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A E S T H E I C

Zerona Invents New Body Shaping Model

The search for a shapelier silhouette continues to drive patients to seek aesthetic therapies. Although more than 300,000 liposuction procedures were performed in 2008, according to the American Society of Aesthetic Plastic Surgeons, there still remains an untapped market of potential patients who are not willing to go under the knife to lose inches. Erchonia Medical (McKinney, Tex.) has created a new body contouring device that not only provides a unique approach to non-invasive, localized reshaping, but an unprecedented business model. U.S. distributor, Santa Barbara Medical Innovations (Santa Barbara, Calif.) designed this novel plan in light of the current economy.

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Zerona Combines Innovative Fat Tx and New Business Model

By Kevin A. Wilson, Contributing Editor

Zerona, manufactured by Erchonia and distributed by Santa Barbara Medical Innovations (SBMI), uses a safe 635 nm wavelength device to achieve fat removal and shrink subcutaneous adipocytes, without invasive surgery. Zerona's basic technology has been around for decades with no recorded incidence of side effects, according to experts. Additionally, SBMI's unique business model is a winwin situation, allowing practitioners to obtain this new technology and begin bringing revenue into the practice without a major outlay of funds.

The Zerona system is an evolution of Erchonia's handheld 635 nm LipoLASER device, which is FDA cleared for use during liposuction to liquefy fat, thus facilitating fat extraction and reducing the incidence of post-operative swelling. Reductions in post treatment pain, bruising and recovery time with the LipoLASER device have also been observed.

Thomas W. Barnes, M.D., medical director of the Cosmetic Surgery and Laser Center (Newport Beach, Calif.), has been using low level laser therapy for about eight years as an adjunct to liposuction, and is an early adopter of Zerona therapy. "In a sense Zerona is the ideal aesthetic device," he said. "It is relatively inexpensive to obtain and operate, and it's easy-to-use. Non-invasive treatment is comfortable, doesn't take much time and is completely safe. Treatment is effective for fat reduction and makes patients happy."



Thomas W. Barnes, M.D. Medical Director Cosmetic Surgery and Laser Center Newport Beach, CA

"The phrase I most often use when describing Zerona is 'game changer,'"

said Frank Ryan, M.D., a plastic surgeon in private practice in Beverly Hills, Calif. "This device is truly amazing and needs to be seen to be believed. It noninvasively treats subcutaneous fat to remove inches from the waist, hips and thighs, as well as other places. This is an aesthetic practitioner's dream."



Frank Ryan, M.D. Plastic Surgeon Beverly Hills, CA

SBMI's innovative business model is also causing industry buzz due to the Zero Up-Front Equipment Investment Model, in which physicians do not buy the Zerona device outright. Practitioners have a device brought to their office and pay for blocks of treatment, with comfortable profit margins. "This business model is part of what makes this novel modality so attractive," noted Dr. Barnes. "In this economy, the easy integration of a safe, effective, exciting therapy that's inexpensive for both patients and practitioners can save your practice. You don't need to lay out a pile of cash in order to begin offering Zerona treatments to patients." This model, Dr. Barnes explained, makes the device ideal for those looking to start a new practice or others in need of a financial boost to help ride out the economic storm.

Zerona is a stand-up platform that delivers a low level wavelength of 635 nm, which research has shown to produce the best effect. Instead of a single emitter, as with the LipoLASER, Zerona emits laser light from five points: one from a center emitter and the others from four flexible arms which can move in multiple directions. Although not telescopic, each arm can be locked into the best position for treatment as determined by the operator.



Before Tx



After Zerona treatments Photos courtesy of Alan Bauman, M.D.



Zerona Tx

"There is a systemic cascade effect that creates transitory pores in fat cells that are not directly under the laser light."



Before Tx



After Zerona treatments Photos courtesy of Alan Bauman, M.D.

Traditionally, according to Dr. Barnes, the center emitter is placed about eight inches above a central location such as the umbilical area. Each of the four flexible arms are then positioned strategically, two on each side, at the hip/thigh and waist/love handle areas, also about eight inches away from the skin. "Treatment of the hips, thighs and waist areas are easily the most requested," said Dr. Barnes. When the device is activated, the patented delivery system emits a scanning laser light from each arm that rotates on a central axis. At eight inches from the skin, the beam is 12 inches wide and covers a large area as it rotates and scans according to a pre-programmed pattern designed to promote the consistent, equal distribution of energy to the designated treatment areas.

Although the mechanism of action is not entirely understood, Zerona treatment is believed to trigger the photochemical up-regulation of natural processes at the cellular level. "Specifically, Zerona seems to stimulate the fat cells to create transitory pores in the cell membrane, causing fat to be expressed into the interstitial space," reported Dr. Barnes. "Within a few minutes of applying external low level laser therapy – in this case using a 635 nm wavelength at low power – it starts a domino effect. Fat flows out from millions of adipocytes. Electron microscopy and multiple studies have revealed that fat leaves the adipocytes without injuring them, causing them to shrivel up."

Once the fat leaves, it can be taken away from the interstitium by the lymphatic system. "One key to successful Zerona therapy is re-treatment within 72 hours," noted Alan Bauman, M.D., medical director of Bauman Medical Group (Boca Raton, Fla.). "If you don't repeat treatment within that time



Alan Bauman, M.D. Medical Director Bauman Medical Group Boca Raton, FL

frame, adipocytes will take up the fat again. Re-treatment keeps the fat in the interstitium long enough for the lymphatic system to remove it for proper metabolism by the liver."

A double-blind clinical trial pitted the Zerona device against a sham laser device designed to serve as a control. After undergoing the requisite number of treatments, Zerona subjects saw an average loss of about 3.5 inches from the waist, hips and thighs. Patients who were treated with the sham laser saw a loss of about a half inch. "By adhering to a course of six treatments scheduled every other day for two weeks, we consistently find that people lose inches," Dr. Barnes stated. "We measure before and after the six treatment program, and commonly see losses of three to six inches from the waist and hip areas, sometimes as much as nine inches."

Areas outside the treatment zones also seem to respond somewhat to Zerona therapy. According to Dr. Barnes this suggests a positive systemic effect that, by his estimation, supports the theory of how Zerona melts inches. "Interestingly when people undergo the Zerona therapy program, we see slimming of areas not being treated directly. There is a systemic cascade effect that creates transitory pores in fat cells that are not directly under the laser light. I regularly observe and document reductions in other parts of the body."

"Patients who received Zerona therapy to their waist, hips and thighs have also seen reductions of up to one inch from the largest point of each upper arm, and anywhere from

one-quarter to one-half inch reduction from the circumference of the knee, presumably the inner knee where most of the fat is," Dr. Barnes reported. "This secondary achievement undoubtedly promotes the visual effect of a reduced, more aesthetically pleasing silhouette by adding a level of consistency to overall reduction that you won't get with another treatment, such as liposuction. It is very exciting to know that this safe, effective treatment has a systemic effect that works all over the body." Spot reduction is also possible, according to Dr. Barnes, by focusing all of the emitters over a single area.

When describing Zerona therapy, Dr. Barnes compares it to facial rejuvenation with ablative CO₂ laser therapy. "The CO₂ laser does not penetrate very deeply," he explained. "It may vaporize the uppermost layers of skin so healthier, younger looking skin can grow, but it also deposits thermal energy below the skin's surface during treatment and up-regulates natural neocollagenesis. In that way Zerona is similar," he continued.

"The energy applied to the skin during low level laser therapy is approximately 15 milliWatts, which is a thousand-fold less energy than what is applied during most traditional laserbased aesthetic therapies. Therefore, laser penetration doesn't create the visible, well-documented results that we consistently obtain with Zerona. It just has to start the cascade, up-regulate the body's natural processes, then the body does the rest."

One obvious concern is unhealthy, elevated lipid levels in the bloodstream, but Dr. Barnes insisted this isn't an issue. "There is no problematic change in the lipid panel. In fact, it appears that high-density lipoprotein (HDL) levels actually increase and levels of low-density lipoprotein (LDL) drop in patients who undergo therapy with Zerona."

Additionally, a major benefit of Zerona therapy is the matter of fewer downsides compared to other fat reduction therapies. "Non-invasive treatment is important of course; however pain medication, topical anesthesia, injection of a tumescent medium – all of which add significant time and some discomfort to the treatment experience – are not needed. Post-operative pain medication is also unnecessary," Dr. Ryan conveyed.

Patients spend relatively little time in treatment compared to other aesthetic therapies. Patients come to the office at the appointed time, check in and are taken to the Zerona room. Photographs and measurements are taken at the initial visit. After the operator sets up the machine, the patient sits under the rotating, scanning laser lights for about 20 minutes each, front and back. Then they go home and repeat the process a few days later until the course of treatment is finished. "There has been absolutely no instance, not one, of any damage or complications whatsoever with this device," added Dr. Barnes.

After treatment, it is recommended that patients make certain lifestyle changes, such as taking supplemental niacin and drinking eight glasses of water each day, which helps maintain and possibly even accelerate the slimming effect and enhance the end result. Adding daily 30 minute walks is also recommended. "We believe these lifestyle changes are essential for promoting lymphatic drainage," said Dr. Bauman.

"I also counsel patients to make other small changes such as not eating late at night, and decreasing their intake of fat and refined carbohydrates," added "High-density lipoprotein (HDL) levels actually increase and levels of low-density lipoprotein (LDL) drop in patients who undergo therapy with Zerona."



Before Tx



After Zerona treatments Photos courtesy of Alan Bauman, M.D.

"My ideal patient is about 20 to 40 pounds overweight, maybe a little more, which is slim enough so that the effects of Zerona treatment translate into visible changes in the silhouette."



Before Tx



After Zerona Treatments Photos courtesy of Victoria Smithers, M.D.

Dr. Barnes. "Inevitably patients ask, 'Wouldn't I lose those same inches if I just implemented these lifestyle changes for two weeks?' In a three center, blinded study, Zerona patients achieved a significant loss of inches while making no lifestyle changes at all. Therefore, the answer is a definite no. We suggest these lifestyle improvements to maximize and maintain results."

Another issue is weight loss. Traditionally it is believed that if you remove so many inches, then a significant drop in weight should be observed as well. This is not necessarily true according to the experts. "In order to lose this many inches in specific areas of the body through traditional diet and exercise, you have to lose a lot of fat throughout, not just subsurface fatty deposits but visceral fat as well, Dr. Bauman explained. "We don't know for sure if the Zerona effect does anything for visceral fat, but removing fat from localized areas near the surface, even throughout the body, won't necessarily result in significant weight loss." Ádditionally, body weight consists of much more than fat, it includes muscle and bone as well as water and other constituents. "That said, many of our patients do experience weight loss, but like liposuction, Zerona isn't a weight loss therapy and should not be looked at that way."

This is where management of patient expectations comes into play. "I've seen results with every patient, but unless I carefully manage expectations some people may be disappointed," noted Dr. Ryan. "We've seen anywhere from 0.5 inches to 3.5 inches off a single body part if treated every other day for two weeks. A patient with realistic expectations will probably be satisfied with the results."

Dr. Barnes believes that Zerona therapy is a tremendous motivator for those

who want to lose pounds. "Maintaining motivation is a problem when trying to lose weight," he said. "Zerona helps motivate. You get this almost instant result, and we only ask patients to make minimal lifestyle changes to maintain and maximize results. People stay excited and motivated. Then, several months later, patients can undergo more Zerona treatments and further solidify their commitment. Nothing motivates like results."

Obese patients may also lose inches, and they are certainly not immune to the fat reduction effects of Zerona's 635 nm laser light. Although therapy is safe and effective for everyone, Dr. Barnes does not think extremely heavy patients are the best candidates for Zerona. "My ideal patient is about 20 to 40 pounds overweight, maybe a little more, which is slim enough so that the effects of Zerona treatment translate into visible changes in the silhouette. This therapy has been evaluated in patients with a body mass index (BMI) higher than 30, and I'm hearing that they get results. However, the effect is less noticeable in a larger silhouette. It's important for this segment of the population to be under the strict guidance of their primary care physician and others to help them manage their weight, since it is a serious health concern.

In terms of improved health, research has shown a statistical correlation between waist size and heart disease risk. "Increases in waist size have been shown to elevate the risk for heart disease, both in the obese and people of normal weight," said Dr. Barnes. "Distribution of excess weight is a factor, and we think Zerona may help alleviate this risk."

According to Dr. Barnes, as far as ease of use goes, Zerona is among the simplest. Any of the appropriate



Before Tx



After Zerona treatments Photos courtesy of Victoria Smithers, M.D.



Before Tx



After Zerona treatments Photos courtesy of Alan Bauman, M.D.

ancillary staff can set up and activate this device, according to Dr. Barnes. Zerona is intuitively designed and has a user-friendly touchscreen interface. "You simply set up the device for the patient, choose your settings and begin treatment. Treatment times are already set and the energy is minimal so it's completely safe for the user to leave the room to tend to other tasks. This makes it very labor-efficient." Also, the platform itself is not very large so it is easy to move.

Integrating Zerona into the practice is also a snap. "If you peform liposuction, this can make it easier and help with post-op healing," said Dr. Barnes. "You can use it for patients who had liposuction and want a touch-up. Meanwhile, anyone can safely undergo Zerona treatment as a stand-alone therapy."

The quest for a more aesthetically pleasing silhouette is, without a doubt, a top aesthetic concern in the U.S. "America is an overweight nation, so much so that you don't even need to quote statistics anymore," said Dr. Barnes. "The fact that body contouring brings so many patients through the door is a major advantage for Zerona. Since it is effective, non-invasive and completely safe, it has the potential to appeal to a huge market of individuals who would otherwise never consider aesthetic treatments, let alone something as invasive as liposuction. We're talking millions of people. Rough economy or not, you can't argue with that kind of potential."

Attractive pricing of treatment is a great way to tap into this market. "Let's say you're looking at about \$500 per treatment, which is a realistic amount," said Dr. Barnes. "In the future I could offer a course of six to nine treatments for around \$4,000. Now I offer that for around \$2,500 because it makes Zerona accessible to a much larger market."

"Whether you perform liposuction surgery or not, aesthetic practitioners will find that Zerona treatment creates a new patient base to expose their numerous other treatments to," Dr. Barnes continued. "In that way Zerona is an excellent practice builder. I've had a significant increase in my liposuction business because of Zerona."

As a distributor, SBMI brings a lot to the table, including a reputation for building brands and generating customer excitement on behalf of multi-billion dollar companies. In addition to offering devices on an almost pay-per treatment basis, the company has spent more than seven years collecting basic data about the U.S. population as it pertains to aesthetic treatments, including demographic information, consumer data, marketing data, medical information and physician data. The analysis of this data allows SBMI to give customers an idea of what they can expect in terms of return on their investment.

"SBMI lays it all out for you," Dr. Barnes said. "If you consider a course of six treatments per patient as bringing in 'X' amount of dollars, you need very few patients per month to make decent money, even with a conservative estimate of how many patients you can expect to bring in. All in all, Zerona is a cost-effective way to expand your patient base in this tough economy without overtaxing your staff. For that reason, I like to think of Zerona as a practice rejuvenator."