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## **Pellets - Hormone Implants: FAQ**

### **Introduction**

Data supports that hormone replacement therapy with pellet implants is the most effective and the most bioidentical “biologically equivalent” method to deliver hormones in both men and women. Implants, placed under the skin, consistently release small, physiologic doses of hormones providing optimal therapy.

### **What are Pellets?**

Pellets are made up of either estradiol or testosterone. The hormones are pressed or fused into very small solid cylinders. Pellets are larger than a grain of rice and smaller than a ‘Tic Tac’. In the United States, the majority of pellets are made by compounding pharmacists and delivered in sterile glass vials. There is an ‘FDA approved’ 75 mg testosterone pellet (Testopel<sup>®</sup>).

### **Why pellets?**

Pellets deliver consistent, healthy levels of hormones for 3-5 months in women and 4-6 months in men. They avoid the fluctuations, or ups and downs, of hormone levels seen with other methods of delivery. Estrogen delivered by subcutaneous pellets maintains the normal ratio of estradiol to estrone. This is important for optimal health and disease prevention. Pellets do not increase the risk of blood clots like conventional (oral) or synthetic estrogen replacement therapy.

In studies, when compared to conventional hormone replacement therapy, pellets have been shown to be *superior* for relief of menopausal symptoms, maintenance of bone density, restoration of sleep patterns, and improvement in sex drive, libido, sexual response and performance.

Testosterone delivered by pellet implant, has been used to treat migraine and menstrual headaches. It also helps with vaginal dryness, incontinence, urinary urgency and frequency. In both men and women, testosterone has been shown to increase energy, relieve depression, increase sense of well being, relieve anxiety and improve memory and concentration. Testosterone pellets increase lean body mass (muscle strength, bone density) and decrease fat mass. Men and women need adequate levels of testosterone for optimal *mental* and *physical* health and for the prevention of chronic illnesses like Alzheimer’s and Parkinson’s disease, which are associated with low testosterone levels.

Even patients who have failed other types of hormone therapy have a very high success rate with pellets. There is no other method of hormone delivery that is as convenient for the patient as pellet implants. Pellets have been used in both men and women since the late 1930’s. [See reference in Dr. Retzler’s “BHRT Position Paper” or on Dr. Rebecca Glaser’s website: www.hormonebalance.org.](#)

### **How and where are pellets inserted?**

The insertion of pellets is a simple, relatively painless procedure performed under local anesthesia (which means a lidocaine injection is used to numb the area). Pellets are inserted in the lower abdominal wall or upper buttocks through a small incision that is taped closed. The experience of the health care professional matters a great deal, not only in placing the pellets, but also in determining the correct dosage of hormones to be used, as well as in treating other issues underlying hormone imbalance.

### **Are there any side effects or complications from the insertion of pellets?**

Complications from the insertion of pellets include minor bleeding or bruising, discoloration of the skin, infection, and the possible extrusion of the pellet. Other than bruising, complications are

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very rare. Testosterone may cause a slight increase in facial hair or acne in some women, especially at higher dosages. Testosterone stimulates the bone marrow and increases the production of red blood cells. All methods of testosterone supplementation can cause an elevation in red blood cell production. If the hemoglobin and hematocrit (blood count) get too high, a unit of blood may be donated.

After the insertion of the implants, vigorous physical activity is avoided for 48 hours in women and up to 5 to 7 days in men. Early physical activity is a cause of 'extrusion', which is a pellet working its way out. Dr. Retzler has performed >500 insertions and has never had a case of pellet extrusion. Antibiotics may be prescribed if a patient is diabetic or has had a joint replaced. However, this is a 'clean procedure' and antibiotics are rarely needed. Dr. Retzler has had 3 cases of skin infection requiring antibiotics since performing pellet implants.

### **Why haven't I heard about pellets?**

This is an excellent question. Pellets are not patented and have not been marketed in the United States. They are frequently used in Europe and Australia where pharmaceutical companies produce pellets. Most of the research on pellets is out of Europe and Australia. Pellets were frequently used in the United States from about 1940 through the late 70's when oral patented estrogens were marketed to the public. In fact, some of the most exciting data on hormone implants in breast cancer patients is out of the United States. Even in United States, there are clinics that specialize in the use of pellets for hormone therapy.

### **Do men need hormone therapy?**

Testosterone levels begin to decline in men beginning in their early 30's. Some men maintain adequate levels of testosterone into their mid 40's to mid 50's, some into their late 70's to early 80's. Men should be tested when they begin to show signs of testosterone deficiency. Even men in their 30's can be testosterone deficient and show signs of bone loss, fatigue, depression, erectile dysfunction, difficulty sleeping and mental decline. Most men should be screened by age 50. It is never too late to benefit from testosterone supplementation.

### **What if my primary care physician or my gynecologist says that there is 'no data' to support the use of pellet implants?**

He or she is wrong. There is a difference between 'no data' and not knowing about or having read the data. It is much easier for busy practitioners to dismiss the patient, than it is to question their beliefs and do the research. After pellets are inserted, patients may notice that they have more energy, sleep better and feel happier. Muscle mass and bone density will increase while fatty tissue can decrease. Patients may notice increased strength, co-ordination and physical performance. They may see an improvement in skin tone and hair texture. Concentration and memory may improve as will overall physical and sexual health. There is data to support the 'long term' safety of hormones delivered by pellet implants.

### **Do pellets have the same danger of breast cancer as other forms of hormone replacement therapy?**

Pellets do not have the same risk of breast cancer as high doses of oral estrogens that do not maintain the correct estrogen ratio or hormone metabolites. Nor do they increase the risk of breast cancer like the synthetic, chemical progestins used in the Women's Health Initiative Trial. Data supports that *balanced*, bio-identical hormones are breast protective.

Testosterone, delivered by pellet implantation, has been shown to decrease breast proliferation and lower the risk of breast cancer, even in patients on conventional hormone replacement therapy. Clinical studies show that bio-identical testosterone balances estrogen and is breast protective. This is not true of *oral*, synthetic methyl-testosterone found in Estratest® or Syntest®, which gets converted to a potent synthetic estrogen, which can stimulate breast tissue. In the past, testosterone implants have been used to treat patients with advanced breast cancer. In

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1940, it was theorized that treating patients with testosterone implants earlier, at the time of diagnosis, would have an even greater benefit, preventing recurrence. Androgens have also been shown to enhance the effect of Tamoxifen<sup>®</sup> therapy in breast cancer patients. [References](#) supporting these statements can be found in the [data section](#) of the website in the 'Breast Cancer Folder' on Dr. Rebecca Glaser's website: [www.hormonebalance.org](http://www.hormonebalance.org) (login: data; password: data). A power point presentation 'Nov 07', summarizing the full text references, may be downloaded and viewed.

### **So, how can my doctor claim that bioidentical hormones are not safer than synthetic, chemical 'hormones'?**

Although some physicians and pharmaceutical companies claim that, 'bioidentical hormones are not safer than synthetic, chemical hormones', this is not true. Bioidentical progesterone (including FDA approved Prometrium<sup>®</sup>) does not increase the risk of breast cancer like the synthetic progestins. Progesterone, used vaginally, does not negate the beneficial effects of estrogen on the heart like the synthetic progestins. Estriol, an estrogen widely used in Europe is a bioidentical hormone, which has never been submitted for FDA approval in the United States. It does not bind strongly to estrogen receptors and does not stimulate breast tissue. Numerous studies have shown that vaginal estriol does not increase the risk of breast cancer. It has safely been used in breast cancer survivors where it lowered the risk of recurrence and death. It is important to understand that *balanced* hormones are the key to health and disease prevention. There are FDA approved bioidentical hormones including Prometrium<sup>®</sup>, the testosterone patch for men, AndroGel<sup>®</sup>, estradiol patches and gels, and the 75-mg testosterone pellet – Testopel<sup>®</sup>. FDA approval is only required if a pharmaceutical company wants to market a drug to the public.

### **Are there side effects to estrogen delivered by pellet implantation?**

When a patient first starts on hormone therapy there may be mild, temporary breast tenderness, which resolves on its own or improves with topical progesterone. Hormone receptors may be very sensitive and take time to adjust. There may be a temporary water weight gain, which will also resolve on its own. Women, especially those who have *not* had a hysterectomy, may choose a different method of delivery of estrogen, as the risk of bleeding is significant. [If you would like more information about this, please see Dr. Retzler's handout "It's Your Choice" regarding estrogen replacement therapy options.](#)

### **How long until a patient feels better after pellets are inserted?**

Some patients begin to feel better within 24-48 hours while others may take a few weeks to notice a difference. Diet and lifestyle, along with hormone balance are critical for optimal health. Stress is a major contributor to hormone imbalance and illness.

### **How long do pellets last?**

Pellets usually last between 3 and 5 months in women and 4-6 months in men. Pellets do not need to be removed since they completely dissolve on their own.

### **Do patients need progesterone when they use the pellets?**

Most times when estradiol is prescribed, progesterone is also prescribed even if the patient has had a hysterectomy. The main indication for the use of *synthetic* progestins, like Provera<sup>®</sup>, is to prevent the proliferation (stimulation) of the uterine lining caused by estrogen. However, there are *progesterone* (not progestin) receptors in the bone, brain, heart, bladder, breast and uterus where progesterone has been shown to have beneficial effects. Progesterone can be used as a topical cream, a vaginal cream, an oral capsule (Prometrium<sup>®</sup>), or sublingual drops. Only oral

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progesterone (100-200 mg) and vaginal progesterone (45-90 mg) have been studied and shown to protect the uterine lining from estrogen stimulation.

If a patient is pre-menopausal, she uses the progesterone the last two weeks of the menstrual cycle (day 1, the first day of bleeding). Hormone therapy with pellets is not just used for menopause since women may experience hormone imbalance during the perimenopausal transition. Levels decline or fluctuate during this time, contributing to debilitating symptoms. Pellets are useful in severe PMS, post partum depression, menstrual or migraine headaches, and sleeping disorders. Pellets may also be used to treat hormone deficiencies (testosterone) caused by the birth control pill or Mirena<sup>®</sup> IUD.

### How are hormones monitored during therapy?

Hormone levels will be drawn and evaluated before therapy is started. This will include an FSH, estradiol, total testosterone (preferred method by LC/MS/MS), and TSH for women. Women also need a negative mammogram performed within a year of insertion. Men need a PSA, sensitive estradiol, total and free testosterone, liver profile and blood count prior to starting therapy. Men also need a normal digital rectal prostate exam performed within a year of insertion. Men are required to test estradiol and blood count levels 3-4 weeks after insertion for safe monitoring. Hormone levels will be reevaluated during hormone therapy, usually prior to insertion of the next set of pellets at 4-6 months; this will ensure that hormone levels do not get too high, and will help determine dosage. After the first year of therapy, hormones levels may be followed less frequently. Men must obtain a digital rectal exam each year. Women are advised to continue their monthly self-breast exam and obtain a mammogram and/or pap smear as advised by their gynecologist or primary care physician.

### How much does this cost?

The cost for the initial insertion of pellets is between \$270 and \$645 depending on the dose of the hormone and the number of pellets needed. Men need a much larger dose of testosterone than women and the cost is higher. Pellets need to be inserted 2 to 4 times a year depending on how rapidly a patient metabolizes hormones. Follow up insertion fees are less than the initial consult.

When compared to the cost of drugs to treat the individual symptoms of hormone decline, as well as the monthly costs of bioidentical hormone replacement, pellets are very cost effective. Pellets have been shown to be more effective at reversing bone loss than any pharmaceutical drug on the market. It is beyond the scope of this handout to examine the cost of drugs used for insomnia, depression, sexual dysfunction, obesity, diabetes, hypertension and more.

### Will insurance cover the procedure?

Dr. Retzler's office does not bill insurance companies directly; however, you can get a health insurance claim form to send for reimbursement. Few insurance companies cover the cost of pellets. Patients may want to contact their insurance companies to see if their costs will be reimbursed. Please remember, prevention is much more cost effective than disease. [Most insurance companies will cover your lab testing. Please ask the front desk for ICD9 \(diagnosis\) and CPT \(procedure\) codes to use when calling an insurance company.](#)