



## Experts Explore Vast Potential of Microwave Technology

With the creation of new markets comes new opportunities. One novel approach in aesthetic medicine uses proven microwave technology to eliminate axillary sweat and odor glands to reduce both hyperhidrosis and osmidrosis. This modality also provides true color-blind axillary hair removal, but more importantly, researchers say these uses only scratch the surface of the full potential of this technology.

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# Miramar Labs Creates New Markets with miraWave Therapy

By Kevin A. Wilson, Contributing Editor

With the introduction of its emergent flagship microwave technology, miraWave®, Miramar Labs, Inc. (Santa Clara, Calif.) is poised for unprecedented growth. The company's first device to utilize this modality is miraDry®, for permanent non-invasive axillary sweat, hair and odor reduction. Steve Kim, chief technology officer and founder of Miramar Labs shared, "In early 2007 we saw underarm sweat as a large, untapped global market, filled with opportunity. Controlling underarm sweat and odor is a multibillion dollar industry worldwide, but at that time therapies mostly consisted of underarm topical deodorants and antiperspirants. On the other end of the spectrum was surgery. That's a wide gulf between treatment offerings so we decided to actively pursue development of a non-invasive, energy-based modality to destroy sweat and odor glands permanently." With that vision, miraDry was created.

"We also wanted it to be affordable for patients and financially attractive to physicians, which meant strong profitability per procedure providing a high ROI and manageable costs overall. We're proud we were able to achieve those goals, Mr. Kim continued. "Physicians who obtain a miraDry device only need to perform about one treatment per week to pay for it within a year, and many do so more rapidly than that. Procedure profitability is further improved because the device is easy and safe enough for trained ancillary staff to operate."

The miraDry device was cleared by the FDA in 2011, followed by CE mark in 2013. In 2015, the miraDry device received FDA clearance for an expanded indication to include permanent hair removal for hair of all colors, leading the company to introduce a new procedure to the marketplace, miraSmooth®. Powered from the same device, this treatment allows practices to target the large hair removal audience with a unique product offering.

With continued development, miraWave technology has the potential to non-invasively treat hair, sweat and odor on other body regions. Additionally, physicians believe it may have more applications, suggesting a bright future for Miramar and early adopters of this powerful microwave technology.

## Microwave Technology in Medical Aesthetics

Microwave energy was selected because it was proven, well understood and seemingly ideal. "Heat is the primary means by which controlled injury is induced non-invasively in aesthetic medicine," Mr. Kim explained. "We thoroughly investigated a variety of issues such as what tissue structures we wanted to affect, what we needed to avoid, and how to overcome whatever obstacles were presented. We worked with scientists that possessed expertise in all of the energy modalities (laser, RF, microwave, ultrasound) available to us to determine the best solution. Microwave energy was the clear winner because it is the only technology that automatically targets the interface between skin and fat where sweat and odor glands reside."

The difference between the way microwaves affect adipose tissue versus skin tissue causes the emitted energy to be reflected back toward the skin, colliding with oncoming energy waves to create peaks, which focus the effect



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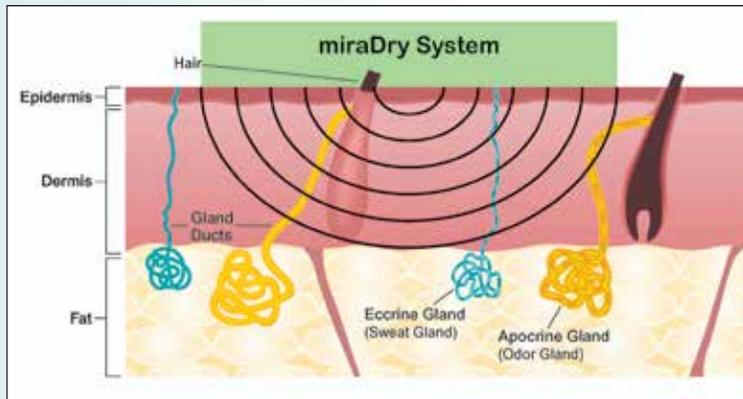
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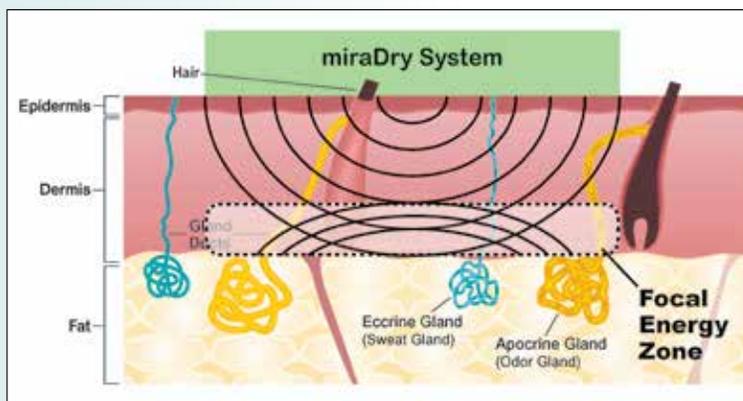
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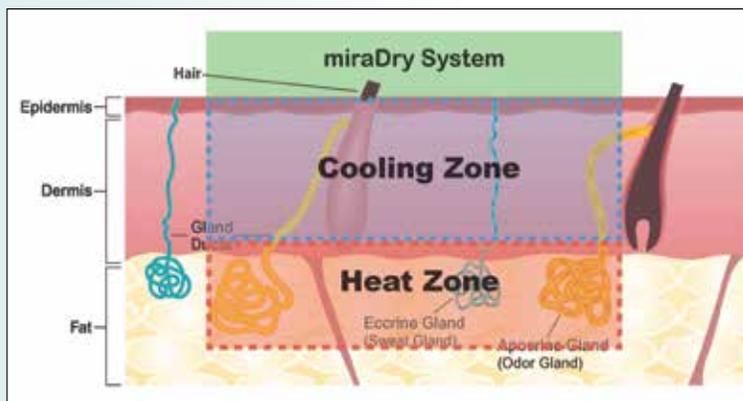
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miraDry delivers focused microwave energy to the dermal-fat interface region where sweat glands reside.



Energy becomes concentrated along the dermal-fat interface and creates a focal energy zone.



Continuous hydroceramic cooling system keeps the heat zone at the level of sweat glands.  
Photos courtesy of Miramar Labs, Inc.

appropriately. Hydroceramic contact cooling prevents thermal injury to the epidermis and the majority of the dermis, while allowing heat injury to be created in the shallow subcutaneous tissue. "For our sweat application, the goal was to raise the temperature of target cells to above 60° C, which causes instant cell death, without damaging the surface skin," Mr. Kim noted. "What we came up with is a device that will automatically focus the energy to that area, regardless of skin thickness, causing thermal necrosis of the apocrine and eccrine glands. This significantly reduces sweat and odor in patients leading to a very high satisfaction rate. We later found that we had permanent axillary hair removal as well."

Selectivity is a key contributor to the success of any medical treatment, and Miramar's miraWave therapy is no exception, according to dermatologist Christine Dierickx, M.D., medical director of the Laser and Skin Center of Boom (Boom, Belgium). "In hindsight it seems obvious to use microwave energy in this way. Microwave energy agitates water molecules, which creates heat. It will be more specific to water, and sweat glands contain more water than neighboring structures in the skin, so this modality will selectively heat sweat glands."

Depth of energy deposition is also important, according to Jeremy A. Brauer, M.D. director of clinical research at the Laser & Skin Surgery Center of New York (New York, N.Y.). "The miraDry device is optimized to deliver microwave energy directly to the depth where sweat glands and hair follicles reside."

According to Dr. Brauer the device is easy to use. "First you have to choose a template which best fits the patient's underarm area, and then use it to mark the area with temporary tattoos," he said. "These guide the operator. Once in place, we administer tumescent anesthesia, and can then safely begin the procedure, following the markings carefully to assure complete treatment based on whichever protocol we need – miraDry for sweat and odor or miraSmooth for hair removal." The result is permanent reduction in axillary sweat and odor, and/or permanent hair reduction regardless of hair color and skin type, most often in a single application.

For Louis P. Bucky, M.D., a plastic surgeon in Philadelphia, Penn., miraDry opens a new avenue of collaboration between plastic surgeons and their patients. "When people think 'plastic surgery' they think of appearance. This

technology provides us with another pathway to address not only the patient's appearance, but their self-image and well-being," he said. "Traditionally we do this through surgical correction, but these concerns can be strengthened by non-invasive solutions for sweat and odor, especially in that segment of the population affected by related disorders. It makes even more sense because some aspects of miraDry treatment, such as the use of tumescent anesthesia, are already familiar to plastic surgeons. Most notably, we are in the lifestyle treatment field; people want to not only look better, but feel better, and this is a prime example of how we can help them."

Joshua Weitz, M.D., clinical director at Dermatology Associates (Rochester, N.Y.) likened sweat and odor reduction to acne treatment wherein the lines between aesthetic and medical can be blurry except in the most severe cases. "Some people may have an obvious medical need, but for others it's a personal choice. And people are naïve not only to this technology, but to other therapeutic options available such as neurotoxins, oral preparations or prescription topicals."

For Dr. Weitz, miraDry has been a home run for sweat and odor reduction. "We chose this technology for our office because it works so well, and we thought it had a lot of potential. Our experience has proven its value because it is so effective, and for patients it has had a real impact on quality of life. We're excited to see how this develops as more people become aware of the technology. Sweat and odor play a powerful role in social interaction, so reduction of these issues is important."

This growing global popularity of miraDry is also the result of a refinement in treatment protocols. "The safety and efficacy of miraDry have been there from the start, but the anesthesia protocol initially involved local infiltration using multiple needle sticks," Dr. Brauer explained. "Originally this technology was designed as a two-treatment protocol, so patients would get treated and then come back three months later for the second session. This worked, but introduction of anesthetic was complicated and time consuming, and therefore less than ideal. Additionally, we found that with higher energy levels we could get down to one treatment most of the time."

Now, with the Optimized Treatment Protocol (OTP) using high volume anesthesia (HVA), the treatment is even more tolerable. "The use of tumescent anesthesia has made a big difference; fewer needle sticks seems to cut down on the bruising we used to see. Making any treatment as close to painless and hassle free as possible is always a main goal for obvious reasons, and patients definitely prefer a single application over multiple sessions," Dr. Brauer added.

"The addition of HVA provides another measure of safety as well," Dr. Dierickx advised. "By using a tumescent method we inflate the area with a relatively large volume of solution, thereby creating a barrier between the skin we wish to treat aggressively and the sensitive underlying tissue, especially the lymph nodes and nerves that innervate the arm to provide sensation and motor function. This gives me added confidence that the chance of potentially injuring underlying tissue structures is minimized, thereby avoiding a temporary alteration of sensation, strength and motor function in the arm and hand. Up to now, using this protocol, every one of my patients has been satisfied with the procedure and the results."

Cynthia Diehl, M.D., owner of Diehl Plastic Surgery in Raleigh, N.C., described the cross section of patients that may comprise a typical market for miraDry. "You



miraDry treatment  
Photo courtesy of Miramar Labs, Inc.

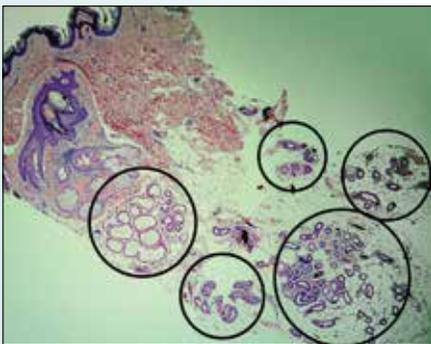


Starch iodine test in axillary region three years after miraDry Tx. Dark areas show where patient is still sweating. Patient is not sweating in treated area.  
Photo courtesy of Larry Fan, M.D.

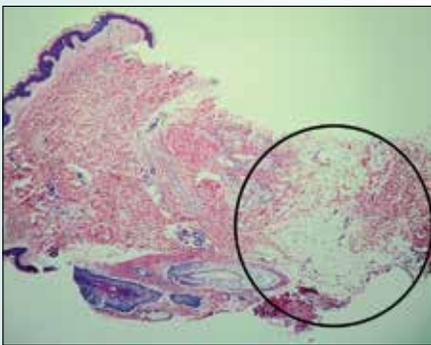
start with the ones who have real, obvious hyperhidrosis, who desperately need this sort of therapy to dramatically improve their quality of life. These people long to feel normal. Then we have professionals who are giving presentations and find underarm sweat distracting, or who are in close proximity to individuals such as patients all day and want to feel less self-conscious. We have people who just get sick of stained shirts or don't want to use aluminum-based or other chemical underarm products. Once this technology becomes further established I think even more people will become interested. Many of our patients come from word-of-mouth referrals."

While there is some recovery involved, patients may return to most normal activities within 24 hours, Dr. Diehl stated. "We're injecting 100 cc to 120 cc of tumescent fluid into each armpit so they feel a puffiness. As that subsides it reveals the inflammatory process, which is part of what demonstrates that the treatment worked; what patients call the lumps and bumps – somewhat tender like bruises. There is temporary reduction of sensation. Discomfort is manageable with OTC analgesia and ice. It may take four to six weeks for the lumps and bumps to fully resolve and a few months for sensation to normalize, but people don't seem to mind because it's only a single treatment, works so well, and offers permanent results."

Nevertheless, expectations management might be the easiest part of the miraDry experience, Dr. Diehl shared. "The success and satisfaction rate with this technology is remarkably high," she said. "With other aesthetic devices we have to overcome media and advertising hype so patients have a fair idea of what they can realistically expect. We simply do not have that problem with miraDry."



Human histology illustrating normal sweat glands before Tx



Absence of sweat glands six months after miraDry Tx  
Photos courtesy of Nobuharu Kushikata, M.D.

## A New Innovation in Permanent Hair Removal

Branded as miraSmooth, permanent, color-blind axillary hair removal with the miraDry device is in some ways a breed apart from laser or light-based hair removal, explained Dr. Brauer. With the latter technologies clinicians are depending on the principle of selective photothermolysis, which has been harnessed for numerous aesthetic and medical treatments over the past few decades. "To be effective you need a target chromophore, in this case pigment in the hair," he began. "Skin pigmentation may be a competing chromophore, especially in the case of darker skin types, so more careful deposition of energy is required and we often use a long pulsed 1064 nm Nd:YAG for this group of patients."

"When treating with microwave energy, we're relying on non-invasive deposition of energy affecting water molecules selectively so we're destroying hair follicles in any growth phase and hair or skin color are non-factors. Additionally, we usually need only one treatment," Dr. Brauer continued. "The downside is that the subcutaneous nodules and cords – the discomfort associated with this therapy – are a somewhat more involved recovery. Also, total time in office is often longer per session. Therefore, it might be looked at as a trade-off between lasers and light providing shorter, but more sessions for some skin and hair types with less than complete clearance, versus microwave energy providing permanent and more complete axillary hair removal for virtually anyone in one longer session, with somewhat more discomfort afterward."

"Studies have shown that with laser hair removal, in a single treatment we may see 15% to 20% reduction," Dr. Dierickx reported. "And as hair diameter

and color is reduced over the course of several applications it becomes more difficult to treat. It is because of these and other factors that a patient may need up to ten sessions to achieve long-term hair reduction. Microwave-based hair removal has been shown to provide up to 70% reduction with a single treatment so apparently it can treat these follicles more thoroughly. In one or two sessions with microwave technology we achieve better results for any hair color or type than we can expect with laser- or light-based modalities in five to ten applications.”



Female patient, age 39 four weeks after miraDry Tx of left underarm. Photo was taken immediately after a 30 minute stationary bike workout in heated room.  
Photo courtesy of Mirimar Labs

According to Dr. Dierickx, in a study first presented by Dr. Brauer at the 2015 annual conference of the *American Society for Laser Medicine & Surgery* in Kissimmee, Fla., patients were recruited specifically for hair removal, rather than sweat and odor reduction, to investigate the effects of treatment on the axillary hairs. “In this study, typical treatment settings were applied: a single pass with energy levels between 3 and 4, using the original intradermal anesthesia protocol,” Dr. Dierickx noted. “They found that hair reduction seemed dependent on the energy level chosen, meaning that more energy meant increased hair reduction.” Dr. Dierickx performed a second study using the HVA protocol at the highest energy setting (5). “We also decided to do a double pass rather than a single pass because pictures from the first study showed that small linear areas were skipped when treating. Since it is difficult to place a pulse exactly next to the previous pulse and one may miss hair follicles, our second pass was made perpendicular to the first pass.” To control any potential increase in incidence of side effects, a split axilla protocol was used in which one side was treated with a single pass, and the other with the double pass pattern. “What we found was excellent clearance of hair with no difference in side effects. Patients reported no more pain, swelling or inconvenience with the double pass side and at nine months out we’ve seen no regrowth of hair in the double pass side. And we included patients with very fine, light hair, which would have been poor candidates for laser or light-based hair reduction.”

### Expanding an Emerging Market

According to Sheila Nazarian, M.D., founder of Nazarian Plastic Surgery in Beverly Hills, Calif., there are financial advantages for physicians bringing this device into their office. “In addition to my medical training I was an economics major in college and hold a Master’s Degree in medical management, because I’ve always been interested in business. I see the challenge with this technology as being one of building awareness,” she explained. “This means marketing, which many of my colleagues are reluctant to do, but is essential to the success of this therapy. Efficacy is not the problem with these procedures, it is awareness.”



Underarm hair before Tx



One year after one miraSmooth Tx  
Photos courtesy of Mirimar Labs



Underarm hair before Tx



One year after miraSmooth Tx  
Photos courtesy of Miramar Labs

Dr. Diehl agreed. "There are people looking for sweat reduction out there doing two neurotoxin treatments a year who could pay the same amount for one session with miraDry, and get permanent results. They just need to know that there is a great alternative. Strangely enough we're getting more referrals than you might expect because the results are so good, especially with the HVA protocol where we can use the highest energy levels in a single application."

Dr. Nazarian described a culture among plastic surgeons in which marketing is seen as less than classy. "It's almost as if having to market yourself suggests that you're not legitimately trained or unethical in some way," she revealed. "The rationale to overcoming this is simple. Who better than us to offer these treatments to patients? If we experts don't get the word out, others will, and they may be less qualified. We need to lead the way into this massive market and preserve its integrity if we're going to fully develop it. We must change with the times."

"In our practice we have signs up everywhere telling patients that miraDry can stop underarm sweat and odor, because we want to raise awareness," said Dr. Bucky. "In my experience people aren't really aware that this exists, but once they become aware they consider it, especially if they feel they have problems with sweat and odor. People are generally quiet about these sorts of issues because they are embarrassed or they don't think there's much that can be done, but our early adopter patients are ecstatic about the outcomes because in many cases they've been life changing. And results are permanent, unlike injectable neurotoxin, which works well, but requires maintenance at least every six months. If we were marketing this more heavily I think we'd be seeing a lot more patients asking about miraDry. The staff also appreciates the procedure because it's easy to perform and patients love the results."

For Dr. Nazarian the results of marketing have been visible. "We have done billboards and while the ROI is not as high as social media, it has been great for branding. Billboards have historically had a stigma, but we see this turning around. Sweat and odor problems are more embarrassing to a lot of people than visible aging, and easier to avoid discussing, so we needed to get the word out. Patients come from all walks of life, beyond actors and models, we've seen so many different types of professionals, from business people sick of sweat-soaked armpits during presentations and the stains that come with them, to people like dental hygienists or physicians who hover over patients and are conscious of their potential sweat and odor. These people won't know miraDry is available unless we tell them." Then there are the medical cases. "We had one girl who went through several changes of clothing daily in school because of sweating, going so far as to wear maxi pads under her arms. So this is a life changing and gratifying procedure that affects quality of life."

Return on investment is also excellent, Dr. Nazarian reported. "It doesn't take many treatments to pay off your cost outlay, and given the sky high rates of success and satisfaction we're seeing, if you put the word out there you can quickly move into profitability," she stated. "I paid off my device in four months of treatments, it's been that successful. If you are aggressive at all you should see profitability on the horizon."

## The Future of miraWave Technology

Having delivered the device as well as a valid and attractive business model, Mr. Kim suggested that more applications are being aggressively researched. "There are places all over the body where sweat, odor and hair might be successfully addressed using our technology," he suggested. "All we need to do is what we did before, study the anatomy, overcome obstacles, and do a better job than what's out there."

"I'm excited to be involved with the miraWave technology because of its potential in the global marketplace," said Rob Ellis, vice president of global marketing at Miramar. "In all my years in this industry I've seen few devices with miraWave's ability to shake up the industry. Not only does this modality do something well like nobody else, featuring technology no one else in aesthetic medicine is using, but it has already seen the hair removal indication added, which is further testament to what this technology may be able to do. We've envisioned a device that's easily expandable and have designed the current platform with that in mind. In the future we expect you'll be able to program in the indication and body area you want to treat, and the platform will modify the settings accordingly."

Dr. Dierickx is a believer in the potential of microwave technology for other uses in aesthetic medicine. "What we have is another mode of delivering heat energy, which is the backbone of many successful therapies we rely on today. The company is examining ways in which we may harness the technology differently to treat other indications and body areas. By manipulating the cooling protocol, for example, we may be able to change the depth at which we deliver energy to target sebaceous glands and treat acne, or target the skin to induce neocollagenesis. This is in addition to finding new ways to treat sweat glands and hair follicles on other body regions."

Patients in Dr. Nazarian's practice are eagerly awaiting further developments to the miraWave platform. "After seeing what miraDry did for them, many patients ask about using it for other body areas such as hand or foot sweat, or removal of hair all over the body," she stated. "Miramar will need to refine protocols and build new, larger microwave applicators, among other things, to make it work but when they do, patients are ready for it."

"As time goes by and awareness grows, I would wager that demand for miraDry will explode," Dr. Weitz speculated. "At our practice we're focused mostly on non-invasive modalities, maybe 70% medical, 30% aesthetic and miraDry has the highest percentage of satisfaction of anything we've ever offered. We perform a lot of treatments and our success rate to date is 99.4%, and there is no arguing against that." ■

