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Eight Minute Circumferential Vaginal RF Breakthrough Transforms Feminine Rejuvenation

By Kevin A. Wilson, Contributing Editor

“With technologies like ULTRA Femme 360 women finally have a safe, effective treatment that can work wonders comfortably and with no downtime. Of course they’re going to take advantage of this! Women no longer have to accept things the way they are.”



Shelena Lalji, M.D.
OB/GYN
Medical Director
Dr. Shel Wellness & Medical Spa
Houston, TX



Amy S. Carter, D.O.
OB/GYN
Founder
Kansas City Wellness Center and
Medical Spa
Kansas City, MO



Kimberly L. Evans, M.D.
OB/GYN
Kimberly L. Evans, M.D. Obstetrics
Gynecology and Wellness
Houston, TX



**Jason Emer, M.D., F.A.A.D.,
F.A.A.C.S.**
Board Certified Dermatologic Surgeon
Jason Emer, M.D. F.A.A.D., F.A.A.C.S.
Cosmetic Dermatology and Body Contouring
Beverly Hills, CA



M. Christine Lee, M.D.
Dermatologic Surgeon
Director
The Skin and Laser Treatment Institute
Walnut Creek, CA

With best-in-class treatment time at only eight minutes (internally), the ULTRA Femme 360 procedure from BTL Aesthetics (Boston, Mass.) is designed specifically to treat the tissue of women’s intimate anatomy. This revolutionary treatment is safe and effective, as well as comfortable and without downtime. Building on the versatility of the BTL Exilis Ultra 360 platform, this emergent application in the field of feminine health provides added value for adopters. According to physicians, patients experience numerous benefits that positively impact a woman’s physical health and quality of life.

Whether due to aging, menopause, trauma associated with childbirth, or any combination thereof, physical and hormonal changes occur to the female genitalia that have a profound effect on their sexual health and lives. Shelena Lalji, M.D., an OB/GYN and medical director of Dr. Shel Wellness & Medical Spa (Houston, Texas), is lead author of a recent study currently under peer review evaluating ULTRA Femme 360 technology for specific vaginal applications. In her experience, “Internally we see laxity, reduced elasticity and tissue quality, stress urinary incontinence (SUI), reduced secretions and more. This can lead to pain or decreased sensation during intercourse, dryness and irritability, loss of ability to achieve orgasm, and other symptoms of genitourinary syndrome of menopause (GSM). Externally we may see vulvar laxity or even labial hypertrophy due to the loss in elastin and collagen. Excessive redundant tissue can also cause discomfort during sexual activity. Moreover, women may feel uncomfortable or embarrassed by these conditions, leading to reduced self-esteem and other psychological issues regarding sexual health and relationships.”

“In addition to trauma associated with childbirth, women experience loss in elastin and collagen as they age, which go hand-in-hand with reduced estrogen levels,” added Amy S. Carter, D.O., an OB/GYN and founder of the Kansas City Wellness Center and Medical Spa in Kansas City, Mo. “Many changes result from those conditions including reduced lubrication and increased friability of the vaginal wall, leading to greater incidence of irritation and infection, pain during intercourse and/or inhibited sexual function and more.”

Until recently, these women’s health issues have been largely ignored. Culturally, women have been reluctant to discuss these matters, even with their primary care physician. And for generations women have been told that these issues are to be accepted as an inevitable part of life with little chance of real relief. However, the social and cultural climate surrounding the female genitalia is changing, which fosters a more encouraging environment for overall discussion of these indications. “You see this in magazines and on television now more than ever before, which helps us overcome the taboos that have held women back for so long,” said Dr. Lalji.

According to Kimberly L. Evans, M.D., an OB/GYN in Houston, Texas, “Women have traditionally played so many roles, even more so now as we’re expected to have careers in addition to the classic roles. This leaves us less time and energy to take care of ourselves, and thus a greater drive for women to vocalize their needs. As social values change in conjunction with this, more women are talking about these issues and taking control of their quality of life. For a long time we’ve been told that we’re just getting older, that this stuff comes with childbirth, and that’s all there is to it. But this isn’t true anymore. With technologies like ULTRA Femme 360 women finally have a safe, effective treatment that can work wonders comfortably and with no downtime. Of course they’re going to take advantage of this! Women no longer have to accept things the way they are.”

“Heat stimulates neocollagenesis and neoelastinogenesis, which continues over the next three or four months, causing additional tightening and improvement in the elasticity and quality of vaginal wall tissue, plus thickening and plumping of tissue. So you get both an immediate, noticeable effect and a greater long-term effect.”

“So far, the ULTRA Femme 360 has received FDA clearance to provide heating to elevate tissue temperature for selected medical conditions, such as temporary relief of pain, muscle spasms and increase in local blood circulation,” Dr. Lalji pointed out. “This procedure is part of the multi-capability Exilis Ultra 360 platform, which is FDA cleared for wrinkles, rhytides and reduction in the appearance of cellulite.”

The Exilis Ultra 360 device uses monopolar RF and ultrasound to heat and remodel tissue. As shown in a study of the device’s predecessor, treatment significantly reduces skin laxity, wrinkles and the global appearance of photodamage by stimulating neocollagenesis and neoelastinogenesis.¹ Incorporated real-time measurement of local impedance, known as Impedance Intelligence, provides feedback as part of the platform’s Energy Flow Control (EFC™) technology to regulate and maximize therapeutic energy delivery for improved safety and comfort. BTL Aesthetics continues to explore applications and additional clearances for this versatile technology.

Jason Emer, M.D., F.A.A.D., F.A.A.C.S., a board certified dermatologic surgeon in Beverly Hills, Calif., says a course of three weekly treatments is recommended, but patients often report feeling differences after the first session. “Ultimately ULTRA Femme 360 treatment is just deep dermal heating using RF, which as a community we understand very well because it has been thoroughly studied,” he expressed. “Internally we have the full circumference RF heating, which provides a thorough and rapid procedure. External treatment uses a different applicator that is more precise and suited for the labia majora, introitus and perineum.”

With some other devices, users treat different sections of the vaginal wall independently, often with the handpiece in motion to prevent unwanted excess heat buildup. However, “with ULTRA Femme 360 we not only treat more thoroughly, but the movement of the applicator is performed slowly and deliberately, which is easier and more comfortable to perform and undergo,” Dr. Emer continued.

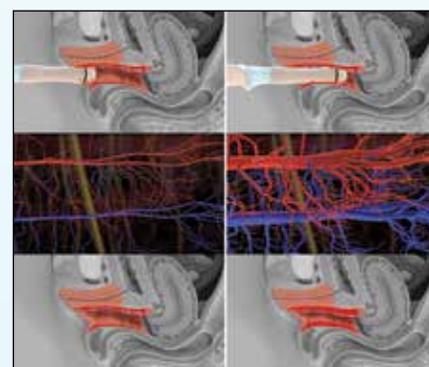
Safety, efficacy and vaginal tissue heating was tested via a numerical model, an agarose vaginal phantom model that simulates dielectric properties of human tissue, and in-house clinical tests. In all three models therapeutic temperatures were maintained over 40° C. Simple-to-perform internal applications take no more than eight minutes – less than half the time noted with some competing RF devices – with an overall session time of approximately 20 minutes when adding an external treatment. The device is very easy to use, allowing delegation to ancillary staff, thus decreasing cost of treatment and increasing profits.

M. Christine Lee, M.D., a dermatologic surgeon and director of The Skin and Laser Treatment Institute in Walnut Creek, Calif., is another pioneer of vaginal rejuvenation technologies. She began specializing in obstetrics/gynecology before switching to dermatology. Her background put her in a unique position to aid in the development in these kinds of technologies and she has been working with several over the last few years, including research with ULTRA Femme 360. “Tissue of the vaginal wall is well suited to treatment in this manner,” she indicated. “The tissue is more hydrated, and there isn’t a thick integument such as with the skin (which has the epidermis), so you get a quicker, more efficient transmission of heat, especially with lasers because you don’t have to deal with the epidermis. RF energy will disperse and deposit heat deeply within the vaginal mucosa, so you see almost immediate contraction and tightening. This heat stimulates neocollagenesis and neoelastinogenesis, which continues



ULTRA Femme 360 internal and external applicator tips

ULTRA Femme 360 Mechanism of Action



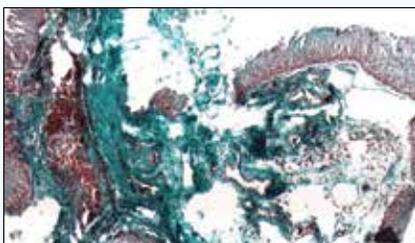
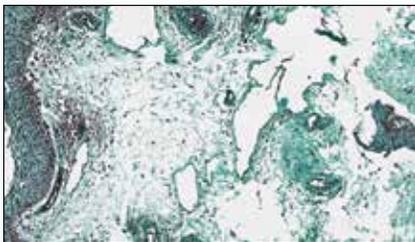
Before Tx

After Tx

During ULTRA Femme 360 treatment therapeutic temperature (between 40° and 43° C) is maintained for 8 minutes. Perfusion in the tissue is significantly increased.

Photos courtesy of BTL Aesthetics

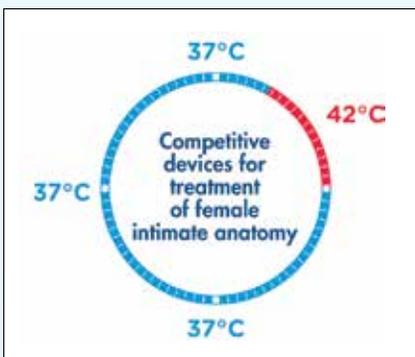
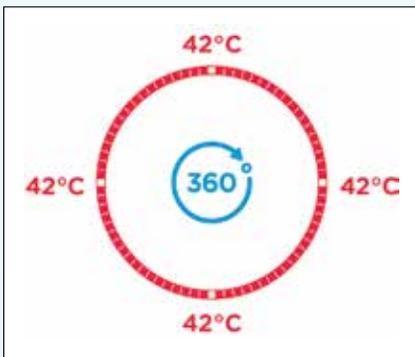
Preliminary Feasibility Study Results



Histology shows an increase in elastin fibers from 10% before Tx (top) to 41% after three ULTRA Femme 360 treatments (bottom). A staining method was used to color the elastin and fiber calculations were examined in a defined area.

Photos courtesy of BTL Aesthetics

Ultimate 360° RF Technology



360° volumetric heating provides faster, safer and more comfortable treatment of women's intimate anatomy.

Photos courtesy of BTL Aesthetics

“Overall outcomes are impressive. There’s improved blood flow and increased sensitivity. The psychological effect is significant.”

over the next three or four months, causing additional tightening and improvement in the elasticity and quality of vaginal wall tissue, plus thickening and plumping of tissue. So you get both an immediate, noticeable effect and a greater long-term effect which manifests over a period of several months, as we’ve seen for decades with energy-based skin tightening and rejuvenation in aesthetic medicine.”

“Vaginal tissue is very vascular, has a lot of collagen, and is very elastic,” Dr. Evans further explained. “It’s built to take a lot of punishment when you think about it, and it’s designed to rebound from that punishment. It also heals very quickly, so this tissue is very amenable to treatment.”

Improved blood flow seen with ULTRA Femme 360 treatments is important to the female genitalia because it enhances oxygenation, brings nourishment and moisture to tissue, and facilitates normal neurotransmission, according to Dr. Carter. “Blood flow also plays a role during sexual activity. As with men who depend on blood flow for erectile function, the tissue of the vagina and clitoris become engorged as well, which is an important part of normal sexual function. Improved blood flow seen with these types of therapies helps to maintain and restore sexual function.”

According to Dr. Lee, one reason RF is more suitable than laser technologies is that it is non-invasive; the invasive nature of ablative laser treatment means elevated risk of infection. The internal applicator design ensures full circumference contact with tissue of the vaginal wall, providing homogeneous distribution of heat throughout tissue. “The circumferential delivery system of RF available with the ULTRA Femme 360 is one of the most thorough methods I’ve seen so far, very fast and efficient, which is why it treats so much more rapidly than other systems.”

“Another advantage is that virtually any woman can undergo treatment regardless of skin color or other factors,” Dr. Evans added. “My patient population, so far, has included women from their 20s through to their 60s. Most are great candidates unless there’s an obvious condition such as extreme obesity affecting the external genitalia, extreme age, menstruation or pregnancy, or presence of a pacemaker. Even women who can’t undergo other forms of treatment due to previous chemotherapy for breast cancer, for example, can see results with ULTRA Femme 360. The effect it can have is so powerful. External genitalia appear younger and more attractive and women who couldn’t enjoy sex feel 20 years younger. These things dramatically improve self-esteem and quality of life.”

Internal therapy with the ULTRA Femme 360 requires a single-use applicator tip that directs the energy toward the entire circumference of the vaginal wall simultaneously. The tip comes in two sizes (24 and 30 mm diameter) ensuring complete contact with the vaginal wall for a thorough treatment of the lamina propria in only eight minutes. Another tip is designed to treat the external genitalia. Both tips utilize an inexpensive grounding pad and are disposable for safety and efficacy purposes. “Therapy is attractively easy and safe enough for trained staff members to perform,” noted Dr. Evans.

The effect of treatment on the vulva and labia majora tissues is profound as well, Dr. Emer stated. “Overall outcomes are impressive with visible improvement in wrinkled structures. There’s improved blood flow and increased sensitivity. The psychological effect is significant. Some women are embarrassed by the appearance of their vulva and when this is improved, they feel better about themselves and more interested in sexual activity.”

“This is a very simple procedure for the practitioner with little to no chance for any user error due to the full-circumference emission of radiofrequency energy, which does not require us to turn or twist the probe or make repeated side-to-side motions. This eliminates inconsistency.”

Dr. Lalji reiterated that the procedure is simple and non-threatening. “We treat internally using the 30 mm and 24 mm internal tips. For tissue redundancy, as well as aesthetic improvement, we perform an external application using the external tip. In either case the patient lies on the table with their legs in the stirrups, with the grounding pad placed on them, and we perform the treatment. The patient feels the insertion of the probe, then a comfortable warmth as we carefully and deliberately introduce and withdraw the probe from the apex to the hymenal ring at the introitus.”

This process is repeated over a period of about eight minutes. “This is a very simple procedure for the practitioner with little to no chance for any user error due to the full-circumference emission of radiofrequency energy, which does not require us to turn or twist the probe or make repeated side-to-side motions. This eliminates inconsistency due to differences between operators, regardless of experience,” Dr. Lalji continued. “Having so little chance of error makes it ideal for delegation to mid-level staff, freeing up my more valuable time.”

“With the external vulvar applicator we’re treating the labia majora, perineum and introitus for patients with hypertrophy or who just don’t like the external appearance, whether they’ve lost elasticity or collagen due to aging or menopause, or have recently had children,” Dr. Lalji added.

The advent of energy based treatments such as the ULTRA Femme 360 fills a wide gap between surgical intervention and less reliable or desirable methods such as creams, lubricants and Kegel exercises. “Externally, the only alternative was labiaplasty, a surgical procedure that many patients simply would not choose due to the downtime involved,” Dr. Lalji noted. “The ULTRA Femme 360 gives us a powerful alternative for treating the internal and external female genitalia. From my clinical experience the therapy is safe, effective, comfortable and convenient for the patient, and outcomes lead to very high levels of patient satisfaction.”

BTL Aesthetics is hard at work investigating and developing the technology, regularly adding new applications to build on the versatility of these treatments as well as its platforms. As previously mentioned, Dr. Lalji is one of the authors of a study (currently under peer review) evaluating the safety and efficacy of RF heating with the ULTRA Femme 360 for the treatment of vulvovaginal laxity and SUI. Study results show that the procedures were well tolerated by all subjects with no incidence of adverse events. During the follow-up, 89% of subjects ‘agreed’ or ‘strongly agreed’ that their SUI condition improved, and 93% ‘agreed’ or ‘strongly agreed’ that gratification during intercourse improved. None of the subjects reported dissatisfaction with treatment.

Based on these findings and patient demand, physicians agree that the market for this kind of therapy is massive as all women will eventually experience menopause, along with other aging-related feminine health issues to a greater or lesser degree, depending on the individual. Women who bear children universally experience their own suite of associated changes as well.

“Just about any woman who has been through childbirth will benefit from the procedure, and at least 80% of women experience uncomfortable symptoms of GSM in their lifetime,” stated Dr. Lee. “The market is huge, so this is a godsend because it is a safe, comfortable, no downtime procedure and very effective. The rise of these



Before Tx

After four ULTRA Femme 360 treatments
Photos courtesy of Shelena Lalji, M.D.

Before Tx

After three ULTRA Femme 360 treatments
Photos courtesy of BTL Aesthetics

“The rise of these types of treatments is truly revolutionary in women’s health. Women have been told for ages that this is just a part of life, but in reality we have options available that are life changing.”



Before Tx



After two ULTRA Femme 360 treatments
Photos courtesy of Kimberly L. Evans, M.D.



Before Tx



After four ULTRA Femme 360 treatments
Photos courtesy of Shelena Lalji, M.D.

types of treatments is truly revolutionary in women’s health. Women have been told for ages that this is just a part of life, but in reality we have options available that are life changing.” In short, virtually every woman will at one time or another be a candidate for this potentially life changing, comfortable, non-invasive therapy.

“I see two groups of patients and we market differently to each,” explained Dr. Carter. “We have those with experience in the aesthetic market, who’ll have much greater savvy and understanding of the whole picture, and much less resistance to (or even greater interest in) trying something new. To them it’s just another therapy option, and they’re familiar with the concept of maintenance treatments and paying out of pocket. On the other side you have traditional OB/GYN patients whose concerns are initially medical. They are used to co-pays and insurance, and may be more hesitant to seriously consider something so novel, especially if they have to pay for it themselves. The ULTRA Femme 360 is ideal for either group because it is safe, comfortable and effective, so it’s easier to justify. And once a patient has undergone even one session they’re likely to want a full course of treatment. Overall, greater awareness will be what drives the conversation. The market is growing dramatically and I’m sure this will continue.”

“Whether patients come into an aesthetic office looking for cosmetic improvement, or an OB/GYN office looking to treat a medical condition, the line is blurred,” Dr. Emer advised. “Plastic surgeons and dermatologists are considered ‘core’ physicians in aesthetic medicine, but when it comes to female genitalia, OB/GYNs are the ‘core’ experts. Regardless, in my experience patients are made comfortable by their trust in the physician expert, be they an aesthetic practitioner or an OB/GYN. Therefore, we approach patients similarly, with expertise and compassion. These people are looking to us for professional help and putting themselves in our hands, so if we can establish that trust, we will succeed.”

“Since these treatments are very successful and give high patient satisfaction, everybody wins,” Dr. Emer continued. “And it is not just about a simple one-and-done approach, there’s always a treatment plan involving additional maintenance over time, which we in aesthetic medicine have a lot of experience with. We don’t have much trouble making women feel comfortable and informed because we have well-trained staff and protocols designed to achieve this.”

Dr. Lalji feels the market might be segregated into three specific categories: younger women after childbirth, somewhat older women who may be experiencing changes due to aging, and women in their 50s and older who’ve been through menopause. “With the recent mothers, immediately after childbirth you have loosening of the vaginal wall. It feels much different; women don’t feel like themselves. They may feel self-conscious about it or their partners may notice reduced sexual sensation. Women in this segment just want to return things to the way they were,” she explained.

“Slightly older women in their 40s are experiencing hormonal fluctuations, tissue quality is degrading as the body’s ability to maintain collagen and elastin becomes compromised, libido and sexual satisfaction are declining along with sexual sensation, and they just don’t feel like they used to,” said Dr. Lalji. “Post-menopausal women are going through the same things to a greater degree, plus thinning of the vaginal mucosa, dryness, painful intercourse and hypertrophy. These women want to remain sexually active and just continue to enjoy life, but it’s a vicious cycle. Each roadblock

“Millions of women have suffered in silence, and they don’t have to anymore. They need to be empowered to share how they feel, and they need to know that they have advocates who can help find solutions.”

to sexual satisfaction leads to reduced libido and self-esteem, which further erodes sexual desire. This may create problems in their intimate relationship, which negatively impacts sexual desire even more.”

Given the potential market, affordability will be a key differentiator. As such, the manageability of treatment costs with ULTRA Femme 360, as with other BTL procedures, is an advantage. “All we need is the grounding pad, disposable applicator tip and ultrasonic gel. This significantly affects marketability because it’s more affordable, making it available to a wider base of patients,” Dr. Emer stated. “When you add in the speed of treatment and ease of use by ancillary staff, these are advantages for both patients and physicians.”

“When I first started working with the ULTRA Femme 360, we took a conservative approach using similar power settings to the maximum power of other non-fractional RF vaginal technology,” Dr. Carter recalled. “While it was certainly a safe setting, we saw only mild improvement. The ULTRA Femme 360 allows us to use higher energies with the same safety. We now normally perform our procedures at 2.5 times our initial power and the positive results for this eight minute internal vaginal procedure have dramatically improved since increasing the energy. Our patients are very pleased with their outcomes and overall satisfaction. We’re fortunate that ULTRA Femme 360 is so safe and tolerable, which makes it easier to study because we can manage the protocols without as much concern for accidentally harming patients.”

In short, the ULTRA Femme 360 treatment is more proof that the apple doesn’t fall far from the tree. In Dr. Lee’s opinion, this makes it a breakthrough in feminine health. “The ULTRA Femme 360 is quick and easy to perform, with no downtime. Demand for these types of procedures has been overwhelming, and women are grateful to finally have non-invasive therapies to treat intimate health issues. Until recently, options have been extremely limited.”

“Looking at the big picture, we should be celebrating that not only are we finally talking about women’s health and wellness, especially sexual health, but we have truly safe and effective therapeutic options that address these concerns,” Dr. Lalji exclaimed. Women do not have to live with these problems the way they used to, not anymore. Women’s sexual health has been largely ignored in our culture for so long, and it deserves the same attention that men’s sexual health has received for the last several decades. Millions of women have suffered in silence, and they don’t have to anymore. They need to be empowered to share how they feel, and they need to know that they have advocates who can help find solutions. Now that we have the means to address these conditions effectively and non-invasively, we must educate the healthcare community as to the safety and efficacy of these treatments so that they in turn can increase awareness and education, remove the stigma, and open up discussions with their female patients, thus reaching more and more women who are suffering and truly need it. The time has come!” ■

Reference:

1. McDaniel D, Weiss R, Weiss M, et al. Two-treatment protocol for skin laxity using 90-watt dynamic monopolar radiofrequency device with real-time impedance monitoring. *J Drugs Dermatol* 2014;13(9):1112-7.



Before Tx



After two ULTRA Femme 360 treatments
Photos courtesy of BTL Aesthetics



Before Tx



After four ULTRA Femme 360 treatments
Photos courtesy of Shelena Lalji, M.D.

ULTRA FEMME 360™

COME FULL CIRCLE FOR
**CONFIDENCE.
RENEWED.**



Intimate
Procedure

BTL AESTHETICS

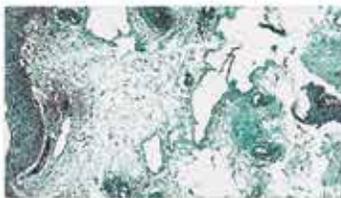
Introducing a **revolutionary 360° technology**, the new ULTRA FEMME 360™ provides the **shortest, non-invasive RF treatment** for women's intimate health and wellness.



EFFICACY

Histology

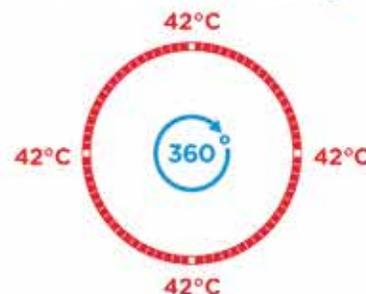
BEFORE: **10%** elastin fibers AFTER 3 TX: **41%** elastin fibers



Courtesy of: BTL Aesthetics

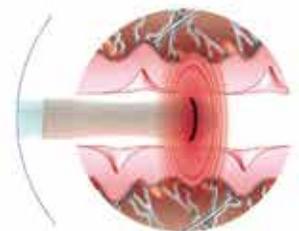
SAFETY

Uniform Distribution of Energy



COMFORT

360° Volumetric Heating



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