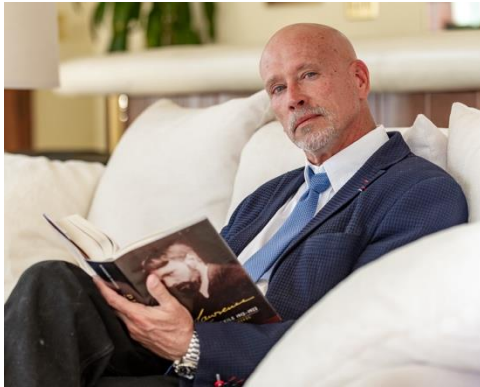


JCPM2023.12.05

Charles Runels, MD



Penile Rehabilitation

The idea of penile rehabilitation is that while you wait for blood flow to recover after prostate surgery, if you do nothing, then the penis becomes less elastic from the lack of intermittent, daily tumescence that would normally occur. So, you do something to cause increased blood flow and daily periods of tumescence to prevent fibrosis and decreased elasticity and to encourage restoration of blood flow and nerve function.

Knowing the research is helpful if you treat men recovering from prostate surgery, which is one of our high-success rate things to do with the P-Shot® procedure. But we haven't had a lot of research supporting what we are seeing clinically. Now we have this one. I love this study.

It came out in July and I'm just now seeing it, so shame on me. It was an in vitro study. They harvested human cavernosal tissue as part of surgery and then, in vitro, added PRP to see what would happen. ¹

¹ Javier et al., "(219) AUTOLOGOUS PLATELET-RICH PLASMA IMPROVES ENDOTHELIAL AND TADALAFIL-INDUCED RELAXATIONS IN CORPUS CAVERNOSUM FROM PATIENTS WITH ERECTILE DYSFUNCTION."

They found that autologous PRP improves endothelial function.

This study is reminiscent of a study that came out around 2010 where they treated diabetic rats with tagged adipocyte-derived stem cells.² The tagged stem cells mostly died, but the investigators documented an increased nitric oxide activity in the penile dorsal nerve of the rats, and an improvement in endothelial cell volume (translation...a harder, bigger penis).

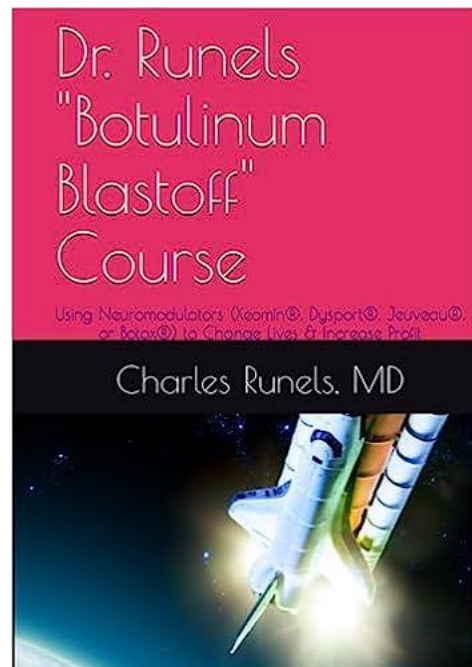
That was the paper that encouraged me to inject PRP into my own penis in early 2010 (as far as I know, the first PRP that was injected into a human penis). Since we know that around 50% of the endothelium of a man is gone by the time he's sixty-five years old, that 2010 rat study said to me that you could maintain some of the volume and function from the associated growth factors (you didn't need the stem cells). The following is the first study I've seen where they followed up with that 2010 study in such a direct way.

When you combine those two studies, you now have cellular growth after a PRP to document why this first paper might be true. Now, combine those ideas with another paper we discussed months ago regarding penile rehabilitation³. All of it comes together saying that you can trigger healthy, penile, endothelial cell growth by injecting PRP.

The usual protocol for penile rehabilitation is a vacuum device combined with daily Cialis; in this study they combined that with using Trimix to cause an artificial erection at one month.

But the usual protocol is to use a daily vacuum device (not the injection) to maintain flexibility of the penile tissue, so you could do all of the above and you would be in concert with the research and offer the best chance of recovering from prostate surgery.

Although I've seen success post prostate surgery with just one injection, if someone's recovering from prostate surgery, the success rate would be expected to be



² Garcia et al., "Treatment of Erectile Dysfunction in the Obese Type 2 Diabetic ZDF Rat with Adipose Tissue-Derived Stem Cells."

³ Chung, "A Review of Regenerative Therapies as Penile Rehabilitation in Men Following Primary Prostate Cancer Treatment."

improved with a series of three P-shots®, eight weeks apart, a daily vacuum device, and daily Cialis, either two and a half or five milligrams a day.⁴

Then, when the erections start to occur, you could back off and hopefully use the Cialis PRN.

Bicycles and ED

Let's swap over to one of my favorite pulpits: I wish more people paid attention to the association of bicycles and ED.

In this study, amateur cycling (not racing competitively) did *not* influence erectile function,⁵ which is encouraging but is in contrast with other studies that show that biking does decrease erectile function.^{6 7}

The take-home here is that you're probably okay if you use a well-fitted seat and a good helmet and just ride on the weekends.

These investigators do acknowledge that ***even with the amateur biker***, there's frequent numbness; that's one of the reasons I quit doing triathlons.

I thought, "Well, it seems to go away after a few minutes. But a numb penis is not something that encourages me to keep riding."

In conclusion, in this study, cycling is usually associated with perineal numbness, even in recreational riding, but that numbness did not lead to a lower erectile function score.

⁴ Done only after the surgeon has cleared them for me to do the procedure or the patient has already undergone the surgeon's complete post op rehab protocol and failed; I do not want to take responsibility for someone else's post op complications (even though PRP should improve post op healing). If the surgeon isn't you, and the patient has not be yet cleared, then get permission to proceed.

⁵ Dr. Duarte et al., "(90) ERECTILE FUNCTION IN AMATEUR CYCLISTS."

⁶ Panara et al., "Adverse Effects of Common Sports and Recreational Activities on Male Reproduction."

⁷ Lui et al., "Association of Bicycle-Related Genital Numbness and Female Sexual Dysfunction."

So, you're encouraged to keep biking, even though your penis goes numb. But I took it as a bad sign, which is why I quit biking competitively and why I think you still should consider the bike as a possible cause of ED in men and to sexual dysfunction in women.

PRP plus Stem Cells for Peyronie's Surgery Post-Op

In this study, they use PRP with stem cells to help someone recover from surgery for Peyronie's disease.⁸

And this brings up that old thing about if you mix PRP with stem cells, which one is actually doing the work. It reminds me of the Pepto-Bismol study: if you take enough Pepto-Bismol, it treats traveler's diarrhea. In one study they gave the pink stuff that the bismuth is dissolved in with Pepto-Bismol. And the other group just got bismuth and the group that got the pink stuff did better for traveler's diarrhea. And you see where I'm going with this.

So, if you mix stem cells with PRP, you have two variables—two simultaneous therapeutics. And I haven't seen any convincing studies that show me that when you do both, the stem cells are doing most of the work.

It could be that PRP, as a standalone, might do as well. No one's done enough studies in that area for me to be convinced. Although it makes sense, the stem cells combined with PRP would work best. Of course, in the U.S., we're somewhat limited by the FDA. I talked with a physician last week who's in Antigua and doing a stem cell clinic there. Because in the US you're at risk if you do that.

In the US, we can't apply this study (the stem cell component) without some risk to your livelihood. But it could be done in other countries and is being done. And again, it's still indicative of what could be possible with PRP by itself.

A similar study using PRP as a stand-alone treatment for Peyronie's

And, of course, that is in concert with Dr. Virag's study where a PRP without surgery worked better than Xiflex for Peyronie's.⁹

⁸ Dr. Christos et al., "(58) 'THE COMBINATION OF PRP AND STEM CELLS IMPROVES ERECTILE FUNCTION AFTER PENILE RESTORATION FOR PEYRONIE'S DISEASE WITH GRAFTS.'"

⁹ Virag et al., "Evaluation of the Benefit of Using a Combination of Autologous Platelet Rich-Plasma and Hyaluronic Acid for the Treatment of Peyronie's Disease."

So, at least it's new information and at least it's not in conflict with what we've already talked about.

Birth Control Pills and Sexual Function—It may be worse than you think

Now for the main thing I wanted to get to today, which is that when you look at women who are on birth control pills, there is a definite reduction in testosterone and often a detrimental effect to sexual function (and more).

So, (see diagram in the video) you have the brain and pituitary gland, which secretes LH and FSH, which goes to the ovaries and tells the ovaries to secrete estradiol, estriol, and estrone. But there's also DHEA that goes to testosterone. Of course, the adrenals make some, too.

When you take birth control pills, remember there's a feedback loop. So, this goes back, feeds back to the hypothalamus, and regulates that, including the testosterone. So, when levels are at a certain normal level, just like with thyroid, once the level is where it needs to be, these are cut back. And, of course, that leads to infertility, which is the whole goal if you take birth control pills.

So, your exogenous birth control pills tell the pituitary gland to change and decrease these gonadotropin levels. And so there becomes infertility. But the other side effect is testosterone goes down.

And so let me say that again. We all know it, but just think about it like meditating. You know the sun goes down every day, but you still may want to go watch it now and then just to ponder it.

So, let's ponder this for five more seconds.

Normally, the pituitary gland secretes TSH, which tells the thyroid to secrete thyroid. When thyroid T-III and T-IV are adequate, TSH goes down. Part of the way you diagnose menopause is if the pituitary gland isn't seeing enough of these E-II and testosterone levels, LH and FSH go out the roof to kick the ovaries into activity. And so these become elevated.

Same with hypothyroidism. The thyroid's not working; your TSH goes up.

And then the reverse happens when you take birth control pills and tell the pituitary gland that you have enough estrogen, or depending on the makeup of the birth control pill, progesterone or whatever milieu that you have in the various birth control pills, but any way you do it, there becomes a decrease in LH and FSH and a drop in testosterone level. That may vary some depending on the type of birth control pill, but it drops.

“Any way you do it, with BCPs, LH and FSH drop, and so does testosterone.”

If you don't meditate on what happens because of that drop in testosterone level, and someone shows up in your office complaining of decreased arousal, anorgasmia, or dyspareunia, and you do an O-Shot® without noting that because they're on birth control pills, they have likely have a near zero testosterone level, you may be giving less than an optimal help for that woman. You may help her with dyspareunia. There's a small chance, I think 30% or less, with a zero testosterone level, you might even restore her orgasms and her libido. But it's much less likely if you're trying to treat a hormonal problem by improving the health of the tissue of the vagina. And research backs that up, which is what we're about to look at.

Oftentimes, people come to see me, and they'll have a tiny little clitoris, and I'll find out they've been on birth control pills (BCPs) because of menometrorrhagia since they were 13. That's one of the indications for BCPs.

But, imagine if you blocked testosterone production in a male when he was 13. Would his genitalia develop normally? Let me say that again. If you block testosterone production in a male at 13, would his genitalia develop as it would should he have had that testosterone?

I think not.

Yet, does anyone say that to the 13-year-old girl or her mother or father before starting her on birth control pills at 13?

I'm not recommending that birth control pills be purged from our pharmacia, but that should be thought about and should be talked about so that everybody considers the possibilities.

There's also a form of dyspareunia, actually, Andrew Goldstein did a study and found a gene marker for it. But there's a form of dyspareunia that can happen after being on birth control pills. That does not resolve when you discontinue the BCPs. Maybe it would resolve with our O-Shot®, we do not know, but otherwise it does not resolve even after discontinuation of the birth control pills.

So to me, this is huge and you can see their conclusion there. But I like this study because they go into some of the variations that might happen based on changing which birth control pill you use.¹⁰ And I'm not diving into that part because I no longer prescribe birth control pills, but many of you do. And so it might be worth knowing this. And I have people who show up on birth control pills. When they do, I don't meddle with the other doctor's prescription, but I might do my O-Shot® and send the person back to have a change in the birth control pill.

¹⁰ Handy et al., "Reduction in Genital Sexual Arousal Varies by Type of Oral Contraceptive Pill."

Vitamin D helps preserve erectile function

I forgot to show you this one about vitamin D deficiency.¹¹ This is not the first time I've seen this. If you think about vitamin D as a hormone instead of a vitamin, then it makes sense that if you just need to take the stuff, I mean immune system, you need to make sure your patients are being adequately replaced if they're low. They talk about the details of the sex ED function scale. But the bottom line is you need to put people on it if they're low and you're doing P-Shots®.

More about BCP's & Sexual Dysfunction and What to Do

But let me go back. I want to find another study.

Yes, this is the part I want to just read these two paragraphs. Hormonal contraceptives, because the reason I like this paragraph, it goes A implies B, which in B implies C, and C implies D and D implies E. And they back up that logic. I just drew you a picture of it, but here it is documented A to B to C to D, and the end result is, well, you'll see. Hormonal contraceptives seem to be responsible for a decrease in circulating androgen levels. Now, remember that we wouldn't tolerate that in a male. We would not tolerate cutting androgen levels in a developing teenage male, but we do routinely, I think without adequate discussion in females. Okay, baseline serum levels of estradiol were decreased. Baseline serum levels of progesterone as well as inhibition of oxytocin functioning.

Think about that. We didn't cover it, but that has been associated with *women choosing a different partner while on birth control pills than the personality they would choose if off of birth control pills.*¹² Think about what that does to a relationship.

Okay, here's the quote I was looking for:

These hormonal alterations can be translated into negative effects of the female sexual function with reports of a decrease of the libido, increased sexual jealousy and alterations on women pair bonding behavior, desire, autoeroticism.¹³

¹¹ Dr. Luca et al., "(145) VITAMIN D DEFICIENCY IS ASSOCIATED WITH SEXUAL FUNCTION IMPAIRMENT."

¹² Casado-Espada et al., "Hormonal Contraceptives, Female Sexual Dysfunction, and Managing Strategies."

¹³ Casado-Espada et al.

So, their initiation of sex is going to go down. Sexual fantasies go down. However, the relevance of the changes in androgen levels for individual women are unclear. Some may be sensitive more than others. And of course we see that with everything. So, yay for the disclaimer, but doesn't negate the fact that we should be diligent about watching for this.

Furthermore, while there is conflicting information concerning a link between progestin and libido, evidence suggests that estrogens play an essential... That part, if you look at the research, it is conflicting. But I found, some of you know I did test hormone replacement for over 3000 women before I made that not the main thing I do. And so I have to be stupid not to notice something, maybe something that's not quite documented. But this is talked about here.

But what I found was that many women would develop their sexual function back in spades with just testosterone. And of course the liver changes some of that back to estrogen, which is why the bodybuilders develop female breasts sometimes. And most of my patients could get adequate estrogen levels with just the liver aromatization of testosterone, but not all of them. And some of them needed that extra estradiol pellet or cream or estriol, whatever it gave them to fully function sexually.

Okay. Multiple lines of evidence suggest the hypothalamic peptide Oxytocin is a key factor in pair bonding.

“Negative effects on some areas of female sexuality have been described with hormonal contraceptive, sexual desire, frequency of intercourse, arousal, pleasure, orgasm, sexual thoughts, interest and enjoyment.”¹⁴

And they've listed references for all those things. And all those things, if you go back to that picture I just drew for you, would be absolutely expected if you just think about that picture and the feedback loops. But yet we still, I think understandably want to prevent pregnancy, which let's face it. It's a life-threatening event and it's a life severely disturbing event in a thirteen-year-old girl.

This the treatment part. I will quit reading after this paragraph.

With regard to treatment options, few clinical remedies or recommendations exist. Okay. No clear guidelines exist for the management of sexual dysfunction associated with birth control pills. Okay, so they go through some possibilities, and I'm going to tell you my apparel after I read this to you. Okay. Oh, actually I've already got it highlighted. With regard to other possible strategies, again, of course, we just got through looking at, I gave you a paper where you can look at the different birth control pills, and so your pelvic floor physical therapists. See, this is where I start to you sound, you can hear the sarcasm

¹⁴ Casado-Espada et al.

in my voice. ***If your testosterone level is low, yep, you can go do some Kegels and we know Kegels improve sex. But what you really want to do is bring the testosterone level up.***

A sexual health specialist, yep, we can talk about it. Sex therapist, we can talk about it. And all those things can help; actually, the sex therapist may be needed when the woman gets her sex drive back and now her husband can't keep up. That's an option.

So, all those things are still around, but what you really want to do is fix the testosterone level, which has dropped because of the birth control pills.

So, this is where we get to the last part, and this is how I think about it when I do O-Shots® or when I see a woman who's on birth control pills with that menu of problems we just talked about desire and of course arousal, sexual thoughts, interest, enjoyment.

Remember Emerson said sex, or he said beauty, but he would've said sex, I think, had he lived in 2023. *Beauty is the scaffolding of love. Well, sex is the scaffolding of love. And imagine trying to start a new relationship with a new marriage without these things.*

And we did a paper about six months ago here on the journal club where they looked to see what's the main thing when it comes to a young married couple, or a young couple who's trying to make a go of it. The good sex makes up for leaving the toilet seat up or whatever else bothers people. Okay, I'm ranting now. But again, this is not just a little thing that happens. And when you think about all of the women on birth control pills, and you think of that list of problems, then is it any wonder that 40% of women have enough sexual dysfunction that they're psychologically distressed by it? So, yay for us for thinking about ways to make it better. So, let's look at this.

With regard to other possible strategies against sexual dysfunction for women on birth control pills, some studies show positive results with ***exogenous testosterone***, exogenous estrogens, DHEA. And then I'm a big fan of Wellbutrin and a little Viagra, and I would add to that list, an O-Shot®. But the pearl I want to give you here is this.

There's three references for it. I cannot tell you how many happy, delighted husbands and wives or just a woman who's trying to function even if she makes love to herself. So just feeling whole, again, a young woman trying to do her life and she's on birth control pills, but she wants to stay on birth control pills.

That is the keys to the kingdom. Now when you exogenous, give her a little testosterone to go with her birth control pills, and you tell her that if she gets pregnant or when she decides to go off the birth control pills, you're going to stop the testosterone, too.

And she needs to go through two or three cycles, everything kind of wash out and then get pregnant. Or if she gets pregnant on birth control pills, let you know and you're going to stop exogenous testosterone. And that's a lot out there. And I have to take a break from reading it because now, for over

20 years, the research is so strong and so mounting and so voluminous about the beneficial effects of testosterone on women, and yet it's still not recommended by some of the ivory tower powers that be. And there's still no FDA-approved version of it for women.

A Theory about Why We Still have no FDA Approved Testosterone for Women (and why it matters)

Part of that vicious cycle, I think, now what I just told you is a fact, everything I just said was a fact, now I'm about to give you an opinion. That could be wrong and all those facts could be wrong. This whole thing could be made up and wrong 20 years from now.

But *I'm about to give you an opinion from 30 years of taking care of women with sex problems*: most of your colleagues don't consider it mainstream medicine until insurance pays for it. Insurance usually won't pay for it until the FDA approves it. And to get a medication approved for sex for women is a different criterion than it is for men.

Let me say that once more because I'm explaining why I think this is still not mainstream. Everybody's doing it. And there's malpractice if you don't. ***This means giving a woman on birth control pills, even a young woman, a little extra testosterone so her clitoris and her brain and everything else that's supposed to get testosterone develops properly.*** Or if she's postmenopausal and she's taking it for, I don't know, whatever she's taking it for, or she's got polycystic ovarian disease, or she's got whatever, endometriosis and she's not getting testosterone because of the feedback loop with the anterior pituitary gland, then give her a little extra testosterone.

But you measure it. You don't get above what would be physiologically necessary for her without replacement. And the reason I think it's not being done is that for most of your colleagues to start doing something, they want to see it paid for and by insurance. And ***they let insurance define what is good medicine. And until insurance approves, it's suspect.***

Do you think the powers that be are somehow influenced by the big insurance carriers? No, that couldn't happen. But then for the insurance to approve it, they want the FDA to approve a version for women.

Now here's the big catch: To prove that a medication is beneficial to a woman sexually is a different and harder to meet criterion than it is to prove it to be beneficial for a man. To prove that, unless something is changed, I heard Irwin Goldstein rant about this during a lecture, and he's, in my opinion, the godfather of sexual medicine; it's one of his pet peeves as well, ***that to prove a medication works for a man, you just have to document that his penis gets hard. To prove that a medication works for a woman, you have to document that her sexual satisfaction is improved.*** But think about all that's

involved with satisfaction. We had a woman in our first O-Shot® study document who had less satisfaction. But, when I asked her what happened, she said, "Well, I'm less satisfied because my boyfriend cannot keep up with me anymore. My libido and my orgasmic desire are out running my...".

Well, that should be considered a win. But by the FDA guidelines, it's a loss because she's less satisfied after the procedure.

To prove a medication works for a man, you just have to document that his penis gets hard. To prove that a medication works for a woman, you have to document that her sexual satisfaction is improved.

So, demanding satisfaction before FDA approval, and FDA approval before insurance pays, and insurance pays before it goes mainstream—all that means that we will probably not see a female version of testosterone.

Now, some of that was me making up stuff about how I think it's all working together, but those individual pieces are all accurate except for, you'll have to decide if you believe me or not, that most of your colleagues don't consider something mainstream and prescribable until insurance pays for it.

But you can't blame them. It's not like they're stupid people; they're brilliant people. But they're fearful because they're afraid of what will happen if someone pushes them in front of a board of some kind.

So, if you do this, you've got research to back it up. You have thousands of doctors now to back you up. I got in trouble with my medical board when I first did this. Because remember, this was 23 years ago. People in my town were still prescribing Estratest (Premarin combined with testosterone in a tablet), which always aggravated me because I knew my bodybuilder friends would not even take oral testosterone because of the liver problems that come with it. But that was the main thing in my town. And I was keeping people on their birth control pills and giving them a little touch of testosterone to go with it—no bad outcomes from the patients. But a doctor reported me to the board after I got one of his patients well. The board demanded that I stop doing it because an endocrinologist they consulted said it was not in guidelines with the American Board of Endocrinology.

So, doing this, your colleagues know the risk of that trip to face their medical board, even if the outcomes are good. There is much less political risk I think now than it was 23 years ago. But there's a lot of politics as you know that are blunting the practice of medicine. And so you have to make your own decision on that. But that's my pearl, and you now have the papers to back it up—just add a physiologic replacement dose of testosterone to the BCP's. And I recommend you start with not a pellet because I think it's best to give them depo of testosterone and get a feel for how they're responding to it, and then adjust your pellet or your creams based on how they respond after achieving a normal level.

So, that's my pearls about what to do with women with birth control pills and decreased libido and anorgasmia. I want to give you references and papers about it, and then you'll need to decide how you will practice it.

The big takeaway is ***if you're doing O-Shot® procedures, you should at least think about the effects of testosterone changes with BCPs. And at a minimum, if someone's on birth control pills, consider swapping to one that interferes less with testosterone levels.***

Here's an email you could send

Copy and paste the following into a new Word document. Then edit it so that it sounds like you. Add a story or a personal observation if you have time, then fill in the information with your phone number, etc and send it to your patients:



Hello

In the Nutcracker ballet, there is one scene in the production where the children are all off the set, and one man and one woman dance together in a way that celebrates the love that is the subject of poems, that is the start of families and the reason for wars.

But, when there are sexual problems (pain, loss of desire, no orgasm), that dance can become a depressive shuffle that leads to the strain of relationships, psychological distress for both partners, and the breaking of families.

The number of women who suffer significant sexual problems and relationship trauma because of birth control pills continues to be under-discussed, under diagnosed, and under-treated.

Here's a quote from one of my favorites in the stack of references you will find at the end of this email (Casado-Espada, 2019):

“Negative effects on some areas of female sexuality have been described with hormonal contraceptives, such as sexual desire [2,6,10,54](#), frequency of intercourse [2,54](#), arousal [2,54](#), pleasure [2,54](#), orgasm [2,54](#), sexual thoughts [54](#), interest, and enjoyment [6,54](#).”

The part of the Nutcracker dance where the male lifts the woman up into the air (representing the ecstasy of love in all of its forms) is too often turned into a painful shuffle by the side effects of birth control pills. I am NOT recommending the complete discontinuation of oral birth control pills. But, those prescribing them and those taking them should understand the risks of the medications, how to watch for those risks, and what to do about them.

Though we offer the [O-Shot® procedure](#) as a way to improve the health and function of the vaginal tissue and the surrounding area, such changes can be of little benefit to the many women who may also be suffering from the effects of birth control pills (even if the pills were discontinued years ago).

If you would like to talk with me about ways we can use a combination of therapies to improve the entire [female orgasm system](#) (for you or someone you love), please contact me.

Best regards,

(Your name)

(Your phone number)

(Your email)

([link to make an appointment](#))

([Link to your page about the o-shot](#))

([Link to your page about hormone replacement](#))

References:

1. Bancroft J. The endocrinology of sexual arousal. *Journal of Endocrinology*. 2005;186(3):411-427. doi:10.1677/joe.1.06233
2. Casado-Espada NM, de Alarcón R, de la Iglesia-Larrad JI, Bote-Bonaecha B, Montejo ÁL. Hormonal Contraceptives, Female Sexual Dysfunction, and Managing Strategies: A Review. *J Clin Med*. 2019;8(6):908. doi:10.3390/jcm8060908
3. Castro AI, Gomez-Arbelaez D, Crujeiras AB, et al. Effect of A Very Low-Calorie Ketogenic Diet on Food and Alcohol Cravings, Physical and Sexual Activity, Sleep Disturbances, and Quality of Life in Obese Patients. *Nutrients*. 2018;10. doi:10.3390/nu10101348

4. Najmabadi S, Schliep KC, Simonsen SE, Porucznik CA, Egger MJ, Stanford JB. Characteristics of menstrual cycles with or without intercourse in women with no known subfertility. Hum Reprod Open. 2022;2022(4):hoac039. doi:10.1093/hropen/hoac039
5. Pinkerton JV, Blackman I, Conner EA, Kaunitz AM. Risks of Testosterone for Postmenopausal Women. Endocrinol Metab Clin North Am. 2021;50(1):139-150. doi:10.1016/j.ecl.2020.10.007
6. Romaniuk B. THE ANALYSIS OF THE IMPACT OF THE TYPE OF CONTRACEPTION USED BY WOMEN ON THE LEVEL OF THEIR SEXUAL SATISFACTION AND COMFORT OF USE. Wiad Lek. 2022;75(10):2347-2352. doi:10.36740/WLek202210106
7. Sex-Dependent Effect of Platelet Nitric Oxide | Elsevier Enhanced Reader. doi:10.1016/j.jacbts.2021.10.009

The Scariest Question This Week—Please Read..

This note was sent to one of our teachers this week...

"I just took your course." [I removed the name to protect the innocent because this is not what the teacher taught.] "It was wonderful. I have a question about PRP tubes.

I've been doing PRP for about five months and have always ordered my supplies from IPPO Care [which I'm not familiar with. I still don't know what they were using.] But recently, these tubes were on backorder. So, I placed an order on Amazon for PRP tubes to get me buy until the shipment came in. I used these tubes on two patients. Both had severe pain afterward to the point they felt like they needed ER attention."

[Are you squirming? I'm squirming.]

"The only thing different with these patients were the tubes I used. I have, of course, been super concerned about them and will not be using those tubes any longer. But I'm wondering if you've had an experience like this or heard of someone like this, something like this happening and how you went about managing patients in this situation medically. I'm assuming that the pain will be self-limiting, but if it goes on longer than a few days, I'm wondering what the next course of action should be."

[Charles Runels, MD](#)

Page 14 of 22

My advice: The next action should be to throw away that stuff you bought on Amazon, say your prayers of repentance, and do what you were supposed to do in the beginning after your course: log into our website and watch the videos. When people log onto our membership website, there's a click and agree that we're going to follow our protocols—which means using kits approved by the FDA-approved for preparing PRP to go back into the body (NOT the same thing as isolating platelets for a lab test).

In other words, if this patient has some bad outcome, I'm going to have to say I don't even know what you did. I can't help you. We should not be using PRP tubes ordered from Amazon because you cannot buy a kit there that's FDA-approved for putting PRP back into the body.

So, let me break that down. You can get tubes for about six bucks a piece off of Amazon and a centrifuge for \$500 that will separate blood, and then you can pipette off the PRP. You're using that tube, though, for something it was not made to do. And we've now had more than one case of serum sickness, with fever and sick as dirt when a provider has broken this rule. And now this one with severe pain that was still going on, severe enough to need the ER from people using something other than what we recommend as a group, not recommend, but what we demand to comply with our protocols.

If you want to be saying you're doing an O-Shot®, that is a kit that was designed and approved by the FDA to prepare platelet-rich plasma to be put back into the body. So, it's autologous because you took it from the patient. It's homologous use because you're using the platelets to do what they were intended to do, which precipitates new healthy tissue growth and fights infection. And with collagenesis, neurogenesis, and angiogenesis, we want all of those things in our procedures. And you're minimally manipulating it because all you're doing is separating blood components. But to do that with a kit, the difference is that it looks like just a tube. But the difference is the anticoagulant and, more importantly, the way the tube is sterilized with gamma radiation versus chemicals.

So, if you're just preparing platelets, if you're separating blood components for analysis in the laboratory, you can use chemicals within that tube that you would never put into a human body. And you can get those tubes for \$7 a piece off of Amazon. And you will hurt people if you use them to do our procedures.

Part of the reason we do our price point protection is so that we can maintain a price that allows you to afford the proper device and still make enough profit to pay your staff, pay the bills, and buy gas money to get home. Because it's not just a shot. It is a procedure. And the procedure involves how you prepare the blood, who you treat, who you don't treat, what else you think about.

You can pay your nursing assistant to give a B12 shot. But you can't pay your nursing assistant to go inject a vagina because you have to know how to prepare the blood. You have to talk to the person to understand if it's going to help them or not. You have to be more exact about where you put the needle. You have to know how to do follow-up. And you can't do that for 50 bucks without losing money. And

you sure can't do it for 50 bucks. Even if they gave you the kit, you couldn't do it for 50 bucks without losing money because it takes time.

But if you're going to buy an FDA approved kit, you're going to have to spend more than that. You're going to have to spend enough money that you need our full price point to be able to afford the time and do all the things you have to do for the procedure.

Remember, our names are trademarks. That doesn't mean a material. O-Shot® does not mean PRP. O-Shot® means how you're going to prepare the platelet-rich plasma, who you're going to treat, what you're going to say to them, what else you're going to do with them, what you're going to do after you treat them. And of course how much and where you're going to put the needle, how you're going to anesthetize them, what medicines you're going to stop and start. That is not just a shot. So our O-Shot® procedure is not just a synonym. It is everything but a synonym for platelet-rich plasma.

Okay?

So, that's me ranting because I don't know what this person did.

I don't know what they stuck into the person's vagina. I don't know what's going to happen to them. And there's no way that I can in good conscience take up for this doctor if something bad has happened. Now, we've had, since this is seldom done within our group, we've had now 13 years of doing O-shots® with no serious sequelae that we know of. We've had nuisance problems, loss of sensation, hypersexuality, urinary frequency, dysuria, but we've had easily over 200,000 procedures now, probably significantly more than that, and no serious sequelae with those other symptoms being fleeting.

Anyway, so I'm through ranting. Go to our website ([login→dashboard→materials & supplies](#)) and we have a list of FDA approved devices. **Devices come and go off that list depending on what's going on medically and how the different companies are treating our people.** So, look at it. If you log into our membership site and you go there, you'll be on the dashboard, then you go to the materials and supplies and you'll see our recommended kits.

I wouldn't take for granted that what was there once is still there because things change about how the companies are treating our people and about what we hear about different kits. But that is a huge part of what you're doing. And with that, that leaves us with 10 minutes to spare if we shut it down. Let see if there are any questions before we do. And that's all I have for today. I hope that was helpful to you.

What to do if you want to introduce our procedures as something new in your clinic

Veronica says (in questions) she works in urology and would like to offer this at our practice. How do you present it to the clinic and being compensated?

This is an all cash procedure. And again, I think that's part of the reason FDA hasn't approved it. Because PRP is not a drug. We'll probably never have a huge budget for it. And there's no FDA approved testosterone for women, as you know, for the reasons I think that I just described. We have more and more urologists in our group. What I'd recommend Veronica is go to our directory for the O-Shot® or the P-Shot®, whichever one you're thinking about implementing. Note the number of urologists there, I mean, brilliant people that are or have been professors of urology at multiple universities. Look at the research. You'll find it if you go like [OShot.com/research](https://www.oshot.com/research), [PriapusShot.com/research](https://www.priapusshot.com/research). You'll see the research.

And then it's just a matter of you go to the head person, show them research, show them our directory and say, "Do you want me to do this?"

If they have a closed mind, I recommend that if you really want to do it, you find another place to work. I actually met one of the pioneers of hyperbaric medicine, which I used to do when I was an ER doctor. Hyperbaric medicine came out of San Antonio. I went there for a class. And he had to roll out hyperbaric medicine for wound care when nobody was doing it. He gave sage advice. You just will never convince a closed mind. And the more you try, the more, I won't use the explicative, but certain bad smelling things, the more you fiddle with it, the worse it stinks. Not that the person stinks, but though if they have thinking that's close to the idea, I think it's best to just say, "Okay," walk away from it and let it drop.

And then you have to decide if you want to still work there or not. Because ***your best punishment is for them to lose you. I mean, I've always found revenge is really a waste of energy. And if I'm a value to a patient or another person rather than seek revenge, it's better for me to just disappear*** and go somewhere else.

And having done that, we have many who have been able to implement these procedures in their practice. But remember, it's normally 20 to 40 years before a new idea becomes acceptable in medicine. It takes at least 10 to do the research. And we're only 13 in from having first injected PRP in the genitalia. So, it usually takes 10 to do the research and sometimes 20, probably longer with us to have enough volume that then another 10 to 20 years later, it's paid for by insurance and it's ubiquitous.

And the other thing that happens is for some reason, many urologists are not used to cash procedures. It's interesting that you can have a penile implant that costs 10 grand, and that's okay. But there seems

to be, at least among some people, a resentment of a procedure that costs \$1,800 or \$1,000 for repeat visits. And they perceive (not knowing that it's just a shot) that somehow we're taking advantage of people, not knowing that we always give money back if people are not happy and there's much more involved in it than just giving a shot.

What about penile traction?

Let's see. Jack has a question that says... Is a Restorex device to straighten his penis is beneficial after a P-Shot®. The study that was done in the British Journal of Urology showing that 51% canceled their Peyronie's disease surgery was from a pump.¹⁵

The reason I prefer pumps versus a traction device is that the pump gives a three-dimensional expansion, which I think is necessary if you're trying to break up scar tissue in Peyronie's. Certain people are selling a traction device, so they want to make it look better on paper. And I realize that some studies are showing that using a traction device before a penile implant allows you to place a larger implant. So, I'm not saying they're of no use. But there are two or three other reasons why I prefer a pump. One is that you get that three-dimensional stretch, which is more likely to break up the scar tissue from Peyronie's. Just makes sense that it would. But the other is you have research supporting that idea. And then the last is that if you think about it from our PRP standpoint, one way to activate platelets is through a vacuum.

When you have a difficult phlebotomy, it causes thrombosis, and you get a clot in your phlebotomy device. Well, if you're using a vacuum device and you're using it properly, you're activating the platelets within the penis when you do it. And there's research showing that short bouts of hypoxia, David Harsfield brought that up in one of our calls about six months ago, short bouts of hypoxia can trigger collagenesis and angiogenesis.^{16 17} So, those are the reasons I like the pump versus traction device.

If he wants to use a traction device as well, I mean he can put it on his penis, put it on his nose, I don't care. I don't think it's going to hurt anything. But if he really wants the best effect for Peyronie's, I think he gets a P-Shot® and he follows that whole protocol, which you'll find at Priapusshot.com/peyronies.

Good. You said you put him on the pump.

¹⁵ Raheem et al., "The Role of Vacuum Pump Therapy to Mechanically Straighten the Penis in Peyronie's Disease."

¹⁶ Welliver et al., "A Pilot Study to Determine Penile Oxygen Saturation Before and After Vacuum Therapy in Patients with Erectile Dysfunction After Radical Prostatectomy."

¹⁷ Lin and Wang, "The Science of Vacuum Erectile Device in Penile Rehabilitation after Radical Prostatectomy."

Those are the reasons why. And again, I could be wrong. Whatever. I'm sure something I say today will be shown to be wrong 20 years from now. But this is my best idea for today.

Oh, you're welcome. So, Jennifer says, "Thank you for the article." You might want to pull up the one from last week too, Jennifer. There was one that talked about what I call the sex muscles, which are perineal muscles, superficial, transverse perineal, deep transverse perineal, ischial cavernosis, elbow spongiosis. Those are not part of the pelvic floor. And I think that [injecting PRP in the perineal body immediately postpartum may do some wonderful things](#). And you would be backed up by mountains of research that is being done in the muscles of injured athletes.^{18 19}

So, when you have research that shows something works on the toe, you don't really need research to show that it works on the finger. Or you could argue to that effect.

But I know some of our obstetricians are adding an O-Shot® in the delivery room to help prevent urinary incontinence. You might make it part of the optional things that you do as part of the delivery before you head out the door to help prevent that. If you do, I would recommend a regular O-Shot® the way we do it, and then another five ccs divided between the perineal body and perhaps laterally into the area of the bulbospongiosis or [maybe in the labia majora](#)²⁰. So, think about it and look at that journal club from last week and you'll see some stuff about it.

And I think with that, we'll call it a day. Thank you guys. I'm honored to have so many smart people. I don't see any more questions. But to have this many people thinking about stuff at the same time.

One Last Serious Warning

I'll leave you this one last thing.

If you're not using an FDA approved PRP kit, and you are injecting PRP, your medical license is at risk.

By the way, nobody pays me money to say that; no PRP device company pays me any money. I do that so that (turn down much money—I could market my own kit), so I can tell you without bias that those are the kits I've used that work and are safe. Some of them have been put on. Some of have been put

¹⁸ Moura et al., "A Biomechanical Perspective on Perineal Injuries during Childbirth."

¹⁹ Bubnov, Yevseenko, and Semeniv, "Ultrasound Guided Injections of Platelets Rich Plasma for Muscle Injury in Professional Athletes. Comparative Study."

²⁰ Hexsel et al., "Soft-Tissue Augmentation With Hyaluronic Acid Filler for Labia Majora and Mons Pubis."

off. Those are the kits that I currently recommend. And if you're using something else, I recommend you swap it.

Hope you guys have a wonderful day. Bye-bye.

References

Bubnov, Rostyslav, Viacheslav Yevseenko, and Igor Semeniv. "Ultrasound Guided Injections of Platelets Rich Plasma for Muscle Injury in Professional Athletes. Comparative Study.," n.d., 5.

Casado-Espada, Nerea M., Rubén de Alarcón, Javier I. de la Iglesia-Larrad, Berta Bote-Bonaechea, and Ángel L. Montejo. "Hormonal Contraceptives, Female Sexual Dysfunction, and Managing Strategies: A Review." *Journal of Clinical Medicine* 8, no. 6 (June 25, 2019): 908.
<https://doi.org/10.3390/jcm8060908>.

Chung, Eric. "A Review of Regenerative Therapies as Penile Rehabilitation in Men Following Primary Prostate Cancer Treatment: Evidence for Erectile Restoration and Cavernous Nerve Regeneration." *Asian Journal of Urology* 9, no. 3 (July 2022): 287–93.
<https://doi.org/10.1016/j.ajur.2021.11.005>.

Dr. Christos, Fliatouras, Karypidis Dr. Nikolaos, Spinos Dr. Theodoros, and Konstantinidis Dr. Konstantinos. "(58) 'THE COMBINATION OF PRP AND STEM CELLS IMPROVES ERECTILE FUNCTION AFTER PENILE RESTORATION FOR PEYRONIE'S DISEASE WITH GRAFTS.'" *The Journal of Sexual Medicine* 20, no. Supplement_4 (July 1, 2023): qdad062.108.
<https://doi.org/10.1093/jsxmed/qdad062.108>.

Dr. Duarte, Brito, Alberto Dr. Jose, Ferreira Dr. Ana, Gomes Dr. Gustavo, Eliseu Dr. Miguel, and Lourenço Dr. Mario. "(90) ERECTILE FUNCTION IN AMATEUR CYCLISTS." *The Journal of Sexual Medicine* 20, no. Supplement_4 (July 1, 2023): qdad062.096. <https://doi.org/10.1093/jsxmed/qdad062.096>.

Dr. Luca, Boeri, Pozzi Dr. Edoardo, Belladelli Dr. Federico, Fallara Dr. Giuseppe, Cilio Dr. Simone, Lanzaro Dr. Francesco, Bertini Dr. Alessandro, et al. "(145) VITAMIN D DEFICIENCY IS ASSOCIATED WITH SEXUAL FUNCTION IMPAIRMENT: FINDINGS FROM A CROSS SECTIONAL STUDY." *The Journal of Sexual Medicine* 20, no. Supplement_4 (July 1, 2023): qdad062.012.
<https://doi.org/10.1093/jsxmed/qdad062.012>.

Garcia, MM, TM Fandel, G Lin, AW Shindel, L Banie, CS Lin, and TF Lue. "Treatment of Erectile Dysfunction in the Obese Type 2 Diabetic ZDF Rat with Adipose Tissue-Derived Stem Cells." *The Journal of Sexual Medicine* 7, no. 1 Pt 1 (January 2010): 89–98.
<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2904063/>.

- Handy, Ariel B, Leah N McMahon, Irwin Goldstein, and Cindy M Meston. "Reduction in Genital Sexual Arousal Varies by Type of Oral Contraceptive Pill." *The Journal of Sexual Medicine* 20, no. 8 (July 31, 2023): 1094–1102. <https://doi.org/10.1093/jsxmed/qdad072>.
- Hexsel, Doris, Taciana Dal’Forno, Patricia Caspary, and Camile L. Hexsel. "Soft-Tissue Augmentation With Hyaluronic Acid Filler for Labia Majora and Mons Pubis." *Dermatologic Surgery* 42, no. 7 (July 2016): 911–14. <https://doi.org/10.1097/DSS.0000000000000733>.
- Javier, Angulo, Fernández-Pascual Dr. Esaú, Curvo Dr. Raphael, Fernández Dr. Argentina, Bueno José Luis, Martínez-Salamanca Juan Ignacio, and Instituto de Salud Carlos III Funding: Ministry of Economy and Competitiveness and co-financed by FEDER funds PI17/02001, Spanish Government. "(219) AUTOLOGOUS PLATELET-RICH PLASMA IMPROVES ENDOTHELIAL AND TADALAFIL-INDUCED RELAXATIONS IN CORPUS CAVERNOSUM FROM PATIENTS WITH ERECTILE DYSFUNCTION." *The Journal of Sexual Medicine* 20, no. Supplement_4 (July 1, 2023): qdad062.007. <https://doi.org/10.1093/jsxmed/qdad062.007>.
- Lin, Haocheng, and Run Wang. "The Science of Vacuum Erectile Device in Penile Rehabilitation after Radical Prostatectomy." *Translational Andrology and Urology* 2, no. 1 (2013).
- Lui, Hansen, Nnenaya Mmonu, Mohannad A. Awad, Nikan K. Namiri, Micha Y. Zheng, Gregory M. Amend, Michael L. Eisenberg, and Benjamin N. Breyer. "Association of Bicycle-Related Genital Numbness and Female Sexual Dysfunction: Results From a Large, Multinational, Cross-Sectional Study." *Sexual Medicine* 9, no. 3 (May 25, 2021): 100365. <https://doi.org/10.1016/j.esxm.2021.100365>.
- Moura, Rita, Dulce A. Oliveira, Marco P.L. Parente, Nina Kimmich, and Renato M. Natal Jorge. "A Biomechanical Perspective on Perineal Injuries during Childbirth." *Computer Methods and Programs in Biomedicine* 243 (January 2024): 107874. <https://doi.org/10.1016/j.cmpb.2023.107874>.
- Panara, Kush, John M. Masterson, Luis F. Savio, and Ranjith Ramasamy. "Adverse Effects of Common Sports and Recreational Activities on Male Reproduction." *European Urology Focus* 5, no. 6 (November 2019): 1146–51. <https://doi.org/10.1016/j.euf.2018.04.013>.
- Raheem, Amr Abdel, Giulio Garaffa, Tarek Abdel Raheem, Michelle Dixon, Amanda Kayes, Nim Christopher, and David Ralph. "The Role of Vacuum Pump Therapy to Mechanically Straighten the Penis in Peyronie’s Disease." *BJU International* 106, no. 8 (2010): 1178–80. <https://doi.org/10.1111/j.1464-410X.2010.09365.x>.
- Virag, Ronald, H  l  ne Sussman, Sandrine Lambion, and Val  rie de Fourmestraux. "Evaluation of the Benefit of Using a Combination of Autologous Platelet Rich-Plasma and Hyaluronic Acid for the

Treatment of Peyronie’s Disease.” *Sexual Health Issues* 1, no. 1 (2017).
<https://doi.org/10.15761/SHI.1000102>.

Welliver, R. Charles, Clay Mechlin, Brianne Goodwin, Joseph P. Alukal, and Andrew R. McCullough. “A Pilot Study to Determine Penile Oxygen Saturation Before and After Vacuum Therapy in Patients with Erectile Dysfunction After Radical Prostatectomy.” *The Journal of Sexual Medicine* 11, no. 4 (April 1, 2014): 1071–77. <https://doi.org/10.1111/jsm.12445>.

ⁱ Dr. Virag did not use a placebo, he did a direct comparison of PRP with Xiaflex, because injecting saline into tissue is not a placebo in a soft tissue regenerative study. A fact that others would benefit by noticing.

Relevant Links

Next [hands-on workshops with live models](#)←

[Cellular Medicine Association](#)←

Apply for further [online training for multiple PRP procedures](#)←

[Dr. Runels Botulinum Blastoff Course \(includes how to treat depression, bruxism, migraines, and ED using toxins\)](#)←

[Priapus Toxin™](#) is now part of the [P-Shot® online training](#)←