

What are the Differences Between ThermiVa Radiofrequency and FemiLift/MonaLisa/IntimaLase lasers for use in Aesthetic Vulvovaginal Therapies?

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I am writing this piece to an audience of both lay person (or potential patient) as well as clinician (MD, RN, PA) to give my personal views on the new ThermiVa technology and how it stacks up to the numerous laser devices for the purpose of feminine rejuvenation. These are my views and do not necessarily reflect the views and opinions of Thermi, the company. This was written as response to an article Dr. Steven Gitt wrote on September 28, 2015 and published on LinkedIn Pulse.

<https://www.linkedin.com/pulse/what-differences-between-femilift-thermiva-steven-gitt-md-facs>). I believe it best to review Dr. Gitt's written opinion and compare and contrast it with mine to get a balanced take on this important emerging topic.

There has been an amazing and rapid growth in the field of non-surgical feminine rejuvenation. In 2005 we were perhaps the first center to provide non-surgical tightening of the vulvar structures using CO2 lasers and later on Erbium 2940 lasers. We used ablative settings and progressed to fractional ablative and non-ablative methods. We were able to get tightening of the labial and internal vaginal skin but at quite a cost in terms of pain and recovery and skin discoloration. The tightening obtained with the most effective CO2 lasers on external vulva were impressive for a short period of time until gravity and aging effects wore out the effects in a few months. Using the highest powered CO2 lasers intravaginal, tightening effects were obtained but the downtimes were many many weeks to months. Depending on where you focused the lasers and what tissue you shrunk down you would get some improvement in continence in some patients. But these ablative lasers were not known to improve vaginal moisture or help atrophic vulvovaginitis. Today's lasers, both CO2 and Erbium, are used with less power and with less to no ablative effects but are better in improving vaginal moisture with very little downtime. They give enough tissue tightening effects to help reduce incontinence also when the pubocervical fascia are treated. This is the case with FemiLift or MonaLisa, both fractional CO2 lasers. This is also the case for IntimaLase using 2940 Yag lasers. These three systems, released in the US within the past year or so, are the state-of-the-art for the laser arm of feminine rejuvenation. They will battle for laser supremacy in the market filled with over a dozen laser copycats. However, when looking objectively at choices, ThermiVa radiofrequency technology is rapidly becoming the standard by which all feminine rejuvenation devices are being compared to and judged by. Why such a little company is making huge headways in the industry dominated by laser titans? There are many reasons why Thermi is the fastest growing small company in the industry. As the

director of the team that put ThermiVa together I would like to share my views that will be based on my personal clinical use of ThermiVa since its inception as an idea in 2009.

Laser companies have known for some time now that the tightening effects of lasers on skin were not satisfactory and not impressive. They have focused their energies on skin smoothing, skin texture, wrinkling, treating sun damage, and blood vessels. Since the advent of Thermage RF treatments and less so infrared devices, the swing for skin tightening has convincingly swung away from lasers. Clinical research and experience has proven radiofrequency to be the winner at this point in time when it comes to consistent and non-surgical/non-ablative treatments for skin tightening not just in the face and body but in the feminine regions. There is a reason large laser companies like Cynosure have purchased RF companies like Ellman. To obtain RF technology for tissue shrinkage.

Enter ThermiVa, a unipolar radiofrequency device with FDA clearance for dermatologic use. It has a broad FDA clearance purposely obtained because of the wide spectrum of clinical effects it is able to bring to treated skin. This is not the radiofrequency system that “many feel that their effectiveness remains unsatisfactory.” Early RF systems were known to cause lots of pain with little consistent clinical effects. Those systems blasted RF heat and used cooling measures to reduce the pain. There was not sustained heat given to tissues. They were “blast and cool” devices. In contrast, ThermiVa applies heat (40-45 Celsius) that is sustained and comfortable because it is “Temperature Controlled.” ThermiVa uses very smart software and technology that is able to slowly heat tissues to targeted temperatures and then maintain the temperatures there to obtain the tissue contraction “blast and cool” methods could not achieve consistently. RF science and use on vulvovaginal tissues started around 2009 in our office, years before any vulvovaginal laser technology was used in the U.S. to treat vulvovaginal issues. It is not accurate to say that there is little research regarding long term results of RF devices. I have reported on the results of RF use on vulvovaginal tissue and its safety and excellent efficacy almost every year since 2009 at my yearly CAVS meetings (Congress on Aesthetic Vulvovaginal Surgery). Every year I showed dozens of photos and clinical studies. More recently my Pilot Study has been published and the ThermiVa multi-site IRB has been completed. Safety has been established clearly as no blisters or burns or adverse events have occurred since 2009. Blister and burn temperatures at 55 Celsius are not reached by ThermiVa.

So what can ThermiVa do? It can do two things well. First, it can tighten vulvovaginal tissues uncontestably better than any laser system on the market. Hands down. No contest. It can tighten the labia majora sagging dramatically to levels not seen by laser systems both CO2 and Erbium, both ablative and non-ablative, both fractional and non-fractional. There are dozens of photos on www.thermiva.org and other websites showing the amazing tightening effects externally with the use of ThermiVa. Go try to find a single set of photos showing the Before and After tightening effects of any laser system and compare them to ThermiVa. They will be hard to find because the laser systems, like FemiLift or MonaLisa or IntimaLase, are not routinely used to shrink the labia majora. In fact, you need a separate hand piece and anesthesia if you choose to use it for the labia majora. There is significant downtime with that ablative treatment. Common sense dictates that laser companies with good results of their tightening would be proud of their outcomes and show them off on their websites and brochures. Common sense would also find owners of laser

systems proudly displaying the results of FemiLift or MonaLisa or IntimaLase. Good luck finding those photos of their results. Here is the kicker, RF is known to shrink moist mucosal tissues even better than external dry skin and that is exactly what we find. ThermiVa's internal treatments of the vagina are superior in tightness than any currently available laser system geared for vaginal rejuvenation. This is from my personal examination of hundreds and hundreds of women who have received ThermiVa treatments and comparing them to my years of laser use. This has been clinically confirmed by dozens of ThermiVa users. One more thing, with the tightening of vaginal tissues, you can target the tightening effects to the area of the urethra called "pubocervical fascia." This results in the amazing reduction in leaky bladder. Both stress incontinence (leaking from increased pressure such as a cough, sneeze, jump) and overactive bladder are relieved consistently. The tightening is immediate and many are dry after just one treatment. Dribbling goes away, urge symptoms subside. In fact, the effects of radiofrequency on the bladder are just about as good as any of the anticholinergics drugs available without the dry mouth and constipation. Urogynecologists who have ThermiVa have reported dramatic reduction in number of slings needing to be placed and number of prescriptions written for overactive bladder. No mesh, no drugs. I have not seen this type of dramatic effects with laser based systems though some do claim to be able to help.

Secondly, Thermiva increases blood flow. This is perhaps the "Biggest Deal." It is true that vaginal and vulvar biopsies have not been published to show the microscopic effects and those studies are not quite complete yet. But on visual exam, a macro exam, you can see vessels forming on labial and vaginal tissues. The increased blood flow is real as evidenced by the increased transudate from arterioles going into the vaginal canal and resolution of the dry vagina. This effect is one of the few things in my practice that I can say is 100% since not a single patient has failed treatment for atrophic vulvovaginitis (dry vulva and vagina). Along with the increased blood flow also comes the improvement in the sensitivity of the vulvar structures, the clitoral region, and internal vagina. Akin to "Female Viagra" due to the increase in blood flow to the genital structures treated. Treatment of the G-Spot areas have increased sensitivity there and have improved orgasmic response consistently. Because of this increased blood flow there is increased production of collagen. Tighter new collagen that is more pliable and soft. This is both from patient report and physical exam. For example, even the most atrophic vagina with a pinpoint hole for entry (not at all amenable to the large FemiLift or MonaLisa laser hand pieces) will get softer, more pliable, and moist that will even allow for comfortable sex after 3 treatments! ThermiVa's thin and gently curved hand piece allows for such delicate treatments. Because of blood flow ThermiVa does result in collagen regeneration that is needed for thickening of the vaginal lining and resolution of painful intercourse. Again, for clinical proof, look at the photos on www.thermiva.org. Lots of photos on the improved blood flow resulting in increased moisture.

What about the comment that ThermiVa is not able to get hot enough and "heats tissue to 50 Celsius, which may be too hot for a Jacuzzi but quite insufficient to cause collagen generation." This lacks clinical truth. There are many studies that show that tissue tightening occurs at around 42 Celsius and that it is both temperature plus time of exposure to heat that matters. ThermiVa can comfortably bring vulvovaginal tissues to 40-45 Celsius for 3-5 minutes and cause

immediate tissue contraction you can see during the treatment then tighten even more over the next 3 months. Again, look at the pictures. There is significant collagen regeneration.

Is FemiLift and other lasers like MonaLisa and IntimaLase really less expensive over the long haul over ThermiVa? Let's do some math. First, you can buy 2-3 ThermiVa systems for the price of one laser system. ThermiVa costs the doctor \$65,000. MonaLisa is \$175,000. FemiLift and IntimaLase are somewhere in between. Those prices are going down because of pricing pressure ThermiVa has exerted on the market. A good thing for doctors and patients both. So who has the larger lease payments and may need to charge more per treatment? For the patient, the average cost of 3 ThermiVa treatments is \$3500 in Southern California. Laser treatments are more expensive at some places and less in others. ThermiVa does need maintenance about once a year as do laser treatments. There is zero price advantage for laser systems over ThermiVa for both the doctor and the patient. It is inaccurate to say that ThermiVa treatments will be more expensive in the long run. I have had many calls and emails from doctors across the country asking me if there is a way to part with their expensive lasers and trade up to cost effective ThermiVa systems. They see the tsunami wave of ThermiVa damaging their laser vaginal rejuvenation business. I have not heard of a single ThermiVa user trading for a laser system. Just does not happen with happy doctors with a device that is game changing. The acceptance of ThermiVa has been widespread from OBGYNs, Plastic Surgeons, Dermatologists, Cosmetic Surgeons, and even bread and butter Primary Care doctors. You do not have to own a laser center or be a plastic surgeon to use ThermiVa successfully. When treatments are completed properly you cannot tell if it was done by a gynecologist or plastic surgeon.

So let's go point for point on a few things now:

Costs: ThermiVa is significantly cheaper for the doctor to use and probably about the same for the patient. The single use hand piece is cheap and disposable. The system warranty costs are a fraction of what laser companies charge.

Availability: ThermiVa is rapidly growing in availability worldwide because it is more affordable and fits the practice of gynecologists better than laser systems. Even plastic surgeons are opting out for ThermiVa over lasers since they own so many already.

Safety: No known adverse reactions or complications with ThermiVa. No blisters or burns. No need for a special laser room with signage, no need to use laser glasses or smoke evacuators or masks for the venereal wart viruses that may get in the air with laser systems when they smoke tissues.

Simplicity: ThermiVa is a simple lightweight box that can be carried or pushed from room to room or office to office quite easily. About the size of a small gym bag. No reticulating arms or smoke evacuator or mirrors to align and worry about. You press button to start it, raise or lower the temperature, use a simple disposable wand. Super simple controls without having to worry about watts, spot size, depth of penetration, patterns.

Convenience: ThermiVa has a single use wand. No cleaning of wand. No cross contamination. No sharing of vaginal hand pieces. You know it is a brand new and clean wand when you open the package yourself. Plus, with not having to switch hand pieces, there is no downtime when you go from external to internal treatments and no need to disconnect and reconnect anything. It is a totally seamless procedure.

Anesthesia: ThermiVa does not need any type of anesthesia. Laser systems typically do not need anesthesia for internal vaginal treatments but will most likely need anesthetic cream for treatment of the vaginal opening and labia majora. ThermiVa treatments feel like a warm stone massage while laser treatments are known to give prickly and pokey sensations during treatment. Downtime: Zero downtime for ThermiVa. You can have sex, go to the gym, do anything you want to immediately after treatments. There is no abnormal discharge after treatment. Laser systems claim no downtime also but there is a discharge from the ablative or resurfacing effects for 5-7 days. It is not appropriate to claim that there is no downtime or discharge with the use of FemiLift or MonaLisa or IntimaLase.

Versatility: Excellent for

Labia Majora Laxity: Non-surgical treatment

Vaginal Laxity: Non-surgical treatment

Atrophic Vulvovaginitis: Non-hormonal treatment

Stress Incontinence: Non-mesh treatment for mild to moderate incontinence

Overactive Bladder: Non-drug treatment

Pelvic Prolapse: Can reduce a fallen bladder or fallen rectum about one stage so that surgery may be avoided

Orgasmic Dysfunction: Average reduction in time to achieve orgasm is 50% in those with a problem achieving orgasms

Repetitive Vaginitis: Normalizes vaginal pH

Repetitive UTI: Normalizes vaginal tissues and vaginal pH

Lichen Sclerosis and Hyperplastic Dystrophy: Adjunct to steroid and PRP

Results: Patient satisfaction is very high with ThermiVa and the stories told are simply amazing. It is more than just tightening of the feminine structures! ThermiVa addresses the complete spectrum of feminine rejuvenation. Pelvic pain and discomfort from atrophy or dryness improves. Everyone who is dry and atrophic gets moister (even irradiated pelvis). Results for incontinence are similar to surgery and drugs. Improvement in orgasmic response is consistent for those who suffer with orgasmic dysfunction.

Doctor Training: No laser training needed with ThermiVa. Simple procedure. If you can do a Dilation and Curettage you can do ThermiVa.

Doctor Support: ThermiVa support is rapid and immediate and the reps are always available. They provide on-site training by their nurse instructors and also offer free webinars and live training at established centers such as mine.

I hope the time I have given thoughtful comments on this subject of ThermiVa versus lasers helps bring out facts and straighten out inaccuracies on what ThermiVa can and cannot do and shed light on the marvelous new non-invasive therapies now available to our beloved women. That is in fact 100% of my practice and 100% of my focus.

Warmest regards,

Red Alinsod, MD