Florida Center for Hormones and Wellness

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O-SHOT® INFORMED CONSENT

A. Purpose

Using blood-derived growth factors (platelet rich fibrin matrix [PRFM]), the O-shot® is a safe procedure for renewing the tissues of the female genital area (vagina, clitoris and urethra).

B. Benefits

This treatment is natural in that healing factors and cells are harvested from your own body and then injected into the specified areas. Since a distillate of growth factors from your own blood (PRFM – Platelet Rich Fibrin Matrix)) is used, there should be no side effects from the material injected. The body reacts to the treated cells as it does to a wound and immediately starts repairing the tissue. This builds the underlying tissue with tightening, smoothing, and increased blood flow (which makes the color more attractive). You should see improvements immediately, although there is usually a return to prior treatment status in 3-5 days as the water is absorbed and prior to the complete action of the cellular regenerative process. Within 2-4 weeks you will see improvement with continued changes for 12 weeks.

There's actual growth of new tissue by stimulation of your own stem cells, so the change is not from something foreign being in the body but from the body actually rejuvenating and growing. The PRFM stimulates new blood flow with new blood vessels (neovascularization).

The results of this treatment should last, but results may vary and research documenting the longevity or results are ongoing.

C. Treatment

You may take a pain medication, such as Tylenol™ or a prescription medication may be requested. You may ask for an anti-anxiety medication to use prior to the treatment. A numbing cream (lidocaine, bupivacaine, and tetracaine) is applied to the genital area (vagina, clitoris and peri-urethral areas). Also, in most cases a small amount of local anesthetic may be used.

Approximately 20 – 60 cc (less than ¼ cup) of blood are drawn in the same way blood samples are taken for routine lab tests. The tubes of blood are centrifuged (spun) to separate the component cells. Platelets (clotting cells) and healing/growth factors are separated and used for this procedure. The platelets are treated with calcium chloride (which tricks the cells into thinking that they are in the body and the body has been injured). The platelets release growth factors into the liquid of the tube. The liquid is transferred into a syringe and injected into the face using a tiny needle and a process is used to distribute the growth factors and increase their effectiveness.

D. Potential risks and discomforts

The primary risks and discomforts are related to the blood draw where there is a slight pinch to insert the needle for collection and there is a potential for bruising at the site. A numbing cream may be used to minimize this, however.

The injections at the treatment locations cause pain similar to an intramuscular injection (since a small needle and numbing cream are used). There is a potential for bruising at the injection sites. Pain from bruising could occur. Smokers have less positive response to this treatment than non-smokers, since the toxins in cigarette smoke block the response of the stem cells. There may be some variation in achieving the results obtained as everyone's body type is different and may have a different response. The introduction of the needle into the skin always presents the possibility of infection, scarring, loss of sensation, or change in muscle strength.

E. Other Potential Risks (this list is exhaustive. The likelihood of any of these occurring is EXTREMELY remote)

Bleeding, Infections, Urinary retention, No effect at all, Allergic reactions, Constant awareness of the G-Spot, A sensation of always being sexually aroused, Constant vaginal wetness, Mental preoccupation of the G-Spot, Alteration of the function of the G-Spot, Sexual function alteration, Hematoma , Urethral injury (tube you urinate through), Urinary retention, Hematuria (blood in urine), UTI (Urinary Tract Infection), Urinary Urgency (feel like you always have to urinate), Urinary Frequency, Increased/worsening nocturia (waking up several times at night to urinate), Change in urinary stream, Urethral vaginal fistula (hole between urethra and vagina), Vesico-vaginal fistula (hole between bladder and vagina), Dyspareunia (Painful intercourse), Need for subsequent surgery, Alteration of vaginal sensations, Scar formation (vaginal), Urethral stricture

(abnormal narrowing of the urethra), Local tissue infarction and necrosis, Yeast infections, Vaginal Discharges, Spotting between periods, Bladder Pains, Overactive Bladder (OAB), Bladder Fullness, Exposed Material, Pelvic Pains, Pelvic Heaviness, , Erosions, Fatigue, Damage to nearby organs including bladder, urethra and ureters, Alteration of bladder dynamics, Post-operative pain, Prolonged pain, Intractable pain, Alteration of the female sexual response cycle, Failed procedure, Varied results, Psychological alterations, Relationship problems, Sex life alteration, Decreased sexual function, Possible hospitalization for treatment of complications, Lidocaine toxicity, Anesthesia reaction, Embolism, Depression, Reactions to medications including anaphylaxis, Nerve damage, Permanent numbness, Slow healing, Swelling, Sexual dysfunction, Allergy, Nodule formation

F. Post-treatment

The post treatment therapy has been explained at the time of injection and I acknowledging that written instructions were given and are understood.

G. Follow-up

One of the office staff will follow-up with you to check on your progress and answer any questions. You may call the office to report on your progress or ask questions.

H. Privacy.

Your privacy is protected as described in our office Privacy Act Document.

PHOTOGRAPHS

I authorize the taking of clinical photographs and their use for scientific purposes both in documentation of this procedure and for publications and presentations. **I understand my identity will be protected**.

I request that no photographs be taken: _____(Initials)

CONSENT

I am aware that full correction is important and that follow-up enhancement treatments may be needed to maintain the full effects. I am aware that the duration of treatment is dependent on many factors including but not limited to age, sex, tissue conditions, my general health and life style, and sun exposure. The correction, depending on these factors may last 18 months and in some cases shorter and some cases longer. I have been instructed in and understand post-treatment instructions and have been given a copy of them.

The nature and purpose of this procedure, with possible alternative methods of treatment as well as complications, have been fully explained by the healthcare practitioner or the staff. No guarantee has been given by anyone as to the results that may be obtained by this treatment. I have been asked to sign this form after my discussion with the healthcare practitioner. By signing below, I understand this is a cosmetic procedure that may be considered not medically necessary and may not be paid for by any third party payor. Payment for this treatment is my responsibility. I acknowledge that I have read and understand the foregoing and agree to the treatment with its associated risks. I have had enough time to consider the information from my healthcare practitioner and feel that I am sufficiently advised to consent to this procedure. I hereby give consent to perform this treatment.

I have been given an opportunity to ask questions and all of my questions have been answered. I accept the risks and complications of this procedure.

If this procedure involves the use of other materials (like a hyaluronic acid filler—(Juvederm or Restylane) or a neuro-blocker (Botox or Dysport), a separate and additional consent form may be used.

An electronic copy of this document shall carry the same weight as an original

Patient Signature: _____ Date: _____