

Fractional CO2 Laser Therapy (MonaLisa Touch™) for Vaginal and Vulvar Skin Conditions

This roundtable discussion, sponsored by the International Academy of Pelvic Surgery (www.academyofpelvicsurgery.com), is intended to discuss the use of a unique fractional CO2 laser therapy called MonaLisa Touch for treating vaginal and vulvar skin disorders. The original research done on this treatment was performed at the San Raffaele Hospital in Milan, Italy. Dr. Eric Sokol and I were fortunate enough to be exposed to this treatment in January of 2014 and initiated the first US trial. The therapy has now been commercially available in the United States since January of 2015 and the initial response has been extremely positive. This roundtable is a discussion by six of the early adopters as well as Dr. Sokol regarding their initial experience with the therapy. Also discussed is the mechanism of action, how best to market the therapy to your patients, as well as tips and tricks on performing the procedure.

—Mickey Karram, MD

The technology, trial and treatment experience

Dr. Karram: Dr. Sokol, you and I performed the first study in the United States using MonaLisa Touch laser therapy. Can you tell us your initial thoughts about it prior to doing the study?

Dr. Sokol: I thought it was intriguing. We see primarily postmenopausal women and they come to us from all over the country and all over the world for complex pelvic floor problems. We also see cancer patients referred with pelvic floor complaints. Particularly for breast cancer patients, we often run into the problem that they're not really candidates for traditional therapies such as vaginal estrogen. So this was intriguing for that reason; it was very different. The most intriguing part, and the way it was posited to me before I had any experience with it, was that this was a very fast, relatively painless way to induce changes in vaginal skin that didn't require hormones.

Dr. Karram: What were your initial impressions after seeing it in action?

Dr. Sokol: After seeing it done in Italy and talking to patients six months to a year after having had it done, I remember thinking, this is almost too good to be true. It seemed super easy to do, and as someone who develops technologies, I know that you want something that is easy to do, reproducible and good for patients—kind of the holy grail of treatment. That's when I wanted to research it and get involved.

Dr. Karram: Could you review with us the results of the study?

Dr. Sokol: We just presented the official three-month outcome data at the North American Menopause Society meeting in Las Vegas (Sept. 30–Oct. 3). It was a prospective study of 30 postmenopausal women designed to evaluate the safety and efficacy of the laser to treat what at the time was called vulvovaginal atrophy but is now called genitourinary syndrome of menopause (GSM). We had some secondary objectives as well, designed very similarly to the Italian trials. We looked at the vaginal health index (VHI) score and we assessed the effect of treatment on the pliability of the vaginal wall, by looking at the maximum dilator size patients could use before and after the treatments. We looked at the change in vaginal pH. We also looked at sexual quality of life using the FSFI

(Female Sexual Function Index), and overall quality of life with the short-form SF-12 questionnaire.

Generally speaking, we were looking at global vaginal atrophy symptoms, including pain, burning, itching, vaginal dryness and dyspareunia as well as dysuria. We followed up with each patient a week after treatment to make sure there were no adverse events, and treatments were spaced six weeks apart.

We also looked at what I consider very important: overall patient satisfaction using the PGI-I (Patient Global Impression of Improvement) scale, but also physician satisfaction. A goal for new technologies should be to simplify both the patient and physician experience.

In general, all symptoms of GSM significantly improved, as did maximum tolerable dilator size and FSFI scores. We also had several women who were able to become sexually active after many years of not being able to do so. What was most impressive, to me, was the rapid resolution of vaginal dryness. We're coming up on one-year follow-up for all 30 patients and will be sharing that data in the future, but I can say that at one year out, my overall impression is very positive.

Dr. Karram: Can you describe the mechanism of action of the MonaLisa Touch treatment?

Dr. Sokol: Stefano Salvatore¹ has published on that topic and we are starting a small study looking at that very question. But basically, under electron microscopy, we see fine collagen that is laid down after the laser treatment, probably by inducing a very small thermal injury, and then getting a new ingrowth of cells and then a laydown of extracellular matrix. It's like a heat-shock response; the heat-shock proteins get activated and other growth factors come into play to induce type 1 versus type 3 collagen.

Dr. Karram: What has been the feedback from patients?

Dr. Sokol: My patients have loved it, and I've enjoyed being able to treat someone on the spot and even just days later, having them call to say they feel much better. And I've asked patients when I've seen them if things improved soon after treatment, and many said yes, within days, in terms of vaginal lubrication. I think this holds tremendous promise.

Tips and Tricks for Performing MonaLisa Touch Treatment

Early adopters of the technology should be aware of the following pearls regarding successful administration of the treatment.—Mickey Karram, MD

1. Feel free to use some anesthetic gel at the introitus in patients with severe atrophy to avoid significant pain and discomfort with initial insertion of the probe. We prefer EMLA cream applied a few minutes before the treatment and then it needs to be wiped off prior to inserting the probe.
2. Make sure that the probe reaches the top of the vagina. This is an area of extreme atrophy especially in post-hysterectomy patients, so you want to make sure that the probe comes in contact with the vaginal vault or the cervix.
3. The actual withdrawal of the probe is intended to be at 1 cm intervals. This should be as precise as possible; however, there is room for error in that regard.
4. Many patients with Genitourinary Syndrome of Menopause have more severe atrophy in the introital area due to the combination of vulvar atrophy as well as vaginal atrophy. As the circular probe reaches the introitus, at times it is difficult to efficiently treat the area of the vestibule and posterior fourchette with this probe. We have now added in these patients a dual

probe technique in which we will switch to the vulvar or flat probe to more effectively treat this area. This is done using the mild settings and treatment of this area is under direct visualization, with overlapping of the treatment areas being well expected. I usually treat the vestibule from three o'clock to nine o'clock, the entire posterior fourchette, and at times the upper part of the perineum. The regime I would recommend would be traditional vaginal treatment for the first treatment. For those who report that they had significant improvement in the vaginal canal but continue with insertional dyspareunia, I would initiate the dual probe technique on the second and third treatments.

5. For patients undergoing vulvar treatment, we have patients apply a topical anesthetic similar to EMLA, 20–25 minutes prior to treating the area. In patients with excessive pubic hair in the area to be treated, we recommend trimming this hair prior to placement of the EMLA cream.

Dr. Karram: Dr. Dell, approximately how many patients to date have you treated with the MonaLisa Touch laser treatment?

Dr. Dell: We've treated approximately 130 patients and have delivered more than 450 treatments. While the standard protocol is three treatments per patient, my center is very much involved in developing the protocols for the vulvar treatment for external skin atrophy and lichen sclerosus, so some of those patients are getting vulvar procedures as well.

Dr. Karram: How does this type of laser treatment in the vagina compare to fractional CO₂ lasers that historically have been used on the face?

Dr. Dell: Great question, and I think we have to address it in two parts as it relates to the dual-probe approach.

The fractional CO₂ laser of course has become the gold standard for treatment on the face in the hands of dermatologists and plastic surgeons. There are tremendous benefits of the fractional approach with its matrix penetration of dots, if you will. It's this same technology we now can deliver both vaginally and to the vulvar tissue. There are two separate aspects: the vaginal probe utilizes a different laser pulse or emission mode, specifically developed for vaginal mucosa to maximize the benefit of how that laser pulse is delivered. We then change the emission for the vulvar probe to use the exact same approach that would be used on the face because this is outer skin and a different tissue type than vaginal mucosa. So it is fractional CO₂ but using different emission modes to treat both the vaginal and the vulvar tissue.

Next: Patient selection and technology potential

1. Stefano Salvatore, MD, head of urogynaecology, San Raffaele Hospital, Milan, Italy. Dr. Salvatore conducted the original studies of MonaLisa Touch treatment.

Patient selection and technology potential

Dr. Karram: Dr. Dell spoke of his experience treating both vaginal and vulvar tissue. Are others on the panel looking at other ways to utilize this technology?

Dr. Sophocles: Yes—if you think about how this works, it should work on the vulvar tissue as well. It's a matter of how the settings need to be tweaked and how many treatments and how far apart. I think that bladder symptom improvement in postmenopausal women with urinary urgency and frequency is also an underappreciated advantage of the treatment.

Dr. Kubricht: Chronic cystitis in postmenopausal women is probably the number one secondary indication that I treat patients for. Since 2002, when the association between estrogen and breast cancer became familiar to the public, the incidence of recurrent vaginitis, vaginal atrophy, vulvovaginal atrophy and recurrent UTIs has gone up dramatically. Until now we've fought the battle of, "I don't want to be on a hormone and therefore the end result is I'll have more urinary tract infections." So when I see someone with recurrent UTIs and they're postmenopausal, this comes to the top of my list of things to offer the patient, because I know the probability of their wanting to be on a hormone is low if they're not already on one. So I strongly advocate that.

Recurrent UTIs is the most common reported symptom I treat for, followed by vaginal atrophy and third, vaginitis. We counsel patients that vaginal atrophy is what we're treating and that anything beyond that is what we in Louisiana call "lagniappe"—it's all extra.

Dr. Dell: One of the obvious targets is inflammatory disease process conditions, of which lichen sclerosus is the most common. We're seeing very encouraging results by using external probe therapy on these patients. These are patients who in many cases for years have suffered tremendously despite all of the various creams and steroids and topical treatments we've had to offer. We've just completed a 15-patient pilot trial for treating lichen sclerosus and are seeing very encouraging results clinically overall for that condition.

Aside from that, for a tremendous number of patients who don't have a clear disease process of the vulvar skin but have significant atrophy, loss of elasticity, tenderness, discomfort and the like of the outer skin tissues, we're

finding that the standard vaginal approach of the MonaLisa Touch does not adequately treat those anatomic areas. So we are finding that we are using the vulvar probe more and more in conjunction with the standard vaginal approach to address the posterior fourchette, the perineal body and the surrounding vulvar tissue.

Dr. Karram: How do you think this treatment compares with other more conventional treatments for atrophy or GSM, such as vaginal estrogen cream or Osphena®?

Dr. Castilla: I think you have some self-selected patients who do well on conventional treatments—"I'm used to this, it works for me." But overall, their results are about average. We have not seen the dramatic improvements we are seeing with the laser when we treat women with vaginal estrogen or Osphena.

Dr. Karram: Dr. Dell, your practice is a urogynecology subspecialty practice. Does this technology have a place in a community-based gynecology practice?

Dr. Dell: Absolutely, I think it does. The ideal fit of this technology is the common patient who is the middle of the bell curve and who is in the hands of the busy community gynecologist. Where I think caution needs to be exerted is that as we get into expanded vulvar protocols where we're pushing the envelope, or for certain patient types such as someone experiencing mesh erosion, which need to be handled with extreme caution, I think protocol development for difficult patient types may need to be handled in the training and teaching centers, but that doesn't prevent the heavy use and wide availability of the standard approach in the hands of community physicians.

Dr. Karram: Dr. Sophocles, could you tell us who in your mind is the most ideal patient to benefit from this treatment?

Dr. Sophocles: I think the ideal patient is the postmenopausal female with dyspareunia or vaginal dryness as her most bothersome symptom, plus or minus LUTS symptoms. The restoration of healthier tissue with enhanced capability to generate moisture, and improved elasticity makes for improved quality of life. Many of my patients with chronic UTIs, or urinary symptoms not

helped with medication or biofeedback are finding improvement after CO2 micro ablative laser.

Breast cancer patients who have taken antineoplastics such as aromatase inhibitors suffer severe debilitating atrophy of genital tissues. While centers such as MD Anderson and Memorial Sloan Kettering have found positive safety profiles in administration of low-dose vaginal estrogen to breast cancer patients, the practicing gynecologist still shies away from prescribing vaginal estrogen for treatment of GSM in breast cancer patients. Most breast cancer patients then suffer doubly from GSM due to lack of estrogen and an exacerbation from the medications they take to prevent recurrence of their breast cancer. We have never had tools in our toolbox to help these women. Until now. The CO2 micro ablative laser is the only safe option for these women, and it is exciting and gratifying to have something to offer them.

My experience with vulvar applications of the laser has been promising but I think we need robust trials comparing various treatment regimens in order to elucidate the proper number of treatments and to create practice algorithms for women with vulvar dystrophies and inflammatory vulvar processes.

Dr. Karram: Could you take us through the typical regime of treatments that are recommended in patients that you feel are good candidates for this treatment?

Dr. Sophocles: The treatment options are threefold: option one is topical vaginal estrogen, either cream, pill or a ring. Option two, a non-estrogen, non-hormonal daily tablet—ospemifene or Osphena. And three, the MonaLisa Touch. (Lubricants are not really a treatment option; they're a symptom reliever. Lubricants and vaginal moisturizers do of course have an important place in our armamentarium to combat dyspareunia.) I present all three unless the patient has contraindications for any. I present them in that order—in the order of what I believe the patient might have heard of first to what they may know the least.

Dr. Karram: How do they react when you tell them about the laser?

Dr. Sophocles: Some are worried that it will be painful. I explain that lasers have been used in gynecology for decades, and that the gentle, microscopic “pinpricks” that the MonaLisa makes are just tiny “injuries” which stimulate a healing response, which creates new collagen and blood vessel formation. Once patients understand that it is a natural body response and lacks risks and side effects of medical therapy, they are usually very interested. Most patients fear pain and side effects. Once you help mitigate those fears, they are very accepting of the procedure. I explain also that it is new in this country, but that somewhere between 15,000 and 20,000 procedures have been done worldwide with an excellent safety profile.

Dr. Karram: Dr. Croak, as a urogynecologist, how have you utilized MonaLisa Touch treatments in your practice?

Dr. Croak: It's been a very nice addition to my practice. Treatments started in early June, and they have ramped up in volume ever since. I will say that the therapeutic results have lived up to the patients' expectations. Nine out of 10 women coming back for their second treatment reported some form of benefit from the first treatment alone. There seems to be a myriad of symptom improvement, the most common being less dryness and painful intercourse, and better lubrication. I have also seen reductions in urgency, frequency and UTIs. I have had four patients with vulvar lichen sclerosus who are still in treatment, but were having no problems after their first session based on a one-week follow-up phone call.

Dr. Karram: Dr. Kubricht, as the only urologist on this panel, can you tell us how you got involved with this treatment and how you have been offering it to your female patients?

Dr. Kubricht: My practice focuses on female pelvic medicine, so I have a primary female practice. I got involved with lasering about four years ago doing laser hair removal, and once I was in that space I became aware of what was happening with the MonaLisa overseas. I then became involved with the technology once it came to the United States and was cleared by the FDA.

With a primary female practice, I use the laser quite heavily. I use the laser for treatment of atrophic vaginitis, vulvovaginal atrophy. I currently use it as a primary treatment modality by giving my patients an opportunity to choose between hormonal therapy, topical hormonal therapy or the MonaLisa.

In the event of patients who have contraindications to hormones, I explain what the contraindications are and why they are of concern and uniformly offer this as an option to all patients with breast cancer, clotting disorders, history of strokes, TIAs and similar coagulation abnormalities.

Dr. Karram: How many patients have you treated?

Dr. Kubricht: We've treated well over 100 patients and have actually had such a good experience that we appear to be on par with all the outcomes and findings reported in the FDA trial as well as in the European literature.

We have well over 60 patients who are past the three-month mark since their final treatment. I arbitrarily established three to four months as a follow-up time after the last MonaLisa treatment and have advised patients that after one year they may begin to have recurrence of symptoms that would require retreatment. At these follow-ups, patients are reporting good results and they're happy.

Dr. Karram: Do you think this is a treatment that could be adopted by most urologists who are comfortable doing pelvic exams?

Dr. Kubricht: Without a doubt. Urologists have been using lasers in surgery for many years—stone surgery, bladder tumor surgery, prostate surgery—so even though the average urologist may not have a heavy female practice, they do all see the same problems that come from vulvovaginal atrophy. The recurrent UTIs, the dyspareunia, the recurrent vaginal infections—even though they're urologists, they still see a lot of that as well. So it's an easy extension to begin to offer that just in the generalist practice.

Dr. Karram: Are you seeing many breast cancer patients, and if so, how do they come to you?

Dr. Kubricht: I would say the majority of the patients we treated initially were all breast cancer survivors. We have a steady referral pattern already in place now from medical oncologists, radiation oncologists and breast surgeons, who are all referring patients now for this treatment because it's had such an impact on their care.

All of our specialties deal with the negative aspects of breast cancer treatment and the absence of hormones, and thus the cancer surgeons and oncologists have become some of our biggest physician advocates.

This referral pattern developed once the technology became available and it honestly did not take much to educate these physicians and say: we have a population of patients who are suffering and here is something that could potentially change their lives with very little effort.

Dr. King: Initially I thought that breast cancer patients would be the majority of who I'd see for MonaLisa, but interestingly, in about 90 percent of breast cancer patients I've seen, their oncologist has allowed them to be on vaginal estrogen. I'd say they account for about 25 percent of my MonaLisa patients, and for them it has worked incredibly well. And they are so relieved to find out that there's another option. I'm also seeing uterine cancer survivors, none of whom were on estrogen.

Next: Practice building with MonaLisa Touch marketing

Practice building with MonaLisa Touch marketing

Dr. Karram: Dr. Croak, I understand you have been very successful doing some direct-to-consumer marketing around this treatment. Could you describe how you approached patients in the community regarding educating them on the potential benefits of MonaLisa Touch treatment?

Dr. Croak: I have a rather large practice, so my staff sent a letter to our peri- and post-menopausal patients. In the first three months we sent over 3,000 letters in a graduated allotment so as to not overwhelm the schedule with potential appointments. The letter talked about the technology, its indications, and the fact that there was good scientific evidence behind the therapy. The letter also explained why the MonaLisa Touch could help women who couldn't take estrogen, and it even employed some of the marketing testimonial language such as "life-changing" and "game-changing."

In addition, the letter invited these patients to a seminar. I started offering monthly educational seminars at my preferred hospital, whose staff was kind enough to lend me the meeting space. I also distributed brochures promoting the seminar in the hospital and had flyers

available in my waiting room. Patients who attended the seminar and signed up for treatment that evening received a 20 percent discount.

I think the one-two punch of the letters and the seminars really was effective. The first lecture given in June had about 30 women attend; 17 signed up for treatment and 12 actually followed through with therapy. In July I had over 40, and in August I had 58 attend, with over 20 people signing up each time for the discounted treatment package. Consequently, I've been busy. I think what you lose in the higher fee you gain back with more volume.

My practice also ran nice color ads, quarter-page ads in *Toledo Healthy Living News* and *The Maumee Mirror*, a suburban paper, which brought in about a dozen patients. These local papers graciously ran articles as part of the advertisement package. So, the advertising paid for itself. I am now starting to see patients who don't want to wait for a seminar and want to be treated right away; that's a paradigm shift. I am seeing increased demand and subsequently, have raised the fee slightly. Overall, my price point is still a good deal, especially with the discount.

Practice Pearls from the Panel: Promoting MonaLisa Touch Laser Treatment

- Don't underestimate the effectiveness of a simple letter (or if you have EMR, an email) to patients announcing this technology.
- Offer monthly seminars to the public with a discounted fee to those who sign up for treatment while at the seminar. Ask your hospital to lend you the meeting space.
- Track seminar attendees to know which MonaLisa patients have had many of their questions already answered, to minimize unnecessary counseling time.
- Consider hiring or assigning a dedicated employee to book, counsel and consent MonaLisa Touch patients to save physician time.
- Inform oncology colleagues about the benefits of MonaLisa Touch for their patients for whom estrogen is contraindicated, e.g., an open house at your offices.
- Reach out to the female cancer survivor community.
- Ask area hospitals if they will allow distribution of seminar flyers or patient brochures.

Dr. Karram: Can others talk a little bit about some of the things that you have done within your practice to let women be aware of this therapy?

Dr. King: First, we promote it on our website. I do go on the radio regularly, local talk shows. I speak at women's luncheons. I haven't done any ads yet. The vast majority have come from talking with my patients, and if they have any issues whatsoever, I let them know that this is available. We have the brochures, but it is mostly me speaking with patients when they come in for their exams.

Dr. Castilla: Our first step was to hire an employee specifically for the program, because there were going to be a lot of questions and we needed someone to be an advocate for the patient and navigate her through the process. It's expensive to do that but well worth it. We have a dedicated phone line for this employee and any time a patient has questions, they can call. We've also done a lot of advertising.

About half of the women we've treated have been our own patients, but half have come from outside the practice. Advertising is pricey, but it's been worth it; I know it's driving patients to the website, where they're finding out more about the procedure.

We've also held monthly seminars in our offices. Patients can come in and meet the physicians and learn a little bit more about the procedure. We give patients a discount if they come to the seminar. We promote the seminar in our advertising and we also direct market to our patients through our EHR using their email addresses. We stratified the list; we only emailed those over the age of 40.

It's been really successful for us. I would say that the other two mature practitioners and I are doing two to three new cases a week, which is huge when you extrapolate that monthly.

Dr. Kubricht: We've held open houses for the general public for several months now. Turnout has been very good, very consistent. We also offer a discount to patients who attend the seminar and sign up for treatment. We keep track of who attends and we put that in our records so if they sign up we know that they were educated. You then don't have to spend as much time explaining the procedure because they already know what there is to know.

Dr. Karram: How did you educate your oncology community? What was your process?

Dr. Kubricht: When we first got the laser, we had an open house, a 45-minute seminar to show the technology. We invited every oncology practice in our city to attend, their nurses, specifically, as well as the physicians. For those who did not attend, all it took was a phone call.

Dr. King: I took the local oncologist out to lunch to tell him about MonaLisa. He hadn't heard of it, and breast cancer patients are the majority of his practice.

Dr. Karram: Are patients calling up out of the blue to schedule the procedure?

Dr. Castilla: We actually direct them to the seminar first, and I'll tell you why: if I have a patient I've never seen before, I have to meet her, take a history and eventually I'll do a physical exam on her. But it takes a lot of time for me to walk someone I've never met before through the entire process. So I want our employee, Jennifer, to do that. And if they come to the seminar, it saves a lot of time explaining, counseling them and so on. In other words, if the patient comes to the seminar, then I can see them, consent them, take a quick medical history and do a physical exam, and my total time has been the seminar and maybe 15 minutes. So we want them to go to the seminar first.

Dr. Karram: So it's like having that counseling once with 60 people versus having to do it 60 times, one by one.

Dr. Castilla: Exactly. And for the patient, there's less pressure to decide about the procedure. Patients want that anonymity. If they have further questions, they can always call Jennifer afterward and follow through.

Dr. Karram: Do any of you get patients via word of mouth?

Dr. Sokol: We have people calling every day asking for this. They're calling from all over; we've had calls from Singapore and Moscow. I don't know how they're hearing about it. We have a long waiting list.

Dr. Castilla: Our first seminar was in June; we had about 60 people. We also had 60 people in our August seminar, but the interesting thing in August was that many people had come from the community who had heard about the treatment through word of mouth—already within a couple of months. And that seminar yielded a higher percentage of people signing up for the procedure the same night.

Dr. Sophocles: We've had people come from pretty far away after hearing word of mouth. I've had walk-ins. I had a walk-in from six hours away: she had heard about the MonaLisa Touch and she arrived in tears. She said, "I haven't had sex in eight years, my marriage is almost destroyed because of it, and I thought there was something wrong with me. My friend came here and had this done and she called me, and I just got in the car and drove." So we treated her that day and she's over the moon.

Dr. Karram: Have you had difficulty getting patients to pay out of pocket for this procedure?

Dr. Castilla: To be honest, we live where the demographic doesn't really balk at the cost. Some have said they'll wait for their healthcare or flexible spending account to get enough money in it. But we haven't had anyone say it's way too expensive. A lot of my patients do Botox and fillers and have had plastic surgery, so it hasn't been an issue for us.

Dr. Sophocles: Initially, cost of the procedure was an issue for my patients. We have a mixed population, and for many of these patients, if cost were not an issue, they'd do it, because they would not have to worry about compliance and messy creams and inserting something; they don't want to deal with side effects or risks of any of the meds. One of the reasons I've done so many cases—more than 350—is that I've done many gratis so I could get a few hundred cases under my belt. So initially, most patients opted for the procedure. Now that I charge it's a different percentage, but with 6,000 patients in my practice, I'm having this conversation 10 times a day, and I'd say I'm now treating five patients a day.

Dr. King: In my practice they pay per treatment, but it's important to understand that many of these patients are already on estrogen. For the woman in her 50s who is not on estrogen, I tell her she's probably going to need three treatments to bring her vagina back, and I offer a slight discount for paying up front for all three treatments. That does encourage them to come back. But I've had several people who were on vaginal estrogen and just weren't getting to where they needed to be, and they have chosen to pay per session even though they're not getting that discount. In those cases, all have come back for a second treatment, while some have not come back for the third because after the second they're completely fine.

Dr. Karram: So you're using MonaLisa Touch as an adjunct treatment to vaginal estrogen?

Dr. King: Exactly. I've found that if they've been primed with estrogen, two treatments gets them perfect. Let me offer one example where I was most astounded: My patient was 60 years old, 10 years postmenopausal, no estrogen, severe pelvic prolapse. Absolutely, positively needed surgery. But her tissue was nowhere near ready. I put her on vaginal estrogen. She was one of the first people I treated with the MonaLisa and we talked about it as a possibility. She asked if we could do both and I said of course we can. She received her first MonaLisa treatment

that very first day. Six weeks later she came back to see if her tissue was healthy enough for surgery and I said, you know, it's almost there but let's do one more MonaLisa. So we did a second treatment that day. Three weeks later I did her surgery. Her tissue dissected like somebody who was 30 years old.

Dr. Karram: When patients do pay, do they feel the results were worth the investment?

Dr. Castilla: We're still in the infancy with this; most of my patients are on their first or second treatment. But those who have commented have said, "This is a godsend. It's saving our marriage, our relationship. It's saving *me*." They cannot believe what a difference it's made.

Dr. Sophocles: Out of more than 350 patients, including more than 150 who paid out of pocket, I haven't had anyone say it wasn't worth it.

Dr. King: I've had zero complaints. People think of Aspen as only wealthy people, but there are only 6,000 people here year-round, and it is mostly blue-collar. There is a large Hispanic population and I've seen that most are used to paying cash for everything, so it hasn't really been an issue. There's a mentality that insurance should pay for this, but if you point out the cost of vaginal creams, which have shot up in price and are very expensive, say, \$100 or \$200 a month, plus the hassle, the MonaLisa Touch actually compares very well from a cost standpoint as well as a hassle-free standpoint.

Dr. Dell: After hundreds of treatments in over a hundred patients, I would say the clear quality of life improvement is in the range of 95 percent. For properly selected patients with appropriate expectations, it truly is an unbelievably rare case that the patient does not notice significant improvement from a quality of life standpoint, and I would say that is mirrored by what we see clinically and upon physical exam as the patients move through the treatment.

Dr. Kubricht: The interesting point that I've made to others is that this is the first treatment modality I can think of in my career where patients will pick up the phone to take the time to tell you how good they are doing as opposed to what is traditional in medicine, which is that we don't hear from you unless you're having a problem. That's one of the biggest differences I've seen with this treatment over anything else.

End of series

Moderator

Mickey Karram, MD



Dr. Karram is an internationally renowned urogynecologist and pelvic surgeon. He is currently the Director of Urogynecology and Reconstructive Pelvic Surgery at The Christ Hospital and Professor of Obstetrics & Gynecology and Urology at the University of Cincinnati. He has published more than 190 scientific articles and book chapters and has co-authored textbooks entitled "Urogynecology & Reconstructive Pelvic Surgery" and "Atlas of Pelvic Anatomy and Gynecologic Surgery." He is past president of the American Urogynecology Society and previous editor in chief of the International Urogynecology Journal.

Panel



Julie Anne Castilla, MD, FACOG

Dr. Castilla is a partner in Arizona Women's Care, a five-physician obstetrics/gynecology practice in Scottsdale, AZ, with a history of bringing new technologies to the region. Dr. Castilla's areas of interest include infertility and high-risk obstetrics.



Andrew J. Croak, DO, MS, FACOG

Dr. Croak is medical director of the Northwest Ohio Center for Urogynecology and Women's Health, where he leads a solo practice. Dr. Croak also teaches at Ohio University College of Osteopathic Medicine, Mercy St. Vincent Medical Center, Toledo.



Jeffrey R. Dell, MD, FACOG, FACS

Dr. Dell is medical director of the Institute for Female Pelvic Medicine in Knoxville, TN. One of the nation's first board-certified urogynecologists, Dr. Dell participates in clinical research trials and regularly serves as organizer, invited lecturer and visiting professor at local, national and international events. He is currently conducting research on MonaLisa Touch.



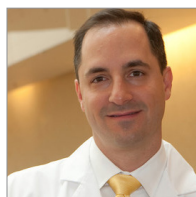
Gail King, MD, FACOG

Dr. King is founder and medical director of the Aspen Center for Women's Health as well as Regen Aspen. She is a fellow of the Laser Vaginal Rejuvenation Institute and is the author of the 2015 book, *Legs Up: The Troubleshooting Guide for Your Vagina*.



William S. Kubricht III, MD, FACS

Dr. Kubricht is a partner in Louisiana Urology, a nine-physician practice in Baton Rouge. He formerly taught at Louisiana State University Health Sciences Center in Shreveport, where he founded the section of female urology, neurourology and reconstructive pelvic surgery. Dr. Kubricht has authored numerous international publications and presentations.



Eric R. Sokol, MD, FACOG

Dr. Sokol is associate professor of obstetrics and gynecology (gynecology-urogynecology) and of urology at The Stanford University Medical Center. Widely published, his research is focused on the development and evaluation of cutting-edge minimally invasive treatment modalities for incontinence and prolapse. He is currently conducting research on MonaLisa Touch.



Maria Sophocles, MD, FACOG, NCMP

Dr. Sophocles is founder and director of Women's Healthcare of Princeton in Princeton, NJ. An early adopter of emerging technologies in gynecology, Dr. Sophocles is currently conducting research on MonaLisa Touch, developing protocols for transgender gyn care, and serves as a mentor and lecturer for numerous national and international healthcare organizations. Practicing medicine in Switzerland and Italy helped her appreciate the need to look beyond our borders for alternatives to or advances in women's healthcare.