Outcomes with the "V" Implantation Technique vs. Standard Technique for Testosterone Pellet Therapy

William Conners, MD, Kevin Flinn, RN, and Abraham Morgentaler, MD

Men's Health Boston, Beth Israel Deaconess Medical Center—Harvard University Medical School, Division of Urology, Boston, MA, USA

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ABSTRACT

Introduction. Standard technique (ST) for implantation of testosterone pellets involves making a single linear track in the subcutaneous tissue of the buttock from the incision. After our initial experience with this modality, we modified this surgical technique to our current "V" technique (VT). This involves two tracks both caudally directed and emanating from the same skin incision but angulated approximately 10–15 degrees apart. While this allows additional pellets to be inserted more easily, and increased space to place those pellets further from the skin incision, it minimally increases the surgical procedure.

Aim. We sought to examine the impact of this technical modification on therapeutic efficacy and surgical complication rates.

Methods. Retrospective chart review of all patients treated with testosterone pellets at our institution.

Main Outcome Measure. Complication rates for infection, extrusion, hematoma, and pain.

Results. One hundred sixty-eight patients underwent 281 implantation procedures (40 via ST and 241 via VT). The mode number of pellets used with ST was 8 (range 6–8) and with VT was 10 (range 10–13). Incidence of pellet extrusion was 7.5% with ST and 0.8% with VT. Infection complicated ST in 5% of cases but only 1.2% with VT. No cases of hematoma were seen with ST but 1.2% of VT cases. Pain prompting discontinuation of therapy was seen in 7.5% with ST and 1.7% with VT. Significant pain without discontinuation was seen in 5% with ST and 1.2% with VT. Only in 1 of the 3 cases of hematoma was the individual on blood thinners. Fifty-eight other insertions were performed on blood thinners without significant hematoma. None of the individuals who developed infection or bleeding required additional surgical therapy.

Conclusions. VT allows successful placement of larger number of pellets, with low rates of complications, especially extrusion, even in men on anticoagulants. **Conners W, Flinn K, and Morgentaler A. Outcomes with the "V" implantation technique vs. standard technique for testosterone pellet therapy. J Sex Med 2011;8:3465–3470.**

Key Words. Testosterone; Hypogonadism; Outcomes; Testopel; Subcutaneous Testosterone Pellet Implant

Introduction

In recent years, there has been an increased awareness of the importance of testosterone deficiency (TD) and its treatment with testosterone therapy (TTh). Symptoms of TD include decreased libido and erectile dysfunction, as well as reduced energy, impaired mood, decreased muscle mass and strength, and increased abdominal fat [1,2]. TD has also been shown to be associated with increased risk of the development of diabetes, the metabolic syndrome, and osteoporosis [3–5]. Improvement in the characteristic symptoms of TD is seen in a high percentage of affected individuals. In one clinical study, 70% of men with TD who received TTh noted improvement in libido, erectile function, mood, or energy [6].

TTh can be accomplished through a variety of methods. The oldest modality of TTh is intramuscular injections, in the form of testosterone cypionate or enanthate, typically administered every 1–3 weeks [7]. A longer lasting injectable form, T undecanoate, is available in many countries but not in the United States. The short-acting formulations available in the United States provide excellent serum testosterone (T) concentrations

but require frequent injections, and can produce a roller-coaster effect as serum levels rise and fall [8].

The most frequently used TTh modality in the United States currently is topical gel therapy [9,10]. Gels avoid the need for injections but require daily application, may cause skin irritation, and carry a black-box warning regarding the risk of transference to women and children [11–14]. Less commonly used agents include oral testosterone, which carries potential for significant liver toxicity for formulations available in the United States [15], a twice-daily buccal pastiche, and a topical patch that carries a greater incidence of skin reaction [16] as well as less robust peak serum levels than testosterone gel therapies [10,16].

Another option for the treatment of TD is testosterone pellet therapy. Testosterone pellets (Testopel, Slate Pharmaceuticals, Durham, NC, USA) were approved by the FDA in 1972 but were not widely used until 2008. A very limited literature on this product suggests achievement of robust serum T concentrations, and high patient acceptance. A recent Phase IV study of Testopel noted maintenance of normalized serum T at 12 weeks using 8–12 pellets. Serum T returned to baseline by 24 weeks [17]. Testosterone pellets are thus the only current long-acting TTh option in the United States.

One of the areas of uncertainty regarding T pellets is implantation technique.

Testosterone pellets are typically inserted in the upper lateral quadrant of the buttock in an office setting under local anesthesia [18,19]. The pellets dissolve slowly, giving peak testosterone levels within the first 2–3 weeks of insertion, with these peak levels slowly declining over the following months [20]. We started using T pellets in 2008. Our initial practice was to insert six pellets, as indicated in the product literature. The six pellets were lined up within the trocar and displaced in a single line, as described by Cavender and Fairall [18]. Once we observed that a larger number of pellets appeared to provide greater serum testosterone concentrations and longer intervals between treatments, we were required to modify the insertion technique because the maximum number of pellets held at one time by the proprietary trocar was eight. We thus developed the V technique (VT) for testosterone pellet insertion, in which two loads of pellets can be delivered via two tracks emanating from the same skin incision. In theory, the VT would permit the introduction of as many as 16 pellets. In practice, we now most commonly implant 10–12 pellets at each insertion.

Aim

In this study, we compare the outcomes and risks of the VT to the standard, single-pass linear technique.

Main Outcome Measures

Specifically, we investigated the impact of technique on the risk for infection, extrusion, hematoma formation, post-procedural pain, and patient discontinuation.

Methods

Standard technique (ST) for testosterone pellet implantation was performed as follows: The patient is placed in the lateral decubitus position with the legs slightly flexed. The side of implantation is typically rotated for each individual procedure. Local anesthetic (10 mL of 2% xylocaine with epinephrine) is infiltrated widely into the area of the planned incision/implantation. Typically, 2–3 injections are required. Following this, an incision with an 11-blade is made at the level of the superior margin of the gluteal cleft in line with the lateral margin of the gluteus muscle's prominence. This area corresponds roughly to the lateral edge of a pants' back pocket. The proprietary trochar is then introduced into the wound at an approximately 30-degree angle and then advanced to its hub parallel to the skin surface, deep enough to avoid dimpling of the skin surface. The trochar is then partly withdrawn so as to expose the insertion well in the sheath. The inner stylet is withdrawn, and pellets are loaded into the sheath. When all pellets have been placed into the sheath, the inner stylet is replaced and advanced as the outer sheath is withdrawn, depositing the pellets in a single linear tract. The skin is closed with steri-strips.

VT, so named because the scheme of implantation resembles the two arms of the letter "V", was performed as follows: no changes were made to either patient positioning or administration of local anesthetic. An analogous technique was used to place the incision and introduce the trochar. Instead of a single line, pellets were placed along two tracks emanating from the same skin incision. After placement of the first set of pellets as per ST, the trocar is either entirely withdrawn from the incision site or withdrawn to just leave the tip of the trochar within the wound before beginning the second tract. The trochar is then angled 10–15 degrees from the first line of pellets. The second