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RF Microneedling Safety: Reframing the Conversation with Leading Experts Ch. 2

Konika Patel Schallen, MD:
Today we're going to talk a little bit more about safety in radiofrequency microneedling. And Dr. Munavalli is here to tell us about the FDA notification and we're here to have a conversation surrounding safety.

Gilly Munavalli, MD:
Yeah, thank you. I think all of us, that's our paramount focus with our patients: is the technology safe. And at a higher level, the FDA has that same concern. And the FDA has a database that you may or may not realize, which is a self-reporting online database. The acronym is MAUDE, like the name MAUDE, and that database allows anybody to enter in an experience they had that resulted in an adverse event. And that database is query-able and it's relatively standardized, although not all the fields need to be completed. So we did some work with looking at that database itself to see what was going on. And this was in response to sort of a rare step that the FDA takes to single out a type of technology as being potentially dangerous. And that happened back on October 15th or late October of last year where they posted a monograph on their website, stating basically through an analysis of that database and maybe some other data we're not aware of, that patients need to be careful when receiving an RF microneedling treatment of any type.

And they talked about why that is and the scenarios where this can occur and what the patients should really be aware of when you step in and you lay down for that treatment. So I think it was important to bring it to light, but we can look and do a deep dive into that data and see exactly what that shows.

Konika Patel Schallen, MD:
It sounds to me like much of the MAUDE database really spoke to those unmet needs that we talked about in the first segment and these adverse events in large part are because of those unmet needs, but ...

Gilly Munavalli, MD:
Absolutely. Yeah. With generational changes in technology comes some learning and I think that's what we're seeing. But it's also not just the technology, it's how it's being used and the environment it's being used. And we looked at ... We went back about five years, previous publications have looked at a little longer, but this technology has been around for a while. So I think I used my first RF microneedling device 14, 15 years ago. It had no feedback and it had a vacuum assist to help the needles go where they needed to go. So it's not uncommon. And why are we focusing on it now? I think the number of treatments have gone up, the number of manufacturers that are making these available in an FDA approved fashion have gone up, obviously. And you can actually look at the MAUDE database and see which devices caused the issue, and not necessarily who pulled the trigger, but which device caused the problem and what scenario it was in in some cases.

And so we looked at that and we found that of all the ... There's probably 10, 12 devices that are available now in the US that are FDA approved. The majority, I'd say 70 plus percent of them came from one specific device that has a lot of market share, but also is capable of penetrating deeper than any other device, upwards of seven millimeters, and also does not have impedance control or any type of feedback control that will tell the operator where you are, as we talked about, and when it's safe to stop treatment.

Konika Patel Schallen, MD:
I think that device also doesn't have the capacity for the device itself to adjust the pulse duration or energy delivery, so there's a chance of too much energy spiking and creating some tissue atrophy.

Gilly Munavalli, MD:

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Yeah. Handpieces are different on that device. One can go much deeper and it's typically used off the face, but there's ... I think it has been used on the face as well, because it has what we call a rapid or a burst mode, so you can get around that by just utilizing that on the face. And that can cause the energy to go deeper. And this is, I think, where we're dealing with these issues, certainly of fat atrophy or sometimes even of pain that's long lasting because you had a nerve or something that you weren't intending to do.

James Newman, MD:
I agree. And clearly the size of those needles were substantially, over 50% larger than the current technology. And if a patient had to go through a second pass, oftentimes they didn't want to go through that because it was so painful. And so that leads to maybe the number of complaints that were logged into that MAUDE database. And so it's nice to see that the current device actually had zero risk in the MAUDE database, so that's good to hear as well, and it's reassuring to our patients as well.

Cameron Rokhsar, MD:
Absolutely. Also, I find the FDA advisory actually very commendable because oftentimes, even in our practices, when patients come in, they focus on use of a certain device for the goals that they're achieving, without special consideration to who is operating that device, and I think that's a major issue that needs ... We need to shed some light on. These devices don't operate in a vacuum on their own. I like to always mention to my patients, "Well, you know, you could drive a Ferrari. You can have somebody that drives that Ferrari 20 miles an hour and a race car driver, professional driver will drive at 200 miles an hour. It's the same car; that doesn't mean you're achieving the same result with that car." And I think this concept needs to be emphasized because some of these issues that we're experiencing has to do with proliferation of these devices in the wrong hands, and this cannot be overemphasized.

So yes, the device matters, the depth of penetration matters, but who's actually punching in those parameters into the device? Is it a well-trained doctor? Is it a doctor at all? Is it somebody with proper training, right? So I do believe that the FDA advisory brought this issue to the public so that patients become a little more savvy at choosing their healthcare providers and understanding that these procedures are true medical procedures and not just swap procedures.

Konika Patel Schallen, MD:
I think that is absolutely the case, but as these devices proliferate, as you said, training is so important and what the device is capable of doing to prevent problems is also so important.

Gilly Munavalli, MD:
Yeah. The one thing we can't change is what the device is capable of. We just change how we use the device, but without any adequate direction, it's really hard. I mean, you've got factors that most operators wouldn't even think about. When I'm dialing up 3.5 millimeters, is that the needle depth or the energy depth of a delivery? You don't really know. You have to go by what you see and depending on how that needle is driven, typically step motors are different force and pressure, and sometimes you actually, in some cases you have to use your own pressure, which we know is not going to be as consistent on the face especially. So these are things that are out of the control of the normal user, and I think that's also highlighted in the database, because if you look at what devices are having issues, a lot of those devices don't have the feedback we're talking about.

Konika Patel Schallen, MD:

And as you mentioned, burst mode, burst mode is not adjustable. So by definition at that depth, you are going to be beyond the dermis and that is-

Gilly Munavalli, MD:
Well beyond the dermis.

Konika Patel Schallen, MD:
Well beyond the dermis. What do you think Sara?

Sara Hogan, MD:
Well, the FDA warning actually says now RF microneedling is a medical practice. It is a medical procedure which actually adjusts for ... I did a study where we looked at all states, how they defined what a medical procedure is for different cosmetic procedures that are office based. And the majority of states have no comment on energy based devices at all. And now with this FDA warning, it fills in that gap. Yes, there is difference at the state level, but any plaintiff in an injury case can now point to this and say that this is actually a medical practice. And so it's not by any means an indictment on the technology, right? We know it works. We've been using it for over a decade, but it's an indictment on the proliferation and the deployment, the mass deployment of this technology.

Gilly Munavalli, MD:
And the process, right? And the process. We, in North Carolina, for example, there are really three medical boards, you have to be

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careful, three boards. One could be the medical board, the nursing board, and the aesthetician board, and each of those defines what their constituents can actually do in terms of what kind of injury you can cause on the skin, and microneedling, which, the traditional microneedling without energy sort of gave people a false sense of security. And then you add energy and they don't always adjust for that in regulations. And then you've got this whole sort of class or level of people doing treatments with the energy they were never intended to use.

Konika Patel Schallen, MD:
Yeah. So safety built into the device in addition to training, in addition to the right person using the device is so important because the fact of the matter is the devices are there and patients are ... Their health and safety is on the line. So it's important as a manufacturer to make sure that the device is made in the best manner possible.

Scott Gerrish, DO:
And the engineering of our industry moves so quickly and for the boards to keep up with us is hard. And if a machine works, and that's the goal, right? That when it's used inappropriately, it's going to work in the wrong place. And our industry has changed to where a lot is delegate-able. And so these treatments better have self-checks and self kind of regulations to know if you're doing something right or wrong, and a lot of devices don't. And you can get yourself into trouble, especially like we're saying, this industry's changing so very rapidly.

Konika Patel Schallen, MD:
And what about the data collection?

Gilly Munavalli, MD:
Yeah, what does the data show? I think that's the best question. So how we look at this data ... I mean, the database itself makes it fairly easy. You can define a range, you can look at by class of devices, you can look at ... You can query the database in many different ways to get what you're looking at. So we did all that. And in that span of time between, I think 2021 and 2025, we found 80-plus medical reports of injuries. And then when you look at the injuries themselves, we were able to sort of group them in terms of where they were, in a sense severity, but also where they were, what they were causing on the face, face and body, I would say. So with most of the events occurring on the face, and probably the most visible event being something like fat loss, where you've got a depression that is not going to heal on its own necessarily.

So, but other aspects of these needles as they penetrate through the skin from 0.5 millimeters all the way down, at every level they're hitting, if the energy is deployed inaccurately or inappropriately, you can get visible scarring, persistent erythema, hyperpigmentation, changes in texture and tone of the skin and over bony areas or areas where the skin is a little thinner, you can even get more bulk heating and injury.

Konika Patel Schallen, MD:
What's your experience as a plastic surgeon?

James Newman, MD:
So there's a debate amongst us when patients come in to have surgery and some of these types of energy based devices have been used in excess, it does produce a little bit more fibrosis and it can make surgery a little bit more challenging. And so amongst plastic surgeons, we oftentimes have to take a very detailed history to find out what types of treatments have been done because some of these technologies who put in too much energy, their tissues become a little bit more stiff and it puts the patient at a slightly higher risk for complications from surgery when the natural tissue planes are somewhat obliterated and it just makes safety even more of an issue. So I think that with the Candela products, I've done many procedures on patients who've had the Candela product, not an issue. On other types of bulk heating devices that don't have proper feedback, it has been an issue where you get more fibrosis, you get seromas, you just have longer duration of surgery, and then you also have the fat loss.

The most precious tissue on the face is the immediate subcutaneous fat that we really want to preserve. And these devices that you saw in the MAUDE database, that was the biggest complaint. So I think Candela's done their homework and it's a very safe device to use. And as we were kind of talking about, the end users are also very important. And unfortunately, many state legislatures try and usurp the educational requirements in medicine and just feel that they can change regulations without understanding the background and training necessary to do these procedures. So really a lot of times our elected officials are not doing their homework. They're not listening to the medical boards and they're trying to change policy based on just lobbying efforts from things. And so that's a detriment to our patients.

Konika Patel Schallen, MD:
Absolutely.

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Cameron Rokhsar, MD:
In the database, is there any breakdown of the settings where the procedures were delivered? I'd be curious about that.

Gilly Munavalli, MD:
Yeah, fortunately that's the hard part, is determining the exact scenario. In some cases, that information's given as medical or non-medical facility, but it doesn't always say who does the treatment, who delivers the treatment. And some cases the patients don't know. And I think that's reflected in what the FDA's observations and considerations were for patients. If you're coming into an office, you need to ask these questions. Look where you are. Who's going to do the treatment? How much experience have they had? What kind of results are they seeing? What kind of issues do they have? Similar to when you take a medicine and you read the package insert to know what all the side effects are, you need to be proactive as a patient and find out who's doing your procedure. And that was the overriding piece of advice that the FDA gave.

Konika Patel Schallen, MD:
That being said, you bring up a few points here in terms of technical considerations that may address some of those top adverse events that we saw in the database like atrophy or scarring.

Gilly Munavalli, MD:
Yeah, you could go all the way back to the needle design you talked about and the atraumatic versus traumatic insertion of the needles is dependent on the thickness, the sharpness, and the motor driving that, and how does that show up? That shows up as unintended injury and heat through the heat deposition in the high dermis, the epidermis or prolonged heat of deeper structures. And we just don't have that with the Profound. So our conclusions from the study were really that looking at this data and we are having, more studies are being published on this out. I think our goal is to educate the public that RF microneedling is safe first and foremost, who's doing the treatment, where it's coming from, and what are they using? What device are they using? Ask these questions because the data shows us these complications are real. Some of them are not spontaneously healable, I would say, or won't spontaneously resolve on their own and they'll leave permanent defects in facial contouring that are, they're going to be hard to treat and hard to correct.

Konika Patel Schallen, MD:
As you mentioned, fat's the most valuable tissue.

James Newman, MD:
That's right. So oftentimes we have to replace the lost fat by doing fat grafting. And so that's the last thing a patient wants to have to happen is to do another procedure to correct something that they didn't think would be possible. And so it behooves us all to make sure that our patients are well educated. And I think that when done properly, microneedle radiofrequency shows great results and we'll be sharing some of these results later today in the slideshow. So it's always about the consumer just has to have more awareness and that's happening now more on social media. And to have the FDA to come in and create this kind of thing, you know that the pendulum has swung a little too far with this procedure just being in the wrong hands and some of the technologies just being not well understood. So hopefully things will kind of come back and we'll see less complications in the MAUDE database.

Konika Patel Schallen, MD:
I think we will, as we really start to hone in on devices that can help bring safety to the market.

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