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• Revitalisation de la muqueuse vaginale
• Traitement de l'incontinence urinaire d'effort et mixte
• Rééquilibrage du pH vaginal
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Is vaginal fractional CO_2 Laser treatment effective in improving overactive bladder symptoms in post-menopausal patients? Preliminary results

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Abstract. – OBJECTIVE: To evaluate the role of vaginal fractional CO_2 laser treatment in the relief of Overactive Bladder (OAB) symptoms in post-menopausal women.

PATIENTS AND METHODS: Post-menopausal women who complained of one or more symptoms related to vulvo-vaginal atrophy (VVA), who experienced symptoms of OAB and who underwent vaginal treatment with fractional CO_2 laser were enrolled in the study. At baseline (T0) and 30 days post-treatment T1), vaginal status (using Vaginal Health Index – VHI), subjective intensity of VVA symptoms (using a visual analog scale – VAS) and micturition diary were evaluated. OAB symptoms were also assessed using a validated questionnaire.

RESULTS: Thirty patients were enrolled. A statistically significant improvement in VVA symptoms was observed and in VHI at T1 ($p < 0.0001$). A significant improvement was also identified in the micturition diary, in number of urge episodes and OAB-q ($p < 0.0001$). Nine of the 30 patients suffered from incontinence episodes, and had improved at T1.

CONCLUSIONS: In our experience, fractionated CO2 laser vaginal treatment has proved to be effective in improving OAB symptoms in post-menopausal women. Moreover, it is a safe and efficacious measure for the relief of VVA related conditions. Further long-term studies are needed to confirm these preliminary results.

Key Words:
CO_2 laser, Overactive bladder, Menopause, Vulvo-vaginal atrophy.

Introduction

Vulvo-vaginal atrophy (VVA) is defined as the progressive involution of urogynecological mucous membranes and tissues due to the menopausal drop in oestrogen levels[1,2]. It may lead to the occurrence of bothersome symptoms (vaginal dryness, itching, burning, irritation and dyspareunia), with a significant impact on quality of life (QoL) and sexual function[3,4].

Resolving "vulvo-vaginal aging symptoms" is a very timely issue, firstly because, considering the progressive aging of the general population, women may complain of these symptoms for more than one-third of their lives[5]. Many hormonal and non-hormonal strategies have been proposed to alleviate VVA symptoms[5-8], with the aim of identifying an effective, safe and long-term therapeutic option. Recently, by applying the principles of regenerative and anti-aging medicine, the use of fractional CO_2 laser has been extended to treating patients with VVA symptoms[9,10].

Through the topical remodeling of connective tissue and the production of new collagen, elastic fibers and other components of the extracellular matrix, laser CO_2 effects appear to overcome the negative vaginal changes related to climacteric estrogenic fall, with significant relief of related symptoms[9,10].

Data from our recent study indicate a significant improvement in VVA symptoms ($p<0.0001$) in women who underwent 3 sessions of fractional CO_2 laser vaginal treatment, with a relevant increase in vaginal health index (VHI) scores ($p<0.0001$) and a good level of satisfaction for the procedure[11]. During data collection for this study, an unexpected event occurred. A sample of menopausal women who had complained of urinary

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problems, such as urgency or frequency, (in addition to VVA symptoms), reported a concomitant relevant improvement in urinary symptoms, after CO_2 laser treatment.

Starting from these clinical observations, we decide to evaluate the possible role of fractional CO_2 laser vaginal treatment in the relief of over active bladder (OAB) symptoms in post-menopausal women. Moreover, VVA symptom and VHI score improvements were also analyzed in the same study population.

Patients and Methods

Study Patients

The enrolled patients for this prospective observational pilot study were menopausal women who had complained of one or more symptoms related to VVA, who experienced symptoms of OAB and who underwent vaginal treatment with fractional CO_2 laser from January 2014 to January 2015. The inclusion criteria consisted of menopausal status (including early forms), one or more vulvovaginal symptoms (e.g., itching, burning, reduced lubrication, superficial and/or severe dyspareunia), non-response to previous oestrogen or local therapies, and diagnosis of OAB syndrome.

We defined OAB syndrome as all the cases which in woman complained for ≥3 months frequency of micturition on average ≥8 times per 24 h and at least three episodes of urgency (grade 3 or 4), with or without incontinence, during a 3-day micturition diary period at baseline[12].

Exclusion criteria at study entry were considered: clinically significant bladder outflow obstruction, significant post-void residual (PVR) volume (>200 ml), associated stress urinary incontinence (SUI), diabetic neuropathy, use of concomitant urinary incontinence medications, symptomatic urinary tract infection, active genital infections, previous pelvic radiation therapy, or previous or current malignant disease of the pelvic organs, pelvic organ prolapse (POP) stage >II (according to the *Half Way System* for the quantification of POP)[13] and/or the use of HRT (systemic or local) up to 6 months before the study recruitment period.

Patients who used vaginal lubricants or any other local preparations were asked to suspend the application of these treatments and were included in the study after 30 days. Women who were using psychotropic drugs were excluded.

The study was approved by the Hospital Research Committee. All patients who were recruited for the study signed an informed consent form.

Laser Device

A fractional CO_2 laser system (SmartXide^2 V^{2}LR, Deka m.e.l.a., Florence, Italy) was equipped with a Vulvovaginal Laser Reshaping (V2LR) scanning system and appropriate probes for the vaginal area. This treatment modality is based on the interaction between a specific CO_2 pulsed laser and the vaginal mucosa.

A laser beam is emitted fractionally, and the CO_2 laser is focused in small spots (called DOTs) that are separated by healthy tissue. The laser beam penetrates the tissue and releases heat only when the set depth is reached. With software control and a radiofrequency system that feeds the laser source, it is possible to select the D-Pulse mode, the depth (SmartStak parameter, from 1-3) and the quantity (power, dwell time and spacing) of heat to be transferred to the tissue. The SmartStak function allows for the careful control of the vaporization depth and thermal action. Successive pulses are emitted in the same area for a Stack variable of 1-3 (in the vaginal application).

Every pulse is composed of a constant high-energy peak power to produce rapid ablation of the epithelial component of the atrophic mucosa, followed by longer emission times (dwell time) that allow the CO_2 laser to penetrate further into the mucosa. The pulses are distributed over the vaginal wall and are spaced (DOT spacing) to cover the entire treatment area. A specific probe is used to deliver the pulses, which allows for energy emission at 360°.

In this study, a calibrated probe was specifically utilized for vaginal application, easily inserted into the vaginal canal. The laser is projected towards a 45°-oriented mirror that is placed at the tip of the probe to be reflected on the vaginal walls but not the uterine cervix. To completely treat the vaginal area, it is necessary to emit many laser spots while progressively extracting the probe from the vaginal fundus up to introitus.

Each treatment spot consists of two passages: after the first energy release, the probe is rotated approximately 2 cm (using the regulatory tool) clockwise while remaining at the same vaginal distance.

Laser Treatment

Each patient was treated with the fractional CO_2 laser system using the vaginal probe. All patients underwent a complete cycle of three treat-

ment sessions that were spaced over a period of at least 30 days.

For each patient, a Pap test and vaginal swabbing were performed to rule out local lesions or infections. The procedure was performed in the outpatient clinic by two operators (A.P. and G.C.), and the patients did not receive analgesia or anaesthesia. The settings for intra-vaginal treatment were a *DOT power* of 40 watts, a *dwell time* of 1,000 µs, D*OT spacing* of 1,000 µm, *SmartStak* 2 and the *D-Pulse* mode; when necessary, the *DOT power* was reduced to 30 or 20 watts for the treatment of the vaginal introitus, which is a highly sensitive area (Figure 1).

As previously reported[11], before all treatment sessions, we proceeded to positioning of the speculum and observation of the vagina using colposcopic vision (Vaginal Health Index – VHI scoring was performed during this phase).

No local therapy was recommended after the laser sessions. To avoid vaginal irritation during the healing process, patients were advised to avoid coital activity at least for a week following each laser application. Any secondary or collateral effects of the treatment were recorded. For study analysis, two relevant time points were considered for the evaluation of treatment results: baseline (T0) and 30 days after the last laser application (T1).

Study Data

Relevant demographic characteristics, pre-treatment clinical data and inclusion/exclusion criteria were recorded at T0. At T0 and T1, the vaginal status of the patients was evaluated using VHI score (obtained using colposcopic vision), which consisted of the following 5 parameters: elasticity, fluid volume, pH, epithelial integrity and moisture. Each parameter was graded from 1 (worst condition) to 5 (best condition).

Intensity of VVA symptoms was also evaluated at T0 and T1 (vaginal itching, vaginal burning, vaginal dryness and dyspareunia) using a visual analog scale (VAS), which is based on a score from 1 to 10, where 1 indicates the absence of symptoms and 10 indicates severe symptoms ("as bad as it could be").

At T0 and T1, eligible patients adduced a micturition diary, which was to be completed during the 3 days preceding the visit. In the diary, patients were asked to specify the number of micturitions, number of urgency episodes and number of incontinence episodes, for every considered day.

Moreover, patients rated the degree of associated urgency on the five-point Patient's Perception of Intensity of Urgency Scale (0, no urgency; 1, mild urgency; 2, moderate urgency; 3, severe urgency; and 4, urge incontinence)[12], and only cases

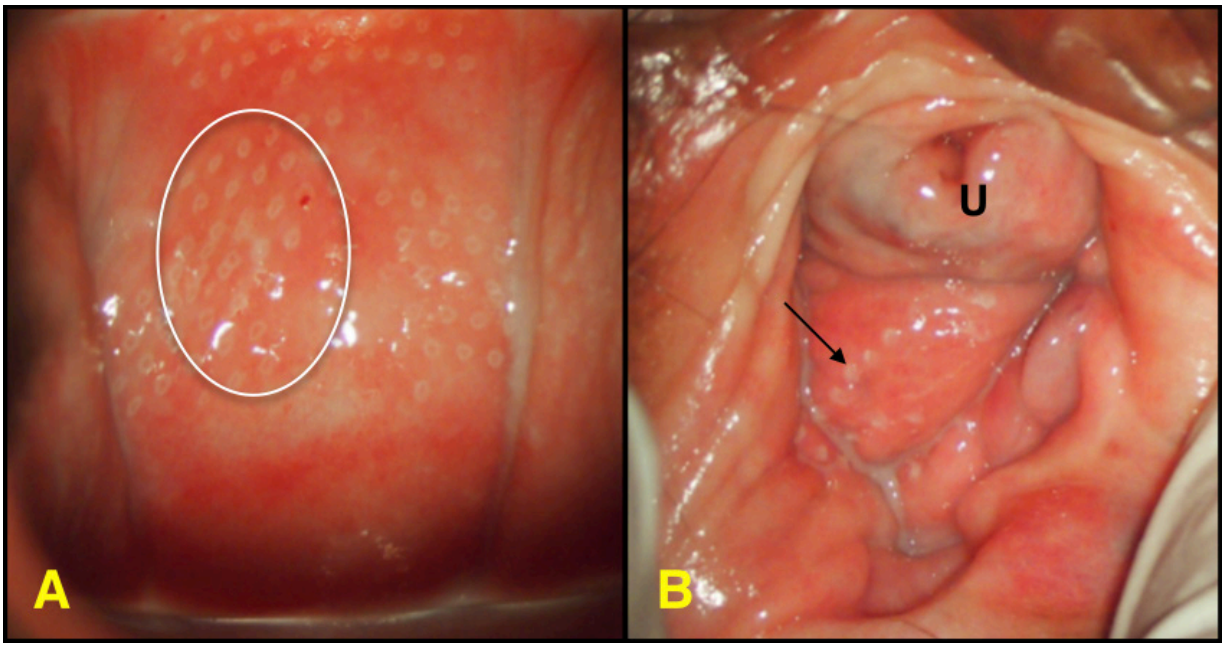

Figure 1. ***(A-B)*** Colposcopic view of vaginal walls immediately after a session of fractional CO_2 laser therapy. In ***A*** e ***B***, macropores of thermal ablation zones are highlighted in anterior vaginal wall (withe ring) and sub-urethral area *(arrow)*; U: urethral meatus.

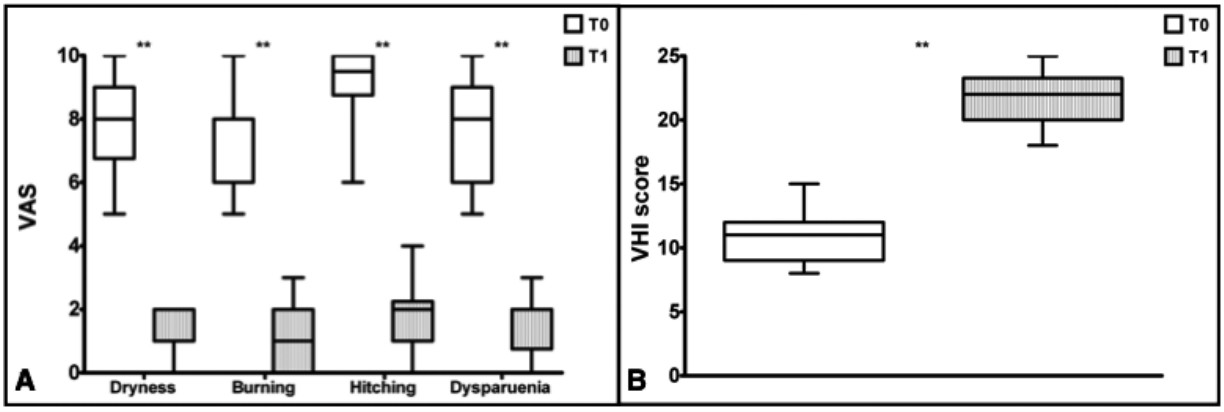

Figure 2. ***(A-B).*** VAS – dryness, – burning, – itching, – dyspareunia ***(A)*** and VHI score ***(B)*** are represented by Box-whiskers (medians, 1st and 3rd quartiles, minimum and maximum values). Statistical analysis was performed using Wilcoxon test, **means $p<0.0001$.

of 3 and 4 degrees of intensity were considered for analysis.

Overactive bladder symptoms were assessed using the validated Overactive Bladder Questionnaire Short Form (OAB-Q SF)[14].

Eventual adverse events which occurred or were referred by patients (during, immediately after treatment sessions, and until the end of study) were recorded. We considered any disorder, discomfort or injury, both local and general, arising in relation to the application of the vaginal fractional CO_2 laser as an adverse event.

Statistical Analysis

Statistical analysis was performed with SPSS for Windows (version 17.0, SPSS Inc., Chicago, IL, USA). Data were presented as median/IQR. Differences between VAS at T0 and T1 were analyzed with Wilcoxon test. Statistical significance was set at $p<0.05$.

Results

In the study period, 30 patients were enrolled. Demographic characteristics are reported in Table I. Patients had used systemic HRT and/or vaginal estriol with no benefit, before vaginal CO_2 laser treatment, in 20% and 36.7% of cases respectively. All patients included into the study completed the study-protocol and carried out the final evaluation at T1. We observed a statistically significant improvement in VAS parameters concerning dryness (8/3 *vs.* 2/1.25; $p<0.0001$), burning (8/2.25 *vs.* 1/1; $p<0.0001$), itching (8/2 *vs.* 1/2; $p<0.0001$) and dyspareunia (9.5/1.25 *vs.* 2/1.25; $p<0.0001$) (Figure 2A).

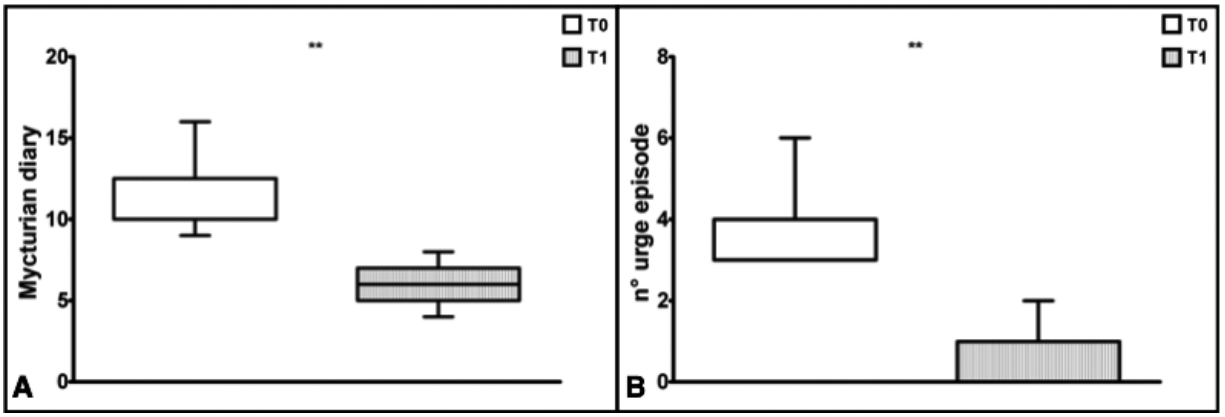

Figure 3. ***(A-B)*** Micturition diary ***(A)*** and n° urge episodes ***(B)*** are represented by Box-whiskers (medians, 1st and 3rd quartiles, minimum and maximum values). Statistical analysis was performed using Wilcoxon test, **means $p<0.0001$.

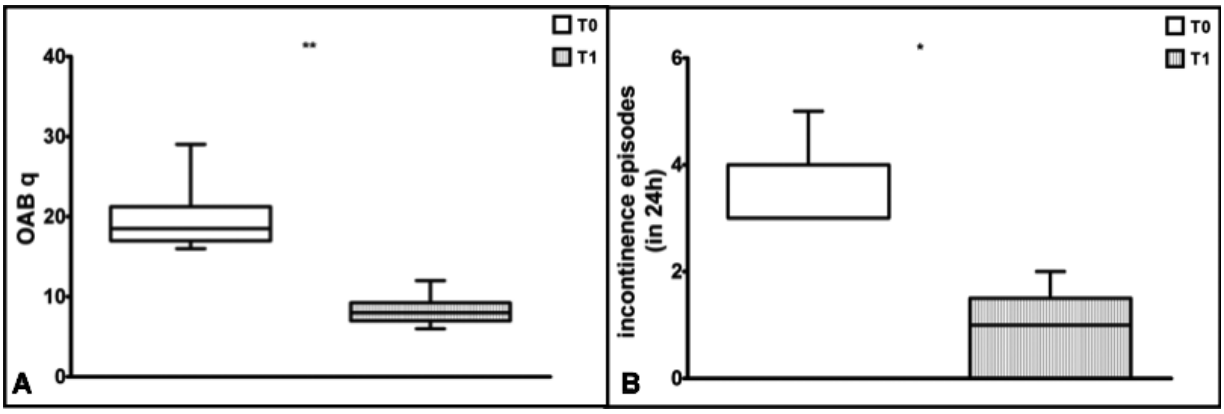

Figure 4. ***(A-B)*** OAB q ***(A)*** is represented by Box-whiskers (medians, 1st and 3rd quartiles, minimum and maximum values). Statistical analysis was performed using Wilcoxon test, **means $p<0.0001$. In ***B***, incontinence episodes (in 24h) are represented by Box-whiskers (medians, 1st and 3rd quartiles, minimum and maximum values); statistical analysis was performed using Wilcoxon test, *means $p<0.05$.

We also reported a significant improvement in VHI at T1 (11/3 *vs.* 22/3.25; $p<0.0001$) (Figure 2B), in micturition diary (10/2.5 *vs.* 6/2; $p<0.0001$) (Figure 3A), in number urge episodes (3/1 *vs.* 0/1; $p<0.0001$) (Figure 3B) and in OAB-q (18.5/4.25 *vs.* 8/2.25; $p<0.0001$) (Figure 4A). Nine of the 30 patients suffered from incontinence episodes, and had improved at T1 (3/1 *vs.* 1/1.5 episodes in 24 h; $p=0.006$) (Figure 4B).

No significant differences were observed between patients or between the sessions for the same patient. No adverse events due to fractional CO_2 laser treatment occurred. In no case was it necessary to stop the procedure because of patient pain or intolerance. No local therapies were prescribed to any patient after the sessions of laser treatment.

Discussion

Overactive bladder is a wide-spread problem characterized by symptoms of urinary urgency, frequency and nocturia, with/without urgency incontinence (UI) and in the absence of lower urinary tract infection[15,16]; it may cause significant disability, reduced QoL, along with social relationship and sexual function deterioration[17,18]. It is known that this chronic condition requires life-long therapy to control symptoms, with the aim of restoring QoL while balancing efficacy and side effects[19].

Generally, an early approach to the problem involves conservative measures such as dietary controls, fluid modification and pelvic floor muscle rehabilitation, but the results are frequently poor. Antimuscarinic agents are used as first-line pharmacotherapy in the management of OAB, with well-documented effectiveness in the clinical literature[18,20]. However, patients often discontinue this therapy for many reasons including intolerable side effects (dry mouth, constipation and blurred vision) or/and lack of sufficient symptom relief[21,22].

A recent pharmacological alternative is mirabegron, a β3-adrenoceptor agonist that elicits bladder relaxation during the storage phase of the micturition cycle, without inhibiting bladder voiding[23]. It provides treatment benefits in OAB patients and its tolerability profile suggests that it may represent a valuable therapeutic option[24,25]. However, randomized prospective trials are still lacking[23]. Likewise, with regard to intravesical botulinum toxin for management of OAB, a few controlled trial data exist on its benefits and safety[26]. Reported adverse events following botulinum toxin administration may be related to the drug (constipation, transitory asthenia, dry mouth) or the associated procedure (pain, haematuria)[26]; moreover, robust data are required on long-term outcomes and optimal dose of botulinum toxin.

Table I. Demographic characteristics of the study population.

Age (median/IQR)	56/8.5
Body Mass Index (median/IQR)	23.9/3.49
Parity (median/IQR)	1/1.25
Smokers (n, %)	5 (16.7)
Urge incontinence (n, %)	7 (23.3)
Previous HRT (n, %)	6 (20)
Previous vaginal estriol (n, %)	11 (36,7)
Other previous therapy (n, %)	21 (70)

Finally, neuromodulation therapy could be another possible approach[19]; in particular, sacral nerve stimulation with an implantable device has demonstrated the efficacy in managing OAB symptoms[27]. However, it has been limited in clinical practice due to several factors including invasiveness, associated costs, limitations in older adult patients and those who are frail or who have several medical comorbidities[28].

In this pilot study, we assessed the clinical effects of fractional CO_2 laser vaginal treatment on the main symptoms associated to OAB syndrome, such as frequency, urgency and eventual incontinence episodes, in a sample of post-menopausal women. Our results indicated a significant reduction of number of micturitions and number of urge episodes (p<0.0001) in women who underwent 3 sessions of vaginal CO_2 laser treatment. Concerning the subgroup of patients suffering from urge incontinence, a significant reduction in the number of daily episodes was shown (p<0.0001). Moreover, the changes of OAB-q score in T1 indicated a subjective significant improvement (p<0.0001), with particular reference to the incidence of OAB problems in QoL of the patients.

Finally, results of this study confirmed that CO_2 laser treatment was effective in improving VVA symptoms and VHI scores (p<0.001) at a T1 follow-up.

The observed phenomenon on OAB symptoms is explained starting from the anatomical characteristics of the urogenital tissue. It has been well demonstrated that urogenital organs are highly sensitive to the influence of oestrogen; oestrogen receptors have been found in the urethra and bladder trigone, as well as in the round ligaments and levator ani muscles[29]. As occurs in vaginal tissue, the progressive decline of estrogens during the climacteric produces atrophy of the urethral and bladder mucosa, causing urinary urgency, frequency and nocturia-OAB symptoms; accordingly, atrophy of muscles and reduction of collagen content may be important factors in the increased prevalence of urinary incontinence[30].

As previously reported[9], fractional CO_2 laser system can irradiate deeper layers of the vaginal wall and ultimately reactivate the extracellular matrix and collagen synthesis, with beneficial effects in the 3 layers of the vaginal wall (in contrast to estrogens or other local therapies that only treat the epithelium). In this way, it is possible to presume that the "regeneration" effect of the vaginal laser CO_2 treatment also involves the lower urinary tract (urethra and bladder), with a significant improvement of urogenital aging symptoms.

To the best of our knowledge, this is the first experience on the topic in international literature; however, this study has some limitations. First of all, the absence of randomization or a control group of patients; secondary, the small sample size considered and lack of long-term follow-up. Further studied are needed to confirm these results and to define the potentialities of this approach.

Based on these preliminary results, it would be advisable to perform a new study that includes a control arm (e.g. intravaginal estriol administration) to compare laser CO_2 with other proposed therapeutic options, in the contemporaneous relief of VVA and OAB symptoms, evaluating the long-term outcomes.

Conclusions

Our preliminary results suggest that fractionated CO_2 laser has a role in improving OAB symptoms in post-menopausal women. Moreover, achieved data confirmed that it is a safe and effective measure for the relief of VVA related problems. Considering the lack of a shared guideline for the management of OAB syndrome, we think that this study could lead the way to an alternative approach, tailored for menopausal women complaining of VVA and OAB symptoms.

Conflicts of interest

The authors declare no conflicts of interest.

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Les paramètres utilisés (sur la base des études d'efficacité et d'innocuité immédiate menées ex-vivo) : puissance de 20 à 40W, temps d'impulsion de 1000 µs, espacement des micro-points de 1000 µm, stacking de 1 à 3.
La pièce à main est introduite dans le vagin sans lubrifiant puis on procède au traitement à 360 degrés de toute la paroi vaginale (hors col utérin). Le cycle de traitements comprend 3 séances espacées de 4 semaines. Les rapports sexuels sont évités pendant 3 jours après chaque séance en raison d'une réaction inflammatoire de 48h.

Les critères d'efficacité, selon les études déjà publiées
Ce sont :
- Les 5 items du score VHIS (Vaginal Health Index Score) : élasticité, volume des secrétions, le pH, l'intégrité épithéliale et l'hydratation. *(Figures 2 et 3.)* Ces items sont côtés de 1 à 5 (AVV effective si < 15) à T0, T1, T2 et à T3. (Le pH est prélevé aux parois latérales du vagin).

Score	1	2	3	4	5
Elasticity	none	poor	fair	good	excellent
Fluid Volume (Pooling of Secretion)	none	Scant amount, vault not entirely covered	superficial amount, vault entirely covered	moderate amount of dryness (small areas of dryness on cotton tip applicator)	normal amount (fully saturates on cotton tip applicator)
pH	≥ 6.1	5.6 - 6.0	5.1 - 5.5	4.7 - 5.0	≤ 4.6
Epithelial Integrity	petechiae noted before contact	bleeds with light contact	bleeds with scraping	not friable – thin epithelium	normal
Moisture (Coating)	none, surface inflamed	none, surface not inflamed	minimal	moderate	normal

Table 1: Gloria Bachman Vaginal Health Index (VHI).

Figure 2 - Le Vaginal Health Index

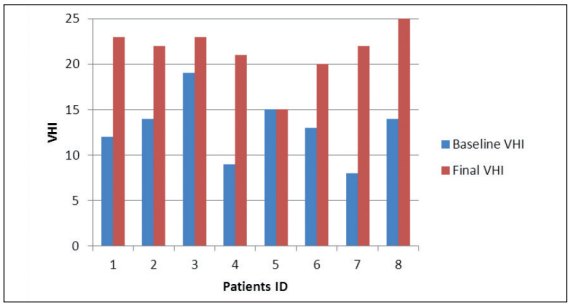

Figure 3

- Autres données cliniques supplémentaires :
  - Pâleur de la muqueuse (cotée de 0 à 3 ; 3=pâleur maximale)
  - présence ou non des rides vaginaux (de 0 à 3 ; 3=présence normale des rides),
  - diamètre de l'orifice vaginal
- Sur l'atrophie de la muqueuse vaginale (morphologie des cellules épithéliales aux frottis vaginaux)
- Sur l'intensité des symptômes suivants : brûlures, vaginales, prurit vaginal, sécheresse vaginale, dyspareunie et dysurie sur une échelle visuelle analogique EVA
- Sur les scores de qualité de vie sexuelle (FSFI) de T0 à T3.

Comment ça marche ? Le Ground Matrix

La lamina propria (elle est située juste sous la muqueuse car il n'y a pas de sous-muqueuse) est constituée de tissu conjonctif riche en fibres collagènes et élastiques et en nombreux vaisseaux et lymphocytes. Ce tissu conjonctif « nourrit » la muqueuse vaginale et est indispensable à son architecture et à sa physiologie.

Afin de comprendre l'action du Laser fractionné CO2, il est important de se remémorer la physiologie de ce tissu conjonctif situé sous la muqueuse encore appelé Ground matrix.

Le Ground matrix est principalement constitué de macromolécules, appelées protéoglycanes, qui sont liées par des protéines spécifiques à de longues chaînes d'acide hyaluronique. Les protéoglycanes ont donc ainsi la capacité de retenir de grandes quantités d'eau. On comprend que le niveau d'hydratation de la lamina propria dépend de ces molécules.
Les conditions physiologiques optimales de la muqueuse vaginale dépendent de la richesse en eau de la matrice extracellulaire et aussi de fibres collagènes bien structurées. La présence abondante de molécules d'eau entraine une perméabilité plus élevée qui, d'une part favorise le métabolisme de la muqueuse en termes d'apports de métabolites, de nutriments, etc. en provenance des capillaires, tandis que d'autre part que le drainage des déchets de substances est facilité vers les vaisseaux sanguins et lymphatiques. Si le tissu conjonctif est pauvre ou ne contient pas beaucoup d'eau, la muqueuse ne recevra pas les éléments nutritifs nécessaires à son développement correct et à son hydratation physiologique.

Durant la ménopause ou tout état de carence estrogénique comme beaucoup de femmes ayant eu un cancer du sein (mais aussi une majorité de femmes ménopausées ne recevant pas d'estrogènes sous quelque forme que ce soit), les fibroblastes de la muqueuse vaginale sont « en repos métabolique » sous l'état de fibrocytes. Les fibrocytes sont incapables de produire activement l'acide hyaluronique et les autres molécules nécessaires la constitution d'un tissu conjonctif adéquat.

Il en résulte une muqueuse sèche, moins humide, moins vascularisée et donc plus fragile et plus vulnérable aux infections.

Un tissu conjonctif à faible teneur d'eau explique un transport plus difficile vers l'épithélium - à l'endroit même où les agents infectieux l'agressent - des éléments nutritifs et des défenses lymphocytaires en provenance des vaisseaux sanguins.
Le traitement du Syndrome Génito urinaire cherche à rétablir et à promouvoir un métabolisme vaginal comparable à celui des femmes non carencées en estrogènes grâce au rétablissement de la synthèse, non seulement de collagène, mais aussi d'acide hyaluronique des glycos aminoglycanes et des protéoglycanes, permettant alors à la muqueuse vaginale de retrouver son hydratation, son architecture et toutes ses caractéristiques de tissu sain et jeune.

Actions du laser fractionné CO2

Le laser SmartXide a démontré sa capacité à activer fonctionnellement les fibroblastes de la muqueuse vaginale (observations microscopiques simples et électroniques).
Les mécanismes biochimiques sous-jacents de ces phénomènes de régénération s'expliquent par l'effet thermique spécifique provoqué par l'irradiation.

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Atrophie vulvovaginale et Laser Fractionné CO2

DR

David Elia
Gynécologue, Paris

Le laser fractionné CO2 offre une solution thérapeutique chez les femmes ayant eu un cancer du sein et souffrant d'atrophie vulvo-vaginale. Son effet positif est perçu dès les premières semaines suivant la première application. Son utilisation est simple, ne nécessite aucune anesthésie, et est réalisable au cabinet du médecin.

Les femmes atteintes de cancer du sein sont le plus souvent en situation de carence estrogénique : par arrêt d'un THS en cours, par les effets le plus souvent définitifs d'une chimiothérapie avant la ménopause, en raison de l'hormonothérapie adjuvante (Tamoxifène, anti aromatases), par éventuelle décision d'ovariectomie.
Ces femmes ont un risque 5 à 6 fois supérieur aux autres femmes de ressentir des symptômes gênants de carence estrogénique. Et ceci d'autant plus qu'elles sont jeunes [1,2,3,4].

Les thérapeutiques disponibles pour cette population se sont jusqu'ici révélées peu efficaces en raison de l'impossibilité de leur proposer une hormonothérapie de substitution estro ou estro- progestative.

Le syndrome Genito urinaire

Le Syndrome Génito urinaire de la Ménopause (SGM) [5], anciennement désigné sous le terme d'Atrophie Vulvo Vaginale (AVV), est un ensemble de signes comprenant la dyspareunie (douleur pendant les rapports sexuels), la sécheresse vaginale, l'irritation - tous symptômes qui peuvent affecter la sexualité - les relations affectives et les activités banales de la vie quotidienne.
Le SGM induit cliniquement des modifications des petites et grandes lèvres, du vestibule et de l'orifice vaginal, de l'urètre et de la vessie.
Une étude (USA) [6] portant sur 30 146 femmes souffrant d'AVV permet de se faire une idée de l'incidence de ces symptômes : les plus communs sont la sécheresse (55 % des participantes), la dyspareunie (44 %) et l'irritation (37 %). 59 % des femmes concernées considèrent que cela a un impact négatif dans leur vie quotidienne. En outre, on retrouve ici une perturbation du sommeil, une diminution du bonheur de vivre en général, du tonus pour respectivement 24 %, 23 %, et 23 % des participantes. Peu de femmes attribuent ces symptômes à la ménopause (24 %) ou aux changements hormonaux (12 %).
Les solutions thérapeutiques du SGM sont peu nombreuses pour les femmes ayant eu un cancer du sein. Car l'administration d'estrogènes locaux est polémique dans cette population. « *C'est le traitement le plus efficace pour traiter les symptômes modérés à sévères d'AVV… Mais les données sont insuffisantes pour confirmer la sécurité de l'estrogénothérapie locale chez les femmes atteintes d'un cancer du sein* » [7]. Quant au THM, il est strictement contre indiqué dans cette population.
Parmi les solutions récentes, le laser fractionné CO2 offre des perspectives thérapeutiques très intéressantes. Nous aborderons dans un autre article les progrès induits par les infiltrations vaginales d'acide hyaluronique (Desirial®) apahel.

Le laser fractionné CO2 *(figure 1)*

Figure 1- Le laser fractionné CO2 Monalisa® -Deka

Le laser fractionné CO2 se profile aujourd'hui comme une solution thérapeutique potentielle d'AVV. Les lasers CO2 fractionnés sont déjà connus et bien documentés pour leurs effets de stimulation collagénique et de remodelage dermique au niveau cutané [8, 9, 10, 11, 12, 13].
L'idée d'en appliquer les effets à la muqueuse vaginale date de quelques années déjà.

Les modalités du traitement

Les patientes sont traitées avec la pièce à main spécifique gynécologique d'un laser ablatif CO2 fractionné 40W (SmartXide² V2LR – DEKA), sans anesthésie préalable. Il s'agit d'un dispositif médical, bénéficiant d'un marquage CE et de classe 2b.

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LA SOLUTION MONALISA TOUCH ™

Durant la ménopause mais aussi dans des situations particulières, les femmes souffrent de troubles intimes..... C'est un problème répandu mais simple à résoudre.
Pourtant peu de femmes osent en parler.

MonaLisa Touch™

Procédure

La procédure assistée au laser (mini-invasive) ne nécessite pas plus d'une heure et en général aucune anesthésie. Les résultats sont perceptibles dès la première séance.

Actions bénéfiques

L'action de stimulation du laser sur le collagène améliore l'état de la muqueuse qui revêt les parois du vagin et facilite la réhydratation et la restauration fonctionnelle des tissus vaginaux.

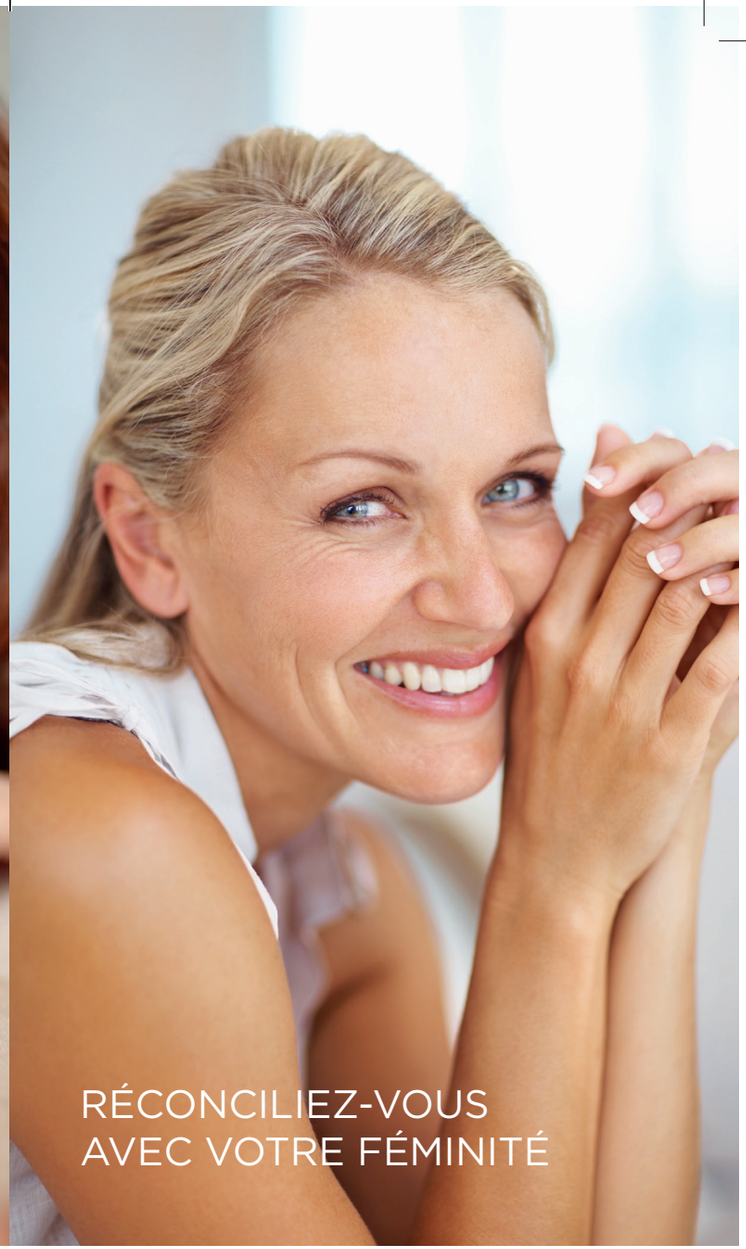
Temps de récupération

La plupart des femmes ne notent que des effets secondaires transitoires sans aucune gravité qui disparaissent généralement après un ou deux jours de repos.

NOUS POUVONS VOUS AIDER

Centre Laser Espace St-Honoré
11 bis rue Portalis - 75008 PARIS
tel: 01 55 37 93 15
espace_laser_st_honore@hotmail.com
espace-laser-st-honore.com

CENTRE LASER
ESPACE SAINT HONORE



RÉCONCILIEZ-VOUS AVEC VOTRE FÉMINITÉ

MonaLisa Touch™

PRÉSERVEZ VOTRE QUALITÉ DE VIE

L'amincissement de la muqueuse vaginale est associée à un appauvrissement en fibres collagènes et à une sécheresse vaginale.

Ces anomalies sont responsables de douleurs, d'irritations et de prurit.

Si de tels troubles sont négligés, ils peuvent avoir d'importantes répercussions sur votre sexualité, votre qualité de vie et altérer la relation avec votre partenaire.

LA SECHERESSE VAGINALE

La moitié des femmes en souffrent au cours de la ménopause. Cette affection peut avoir un retentissement majeur sur leur sexualité et sur leur vie de couple.

La ménopause a toujours été considérée à tort comme une maladie chronique dont les symptômes sont inévitables.

La diminution de la sécrétion hormonale oestrogénique est responsable de cette situation:

- *La muqueuse vaginale s'amincit, devient plus fragile et moins lubrifiée.*
- *Les femmes ressentent alors des sensations de démangeaisons et de brûlures dans la région vulvo-vaginale.*

Des troubles à type de cystites et d'envies fréquentes d'uriner y sont associés.

Enfin les douleurs fréquentes lors des rapports sexuels nuisent profondément à l'harmonie du couple.

Si vous reconnaissez ces symptômes, parlez en à votre médecin qui vous conseillera au mieux et saura vous proposer le traitement le plus adapté.

LES SOLUTIONS CLASSIQUES

Le traitement hormonal substitutif (THS) proposé dans les troubles de la ménopause depuis environ 40 ans est aujourd'hui sujet à de nombreuses controverses.

Certains médecins considèrent que le THS est un facteur de risque pour le cancer du sein et pour les maladies cardiovascu laires.

Les traitements locaux lubrifiants sont prescrits mais il semblerait que les femmes ne les utilisent que sur une courte durée du fait de leur caractère contraignant.

MONALISA TOUCH

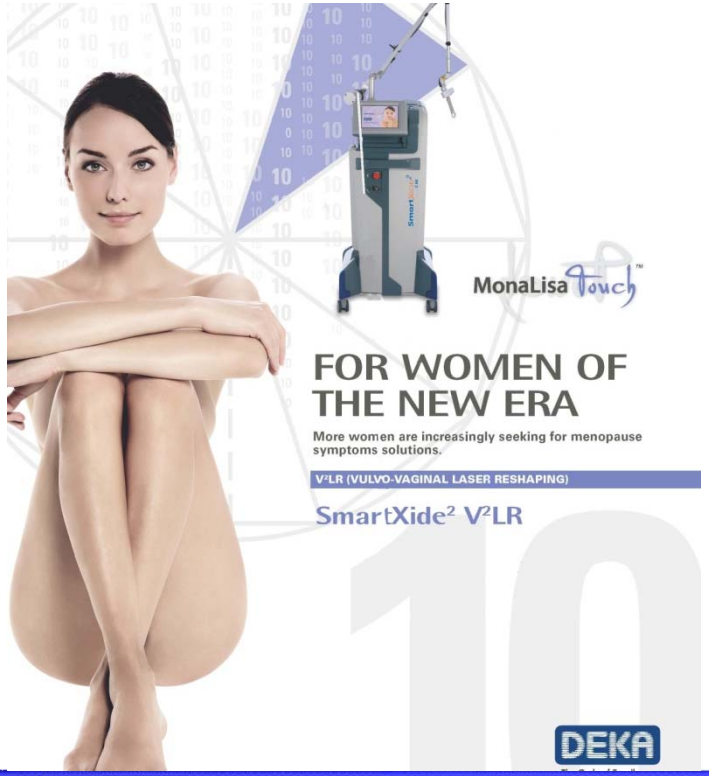
Vulvo-Vaginal Laser Reshaping (V2LR)

Results from San Marino Hospital

Maurizio Filippini, MD

Head of Functional Deptartment
Gynecologic Endoscopy
San Marino State Hospital
San Marino Republic

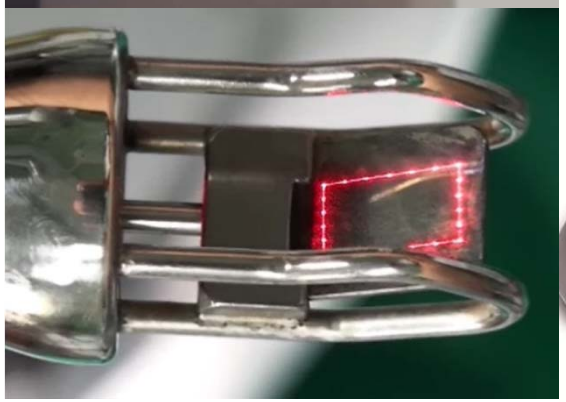
State Hospital – San Marino Republic



TREATMENTS SET-UP

VAGINAL TREATMENT HANDPIECES

360°

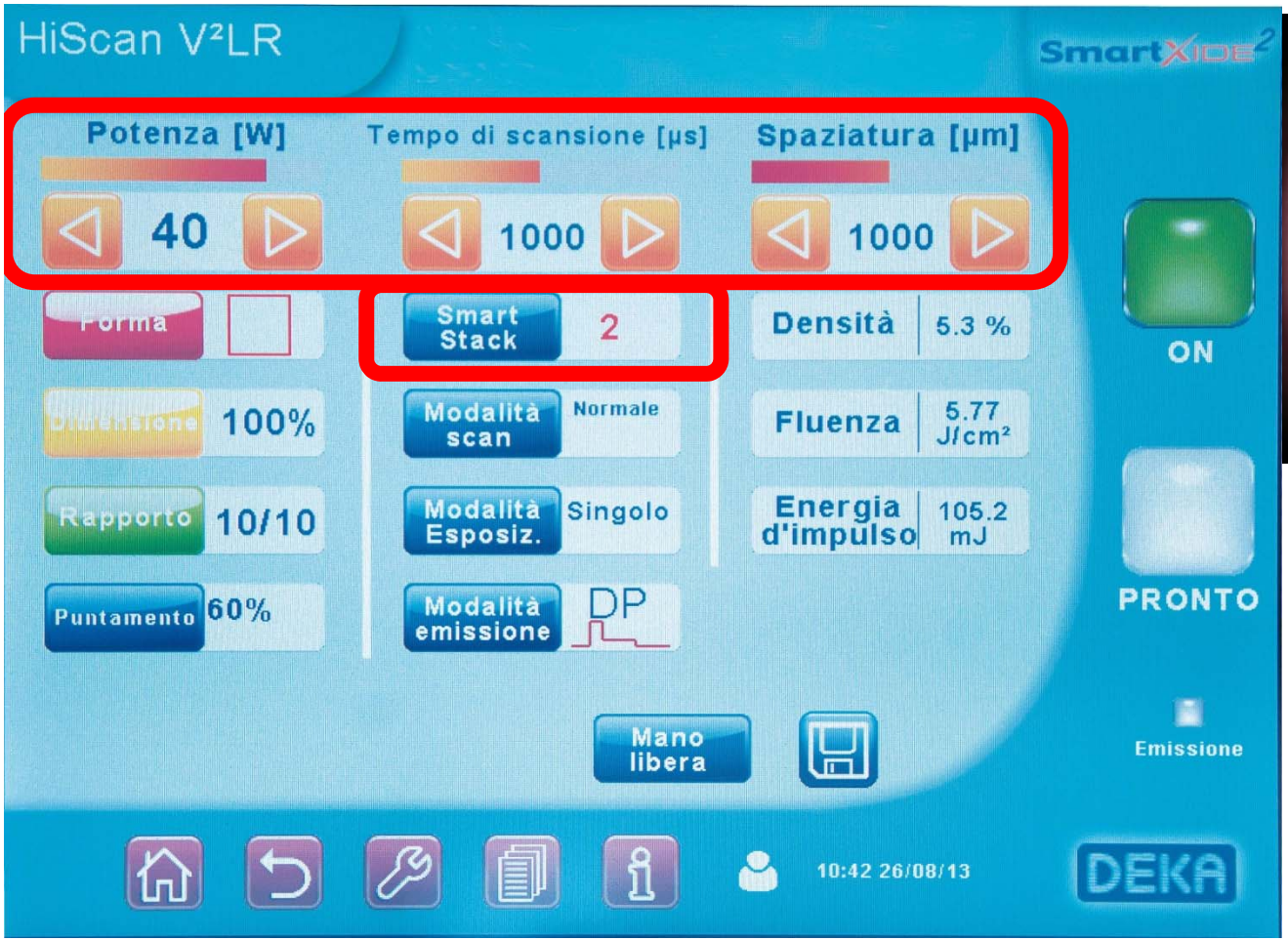


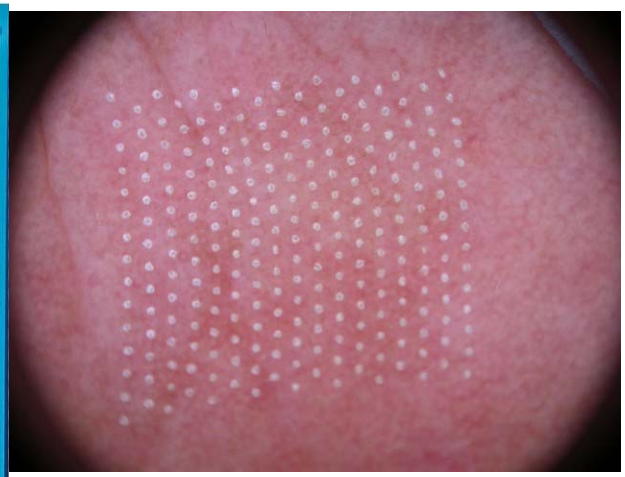
120°

90°

State Hospital – San Marino Republic

VAGINAL TREATMENT SETTING





1000 µm

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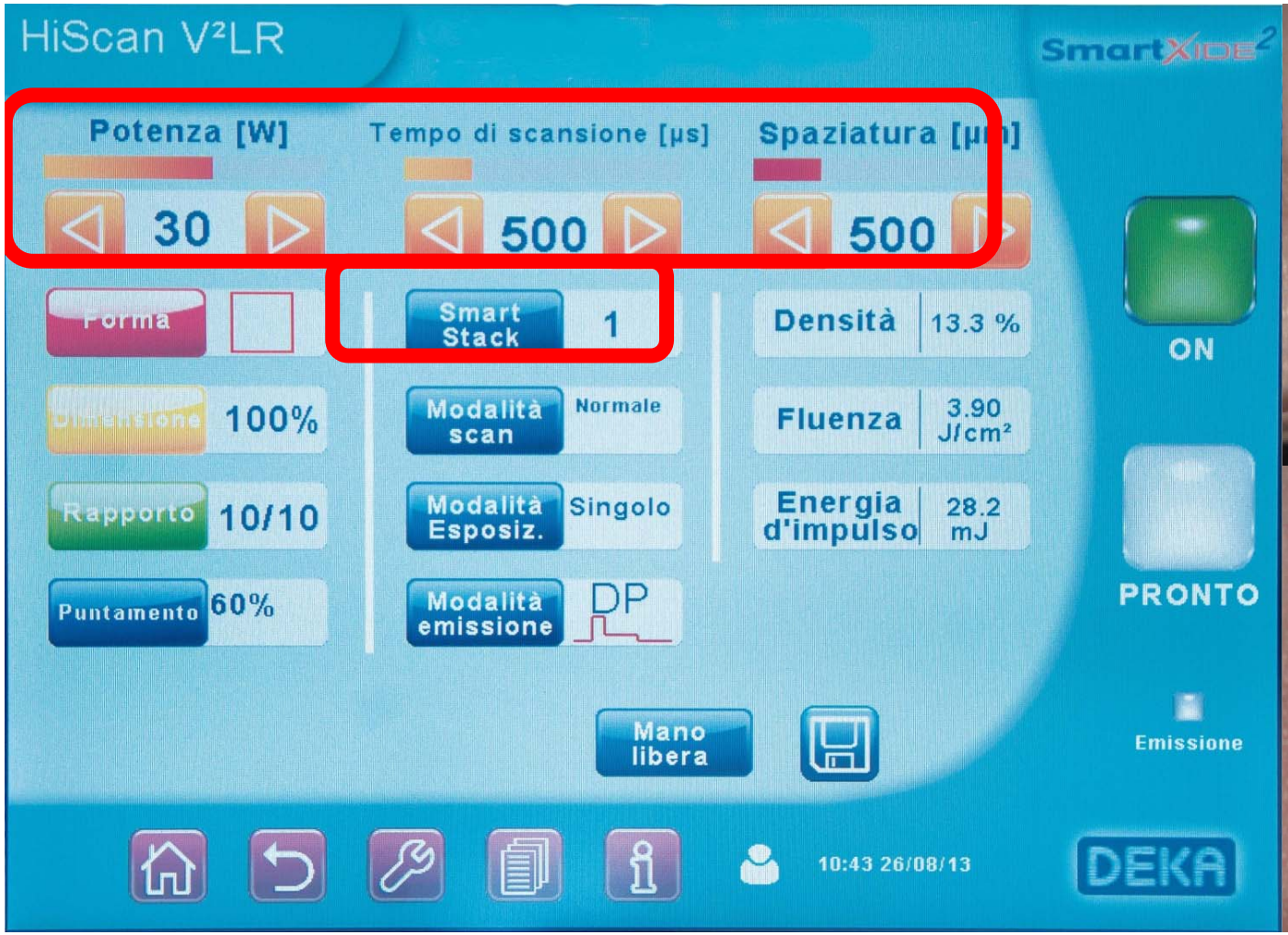
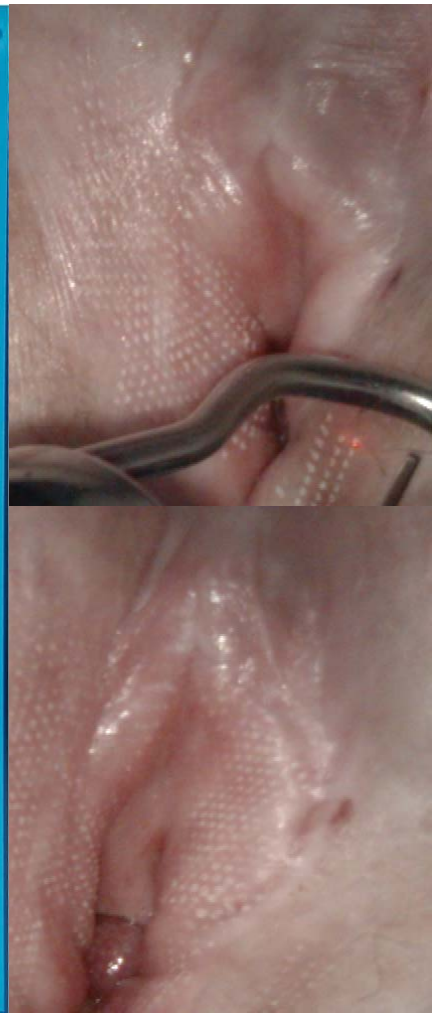
VULVAR TREATMENT - HANDPIECES

VULVAR TREATMENT - SETTING





RESULTS

TREATMENTS - FROM 23.01.2013 TO 23.04.2014

235

MonaLisa Touch™

158

TREATMENTS – FROM 23.01.2013 TO 23.04.2014

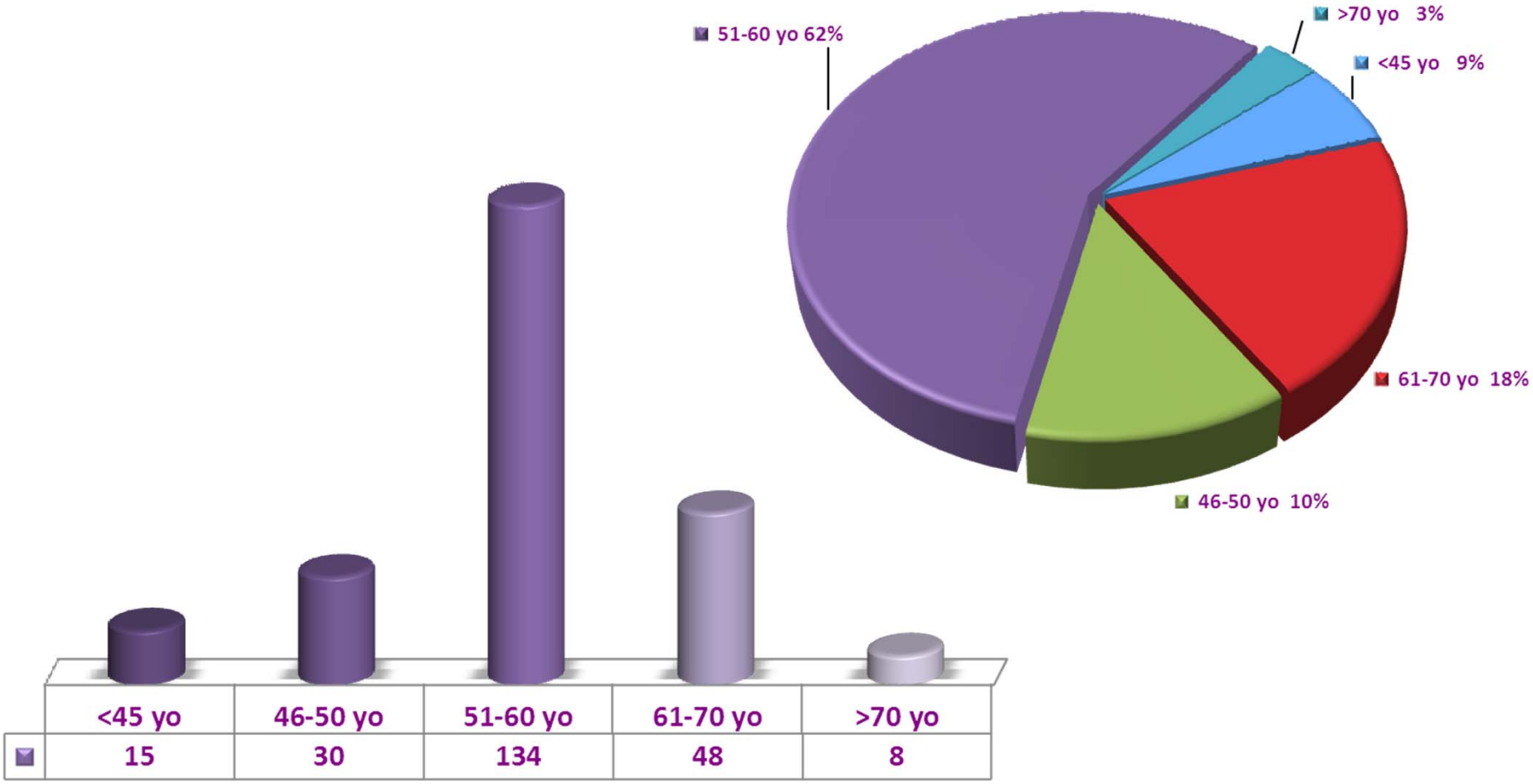
125

INTROITUS

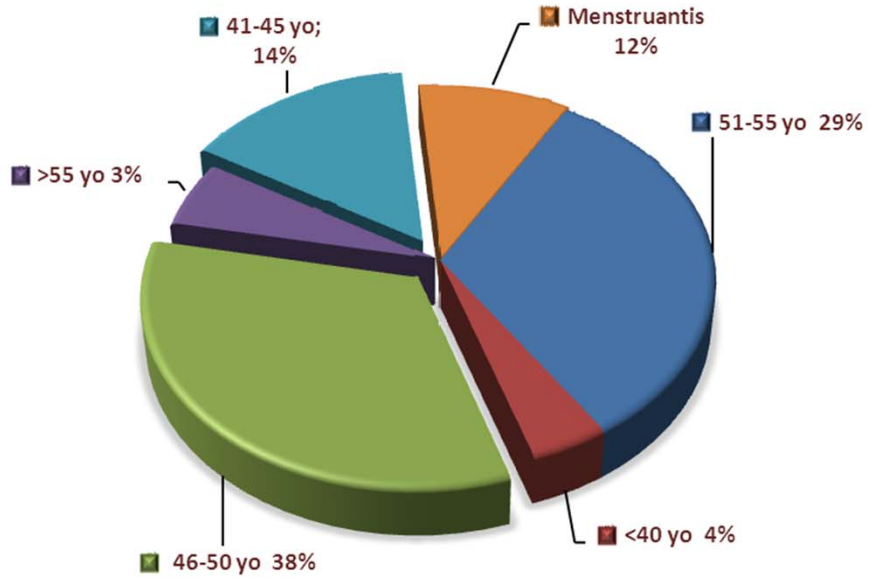
50

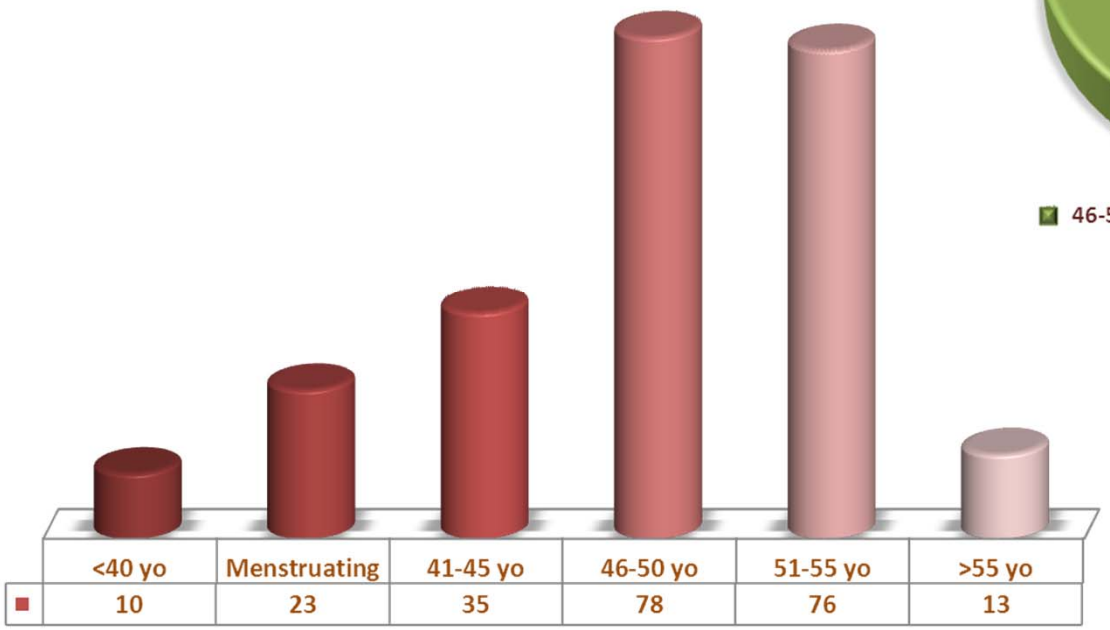
VULVA

PATIENTS AGE DURING TREATMENT



AGE OF MENOPAUSE INSURGENCE

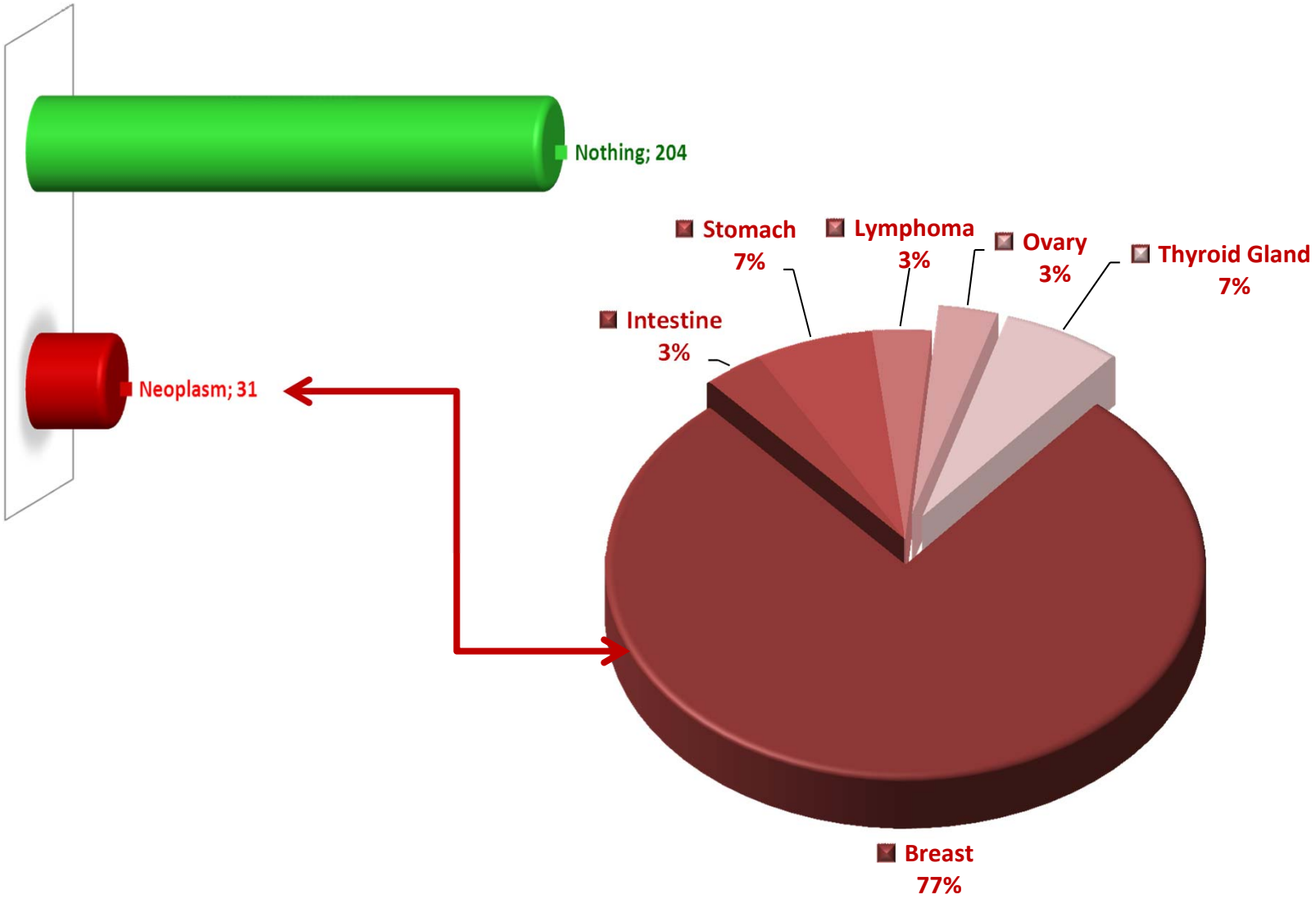




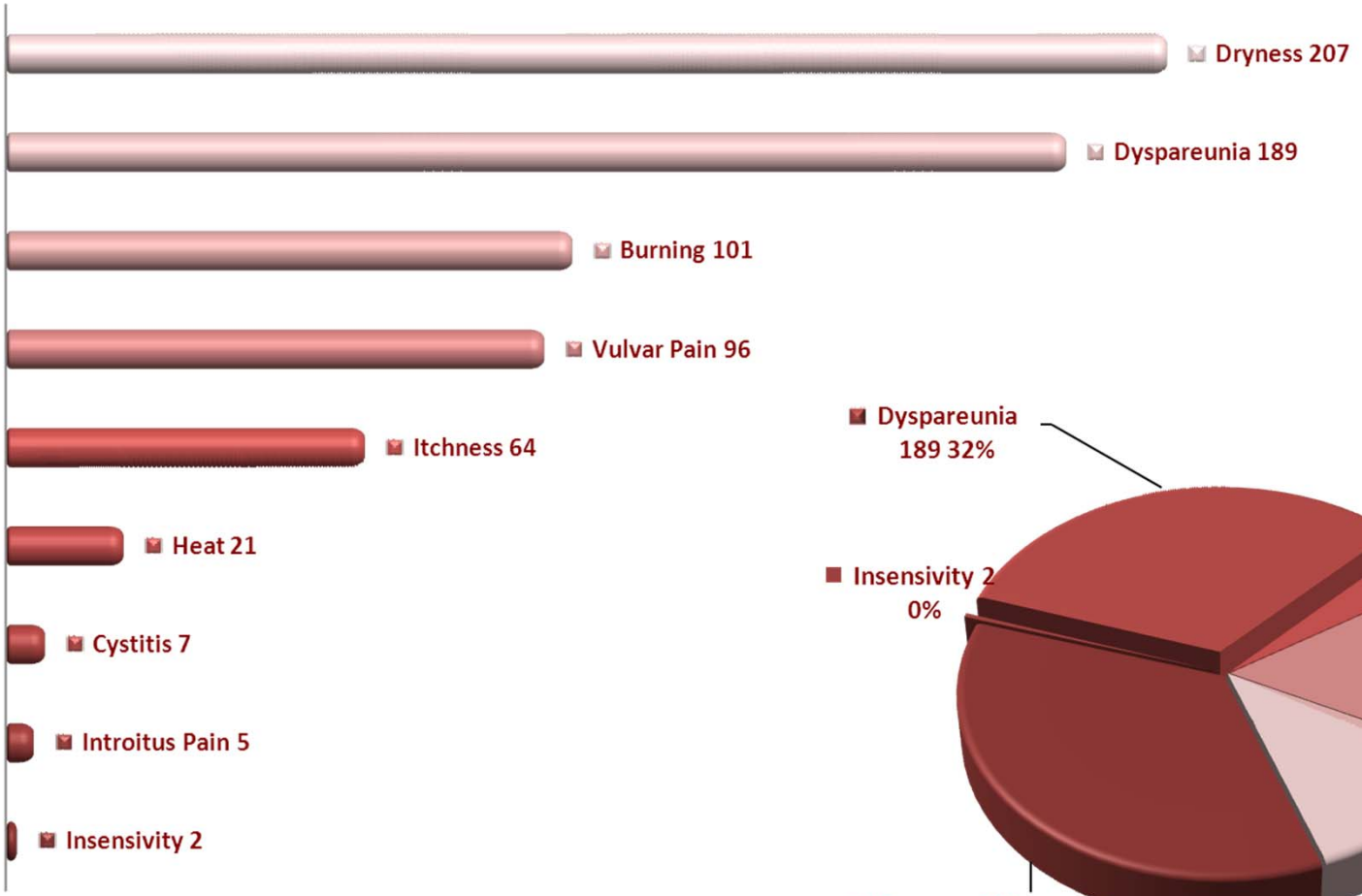
	<40 yo	Menstruating	41-45 yo	46-50 yo	51-55 yo	>55 yo
■	10	23	35	78	76	13

State Hospital – San Marino Republic

ASSOCIATED NEOPLASM PATHOLOGY

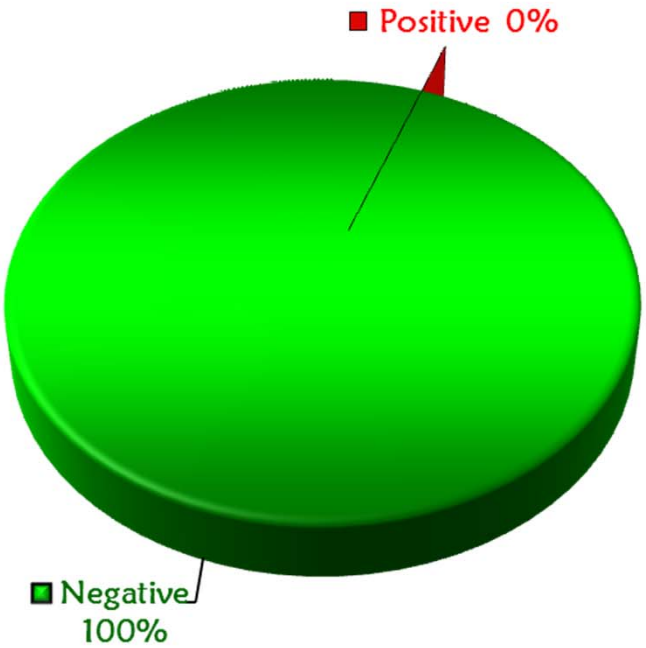


SYMPTOMS REFERRED BY PATIENTS

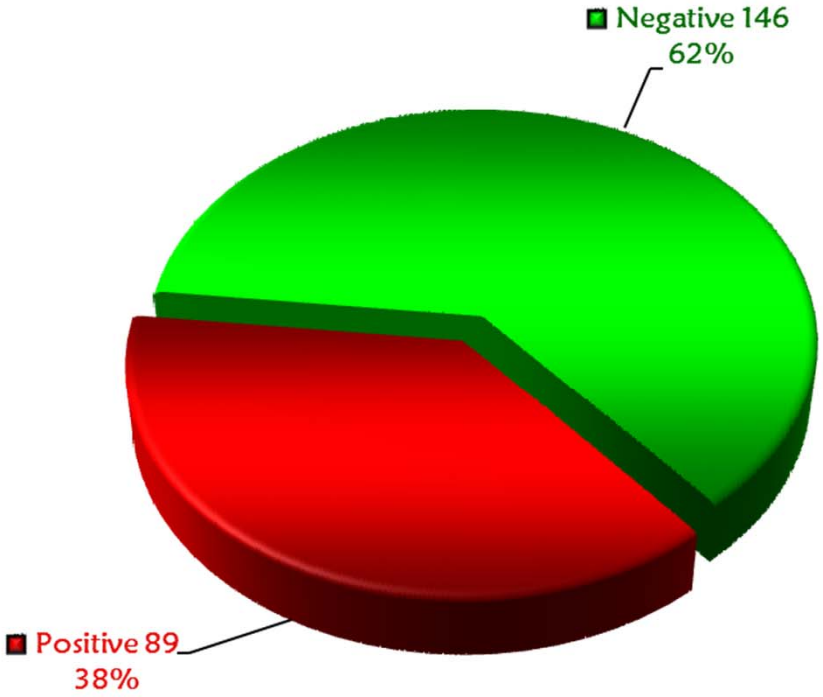


PRELIMINAR EXAMS RESULTS

PAP-TEST

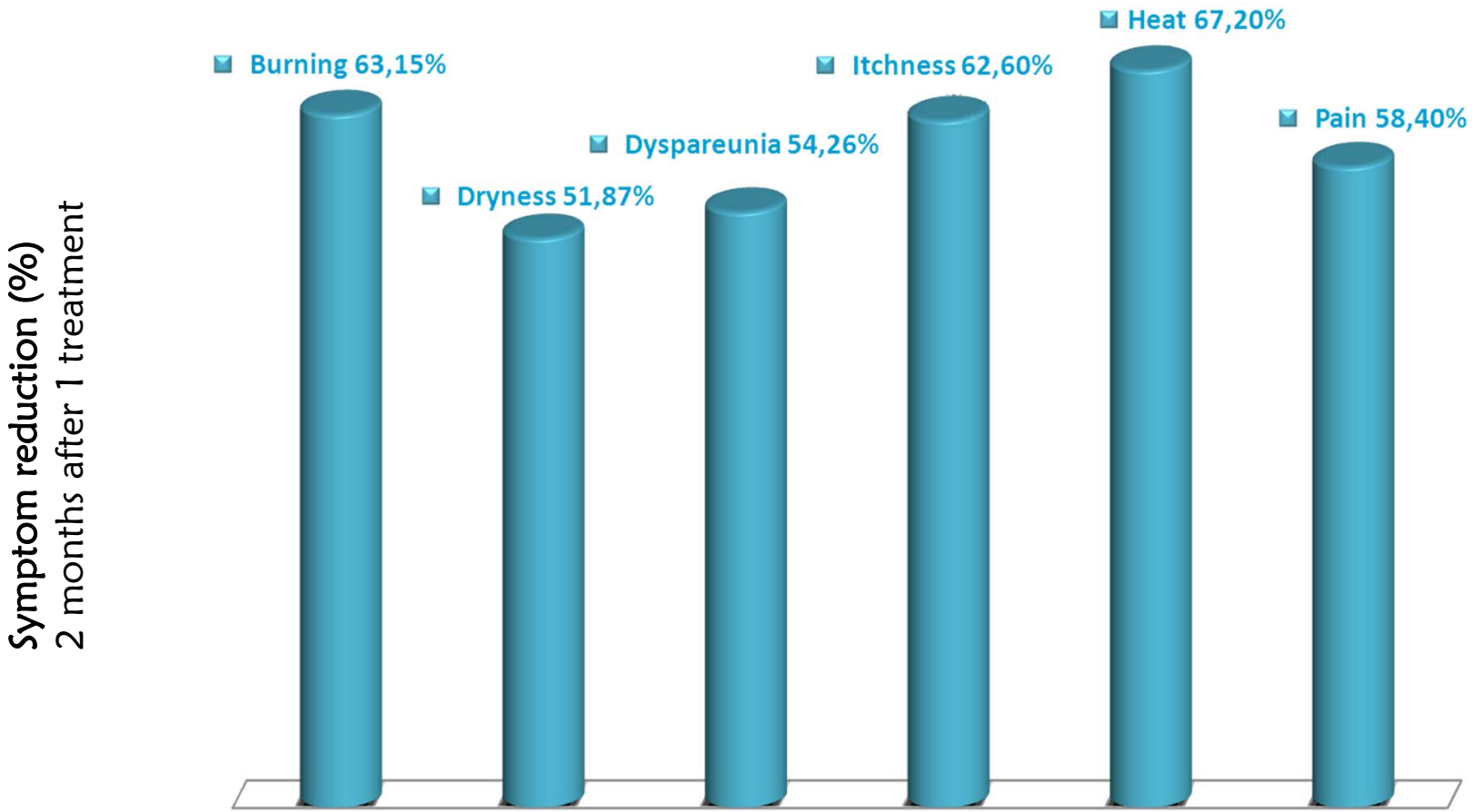


SWAB

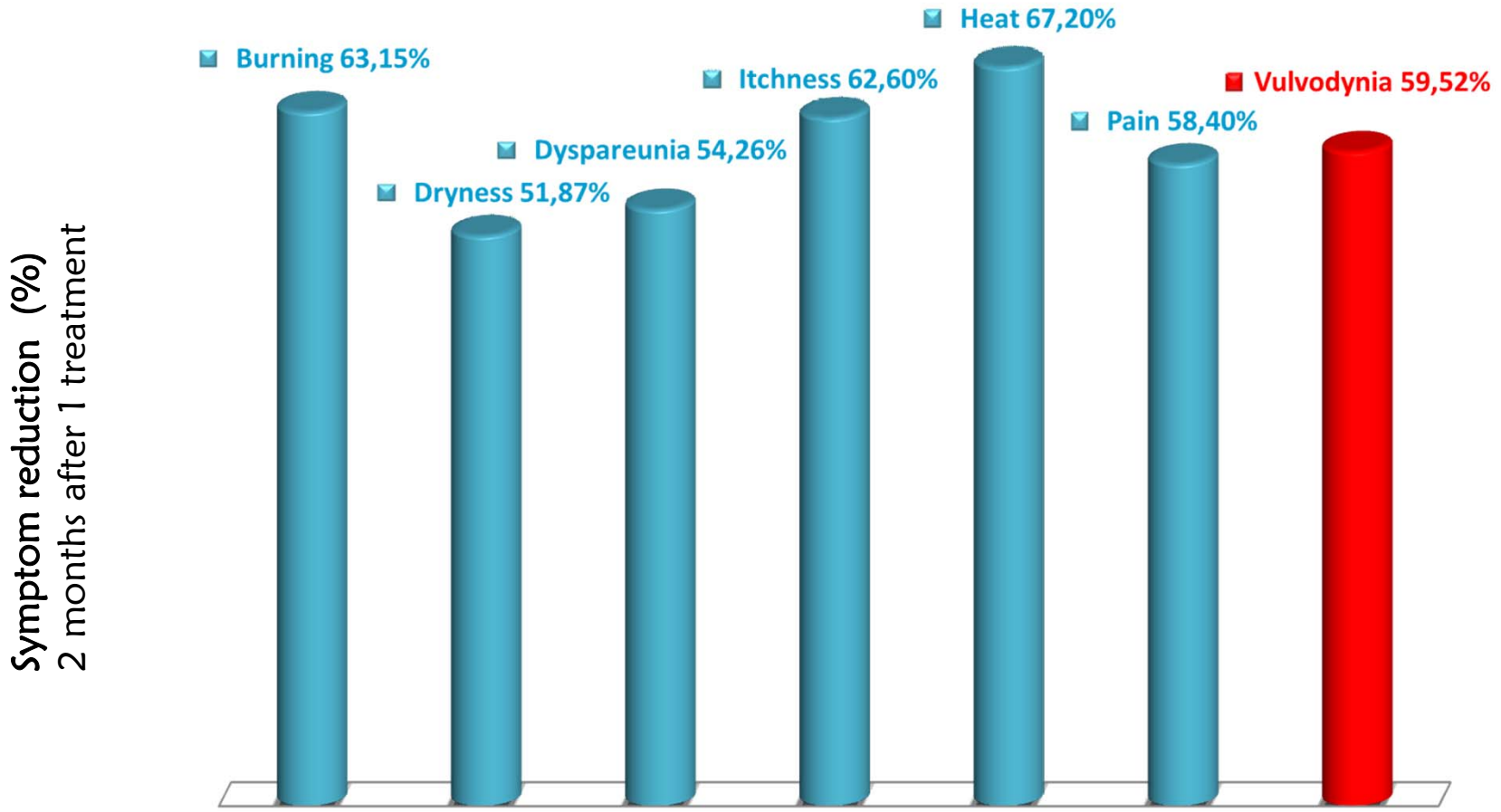


21 E. COLI
5 ENTEROCOCCO
19 GADNERELLA
35 STREPTOCOCCO
2 UREAPLASMA
4 KLEBSIELLA
2 CANDIDA
1 PROTEUS
2 PSEUDOMONAS

VAGINAL ATROPHY SYMPTOMS REDUCTION



VULVODYNIA SYMPTOM REDUCTION



SURE AND EFFECTIVE MonaLisa Touch® is the first laser treatment for menopause-related problems to be approved by the international medical community.

Six scientific publications between 2014 and 2015 confirm the effectiveness and safety of CO_2 fractional laser treatment, now approved worldwide

Professor Stefano Salvatore, Director of the Functional Unit of Urogynaecology at the San Raffaele hospital in Milan, is among the authors of international publications about MonaLisa Touch® and will shortly be appointed as the new president of EUGA, the European Urogynecological Association

April 2015 - Over the last year six articles have been published by the most prestigious international scientific reviews confirming, including by the scientific community, the effectiveness and safety of the **MonaLisa Touch® CO_2 fractional laser treatment**.

The publications are amongst the most authoritative: one in *The Journal of Endometriosis and Pelvic Pain Disorders*. two in Climacteric (the official journal of the International Menopause Society), one in *Maturitas*, one in *Lasers in Medical Science*, and one in *Menopause* (the official journal of the *North American Menopause Society)*.

***Peer reviewed* scientific publications**, controlled by impartial scientific bodies, agree in pointing out the **MonaLisa Touch®** treatment, developed by Italian company DEKA, as a great innovation in treating symptoms linked to **vulvovaginal atrophy**.

This is a unique result, obtained by banking on professional and scientific rigor: **DEKA is the first and only company in the sector to have received approval at worldwide level**, in international scientific publications, in regard to the validity, effectiveness and safety of CO_2 fractional laser treatment used to combat menopause symptoms.

MonaLisa Touch® is a mini-invasive laser procedure treating the effects of ageing on the internal tissues of the female genital apparatus with an **advanced vaginal photorejuvenation technique**. The technique is based on the **SmartXide^2 system**, which guarantees reliability and a very high performance level thanks to a CO_2 laser source which emits a pulse, specially developed for this type of treatment.

The CO_2 laser, controlled by appropriate computerized systems (**exclusive DEKA technology**), determines a regenerating action of the aged fibres and induces production of new collagen, so as to correct the volume of the mucous membrane and remodel it, also restoring hydration and elasticity effectively and painlessly.

The therapy, generally completed in ten minutes, can give benefits right from the first treatment. Further, it has no collateral effects and is also good therapy for the treatment of vaginal tissue following operations for gynecological tumors (ovaries, uterus) and breast tumors.

The worldwide scientific community has found evident improvement in the patient's quality of life: the symptoms of vulvovaginal atrophy, including **burning, itchiness, dryness, dyspareunia, laxness and problems connected with urinary incontinence, are significantly reduced at 12 weeks** from treatment

with **MonaLisa Touch®**. To this can be added an improvement in women's sexual life when they have undertaken this laser treatment (*International Menopause Society*).

In general, **91.7% of patients are satisfied or very satisfied with the treatment**. Moreover, no collateral effect has been encountered, thus also confirming the safety of the **MonaLisa Touch®** CO_2 laser treatment (*Maturitas*).

At twelve weeks from use, the laser has been effective in **reducing dyspareunia in 100% of patients**, all satisfied by the results obtained (*Journal of Endometriosis and Pelvic Pain Disorders*).

Studies carried out confirm that the microablative CO_2 fractional laser can induce a **remodeling of the connective vaginal tissue without causing damage to the surrounding tissues** (*The Journal of the North American Menopause Society*).

Professor Stefano Salvatore, Director of the Functional Unit of Urogynecology at the IRCCS San Raffaele hospital in Milan, soon to become the president of the **European Uro-Gynaecological Association (EUGA)**, is the author of four publications on the *MonaLisa Touch®* and is among those who have contributed to the validation of the methodology: "*When, five years ago, with **Dr. Zerbinati** (dermatologist) and **Professor Calligaro** (histologist), we began clinical and scientific validation of the MonaLisa Touch procedure, I did not expect such outstanding results. **The simplicity, mini-invasive nature and safety of the procedure**, performed totally in day hospital and which requires no other type of preparation such as analgesics or anesthesia, **constitutes a true revolution in the gynecological field**. In a short time we succeeded in getting **important and incontrovertible results**, which also took into account the perception of women with respect to post-treatment improvement. Italian and overseas physicians came to us to learn how the therapy functions and **today MonaLisa Touch is present all over the world**. Prestigious U.S. centers (such as Stanford University or the University of Cincinnati), after a short training period held by us, have commenced using MonaLisa Touch with great enthusiasm and have obtained results of the same level attained by us. Today women live more than a third of their lives after menopause, thanks to various medical-social and behavioral factors. **I am glad to be able to say that MonaLisa Touch contributes to adding quality of life**".*

More info at **www.monalisatouch.com**

About DEKA.

DEKA develops and markets laser and light-based systems allowing dermatologists, plastic surgeons, gynecologists and other medical practitioners to perform non-invasive and minimally invasive procedures to rejuvenate vaginal mucosa, treat ENT benign and malignant tumors, remove skin wrinkles, vascular and benign pigmented lesions, multi-colored tattoos, eliminate unwanted fat by DEKA-invented laser lipolysis, reduce cellulite, treat many important dental diseases. DEKA produces a broad range of laser and lightbased energy sources including CO2, Alexandrite, Diode, Nd: YAG, Er:YAG, pulsed dye, Q-switched lasers, intense pulsed and excimer lights, and radiofrequency technology. DEKA sells its products globally under its brand name through a direct sales force in the Italy, France, Japan and USA, and through international distributors in approximately 80 countries.

For corporate or product information, visit DEKA's website at
www.dekalaser.com

PUBLICATIONS

Histological study on the effects of microablative fractional CO_2 laser on atrophic vaginal tissue: an ex vivo study. S. Salvatore et al. **Menopause** 2015 Jan 20. doi: 10.1097/GME.0000000000000401. [Epub ahead of print]

Vulvo-vaginal atrophy: A new treatment modality using thermo-ablative fractional CO_2 laser. A. Perino et al. **Maturitas.** 2015 Mar; 80(3):296-301. doi: 10.1016/j.maturitas.2014.12.006. Epub 2014 Dec 25

Sexual function after fractional microablative CO_2 laser in women with vulvovaginal atrophy. S. Salvatore et al. **Climacteric** 2014 Dec 16. doi:10.3109/13697137.2014.975197 [Epub ahead of print]

Microscopic and ultrastructural modifications of postmenopausal atrophic vaginal mucosa after fractional carbon dioxide laser treatment. N. Zerbinati et al. **Lasers Med Sci** 2015 Jan, Vol. 30, No. 1:429-36. doi: 10.1007/s10103-014-1677-2. Epub 2014 Nov 20.

Microablative fractional CO2 laser improves dyspareunia related to vulvovaginal atrophy: a pilot study. S. Salvatore et al. **Journal of Endometriosis and Pelvic Pain Disorders** 2014. DOI:10.5301/je.5000184. Epub 2014 Jun 20.

A 12-week treatment with fractional CO2 laser for vulvovaginal atrophy: a pilot study. S. Salvatore et al. **Climacteric** Aug 2014, Vol. 17, No. 4:363-369. doi: 10.3109/13697137.2014.899347. Epub 2014 Jun 5.

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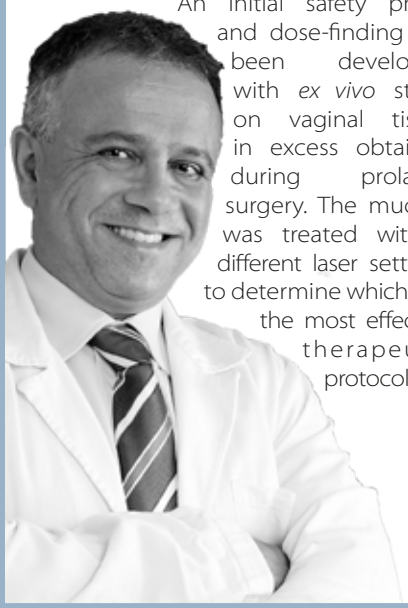
Editorial

When I first came across the world of laser application in gynecology about 7 years ago, I had to overcome a great deal of skepticism and apprehension due to lack of knowledge in this field.

Through the procedure, validation and evaluation of MonaLisa Touch®, involving the use of DEKA fractional CO_2 laser, I have seen incredible regenerative capacity of this emerging therapy.

MonaLisa Touch® validation was divided into various stages, mirroring the steps used in pharmaceutical industry for new medicinal products. Such approach is unusual even when it comes to many innovative surgical techniques.



An initial safety phase and dose-finding has been developed with *ex vivo* study on vaginal tissue in excess obtained during prolapse surgery. The mucosa was treated with 5 different laser settings to determine which was the most effective therapeutic protocol.

The preliminary research successfully identified which parameters ensure maximum safety and efficacy, as well as to observe its mechanism of action in the vaginal lamina propria. Subsequent studies helped determine the average number of treatments to be administrated (i.e. 3 sessions) in women being treated for post-menopausal vaginal atrophy.

We also objectively and subjectively described the very high treatment efficacy related to vaginal atrophy symptoms. As a matter of fact, women reported a new outlook on their sexual life and improved quality of life.

Other studies are currently under way at San Raffaele Hospital in Milan and may lead to further possible indications for this therapeutic approach.

To conclude, I would never have been able to gather the data published on Monalisa Touch® until now without the contribution and support from my team who deserve my sincere thanks. I am also very grateful to Prof. Alberto Calligaro, Prof. Nicola Zerbinati and Prof. Rossella Nappi for their indispensable collaboration.

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Climacteric - Vol. 17, No. 4, 2014. Epub 2014 Jun 5

A 12-week treatment with fractional CO_2 laser for vulvovaginal atrophy: a pilot study

Salvatore S, Nappi RE, Zerbinati N, Calligaro A, Ferrero S, Origoni M, Candiani M, Leone Roberti Maggiore U

Abstract

Objective

This pilot study aimed to assess the efficacy and feasibility of fractional CO_2 laser in the treatment of vulvovaginal atrophy (VVA) in postmenopausal women.

Methods

VVA symptoms were assessed before and after three applications of laser over 12 weeks in 50 women (age 59.6 ± 5.8 years) dissatisfied with previous local estrogen therapies. Subjective (visual analog scale) and objective (Vaginal Health Index Score, VHIS) measures were used during the study period to assess VVA. Quality of life was measured by using the SF-12. A subjective scale to evaluate the degree of pain related to the laser application and the degree of difficulty to perform the laser procedure was used.

Results

Fractional CO_2 laser treatment was effective to improve VVA symptoms (vaginal dryness, vaginal burning, vaginal itching, dyspareunia, dysuria; $p < 0.001$) at 12-week follow-up, as well as the VHIS (13.1 ± 2.5 at baseline vs. 23.1 ± 1.9; $p < 0.001$). Both physical and mental scores of quality of life were significantly improved in comparison with baseline ($p < 0.001$). Satisfaction with the laser procedure was reported by 42 women (84%) and a minimal discomfort was experienced at the first laser application, mainly because of the insertion and the movements of the probe. Finally, the technique was very easy to perform in all women starting from the second application at week 4 and no adverse events were recorded during the study period.

Conclusions

A 12-week treatment with the fractional CO_2 laser was feasible and induced a significant improvement of VVA symptoms by ameliorating vaginal health in postmenopausal women. Further controlled studies should be performed to confirm the present data and to assess the long-term effects of the laser procedure on vaginal tissues.

Journal of Endometriosis and Pelvic Pain Disorders - Vol. 6, No. 3, 2014

Microablative fractional CO_2 laser improves dyspareunia related to vulvovaginal atrophy: a pilot study

Salvatore S, Leone Roberti Maggiore U, Origoni M, Parma M, Quaranta L, Sileo F, Cola A, Baini I, Ferrero S, Candiani M, Zerbinati N

Abstract

This pilot study aimed to assess the efficacy in treating sexually active menopausal patients who had dyspareunia related to vulvovaginal atrophy (VVA).

The intensity of VVA symptoms was recorded for each patient. Patients were administered the Short Form 12 (SF-12) and the female sexual function index (FSFI) to assess quality of life and sexual function, respectively. An objective evaluation of female urogenital health was performed using the Gloria Bachman Vaginal Health Index (VHI).

At 12-week follow-up, the laser treatment was efficacious in improving dyspareunia in 100% of patients included in the study (n = 15). The intensity of dyspareunia significantly decreased from baseline (8.7 ± 1.0) to 12-week follow-up (2.2 ± 1.0; $p < 0.001$). In addition, all other VVA symptoms significantly ameliorated at the same follow-up. Furthermore, after the treatment, a significant improvement in quality of life (QoL) and sexual function were shown.

This pilot study demonstrated that treatment with the microablative fractional CO_2 laser of patients with dyspareunia related to VVA was efficacious at 12-week follow-up.

Lasers in Medical Science - Vol. 30, No. 1, 2015. Epub 2014 Nov 20

Microscopic and ultrastructural modifications of postmenopausal atrophic vaginal mucosa after fractional carbon dioxide laser treatment

Zerbinati N, Serati M, Origoni M, Candiani M, Iannitti T, Salvatore S, Marotta F, Calligaro A

Abstract

Vaginal atrophy occurring during menopause is closely related to the dramatic decrease in ovarian estrogens due to the loss of follicular activity.

Particularly, significant changes occur in the structure of the vaginal mucosa, with consequent impairment of many physiological functions. In this study, carried out on bioptic vaginal mucosa samples from postmenopausal, nonestrogenized women, we present microscopic and ultrastructural modifications of vaginal mucosa following fractional carbon dioxide (CO_2) laser treatment. We observed the restoration of the vaginal thick squamous stratified epithelium with a significant storage of glycogen in the epithelial cells and a high degree of glycogen-rich shedding cells at the epithelial surface.

Moreover, in the connective tissue constituting the lamina propria, active fibroblasts synthesized new components of the extracellular matrix including collagen and ground substance (extrafibrillar matrix) molecules.

Differently from atrophic mucosa, newly-formed papillae of connective tissue indented in the epithelium and typical blood capillaries penetrating inside the papillae, were also observed. Our morphological findings support the effectiveness of fractional CO_2 laser application for the restoration of vaginal mucosa structure and related physiological trophism. These findings clearly coupled with striking clinical relief from symptoms suffered by the patients before treatment remodeling of vaginal connective tissue without causing damage to surrounding tissue.

Climacteric - Vol.18, No. 2, 2015. Epub 2014 Dec 16

Sexual function after fractional microablative CO_2 laser in women with vulvovaginal atrophy

Salvatore S, Nappi RE, Parma M, Chionna R, Lagona F, Zerbinati N, Ferrero S, Origoni M, Candiani M, Leone Roberti Maggiore U

Abstract

Objective

To investigate the effects of fractional microablative CO_2 laser on sexual function and overall satisfaction with sexual life in postmenopausal women with vulvovaginal atrophy (VVA).

Method

This prospective study included 77 postmenopausal women (mean age 60.6 ± 6.2 years) treated for VVA symptoms with the fractional microablative CO_2 laser system (SmartXide^2 V^{2}LR, MonaLisa Touch®, DEKA, Florence, Italy). Sexual function and quality of life were evaluated with the Female Sexual Function Index (FSFI) and the Short Form 12 (SF-12), respectively, both at baseline and at 12-week follow-up. A 10-mm visual analog scale was used to measure the overall satisfaction with sexual life and the intensity of VVA symptoms (vaginal burning, vaginal itching, vaginal dryness, dyspareunia and dysuria) before and after the study period.

Results

We observed a significant improvement in the total score and the scores in each specific domain of the FSFI at 12-week follow-up compared to baseline ($p < 0.001$). After concluding the laser treatment, the overall satisfaction with sexual life significantly improved ($p < 0.001$). Seventeen (85%) out of 20 (26%) women, not sexually active because of VVA severity at baseline, regained a normal sexual life at the 12-week follow-up. Finally, we also found a significant improvement in each VVA symptom ($p < 0.001$) and in quality-of-life evaluation, both for the scores in the physical ($p = 0.013$) and mental ($p = 0.002$) domains.

Conclusions

Fractional microablative CO_2 laser treatment is associated with a significant improvement of sexual function and satisfaction with sexual life in postmenopausal women with VVA symptoms.

Maturitas - Vol. 80, No. 3, 2015. Epub 2014 Dec 25

Vulvo-vaginal atrophy: A new treatment modality using thermo-ablative fractional CO_2 laser

Perino A, Calligaro A, Forlani F, Tiberio C, Cucinella G, Svelato A, Saitta S, Calagna G

Abstract

Objective

To evaluate the efficacy and feasibility of thermo-ablative fractional CO_2 laser for the treatment of symptoms related to vulvo-vaginal atrophy (VVA) in post-menopausal women.

Methods

From April 2013 to December 2013, post-menopausal patients who complained of one or more VVA-related symptoms and who underwent vaginal treatment with fractional CO_2 laser were enrolled in the study. At baseline (T0) and 30 days post-treatment (T1), vaginal status of the women was evaluated using the Vaginal Health Index (VHI), and subjective intensity of VVA symptoms was evaluated using a visual analog scale (VAS). At T1, treatment satisfaction was evaluated using a 5-point Likert scale.

Results

During the study period, a total of 48 patients were enrolled. Data indicated a significant improvement in VVA symptoms (vaginal dryness, burning, itching and dyspareunia) ($P < 0.0001$) in patients who had undergone 3 sessions of vaginal fractional CO_2 laser treatment. Moreover, VHI scores were significantly higher at T1 ($P < 0.0001$). Overall, 91.7% of patients were satisfied or very satisfied with the procedure and experienced considerable improvement in quality of life (QoL). No adverse events due to fractional CO_2 laser treatment occurred.

Conclusions

Thermo-ablative fractional CO_2 laser could be a safe, effective and feasible option for the treatment of VVA symptoms in post-menopausal women.

Menopause - Vol. 22, No.8, 2015

Histological study on the effects of microablative fractional CO_2 laser on atrophic vaginal tissue: an ex vivo study

Salvatore S, Leone Roberti Maggiore U, Athanasiou S, Origoni M, Candiani M, Calligaro A, Zerbinati N

Abstract

Objective

Microablative fractional CO_2 laser has been proven to determine tissue remodeling with neoformation of collagen and elastic fibers on atrophic skin. The aim of our study is to evaluate the effects of microablative fractional CO_2 laser on postmenopausal women with vulvovaginal atrophy using an ex vivo model.

Methods

This is a prospective ex vivo cohort trial. Consecutive postmenopausal women with vulvovaginal atrophy managed with pelvic organ prolapse surgical operation were enrolled. After fascial plication, the redundant vaginal edge on one side was treated with CO_2 laser (SmartXide^2; DEKA Laser, Florence, Italy). Five different CO_2 laser setup protocols were tested. The contralateral part of the vaginal wall was always used as control. Excessive vagina was trimmed and sent for histological evaluation to compare treated and nontreated tissues. Microscopic and ultrastructural aspects of the collagenic and elastic components of the matrix were studied, and a specific image analysis with computerized morphometry was performed. We also considered the fine cytological aspects of connective tissue proper cells, particularly fibroblasts.

Results

During the study period, five women were enrolled, and 10 vaginal specimens were finally retrieved. Four different settings of CO_2 laser were compared. Protocols were tested twice each to confirm histological findings. Treatment protocols were compared according to histological findings, particularly in maximal depth and connective changes achieved. All procedures were uneventful for participants.

Conclusions

This study shows that microablative fractional CO_2 laser can produce a remodeling of vaginal connective tissue without causing damage to surrounding tissue.

Current Opinion in Obstetrics and Gynecology - Vol. 27, No. 6, 2015

The use of pulsed CO_2 lasers for the treatment of vulvovaginal atrophy

Salvatore S, Athanasiou S, Candiani M

Abstract

Purpose of review

This article reviews the literature regarding the safety and efficacy of the use of a pulsed CO_2 laser for the treatment of vulvovaginal atrophy (VVA).

Recent findings

Prospective observational studies have demonstrated histological changes after the use of pulsed CO_2 laser vaginally in atrophic conditions. Increased collagen and extracellular matrix production has been reported together with an increase in the thickness of the vaginal epithelium with the formation of new papilla. Three different observational studies reported a significant improvement of VVA assessed subjectively (with a 10-point visual analogue scale) and objectively (using the Vaginal Health Index) after a cycle of three treatments of pulsed CO_2 laser. Also sexual function (assessed with the Female Sexual Function Index) and quality of life (evaluated with the SF12 questionnaire) significantly improved. No complications or sideeffects were reported during or after the laser procedure that was performed in an outpatient setting.

Summary

Increasing evidence with histological and clinical data supports the use of pulsed CO_2 lasers in the treatment of VVA; however, no randomized control trial (sham versus treatment) has yet been produced and no data on the duration of therapy are currently available.

Archives of Obstetrics and Gynecology - 2016 May 12

Fractional CO_2 laser for vulvovaginal atrophy (VVA) dyspareunia relief in breast cancer survivors

Pieralli A, Fallani MG, Becorpi A, Bianchi C, Corioni S, Longinotti M, Tredici Z, Guaschino S

Abstract

Purpose

The aim of this study was to evaluate the efficacy of fractional CO_2 laser therapy in breast cancer survivors as a therapeutic method for vulvovaginal atrophy (VVA) dyspareunia.

Methods

50 patients (mean age 53.3 years) underwent fractional microablative CO_2 laser treatment for dyspareunia in oncological menopause (mean time of menopause 6.6 years). The Gloria Bachmann's Vaginal Health Index (VHI) score was chosen as system to evaluate the presence of VVA and its improvement after the treatment. Intensity of dyspareunia was evaluated using a visual analog scale (VAS).

Results

Data indicated a significant improvement in VVA dyspareunia ($p < 1.86e-22$) in breast cancer survivors who had undergone 3 sessions of vaginal fractional CO_2 laser treatment. Moreover, VHI scores were significantly higher 30 days post-treatment (T4) ($p < 0.0001$). 76 % of patients were satisfied or very satisfied with the treatment results. The majority (52 %) of patients were satisfied after a long-term follow-up (mean time 11 months). No adverse events due to fractional CO_2 laser treatment occurred.

Conclusions

The treatment with fractionated CO_2 laser appeared to be a feasible and effective treatment for VVA dyspareunia in breast cancer survivors with contraindications to hormonal treatments.

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