies for pellet implant procedures, as well as many other ancillary services. For more information visit their website <http://wmpginsurance.com>, or Call 855-851-2968.

Q: Will I need a surgical suite in my clinic or can this procedure be performed in an examination room?

A: The pellet implant procedure does not require a surgical suite and can be done in an examination room that is maintained using standard sterilization procedures.

Q: How much time is required to administer the pellet procedure?

A: The pellet implant procedure takes approximately 10 minutes from initial room set-up to completion. The area is prepared with a local anesthetic, the pellets are inserted with a disposable trocar, and the insertion site is closed with sterile strips. It is a fairly simple procedure that is easily scheduled in to your daily routine.

Q: Do I need to purchase special equipment to implant pellets?

A: The only equipment that is required for the pellet implant procedure is the trocar kit, which includes a disposable trocar and all necessary supplies to administer the procedure. Supplied by Jade Engineering.

Supporting Information:

Hormonal profiles in postmenopausal women after therapy with subcutaneous implants

Margaret H. Thom, W. P. Collins and J. W. W. Studd, *BJOG: An International Journal of Obstetrics & Gynecology*, Volume 88, Issue 4, pages 426–433, April 1981

Pharmacokinetics and pharmacodynamics of testosterone pellets in man

David J. Handelsman, Ann J. Conway, and Lyn M. Boylan, *The Journal of Clinical Endocrinology & Metabolism*, Volume 71, Issue 1, October 23, 1989

Pharmacokinetic evaluation and dosing of subcutaneous testosterone pellets

Alexander W. Pastuszak, Harsha Mittakanti, Joceline S. Liu, Lissette Gomez, Larry I. Lipschultz, Mohit Khera, Scott Department of Urology, Baylor College of Medicine, Houston, Texas; and the Department of Urology, Feinberg School of Medicine, Northwestern University, Chicago, Illinois.

Subcutaneous hormone implants for the control of climacteric symptoms: a prospective study

M. Brincat, J.W.W. Studd, T. O'Dowd, A. Magos, L.D. Cardozo, P.J. Wardle, D. Cooper
The Lancet Volume 323, Issue 8367, 7 January 1984, Pages 16–18
Originally published as Volume 1, Issue 8367

Testosterone release rate and duration of action of testosterone pellet implants

S. Kelleher, C. Howe, A. J. Conway and D. J. Handelsman, Department of Andrology, Concord Hospital and ANZAC Research Institute, University of Sydney, Sydney, NSW, Australia, *Clinical Endocrinology*, Volume 60, Issue 4, pages 420–428, April 2004

Bone mineral density outcomes following long-term treatment with subcutaneous testosterone pellet implants in male hypogonadism

Margaret R. Zacharin, Joseph Pua and Shankar Kanumakala
Clinical Endocrinology, Volume 58, Issue 6, pages 691–695, June 2003

An analysis of testosterone implants for androgen replacement therapy

David J. Handelsman, Mary-Anne Mackey, Chris Howe, Leo Turner and Ann J. Conway, *Clinical Endocrinology*, Volume 47, Issue 3, pages 311–316, September 1997

Supporting Information (continued):

A comprehensive review of the safety and efficacy of bioidentical hormones for the management of menopause and related health risks

B Hormones - Altern Med Rev, 2006, D. Moskowitz

Randomized cross-over clinical trial of injectable vs. implantable depot testosterone for maintenance of testosterone replacement therapy in androgen deficient men

Carolyn Fennell, Gideon Sartorius, Lam P. Ly, Leo Turner, Peter Y. Liu, Ann J. Conway and David J. Handelsman, Andrology Department, Concord Hospital & ANZAC Research Institute, University of Sydney, Sydney, NSW, Australia
Clinical Endocrinology (2010) 73, 102–109

Influence of implantation site and track geometry on the extrusion rate and pharmacology of testosterone implants

S. Kelleher, A. J. Conway, D. J. Handelsman, Department of Andrology, Concord Hospital and ANZAC Research Institute, University of Sydney, Sydney, Australia
Clinical Endocrinology (2001) 55, 531±536