FRACTIONAL/PIXEL CO_2 LASER THERAPY (FEMILIFT) FOR GENITOURINARY SYNDROME OF MENOPAUSE (GSM): ROUND TABLE DISCUSSION

A roundtable discussion, held in Rome on April 19, 2016 and sponsored by the European Society of Aesthetic Gynecology (ESAG), aimed to collect information from gynecologists and urogynecologists around the globe, who bring years of experience in treating thousands of women for genitourinary syndrome of menopause (GSM)-related symptoms. All participants have been using the FemiLift – Pixel/Fractionated CO_2 laser for several months/years.

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Introduction

Prof. Tadir: Having 40 years of experience with laser in gynecology, and in developing tools and treatment protocols for minimally invasive surgery, I have to admit that my initial reaction to publications on "vaginal rejuvenation" was somewhat skeptical. The results looked "too good to be true". However, the unprecedented wave of publications, originating from different countries, presenting coinciding results, is convincing. We face a significant breakthrough in women's health. Prospective research protocols (https://clinicaltrials.gov/) indicate that the medical community is taking this "new era" seriously.

In order to collect valuable data, reach reasonable conclusions, and guide future research, we gathered this panel of experts here in Rome, just before the ESAG meeting. Before we start our discussion, I take the liberty to quote Abraham Lincoln who said: **"You can fool all the people some of the time, and some of the people all the time, but you cannot fool all the people all the time".**

Tadir: *Given that this group of experts already performed thousands of Vaginal Rejuvenation (VR) procedures with the Pixel/fractional CO_2 laser (FemiLift), let's discuss the bottom lines. What is your overall impression? What are the main indications for which you find benefits from the FemiLift procedures? Please relate to the learning curve of the device. What level of surgical expertise is needed in order to conduct a safe procedure?*

Dr. Bader: During the last 4 years, I treated 987 patients in three different clinics, in London, Athens and Dubai. The main indication for which I use the FemiLift is vaginal relaxation and the second most common indication is stress urinary incontinence (SUI). I see some differences in patient preference, namely, patient priorities differ from one culture to another. For example, in the U.K., it is easier to discuss SUI as compared to Greece. In contrast, sexual quality enhancement is more important to the Middle East as compared to everywhere else I practice, as the local culture and habits allow men to marry more than one wife, motivating women to conserve or even enhance their bodies, including the intimate area.

The procedure is very simple, both to perform and to teach. No prior surgical skills are needed and once the doctor, be it a gynecologist or dermatologist, performs 3-5 cases, he/she has mastered the procedure. Interestingly and surprisingly, sometimes I find it more difficult to get the gynecologist to adopt the procedure. I am not sure why. But it is a matter of time until it will be widely adapted.

Dr. Martinec: I have a busy clinic in Slovenia. Between Sept. 2012 and Jan. 2014, I performed 332 procedures with the Er:YAG, mainly for SUI and vaginal laxity (VL). In the last 27 months, 388 procedures performed with the FemiLift for these two indications. From the practical and protocol point of view, the procedures are similar. Based on patient feedback I personally prefer the CO_2 laser, but this opinion is not based on scientific evaluation. The procedure is very simple and the system is user-friendly. The main indication in which I see benefit for the patients is in treating mild to moderate SUI and in improvement on vaginal laxity and dryness, as well. So far, I treated 388 patients with FemiLift, and analyzed data of 94 patients with follow-up of up to 9 months will be presented tomorrow at the ESAG conference. To give you some highlights of the data analyzed so far: the peak age group was 40-49 years-old, and 44% of the total number of patients were post-menopausal. The main patient complaints prior to the procedure were leaking urine following coughing, sneezing and physical activity. The most significant improvement was on SUI symptoms after coughing & sneezing. 28% or the treated patients did not have SUI and 47% of the patients experienced an episode of urinary leakage once a week. Regarding VL: among the 94 patients, 52 reported VL pre-treatment. In this group, 16 reported no VL following the treatment. Similar data was reported on the improved vaginal dryness. When I collected the complications and patient complaints of the entire group of 388 treated patients, about 45% had vaginal discharge for 3-7 days after the first treatment session, 80% of them in the first 3 days. Five patients reported uncontrolled urination for 24-48 hours, two patients reported elevated body temperature for one day, and one patient had mild vaginal adhesions, which I gently treated with hyaluronic acid and confirmed good outcome on follow-up.

Just for your information, the oldest patient treated was 92 presenting SUI. This lady was happy with the outcome, mainly because SUI symptoms improved significantly, she felt stronger pelvic support which helped in walking and improved her quality of life. However, because this is not a usual case she was excluded from the data analysis.

Prof. Scollo, Dr. Scibilia: From a technical point of view, the laser procedures are very simple and just a "low level prior expertise" is required. However, the mechanism of tissue remodeling is not clearly understood and requires more basic research in order to develop optimal treatment protocols. Clinically, this treatment concept opens a wide range of potential applications in treating GSM

symptoms, including SUI. We evaluated the potential advantage of FemiLift in menopausal cancer patients and currently, based on the Pixel/Fractional CO_2 laser concept, we use a dedicated delivery system to treat Lichen Sclerosus (LS) on the vulva.

Prof. Femopase: Our reported outcome of 131 patients who met the inclusion criteria for the SUI – FemiLift study, ages 35-60, assessed with ICIQ-SF (Short Form of the International Consultation on Incontinence Questionnaire): 82% of the patients reported a significant decrease in the frequency of SUI-related events, and all patients noted improvement in their quality of life as related to their urinary problems. It is an ambulatory, fast painless and easy procedure.

Dr. Elias: I agree with the panel experts in all their comments. The FemiLift procedure is easy, and user-friendly, but for the treatment of urinary incontinence, be it SUI, or any other form of urinary leakage, a urogynecologic background is important in order to select the optimal patients for this technique, and select the proper laser protocol to optimize the outcome. I used the Pixel/Fractional CO_2 laser for other indications, with good results. These include: dyspareunia caused by vulvar and vaginal atrophy, vaginal tightening in young women, and post-partum dyspareunia.

Prof. Tadir: *In summing-up all comments it is obvious that SUI is mentioned, however, data published in peer-review journals is minimal. Let's focus on this indication. Dr. Martinec detailed her impressive results with patients who report improved control of urination, and Dr. Elias report on SUI is in-submission for publication. Let me add another piece of information which is not "scientific", but interesting. In a recent meeting, two ladies, gynecologists from Dubai, who treated over 1000 women with fractional CO_2 laser for vaginal tightening reported that even though urinary incontinence was not the primary indication, many women reported improved control of urination following the procedure..*

Prof. Scollo, Dr. Scibilia: For all our SUI patients, we use a stress test, with 300 ml of bladder filling, and a standard questionnaire. A urodynamic test for all patients might be the best way to evaluate the preferred patient selection and the outcome, but this is not practical as a routine test. Currently, for publication purposes, we evaluate the outcome in patients who did have a complete urodynamic evaluation. This will enable us to generate guidelines for patient selection and to predict the duration of the outcome. In our practice, we focus on cancer patients. We noted an improved control of urination in cancer-related menopausal symptoms. This is probably related to their younger average age, and shorter menopausal time as compared to physiologic menopause. Since these patients can't use hormonal alternatives, they are grateful for this alternative and for the improvement in their quality of life. We also closely monitor the duration of effect, to avoid s rebound effect and to decide when to perform a "maintenance treatment".

Dr. Bader: For the SUI patients, I focus on the upper part of the vaginal wall and perform three laser exposures at 11-12-01OC, under the mid-urethra, and up to 1 cm above and below the upper and lower level, to mimic the concept of the urethral sling. The longest period of follow-up I have done is 3 years' post-treatment. An impressive case of cure of type IIa - SUI achieved just after the 2nd session, and maintained for 3 years. This was published as a case report in Hellenic Journal of Obstetrics and Gynecology (HJOG/2015).

Dr. Elias: As a trained urogynecologist, I am used to the Blaivas classification. I have found that best results are achieved with no, or minimal prolapse (Blaivas I or IIa). Assessment of pelvic floor damage

according to De Lancey, is important for my decision, and I did find the Q-Tip test, as an indication for urethral hypermobility, a good outcome predictor for the FemiLift procedure. Patients with pathological Q-Tip test (over 45o) might have hypermobility and damage to the urethral support. I Follow the concept that patients with urinary incontinence who most benefit from the FemiLift CO_2 laser are those without severe damage to the pelvic floor.

I treat the entire vaginal wall in all patients, but in the SUI patients, I add an "anterior wall protocol", which is an overlapping treatment at 11-12-01OC on the mid – anterior urethra. Patients are treated three times, at 4-week intervals, with a follow-up session at 6 months and a touch-up treatment, if needed. It is my impression that patients with hypo-estrogen-related urinary symptoms are cured, or at least experience temporary improvement.

Dr. Martinec: My treatment protocol is the same for GSM, with or without urinary incontinence. Some of my GSM patients who did not have urinary problems, reported reduced nocturia following the FemiLift procedure. My standard protocol includes two treatment sessions, 4 weeks apart, and if needed, a 3rd session after six months. The longest post-FemiLift follow-up in my clinic is 27 months. About 60% of my patients maintain positive results after the 2nd session, and I usually recommend an additional treatment once every 2-3 years.

Prof. Scollo - Dr. Scibilia: For vaginal atrophy as part of GSM, the entire vaginal wall is treated. If SUI is the main symptom, only the anterior wall is treated. We always use the Vaginal Health Index Score (VHI-S), assess infections, and in some cases, measure vaginal pH changes. Our longest follow-up is 12 months and the outcome will be reported in the near future. Our protocol includes 3 treatment sessions, at 4-week intervals. At this point, we do not offer a late "touch-up" session.

Prof. Tadir: *It is known that several prospective SUI studies are in progress. Once completed, we may learn some new lessons about the physiology of urination. The fractional laser technology may become an important tool in the armamentarium of minimally invasive solutions, in the same way that TVT revolutionized this field in the nineties. Let's move ahead to your experience utilizing the Fractional/Pixel CO_2 laser technology on the vulva.*

Dr. Bader: I use the laser for all external genitalia procedures. The hand probe is used for skin whitening and the focal laser hand piece for cutting and removing the excess tissues, either in labia minora, majora or clitoral hood skin. Lately, I introduced the de-focused hand piece "FemiTight" for labia majora tightening, and for perineal relaxation correction. Results are good.

Dr. Elias: For bleaching and/or tightening of the labia majora, I use the 9X9 dermal probe at high, 5 Hz. 30/60mJ per pixel. I use the 9X9 dermal probe at high, 1-2 Hz, 30/60 mJ per pixel, according to pain tolerance, and apply topical anesthetics. For the treatment of introitus atrophy, the FemiLift is turned on Low-10/20mJ – 1.5Hz repeat mode and a topical anesthetic is applied. The new de-focused hand piece offers a good option as well.
Regarding Lichen Sclerosus (LS), my initial experience with the Pixel technology is very promising. Two postmenopausal patients, resistant to conventional treatment with topical steroids, became asymptomatic shortly after three pixel CO_2 laser treatment sessions. Healthy tissue was maintained throughout the 6-month post-treatment period. Histological assessments showed a trophic epithelium with acantotic areas, and without superficial hyperkeratosis. Documentation of these cases has been submitted for publication.

Prof. Scollo / Dr. Scibilia: We started using this technology for pathological lesions such as LS, with promising results. Follow-up, which includes clinical findings and histology, is in progress. Rarely, patients reported having local recto-vaginal pain following treatment.

Prof. Tadir: *Several prospective studies on Lichen Sclerosus are in progress. Based on histologic evaluation, preliminary data indicate tissue healing. Once confirmed, this technology may offer, for the first time, a curative effect, unlike the known symptomatic effect with topical corticosteroids or estrogens. Dr. Martinec: You have the longest experience in this panel with Er:YAG and CO_2 laser, and we are looking forward to your presentation at the World Congress tomorrow on The G-Spot issue. Did you get any comments from patients regarding their post-treatment G-Spot orgasm, or questions regarding post-treatment vaginal delivery?*

Dr. Martinec: Some patients reported better feeling around the clitoris and improved sexual performance. I did not get any complaint, but once I review the literature for my G-Spot presentation, I will add more specific questions for future follow-up. It is my impression that improved vaginal elasticity and tissue relaxation post-treatment, will ease tolerance of pressures during future pregnancies.

Prof. Femopase: Proper education, and basic understanding of "sexology" are the most important tools when we approach the public, and medical professionals who are involved in this sensitive area. This means, disseminating basic knowledge of anatomy and physiology of external genitals, and giving deeper knowledge of universal rights on sexual health.
I am convinced that the FemiLift procedures, with its unique tissue effects, above and beyond "simple aesthetics practice", might play and important role in sexological intervention.

Prof. Tadir: *Do you have any recommendations regarding a dedicated informed consent for such fractional laser procedures?*

Dr. Bader: I routinely use the "Pre-FemiLift dedicated disclosure and informed consent".
These documents, prepared by Alma Laser, are available for the panel's review.

Prof. Tadir: *What is the panel's protocol for local anesthetics?*

Prof. Scollo / Dr. Scibilia: We use lidocaine/prilocaine (EMLA cream) for treating the distal vagina and vulva.

Dr. Elias: I use topical anesthetic cream (5% lidocaine + 7% tetracaine) applied topically on the vulva and introitus, about one hour before the procedure, and local cooling (ice or cryo-zimer device) as I start the procedure. Following treatment, patients are instructed to use anesthetic cream on the external areas, three times a day, for one week.

Dr. Martinec: According to my protocol, 23% lidocaine, and 7% tetracaine is applied topically around the introitus area.

Prof. Tadir: *What is the panel's experience with the need for the "FemiLift Slim", the small size probe?*

Dr. Martinec: It is my estimation that the slim probe is needed in about 5% of patients: mainly post-radiotherapy, or many years post-menopause..

Dr. Elias: It is a very useful device, and I use it in about 30% of my post-menopausal patients. In elderly patients, the standard probe might not be suitable. The disposable cover of the FemiLift probe is ideal to prevent infection and contamination. I recommend performing the procedure with a

headphone, to keep the patient relaxed. With no pain, relaxation eases the procedure.

Prof. Scollo / Dr. Scibilia: Same experience. We treat many menopausal and oncologic patients and use the "slim" device in 30% of our procedures.

Prof. Tadir: *How often you see vaginal discharge post FemiLift procedure?*

Dr. Bader: Almost all patients are reporting white transparent or pinkish discharge for few days after the treatment. I consider it normal reaction of the tissues to laser energy. Patients advised to ignore unless they have dark yellow or greenish discharge with the typical fishy smell. If Candida infection is diagnosed, this is treat with Fluconazole and FemiLift is delayed.

Dr. Martinec: Bloody or white vaginal discharge is seen in about 50% of patients and last for 3-7 days, and treated with hyaluronic acid.

Prof. Tadir: *Do you have any comment about the way these procedures are marketed?*

Dr. Bader: Having experience in three different countries, performing FemiLift in London, Athens & Dubai, I do advertise this treatment according to the local mentality, and take into consideration the cultural differences. For example, in Dubai, the concept is more advertisement for vaginal tightening and less for SUI. It happens because some local cultural characteristics. In the Greek society, it is easier to discuss SUI treatment rather than discussing improved sexual life. The UK society is mixed and universal, so marketing is broad.

Prof. Scollo / Dr. Scibilia: The doctor's role is just to be honest, to avoid over-expectations while using proper patient selection.

Dr. Martinec: My preferred marketing is patient education about SUI and vaginal laxity. I started a new educational program about post-delivery vaginal rehab.

Prof. Tadir: *Dr. Bader and Dr. Martinec: with your extensive experience, longest follow-up, and educational experience, would you like to make some concluding remarks?*

Dr. Bader: I have tried the diode 980nm & 1470nm lasers, as well as the Er:YAG. The Pixel/Fractional technology is preferred, it is safe and provides a long-lasting effect. Some other lasers could give you good results, but the fact that CO_2 combines minimal ablation and a deeper thermal effect, are the most significant factors contributing to its ability to induce vaginal rejuvenation

Dr. Martinec: Having long-term experience with different laser wavelengths, it is my impression that results are better with the CO_2 laser.

Prof. Femopase: Since 1989 we use the CO_2 laser for reconstruction of the external genitalia (labioplasty and reduce tension of the labial glands) which improves orgasmic response. During this time, we performed more than 500 procedures using the "conventional" laser. We never had any serious complication, as the pudendal nerve runs under deeper anatomical planes. We use two modalities: ablative, to remove excessive tissues, and defocused laser beam to induce thermal effect, causing retraction of areas involved during the orgasmic response. The FemiLift – Fractional / Pixel CO_2 laser technology - gives us a new dimension in the treatment vaginal and vulvar rejuvenation.

Prof. Tadir: *Data published so far, and the collective information gathered by experts is convincing, suggesting that we face a "game-changer" in the*

treatment of GSM. Basic research on mechanisms of vaginal tissue rejuvenation, and prospective clinical studies are on-going. Once completed, solid data of tissue remodeling may re-define our understanding of vaginal physiology and control of urination. We hear about more innovations such as fractional laser treatment primed by topical estrogen, intra-urethral fractional laser, and studies about the potential healing effect of pathological conditions such as Lichen Sclerosus. These are exciting times for pioneers. I would like to congratulate Dr. Bader for organizing the World Congress of the newly formed E.S.A.G. starting tomorrow, with so many leading figures from all over the world.

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