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The following is an edited transcript of the *Journal Club with Pearls & Marketing* (JCPM) of March 12, 2024, with Charles Runels, MD.

The video of this live journal club can be seen here ←

Topics Covered

- Striae—the types of and which treatments give the best chance of complete resolution
- An email you can send if you do the Vampire Facial®
- Regional block vs ring block before treating for hair loss, which works best)?
- PRP autologous and allogenic for rotator cuff injuries
- 30 minutes first thing, thinking and writing about one thing are the keys to the kingdom.
- How often can you do the P-Shot® procedure?
- What are the guidelines for the off-label use of FDA-approved drugs and how often is it done?



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® procedures.

Welcome to the Journal Club. We have some new research that should be useful to you. We'll have a paper about striae. If you think about what's happening with a lot of people losing significant

amounts of weight with the new drugs on the market and with spring here and people wearing fewer clothes, it's a great time to both know how to treat striae and to let people know that you know. If someone liked doing this, they could make a whole career, a significant amount of people happy, and a noticeable amount of money just treating striae. So, we have a review of that and then an article about treating hair with or without minoxidil and, to go along with the striae treatment, a look at using a regional block versus a ring block for treating hair (which is best), and a quick look at treating rotator cuff injuries.

So we'll start with research, but then, when it comes to the marketing, I think it might be useful to go over a system I've used 1998, when I built the first website for my general practice, for just a simple way to create content, stay up to date, and market your practice all at the same time. It's a twist on something I've talked about before, but hopefully, a clearer way of thinking about it, that may be of use to you. Then, I'll answer one question that came up about how often to do the P-Shot®. One of our

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providers wondered if it might work better if you did it every couple or three days instead of every three months. So, we'll get to that. But let's start with the research.

Striae: the types of and the treatments most likely to give complete resolution

In this article, they do a nice job of defining the different types of *striae distensae* or stretch marks.¹ This paper is a nice reminder that striae occur on the back of males as they grow their shoulders in adolescence, in females as the breasts develop, and in the abdomen. They occur with pregnancy (gestational stretch marks), the buttocks, thighs, and kneecaps. Those are the most common places. Then, you have white and red striae, where the red is more acute.

They narrowed it down to 151 studies. The highest complete resolution rate for the red striae was with a laser (for an energy-based treatment), and for a mechanical-based complete resolution, it was microneedling. So, they're looking at studies where it just went away versus no effect or minimal effect. So, for complete resolution, the most consistent was the laser, but next in line was microneedling.

And, of course, the great thing about <u>micro-needling</u> is that it can be done with all skin types and with less risk because there's a risk for every skin type with a laser.² If you've got a laser in your office, this paper can be used to brag about it. But if you don't have a laser in your office, but you have a microneedling device, you can use this paper to let your people know that you have a safe way to treat stretch marks for all skin types. So, we're in strong standing with our microneedling; and it's better with the PRP.³ You do have to go deep when treating postpartum striae; you have to go around two millimeters or more to see the best results.⁴

They made a big point that just using Retin-A for your pregnant ladies has a nice result, too. So, topicals remain less effective, and none have led to a complete resolution. But even though topical Retin-A for stretch marks postpartum works well, at least one study showed that our Vampire Facial® techniques work better.⁵

Knowing how to do something is no good if people don't know that you know. So, if you have a microneedling device, an email that might go out or your social media post would be something like...

The people who complain about this the most are the people in their thirties to mid-forties. They're old enough to have the stretch marks, but still young enough to want to show up at the beach or the swimming pool in a bathing suit. So, an email could go out saying,

Here's an Email You Could Send if You do the Vampire Facial® Procedure

- 1. Copy and paste the following message into a new Word document.
- Then edit it so that it sounds like you.

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- 3. Add a story or a personal observation if you have time.
- 4. Then fill in the information with your phone number, etc. and send it to your patients.



Hello,

Spring is here, and stretch marks become a more unwelcome nuisance with the warm weather. I wanted you to see a recent review article about how we have tools that can make those stretch marks (striae distensae) less noticeable and sometimes completely go away.

Here's where to read the research (click).

If you think may help you or someone you love, please contact us.

Sincerely,

(your name)
(your phone)
(your email address)
(your webpage about the vampire facial if you are on of our providers)

And this is news, as you can see, because it just came out this month, and that makes it news.

To remind you guys, whenever you watch whatever news you watch, whether it's Apple News or CNN or Fox or Wall Street Journal or the Guardian, they're often curating news that comes out in our literature. News reporters might say, "The New England Journal reported this is about weight loss." Or I saw something on one of the news channels the other day where they quoted another article showing that walking was good for your heart as if we haven't seen tens of zillion of those already. But it's nice to be reminded. The point I'm making is that, even if you're watching CNN or whatever your favorite news channel is, they're reporting on events, but they're also reporting on another medium's (news) report.

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So your journal article in the New England Journal or whatever open source journal you're looking at is recent medical research/news, but if CNN or Fox can curate that and bring it to their viewers, even more so, your patients want you to do the same thing. So, if new research is relevant to your practice and to your patients, it becomes a much higher-level way to market your practice, rather than, I think, doing entertaining dances and songs on TikTok; if that's your thing and you're good at it, go for it.

But if you're like me and you're going to starve to death if your groceries depend upon telling jokes or doing dances, then that's how you convert everything we talk about here to a marketing message and, at the same time, enhance your reputation.

Ring Block vs Regional Block for Treating Hair Loss

Okay, so here's the article about blocking, and they're only talking about treating the frontal part of the scalp, not the occiput.⁶ They found that there's significantly less pain with a regional block versus a ring block.

If you go to our website, we have one for hair specifically, but I put the hair instructions on the <u>Vampire Facelift® membership website</u>. Dr. Stefan has been a decades-long hair transplant surgeon and he also treats alopecia with PRP. So he's an extremely experienced hair expert who shows you how he treats and blocks the scalp. And then, there's me in this video, and there's another one, and there's another one. But in the article we're about to look at next⁷, their method of anesthesia was just ice. And if you're good enough at this, if you've done a few of them, you can do a treatment in less than a minute, especially if you're just treating the frontal area. So, I would argue that, for most people, ice and just being fast when you're injecting is the way to go versus if you're doing a transplant, that's a different matter, or if it takes you longer than a minute, then you should block it. If you follow the ways I show you how to do it here on this website, by the time you're doing the second or third one, you'll be doing this in around 45 seconds, the entire scalp, without rushing. So, I recommend you look at that if you're one of our facelift providers; you have that as part of what we give you. Let's jump back to the research.

The bottom line is that I don't think you necessarily have to block it at all, but if you're going to block it, then doing a regional block seems to work better than a ring block.

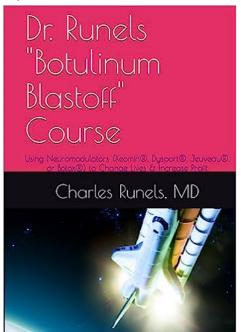
I was at one class or one person's office teaching, and one of the students was an anesthesiologist. And his ring block was he just took a spinal needle, put it on a syringe, and just threaded it all the way across the forehead and then, did one retrograde injection of lidocaine across the whole forehead. It looked brutal, but it worked. That's one way. Most people, when they do a ring block, they do multiple little injections, and you can do it carefully and make it near pain-free, but before you're halfway through with your ring block, I could have treated two scalps. And so can you, if you follow our instructions.

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They did teach me something about the regional block though.

I normally just do this one injection over each eye, but if you use their technique, you inject here and then, you go two centimeters and do another injection there. And they show you that in the article, which is open-source and downloadable. And so, how would you convert this? Remember, I always talk to my patients as if they're doctors. If they're smart enough to drive here often to pay you a thousand dollars, they're smart enough to read and look up the words they don't understand. They can read almost everything we can read because it's not decoding integrals in calculus. It's just information.

So, if I wanted to treat more hair instead of the one we just covered with striae, I would write an email



about this article. You can see it came out at the end of January this year, published at the beginning of February, and that makes it news. Then that gives you a reason to talk about it.

So, your email goes...

"Hey, there's more research about treating hair with PRP. We know it works for most people, and now, more research shows that, when you combine it with ROGAINE or minoxidil, it works better."

In this study, they found that, at a month, you couldn't tell much difference in the number of hairs, but they were already thicker. And the people who got minoxidil combined with the PRP and were treated once a month, by the time you got to three months daily with the minoxidil, once a month with the PRP, and by the time you got to three months, the hairs were thicker. The hairs were also more plentiful in the group that got

minoxidil combined with the platelet-rich plasma.

But, minoxidil is not benign. I don't know what type, but I know when I use minoxidil, I get some dysrhythmias, and it is known to be a side effect that people can get atrial fibrillation and others. So it's not benign, but for most people, it's acceptable and has minimal side effects. So, I'm not saying you don't use it.

And so, your communication to your patients might be...

"Hey, we have more research showing that, when we combined our PRP treatments for hair loss with minoxidil, we get a better result. Here's a link to the research. If you think this might help you or someone you love, give us a call."

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That simple.

PRP autologous and allogenic for rotator cuff injuries

Okay, the last research paper that I thought was interesting and practical this week. I go through quite a number in different arenas looking for the stuff that could change what you do, give you more confidence in what you're already doing, or give you a reason to talk to your patients and give them more confidence in what you're doing.

That's what I'm looking for. There are interesting things about gene markers and other topics that don't change your practice; that I skip over. And hopefully, I'm bringing you stuff that does what I just said.

This one is it's dear to me because I tore the rotator cuff in my left shoulder back in college from too much swimming, and my right shoulder recently after spending lots of time playing pickleball with the family during the Christmas holidays; but I had a friend of mine inject my right rotator cuff using ultrasound, which I don't think is necessary, but he did it a few weeks ago.

It hurt like a maniac, but the shoulder is tremendously better. This research shows what you probably already know if you've been showing up even occasionally to our Journal Club: when you use prednisone, you get a very quick attenuation of the pain short-term. By the time you get two to three months out, however, those who get platelet-rich plasma are doing much better, both with the pain and with objective measures of joint healing.⁸

If you're not injecting joints and you're doing family practice or general medicine of any kind or sports medicine, especially if you're doing general practice, a lot of people show up with shoulder pain, and this is not a dangerous injection, and it's easy to learn. So, I recommend that you learn how to do this, and I'll put in the email that goes out, I'll put a link to online ways to learn it.

The other point of this article, and we'll swap to the marketing part, is they looked at allogenic versus autogenic or autologous.

So the blood that went into my shoulder came from me, but I know there are people in our group that are doing interesting things where they're getting the platelets or even plasma from younger people and injecting into people like me in their sixties or seventies and somehow something's working perhaps better. But most of us are not doing that yet. For most of us, I think the point to be made with your patients is that there's strong research that just came out showing that, yes, if you're putting PRP into the shoulder for a rotator cuff injury, you're doing better medicine than if you're slamming it with cortisone.

The Simple Practice that Will make you a better physician and market your practice

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I'm a big fan of Cal Newport, I recommend you read everything the man writes. He's a mathematician whose claim to fame is he started writing about the fact that, really, most of the good stuff comes out of times when you're quiet and not distracted, but those times have become much less common now. For fear of being boringly nostalgic, there was no cell phone when I was a kid, so I would go walking and playing, and my instructions were to be home by dark. I would ramble in the forest near my home or the neighborhood, and there was no distraction by anybody, whereas now, of course, the kids and adults are sitting and fiddling with their phones. One research report by one of the apps, RescueTime, showed that, on average, people check one their inboxes every six minutes.

I don't know how you function doing that. So whether they're checking their dings on their TikTok, their Facebook, their chat box, or their Slack, you start looking like you're doing something, but you're just clicking buttons.

I'm now learning how this relates to marketing, but I want to show you this book. And if you don't know this author, I would like you to know him.

Then I'll come back to the marketing piece.

That's the new book, <u>Slow Productivity</u>, and it relates to other things we've discussed here, such as note-taking and pulling ideas out of your brain or developing ideas. But it starts with being productive, which doesn't mean clicking buttons. So he starts by making the point that, if you were measuring a farmer, you could easily measure productivity by pounds of potatoes or something, or if you're Ford, you can measure the number of cars per hour of manual or people labor.

But how and what do you measure that when you're a thinking person?

Number of patients? Number of articles published? Amount of money made?

You can publish articles that are cliche almost or rehashing with no new ideas or poorly done. Or you can have the one landmark paper that took you 10 years to think about, that changes medicine, which one is more productive?

With mental work is much harder to measure productivity.

One of the things that I've started measuring is a very, very simple thing that brings us back to marketing, and it comes from a lifetime of trying to beat stuff out of my brain, but it also comes from various other sources.

In the Cal Newport book, he talks about a guy that wrote, 50 books or so; but he spent a week and a half on his back staring at the trees on a picnic table at his house trying to figure out how to integrate some information that he had gathered over a year and a half doing research. That would not look very

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productive if you just walked by his house and saw him supine staring at the sky. So how do you measure productivity with thinking work?

I want something that I can measure at the end of the day. I'm about to give you something that I measure that flips into ways to market things, which has worked for me.

There are other ways, but this has worked for me. So it's simply this is: you wake up in the morning, other than whatever it takes to get at least semi-awake, and for me, that's brushing my teeth, some source of caffeine, because I've got old enough to need that, splash some water on my face and sit down and do the next thing I'm about to tell you, which will make you smarter and help your marketing.

If I even get dressed, it's just for warmth. Most of the time, it's robe enough to be not in the wind. Hemingway would wake up and walk naked to his writing table; he liked to become fully awake while looking at the page as the sun came up. This is what I'm recommending. Before you text, before you look at an email, I admit I often look at one news app just to make sure there are no bombs aimed our way and that my soldier son is not on the plane to go somewhere where bombs and bullets are flying. And then, with that, I do what I just told you. And then, I sit down, and the thing that I measure is just time. I do 30 minutes of just thinking about one thing. And that thing, it changes, but not day to day.

I pick a thing about which I want to know as much as anybody else on the planet Earth; no one is going to know more about this thing topic than me—that includes people in the past or at the current moment.

And imagine if you narrowed the topic enough that you could read everything ever written.

Lately, I've been reading about the autonomic nervous system in women and how it affects a sexual response. That is it. That spun off something else I read about, which spun off from something else I read about. And so, it's a series of sine waves, where you go from knowing something, maybe a pretty good bit, maybe not so much compared to all there is to know, but you read about it for 30 minutes every morning (except if you take that one day a week for the Sabbath or whatever you do for your one day). But other than your rest day, you always read about that one thing in the first 30 minutes of the day. I did it a couple of weeks ago, first thing in the morning, while sporting a fever. I've done it when I've lost loved ones and am heavy with grief. I've done it in pain after an injury. You never miss. Never.

There is no excuse. 30 minutes thinking about your topic or reading about it. Lately, often these days, I will stare for the whole 30 minutes at one picture in Netter trying to understand it, reading, wanting to understand every mark on every part of one picture, sometimes for days at a time. And then, you make notes. The notes go on a piece of paper (not a computer) using a pencil or a pen. And I have a pen that's just for that thing in the morning, and I make notes. It might be notes about what I just thought, about what I've been staring at for the past three days, or it might just be my own words, describing in very concrete terms that, for example in regard to my current topic of choice, how the cavernous nerves Charles Runels, MD

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(autonomic) connect to the dorsal nerve (somatic) of the clitoris. In a recent study of guinea pigs, they are directly connected. That's what I read this morning during those 30 minutes of staring at the literature regarding the autonomic nervous system and how it affects sex in women.

To further elaborate: there is no sex before you do the 30 minutes. There's no shower. I've tried reading and praying and yoga and running and everything under the sun to try to make the muse talk to me more plainly and more profoundly, but nothing works better than just brushing my teeth, getting some caffeine, and just sitting down with a stopwatch determined to think about that one thing for 30 minutes before I do anything else—and make notes about what I think.

Once you get those notes, send them to your people (email). Eventually, it gets integrated into your book or your next research project. Still, at that point, you are just curating what's already out there.

Let me review: the simplest way to create content/marketing is to state the obvious. For example, "A stitch in time saves nine." Cliché stuff that does not offend your tribe or probably anyone else (this is for the spineless). It amounts to 95% of the clicking online, which is when people come out with cute little pictures, cute little poetic or snarky ways, clever ways, or funny ways to say the obvious. And everybody agrees with it, and they click, and thumbs go up. To me, that's mindless.

Why talk about the obvious and widely known?

The next level is what I'm talking about now. You get up every morning and think about that very narrowed-focused thing you want to think about. And if you do 30 minutes today and you don't get to it again until the next day, it's okay; you have patients, you have a family, you must put gas in your car, you must eat dinner and play with your children and make love to your lover, and you need to live your life. But, you do the 30 minutes going deep.

You do less well if you try to make something about which you are thinking into the only thing you do all day. Then it eventually becomes torment, and your brain shuts off, and you start to dread it. Even if you stick with it, when your focus stays narrow all the time, your new ideas do not come. So I usually shoot for at least one 30-minute session, and I like to get three of those 30-minute sessions in (with short breaks if I want them), then I do my day (all the other tasks).

Remember, with the first level, you're just stating the obvious; everybody already knows it. With this next level, you start to curate the information you're learning from that 30 minutes of focus, narrow reading, and thinking into the known but at an unusually granular level where what are considering is less widely known.

As an example, lately I have been diving very deep into the anatomy and function of the autonomic nervous system as it relates to female sexual function. And what I am writing is right there in Netter's and it's in the 2011 version, and that atlas cost about \$800; most people will not buy it. They're

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supposed to be coming out with a new version, and when they do, I will buy that one too. I spend an embarrassing amount of money going deep. Sometimes, I must order an odd book that was published a century ago on eBay to be sure I am not missing something.

But, in the twelve-year old version of Netter's atlas, you can see how the parasympathetic ganglion are in the wall of vagina and how they connect to the inferior hypogastric plexus—it's been there, but most have not spent day after day thinking about it. You can also read in that same book about how the inferior hypogastric plexus eventually leads to the lateral hypothalamus, which is responsible for arousal. So, it's not stating the obvious, but it's stating what's already known that you uncover and deeply consider when you go very deep and narrow with your reading. So, I'm curating information that maybe most people aren't considering—but it is not unknown.

Then, at the next level, you start to comment on what you're curating.

That's what we're doing now.

You become part of the grown-up conversation.

I am not the smartest person I know; but this practice does not require that have a stellar IQ. I do not even know my IQ: I am afraid if it is low, I will become discouraged and if it is high I will become prideful and lazy, so I see no reason for knowing. The practice seems to me to be more important than the IQ (assuming a minimal level of probably somewhere around 120).

As another example, every week on this journal club, I read and curate what is the most practical, useful information in the literature about something very narrow: how to directly affect the cells of the body and in so doing improve tissue health and, therefore, the body's health and function. Mostly we talk about PRP as that strategy, but we also consider other therapies. That's what this Journal Club is about, at least the research part of it. And so then, as I present it, I comment on what I think about it, but I'm curating something that's not widely known because it just came out and then commenting on it.

Then, the next level up is when you start to see new connections that aren't in the literature yet because you're diving in so deep.

And then, you start to see things that might combine, that are there, but the combinations haven't been talked about. And that's how research happens because there's nothing new under the sun. Everybody's standing on the backs of the people who wrote previously about the subject matter that's being recombined.

So, in summary, these are the different levels of practice (and most people stop at level one):

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- 1. First, it's stating the obvious and widely known, to get clicks, which some people have made fortunes doing. You have two Kardashian sisters who are billionaires for doing stuff like that; it's the cute little picture that people click on your Facebook or your TikTok page.
- 2. Then, the next level is diving deep and curating and putting the news out there about a narrow subject matter.
- 3. And next level is commenting on what you find in level 2.
- 4. Then, the next level is seeing the new combinations that come from now being part of the grown-up conversation.

So, if you're doing the above practices regularly, you get up and read for 30 minutes, and then you write about what you're reading, people will start coming to see you from everywhere.

And you may look around one day, and you've still got ink stains on your fingers, and you don't even know how you landed there, but you're on stage somewhere, teaching people about what you figured out during those 30 minutes a day—even if you live in a little 3-red-light town in Alabama.

So that's my marketing tip. It feels like it could be more than that; but that's my marketing tip for today.

For example, in relation to today's topics, you could say, "I'm going to know more about striae than anybody else."

Those who did the review we covered today came up with 150 articles. So, you could start with those and read all 150 of them and write about them; as you read them, write about what you're reading to your patients and make videos about it. And I promise you, by the time you get to the 150th article (at 3 articles a week, it would take you about a year), you're going to have your office filled with people who want to pay you to treat their striae, and you will be giving them the best treatments possible.

How often can you repeat the P-Shot® procedure?

Okay, so with that, I have one question to answer that was sent to me this week: "How often can you repeat the P-Shot®...every few days?"

The short answer is nobody knows.

A study needs to be conducted on that. But I know from studies that have been done that, in orthopedic research, the endpoint (when maximum results occur after one treatment) is often six months out. In wound care research, the endpoint is usually 12 weeks out, with 80% effectiveness at eight weeks. Anecdotally, in our group, we see the best results for all of our PRP procedures, around 12 weeks or more, 12 to 15 weeks out.

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In contrast, for Peyronie's disease, Dr. Virag in his study injected PRP every week. Most of the studies of the effects of PRP use and end point of eight or 12 weeks. If you look at how long does it take to grow a new layer of skin, it's about six weeks. If you're using Retin-A, it is around the 12 weeks, because you have time to grow two layers of skin. And you'll start to see the dramatic effects of Retin A (which also works at the cellular level to change collagen production) at six weeks, but not at three days.

Another thing to consider, a hair transplant surgeon told me 10 years ago that he had quit doing hair transplants on women because if you would just inject their scalp with PRP and be patient, at the end of a year, not three months or six months, but a year, they would be satisfied with their hair. And that's all you needed to do.

So, he didn't think it was even ethical for him to keep doing hair transplants on women or even repeat PRP injections. This was, again, more than a decade ago. And then, when more studies started coming out, most showed treating once a month for three treatments. So, I had my skepticism; maybe those next two treatments are not even needed. It's just something you're doing. But if you had left the patient alone, you would have seen equal results. But someone finally did the study, and yes, one group got once-a-month treatments, and the other group got only one treatment, and then, both groups were checked at three months. And the group that got once a month did better.

We don't know the answer in regard to our P-Shot®, but based on the research and based on clinical practice, here's my thinking: it could be difficult to get people to drive to your office, pay you money, and take hours off from their work and their family to do it or get on the airplane, in some cases, to see you weekly. And if they did, but you could get even just similar results with treating them every 3 months, why put that burden on them?

Ideally, if you could just be the almighty most powerful wizard on the planet, you would just speak the words, and the hair would grow, or the penis would stiffen. The next step down from that would be to take a magic wand and wave it over their scalp one time, and hair grows. The least magical would be having to bring me back and stick my head with a needle or my penis with a needle three times a week. So doing more frequently doesn't get you magic points unless it's getting you dramatically better results. As a matter of fact, it can be a way of sending your patients away because if you're going to see them three times a week, you don't want to do that for free. So, you'll be charging them. You have the time involved with drawing their blood, the phlebotomy, the pain, and inconvenience of doing what you're going to do, their time, your time, and then, them paying you for three times a week.

So, with that in mind, what I came down to with the procedures and what we're running with until someone does research that shows a better way is that it takes about 12 weeks for optimal effect in the wound care studies, with which you can watch and measure the progression. And it makes sense when you consider the life cycle of the dermis that you're going to see something similar with our procedures.

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That was Sclafani's noticing, too, when he used PRP to treat the nasolabial folds.¹⁰ He watched for 12 weeks, and most of the effect was there at eight, yeah, at eight weeks. So I prefer people to come no sooner than 12 weeks, because if they're coming every week, their expenses go up when they might've gotten just as good results waiting for 12. The downside to that is, if their marriage is on the rocks and they're not functioning and their sex is broken, they don't want to wait three months; their lover may be gone by then. So, I will see them at eight weeks, but I feel like treating them before eight weeks is like over-fertilizing your lawn.

Remember, these are not immediate pharmacological effects. They're growth effects. So if you inject IV morphine, if they're not better in 10 minutes, you probably need more medicine. But PRP (and other regenerative therapies) trigger pluripotent stem cells to grow new tissue, which takes time.

So I wouldn't put fertilizer on my lawn and go back two days later and say, "Oh, I don't see any new grass, so let me re-fertilize."

Maybe that's a half-brained, inaccurate metaphor, but it could apply.

So I prefer to be kind and tell people, "At any point, if you just feel like you were not delighted and want to go away, then okay, here's your money back. I'll give you your money back the day after I treat you if you want, but I will not be your doctor anymore and treat you six weeks from now if you have gotten your money back in a week. So, I prefer you give it eight weeks, and then, if you're still unhappy, I'll repeat it or give you all your money back (your choice). But if you're seeing effects, you should pay me to do this again to see if we can get even better effects."

That's how I handle it, and I know that that's a long explanation, not a definite one.

From our survey data, we know that somewhere around 60% of our people love the O-Shot after one treatment—that's including the hard cases, hard to treat, hard to get results, compared with even the easy stuff, like stress incontinence in women. And we know that around 80% of our patients love everything we do (including the hard-to-treat cases) after the second treatment. And that's waiting eight weeks between. Knowing that some people have their patients sign up for three treatments back-to-back. Oftentimes, you'll see a woman who sees her incontinence improve on the first treatment, and her sex gets better after the second treatment.

I have found that I feel better just charging them for each treatment because if 60% are happy with one, I don't want them to have to pay me for two. On the other hand, sometimes I wonder, when I stopped at one, would they have been happier if we had done two? So, I can't argue with having people sign up for a bundle of two or three treatments, especially in the hair or women with incontinence and sexual problems, or you can make the same case for Peyronie's disease. You're probably going to need more than one treatment.

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On the other hand, from having done this now for more than a decade and talked to our literally thousands of providers, I think you're best waiting at least eight weeks before you repeat the treatment, or you might wind up exhausting your patient's time and bank account, where they're more likely to give up after three treatments a week apart, than they are if you wait eight weeks before the second treatment—therefore giving it time for them to see the results.

So, in short, I recommend you wait at least eight weeks between treatments. And I can't argue with selling them in packages of two or three. I think that's a matter of taste, but you should always be ready to give people all their money back, anytime they ask you. The consequences are that they lose you as a provider of the procedure in the future.

People worry, "Well, won't they take advantage of you when you offer money back?"

Yep, some people will, and those are the people I'm talking about. If they want to have it again, they'll have to find another doctor, but most people are honest, or Walmart would be out of business and L.L. Bean and all those other companies who give money back to the customer any time they ask. By far, most people in the world are honest. And so, if they're not happy with your stuff, either repeat it or give them their money back, and you'll be happy and sleep well, and they will be grateful that at least you weren't damaging and you did your best.

Yep, Patrick, thank you. Hair works better in a series and meta-analysis systemic reviews, a slight advantage to closer intervals. Oh, I didn't know that. Thank you. If you want to unmute, so you can teach me about that. However, according to Patrick, some studies show that closer intervals, like two weeks, work better than every four weeks. That's good info. If you want to tell us more about it, push the button, and I'll unmute your microphone.

What are the policies regarding the writing of prescriptions off-label?

What other questions? Debra says, "Can you review what you found is or isn't needed by providers to report on results of off-label treatments they're doing on off-label?"

Yes, there are some very good and specific articles about what to do if you're doing on or off-label treatments. 11 12 13 14 15 16

Multiple studies have come up with different numbers, but 21 to 31% of the prescriptions written by primary care physicians are off-label.¹³ There are certain populations that are very difficult to study, like children or pregnant women. And the mechanics of it are so difficult to get something approved by the FDA that it's easier for the company to just not push it to on-label indications. And we, as physicians, of course, the FDA does not regulate the practice of medicine. They regulate what manufacturers can advertise and what medicines can be sold under what claims.

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So there's a known phenomenon called orphan drugs or orphan indications, where the research is stacked up beyond what most people would refute. For example, Wellbutrin to help with depression without killing sex drive or botulinum toxin for smokers' lines. Those are off-label things, even though we know it works, they're off-label and they're likely to never be on-label, because the amount of research needed to be done is beyond reason, because of the population being studied and because of the quirks of certain indications.

Like when you're trying to prove drug works for female sexual function, it's more difficult than with men. The endpoints are different. For a male, you must prove his penis gets harder. You must show satisfaction for a female, which is an autonomic emotional thing, not something you can measure with a ruler. So back to your question, Debra, and I'll put links to this in the email that goes out, but what's accepted in the discussions, and there are a lot of them about what makes it acceptable, is there needs to be something with research backing up the logic behind what you're doing, you must keep your own personal records in your charts about what happens. It doesn't mean you have to report it in a study, but you keep your personal records. And for us with sex, it's the Female Sexual Function Index or Female Sexual Distress Scale or, with men, the SHIM score, one of those accepted instruments that keep track of sexual function, all of which can be downloaded from your membership website, with apps out there, that will help you score it.

Or it could be done manually. But you keep records, and you have science to back them up. And you have someone with a problem that doesn't have another treatment that, had you offered it, it would've been likely to be accepted.

Let's take smokers' lines. That's an off-label use of botulinum toxin. And if you say to your patient, "This is off-label. It has the same contraindications as botulinum toxin used for migraines. Don't be pregnant; don't have myasthenia gravis. Do you want it? I have nothing else I can do for this other than laser you and give you Retin-A."

And the person says, "Yes, our options are few. The science backs it up. It's off-label. Whip out your insulin needle and me botulinum toxin injections in my lip."

Same thing with Wellbutrin to help with sex drive in women. They're on SSRIs. They don't have a sex drive. The research is phenomenally strong, and the science behind the neurotransmitters is that if you give them Wellbutrin, it's going to help their sex drive—but it is an off-label use.

I don't think you'll ever see an on-label indication for that. The tragedy is that some of our colleagues will not do many off-label prescriptions, especially if insurance doesn't cover them. And often insurance won't cover it until it's on-label, so there's this orphan indication, orphan populations, for which we will likely never have on-label treatments. Many treatments will never likely be on label.

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So, some orphan indications are not likely to see many on-label treatments, and for the patient to benefit from off-label treatments with supportive research, it takes a doctor willing to say, "Okay, we don't have other options that you want. The research supports us in doing this; let's do it. I'll keep track of what happens in the chart. You will sign a consent form that says you know the risks and benefits, which is an off-label, non-FDA-approved use. And then, you go about your business."

And somewhere around 25% of the prescriptions written by primary care doctors are written for off label use in the way we just described.¹³

With that, we'll call it a day. Thank you for being here. I hope you found something useful that will help you care for the people who come to your for help. Goodbye.

References

- 1. Zhu CK, Mija LA, Koulmi K, Barankin B, Mukovozov I. A Systematic Review on Treatment Outcomes of Striae. *Dermatol Surg.* Published online March 7, 2024. doi:10.1097/DSS.000000000000151
- 2. Alster TS, Li MK. Microneedling Treatment of Striae Distensae in Light and Dark Skin With Long-Term Follow-Up. *Dermatol Surg.* 2020;46(4):459-464. doi:10.1097/DSS.00000000000000181
- 3. Sany I, Mohamed Sobhi R, Badawi A, Mohamed Elmaadawi Z, Mostafa PIN. Comparative Study Between the Efficacy of Fractional CO2 Laser/Radiofrequency, PRP and a Combination of Both in the Treatment of Striae Distensae: A Pilot Study. *Clin Cosmet Investig Dermatol.* 2022;15:1687-1694. doi:10.2147/CCID.S365952
- 4. Hersant B, Niddam J, Meningaud JP. Comparison between the efficacy and safety of platelet-rich plasma vs microdermabrasion in the treatment of striae distensae: clinical and histopathological study. *J Cosmet Dermatol.* 2016;15(4). doi:10.1111/jocd.12246
- Gamil HD, Ibrahim SA, Ebrahim HM, Albalat W. Platelet-Rich Plasma Versus Tretinoin in Treatment of Striae Distensae: A Comparative Study. *Dermatol Surg.* 2018;44(5):697-704. doi:10.1097/DSS.00000000001408
- 6. Nagaja SA, John RS, Kumar SP, Krishnan M. Comparison of the Efficacy Between Regional Nerve Block and Ring Block as Local Anesthetic Techniques for Platelet-Rich Plasma Treatment. *Cureus*. Published online February 9, 2024. doi:10.7759/cureus.53901
- 7. Ruthvik S, John RS, George M, et al. Comparison of Efficacy of Platelet-Rich Plasma With and Without Topical Minoxidil for Hair Growth in Patients With Androgenetic Alopecia: A Prospective Study. *Cureus*. 2024;16(2). doi:10.7759/cureus.53875
- 8. Gupta A, Migliorini F, Maffulli N. Management of rotator cuff injuries using allogenic platelet-rich plasma. *J Orthop Surg.* 2024;19:165. doi:10.1186/s13018-024-04657-4

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- 9. Virag R, Sussman H, Lambion S, de Fourmestraux V. Evaluation of the benefit of using a combination of autologous platelet rich-plasma and hyaluronic acid for the treatment of Peyronie's disease. Sex Health Issues. 2017;1(1). doi:10.15761/SHI.1000102
- 10. Sclafani AP. Platelet-rich fibrin matrix for improvement of deep nasolabial folds. *J Cosmet Dermatol.* 2010;9(1):66-71. doi:10.1111/j.1473-2165.2010.00486.x
- II. Commissioner O of the. Understanding Unapproved Use of Approved Drugs "Off Label." FDA. Published April 18, 2019. Accessed February 11, 2024. https://www.fda.gov/patients/learn-about-expanded-access-and-other-treatment-options/understanding-unapproved-use-approved-drugs-label
- 12. Hames A, Wynne HA. Unlicensed and off-label drug use in elderly people. Age Ageing. 2001;30(6):530-531. doi:10.1093/ageing/30.6.530-a
- 13. Radley DC, Finkelstein SN, Stafford RS. Off-label Prescribing Among Office-Based Physicians. *Arch Intern Med.* 2006;166(9):1021. doi:10.1001/archinte.166.9.1021
- 14. Ren Z, Bremer AA, Pawlyk AC. Drug development research in pregnant and lactating women. Am J Obstet Gynecol. 2021;225(1):33-42. doi:10.1016/j.ajog.2021.04.227
- 15. Van Norman GA. Off-Label Use vs Off-Label Marketing of Drugs. JACC Basic Transl Sci. 2023;8(2):224-233. doi:10.1016/j.jacbts.2022.12.011
- 16. "Off-Label" and Investigational Use Of Marketed Drugs, Biologics, and Medical Devices Guidance for Institutional Review Boards and Clinical Investigators. Published January 1998. https://www.fda.gov/regulatory-information/search-fda-guidance-documents/label-and-investigational-use-marketed-drugs-biologics-and-medical-devices

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