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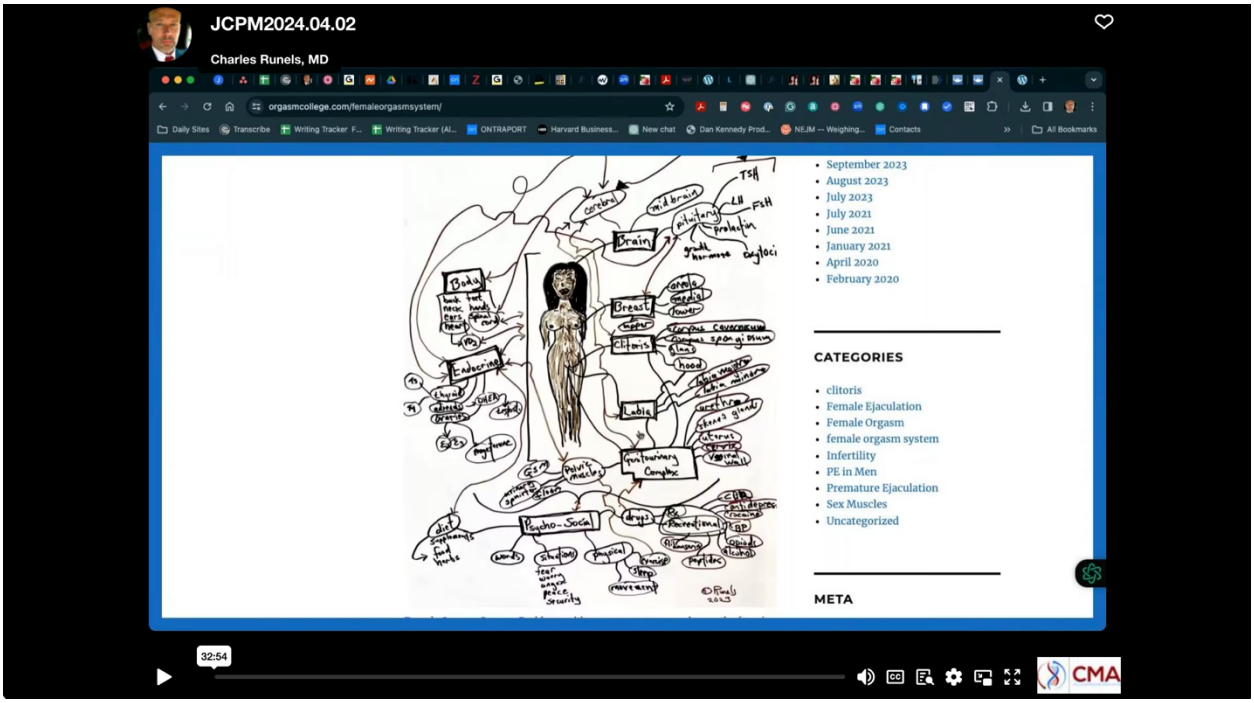
The following is an edited transcript of the *Journal Club with Pearls & Marketing* (JCPM) of April 2, 2024, with Charles Runels, MD, and Alexandra Runnels, MD, FACOG.

>-> The video of this live journal club can be seen here <-<



Topics Covered

- **Documentation of Results following the O-Shot® or the Clitoxin® Procedures**
- **Off-label Prescriptions & "Orphan Therapeutics"**
- **Administering the Female Sexual Function Index to Your Patients**
- **Online Training & Malpractice Insurance for the Clitoxin® Procedure**
- **Why Using the "®" Protects Your Patients**
- **What Went Sideway with Our Priapus Toxin® Procedure & What We Can Do to Make Things Work Better with Clitoxin®**
- **Who Might Benefit from the Clitoxin® Procedure (and the Need for a System Analysis Approach)**
- **More Pearls from Dr. Alex about Doing the Clitoxin® Procedure**

Figure 1. Charles Runels, MD

Charles Runels, MD
Author, researcher, and inventor of the Vampire Facelift®, Orchid Shot® (O-Shot®), Priapus Shot® (P-Shot®), Priapus Toxin®, Vampire Breast Lift®, and Vampire Wing Lift®, & Clitoxin® procedures.

Transcript

Welcome to The Journal Club. It's finally time for us to start talking about the Clitoxin® procedure.[1]

Here's the original article so that you have it handy as we discuss implementation.[2]

Three things we were lacking: (1) agree on how to document the results, (2) understand the indications for doing the procedure, and (3) we need a strong source of malpractice insurance—and all of that's now all in place.

Note: our office is making the certificates that those of you who have taken the test about Clitoxin® will receive. Those of you who are O-Shot® providers (who have not yet taken the test) can do that for free by simply logging in, studying the videos and supporting material, and taking the test.

Let's start with documentation.

[1] "Clitoxin® – Botulinum Toxin for Improved Sexual Function in Women."

[2] Runels and Runnels, "The Clitoral Injection of IncobotulinumtoxinA for the Improvement of Arousal, Orgasm & Sexual Satisfaction- A Specific Method and the Effects on Women."

Documentation of Results following the O-Shot® or the Clitoxin® Procedures

Here are two articles I've put in the handout section for you to download regarding the Female Sexual Function Index (FSFI).[3] [4] I have also used the Female Sexual Distress Scale-Revised (FSDS-R).[5] [6]

If you look at the original article we did about the O-Shot® procedure,[7] we used both scales, and you can do that; but if you wish to simplify and do only one survey, the Female Sexual Function Index is better because it offers perspective on multiple domains: lubrication, arousal, desire, pain, orgasm, and overall satisfaction.

However, the FSFI is more troublesome to grade than the FSDS-R. The FSFI can look confusing: first, you grade each question, then sort the answers into groups, add the answers, and then multiply by a varying factor to calculate a score for each domain and an overall score. It's not calculus; it's only adding and multiplying, but it takes a few minutes, which you may not have, so I hired someone to write software that will grade the FSFI for you and hopefully do other useful functions. Again, this article's in your handout.[8]

Here's the other one that talks about the validity of the FSFI, how to administer it, and how to grade it.[9] ***Remember, documenting results is part of what should be done with any off-label prescription***, especially something new.[10] [11] I'll also put these articles in your handouts.

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[3] Rosen, C. Brown, J. Heiman, S. Leib, "The Female Sexual Function Index (FSFI)."

[4] Wiegel, Meston, and Rosen, "The Female Sexual Function Index (FSFI)."

[5] Carpenter et al., "Using an FSDS-R Item to Screen for Sexually Related Distress."

[6] Derogatis et al., "Psychometric Validation of the Female Sexual Distress Scale-Desire/Arousal/Orgasm."

[7] Runels, "A Pilot Study of the Effect of Localized Injections of Autologous Platelet Rich Plasma (PRP) for the Treatment of Female Sexual Dysfunction."

[8] Wiegel, Meston, and Rosen, "The Female Sexual Function Index (FSFI)."

[9] Rosen, C. Brown, J. Heiman, S. Leib, "The Female Sexual Function Index (FSFI)."

[10] "'Off-Label' and Investigational Use Of Marketed Drugs, Biologics, and Medical Devices Guidance for Institutional Review Boards and Clinical Investigators."

[11] Van Norman, "Off-Label Use vs Off-Label Marketing of Drugs."

Off-label Prescriptions & "Orphan Therapeutics"

We frequently write off-label prescriptions. When you prescribe testosterone to women, that's off-label; when you inject botulinum toxin to help smoker's lines, bruxism, or crow's feet, that is all off-label. Research shows that 21 to 32% of the prescriptions written by primary care doctors are off-label.[12] One study confirmed that ***97% (ninety-seven) of hospitalized children are prescribed at least one off-label prescription.***[13]

Many of the well-documented results and benefits of off-label prescriptions will never become on-label by the FDA because the expense and the difficulty of proving an on-label indication can be beyond profitability in hard-to-study populations like children and women who are pregnant or of childbearing age or therapeutic results that are difficult to prove, like sexual dysfunction in women being improved without agreed upon, easily-measured objective findings (as you have with men); these difficult to bring to on-label population/indications are classified as ***"orphan therapeutics."*** [14]

Because of the common use of drugs for some problems, even when there are no on-label indications, ***pharmaceutical companies can be disincentivized to proceed with the expense of obtaining on-label indications***: why spend vast money for a near-impossible study when doctors are already writing prescriptions for the off-label indication?[15]

For an example of why it is easier to obtain FDA-approved, on-label indications for sexual dysfunction therapies in men than for women, consider that you can measure the severity of Peyronie's disease (and the results of therapy) with a protractor. There is no ruler you can buy at the drugstore to measure sexual function in a woman objectively.

So, for men, you can measure results with a protractor from Walgreens; you do not even need to go to an office supply house. You can determine the effectiveness of Viagra with a yes or no question: "Did your penis become firm enough for penetration?"

Such is not the case with women. One of the most accepted measures for the difficult task of measuring treatment in women is the Female Sexual Function Index. Within the domains of that tool, the FDA pays special attention to the satisfaction domain—which (to the consternation of those seeking on-label indications for new drugs for women) can sometimes decrease when other domains improve. For

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[12] Radley, Finkelstein, and Stafford, "Off-Label Prescribing Among Office-Based Physicians."

[13] Moulis, Durrieu, and Lapeyre-Mestre, "Off-Label and Unlicensed Drug Use in Children Population."

[14] Van Norman, "Off-Label Use vs Off-Label Marketing of Drugs."

[15] Van Norman.

example, you could increase a woman's libido, but her satisfaction may decrease because her husband can no longer keep up with her, and in that case (if all women in the study had similar results), the drug would not be approved.

So, by definition, it is difficult and beyond-feasible-expensive to prove effectiveness for the orphan populations and indications, and that is why you will probably never see FDA-approved testosterone for women. That is an orphan indication.

So off-label prescriptions are a necessary and accepted part of medicine, but such prescriptions must be done correctly to protect both patients and their physicians. You don't have to publish a journal article about the results to write off-label prescriptions, but you need research supporting such off-label use, and you must keep records about what happens (objective and subjective findings.

Physicians embrace off-label prescriptions only with science-based strategies and procedures.

Stating the numbers another way, if we had to quit writing all off-label prescriptions, we would lose 21% to 32% of all the prescriptions we write.[16] So, it's commonly done. But, when you write off-label prescriptions for women with sexual dysfunction (whether it's Wellbutrin, testosterone, or BoNT), keep records, and one of the documents to include in your records is the FSFI.

The instrument does not have many questions (it takes about 5 minutes). However, the FSFI can be confusing to grade. For example, you add the scores from questions one and two and multiply by 0.6 to arrive at a score. So, until we get our software written, I recommend that you use the following website to grade the FSFI (shown to me by my brilliant wife, Alexandra Runnels, MD, FACOG): here's the link.[17] That website also provides two useful references about the FSFI, one of which I've already given you in the handouts.

Now that you intend to use the FSFI, how do you practically implement this documentation into the flow of your office procedures?

[16] Van Norman.

[17] Ciorniciuc, "Female Sexual Function Index (FSFI) Questionnaire Calculator."

Administering the Female Sexual Function Index (FSFI)

Our membership site has a downloadable PDF version of the FSFI on the "How to Do" page.

In my office, I print the FSFI and give it to the woman on paper; she fills it out (using a pen, not a computer). Then, I score it. I keep paper charts, so the end of the story—the paper with her handwritten answers, goes in the chart.

If you have an electronic medical record, I recommend doing this on paper, scanning it into your EMR, and then using the website[18] to calculate the results/scores and add that to your notes.

So, documentation of results for the Clitoxin® procedure (or of the O-Shot® or testosterone in women) would include the FSFI done the day you do the treatment or sent to your patient by email before her visit (if you want to save time when you're sitting in front of her and instead of waiting for her to fill it out).

Some of you know, starting in 2003, when I gave up accepting insurance, I had women flying to see me from around the world to my little town because I was early into doing female hormone replacement the way most of you do it now: measuring blood levels and adjusting treatments based on symptoms and normal ranges instead of giving everybody either Premarin or nothing.

Because I was early on (before Suzanne Somers did her first book about hormones), people were flying in from everywhere. But they couldn't fly in, get an order for blood testing, and then return another day. So, in the days before the electronic scheduling and other tools we now use, I would talk on the phone briefly to decide if they were a good match for my practice (that is, if I thought I could help them), and then if they were, I would send them a lab order and they could print off and take to LabCorp; otherwise they'd go to LabCorp and sometimes the staff there couldn't find the order. And I would send the woman all the paperwork to bring when they came to see me in the office. And that works well if they're across the street as well.

I also do SHIM scores on men (pre- and post-procedure) who receive the P-Shot® procedure.

I confess I don't do the surveys with every procedure; maybe I should, but I don't—if someone's coming in for their third O-Shot®, they know they love it, and it's wearing off, and they want another one, I may skip the survey. But if it's a first-time patient, I like to measure at least FSFI, and if you want, in addition, administer the Female Sexual Distress-Revised; it's even faster and easier to score. There are no factors to multiply as with the FSFI.

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[18] Ciorniciuc.

Alex, because you're keeping paper charts, too, please share some of your tips for documentation.

Alexandra Runnels, MD, FACOG:

I'm here; can you hear me?

Charles Runels, MD:

Yes, we can.

Alexandra Runnels, MD, FACOG:

I also use paper charts, and I have the same feeling about EMRs that you do, and probably everybody on this call has. I have suffered through many EMR implementations, and it gives me a seizure to even think about using an EMR. So, I also have paper charts that I use, and if they're scheduled for an appointment for an O-Shot® or now for Clitoxin®, when they come in, their paperwork is done right off the bat. They're handed a piece of paper to fill out, as far as the FSFI questionnaire, and they fill it out as part of "We're checking in."

Figure 2. Alexandra Runnels, MD, FACOG

I could send it to them ahead of time. I've tried doing forms before they show up, but people don't do them that consistently. So, I keep it simple and do it that way. And Christy (my nurse) is wonderful and helpful. She assures that the patients get the paperwork done.

Charles Runels, MD:

Okay, so after you get the form filled out on paper, does Christy enter their answers into the website and grade them? When are you doing that?

Alexandra Runnels, MD, FACOG:

That happens sometimes while they're sitting in front of me (I enter it into the website to score it) and sometimes after they've left, especially if it's their first time to fill it out and they're coming back for

another visit later. But moving forward, I want to start using it more to manage expectations of the procedures that we're doing. I haven't used it for that purpose, but that is part of my plan.[19]

Online Training & Malpractice Insurance for the Clitoxin® Procedure

Charles Runels, MD:

Okay, a quick note about insurance. Let me swap over to a different website. When you go to our O-Shot® membership site, go to the dashboard if you ever get lost. It may be worth going through this step-by-step course even if you've been in the group a while. The steps look voluminous, but many only take a few seconds. This course gives you the best chance of success with the O-Shot® procedure.

And then, to learn how to do the Clitoxin® procedure, you go here, and it's just a few videos.[20] (For those who are not yet O-Shot® providers, the application for online training can be found here: https://oshot.info/members.

I don't have the test automated yet. Copy and paste the questions, add your answers, and then email us the answers, and we'll send you the certificate.

And no matter who you're using for your malpractice carrier, ***the best option for explaining it to them to get coverage (because we have over a decade of success with minimal unwanted sequelae) is to tell them this is an add-on to the O-Shot® (which it is).***

You're still injecting in the same places. You're just adding BoNT to the clitoral injection (not to the anterior vaginal wall), which has been used for at least two decades in the bladder and for vaginismus in women of childbearing age. You're just using BoNT in addition to the PRP, and you're putting it in a different place (the clitoris) than where BoNT has been routinely used.

If your carrier hesitates, here's what to do: Study our materials and answer the questions; we will shoot you a certificate; go to our legal page and download our consent form and ask your attorney to modify it for your practice and location; then contact our recommended carrier, and he will likely write your policy for either just the Clitoxin® procedure or for your whole practice (he will want to see your certificate from us and see your consent form).

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[19] Since our study showed that FSFI total scores went up by 12 when BoNT combined with PRP was used, that score could be used as an estimate of what the woman's sexual function might be like after the procedure—assuming best-case scenarios.

[20] "Training for the Clitoxin® Procedure | Scribe."

We're not offering licensing to advertise the Clitoxin® procedure to anyone not in our O-Shot® provider group. If you're doing O-Shot®'s, you already have certain licensing criteria that allow you to study the materials. Then, you've passed hands-on or online confirmation of your understanding of that material and got a certificate. This definite protocol with testing is one reason why our reputation has increased for over a decade.

Why Using the "®" Protects Your Patients

And another tip: I need to edit this. Clitoxin is no longer a TM (™); it's an R (®). That is super important.

This happened with Priapus Toxin®. And pay careful attention to this. Please. The CMA spends a million dollars, plus or minus a hundred grand every year, running off people who want to pretend to be us.

Note: To make an R symbol (®) on a Mac. You push "option" and then the R key, which pops the ® into the copy. That should go everywhere you put the word Clitoxin® and preferably the word "procedure" after it, because that emphasizes that it's not just a shot..

This is a procedure. The injection is only a part of the procedure.

And it isn't just a shot. You must prepare the BoNT. You must know how to prepare the combination if you combine it with platelet-rich plasma (PRP)—including how to prepare the PRP. You must know when and when not to do the procedure, how to follow up, and more. So, it's not just a shot that you can teach to someone who might give B12 shots for you in the office; they cannot just blindly do the Clitoxin® procedure for anyone who walks in.

What Went Sideway with Our Priapus Toxin® Procedure & What We Can Do to Make Things Work Better with Clitoxin®

Because we (the CMA) were so efficient at rolling Priapus Toxin®, when the trademark examiner (at the US Patent & Trademark Office) looked at it, he said, "This is a generic word because look at all these people who are doing it."

So, we checked all the names he gave us as evidence that it had gone generic. Every name he gave us (as evidence that it was a generic name) was one of our providers, so it had not gone generic. But, because we had such rapid dissemination of the idea, the trademark examiner initially balked a t granting us the R symbol and wanted to claim it was generic. That would not have happened had all our providers used the R symbol after the name, indicating their understanding that this is a trademark name and that they're a licensee.

Note: The symbol can be written like this: (R). Or, it can be written like this: ®.

Yes, the examiner could have just visited our directory and quickly confirmed that everyone he identified as an infringer was someone in our group, but it's government workers; not that that's a bad thing, but there's no profit incentive for the examiner to do that. So, I must make their job very easy. The ® symbol used by our members makes it possible for us to keep our names[21] from going generic and, therefore, be able to keep every Joe Blow person with a hair salon from claiming to be offering our procedures.

Without the enforcement of our trademarks, if somebody wanted, they could say Clitoxin® and make up anything, like it's painting fingernail polish on the end of a clitoris. They could make up whatever they wanted for any of our names. A Vampire Facelift® could be putting red clay on your face.

Without trademark enforcement, people would be hurt by those doing crazy things—using our good reputation to lure people to injury.

The only reason our names maintain their value is (1) the quality of our providers, (2) the effectiveness of our protocols, and (3) because we spend a million dollars a year running off people who use our trademarked names to advertise sometimes bad medicine illegally.[22]

So when you roll this out on your website, if you have a Mac, hold down the "option" button and then push the "R," and stick ® behind the word—Clitoxin®.

I'll have to correct some of our web pages because we still have the ™ sign, and recently, we secured the ®.

A Lawyer Pearl: The approval timing by the government agencies for intellectual properties (like the ®) varies based on the country. Some are faster than others. We don't have the ® in every country yet. But once it's approved in any country (because any country can look at this website), it gets an ®.

Our Clitoxin.com website will evolve. Hopefully, you (our CMA members) will start sending me videos about the procedure that you made. I'll push this (the video of our initial presentation) back to a

[21] Vampire Facelift®, Vampire Facial®, O-Shot®, Orchid Shot®, Priapus Shot®, P-Shot®, Vampire Breast Lift®, Vampire Wing Lift®, Vampire Hand Lift®, Vampire Hair®, Priapus Toxin®, & Clitoxin® are all trademarks licensed only to member of the Cellular Medicine Association.

[22] This $1,000,000 per year is spent (1) for in-house staff handling reports and gathering data, (2) for our trademark attorney in Chicago to litigate when needed, and (3) for Brandshield.com—we average the takedown of 1.6 websites or social media accounts ***per business day*** from the people who use our trademarked names illegally.

research page and put videos made by our providers on the home page, and I think we'll probably get some press as well—which we will also feature.

I have not yet completed the press release. I haven't pushed the buttons (to make it go viral) yet because I want you guys to be ready when I do.

Who Might Benefit from the Clitoxin® Procedure (and the Need for a Systems Analysis Approach)

I would also be grateful if you could help me with this, Alex. I know I harp on this a lot, but this is important: systems analysis.

As an example of the importance of systems analysis, there was a woman who saw a plastic surgeon in New Orleans for dyspareunia (someone not in our group), and the plastic surgeon had a new vaginal laser. He did the laser on her in hopes it would help her dyspareunia, but her pain worsened.

Then, the woman (a petite Japanese lady) saw one of our providers, and our O-Shot® provider (a gynecologist) discovered that the petite lady was married to King Kong. So, she did not need a tighter vagina. She needed an O-Shot® to help her with dyspareunia and a dilator, and she soon enjoyed pain-free sex with more intense orgasms with her husband.

In other words, just like every other part of medicine, there should be a systems analysis—not a magic-bullet approach to our patients. And most of you guys do think this way.

This is my sketch of the female orgasm system thus far.

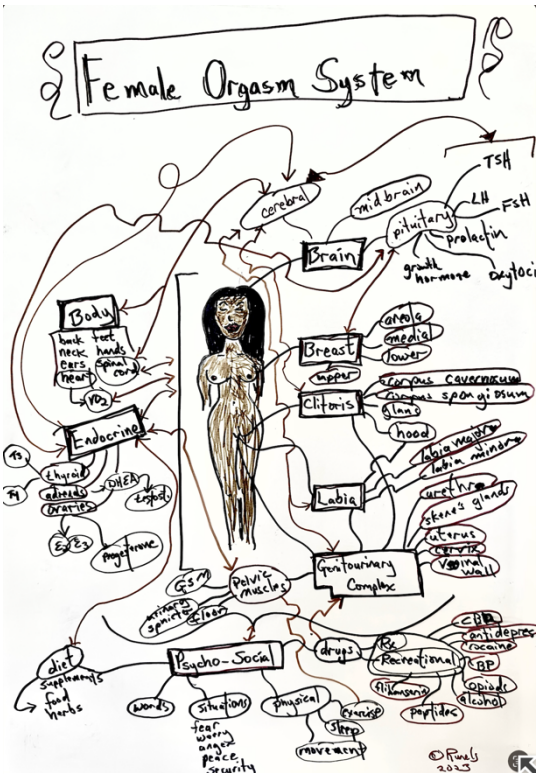
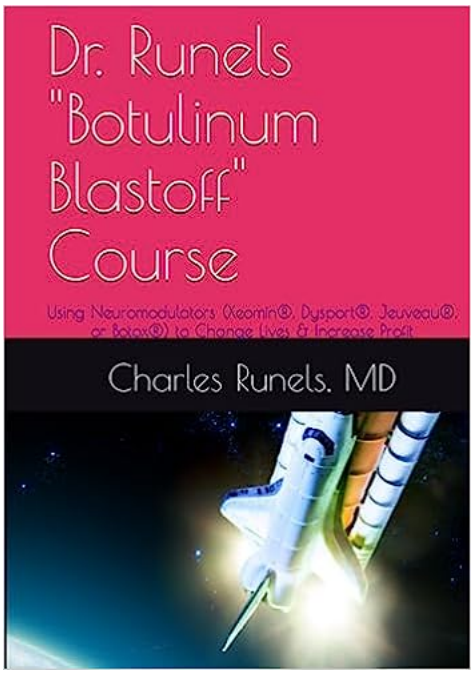


Figure 3. Preliminary sketch of the female orgasm system with feedback loops.

Clitoxin® came out of my three-year pursuit of coming up with a neat poster that summarizes everything that's involved in the sexual or orgasmic response.

This is one of the websites that feeds us patients. And I'll put this in the chat box, too. It's mostly tongue-in-cheek, but whatever. It's half fun and half serious. However, I have a website called Orgasm College[23] and a course called the *Female Orgasm System*.[24] Eventually, I think I'll issue diplomas to people who pass the test on this, but it has been two or three years now that I wake up meditating on this. That led to figuring out Clitoxin® because when I started looking at the autonomic system, it connected to the midbrain, where the arousal center is.



But any one of those circles on that chart could go away and goof up sex; every component of the system is necessary for the system to work.

For example, let's pick the hood. The clitoral hood could be phimosed from lichen sclerosus—preventing normal stimulation of the clitoris, which could goof up your sex.

Pick something else. You could have a pelvic floor muscle that's hurting. In the pituitary, you could have a microadenoma causing hyperprolactinemia or a micro-infarction (from head trauma) causing growth hormone deficiency. Or, you could have hypo or hyperthyroidism. Or your thinking brain could be telling you scary things because you were abused, and you're remembering what happened to you as a child. You could have a spinal cord lesion. Any one of these hormones could be goofed up. You could be eating supplements that are making you anxious or depressed. You can go on and on.

Any circle on that diagram of the system could be goofed up and goof up your sex. So the idea that I could say, "Just inject botulinum toxin in the clitoris, and it could fix any circle (any component and any broken feedback loop)," would be ludicrous.

And so would it be if I said the same about an O-Shot® (PRP done in our specific way) or a labiaplasty or a vaginal laser or a testosterone shot or psychotherapy. There is no one treatment that would correct everything that could go wrong with any one of those parts of the orgasm system.

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[23] "Orgasm College™."

[24] runels, "Female Orgasm System."

Remember, a system is a collection of individual components with feedback loops that work together to accomplish a purpose.

So, let's quickly look at something. Here's a primary view of the respiratory system. As an ER doctor (which I did for 12 years), shortness of breath is a commonly heard complaint. If someone comes in with dyspnea, it could be a foreign body in the trachea, laryngeal spasm, or angioedema of the larynx caused by an allergic reaction. It could be an abscess in the pharynx. It could be a collapsed lung (usually seen in a tall, skinny teenage boy). It could be bronchitis, pneumonia, or bronchospasm, or pulmonary edema. It could be anemia or profound anemia. It could be cyanide poisoning. You could go on and on.

So, when someone shows up with dyspnea, you use your history and physical exam, meditate on which part or parts of the system are broken, and then choose the right therapy.

It could also be (with dyspnea) that they're suffering an anxiety attack, in which case maybe they need medications or they need psychotherapy or hypnosis. But I won't offer family therapy for a foreign body in the right mainstream bronchus where the kid breathed in a penny. And I think it's just as ludicrous to do family psycho-sex therapy on someone who's got a tearing, hurting episiotomy scar that might be helped by a platelet-rich plasma (an O-Shot®). On the other hand, after you make them better, they may need therapy because now the sex is so good the husband can't keep up. So, there's always room for improvement in the art of lovemaking, so counseling can always help. But it’s not the magic bullet, nor is the Clitoxin® procedure.

If you go back to the system, imagine not being sick. Imagine increasing your VO2 max to where you have the ultimate respiratory system, and you can run a marathon on Pike's Peak at 14,000 feet. In that case, you are not moving from sickness to well, but rather form well, but even better. In that case, you will consider how to tune up every part of the system. You'll train at altitude, so you get an erythrocytosis. You may even dope and illegally take a transfusion right before you run. You might use a bronchodilator, on and on. So, in the same way, we can think about female sexual function in terms of pathology, which is the way I recommend you think about it, or we can think about making good sex into something beyond what most think possible. That’s a legitimate idea, but I don't think that we should advertise this as a way to make normal better, although people will come to you for that. And it will sometimes do that. I don't think it's the best marketing. It sets you up. Just like you don't advertise testosterone to make normal men able to pick up heavier weights or look prettier in the mirror, you can advertise it for erectile dysfunction and depression.

So, in the same way, I think you think about this in terms of what you can help with it. Well, if you look at the study that we did, which is also in your handouts, you'll see that (it was Alex's patient) the woman who was postmenopausal and not hormonally replaced and having pain still had some improvement (after the Clitoxin® procedure), but she had the least impressive improvement of those who completed

our survey; while those who were premenopausal or postmenopausal and hormonally replaced, but still not happy with their sexual response, they did the best.

So I think for pain or for the woman who's not hormonally replaced, especially if her testosterone is still low or she has hyperprolactinemia, they're not going to do as well with just the botulinum toxin injected into the clitoris. On the other hand, our full-blown O-Shot® procedure, including the anterior vaginal wall or strategically placed PRP in the pelvic floor or the posterior fornix and other places where pain might occur, as we've discussed for a decade now, might be helpful.

More Pearls from Dr. Alex about Doing the Clitoxin® Procedure

But pearl's about doing that when you combine the two, which I think will be most of your patients, but if you spin a gel kit, you'll get about six CC's because the woman won't have a crit of 50. It's more likely to be 40. So you'll take two of that and combine it with botulinum toxin the way we show you how in that video, and that goes in the clitoris, and then the other four still goes in the anterior vaginal wall and other places. But you don't put the botulinum toxin in with that. And we don't know. We haven't done this study, but my suspicion is, because we're injecting anterior vaginal wall near the urethral sphincter and probably into certain layers of that sphincter, if you're going where we suggest, which is the most distal part of the urethra, you might be going into the urethral sphincter where relaxation of muscle is not such a good idea.

So it might occur to you, "Oh, if putting botulinum toxin, the clitoris activates the autonomic nervous system and increases arousal, then let's put it in the anterior vaginal wall as well." And you may try that on your wife or your mother, and they'll be okay if they start peeing on the floor, but I recommend you not do that with your patients. So the combination procedure would be botulinum toxin just in the clitoral part, combined with the PRP and then only PRP in the anterior vaginal wall. Alex, I've been talking too long. What else would you say on anything that I've just said?

Alexandra Runnels, MD, FACOG:

I love the last thing you said. I think it's important that everybody hears it because it probably could get confusing since when we do the Priapus Toxin®, we put it everywhere, in the glands and in the corpus cavernosum. So, I think it's a great point. It's amazing that females are continent in the first place with the little, short urethras that we have, and the continence mechanism is still mysterious in women. So, I agree that as far as being cautious about getting botulinum toxin into that urethral sphincter, I think that's an important point.

The other thought that I had while you were talking about pain is another patient who came to see me for a clitoral hood release. She had adhesions between her clitoral hood and her clitoris and a long history of strange pain, pelvic pain, and clitorodynia. I talked to her about everything I could do for her

and did an O-Shot®. I put Clitoxin® in her clitoris, and I regret doing that for her because it did what it does for everybody that I've seen. It increases blood flow and clitoral engorgement and sensation. But for her, sensation is such an issue that she's struggled with trying to figure out what to do with the painful sensations that are now amplified. So, I think it is a good lesson for me and everybody else on this call to hear, and I think for her, I wish I had just done a regular O-Shot®.

Charles Runels, MD:

Okay, that makes sense. That reconfirms what we just said: it's probably not the best thing for pain. In a previous journal club, you talked about a woman who was scheduled for fat transfer to labia majora, canceled after Clitoxin® because the increased blood flow caused increased volume and rigor, and she got a healthier-looking labia majora after injecting the botulinum toxin into the clitoris. So, it makes sense that if someone has a clitoris that's struggling underneath phimosis and then there's more circulation, there might be more discomfort. But I'm sure you'll take care of that with your clitoral release, and everything's going to be wonderful.

Summary

That covers it, Alex. Unless you have something else, we'll shut it down.

We talked about indications for the Clitoxin® procedure. To summarize, this would not be for pain. I like to think of this gradual increase in arousal until it's desire. And then there's this extreme urge to have sex, and then there's sex and then orgasm. And then, in men, there might be a refractory period. In women, not so much. Maybe there are more and more orgasms, but it's not zero to 60 in one second.

If this is working the way we think it is and the way it appears to be working, with the Clitoxin® procedure, we are raising the baseline threshold, so the woman is quicker to become aroused as if the midbrain is already at a slightly aroused state (or at least very near arousal) all the time.

We also know that multiple studies, starting in the 1950s, have shown that botulinum toxin (BoNT) causes neurogenesis and collagenesis neovascularization. Multiple wound care studies have been done.

We also know that BoNT causes smooth muscle relaxation with increased blood flow, and that may be all that's happening with our Clitoxin® procedure, but (because the results with PDE5Is in women were modest at best) we're suspicious that effects on the autonomic nervous system by the BoNT (through activation of the parasympathetic ganglion lining the vaginal wall and subsequently activation of the arousal center in the hypothalamus) may play a significant part in the mechanism of action. And that's not a big stretch because all that would be necessary for that to happen is for the BoNT to behave in the clitoris for sexual dysfunction as it behaves in the procerus for migraine (where it migrates along the

axon to activate the trigeminal ganglion and block the pain fibers from the meninges and increase parasympathetic tone).

Also, using a systems analysis approach, Clitoxin® is not likely to help a woman with very low testosterone levels or who suffers from pelvic floor pain, but it might help a woman with dyspareunia from dryness who cannot be on hormones because of breast cancer, or a woman for whom you've done everything else that you can do with decreased arousal or orgasm.

Maybe that same woman who cannot be on hormones might be helped by our O-Shot® combined with Clitoxin® by raising that baseline arousal level. We don't know.

Keep the picture of the female orgasm system in mind
realizing that
all we are doing with the Clitoxin® combined with the O-Shot® procedure is
making the tissue healthier in the vaginal wall,
also, in the periurethral area,
(neurogenesis, neovascularization, and muscle strengthening of the urinary sphincter),
and increasing blood flow in the clitoris,
and activating the midbrain
through the inferior hypogastric plexus
by way of the ganglion
in the lateral vaginal wall.

That's what we think is happening.

Regarding **pearls** for the Clitoxin® procedure, some women want the botulinum toxin (no PRP). I would steer them away from that because the PRP increased the effectiveness of the botulinum neurotoxin by 50%; however, maybe they had an O-Shot® last week or last month. And so they only need the Clitoxin® procedure.

When you do the Clitoxin® procedure combined with the O-Shot® procedure, do not add the botulinum toxin to the anterior vaginal wall part of the procedure.

Obtain our **certificate of training** for Clitoxin® and the **consent form** with your letterhead and **edited by your attorney** to facilitate malpractice coverage. The contact info for a potential carrier is on our website.

For **documentation**, I gave you the link for the Female Sexual Function Index (FSFI) to grade it. That text and the score should go in your chart.

Our Clitoxin® certificate will only be offered to O-Shot® providers and mailed within two business days of completing our online test or a hands-on workshop. So, if you are already an O-Shot® provider, log in to the membership site and take the test so we can get the certificate to you. Then, an icon will appear with your name on the directory so the women who may be helped will know how to find you.

Alex, add whatever you think would help, and then we will end our meeting.

Alexandra Runnels, MD, FACOG:

We covered a lot.

Charles Runels, MD:

All right, well, I want to brag on you. ***This research would not have happened without Alex. She's a statistician. She's brilliant. She's an excellent surgeon. And she's got a deep understanding of this procedure and what happens when you do it. So, thank you, Alex***, and I appreciate you being on the call.

Okay, you guys have a good day. Bye-bye.

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Tags

Charles Runels MD, Alexandra Runels MD, Clitoxin®, O-Shot®, Female Sexual Function Index, FSFI, female sexual distress, documentation, off-label prescriptions, malpractice insurance, botulinum toxin, PRP (Platelet Rich Plasma), erectile dysfunction, Peyronie's disease, sexual function measurement, EMR (Electronic Medical Records), malpractice coverage, trademark protection, sexual health, pain management, arousal enhancement, neurogenesis, collagenesis, neovascularization, smooth muscle relaxation, breast cancer patients, hormone replacement, sexual dysfunction, labiaplasty, vaginal laser, testosterone treatment, pelvic floor pain, libido enhancement, orgasm system, sexual response, hormone levels, sexual satisfaction, sexual therapy, respiratory system analogy, systemic approach to sexual health, urinary incontinence, vaginal health, sexual arousal, vaginal wall injection, anterior vaginal wall, urethral sphincter, parasympathetic ganglion, hypogastric plexus, neurogenic effects, clitoral health, sexual wellness, medical documentation, hormone therapy contraindications, patient expectations, procedure outcomes, patient counseling, medical research, healthcare innovation

Helpful Links

→ Next Hands-On Workshops with Live Models ←

→ Dr. Runels *Botulinum Blastoff Course* ←

→ The Cellular Medicine Association (who we are) ←

→ Apply for *Online Training for Multiple PRP Procedures* ←

→ Help with *Logging into Membership Websites* ←

→ The software I use to send emails: ONTRAPORT (free trial)←

→ Sell O-Shot® products: You make 10% with links you place; shipped by the manufacturer), this explains and here's where to apply ←