THE

BTL SUPPLEMENT

BTL Exilis Ultra Combines RF and Ultrasound for Superior Outcomes

By Jeffrey Frentzen, Executive Editor

Increasingly, patients are demanding non-surgical options for body contouring and skin tightening procedures. Body shaping includes a range of procedures that encompass both subtle and profound improvements, such as toning, tightening and smoothing on large and small body areas. New energy-based approaches for these and related procedures, such as cellulite and fat reduction, along with rejuvenation of the face and hands, continue to grow in popularity due to strong consumer interest.





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Jason R. Lupton, M.D. Dermatologic Surgeon San Diego, CA



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Before Tx



After six Exilis Ultra Tone treatments
Photos courtesy of Jason R. Lupton, M.D.

"You can use it on any skin type, and it is relatively painless. There are many devices that are a lot more painful, but there is very little pain or discomfort associated with the BTL Exilis Ultra treatments."

Exemplifying this new approach, the BTL Exilis Ultra[™] from BTL Aesthetics (Framingham, Mass.), employs a breakthrough combination of radiofrequency (RF) and ultrasound in a single aesthetic platform. This next-generation Exilis system can address a variety of cosmetic issues more smoothly and with a combination of energies that help to optimize the patient's experience.

Non-surgical, non-invasive aesthetic procedures and in particular those involving skin tightening are on the rise. According to 2015 statistics published by the *American Society of Aesthetic Plastic Surgeons* (ASAPS), cosmetic procedures have increased by 39% since 2011, with skin tightening treatments posting a significant 58% increase between 2014 and 2015.

In a recent market study, Medical Insight, Inc. (Aliso Viejo, Calif.) noted that the emerging market for energy-based devices and body shaping / skin tightening segments will experience solid annual gains of 6.2% and 13.8%, respectively, as demand for these products results in increased sales. With this in mind, the BTL Exilis Ultra is poised to excel in such an environment as most energy-based devices cannot boast its high level of versatility and cost-effectiveness.

Notably, its built-in, adjustable cooling system can reach optimal therapeutic temperatures faster than would be possible using either modality by itself. In addition, the larger applicator contains a cooling tip, allowing physicians to adjust the level of penetration for enhanced results, as well as provide multipurpose treatments.

With other important features, such as operator ease-of-use and a convenient user interface, the benefits of the BTL Exilis Ultra also extend to a practice's return on investment (ROI) and the fact that the system requires only the most minimal, inexpensive disposables.

RF-based energy has been scientifically verified to improve the appearance of skin laxity and provide overall anti-aging effects by increasing dermal collagen and elastin fibers. In a 2014 study published in the *Journal of Drugs in Dermatology*, an evaluation of the Exilis technology demonstrated a 35% reduction in skin laxity, a 42% reduction in fine lines and wrinkles and a 33% decrease in the appearance of photodamage.

Additionally, the BTL Exilis Ultra is, "Colorblind," expressed Grace S. Liu, M.D., a dermatologist in Newport Beach, Calif. "You can use it on any skin type, and it is relatively painless. There are many devices that are a lot more painful, but there is very little pain or discomfort associated with the BTL Exilis Ultra treatments. It's also very safe because if you are not in contact with the skin then the handpiece will stop delivering energy. There is no need for protective eye wear, either."

As well, the system's heating process is very smooth due to simultaneous exposure to monopolar RF-based energy and high frequency ultrasound.

Diffused ultrasound adds novel energy components to the BTL Exilis Ultra technology, Dr. Liu said. "This causes a vasodilation effect that allows for more transmission and greater conductivity of the heat to the target body area. It increases cell permeability and decreases tissue impedance, which is the resistance to the heat. The

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ultrasound element allows the unit's RF energy to heat the tissue faster, easier and more effectively. At the end of the day, my patients tell me that they do not experience pain and they look and feel better. Therefore, we have been very happy with the device."

This synergistic combination of RF energy and ultrasound — in addition to the adjustable cooling system — allows physicians to perform consistently effective treatments that are specific to various body areas.

For instance, the system's Ultra Tight procedure targets the eyes, neck, face and chest; Ultra Plump takes care of the lips; the Ultra Lift treats buttocks, legs and arms, Ultra Tone works on the core fat areas and the knees; and Ultra Smooth tackles hands and the appearance of cellulite. Even external vaginal rejuvenation is on the menu of therapies, via the Ultra Intimate treatment.

Jason R. Lupton, M.D., a dermatologic surgeon in San Diego, Calif., has performed face and body skin tightening therapies for three years using the BTL Exilis Elite™. "Exilis has been such a popular treatment in my practice that I was an early adopter when the device was recently upgraded to the new Ultra," he stated. "It utilizes both RF energy and non-focused ultrasound to heat skin tissue and deliver energy to tighten skin and reshape the body."

While BTL Exilis Ultra is FDA cleared for the treatment of wrinkles and rhytides, and a reduction in the appearance of cellulite, a 2016 French study of the device demonstrated its efficacy for abdominal circumferential reduction.

Physicians evaluated 22 subjects between 22 and 60 years old with a BMI greater than 25, plus visible fat deposits. All study patients were given four treatments every 7 to 14 days, following the system's standard protocol. In the end, the average circumferential reduction of the abdominal area measured at the umbilicus level was an impressive 4.1 cm (ranging from 3.4 cm to 4.6 cm).

Upon weighing the efficacy shown in this study's results, physicians noted that the simultaneous emission of ultrasound and RF basically delivers a mechanical effect that is more aggressive than RF alone. As reported by Dr. Lupton, "It is this design that allows for the many newer indications. The procedures available with this device have less discomfort and, therefore, more areas can be treated without pain, especially the arms, butt or the abdomen."

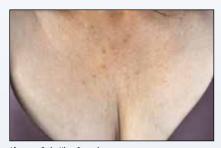
One of the more remarkable aspects of the BTL Exilis Ultra, according to Dr. Liu, "Is that everyone is a candidate. The only people that are not candidates are people with pacemakers, because the RF energy interferes with it, or women that are pregnant and nursing," she noted.

According to Dr. Lupton, "An ideal patient would be in their 30s to 50s, although this ranges actually quite a bit. They are in relatively good shape and do not have excessive tissue laxity that would require surgery."

The BTL Exilis Ultra has allowed Houston, Texas-based dermatologist Suneel Chilukuri, M.D., to apply Ultra Lift therapies to the backs and sides of the arms, as



Before Tx



After two Exilis Ultra Smooth treatments Photos courtesy of Jason R. Lupton, M.D.



Before Tx



After two Exilis Ultra Tight treatments Photos courtesy of Jason R. Lupton, M.D.



Before Tx



After one Exilis Ultra Smooth Tx Photos courtesy of Grace Liu, M.D.



Before Tx



After four Exilis Ultra Lift treatments Photos courtesy of Suneel Chilukuri, M.D.



Before Tx



After one Exilis Ultra Plump Tx Photos courtesy of Grace Liu, M.D.

"It is extremely effective and multipurpose, and it works on far more body areas than any other device in its class. We don't even know yet all the things that can be done with it."

well as the outer and inner thigh all with consistent success. In addition, he has treated the knees using Ultra Tone and performed facial procedures via Ultra Tight and Ultra Plump. "We are getting more rosy colored, fuller lips," he said, referring to the latter procedure.

Ultra Plump can also be a valuable adjunct when employed with dermal filler treatments. "When we do the Ultra treatment in combination with injectables, we find that the dermal fillers and neurotoxins have lasted longer," Dr. Chilukuri pointed out.

"We are even treating the ankles and the calves," Dr. Chilukuri added. "Instead of doing liposculpting and similar procedures, patients that have cankles can receive Exilis Ultra treatments and obtain discernible calves and ankles," he expressed. "The possibilities are only limited by the imagination. At this point, we're looking around to find new places to treat."

In Dr. Chilukuri's experience, the BTL Exilis Ultra is the most powerful device of its kind on the market. "We are heating the skin within one minute or less, so now our treatment time is remarkably decreased, the patient is obtaining more of an effect, and we are seeing immediate tightening. In addition, there is no downtime," he expressed.

According to Christine Lee, M.D., a dermatologic surgeon in Walnut Creek Calif., "It is best to give multiple treatments, but you can see tightening after the first application. I tell patients that they will continue to get better results if they do a series of sessions. And of course they need to do maintenance afterwards."

This system comes with large and small handpieces that can be used on any part of the face and body. "You can even treat ear lobes, the inside of the armpit and elbow, and behind the knees and ankles. Those hard to reach areas," Dr. Lupton emphasized.

The market potential of the BTL Exilis Ultra is huge, noted Dr. Chilukuri. "It is extremely effective and multipurpose, and it works on far more body areas than any other device in its class. We don't even know yet all the things that can be done with it. It comes down to the practitioner being creative and artistic with this device."

Dr. Lupton agreed, suggesting that it would become a workhorse in any practice, "Because of its efficacy, relative ease of use and ability to be performed by qualified staff members."

"It's to the point where the machine is booked out every day," Dr. Liu added. "You have to allot a certain amount of time based on the area being treated. If you're doing a facial area then they have to repeat the treatment in two weeks. For the body areas, we typically perform two to three subsequent sessions. Patients become really excited about their next application because they see the results so quickly. There aren't too many devices on the aesthetic market that people will say they love and need to have. This is one of them."

Patients have seen dramatic facial tightening results via Ultra Tight. "Most people are getting anywhere from 30% to 40% tightening on treatment areas," said Dr. Lee. "The younger they start, the better. Most people who have mild to moderate laxity are going to get, conservatively, up to 40% improvement. But I've seen as high as 70% tightening

"I usually recommend two to four sessions for the neck and face, and four to six applications for any body area. Many of my patients begin treatment on one area of their body and then add others after seeing the changes."

depending on how many sessions they receive. It also depends on how loose the skin is to start, how responsive the patient is, and how many applications they do."

The smaller applicator is appropriate for the eyes, as well, stated Dr. Chilukuri. "We are getting an immediate lift. Other RF devices that work around the eyes might require multiple sessions to achieve a noticeable change, whereas with Ultra Tight we are seeing a good improvement after only a single treatment."

BTL has a protocol for the eyes, Dr. Liu noted. "Just don't point the tip at the globe of the eye," she stated. "The path you take to get to the eyelids is very clear-cut in the videos and training. You do not go on top of the globe itself, though."

Dr. Lupton has used the entire range of BTL Exilis Ultra procedure types on the eyes, lips, neck, jawline, arms, knees, abdomen and buttocks. "We have seen significant changes in all of these areas after a series of treatments. I usually recommend two to four sessions for the neck and face, and four to six applications for any body area," he said. "Many of my patients begin treatment on one area of their body and then add others after seeing the changes."

With hand rejuvenation, the device helps to produce more collagen and elastin for plumping, noted Dr. Chilukuri. "The epidermis and the dermis thicken. I'm also doing combination therapy on patients' hands, using Radiesse for Hands to produce immediate plumping; but, I follow with Ultra treatments, which have the potential for maintaining that rejuvenation effect."

This system can also tackle cellulite via the Ultra Smooth treatment. "For the person that doesn't want an invasive procedure we offer very comfortable results," said Dr. Liu.

Cellulite treatments are a multi-pronged approach, Dr. Chilukuri pointed out. "It is a combination of treating the fibrous bands with some fat in that area, as well as skin laxity. Just using the Exilis Ultra by itself, I see a significant reduction in the appearance of cellulite. When I combine it with the BTL Cellutone™ device, I notice a significant enhancement in regards to skin toning and textural irregularities. It's not a complicated procedure and does not require the depth of experience or skill involved in doing some of the other treatments on the market."

Another popular procedure, Ultra Lift addresses buttock lifts. "We try to achieve contracture by delivering collateral heat all the way down to the muscle," expressed Dr. Chilukuri. We see some tightening effects from that. Using the Exilis Ultra, it's like being an artist. You are able to fine-tune exactly where you want to lift and tighten. There is contracture of the skin, and in addition you are creating new collagen and elastin in that area."

The Ultra Intimate procedure allows practitioners to perform external vaginal rejuvenation. Prompted by robust media and consumer interest, non-surgical vaginal rejuvenation procedures have become more popular in recent years, motivating increasing numbers of practitioners to offer such procedures. According to ASAPS statistics, the number of all feminine rejuvenation procedures performed in the U.S. increased by 64.4% from 2011 to 2012, with a 44% increase during 2013.



Before Tx



After two Exilis Ultra Tight treatments Photos courtesy of Jason R. Lupton, M.D.



Before Tx



After two Exilis Ultra Tight treatments Photos courtesy of Jason R. Lupton, M.D.



Before Tx



After four Exilis Ultra Smooth treatments Photos courtesy of Guernsey Skin and Beauty



Before Tx



After three Exilis Ultra Lift treatments Photos courtesy of BTL Aesthetics

"I would estimate that more than 75% of the patients I see who undergo a BTL Exilis Ultra procedure end up doing at least one other body area because they were pleased with the their initial treatment."

In Dr. Lee's opinion, this is an area of high demand and the Ultra Intimate procedure offers a safe treatment that is very well tolerated by all skin types. "It is non-invasive and not painful," she stated. "Patients receive visible tightening and remodeling, which is highly desirable for women now."

Although several energy-based devices are used internally and can be quite painful, "The Ultra Intimate procedure is purely cosmetic for external treatment only," Dr. Lee added. "It is a great add-on to your list of therapies, maximizing the potential profitability of your device by introducing additional applications. OB/GYNs are busy taking care of the other gynecologic needs of their patients. So for us, it makes perfect sense for cosmetic surgeons and dermatologists to address the aesthetic concerns."

The ideal patient for Ultra Intimate is someone that does not present medical needs that would require a urogynecologist or OB/GYN, Dr. Lee expressed. "Often, the patient is seeking some improvement in the appearance of their external genitalia. Usually, it is from aging, childbirth, or they are starting to get some looseness of the tissue in that area and they would just like to have everything tightened up."

In a clinical study published in *Lasers in Surgery and Medicine*, 17 women aged between 27 and 56 years received four consecutive Exilis treatments at one-week intervals for labia tissue tightening. Post treatment evaluations showed overall improvement in vulvar appearance, with nearly 75% of the women recording moderate to excellent improvement.

As part of the Ultra Intimate procedure, practitioners must be comfortable doing a pelvic and a gynecologic exam," Dr. Lee stated. "You have to be able to determine whether or not the patient has uterine prolapse. If you don't feel comfortable with that you should probably have that patient cleared by a gynecologist before your attempt to do any cosmetic work. Patient satisfaction has been very high because most patients are very grateful to have some improvement in that area."

Patient satisfaction with BTL Exilis Ultra treatments overall has been very high, as well, concurred Dr. Lupton. "I would estimate that more than 75% of the patients I see who undergo a BTL Exilis Ultra procedure end up doing at least one other body area because they were pleased with the their initial treatment."

Moreover, it is not only popular with his patients; from a business and ROI stand-point it is also popular with Dr. Lupton himself. "The efficacy of this new device is evidenced by years of happy customers," he said. "ROI has been higher with the Exilis than any other laser or energy-based device in my practice. In addition, I paid it off within the first six months of owning it. I feel this was extremely fast."

"The ROI on the Ultra is a no brainer," stated Dr. Chilukuri, adding that it has the strong potential to increase the number of patients that qualify for non-invasive body shaping and tightening treatments, as well as enable a much wider portfolio of indications when compared to other energy-based aesthetic systems. "And it provides shorter treatment times," he said.

"Any provider that is interested in facial tightening should look at the Exilis Ultra, because you can treat both face and body, and you will expand the number of indications that you offer your customers much more than ever before."

"We've had the Ultra for around five months and we've already paid it off. Every treatment we do going forward is just a profit center," Dr. Chilukuri added. "My favorite part, just as with the BTL Vanquish ME, is that there are really no consumables to speak of."

Dr. Liu agreed, "This device requires minimal consumables. Just the cost of grounding pads and gel. BTL's grounding pads, by the way, are good quality. The consumable is practically zero cost to my practice. You have to consider the cost of the operator, though."

As an added incentive, BTL has rolled out a generous subscription plan that features a minimal down payment, no credit check and monthly payments of less than one treatment package per month. Also, BTL holds the paper while the plan is in force. Although practices can opt out after the first year, those that stay have the ability to upgrade to future Exilis platforms at no charge.

When it comes to marketing the system, Dr. Chilukuri advocates creating attractive "discounted packages" to offer patients, capitalizing on the ability to successfully roll BTL Exilis Ultra treatments into combinations with other therapies.

"We are bundling it with some of our other devices," he noted. "For instance, say someone has spent \$4,000 on fillers in the face. I will tell that person I can also treat your neck with the Ultra so that it looks as good as your face, and the first treatment is complimentary. When they see the results, they turn around and ask for a full package of three or four Ultra treatments. They are willing to pay for that because they see the immediate results."

Along with providing marketing assistance, BTL's training and after-sale support is also impressive, Dr. Lupton stated. "The device is simple to use but BTL provides significant training. I have been impressed, as well, that training and support have continued on a regular basis, even though I purchased my original device several years ago. They seem to be committed to making sure their systems are being used to their full potential and that all staff members are appropriately trained."

"The Company is very interested in attaining physician or provider feedback for its research and development team," Dr. Liu added. "Whatever we tell them is examined and analyzed quite thoroughly, so they are constantly trying to improve the technology."

The BTL Exilis Ultra's safety profile is very solid, said Dr. Lupton. "We have performed more than a thousand treatments to date and have never had even a single problem. I'm not sure I could say that about any other unit in my office right now. Overall, Exilis has been an incredible addition to my array of lasers and energy devices, and I have 14 devices total right now."

As reported by Dr. Liu, "Any provider that is interested in facial tightening should look at the Exilis Ultra, because you can treat both face and body, and you will expand the number of indications that you offer your customers much more than ever before."



Before Tx



After four Exilis Ultra Intimate treatments Photos courtesy of Ivan Fistonic, M.D., Ph.D.



Before Tx



After four Exilis Ultra Intimate treatments Photos courtesy of Ivan Fistonic, M.D., Ph.D.

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BTL EXILIS ULTRA™

THINK DIFFERENT TREAT DIFFERENT

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The ASDS found skin tightening and wrinkle reduction to be the most popular aesthetic procedures consumers are seeking. Consumers, in general, are extremely bothered by sagging facial skin (67%), excess fat under the chin and neck (67%) and excess weight (88%). What if you can treat these problem areas, as well as provide solutions for 2016's most desired procedures, namely butt lifts, arm lifts and lip enhancements?



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American Society for Dermatologic Surgery (ASDS) 2005 Consumer Survey on Cosmetic Dermatologic Procedures.

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