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INTRAcel's FRM Technology Addresses Market Demand

By Kevin A. Wilson, Contributing Editor

Delivering radiofrequency (RF) energy via an array of fractional microneedles, INTRAcel from Jeisys Medical, Inc. (Seoul, Korea) treats all skin types rapidly and effectively with drastically reduced incidence of post-inflammatory hyperpigmentation (PIH). As well, since the depth of penetration is adjustable, this device can be used for a variety of indications.

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"I believe INTRACel represents a new standard for rejuvenation and acne scarring for all skin types, with little downtime."

This technology is known as fractional radiofrequency microneedle (FRM). "Needing only topical anesthesia, with no oozing and very little, if any bleeding, no hematoma or major edema after the procedure, and the 49 needle tip, the entire office visit is very brief compared to many other therapies," said Klaus Fritz, M.D., director of the Dermatology and Laser Centers (Landau, Germany) and lecturer at Universität Bern (Switzerland) and Universität Osnabrück (Germany). "This makes FRM with INTRACel a true lunchtime procedure, a distinct advantage when dealing with busy professionals, which aesthetic practitioners often do."



Klaus Fritz, M.D.
Dermatology and Laser Centers of Landau and Kandel
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Dr. Fritz explained that with INTRACel, RF energy creates controlled heat injury at each treatment site, denaturing collagen without noticeable damage to the epidermis. "The needles are even smaller in diameter than the 32 gauge needle used for neurotoxin injection, so the impact to the epidermis is negligible at most," he said. "Although the U.S. Food & Drug Administration (FDA) would technically refer to this as an invasive procedure, it is largely non-invasive because barrier function is virtually preserved. Fractional ablative lasers, for example, must damage the skin and it takes a few days for barrier repair to take place, depending on the size of the ablation area."



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According to R. Stephen Mulholland, M.D., F.R.C.S.(C), medical director of SpaMedica Cosmetic Surgery and Laser Skin Care Spa (Toronto, Ontario, Canada), INTRACel is indicated for general tightening, textural improvement, enlarged pores, acne scars and wrinkles.

"When you depress the foot pedal, needles project from the handpiece through the dermal-epidermal junction into the dermis at a preselected depth (0.5 mm, 0.8 mm, 1.5 mm or 2.0 mm as determined by the user). Each needle in the 7 x 7 array has an insulated coating so RF energy can be delivered in a discreet packet for selective deposition exactly where you want the thermal experience to occur. The only stimulation of the epidermis occurs during needle insertion, which is extremely minimal. This is responsible for the reduced potential for PIH."

While the INTRACel device was originally developed to treat acne scars, it may also be successfully used for skin tightening in rejuvenation treatments and for striae on the body, stated dermatologist Marge Uibu, M.D., chief physician at Ihoakatemia (Helsinki, Finland). "I believe INTRACel represents a new standard for rejuvenation and acne scarring for all skin types, with little downtime," she said. "One great advantage with INTRACel is that the result is very natural looking. You see great improvement but the skin does not look treated. I have used INTRACel to treat the full face, neck and décolleté in one session because of the adjustable needle depth and energy level. I have also used it to tighten the skin of the upper arm and elbows and striae on the body."

"Variable needle depth allows you to effectively address specific pathologies targeted for the patient in front of you," explained Dr. Mulholland. "If they have superficial



Chin before Tx



Chin after INTRACel Tx

Photos courtesy of Klaus Fritz, M.D.



Marge Uibu, M.D.
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"While other microneedle RF devices can treat without PIH or burning, and will succeed at tightening, they do not feature adjustable needle depth."



Before Tx



After INTRACel Tx

Photos courtesy of R. Stephen Mulholland, M.D., F.R.C.S.(C)

rhytides, for example, you can choose superficial depth and create superficial thermal injury, but the same patient may also present with deeper lines in the upper lip, which would require deeper deposition of RF energy. You may also sequentially layer individual packets of thermal injury at different depths within the dermis. This ability to create such a wide variety of effective wound patterns gives us a lot of control and handles different pathologies in a single treatment session. When layering passes I usually start deep and move upward, because if you begin superficially and work downward this makes it harder to readily assess deep treatment results."

Strength of the RF emission is adjustable as well, ranging from level 1 through 7. "Differences in skin impedance make it impossible to accurately measure energy delivery, but assuming that impedance is 200 ohms (Ω), level 1 delivers approximately 0.4 J and level 7 is about 2.4 J," said INTRACel pioneer Takashi Takahashi, M.D., director of the Takahashi Clinic (Tokyo, Japan). "While other microneedle RF devices can treat without PIH or burning, and will succeed at tightening, they do not feature adjustable needle depth," he said, "and thus cannot be readily used to treat rosacea, telangiectasia or striae. Also, INTRACel's array of 49 needles makes treatment more rapid than other devices. I can treat the full face within 20 minutes and I always make at least six passes during one session, so this is indeed a rapid treatment."



Takashi Takahashi, M.D.
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Furthermore, INTRACel's needles penetrate for only a fraction of a second, just long enough for energy to be delivered, explained Dr. Fritz. This speeds treatment and reduces damage to the skin. "When the needles are withdrawn, there is no wound because tissue pressure closes it automatically. There may be some irritation, as always when you inject, and if there is minor bleeding you just wipe it away. After about 20 minutes the patient can begin preparing to leave. If a patient had an incidence of herpes infection immediately after treatment, the preserved barrier would inhibit spreading so it is not a big issue. With fractional ablation, this would be a much more serious complication."

When asked about another well known microneedle system, Dr. Mulholland noted, "this other microneedle system is more for the lower face and jaw because each energy pulse lasts four seconds; it's more designed for tightening, not texture and fine lines. INTRACel has a much higher pin density and energy deposition takes place within about 0.2 seconds, which allows you to treat fairly quickly. You must achieve adequate anesthetizing, using topical anesthetic and perhaps combining with local anesthetic in the forehead area, but usually you can get away with performing mild-to-moderate treatments under topical anesthetic alone."

Simple EMLA cream will often suffice for topical anesthesia, stated Dr. Fritz. "At the recent 5 Continents Congress (5CC) in Cannes, France (September 2011), we also discussed a method that I use, which involves INTRACel with zero RF and the lowest depth setting (0.5 mm needle penetration) before application of topical anesthesia, to improve penetration and speed up the effect of topical lidocaine applied afterward; however, there are many effective methods. I also use a Zimmer cooler with the procedure."

Dr. Uibu feels INTRACel is an easy office-based procedure to perform and easy to learn as well. "Downtime is practically non-existent. INTRACel gives such great results, true, natural looking rejuvenation with almost no downtime; just some erythema and

"INTRACel excels at treating acne scars. Acne scars are one of the most difficult things to treat, and successful treatment has a significant impact on a patient's quality-of-life and self-image."

edema resolving within a few days at most. These normal, transient, procedure-related symptoms often resolve much more rapidly, even within 24 hours. The combination of treatment variety, safety and no downtime make INTRACel one of the best devices on the market today."

Yan Trokel, M.D., director of The YAN Center for Corrective and Cosmetic Surgery (New York, New York, U.S.), agreed. "For safe and optimum results, you have to pair the power level and the depth. Essentially, we don't want to go higher than power level 2 at 0.5 mm depth; level 3 at 0.8 mm depth; or level 4 or 5 at 1.5 mm depth or greater. By following these guidelines, we significantly reduce the risk of PIH.

"INTRACel excels at treating acne scars," added Dr. Trokel. "Acne scars are one of the most difficult things to treat, and successful treatment has a significant impact on a patient's quality-of-life and self-image. We start with higher power and deeper penetration. I might go as high as level 5 at the 2.0 mm depth and work my way toward reduced power level and depth on subsequent passes."

Typically, for skin rejuvenation, patients come in for a series of three superficial treatments, performed once monthly. In the initial session, Dr. Trokel starts in the mid-dermis at a depth of 1.5 mm at power level 4. "With each subsequent treatment, I'll back it down one power level and depth setting, so in this case I'd move down to 0.8 mm depth and power level 3, and then to 0.5 mm at power level 2. This results in skin tightening, a decrease in pore size, new collagen formation and a radiant glow."

As with many devices the full result will mature over the course of several months. "The healing cycle that delivers the final outcome is well known and cannot be rushed," Dr. Trokel explained. "Visible results begin to show as early as one week after the initial treatment. Results will continue improving with time. A month after the first treatment, patients begin to appreciate a more dramatic result, for example acne scars will be less visible, skin will be tighter and pore size diminished. For severe cases, I will most likely perform another treatment, but in most cases a single treatment does the job."

According to Dr. Trokel, the number of passes depends on the indication being treated. "For lighter rejuvenation I'll normally do two or three passes, starting at power level 3, depth of 0.8 mm, with 50% overlap. For the next pass or two I'll reduce power and depth to power level 2 and depth level of 0.5 mm. For deep scars and moderate lifting, I start at a power level of 5, depth of 2.0 mm, with 50% overlap. I'll reduce the settings to power level 3, depth of 0.8 mm for the next pass and do the final pass at power level 2, depth level of 0.5 mm. The entire treatment takes maybe 20 minutes. Most cases require a topical anesthetic but for greater depth and higher power settings, Dr. Trokel uses facial nerve blocks to anesthetize the facial region.

When treating the perioral area, the versatility of INTRACel becomes more apparent, Dr. Mulholland noted. "For someone with fine lines of the lower lip, I find it helpful to do a deeper pass at 0.8 mm first and come back with a very superficial pass for additional tightening and skin enhancement. When it comes to the upper lip I'll sometimes do three layers, going as deep as 2.0 mm. Multiple passes at different layers will treat thicker rhytides and lines quite well. With something like a laser you have to overheat the superficial layer in order to deposit therapeutic levels of energy deep enough, with greater risk



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Before Tx



One month after INTRACel Tx

Photos courtesy of Marge Uibu, M.D.

"For more than 20 years we've known that RF was highly effective for non-surgical tightening, but we could not properly deliver the energy, and now we have an excellent mode of delivery."

of permanent perioral pigmentation problems, and certainly a longer downtime since the epidermal-hypodermal junction is more extensively injured," he elaborated.

Although INTRAcel therapy is very safe and effective, expectations management is still essential to success, noted Ching-I Victoria Lu, M.D., a dermatologist at I-Skin Laser and Skin Care Center in Taiwan. "For more than 20 years we've known that RF was highly effective for non-surgical tightening, but we could not properly deliver the energy," she said, "and now we have an excellent mode of delivery. However, this is not surgery and we do not cut sagging skin or alter facial structure. We can only produce more collagen and elastin. The ideal patient has mild-to-moderate skin laxity including periorbital fine lines and slightly loose upper eyelids, mild-to-moderate eye bags and nasolabial or macrolabial folds. Perhaps the jawline is beginning to lose definition due to moderate submental laxity. The patient should not have much lipoatrophy. For an acne scar patient, some laxity is also ideal."



Ching-I Victoria Lu, M.D.
Dermatologist
I-Skin Laser and Skin Care Center
Taiwan

Along these lines, Dr. Takahashi cautioned that certain patients are not candidates for INTRAcel FRM therapy. "RF current should never be used on patients with metals in their body, such as a pacemaker. In addition, as with many therapies, INTRAcel is not recommended for use on pregnant women."

While INTRAcel doesn't replace laser treatments, it's a nice complement, according to Dr. Mulholland, and it is certainly a substitute for patients who are prone to inflammatory reactions or pigmentation problems. "Lasers create a strong injury to the dermal-epidermal junction and many patients need that, but it is not tolerable for darker skinned patients. Also, if you want to go deeper with lasers, you must ramp up the energy and bore through the epidermis. Either way there's more downtime, and a lot of patients don't want that."

While the science behind INTRAcel technology remains in its infancy, Un-Cheol Yeo, M.D., Ph.D., a dermatologist at the S & U Skin Clinic (Seoul, Korea) presented the results of an early study at the 12th symposium of the Association of Korean Dermatologists in 2009 (Seoul, Korea), which histologically examined the healing response after FRM with INTRAcel.

Thermal damage was localized and limited to the reticular dermis at each micro-injection site with no observed thermal damage to the epidermis or upper dermis, other than what resulted from the micro-injection itself. Collagen denaturation was confirmed by staining, with neocollagenesis shown at ten weeks post treatment. RT-PCR testing at 70 days revealed the presence of factors suggesting an upregulated healing response. Higher energy treatment was associated with increases in neocollagenesis and fibroblast production.

After Dr. Yeo's initial investigation, a clinical trial by Dr. Takahashi enrolled 60 subjects (men and women, mean age 41.2 ± 23.5 years) presenting with scarring, facial laxity or enlarged pores. Patients received a single full-face treatment with INTRAcel. Transient edema and erythema was experienced by all patients and resolved within two days. Slightly more than 10% experienced dry skin resolving within two weeks. At the three month follow-up no complications or severe adverse events were observed. Patient satisfaction was reported as greater than 80%, with self-assessment showing moderate to significant improvements for all three treated indications.



Before Tx



One month after INTRAcel Tx

Photos courtesy of Ching-I Victoria Lu, M.D.

"Basically, by sparing thermal injury to the epidermis, this versatile technology allows you to treat a lot of different patients. That makes all the difference and almost makes this technology indispensable."

A new study by Dr. Takahashi, which is currently being prepared for publication, involved the use of INTRACel for acne scars. After enrolling 100 patients presenting with mild-to-severe acne scarring, single FRM treatments were performed, with management for one week and follow-up at one month post treatment. Preliminary results revealed high patient satisfaction and significant improvement of acne scarring, enlarged pores and chronic redness (such as slight rosacea). Average improvement of acne scarring exceeded 90%. Transient minor complications such as edema and erythema resolved rapidly. "I am confident that further analysis and clinical experience will not only allow us to refine our technique, but improve outcomes and reveal protocols for new indications as well," Dr. Takahashi reported.

Although not yet readily available in the U.S., microneedle treatment has been in practice globally for more than a decade, according to Michael H. Gold, M.D., director of Gold Skin Care Center and Tennessee Clinical Research Center (Nashville, Tennessee, U.S.). "We've seen worldwide use of the rolling microneedle therapies for some time, and outside the U.S. there are a few competitors to INTRACel. Jeisys is a leader in the field of microneedle technology. As a technological approach to RF delivery, microneedling is a great way to enhance skin volume through neocollagenesis, and treat scars and wrinkles aggressively with minimal downtime and high satisfaction."

Globally, the appeal of a device such as INTRACel is great, said Dr. Fritz. "In Europe we have a variety of skin types, but in areas where darker skin is prevalent, such as Asia, this device will be more important because of the strong concern about PIH. In Europe and the U.S., where populations are more diverse, the market will still be there."

"Basically, by sparing thermal injury to the epidermis, this versatile technology allows you to treat a lot of different patients," said Dr. Mulholland. "That makes all the difference and almost makes this technology indispensable, because many patients aren't going to benefit from disruption to the dermal-epidermal junction. The minimal mechanical disruption with INTRACel is a far cry from that, and with the adjustability of needle depth and RF energy deposition, you have the flexibility to treat based on what the patient presents with rather than the limitations of the technology you happen to own."

All New INTRACel Features Feedback Mechanisms

While PIH is virtually irrelevant with a device such as INTRACel, skin impedance influences therapeutic RF delivery greatly. A distinctly different device recently unveiled by Jeisys at 5CC, currently called the 'All New INTRACel,' includes an impedance monitoring function to provide feedback and maximize therapeutic energy output. "The ability to monitor impedance measurements helps the All New INTRACel more effectively deliver energy," explained Dr. Gold, "because each patient's skin is different and there are also differences in impedance within tissue itself."

Dr. Yeo added, "Like the original INTRACel, the All New INTRACel is also very effective for both selective thermal treatment of the dermis and avoiding thermal injury to the epidermis, with benefits such as reduced downtime and avoidance of PIH."

Additionally, the All New INTRACel is a three-fold treatment platform that includes deep monopolar RF (FRM monopolar) and superficial RF rejuvenation (SRR), non-invasive components, as well as the FRM bi-polar mode from the original INTRACel. Capable of delivering each distinct therapy individually, as well as in combination is a unique advantage making this new device more versatile.



42 year old male before Tx



42 year old male one month after INTRACel Tx

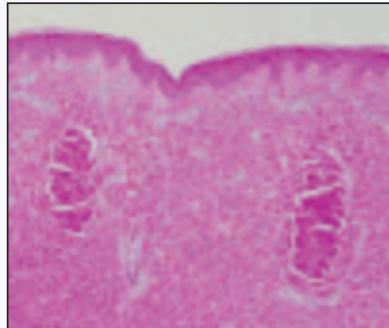
Photos courtesy of Takashi Takahashi, M.D.



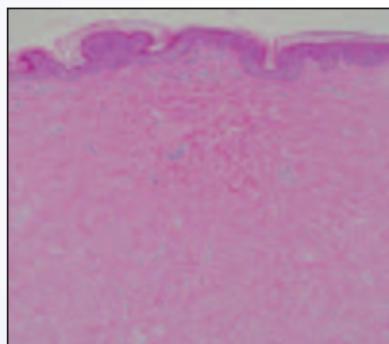
Before Tx



After Superficial RF Rejuvenation Tx



Bi-polar biopsy test



Monopolar biopsy test

Invasive RF
dermal tipSublative RF
epidermal tip

"No single treatment is going to apply to all patients, so in the foreseeable future a versatile platform device like the All New INTRAcel is going to have a significant impact on what we do in aesthetic medicine."

This combination treatment is called Three Layer Therapy (TLT) and treats all skin layers from the surface and epidermis down to the dermis. As Dr. Yeo explained, "The FRM bi-polar mode creates coagulative necrosis zones in the dermis, and is good for scar treatment. Energy from FRM monopolar mode is of slightly lower intensity and is, by nature, delivered differently. This mode is ideal for deeper treatment so it's good for lifting and tightening. SRR is more ideal for superficial indications such as fine wrinkles and skin tone improvement through soft peeling of the stratum corneum and pellicle. In particular, the combination of those three treatments provides very good results and patients are quite satisfied."



Un-Cheol Yeo, M.D., Ph.D.
S & U Skin Clinic
Seoul, Korea

In practice, the first treatment with the All New INTRAcel is usually performed using the FRM monopolar mode at a depth of 2.0 mm to stimulate neocollagenesis and create a lifting effect. SRR mode is used as a second step for soft peeling the epidermis approximately three weeks after the first treatment. About

one week later, FRM monopolar or bi-polar is used with a needle depth of 0.8 mm in the mid-dermis. "According to biopsy and other tests, lower energy delivery, such as that seen with FRM monopolar mode, causes thickening of collagen fibers, whereas higher energies upregulate fibroblast production in FRM bi-polar mode," said Dr. Yeo.

Historically, Dr. Fritz explained, monopolar RF was stronger and went deeper than bi-polar RF, but was not easy to control and therapeutic effect was not easy to reproduce. "That was the trade-off; controlled deposition of energy using bi-polar RF didn't go deep enough, but stronger monopolar RF energy would dissipate and cause heat and pain where we didn't want it. With the All New INTRAcel, deep delivery of bi-polar RF is still effective and controlled, but limited to the area between the needles, with some effect in nearby tissue. The microneedle delivery of monopolar RF bypasses the dermal-epidermal junction and goes deeper than the bi-polar, to 3 or 4 mm. Adding the superficial RF increases versatility."

In Dr. Gold's opinion, the impedance monitoring function is essential when using the FRM monopolar mode. "The feedback mechanism automatically calculates the output value and applies it to each shot. The difference in delivery between monopolar RF and bi-polar RF make this necessary to maximize safe and effective intradermal monopolar RF delivery," he advised.



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"No single treatment is going to apply to all patients," Dr. Gold continued, "so in the foreseeable future a versatile platform device like the All New INTRAcel is going to have a significant impact on what we do in aesthetic medicine." He added that neither the original INTRAcel nor the All New INTRAcel is currently FDA cleared for use in the U.S. "As safe as these devices are, any device of this kind requires proper training and knowledgeable, cautious use by skilled professionals."

Dr. Trokel feels that "the All New INTRAcel has a lot of potential. I'm excited at the prospect of evaluating this device over the coming months. It delivers the kind of energy you want, where you want it, at the level you want, safely. That's why it works." ■