THE

Clinical roundtable supplement

Study Shows CO₂RE Intima **Improves Vaginal Health with High Patient Satisfaction**

By Kevin A. Wilson, Contributing Editor

Adding versatility and value to the CO₂RE laser system for aesthetic rejuvenation and wrinkle reduction, the new CO₂RE Intima module from Syneron-Candela (Irvine, Calif.) provides physicians with a top tier technology for noninvasive vaginal tissue remodeling that's both patient and user-friendly, meeting a growing need in the field of women's intimate health and wellness. With the CO₂RE Intima module, physicians can remodel and restore the tissue of the vaginal wall and vulvar to improve not only the aesthetic appearance of women's external genitalia (including vulvar dystrophy and dyschromia), but overall functional vaginal health as well, providing a relatively inexpensive treatment with appeal for women of all ages.



Julene B. Samuels, M.D., F.A.C.S. Aesthetic Plastic Surgeon Medical Director and President, Julene B. Samuels, MD, PSC Louisville, KY



Martin Garcia, M.D. OB/GYN Medical Director North Florida OB/GYN Jacksonville, FL



Falguni Patel, M.D. OB/GYN Women's Healthcare & Wellness Aberdeen, NJ



David Shafer, M.D. Plastic Surgeon Shafer Plastic Surgery Manhattan, NY



Kathleen Gilmore, M.D. Procerus Skin Care Ann Arbor, MI



Jennifer Lee, M.D. Medical Director REN Dermatology Franklin, TN



Graceanne SvendsenAesthetician and Laser Specialist
Shafer Plastic Surgery
Manhattan, NY

"All women experience these changes at some point, and the previous treatment offerings do not compare with CO₂RE Intima in terms of risk, downtime, side effects, compliance, safety or results."

Historically, the subject of vaginal health and related conditions arising from childbirth, aging and menopause has been difficult for women to discuss and often considered 'just part of life.' Treatment options ranged from Kegel exercises and hormone replacement to surgery, with a massive gulf in between. Results were less than impressive considering the associated cost and hassle. Treatment with CO_2RE Intima fills this gap as a safe and effective non-invasive alternative with a growing body of science behind it, and demand is skyrocketing as women take notice, according to plastic surgeon Julene B. Samuels, M.D., F.A.C.S. (Louisville, Ky.). "All women experience these changes at some point, and the previous treatment offerings do not compare with CO_2RE Intima in terms of risk, downtime, side effects, compliance, safety or results."

Indicated for the excision, incision and vaporization of tissue, the CO_2RE platform's proven 10,600 nm CO_2 laser is applied fractionally to provide a simple, easy, non-invasive and tolerable treatment via the CO_2RE Intima module. The properties of the fractional CO_2 laser make it ideal for ablation and coagulation of vaginal wall tissue, Dr. Samuels expressed. Moist vaginal tissue is very receptive to the wavelength and the difference in innervation between facial skin (which is more sensitive) and the vaginal epithelium is profound enough to make anesthesia unnecessary. The CO_2RE platform's efficient RF-excited, digital super pulsed laser provides the most effective blend of ablation and coagulation to stimulate neocollagenesis and neovascularization, and the controlled pulse provides consistent, predictable energy deposition that is as comfortable for patients as it is effective. "There may be minor discomfort during external treatments, but those take only a few minutes, making them quite tolerable," she noted.

Aggressiveness of treatment can be modulated within four modes: Light, Mid, Deep and Fusion, which provides a dual-layer fractional deposition of laser energy. The CO₂RE Intima module includes two hygienic, single-use handpieces for vaginal treatment; the Internal handpiece for remodeling tissue of the vaginal wall; and the External handpiece for treatment of the introitis (vaginal opening), aesthetic revision of external genitalia and treatment of pigmentation.

Martin Garcia, M.D., an OB/GYN and medical director of North Florida OB/GYN (Jacksonville, Fla.), is a lead author of a study whose results reinforce CO₂RE Intima's safety and efficacy, as well as its prowess in addressing ancillary conditions. Data was presented in a poster at the October 2016 North American Menopause Society (NAMS) annual meeting in Orlando, Fla. Subjects (n=36, mean age 56±8 years) in the ongoing study received three treatments with the device at intervals of about four weeks. The Vaginal Health Index (VHI), which rates vaginal elasticity, fluid volume (pooling of secretions), pH, epithelial integrity, and moisture coating, individually converting to an aggregate score, was used to measure overall improvement at 1, 3, 6 and 12 months after the final session. Self-reporting of other vaginal symptoms (dryness, dyspareunia, burning, itchiness and dysuria) was taken on a scale where 0=no symptoms and 10=worst possible symptoms. Treatment-related discomfort was assessed on a 10 mm visual analog scale. Data at the one- and three-month time point was presented. "What we have in CO₂RE Intima is a safe and effective device that treats rapidly with little or no

"The handpieces are ergonomic, light and small, and easy to maneuver during treatment, which is important in such a delicate area. Patients relax into the treatment. There is so little discomfort, and treatment is remarkably rapid."

downtime," he stated. "We see patient satisfaction of more than 90%, and reports of little or no discomfort more often than that. Patients note improvement in symptoms across the board. Treatment is quick and without much hassle."

All subjects showed statistically significant improvement in VHI at one month post treatment, and results persisted for those evaluated out to three months. At one month, significant improvement was also seen in related conditions such as dryness, dyspareunia, and/or burning for most patients. Treatment was reportedly very tolerable; side effects were mild and transient. "The lack of discomfort and complications with this modality is almost as remarkable as the results we've been seeing," Dr. Garcia said.

Dr. Samuels was a co-author of this study. "The aesthetic aspect of treatment is impressive, but this is really about women's wellness, and I think we're going to see an explosion in demand for this therapy given its safety, efficacy, tolerability and relatively low cost to treat."

As Graceanne Svendsen, an aesthetician and laser specialist at Shafer Plastic Surgery (Manhattan, N.Y.), shared, "The device is small, portable and easy to use, which is great because space is a commodity in our Manhattan practice. It is well designed for use in the vaginal area. The handpieces are ergonomic, light and small, and easy to maneuver during treatment, which is important in such a delicate area. The platform itself is not imposing or threatening in appearance, which helps women feel comfortable." Patients relax into the treatment, she added. "There is so little discomfort, and treatment is remarkably rapid."

Editor's Note: The following clinical roundtable includes an eclectic group of expert physicians representing the fields of plastic surgery, dermatology, gynecology and family/general practice. All have experience using the CO_2RE Intima module for restoring vaginal health.

What brought you into the feminine wellness market, and why did you choose CO_2RE Intima among the alternatives as a complement to your existing practice?

Dr. Samuels – I was already doing vaginal surgery and using CO_2RE for facial applications so this was a logical next step. CO_2RE Intima is a great tool for women's wellness. With external treatment you can also deal with dyschromia, but the internal treatment conveys a powerful medical benefit that affects a woman's quality of life. CO_2RE Intima is easy to use in the vaginal area by design, and the scanner is in-board rather than in the handpiece itself, which makes it quite light, small and easy to maneuver on the articulating arm. Patients love that the handpiece is disposable and hygienic as well. Users can also vary the aggressiveness of treatment easily with CO_2RE Intima in ways you can't with other devices. It is very easy to switch between available laser energy modes on the user interface screen without the need to change handpieces. The unique digital super pulse with CO_2RE is also more accurate, prevents pulse variation, and there's much less thermal stacking between subsequent pulses.



Before Tx



After two CO₂RE Intima treatments Photos courtesy of Julene Samuels, M.D.

"Often, once the conversation about symptoms like vaginal dryness, atrophy, stress incontinence and vaginal relaxation begins, it's like the floodgates open. Patients share things with us they haven't told friends or family."

Falguni Patel, M.D. – As an OB/GYN and a woman, empowering women to take control of their lives through better head-to-toe health and wellness is very important to me, so this is a natural extension of what I do. I chose CO₂RE Intima because of the greater energy available and the proven pathology from studies showing the structural changes that occur in the vaginal mucosa after fractional CO₂ laser therapy. Also, it's such a versatile platform.

David Shafer, M.D. – The CO_2RE fractional CO_2 laser has been a major part of our practice for non-invasive facial rejuvenation. As we are already fans of the Syneron-Candela lasers, integrating CO_2RE Intima made sense. The devices are safe and effective, but it really comes down to the science behind the mechanism of action and the quality of the actual systems that puts this technology ahead. When the Intima platform was developed for the CO_2RE it was a natural fit. Previously, our only options for vaginal treatment were surgical. Intima provides a non-invasive procedure for patients who either don't require surgery, prefer a non-surgical approach or are better candidates for laser treatment. The actual treatment is quick, painless and effective so our return rate for a second session has been 100%.

Dr. Garcia – As an OB/GYN this is the core of our practice. The depth of penetration and ratio of ablation to coagulation of the fractional CO_2 laser are essential to the remodeling of tissue in the vaginal area. RF treatments do not create the degree of thermal damage needed to induce collagen remodeling. We can also treat pigmentation with the CO_2RE Intima laser by switching modes, which is very easy to do.

Kathleen Gilmore, M.D. – There is already a high interest in non-invasive feminine wellness solutions like CO_2RE Intima, especially among older women who have had the most experience with vaginal atrophy, thinning of the vaginal lining and related diminished function. CO_2RE Intima does a tremendous job of rejuvenating this tissue, and the CO_2RE platform itself was a great way for me to get a CO_2 laser into my office, which I had been wanting to add for a while. We'd already been doing vaginal platelet-rich plasma (PRP) for a while so it was a natural extension of our practice.

Jennifer Lee, M.D. – We've been using CO_2RE for facial rejuvenation, acne scars and more for about three years so I was intrigued by Intima as I learned about the rapidly growing feminine wellness market. Dermatologists are very comfortable treating a wide-range of genital conditions, both in men and women, and genital dermatology was always a special interest of mine. I've lectured on the topic to general practitioners and internists in the past. Often, once the conversation about symptoms like vaginal dryness, atrophy, stress incontinence and vaginal relaxation begins, it's like the floodgates open. Patients share things with us they haven't told friends or family. I think up until now, these symptoms and conditions have been underserved. So when I learned that we could use our CO_2RE laser to address feminine wellness, I knew we needed to offer this service.

What were the challenges to integrating CO₂RE Intima into your practice?

Dr. Gilmore – My focus has been aesthetics, but moving in that direction from family practice isn't very difficult. It's all about addressing sought-after needs that



Before Tx



After three CO₂RE Intima treatments Photos courtesy of Julene Samuels, M.D.

"Treatment restores vaginal function in that these women can have sex, see improved bladder function, and experience more normal secretions with reduced incidence of irritation and dryness."

people will pay for. You have a pre-existing patient base and you can proceed from there. Most practices will typically have relevant equipment already such as examination tables with stirrups, so other than obtaining the device and the requisite training, it's not complicated at all.

Dr. Lee – At REN Dermatology we have a busy aesthetic practice so we were already comfortable with the CO_2RE laser. Not only does it give great results and is easy to operate, it's also very portable and space-efficient. The upgrade was not particularly difficult and the procedure is quick and easy to perform. Really, it was a no-brainer to add CO_2RE Intima.

Dr. Samuels – In the plastic surgery practice the greatest challenge will be learning how to build trust with women and discuss these intimate issues. This was easy for me, as a woman and being experienced with vaginal surgery, but for others there may be a learning curve.

Dr. Shafer – Our episode of *Real Housewives of New York City* was excellent exposure, leading women to start feeling comfortable talking about feminine wellness with us. I joke that of all things, I never imagined that I would be examining a vagina on national television, but it exposed a real concern of patients and helped them to broach the subject. As it is a sensitive topic for some, they often come in for some other treatment and then ask for information on the Intima procedure during that appointment.

What are the most common issues you're treating with CO₂RE Intima; post-childbirth restoration, post-menopause, or purely aesthetic external revision? What have results been like?

Dr. Garcia – This therapy was developed for vulvovaginal remodeling and the studies revolve around its use for related indications, so the bulk of my patient base for this by far is women needing treatment for menopause-related genitourinary conditions, whose estrogen levels are reduced leading to vaginal atrophy. Treatment restores vaginal function in that these women can have sex, see improved bladder function, and experience more normal secretions with reduced incidence of irritation and dryness.

Dr. Patel – I have some patients as young as their early 20s wanting better 'tightness,' women in their 20s or 30s wanting to treat post-partum vaginal looseness, and older women with functional problems stemming from menopause. External revision appeals more to the patient in their late 30s and onward; they're unhappy with the labial laxity and any discoloration occurring as a result of age-related hormonal imbalance. CO_2RE Intima treats this very well, but it's the functional improvements in older women that are most profound.

Dr. Lee – So far we're seeing a mix of patients, including women post-childbirth wanting to treat vaginal changes affecting intimacy as well as for stress incontinence. Some women are additionally seeking aesthetic improvement of the appearance of the labia, but so far that usually isn't the sole motivation. We also have several post-menopausal women receiving treatments. The feedback we have



Before Tx



After two CO₂RE Intima treatments Photos courtesy of David Shafer, M.D.

"I almost couldn't believe the quality of results and improvement until I kept hearing from patients how happy they were. In fact, many patients are noticing benefits after just their first session. It's fun and exciting to get such great feedback."

received from patients has been incredible. I almost couldn't believe the quality of results and improvement until I kept hearing from patients how happy they were. In fact, many patients are noticing benefits after just their first session. It's fun and exciting to get such great feedback.

Dr. Samuels – Most of the time I'm seeing women wanting treatment for vaginal atrophy due to aging, but there are plenty of women coming in after giving birth wanting to address the changes to their vaginas. Most of them also want to treat externally as well, because it's functional as well as cosmetic. This tissue is prone to prolapse during intercourse. In addition, laxity and atrophy of redundant external tissue may cause dryness, chafing and irritation at times. Women care as much about the external appearance as they do the external and internal functional issues. Another segment of the patient population for this that we don't always talk about is breast cancer patients with vaginal atrophy after chemotherapy, perhaps exacerbated by menopause. This does wonders for them, too, as it does for postmenopausal women.

Dr. Shafer – We see everything all the time, many younger patients looking for purely cosmetic effects, but also menopause-aged women looking for the medical advantages as well as cosmetic improvement. The amazing thing about CO₂RE Intima is the efficacy for urinary incontinence, lubrication and tightness. More often, women are looking for the medical wellness benefits.

What is the rough breakdown of new versus existing patients seeking treatment in your office, and how are your marketing efforts tailored to growing this unique aspect of your practice?

Dr. Gilmore – Right now it's about 50/50 with a growing base of new patients. We market internally as well as with sponsored internet ads and through our social media presence. I looked at other feminine treatments and products to see how they were marketed and I noticed that they try to reach a wide age range. A successful company marketing incontinence pads, for example, seemed to be gearing its efforts toward a much younger crowd than I'd expected, which opened my eyes to what we're really looking at here with laser remodeling of vaginal tissue.

Dr. Shafer – Approximately 50% are internal patients versus 50% new patients. We have had a mix of internal and existing patients asking about the new CO_2RE Intima technology, who have subsequently referred outside patients. After the *Real Housewives* episode, we had an additional influx of patients inquiring about vaginal remodeling procedures. We have marketed internally through our newsletter as well as in-office.

Dr. Garcia – We haven't had to market this yet. We have plenty of women coming in with complaints that can be addressed with CO₂RE Intima and when they have undergone successful treatment, word-of-mouth takes over. So it's mostly been from among our patient base, but that's changing. I was an early adopter and I have had people travel from as far as New York for treatment when I was one of the few offering CO₂RE Intima. The results are great. Even women with stress incontinence who may be candidates for a sling find the non-invasive aspect appealing,



Before Tx



After one CO₂RE Intima Tx Photos courtesy of Julene Samuels, M.D.

"I like to bundle a package of three sessions for a somewhat reduced price to encourage patients not only to undergo all three treatments, but to look at this as a course of action rather than an individual treatment. Typically it is after the second treatment that we begin to see the result manifest in fantastic ways."

and with few exceptions they tend to be satisfied with the results and haven't needed the sling.

How have you used bundling, discounting, or other promotions to successfully promote CO_2RE Intima?

Dr. Lee – About \$1,000 per treatment seems to be an average rate from what I've seen. We sell packages of three sessions for \$3,000. We haven't felt the need to do much discounting. In terms of promoting the procedure, we always introduce it at any Open House or other event we host. So even if we're not solely featuring the CO_2RE Intima, it allows our patients to hear about it and ask more questions if interested.

Dr. Garcia – I like to bundle a package of three sessions for a somewhat reduced price to encourage patients not only to undergo all three treatments, but to look at this as a course of action rather than an individual treatment. If a patient only gets one session and things don't change as much as they'd hoped, they may opt out and be unsatisfied before having experienced the results they'd enjoy with three sessions, which is what we recommend. Typically it is after the second treatment that we begin to see the result manifest in fantastic ways. I've had patients having had no sex in several years enjoying sex after the second session, so it's essential to get that commitment from the patient.

Dr. Shafer – We offer individual treatments or bundles of three with a slight discount for added value. For each session, we offer internal or external treatment or both. When purchasing both internal and external applications, we offer a package deal for additional savings.

Dr. Gilmore – We haven't done that kind of marketing, but we do hold mini-seminars to educate patients and get them interested. Most women are going to need this kind of treatment at some point and discussing these issues, in the context of having actual solutions available, is an exciting way to reach people.

<u>Does CO₂RE Intima stand by itself as a good investment, or do you need to more</u> fully exploit the CO₂RE platform's potential to make it financially viable to own?

Dr. Gilmore – I use the CO_2RE platform for other aesthetic uses as well, and it has performed to expectations; we do laser facial rejuvenation as well as neck and chest. The versatility is part of what drew me in, but the vaginal treatment itself would probably be enough to pay for the device.

Dr. Shafer – CO_2RE is a versatile laser. We use it for facial rejuvenation, post-surgical incision treatment and now feminine wellness. The machine has a small footprint, uses standard electrical outlets, is quick to set up, and the software is intuitive. And there are no disposables except for the single-use handpieces when using the CO_2RE Intima module.

Dr. Samuels – I've preferred CO₂RE CO₂ in other applications because it gives me better results with less downtime and discomfort in comparison to its competitors, and I like the versatility, but demand for vaginal treatment is high and growing so



Before Tx



After one CO₂RE Intima Tx Photos courtesy of Julene Samuels, M.D.

"CO₂RE Intima helped us expand our laser center's scope of practice with minimal investment. The value offered by the CO₂RE in terms of facial rejuvenation, post-surgical treatments and the CO₂RE Intima module give us a powerful workhorse that does not just collect dust in the corner."

this pays for itself rapidly, even at a relatively low price point. CO_2RE is not designed as a stand-alone vaginal device, but it's worth it to get one, even if that's all you plan to use it for, because as I understand it CO_2RE is less expensive than some competing devices that don't even have facial applications.

Why would you recommend CO₂RE Intima to colleagues?

Dr. Lee – Not only is the CO₂RE platform versatile, the Intima treatment is so amazing and unique. I think users can be assured of great results (equaling happy patients) with a procedure that's easy, safe, efficient and virtually painless. The demand for this procedure is growing and largely untapped. I'm based in the South (Nashville, Tenn.) and while there is still decorum on publicly discussing these topics, I think women are becoming much more comfortable.

Dr. Shafer – CO_2RE Intima helped us expand our laser center's scope of practice with minimal investment since we already owned the CO_2RE machine. However, the value offered by the CO_2RE in terms of facial rejuvenation, post-surgical treatments and the CO_2RE Intima module give us a powerful workhorse that does not just collect dust in the corner.

Dr. Gilmore – CO_2RE provides a versatile solution that addresses pretty much everything we might treat with a CO_2 laser, and it does a great job. It's important to remember that the learning curve with facial, neck and chest treatments is actually steeper than the vaginal treatment. Remodeling of vaginal tissue with CO_2RE Intima is quite simple to perform; it is safe, rapid and very easy to learn.

Dr. Samuels – Women historically don't easily discuss these issues, but this is changing. Demand will grow with awareness. Women, young or old, lose interest in sex because of discomfort, dryness or they lose the ability to achieve orgasm. This is true for breast cancer patients with medically induced menopause as well. And the external treatment is second to none because we can address pigmentation.

Dr. Patel – Women used to view these aging-related issues as 'just coming with the territory,' when you reach a certain age – sex is over, you have incontinence, dryness and irritation – as just an accepted part of life. That's not true anymore, and as we live longer, why accept such a reduction in quality of life starting in your 40s and 50s when you may live 30 or more additional years? It's very exciting to be able to offer this kind of treatment that has such a powerful effect on women's quality of life, and CO₂RE Intima is an ideal instrument because it is safe and effective with virtually no pain or downtime. To me it is a necessity for any gynecological practice because even without providing aesthetic services, opportunities to use this device will occur on a daily basis. ■