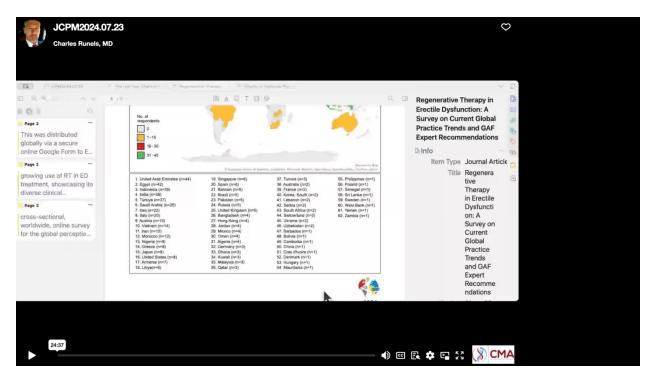
JCPM2024.07.23

The following is an edited transcript of the *Journal Club with Pearls & Marketing* (JCPM) of July 23, 2024, with Charles Runels, MD.

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



Topics Covered

- Survey of Regenerative Therapies World-Wide for Male Dysfunction
- Injection of the Testicles with PRP
- Sexual Function in Women after COVID
- PRP, Male Dysfunction, and Politics
- The Cellular Medicine Association's Purpose
- References

Charles Runels, MD



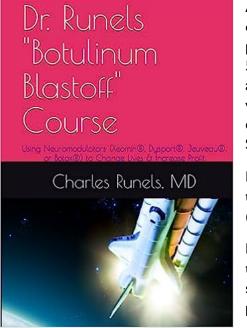
Charles Runels, MD Author, researcher, and inventor of the Vampire Facelift®, Orchid Shot® (O-Shot®), Priapus Shot® (P-Shot®), Priapus Toxin®, Vampire Breast Lift®, and Vampire Wing Lift®, & Clitoxin® procedures.



Welcome to the Journal Club. We have four papers today that I think, will be especially helpful to us. And one, finally a landmark paper. I've been waiting for this to appear. I know several in our group have been doing this, but finally someone published something about injecting the testicles with PRP, so we'll get to that one.

Survey of Regenerative Therapies World-Wide for Male Dysfunction

We'll start with this one, where they surveyed clinics around the world, looking at the prevalence of using regenerative therapy, which they defined as either platelet-rich plasma or shockwave therapy worldwide.¹



And it's as expected, growing in their survey. And look at the countries they looked at, pretty impressive. Covers a lot of places. And there was a percentage that actually surprised me: 54% were using shockwave therapy, 24% platelet-rich plasma, and 14% with a combination of the two. And stem cell therapy was still at 3%, understandably, since that's more time-consuming and threatening to your license here in the United States.

Remember, if you email your patient, and say, "Hey, I've got this thing called the P-Shot®." It can feel like an advertisement (because it is).

But when you have legitimate news happening, and you share that with them, it's the news, and then you can use that as a springboard to talk about your procedure to see if they may potentially benefit.

Charles Runels, MD

¹ Al Hashimi et al., "Regenerative Therapy in Erectile Dysfunction."

But the news is news, and that's why we do the journal club. It's amazing how many articles come out every week when we do this club. We have at least a dozen articles to scan through, and we choose the ones that are most relevant to what we do.

If the news came out and said, "Oh, this doesn't work," well, that would be something we should tell our patients. But when the news supports it, we should also tell them that. So, this was encouraging.

Injection of the Testicles with PRP

What I'm about to show you here, the testicular injection of platelet-rich plasma, pretty outrageous.² I've done it to myself over ten years ago. It's hard to think of a place where I haven't injected myself with platelet-rich plasma—a simple thing to do. I just came in on the underside of the testicle. I mean, you could fill the somatic cord, and uses a 27-gauge needle and inject two ccs into each testicle. Not a big deal.

I do **not** recommend that you do this. I am only saying that I did this to myself a few times to test the concept, and it is not difficult or very painful.

With no anesthesia, there's pressure.

No one wants to be in an altercation and have someone bludgeon their testicles, but there was little pain injecting the testicle—and it felt like that sort of dull pain.

We already have at least a dozen studies showing that such injections help harvest viable eggs from women postmenopausal by injecting the ovaries. So it's not a big jump to think this might be the case. And it was, and **not only did the sperm count go up, but the sperm grew healthier, less fragmentation**.

So, this is a better motility. It's a great one to share with people. I know you have to write certain things and when you're doing a study, you can just say, "Okay, everybody do this." You have to be present some sort of reason, some sort of appearance of being conservative. PRP is never known to cause metaplasia or serious sequelae when you have something this safe. You have something that's safe, and you have people who are desperate to have children. It seems like it's one of those things where there's a great potential benefit and very little potential harm. And as you know, people trying to have children are the only people more desperate than those suffering from end-stage cancer. But no one else is more desperate for help from their physician than those who are trying to seek help for infertility.

² Fazli et al., "Effects of Testicular Platelet-Rich Plasma (PRP) Injection on Sperm Parameters in Men with Severe Oligoasthenoteratozoospermia (OAT)."

And so would you, if you had a son or son-in-law trying to have children, grandbabies, or if you're a woman trying to have children and a man with low sperm counts, would you not want this now?

I think so. I'm embarrassed we didn't do this study a decade ago. To me, this is a landmark study. And it's open source. I'll give it to you and let you share it with people. This is good news, and ironically, it comes at a time when the next study I'll show you is like the criticism that came out a couple of years ago in JAMA; but before I do that, I wanted to show you this.

Sexual Function in Women after COVID

This one surprised me. In this one, they looked at women who contracted COVID and those who did not. And surprisingly, they documented not a big change with COVID in sexual function.³

They did the female sexual function index.⁴

I'm not sure what to do with that because I thought the depression alone would cause changes with sexual function. Seeing this, despite the unprecedented challenges posed by a pandemic, our findings indicate that individuals, regardless of their COVID status, maintain their health and well-being, This is an interesting idea.⁵

I know we looked at one study where COVID infiltrates the testicles and effects on male function,⁶ ⁷ ⁸ it infiltrates the liver or the hair follicle, the brain. So the fact that would not change, there's your picture, just not a big change, looking at COVID and not COVID for sexual function. Interesting. I prefer studies that change the way we practice medicine. This one just left me scratching my head, but there you go. I wanted you to see it.

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³ Demircivi et al., "Effect of COVID-19 Infection on Female Sexual Function," July 19, 2024.

⁴ Rosen, Brown, and Heiman, "The Female Sexual Function Index (FSFI): A Multidimensional Self-Report Instrument for the Assessment of Female Sexual Function."

⁵ Demircivi et al., "Effect of COVID-19 Infection on Female Sexual Function," July 19, 2024.

⁶ Sansone et al., "The Sexual Long COVID (SLC)."

⁷ "Peyronie's Disease in a Patient after COVID-19 Infection_ A Case Report _ Enhanced Reader."

⁸ Chu et al., "COVID-19 Infection Is Associated With New Onset Erectile Dysfunction."

PRP, Male Dysfunction, and Politics

And then the last one is this one where they... This one's more political, but it's worth looking at. They looked at the Canadian landscape.⁹

They did what the article in JAMA did two years ago, where they shopped around to see who was doing plate-rich plasma for erectile dysfunction.¹⁰

It seems that the big thing discussed is the cost. It seems to bother people that we charge more than 50 bucks for the procedure, which is the going rate for injecting a knee, and that somehow, we're doing something wrong by advertising. This is very puzzling to me when you consider that it's hard to watch television without seeing a TV ad advertising PDE5 inhibitors.

I'm not sure why it's okay for pharmaceutical companies to run ads, but a primary care doctor can't have a video educating people about erectile dysfunction and possibilities for treatment. It makes no sense to me.

But I bring it up because it's useful to know there are those who bothered. They're bothered. And so, "researchers needed to understand the effectiveness of therapies to better assist patients in deciding on what's right for them."¹¹

Well, yeah, it is needed.

It's like any new idea. First, you prove the idea, and then you do more and more research to prove the effectiveness of variations. In general, you prove that the idea is possible and then there's an infinite number of variations that could be done. You have changes in volume, the way the PRP is prepared. That alone has many possibilities.

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⁹ Shah et al., "An Overview of the Canadian Landscape on the Use of Restorative Therapies for Erectile Dysfunction and Peyronie's Disease."

¹⁰ "Memo in Response to the JAMA Article."

¹¹ Shah et al., "An Overview of the Canadian Landscape on the Use of Restorative Therapies for Erectile Dysfunction and Peyronie's Disease."

Do you cool the platelets? Do you wash the platelets? Do you have aerobics as before?¹² How do you activate calcium chloride¹³ or calcium gluconate?¹⁴

Do you use a vacuum device after?¹⁵ Do you use thrombin?¹⁶

And then of course, with every variation, there's a logarithmic number of those variations. You could do thrombin combined with aerobic exercise, combined with double spin. You could have a single spin combined with all the different variations of activation, different volumes, and different tissue planes. So yeah, we need a lot more research.

On the other hand, if you're like a man I saw today in my office who's in a healthy marriage after 41 years, in his sixties, and he's got a wife that he adores who is healthy and he's trying to maintain the health of his penis. If he waits until the next 10 or 20 years before this is paid for by insurance and considered standard of care by every urologist on the planet, he will be dirt, as will I. In 20, 30, 40 years, we're all... You know, I'm dirt.

And he's got a wife now.

Charles Runels, MD

¹² Hamilton et al., "Exercise and the Platelet Activator Calcium Chloride Both Influence the Growth Factor Content of Platelet-Rich Plasma (PRP)."

¹³ Toyoda et al., "Direct Activation of Platelets by Addition of CaCl2 Leads Coagulation of Platelet-Rich Plasma."

¹⁴ Fermín et al., "Review of Dohan Eherenfest et al. (2009) on "classification of Platelet Concentrates."

¹⁵ Wang, "Is There Still a Role for Vacuum Erection Devices in Contemporary Sexual Medicine?"

¹⁶ Smith et al., "An Evaluation of the Effect of Activation Methods on the Release of Growth Factors from Platelet-Rich Plasma."

Why would he not want to take advantage of something that makes sense scientifically and does have a growing and pretty high stack of research supporting the idea, an idea that makes sense logically?^{17 18 19} 20 21 22 23 24 25

This includes work by Ronald Virag, who did studies demonstrating that it works better for Peyronie's disease than Xiaflex,²⁶ which is still approved in the U.S. but is no longer offered in Canada or across Europe.

So, it's another hit piece, and I think it's useful to know it's out there. We acknowledge that any new idea needs its challengers, and challengers make us smarter. So, you read it.

You always, always, always, just like Faraday said, you always look for the person who's criticizing you because the only way ideas exist in science is that they are never proven. There's nothing proven. However, you have growing supporting evidence, and an idea stands until someone disproves it. That's how science works.

So, you **welcome the criticism**, read it, and say, "Is there something in here that makes what we're doing no longer scientifically viable? That our critics, who are very strong critics, say something that should make me want to stop offering platelet-rich plasma for erectile dysfunction?"

And they do not. They only say we need more research, which we do, but they mostly focus on the price. I am not sure how they decided about "high" prices because we have... In the neighborhood, they

- ²² Kumar, "265 Combined Treatment of Injecting Platelet Rich Plasma With Vacuum Pump for Penile Enlargement."
- ²³ Liu et al., "Revisiting the Regenerative Therapeutic Advances Towards Erectile Dysfunction."

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¹⁷ Francomano et al., "Regenerative Treatment with Platelet-Rich Plasma in Patients with Refractory Erectile Dysfunction."

¹⁸ Brandeis et al., "(130) Increasing Penile Length and Girth in Healthy Men Using a Novel Protocol."

¹⁹ Finkle, "Sexual Impotency."

²⁰ Siroky and Azadzoi, "Vasculogenic Erectile Dysfunction."

²¹ Casabona et al., "Autologous Platelet-Rich Plasma (PRP) in Chronic Penile Lichen Sclerosus."

²⁴ Matz, Scarberry, and Terlecki, "Platelet-Rich Plasma and Cellular Therapies for Sexual Medicine and Beyond."

²⁵ "Customize: Priapus Shot® | P-Shot® | Official Website - Priapus Shot®."

²⁶ 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."

quoted a neighborhood in the \$1,500 range, but it costs \$400 to get a massage down the street from me. And that only requires a little oil on the hands of someone who went to a six-month class.

To do this procedure, you have to spend time with them. It's not just a shot. You have to draw blood. Use an FDA-approved kit. You have to know the anatomy. Someone has to do the phlebotomy and spin the centrifuge, which is not cheap because this is not a lab kit. This is something made to analyze blood. So their high is an opinion; it's not a fact. It's a political propaganda opinion.

But as far as science cutting down what we're doing in this paper, there is none.

So, that's a relief. But if there is something like that, we should see it and this does not contain that.

But because of these clinics, I want to emphasize that we should always offer money back if someone doesn't think what we did worked well. And it takes eight to 12 weeks, probably 12, to see the full effect, but I don't care if they want their money back to pay the light bill. You give it to them and it takes away the criticism we're stealing from people.

And that's how you do it.

You don't do that with an insurance-based practice because the person's paying a monthly bill to their insurance carrier whether what you do works or not. But in this case, you do. And that keeps you clear from those who would shoot arrows at you.

Now, when this came out in JAMA,²⁷ these people did not make the same mistake that the JAMA article people did.²⁸ In this one, they just talked about who owned the clinic and who they wanted to see better standardization of protocols, but they did not use our trademark names, which is good. I'm sure they read this one (in JAMA), which did use our trademark names, which was a mistake because of what they did... And this one came out two years ago.²⁹ They secret shopped; it's what they call it; it was their words. They secret-shopped people offering platelet-rich plasma for erectile dysfunction.

In their shopping, they looked at people who were offering the P-Shot® and those offering a generic injection of platelet-rich plasma. And they made similar statements to this article looking at Canadian clinics. They said that there's no protocol, there's no standardization of licensing, and we think it costs too much.

²⁷ "JAMA Correction Regarding the P-Shot® (Priapus Shot®) Procedure."

²⁸ "Errors in Text."

²⁹ Shahinyan et al., "Analysis of Direct-to-Consumer Marketing of Platelet-Rich Plasma for Erectile Dysfunction in the US."

Well, cost, again, it's relative. That depends on if you've been married for 41 years, and you think a doctor's time is worth an hour and a half, especially if they need a phlebotomist, an FDA-approved kit, and a brain to understand what and how to treat you and the anatomy. If you think that's worth 50 bucks, then I guess you can think that.

But we think an hour of a doctor's time should be worth at least three times what it costs to get a massage.

And that's not counting goods and keeping the... So, throw that out.

That's an opinion.

But what's not an opinion is that they said all the people they called had no protocol. And that set of people called secret-shop included those offering the P-Shot® and the Priapus Shot®.

And that is factually wrong.

We do have a protocol. We do have standardization. We spend a million dollars a year plus or minus a hundred grand, anywhere from 900,000 to \$1.2 million per year on attorneys.

And we use a company called <u>Brandshield.com</u> and Intellectual Attorneys, not only in the US but wherever we are litigating, that's included has already included South Africa, London, Australia, Brazil, and New Zealand.

We do not allow people to use our name unless they're part of our group, which means that our staff has physically, with their eyeballs, confirmed licensing. So, we have a protocol, and everyone in our group agrees to follow it. We have standardizations of licensing, and everyone in our group has demonstrated those licenses.

So, we spent a little money, and the authors were eventually kind enough to print this correction of their article.³⁰

But their original article was very similar to the Canadian one you saw.³¹

³⁰ "JAMA Correction Regarding the P-Shot® (Priapus Shot®) Procedure."

³¹ Shah et al., "An Overview of the Canadian Landscape on the Use of Restorative Therapies for Erectile Dysfunction and Peyronie's Disease."

So, I wrote a response to their article that I will give you the link to,³² and I will also give you the link to everything we just talked about. I think all of it is open source.

Still, I think the takeaway from today's meeting is that everybody knows someone who is of childbearing age in marriage, and sharing this idea about having a simple and effective way, at least in this study, to increase sperm count is worth doing, just as it is what you should do as a physician. Educate your people; your patients are not...

It's not their responsibility to know what we're able to do. It's our responsibility to keep them up to date. And okay, here's something we've suspected would be possible now. And now there's research showing that it works.

And I think it's possible to offer this for someone who maybe has testicular atrophy after taking their testosterone for years. Maybe also with Klinefelter syndrome, which is associated with testicular atrophy, and it's a simple thing to do.

The Cellular Medicine Association's Purpose

When we created the <u>Cellular Medicine Association</u>, I never intended that everybody using PRP would join our group. That would be unrealistic.

But I did intend that our group be perceived as the premier group of physicians worldwide that has thought deeply about our protocols and shared our information as we are doing now and as we do on our websites, anyone in our group can log into those websites and make comments. And we are close knit. We talk to each other. We've published research. We have more research in the pipeline. And the goal is that we maintain standards that do not fall into the category that is criticized in these two articles. The Canadian one this month and the one from JAMA two years ago.

Questions

All right, I think with that, let me see what questions we have and then I'll put the links in there for you guys and we'll call it a day. Let's see what questions we got. Now they just called, they didn't... They didn't secret shop walking into the office. They just called and surveyed people. Let's see, what else?

Any risk of decreased fertility with the breach of the blood testes barrier? I don't know. It's a good question. In this study, they showed increased motility, increased sperm count, and there was... The sperm were healthier. They weren't deformed and fractionated. Let's see. I think that's everything.

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³² "Memo in Response to the JAMA Article."

Always have amazing... I'm looking at the names on the call and I can't tell you how... You have so many other things you could be doing. It's very encouraging. And as you know, I don't always get them transcribed and recorded as timely as I would like, but you should be able to watch them. There should be an email coming with a link to the unedited, non-transcribed version. And if nothing else, by showing up, my hope is that you stay up to date on arenas that we are working in and always have something fresh to show your people.

By the way, that was \$40,000 from our attorney, two months time and some bantering back and forth. So, I'm sure the authors are wonderful people, but it still took a little persuasion to make that happen. And that's what we do. If we can't do that for our group, then why do we exist?

But it shielded us from the errors of that JAMA article. That's my memo in response to that article, which I recommend you look over because it's my best attempt to explain one of the most important things, which is at the current time, it's only PRP and shock waiver, the only two treatments for erectile dysfunction that hold the possibility of reversing or attenuating the progression of neurovascular disease that causes the problem.

This is not the 1980s when doctors legitimately thought 80% of erectile dysfunction was psychogenic,³³ true statement. And now we know 80% is neurovascular and nothing about Viagra, Cialis or penile implants, Caverject. **None of those things reverse the process**.

So as my patient today told me, "Why should I wait until my penis has progressed until Viagra is needed?"

He currently doesn't need it much, "Or until my Viagra quits working?"

Oh, I forgot, he gets headaches with it. So that's why he doesn't use it. He can tolerate a fourth of the lowest tablet of Viagra, and that's it.

And still, even if he were on it, why? It's the part left out of the articles where they're throwing daggers that men are coming to us because they're not stupid. They realize that **we offer the only thing that can prevent the progression of the etiology** (vascular disease).

So, I put the link to the correction and the JAMA article under the chat box, and I've put the articles in the handout section. There's three of them plus something from last week. I'll give you a minute to download that. Let's see if there's another question. Oh, there we go. There's another question. Yeah. I thank you, Steven, for I'll be in here always. I hadn't seen you in a while. Good to see you. There's still... I just can't bring myself. Yes, there's been a number of articles about adipose-derived stem cells. And as a matter of fact, in 2010, when best I can tell, I was first to inject the penis with just straight up platelet-

³³ Finkle, "Sexual Impotency."

rich plasma, it was a rat study of adipose-derived stem cells where they harvested the penis and documented increased dorsal nerve, nitric oxide activity and endothelial cell growth.³⁴

That study out of Southern California motivated me to do the platelet-rich plasma injection first in my own penis because the stem cells were tagged, and they died. So, the authors postulated that the benefit was from the growth factors and not from proliferation of the actual stem cells. And that research has continued to progress.

I do not want to do it if I still must avoid discussing it because I don't like three-letter people knocking on my door. And so I'm still afraid. Many in our group use it and make stem cells; I'm not condemning anyone. I have a different comfort level about things that might trigger the FDA to look at me.

I know the arguments about why it's okay, but if something... If I can't openly talk about it in a video and put it on my website without fear of a three-letter person showing up, DEA, FBI, IRS, I don't want any of those people knocking on my door—I do NOT want to do it. And if I can't openly talk about it, for someone to say it's okay, as long as you don't talk about it, that feels somehow scary to me. I could be wrong about it, but I don't have any updates on that. Let's see. Yeah, beautiful review. Beautiful review, Heidi. Yeah, you guys give me energy. So, thank you. And I think I'll call it a night with that. See you next week. Bye-Bye.

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Tags

Journal Club, PRP, platelet-rich plasma, shockwave therapy, stem cell therapy, regenerative therapy, erectile dysfunction, sexual function, sperm count, infertility, COVID-19, testicular injection, female sexual function index, Canadian study, P-Shot, PRP for erectile dysfunction, neurovascular disease, erectile dysfunction reversal, regenerative medicine, sexual health, medical research, regenerative treatments, shockwave treatments.

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- => Dr. Runels Botulinum Blastoff Course <=
- => <u>The Cellular Medicine Association (who we are</u>) <= <u>Charles Runels, MD</u>

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