By Edita Krajnovic

An interview with Prof. Marco Gambacciani, Director of the Menopause Center at Pisa University Hospital.

About
Marco Gambacciani, M.D.

Dr. Marco Gambacciani graduated in 1978 from the University of Pisa and finished his residency in Obstetrics and Gynecology in 1982. He then attended the University of California were he undertook his Fellowship in Reproductive Endocrinology. Since 1987 Dr. Gambacciani has been a Professor of Obstetrics and Gynecology and the Director of the Menopause Center at the Santa Chiara University Hospital's Department of Reproductive Medicine in Pisa, Italy. He has also been member of the medical advisory board at Bionovo, Inc. since 2010. Dr. Gambacciani has served as a member of the Executive Committee of the International Menopause Society and is a member of the Executive Committee of the European Menopause and Andropause Society, as well as being a member of other professional societies. He has authored more than 120 papers in peer-reviewed international journals.

FotonaSmooth®: The Best Choice in Terms of Safety, Results and Patient Satisfaction

You have been working with laser systems for treating gynecological disorders since 2013, after being introduced to minimally-invasive Er:YAG technology. What convinced you that traditional treatment methods were not enough?

In the last 40 years I have treated thousands of postmenopausal women. I can say that the management of the postmenopausal years requires extreme personalization according to the needs, characteristics and preferences of each particular postmenopausal woman. That's why there is no best cure, or only choice. One choice, one size doesn't fit all. Consequently, I was excited by this new opportunity to treat vaginal atrophy with the laser. With one machine, by simply changing the settings, we have the ability to treat the initial stages of vaginal prolapse and stress urinary incontinence. It's a great achievement for improving women's well-being and quality of life.

There are many laser manufacturers on the market. You chose Fotona and their FotonaSmooth® gynecological laser. What makes them different from other laser manufacturers?

I reviewed all the available literature back when I approached this new option for my research activities and clinical work. No other machine was able to provide the option to treat, with the same non-invasive technology, either vaginal atrophy, vaginal prolapse, or stress urinary incontinence. In the following years, we have personally established new, and I believe strong, evidence that the Fotona Smooth® technology offers the best choice for the practicing gynecologist in terms of safety, results and patient satisfaction.

One common belief is that clinicians are averse to new technology, but you appear to have embraced it. Which are your favorite technological features of the FotonaSmooth® laser system, and why?

The FotonaSmooth® laser technology is not just minimally invasive, it is a completely non-invasive procedure. The Erbium SMOOTH™ mode is not ablative, causes no bleeding, pain or scars. It is really a patient-friendly procedure. The gentle, but intense heating of the vaginal tissues can guarantee positive results in more than 80% of patients.

Most gynecologists still stick to traditional, often more-invasive gynecological methods such as surgery, and fail to see the benefits of laser technology for both the practitioner and patient. What is your experience? Are your colleagues and patients aware of laser technology and its benefits?

Let's say that the vast majority of OB/GYN practitioners around the world are not aware of this new opportunity. Consequently when they hear about it, they are suspicious, uncertain, and skeptical. They don't believe that such a gentle treatment can offer an effective and long-lasting treatment. The same apply to the vast majority of women. They simply don't know about Erbium SMOOTH™ technology and the Vaginal Erbium Laser (VEL). That's why I started the Vaginal Laser Academy (VELA), an independent scientific organization devoted to women's health and quality of life by developing and implementing innovative VEL medical applications for functional vaginal restoration. VELA promotes Erbium SMOOTH™ laser in schools, local and international meetings, congresses, and encourages the exchange of research and professional experience between members.

> I believe that in the near future a real turning point will be laser treatment for prevention in order to maintain normal vaginal functions.

If we look at specific disorders, vaginal atrophy is a very common indication, affecting over half of post-menopausal women in their 50s and having a significant impact on their quality of sexual life. What is your experience with RenovaLase® when you compare it with standard therapies?

In a word, great! I have treated hundreds of women, and we have published many papers about the significant and rapid effects of RenovaLase®. In normal postmenopausal women, the effects of VEL are very rapid compared with the standard hormonal therapies, but also longer lasting – up to 12-18 months after the laser application. In our studies, 83% of our patients asked to repeat the treatment: in my mind this is the best demonstration of the effectiveness of VEL on vaginal atrophy. VEL is the best treatment for breast cancer survivors. With these women, hormonal therapies are not allowed, and these women, often young in their thirties and forties, are really "lone survivors" left alone by practicing physicians, oncologists and gynecologists. Their sexual life becomes a real nightmare after the iatrogenic menopause. With RenovaLase® the effects are astonishing and their sexual life is not jeopardized by atrophy anymore, without hormones and also without the annoying moisturizers and lubricants.

You also have a lot of experience performing the so-called IncontiLase® treatment for stress urinary incontinence. Could you tell us more about this application and how laser treatment of SUI has improved patient outcomes?

The effects of IncontiLase® on urinary incontinence are really surprising. The effects are evident in my experience after the second and sometimes after the third laser application, but definitely the effects can improve incontinence. Again, the effects are there in more than 80% of our patients, with significant improvement of continence for up to 12-18 months. More than 70% of our patients repeated the treatment, thereby avoiding surgery. Only 7% of the women selected for VEL treatment underwent SUI surgery. I think that with IncontiLase® we can avoid unnecessary surgical procedures, save money as well as patient distress and pain.

Up to now, there were only two solutions available for pelvic organ prolapse: supporting pessaries and surgical mesh. With the introduction of the ProlapLase® minimally invasive laser treatment option, the future of POP treatment is looking bright. What do you see as the main benefits of POP laser treatment?

The effects of ProlapLase® on the initial steps of POP are really encouraging, mainly when we are dealing with a defect of the anterior vaginal wall, the cystocels. However, when a woman is presenting with a severe grade of hysterocele, the prolapse of the uterus with minimal if any prolapse of the vaginal walls, the laser procedure cannot be effective. Patient selection is by far the most important and limiting factor for ProlapLase effectiveness. The gynecologist must select the proper patient: ProlapLase is a great option in young women with anterior wall prolapses or in women of all ages with cases of vaginal laxity, particularly those who have delivered large babies, and it's more common with ageing. The treatment can restore a woman's self-confidence and sexual gratification.

Practitioners don't believe that such a gentle ProlapLase® treatment can offer an effective and long-lasting treatment. The same applies to the vast majority of women.

If we move on to aesthetic laser gynecological treatments, such as vaginal tightening, what is your opinion on the latest innovations in this field of gynecology?

Vaginal tightening is not just an aesthetic procedure, but it is a functional application of the laser, since it does affect sexual functions, sexual response, orgasm and satisfaction. This is a great innovation for women's sexual well-being and quality of life.

Amara's Law states, "We tend to overestimate the effect of a technology in the short run and underestimate the effect in the long run." A laser system is a substantial investment, but are practitioners underestimating the long-term higher value of providing gynecological laser treatments? Has your practice grown since introducing laser technology?

Amara's Law doesn't apply to my own laser experience. I was really skeptical and doubtful in the beginning, I was not a confident user. After just 6 months, looking only at the very first, objective data we were collecting, I already recognized the great opportunity I was experiencing. I definitely gained reputation after introducing VEL in my practice. In addition to the scientific paper I published, the laser gave me the opportunity, after treating many patients, to become a reference physician with my gynecology colleagues. The laser investment can increase gynecology revenue in a very short time.

What emerging trends do you see in minimally-invasive laser gynecology in five to ten years' time? Could you say that soon, modern gynecology without a laser will just not be modern?

I do believe that in the near future the functional vaginal restoration for vaginal atrophy, relaxation and urinary incontinence will be a common practice in gynecology, not only for therapy but also for prevention. This will be the future, a real turning point: laser treatment for prevention in order to maintain normal vaginal functions. Our recent findings suggest to repeat the laser treatment every 12 to 18 months.

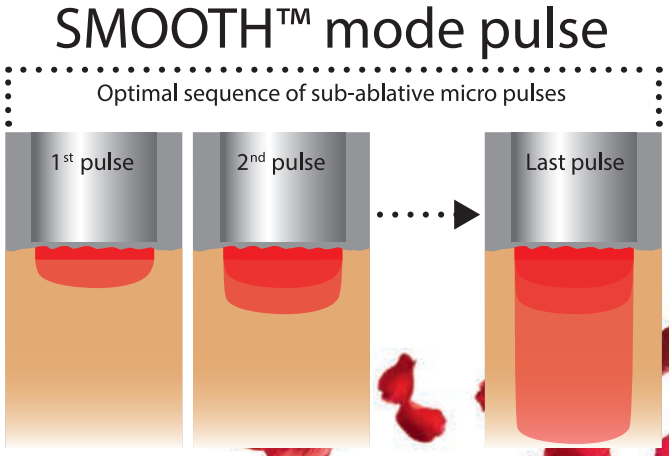
SMOOTH™ mode
A revolutionary technological development for delivering the optimal sequence of heat pulses to the vaginal mucosa

- Delivers patented sequential Er:YAG laser pulses to the vaginal wall mucosa, generating controlled and optimal distribution of heat within the tissue in a non-invasive, non-ablative manner.

- The result is collagen remodeling and neo-collagenesis which strengthens and rejuvenates the vaginal wall, improves the pelvic floor support and diminishes symptoms of pelvic floor dysfunction.

- Highly controlled, safe procedure with no impact to any critical structures, including any penetration or disruption of the mucosal lining.

- **SMOOTH™ mode non-invasive treatments include:**
  - **Stress Urinary Incontinence (IncontiLase®)**
  - **Vaginal Relaxation Syndrome (IntimaLase®)**
  - **Genitourinary Syndrome of Menopause (RenovaLase®)**
  - **Pelvic Organ Prolapse (ProlapLase®)**



Unique sequential SMOOTH™ mode Er:YAG laser pulses generate an optimal structure of heat waves.

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What is your motivation for constant improvement, and what final advice would you offer to your colleagues?

We should cite Steve Jobs' motto, "Stay hungry. Stay foolish". In order to improve our medical skills, we must gain new knowledge. Don't be happy with your yesterday – learn something fresh day after day! As gynecologists, we are used to performing surgery and prescribing hormones, but rarely are we laser experts. The laser training is straightforward: it took me only few sessions to become confident with the procedures, thanks to the well-defined and characterized Fotona applications and protocols. The Fotona laser gave me a great new opportunity to improve my clinical practice in the management of very common female disorders. We can learn from the past, but we can only grow in the future, with passion, confidence and intuition.