Frequently Asked Questions About Hormone Pellet Therapy

Pellet Insertion: Every 3-6 months for women and every 5-6 months for men

These appointments are meant to address minor adjustments in dosage or side effects but if you have complicated medical problems or are having an unusual side effect you will be asked to schedule an appointment with Dr. Frazzetta and blood work will be ordered as indicated.

Will my periods be the same?

Possibly but as the hormones become more in the range of pre-menopause, periods may recur if you are newly menopausal. If they appear after a year of menopause, we may order an ultrasound to make sure the lining of your uterus looks normal.

Are there any side effects and/or complications?

Unlike other forms of hormone therapy, there are fewer side effects than traditional therapy. There will be minor tenderness and or bruising after pellet insertion for 1-2 weeks. This is more common with males due to number of pellets required. Infection and expulsion of pellet are rare.

How long will it take for the pellets to get into my system and work?

24-72 hours. Optimal effects occur about 3 weeks after insertion.

I get horrible headaches-will pellets help me?

Very likely! There has been great success, especially with women who have menstrual migraines, and new migraines that appear after age 35.

Do I need to take other medication?

If you still have a uterus, you will need to be on micronized oral progesterone taken at bedtime as well and possibly if you don't have a uterus.

Why do I need estrogen?

Estrogen has been shown to protect against heart attack, stroke, osteoporosis and Alzheimer's. It also keeps us looking young and healthy!

Why do I need testosterone?

Testosterone is the most abundant sex steroid hormone in women and men. Estrogen is made from testosterone. We need this hormone to keep our thought process's quick and our libido healthy. It improves our bone density, muscle mass, collagen, strength, and prevents some types of depression. It is also the source of our energy and solid sleep.

Will I grow unwanted hair from testosterone?

There is less chance of excess hair growth with natural testosterone than with synthetic hormones. Facial hair will grow with testosterone pellets but usually not worse than when you were in your twenties. This is often managed with tweezing, bleaching, waxing, shaving, or laser hair removal. In general, any areas with hair may be stimulated to grow. Sometimes in a positive way; sometimes in a negative way but usually very manageable. Men or women who are genetically prone to male pattern hair loss may experience hair loss however, there are medications that may help balance this.

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I have no libido-what will this do for that, if anything?

Good hormone balance will typically greatly improve your libido especially with the addition of testosterone in pellet form. It is also important to continually strive to improve your relationship. Dr. Frazzetta may recommended some additional information for you.

6 Week Follow-Up Visit:

This visit is to go over your lab work and physical results. It is a shorter visit, usually 20 minutes. At this appointment, Dr. Frazzetta will recommend when your next pellet should be scheduled and what the dose should be if you choose to continue. Any side effects will be managed at this time.

Yearly care: preventive test and lab

At Montrose Wellness Center we ask that you get the recommended preventive test by your GYN or primary care provider, and that you report back to us with the results; ie any blood work or screening tests. We will not manage the results of these tests but require that you get them to ensure the safety of our treatment.

We may order yearly blood work to see if your treatment is progressing well. You may opt out of these tests if you have them drawn by another doctor or if you are happy with your dosage and have not had any unusual changes in your health. To review the results of these tests we request a follow-up consultation at a separate visit from your pellet insertion if there are any concerns.

Don't fix it if it's not broken!

Once we have you on an effective regiment, and you are feeling well, blood work and consultation visits are not required unless you want them. This is to save you money and to use our time appropriately. So, if you are feeling great, you won't need to schedule an appointment.

Consultations with Dr. Frazzetta:

If you require complicated management, this must be done by Dr. Frazzetta in the office. All questions and consultations must be done with a scheduled appointment within the office.

What do I need for my first appointment? Before we can schedule your first appointment, we will ask that you have a hormone blood panel drawn. This can be done at Dr. Frazzetta's office, your PCP, or hospital laboratory. We also request that you fill out all the appropriate paperwork provided by our office before your first appointment. We do not accept electronic submissions of paperwork. We will request that we receive up to date records of mammogram, DXA (bone density) and PSA (for men).

How much of this is covered by my insurance? Most insurances will not cover the cost of the blood work or it will go towards a deductible. Insurance will not cover pellet procedures. We require payment at time of service. The costs will vary. Forms are available upon request that you can submit to your insurance company if you believe it will be covered by your insurance however, this is the patient's responsibility.

Pellet Insertion After Care

After first night: OK to remove tape, ice pack, and white gauze dressing. It is OK to shower after 24 hours. Leave bandage on for the first shower then remove wet bandage and replace with a new bandage; change daily. It is ok to remove Steri-strips, if they have not fallen off after 7 days.

From day of insertion to day 7:

- NO hot tubs.
- NO hot baths.
- Site may remain tender for 1-2 weeks
- May have slight redness around incision site. This is normal. If redness does not start to resolve
 as the days of healing progress;
 - Apply a warm heating pad or similar, twice a day, for 10-15 minutes or as needed. You
 may use a warm washcloth as well.
- Infection is very rare. However, if redness and swelling increases after 72 hours you may have a
 minor skin infection. Contact the office for further evaluation.

Women ONLY:

- Continue any previous treatments of Estradiol and Testosterone for about <u>3 days</u> post procedure then stop.
- If you are currently taking Progesterone this should be continued.
- NO strenuous exercise or working the gluts for <u>4 days</u> post-pellet insertion (NO biking, spinning, elliptical, squats, lunges, etc). It is OK to walk, treadmill flat, upper body and/or abs.

Men ONLY:

- Continue any previous treatments of Testosterone for <u>3-5 days</u> post procedure then stop.
- NO strenuous exercise or working the gluts for <u>7 days</u> post-pellet insertion (NO biking, spinning, elliptical, squats, lunges, etc). It is OK to walk, treadmill flat, upper body and/or abs.

Local Reaction to the Pellet Implant

Very rarely, a patient will develop a local zone of **redness** (3-8cm) and/or **itching** at the site of the hormone implant weeks after the insertion. There is typically minimal or no tenderness and no other signs of infection. This is likely a local inflammatory response and may be a risk factor for extrusion, ie; the pellet working its way out through the incision or through the overlying skin.

Recommendations:

- Apply a warm heating pad or similar, twice a day, for 10-15 minutes or as needed. You may use
 a warm washcloth as well.
- Oral OTC allergy medications daily: Claritin (generic: loratadine), Zyrtec (generic: cetirizine),
 Allegra (generic: fexofenadine)
- In general, implants are not removed. If there are any questions of infection, please call the office to schedule an evaluation. (970) 252-9644.

Male: Informed Consent for Testosterone Therapy

Testosterone (T) pellet implantation has been used for androgen replacement since 1940. Implants may be manufactured (Testopel) or compounded. The pellets implants are placed under the skin and into the fat of the abdominal wall or upper gluteal area through a small incision using local anesthesia. Complications may occur and may include, but are not limited to, extrusion of the pellet, bleeding, bruising, pain, swelling, skin discoloration, scarring, acne and infection. An ice pack may be applied following the procedure. Pellets dissolve over time, usually every 5-6 months and are not removed. Testosterone may also be replaced using an injection every week or a daily gel.

The dose of T prescribed by Dr. Frazzetta may be higher than historical dosing. T does not cause prostate cancer but may stimulate an undiagnosed prostate cancer. If your PSA is elevated, you will need written approval from your urologist or a primary care physician prior to T therapy. T may also increase the production of red blood cells. If the red blood cell count elevates above normal, you may need to donate blood and/or lower your dose of T. Testosterone decreases sperm production and possibly decrease testicular size and may worsen sleep apnea. Additionally, men predisposed to hair loss may experience this as well. There is no "first pass effect", meaning it avoids the liver and does not increase clotting factors. A few recent studies have suggested an increased risk of cardiovascular events in men receiving T therapy, particularly in men with a history of heart disease. Other studies have shown a decreased risk of heart disease. In June 2014, the FDA issued a warning about the possibly of increased blood clots in veins. *Oral* androgens and other androgen formulations may adversely affect the liver or lipid profiles. Currently, the FDA has only approved treatment for men with T levels < 300, therefore your treatment may be used to treat symptoms of T insufficiency with blood levels higher than this. Data would support this approach.

T is the major substrate or building block for estrogen. Symptoms of excess estrogen include fluid retention, bloating, breast tenderness, irritability and weight gain. You may be treated "off-label" with an estrogen blocker/aromatase inhibitors (anastrozole), which can be combined with T in the compounded pellet implant or taken orally. Finasteride may also be used "off-label" to prevent the conversion of T to DHT which may contribute to male pattern hair loss. T and estrogen levels may be checked to assess the absorption of T and monitor the conversion to estrogen.

- You may elect a trial of T therapy with a short acting T preparation (e.g., gel, shot).
- PSA levels will be monitored 6 months after starting treatment and yearly thereafter.
- If your PSA increases on T therapy, you must see your doctor or urologist for a complete evaluation.
- You may resume therapy after a negative prostate biopsy or clearance from your physician/urologist.
- You must notify the physician of any allergies or bleeding problems prior to the procedure including anti-coagulant, NSAID, or aspirin therapy.
- You should avoid vigorous physical activity for 7 days following the insertion of the pellets.

Male: Informed Consent for Testosterone Therapy

I have read and understand the above information including the procedure, benefits, risks and alternatives to the implantation of T or T+ anastrozole pellets and T therapy. My signature below certifies I have read the above and acknowledge I have been encouraged to ask questions regarding therapy. All questions and concerns have been addressed and answered to my satisfaction. I agree to allow Dr. Gayle Frazzetta to implant the pellets or begin treatment with gel or injectable. By beginning treatment, I accept all risks of therapy and future risks that might be reported.

I understand that Dr. Frazzetta will not be assuming my healthcare unless previously arranged. I am aware that Dr. Frazzetta does not accept health insurance for pellet implant procedures. For any hormone therapy that is not covered by health insurance, payment is due at the time of service. Forms are available upon request for self-admission to insurance. I have discussed any questions or concerns with Dr. Frazzetta. I agree to follow up with my primary care physician for my medical care, annual physical exams and prostate exam as indicated. I understand and agree that my data including lab results may be used anonymously for research purposes and publication. **This consent is ongoing for this and all other future pellet insertions.**

Patient Name:	Patient Signature:	Date: