

# Protocol

## Testosterone Implant Therapy For Women

### Initial Testing

- FSH, Estradiol, Testosterone free and total, TSH
  - Optional: SHBG for calculated free androgen index (vs. free Testosterone)
  - Offer FBS, HbA1C, lipid profile
    - Do not order a test if it will not change therapy
    - Diagnosis: Free T in lower 1/3 of normal. Even women with mid-range free testosterone levels have relief of symptoms.
- MRS Survey (validated survey)

ICD 9 codes; 780.79, 627.2 Pre-printed prescriptions

### Testosterone Pellet Dosing

- Initial dosing of testosterone pellet implant may be based on weight
  - <100 lbs. (45 kg) 80 mg
  - 100-120 lbs. (45-55 kg) 100-110 mg
  - 120-145 lbs. (55-65 kg) 110-125 mg
  - 145-165 lbs. (65-75 kg) 125-150 mg
  - >75 kg 150-225 mg
- Average starting dose, 120 mg
  - Some women prefer to start low. Increase with next insert.
  - Offer to lower the dose for h/o acne (2% of pts.) and facial hair growth (Recommend adding laser hair removal to your practice).
    - Zinc 30 mg., **Eliminate refined carbohydrates (sugars)**
  - Increase the dose for symptom control or to last longer.
  - There are rarely any other side effects
    - *Anxiety* is usually *estrogen* dominance
  - Not a cure all! **'Trouble Shooting'** and **'Hot Flashes'**
  - See handout **'Healthy Hair'**. T *increases* scalp hair growth.

### Options for Therapy

MOST WOMEN DO NOT REQUIRE EXOGENOUS ESTRADIOL

- **BEST OPTION: NO exogenous estrogen**  
T pellets **alone** relieve symptoms in the majority of women.  
No bleeding, weight gain, breast pain, fluid retention or progestin needed.
  - **'It's Your Choice'**. Patients have to understand the concept because their physician may not. (Follicular levels, function of estrogen)

- **TESTOSTERONE IMPLANT ALONE (option)**
  - Most women in the US continue to make estrogens
    - Estrogen dominant society
  - Simplest for patients, especially the elderly (70-95 yo)
  - Patients do great on a T pellet alone
  - Testosterone is the major substrate for estradiol
  - All tissues with estrogen receptors have aromatase
  - Serum levels have no bearing in what is happening at the cellular level
  
- **Testosterone implant with Progesterone (no estrogen)**
  - Sublingual drops or oral capsules for insomnia, anxiety
  - Vaginal cream if GU symptoms are a major issue
  - 50 mg SC Progesterone implant
    - Insomnia, anxiety, stress, hot flashes, neuro-protection
  
- **Testosterone implant with Vaginal Estriol 2mg, Progesterone 100 mg.**  
Apply vaginally 0.2-0.25 cc apply daily for 14 days then 2-3 times per week for vaginal dryness
  - This works well in the majority of patients
  - The patient controls the dose by the frequency of use
  - Explain the benefits of vaginal estriol
    - Used frequently in Europe. Data to support vaginal estriol.
    - Works extremely well for GU symptoms.
    - Does not stimulate the breast tissue or uterine lining
    - Does not increase the risk of breast cancer (RR 0.7)
    - Does not cause weight gain, fluid retention, mood swings
  - Rarely have problems with bleeding (unless E2 used)
  - May add estradiol to the vaginal cream (0.01-0.025 mg/dose)
    - **Leave out the estradiol** for most patients and all breast cancer patients
  
- **Testosterone implant with Estradiol as a patch, gel or vaginal cream/tablet (Vagifem 10-25 ug).**
  - Vaginal estrogen is absorbed. Doses less than 75 ug are considered LOCAL therapy.
    - Vagifem (10-25 ug) IS local therapy
  - The vaginal delivers continuous low doses. Continuous estrogen is not recommended in breast cancer survivors.
  
- **Estradiol Implants are NOT RECOMMENDED**
  - Continuous estradiol stimulates breast tissue and has been shown to increase the risk of breast cancer.
  - Patients will bleed
  - Estrogen *pellet* only if a *surgical hysterectomy*
    - Thin women who cannot retain weight, runners

- Young patient, surgical hysterectomy, both ovaries removed, high FSH

### Follow Up

- Minimal follow-up testing required with testosterone implants alone.
  - No Estradiol therapy/ implants
    - Fewer complaints of anxiety, bleeding, weight gain, bloating, fluid retention
- Less nurse and physician time with follow up labs and phone calls.

### Follow up Labs

- **Testosterone implants**
  - Hemoglobin and Hct annually
  - **OPTIONAL: Annual** Testosterone level at month 3-4 prior to reinsert
    - Every patient has their own replacement level
      - 70-150 (even higher) ng/dL (Maintain T > 70)
      - Circadian release: Levels vary significantly throughout the day (up to 200 ng/dL)
      - Rare to have side effects from testosterone (safe)
  - Will check testosterone if **less than 10 weeks between insertions**
- Check Labs anytime a patient is not doing well.
  - Testosterone, **estradiol**, FSH, TSH
  - Salivary **cortisol**
  - Progesterone may be needed
  - Patient should read 'Trouble Shooting' **prior** to being evaluated.

### Breast cancer survivors

- Permission from or referral from the patient's oncologist
- Prescribe an aromatase inhibitor with testosterone
  - With permission from oncologist consider Testosterone-Anastrozole pellet implant
- Labs should be checked every insert
  - Testosterone, estradiol, estrone, FSH.