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RF Microneedling Safety: Reframing the Conversation with Leading Experts Ch.1

Konika Patel Schallen, MD:

Hello everyone. I'd like to welcome you to our conversation today entitled Radiofrequency Microneedling Safety: Reframing the Conversation with Leading Experts, where we will be talking about safety in RF microneedling and also about next generation technology and all of the benefits that it brings to our customers. My name is Konika Schallen and I am the medical director at Candela Medical. I'll be moderating this series and I'm excited to bring you this expert panel today and I'll have our panel introduce themselves. I'll be starting over here on my left with Dr. Gilly Munavalli.

Gilly Munavalli, MD:

Yes. Thank you, Konika. My name is Gilly Munavalli. I'm a dermatologist in Charlotte, North Carolina. And my practice consists of both cosmetic and medical dermatology and I've been a big fan of RF microneedling technology for probably the last 15 years.

Scott Gerrish, DO:

I'm Dr. Scott Gerrish. I have an aesthetic practice in DC and also Scottsdale, Arizona. Been practicing for almost 30 years now. The practice is aesthetics and regenerative medicine. And we've been working with microneedling radiofrequency for over 10 years and with the matrix for probably the last four years.

James Newman, MD:

And I'm Dr. James Newman. I'm a facial plastic surgeon based on the West Coast in Palo Alto, California, as well as in Dallas, Texas. And we use microneedle radiofrequency quite a bit in our practice. Although we are mostly a surgical practice, we find that the need for microneedle radiofrequency helps our patients achieve better skin quality and we can address all different types of skin colors as well. And I've been using this technology for the past seven years, and I've been in practice for about 20 years, and I'm really excited to share the insights on microneedle radiofrequency with my esteemed colleagues here today. Thank you.

Cameron Rokhsar, MD:

I'm Dr. Cameron Rokhsar. I'm a double board certified dermatologist and dermatologic surgeon. I'm the founder of New York Cosmetic Skin and Laser Surgery Center in New York and associate clinical professor of dermatology at Mount Sinai Hospital. I've been in practice over 20 years and my practice heavily consists of the use of numerous energy-based devices. We have over 40 devices between my practices, and I'm looking forward to this discussion.

Sara Hogan, MD:

I'm Dr. Sara Hogan. I'm a dermatologist with fellowship training in cosmetic and laser dermatology. I'm the founder of a practice, Cosmetica Dermatology in Washington, DC. I have been performing post-market clinical trial research with RF microneedling devices since 2018, and I've had the Matrix in my practice for the past year.

Konika Patel Schallen, MD:

Wonderful. Well, we're very pleased to have you all and all of your experience and expertise, and I think it's going to be a very interesting conversation today. So let's get started. The first thing that we wanted to talk about is really why Matrix. What made Candela come to the market with Matrix, especially when it did. And I will say that at Candela, we saw a definite unmet need with RF microneedling, especially as it relates to all the devices that had been in the landscape prior. There were some things that we knew that radiofrequency did very well. Radiofrequency coagulates the tissue well. Radiofrequency can tighten. It can volumize. We knew that with our previous technologies, Profound, which, Dr. Newman, you have a lot of experience with, and Dr. Munavalli and Dr. Gerrish. So

it was exciting to us, but we also knew with that first generation of RF microneedling technology, there were many issues and many gaps.

And we identified those major gaps as the following. The patients complained about the pain during the treatments. They complained about the downtime, so we saw that as a gap. We also thought that it is absolutely impossible to understand where the tip of the needle is. And so the gap was not knowing in what part of the tissue and whether the needle was even in the tissue or whether it was in the right space in the dermis or whether it was in the adipose tissue. So that was a big gap. Control of energy delivery was a gap. In some cases, in the previous generation of devices, there were issues with peaks of energy or energy not being delivered in the right way, which we know, of course, with all of our experience with Profound, that there's an absolute sweet spot of temperature and energy that needs to be delivered.

And so we saw what was happening with unwanted fat atrophy, with unwanted laxity, inconsistent results and patients saying, "I don't see anything." And so all of those things were things that we wanted to address. And you're all shaking your head, so I'm really excited to hear sort of what's going on when you're shaking your head. What are you thinking? Sara, what do you think about those unmet needs and what was your experience with the previous generation of devices?

Sara Hogan, MD:

Well, you would have to counsel patients that it depended on the operator, it depended on technique. The worst case scenario is they would not see an improvement. Pain management may be an issue. And I think that the Matrix RF does address all of these things in how it's been designed.

James Newman, MD:

Yes. And I would say that Candela has the best of both worlds because in the early days of using the Profound technology and having these needles into the patient's skin, we learned so much data about what happens not only to the collagen, but the elastin as well as the hyaluronic gel in the skin. So the overall composition of the skin and by having that early experience and then being able to figure out how we can make it a more or less invasive type of procedure, and that's what the evolution of the Matrix has become today. And I think all of us can now have patients that can come in, have these procedures done with literally like a weekend type of recovery. Whereas before, some patients would have a little bit longer type of recovery, but we knew that the clinical results were there. And that was based on both histology from actually human patients.

So Candela has that background, understanding what those temperature ranges and the impedance levels are and how we can develop this to have more consistent results with less downtime. And I think that's what our patients demand of us today. And so I'm really excited to see where we are with the current technology.

Konika Patel Schallen, MD:

Can you tell the audience a little bit about that background of the ranges and what you had found?

James Newman, MD:

Yeah. So when we first started doing microneedle radiofrequency, we weren't clear on what would be the ideal peak temperature to produce enough collagen and at the same time not produce unwanted effects of too much coagulation. So it's necessarily true that higher temperatures are not always the best. So although we compared our results at like 70 to 72 degrees and compared it with 67 degrees, and we found out that kind of that moderate temperature level between 66 to maybe 68 degrees was kind of that sweet spot. And we would see the enhancement of not only collagen, but also elastin, which is that wonderful substance in the skin that helps the skin spring back and maintain a certain amount of youthfulness. And we were able to measure true elasticity on patients and found that with the correct temperature range that we could reverse the skin to about two and a half years of youthfulness from doing these things.

So a lot of great data was learned from those early days. And we really thank all the patients who went through some of that little bit more intense recovery with requiring nerve blocks and that sort of thing to kind of gain this data. And the scientists back at Candela with the engineers were able to piece together some of these things and produce what we have today.

Konika Patel Schallen, MD:

That's right. And as you said, so little downtime in comparison for the results. And Matrix, of course, now uses impedance as a proxy for temperature, but it's really the only device that can because it's measuring impedance every two milliseconds. And so it can do that. Tell us what you think.

Gilly Munavalli, MD:

Yeah. I applaud Candela and their engineers for ... You weren't the first on the scene, but you looked at all those unmet needs and all that inconsistency and really with temperature now with impedance, you realize how important feedback really is to the device, to the

operators, someone who looks at endpoints. How do we know that what we're going to deliver is the right amount of energy? And I think that was ... Candela realized the importance of that.

Konika Patel Schallen, MD:

So we talked a little bit about the right amount of energy, but what about depth? How can we see the end of the needle?

Scott Gerrish, DO:

Yeah, and you can't. And we always talk about in medicine, we measure everything. We measure cholesterol, we measure blood pressure, and we have an endpoint, and we know that we were successful. But in aesthetics, a lot of the things we don't measure what we do and have that very objective reference. And this is the first device that actually does that. It brings aesthetics to the standard of the rest of medicine. And anytime you use an energy based device, there's variability because we're relying on the patient to heal and to respond. And if we can take one of the variabilities out, which is we're not at the right depth of delivering the right amount of energy, then we take that variable out, we can add consistency. And that's the one thing that I noticed with the matrix is that consistency just went off the charts because I've been using microneedling radiofrequency for years and all of a sudden the consistency, when we did the initial trials with Candela, that was the first thing I noticed is, wow, from the very first patient, great results. And what I also learned is because of that impedance feedback is a little bit of an ego bruise for me because I had done thousands of microneedling RF and I was like, "I could do this in my sleep." And then you start to get the impedance monitoring like, "Wow, maybe my technique isn't as good as I thought, little bit, not enough pressure. Maybe the skin's bowing a little bit more than I thought and there needs to be more tension." So it keeps you honest and adds consistency.

Konika Patel Schallen, MD

I think that's so true. When you're doing the treatment, it's very easy pulse to pulse to lose your train of thought for just a little bit and you'll be off in that case.

Gilly Munavalli, MD:

Yeah. The skin is not ... It's like an iceberg, some areas are thicker, some areas are thinner. We really didn't have a lot of flexibility in how to navigate through that and find the actual, the best setting for the best anatomic region on the face, and now we can.

Cameron Rokhsar, MD:

I think one of the major issues that was giving the whole industry of RF microneedling a bad rep in the past few years, and it's been very prominent displayed on social media is the issue of fat loss. So that issue had to be addressed at its core level, and I believe that the Candela engineers designed this with that particular issue in mind. And I do want to point out to everybody that that issue of fat loss is not unique to RF microneedling. For those of us who've been using devices for years, we know that the first radiofrequency device that came to the market was Thermage, and Thermage was monopolar radiofrequency bulk heating and certainly Thermage got a bad rep after a few years for fat loss and that issue also became displayed even in latter skin tightening devices that use ultrasound. The first one being Ulthera. People started complaining about fat loss with Ulthera. So it's not just RF microneedling that causes fat loss. The entire energy based devices can cause fat loss. So that issue has to be addressed. What causes fat loss, right?

So fat loss has to do with depth of where you're putting the energy if the energy is being placed too deep. And it's also if you're putting too much energy into the fat. So with Candela's RF microneedling device here, you're trying to control those two parameters in a very scientific manner, right? So the first is depth of penetration. You're going to know where you are. Are you in the dermis? Are you in the fat? Second, what Gilly alluded to, the impedance monitoring is further giving you feedback information where you are. So I think that this device was created with that major issue in mind that the whole industry is being plagued by this kind of problem.

Konika Patel Schallen, MD

Cameron, that's a wonderful way to explain it. I think you're absolutely right that there are many things that we don't know, other devices that we don't know that can be depositing their energy in the fat. And the only way to know this right now is through the impedance, because we can measure the impedance of different depths, and so that helps with the depth, and then the energy delivery. So that's a very interesting way to explain it. And just to finish up before we head into the safety portion of this, I think that's a great segue. Are there any other points that you wanted to discuss about any of your previous experiences and just some anecdotes of what you may have experienced with other microneedling devices that didn't meet the needs at that time of knowing where you were or delivering the energy consistently?

James Newman, MD:

|Well, I'll chime in here because I think the size of the needles and the insulation does matter quite a bit. And many of the previous devices had very large bore types of needles that would create quite a bit of swelling and some scarring and maybe they weren't insulated as well. And so you sometimes get heat transference back up through the insertion area and that could cause some

pigmentation issues. And I think we'll be delving into some of the safety issues that were raised earlier by governmental agencies because of reports of some of these types of things. So I think it's important that we explain to the patients the importance of the size of the needle, the fact that they're insulated and the energy is very well confined to the depth at where we want to place it. And I would further say that anytime you are using any type of device, like the previous monopolar radiofrequency, there wasn't that good patient feedback except for discomfort.

And having that real time feedback is very important. And any device that is coming out now on the market that doesn't have any kind of feedback to the operator, you're not going to get that kind of consistency. And so we always try and explain to patients that the allure of some of these devices that might be less painful or less downtime, but they don't really provide consistency, there's not many clinical studies looking at efficacy, I would be wary of just trying to hop onto the latest, newest thing that might be out there on social media and marketing. So the thing about Candela is that it has all the clinical published studies, you were involved in many of those things, and so we're able to stand behind the treatments that we're providing.

Konika Patel Schallen, MD:

Thank you. I think that's wonderful.

Cameron Rokhsar, MD:

Also in terms of just the evolution of like the protocols, right? When the original RF microneedling devices came to the market, the protocols where we just pick a certain depth and we just do a pass and that's it. And then people clinically later found out that maybe we need to do multiple passes at different depths, right? So, but these devices didn't have the capacity or the capability to be able to deliver the energy in multiple layers of skin. So what did we used to do? We used to dial a certain depth, we used to do a pass, then we used to dial a different depth and we used to go do another pass, right, because we wanted to hit different parts of the skin for optimal results. So now obviously the Candela engineers took that into consideration, this whole evolution of our protocols and put it all into one concept, right?

So we can actually hit multiple layers of the skin at different depths within the same pulse, and that's revolutionary.

Konika Patel Schallen, MD:

And not only is it time saving in the long run, it gives multiple zones of coagulation, lots of flexibility in terms of how that coagulation zone is going to be made. And more importantly, with radiofrequency, it delivers the energy before edema sets in and that there's too much, there's too much edema to improperly deliver the energy. Absolutely. So many different things that Matrix was designed to do to counteract what had been happening before or fill the gaps. And I think that the point that I want to make is that it is a very different breed of RF microneedling devices. It really truly is next generation. Thank you all for sharing your expertise and your experience with, with your previous generations. And with that, we're going to segue into our next piece of this, which will be radiofrequency microneedling safety. Welcome back to our round table on radiofrequency microneedling.