

TriPollar Third-Generation RF Technology Debuts

Originating as monopolar technology – which was considered unpredictable – and advancing to more focused bi-polar delivery, radiofrequency (RF) modalities have continued to evolve over the years in response to consumer demand for safe, effective, non-invasive treatments. Today, a new device, using three to six emitters with overlapping negative energy fields, creates exponentially higher power density for focused delivery to improve efficacy and eliminate discomfort. Moreover, High Definition Thermal Imaging, combined with mobile display capabilities, provides real time temperature feedback and visual mapping for more consistent outcomes.

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**Aesthetic Market Analysis
Non-Invasive Body Shaping
Scar Reduction Advancements**

September/October 2012
Circulation 30,000
www.miinews.com

TriPollar RF Offers Virtually Painless Face and Body Treatment

By Kevin A. Wilson, Contributing Editor

Marketed exclusively in the U.S. by Lumiere Medical (Rockwall, Texas), TriPollar technology from Pollogen, Ltd. (Tel Aviv, Israel) efficiently delivers RF energy using three to six electrodes, attaining results with almost no discomfort. This device, known as the Apollo system, is gentle enough for treating both the face and body, and its thermal imaging system aids in the achievement and maintenance of optimal therapeutic tissue temperature. Treatment is simple enough that it may be effectively employed by ancillary personnel.

TriPollar RF therapy with the Apollo system is a lunchtime procedure, stated Ronald L. Moy, M.D., a board certified dermatologist and dermatologic surgeon in Beverly Hills, Calif. "While it's important to remember that four to six sessions at weekly intervals are required, individual sessions usually take less than one hour, and there is no downtime or side effects to manage. Patients report seeing immediate results after the first application, and final outcomes are long lasting with minimal maintenance sessions. The sensation of treatment has been compared to a hot stone massage, relaxing enough that patients have been known to fall asleep."

Nonetheless, therapy is effective and employs powerful RF energies that have been safely utilized by modern medicine for 75 years. According to Michael H. Gold, M.D., board certified dermatologist, dermatologic surgeon and director of Gold Skin Care Center and Tennessee Clinical Research Center (Nashville, Tenn.), the aesthetic medical industry has been refining the use of RF for

the past decade. "The mechanism of action involved is well understood – RF energy raises the tissue temperature to create a therapeutic effect. Tissue temperature ranges have been well established. While RF technology is not new in aesthetic medicine, with TriPollar the mode of delivery is novel and that is what's responsible for the outcomes achieved without discomfort."

Steven D. Shapiro, M.D., a board certified dermatologist and co-director of Gardens Dermatology & Cosmetic Surgery Center (Palm Beach Gardens, Fla.) compares the energy delivery with different generations of RF to the visual effect of dropping stones into a pond: "Think of monopolar as a single, large stone," he began. "The unfocused waves disperse in all directions so it takes a lot of energy to obtain the tissue heating necessary for therapeutic effect at a specific location. With bi-polar it's like using two stones, with the energy more focused between the stones where the waves converge. It takes less energy to get the same result at a specific point. With TriPollar it's like dropping three stones simultaneously. Again, the point of convergence is where the action is, but each of the three electrodes needs to put out much less energy to achieve the same tissue heating in a more focused path. As a result, TriPollar uses significantly less energy than first generation RF technology, making Apollo a much more efficient and painless device."

Mary E. Hurley, M.D., a board certified dermatologist, president and medical director of North Dallas Dermatology Associates (Dallas, Texas), agreed; "What you have with



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Abdomen before Tx

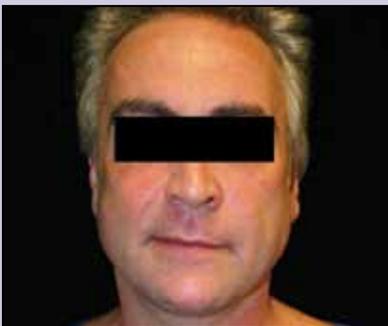


Abdomen after one TriPollar Tx

Photos courtesy of Alex Levenberg, M.D.



Before Tx



After one TriPollar Tx

Photos courtesy of Michael H. Gold, M.D.

this third generation technology is the ability to deliver higher therapeutic energies with lower wattage. In today's market, people are looking toward non-surgical methods to treat the face and body, as seen with the popularity of injectables and skin tightening devices. More than that, they also want results with minimal downtime and discomfort. Any non-invasive treatment that works without pain is going to be valuable."

A key addition to the Apollo is LumiCam, which is a mobile, thermal imaging system that ships with the Apollo device, taking the guesswork out of reaching and maintaining tissue temperature. Utilizing High Definition Thermal Imaging, the LumiCam is FDA approved for the thermal monitoring of skin temperature. Not only does it provide a 20 inch display but the integrated system is mobile as well.

Dr. Moy feels LumiCam is the most advanced diagnostic tool available for RF therapy, representing a great leap forward. "It is well known that the tissue temperature range for maximizing therapeutic effect is somewhat tight, between 40° and 42° C for the face, and between 42° and 44° C for body treatment," said Dr. Moy. "LumiCam uses infrared technology to provide accurate, real-time feedback that is very easy to read and understand. Previous methods of monitoring tissue temperature were effective but less exact because they relied on surface measurements and some mathematical guesswork, and also required temporary cessation of treatment. LumiCam promotes a more fluid, uninterrupted therapy session. The visual confirmation is also entertaining and reassuring for patients, as they

can see for themselves that they're receiving optimal energy delivery." This optimization of energy delivery, coupled with the small footprint of the system and an intuitive graphical user interface, are additional advantages that also make Apollo easy for ancillary staff to use.

Dr. Hurley explained it this way: "The key to the success of TriPollar therapy or any other RF tightening is rapidly achieving the therapeutic tissue temperature window, and then adequately maintaining that, which has always been a challenge. The Apollo system gives us two advantages toward that end, the focused delivery of RF for rapid tissue heating, along with the LumiCam, which gives us the feedback necessary to really hit a home run with regard to tissue temperature."

Since the technology itself is so well established, physicians can use it with confidence, Dr. Gold advised. "It isn't enough to say that this device has peer-reviewed literature behind it. Any device manufacturer will say that," he stressed. "What we have here is a class of technology that has been heavily studied, not only for safety and efficacy but for mechanism of action. We understand the way RF causes collagen denaturation but stimulates neocollagenesis, and we're learning how RF affects subcutaneous fat. This has a remarkable safety profile with only transitory adverse events that resolve within hours. Moreover, RF technology is color blind, so skin type does not factor into the treatment algorithm, which is a huge plus in our ethnically diverse population. TriPollar technology has potential for use



Before Tx



After eight TriPollar treatments

Photos courtesy of Steven D. Shapiro, M.D.



Before Tx



After three TriPollar treatments

Photos courtesy of Michael H. Gold, M.D.

with a variety of indications in the future because of the safety and efficacy, as well as lack of pain and downtime associated with the novel RF delivery system."

Dr. Shapiro served as lead author on a two-center clinical trial¹ studying the safety and efficacy of TriPollar in 37 subjects. Patients were treated for facial wrinkling once per week for eight weeks, with three month follow-up. Safety was determined by physician assessment and efficacy was evaluated by two independent physicians using blind grading of photographs. "What we did was have the evaluators grade photographs without knowing which were before or after, allowing us to eliminate that potential bias. We considered improvement of at least one grade on the Fitzpatrick Wrinkle Scale to be a success, and this was seen in 94% of subjects by one reviewer and 97% by the other. No unexpected adverse events were seen and all patients reported satisfaction with treatment," Dr. Shapiro reported. It is also important to note that patients undergoing TriPollar treatment had access to a safety switch; if they became uncomfortable, they could immediately stop treatment with the push of a button. "During the study, nobody stopped treatment," he added.

One key aspect of the study is that results were much more evident during in-person evaluation of the patient, Dr. Shapiro added. "When you consider that from photos one reviewer scored an average improvement of 1.21 points and the other averaged 1.29, both of which are statistically significant results, you have to factor in how

much better the real results are versus a photo. It's quite remarkable. I can say it's more of a two-point improvement in person."

In November 2011 the Apollo system received FDA clearance for the treatment of facial wrinkle and rhytid reduction. The therapy was also given CE Mark clearance for off-label tightening and cellulite reduction on the body – an indication eagerly being explored in the U.S. Amy Taub, M.D., a board certified dermatologist and founder of the SKINQRI research center (Lincolnshire, Ill.), is an early adopter of TriPollar technology for the body. "The reasons I have come to prefer the Apollo system for body tightening is that we may quickly achieve the optimal therapeutic temperature, yet it is pleasant for the patient to undergo and still extremely effective for a non-invasive technology," she said. "Also, the device is ergonomically designed so there is so much less strain on the operator. Some other non-invasive therapies are demanding enough that your staff shouldn't do more than one or two sessions per day, but with Apollo they can perform treatment throughout the workday. Multiple sessions are required for the full result, but we, and our patients, are happy with the outcomes and the device is very easy-to-use. It's a win-win."

Dr. Taub also elaborated on the three handpieces included with the device. "You have the TriPollar facial applicator; a smaller one for delicate tissue such as in the periorcular area; and the large body applicator, which actually has two sets of three electrodes for a larger treatment area," she pointed out.



Thigh before Tx



Thigh six months after TriPollar treatments

Photos courtesy of Dvora Ancona, M.D.

"So what we have is not only the ability to treat more rapidly, but the capability to customize spot sizes with the attached handpieces so no changes need to occur during the treatment session."

In Dr. Taub's experience, treating the thigh, which is an especially challenging area, is made easier with Apollo. "People want tightening of the thigh area but there are multiple physiological issues there. Between cellulite, laxity and irregular shape you're looking at pockets of excess fat. With the Apollo system we see circumference reductions and overall improvement as well as skin tightening." Though the overall outcome using TriPollar technology is reportedly impressive, "the ease and speed of treatment are an especially big positive for body applications," she added. "Treating from the knee to the buttocks, front and back, is a very time consuming undertaking. Being quicker than other devices and having no associated disposables, Apollo can also be priced more affordably, which patients find very attractive."

Dr. Gold praised the technology's ability to treat the neck. "A saggy neck is a visual cue for aging so correction is important for the overall rejuvenation look, but challenging to treat with most technologies. With the Apollo system you can get great results on the neck without pain, which is just not possible with most devices. In the end you get overall facial rejuvenation with a better global improvement because the jawline is more attractively defined. Even an older patient not wanting surgery, who has realistic expectations and just wants to

look better, can enjoy results with TriPollar technology."

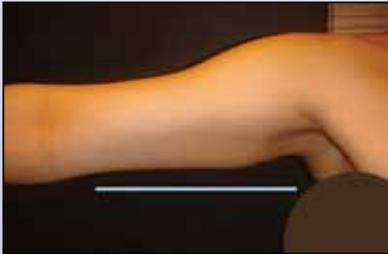
The same goes for other traditionally difficult-to-treat areas, Dr. Gold continued. "Thin skinned areas such as the chest and backs of the hands are also sensitive places people often want to see treated that present a challenge because of the nature of the area. TriPollar RF is painless so patients can stave off invasive procedures for a while by choosing Apollo."

Another advantage with Apollo is that it lends itself well to use with adjunctive therapies, Dr. Hurley noted. "For a real 'wow' factor we like to combine it with other treatments. On the body we may use TriPollar therapy with cryolipolysis for more complete slimming and tightening. Or on the face, we'll often combine Apollo with injectables, depending on the patient's goals. We may combine neurotoxin and TriPollar in the periorcular area for additional tightening. We can do this in the lower face, but with a volumizing dermal filler. One could also use fractional laser therapy for additional surface skin tightening or to deal with texture or enlarged pores." When using dermal fillers with Apollo, Dr. Hurley recommends waiting at least three weeks before applying RF over newly injected filler material, especially in the case of hyaluronic acid products.

"My success rate with Apollo has been very high," said Dr. Gold. "I don't use therapies unless they give me good outcomes and satisfaction in the high 80% or 90% range. With TriPollar 90% of patients are extremely satisfied, which is remarkable when you consider we're talking about a pain-free, non-invasive



Arm before Tx



Arm after three TriPollar treatments

Photos courtesy of Lumiere Medical



Back before Tx



Back after six TriPollar treatments

Photos courtesy of Lumiere Medical

technology." Results with TriPollar RF therapy last for quite a while as well. "With Apollo the outcomes persist with what I would say is minimal maintenance. This is a facet of the business that's not so well studied. Here we have something that gives the patient a nice outcome, and if they return every six months or so, they can freshen up the look and make it last longer."

As with many therapies before and after photography is an outstanding tool to motivate the patient to return, Dr. Gold emphasized. "You can even stop during treatment and give patients a mirror to highlight the 'wow' factor during that first session, allowing them to contrast the treated and untreated areas themselves. Between that and photography, it's very motivating and will turn a skeptic into a believer very quickly. Believe me, when you have a therapy that feels like a soothing massage, photos can be very helpful to the patient because we tend to equate successful outcomes with pain. People want effective but painless treatments, yet they'll be concerned if it's too painless. The LumiCam goes a long way toward helping patients through any issues as well, because it gives them a visual to focus on."

Dr. Moy identified two ideal patient groups, each a growing segment of the aesthetic medicine market. "Many new patients do not wish to undertake the risk of surgery, no matter how manageable the risk may be," he explained. "As cosmetic medicine has progressed and become more accessible to people, we have seen younger and younger entry into the treatment continuum.

This means that a device like the Apollo system appeals to those who do not yet require surgical correction, who may delay surgery for a while by using such treatments regularly. TriPollar technology is great for patients just beginning to notice fine lines or wanting to tighten up a sagging stomach or arms. It is much easier to manage and maintain a youthful appearance if you begin while you are still fairly young."

"What I don't tell patients about this device," added Dr. Taub, "is how surprisingly good the results can be. As a group we in aesthetic medicine have to under-promise and over-deliver, but I've seen some fairly dramatic results in improvement of the appearance of wrinkles and cellulite, with nice tightening and firming, especially when you consider the non-invasive nature of TriPollar technology. So many people want non-invasive, low-discomfort, no downtime treatment these days, and I don't see that trend fading."

For Dr. Gold it comes back to the science. "RF is a well-researched modality and with TriPollar we have a novel expression of that modality. Wherever I go and lecture, whatever I'm talking about, I always say the same thing: Look at the science behind the device you're investing in. If the science isn't there, buyer beware. In this case it isn't even an issue, which is why I think Apollo will be a real success story." ■

References

1. Shapiro SD, Eros Y, Abrahami Y, Leviav A. Evaluation of safety and efficacy of the TriPollar technology for treatment of wrinkles. *Lasers Surg Med.* 2012 Aug;44(6):453-8.