



# MONNALISA TOUCH

Vulvo-Vaginal Laser Reshaping (V2LR)

25 MESI DI ESPERIENZA DELLO OSPEDALE DELLA REPUBBLICA DI SAN MARINO



## UNICO TRATTAMENTO CON LETTERATURA SCIENTIFICA VALIDATA

Microscopic and ultrastructural modifications of postmenopausal Microscopic and ultrastructural modulcations of postment fractional carbon dioxide laser treatment Microablative fractional CO<sub>2</sub> laser improves dyspareunia related to vulvovaginal atrophy: a pilot study Stefano Salvatore<sup>1</sup>, Umberto Leone Roberti Maggiore<sup>1</sup>, Massimo Origoni<sup>1</sup>, Marta Parma<sup>1</sup>, Lavinia Quaranta<sup>1</sup>, Filomena Sileo<sup>1</sup>, Alice Cola<sup>1</sup>, Ilaria Baini<sup>1</sup>, Simone Ferreto<sup>2</sup>, Massimo Candiani<sup>1</sup>, Nicola Zerbinati<sup>1</sup> Stefano Salvatore<sup>1</sup>, Umberto Leone Roberti Maggiore<sup>2</sup>, Massimo Origoni<sup>1</sup>, Marta Parma<sup>1</sup>, Lavinla Filomena Sileo<sup>1</sup>, Alice Cola<sup>1</sup>, Ilaria Baini<sup>1</sup>, Simone Ferrero<sup>2</sup>, Massimo Candiani<sup>1</sup>, Nicola Zerbinati<sup>2</sup> Obstetrics and Gynuecology Unit, Vita-Salute San Figifiable University and IRRCS San Raffaele Hospital, Milan - Italy Department of Obstatrics and Gynuecology IRCCS San Mortino Hospital and National feature for Canzer Reservance Obstetrics and Gynaecology Unit, Vita-Saluts San Raffaele University and IRRCS San Raffaele Hospital, Milan - Italy
 Department of Obstetrics and Gynaecology, IRCCS San Martino Hospital and National Institute for Cancer Reservences
 University of Gence, Genne - Italy G Model
No. of Puges 6 University of Genoa, Genoa - Italy

5 Department of Surgicul and Morphological Sciences, University of Insubria, Varese - Italy Objective: This pilot study aimed to assess the efficacy in treating sexually active menor who had dyspareunia related to vulvovaginal strophy (WA).

Materials and methods: The intensity of VVA symptoms was recorded for each Materials and methods: The intensity of VVA symptoms was recorded for each were administered the Short Form 12 (SF-12) and the female sexual function ind were administered the Short Form 12 (SF-12) and the female sexual function in quality of life and sexual function, respectively. An objective evaluation of female Vulvo-vaginal atrophy: A new treatment modality using quality of life and sexual function, respectively. An objective evalual performed using the Gloria Bachman Vaginal Heelth Index (VHI). performed using the stona Bachman vagnal Health Index (VHI).

Results: At 12-week follow-up, the laser treatment was efficacious in improvi Antonino Perino<sup>2</sup>, Alberto Calligaro<sup>b</sup>, Francesco Fortani<sup>2,8</sup>, Corrado Tiberio<sup>2</sup>, Canada Calligaro<sup>b</sup>, Francesco Fortani<sup>2,8</sup>, Corrado Tiberio<sup>2</sup>, thermo-ablative fractional CO2 laser Results: At 12-week follow-up, the laser treatment was efficacious in improve of patients included in the study (n = 15). The intensity of dysparsunia significant included in the study (n = 15). The intensity of dysparsunia significant included in the study (n = 15). The intensity of dysparsunia significant included in the study (n = 15). Antonino Perino", Alberto Calligaro", Francesco Portanis", L'Orrado Riberto Gaspare Cucinella", Alessandro Svelato", Salvatore Saitta", Gloria Calagna of patients included in the study (n = 15). The intensity of dyspereunia significant included in the study (n = 15). The intensity of dyspereunia significant included in the study (n = 15). The intensity of dyspereunia significant includes the patients of the patients baseline (8.7 = 1.0) to 12-week follow-up (2.2 = 1.0; p-c0.001). In additionally ameliorated at the same follow-up. Furthermore, after the significantly ameliorated at the same follow-up. significantly ameliorated at the same follow-up. Furthermore, and provention in quality of life (OoL) and sexual function were shown. provement in quality of life (OoL) and sexual function were shown.

Conclusions: This pilot study demonstrated that treatment with the Concursions: This pilot study demonstrated that treatment with the of patients with dyspareunia related to VVA was efficacious at 12-y Some effectives accompanying menopause it is due to the depletion of overland to the depletion of the depletion es accompanying menopause it is due to t Keywords: Dyspareunia, Fractional CO<sub>2</sub> laser, Menopause, Vac Meno passe: The Journal of The North American Menopasse Society Vol. 22, No. 8, pp. 000-000 aperienced considerable improvement in quantity of the USDLA No assessed ter treatment occurred. To arbitrary fractional CO<sub>2</sub> laser could be a safe, effective and feasible option INTRODUCTION Vulvovaginal atrophy (VVA) is a physiological process ing from the drop of estrogen that occurs in women Histological study on the effects of microablative fractional CO<sub>2</sub> menopause (1). The vagina becomes narrower and waginal walls appear thinner and less elastic with loss of regarding. The entire vaginal canal becomes narrower and shorter. The waging mal surface appears of an an fitable and often bleeds after minimal nature appears with a particularly the clinoris, becomes arrophic reasons. The valvar area particularly the clinoris, becomes arrophic and envow workers also in all the clinoris and envow workers also in all the clinoris. laser on atrophic vaginal tissue: an ex vivo study and frequently the introitus can constrict. WA is as and inequentity the himorius can consume. Versia as with a progressive lost of elasticity and of rugal fo with a progressive lost of elasticity and or rugal to vaginal lining which becomes thinner and may st trauma. The vulvor area, particularly the clinoris, becomes; and more vulnerable [8].
Vaginal arguing clausers on over the years and negative or equality of life [0.61]. Approximately 50% of postment of the properties of the pro Stefano Salvatore, MD, Umberto Leone Roberti Maggiore, MD, Stavros Athanasiou, MD, 2 vayinar ann's winou uscumes minner and may st chiae. Sexual dysfunctions and absence of sex cniae. Jexual dysluminous and accents on sexual accents on sexual accents on sexual accents with VVA syr Massimo Origoni, MD, Massimo Candiani, MD, Alberto Calligaro, MD, and Nicola Zerbinati, MD4 Objective: Microablative fractional CO2 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

fact, sebaceous glands reduce the productio Tact, sepaceous glanus recurs are processed tions and therefore, during sexual intercourses none and meretore, quring sexual intervolves is decreased and delayed (2). The typical symp are vaginal burning and discharges, itching, c

> nective 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 CO2 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.

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 CO2 laser (SmartXide2; DEKA Laser, Florence, Italy). Five different CO2 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 con-

fractional CO<sub>2</sub> laser on postmenopausal women with vulvovaginal atrophy using an ex vivo model.

Conclusions: This study shows that microablative fractional CO2 laser can produce a remodeling of vaginal

Before the climateric period, the vagina is composed of thick layers of bealthy cells, and extrogen encourages the growth and development of these cells vaginal was a support of them remains until support, and vaginal was properly lawer than the control of the control of courts in the con-sistence of the control of courts in the con-sistence of courts in the control of courts in the courts of the courts in the control of courts in the courts of the courts in the courts of courts in the courts of the courts of courts in the courts of courts in the courts of the courts of the courts of courts in the courts of the courts of the courts of courts in the courts of the courts of the courts of courts of the cou etable [1,2]. The progressive reduction in circulating estrogen, which occurs following the cessation of ovarian function during memorases, induces various metabolic and tissue changes, which commonly approximately approximate menopause, induces various metabolic and tissue changes, which are most prominent in the genital tract due to the particular sentitive and you various in see homone levels [2,3] who explined attention with the professive, chemical professive, chemical professive, chemical professive, chemical professive and the value of the value of the value of the professive chemical professive and tissues due to the menoconsulal droot in extreme house. [4, 6, 7]

tion of the vulvo-vaginal miscous membranes and tissues due to the meropassal drop in estrogen levels [4,5]. Typical symptoms of VM, which reflect these vulvo-vaginal morpho-functional changes, include vaginal dryness, include vaginal v

and (unnoying) to severe (very pointryone).
These symptoms may cause significant emotional distress and by result in sexual dysfunction. The burden of WA on the indimay result in sexual dysfunction. The burden of VM on the indi-vidual and the population is greater than physicians may realize, especially due to socio-cultural barriers and a lack of access to builty for an order to remain community.

especially due to socio-cultural barriers and a lack of access 1
bash care in certain countries [12].

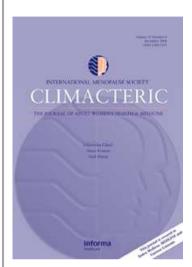
Beause of the prospessive aging of the general population women tray complain of variant aging symptoms (inching burrin reduced tubrication, superficial and/or severe dynameurs are to vivivoraginal arrophy) for more than one third of their lives [1 to vivivoraginal arrophy) for more than one third of their lives [1 to vivivoraginal arrophy) for more than one third of their lives [1 to vivivoraginal arrophy) for more than one third of their lives [1 to vivivoraginal arrophy) for more than one third of their lives [1 to vivivoraginal arrophy) for more than one than a live with the care of the properties of their lives [1 to vivivoraginal arrophy) for persistent symptoms, and systemic horm hormone threapy for persistent symptoms, and systemic horm

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Maurizio Filippini- Ospedale di Stato



#### DUE ARTICOLI SU RIVISTA AD ELEVATO IMPACT FACTOR



CLIMACTERIC 2014:17:1-7

# A 12-week treatment with fractional CO<sub>2</sub> laser for vulvovaginal atrophy: a pilot study

S. Salvatore, R. E. Nappi<sup>6</sup>, N. Zerbinati<sup>†</sup>, A. Calligaro<sup>‡</sup>, S. Ferrero<sup>6,6</sup>, M. Origoni, M. Candiani and U. Leone Roberti Maggiore

Department of Obstetrics and Gynecology, Vita-Salute San Raffaele University and IRCCS San Raffaele Hospital, Milans, \*IRCCS Policlinico S. Matteo Foundation and Department of Clinical, Surgical, Diagnostic and Pediatric Sciences, University of Pavia, Pavia; \*University of Insubria, Varese; \*University of Pavia, Pavia; \*\*Operatment of Obstetrics and Gynecology, San Martino Hospital and National Institute for Cancer Research, University of Genoa, Genoa, Italy

Key words: FRACTIONAL CO., LASER, MENOPAUSE VAGINAL DRYNESS, DYSPAREUNIA, VULVOVAGINAL ATROPHY

#### ABSTRACT

Objective This pilot study aimed to assess the efficacy and feasibility of fractional CO<sub>2</sub> 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<sub>2</sub> laser treatment was effective to improve VVA symptoms (vaginal dryness, vaginal burning, vaginal tiching, dyspareunia, dysuria, p < 0.001) at 12-week follow-up, as well as the VHIS ( $13.1 \pm 2.5$  at baseline vs.  $23.1 \pm 1.9$ ; 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<sub>2</sub> 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.

#### INTRODUCTION

Vulvovaginal atrophy (VVA) is an involution of the mucous membranes and tissues of the vulva and vagina caused by the drop of estrogen that occurs in women during menopause<sup>1-3</sup>. In particular, the vagina becomes narrower and shorter and the introitus can construct<sup>4</sup>. These modifications are commonly associated with the absence of sexual activity and/or with female sexual dysfunction<sup>5,6</sup>. Other typical changes are represented by the progressive loss of elasticity and of rugal folds of the vaginal lining which becomes thin-

ner and may show petechiae. Sebaceous glands reduce the production of secretions and therefore, during sexual activity, lubrication is decreased and delayed<sup>4,5,7</sup>. Patients with VVA complain of vaginal burning and discharges, itching, dryness, irritation, dysuria and dyspareunia<sup>8–11</sup>. Moreover, the weakened tissues are more prone to develop traumas, tears, bleeding and infections<sup>4,7</sup>. Recent reviews<sup>12,13</sup> on the prevalence of VVA symptoms indicate that about 50% of postmenopausal women report at least one symptom associated with the condition. In spite of the relevance of VVA for quality of life, sexual function and relationships at

Correspondence: Dr. U. Leone Roberti Maggiore, Department of Obstetrics and Gynaecology, IRCCS San Raffaele Hospital and Vita-Salute San Raffaele University, Via Olgettina 58-60, 20132 Milan, Italy, e-mail: ulrm@me.com

ORIGINAL ARTICLE
© 2014 International Menopause Society
DOI: 10.3109/13697137.2014.899347

Received 21-01-2014 Revised 09-02-2014 Accepted 25-02-2014 CLIMACTERIC 2014:17:1-7

# Sexual function after fractional microablative CO<sub>2</sub> laser in women with vulvovaginal atrophy

S. Salvatore, R. E. Nappi\*, M. Parma, R. Chionna, F. Lagona, N. Zerbinatti, S. Ferreroi, M. Origoni, M. Candiani and U. Leone Roberti Manuiore

Obstetrics and Gyrecology Unit, Vita-Salute San Raffade University and IRCCS San Raffade Hospital, Milan, "Research Center for Reproductive Medicine, Gyrecological Endocrinology and Menopaure, IRCCS Policlinico S. Mateo Foundation and Department of Clinical, Surgical, Diagnostic and Pediatric Sciences, University of Pavia, Pavia; University of Insubatina, Varesq. (Department of Obstetrics and Gyrecology, IRCCS San Martino Hospital and National Institute for Cancer Research, University of Genoa, Cenoa, Italy

Key words: Fractional Co, Laser, menopause, vaginal dryness, dyspareunia, sexual function, sexual intercourse, valvoractual attachery

#### ABSTRACT

Objective To investigate the effects of fractional microablative CO<sub>2</sub> laser on sexual function and overall satisfaction with sexual life in postmenopausal women with vulvovaginal atrophy (VVA).

Method: This prospective study included 77 postmenopasual women (mean age 60.6 ± 6.2 years) treated for VNA symptoms with the fractional microshlative CO, later oystem (SmartXide<sup>2</sup> V<sup>2</sup>IR, 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 randing scale was used to measure the overall satisfaction with sexual life and the intensity of VNA 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). Sevenetien (85%) do not a 0.0 (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<sub>2</sub> laser treatment is associated with a significant improvement of sexual function and satisfaction with sexual life in postmenopausal women with VVA symptoms.

#### INTRODUCTION

Vulvosaginal atrophy (IVA) defines a progressive age- and extrogen-dependent condition that may lead to the occurrence of symptoms, such as drysess, burning, itching, irritation, discharge and dysuria<sup>1,2</sup>. VVA symptoms can affect up to 50% of postmenopasual women<sup>-1,4</sup> with a significant impact on quality of life and sexual function<sup>1,10</sup>. The drop of estrogen after menopasuse deteremines histological involution both in

the vulva and in the vagina<sup>13,13</sup>, such as thimning, reduced vascularization and elasticity, decreased engorgement and lubrication. All these changes are fikely to produce an altered response to sexual stimuli and to dyspareunia<sup>13</sup>. VVA is therefore generally associated with female sexual dysfunction (FSD)<sup>14</sup>; pain during sexual intercourse, in fact, often co-exists with a decline in women's delire, arousal, organs and frequency of sexual activity throughout the menopausal transition and beyond <sup>15-17</sup>.

Correspondence: Dr U. Leone Roberti Maggiore, Obstetrics and Gynerology Unit, IRCCS San Raffaele Hospital and Vita-Salute San Raffaele University. Via Olgettina 58-60, 20132, Milan, Italy, E-mail: ultimigmo.com

ORIGINAL ARTICLE © 2014 International Menopause Society DOI: 10.3109/13697137.2014.975197 Revised 15-04-2014 Revised 21-09-2014 Accepted 61-10-2014





# MONNALISA TOUCH

# " NON E' UN TRATTAMENTO ESTETICO MA FUNZIONALE »





# RISULTATI



### NUMERO TRATTAMENTI ESEGUITI DAL 23.01.2013 AL 20.02.2015

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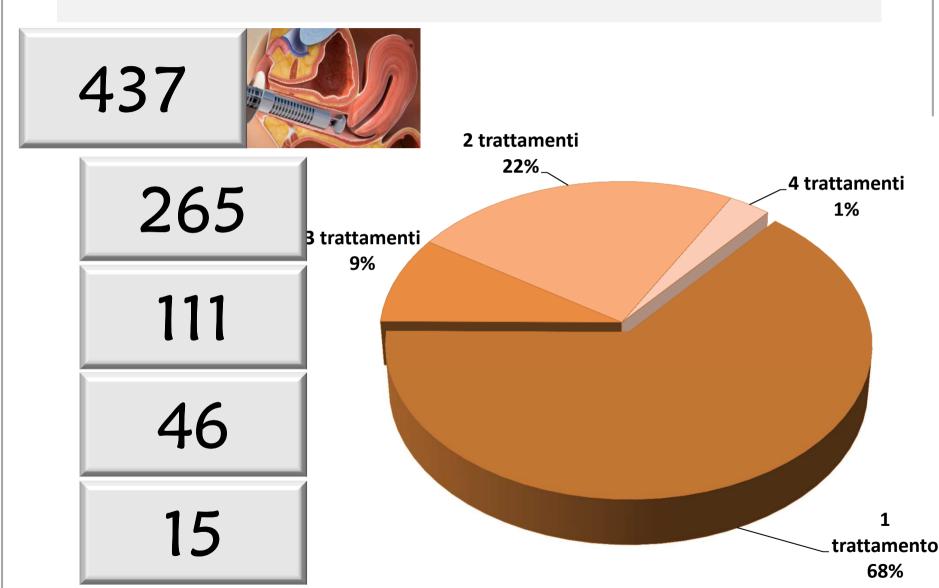
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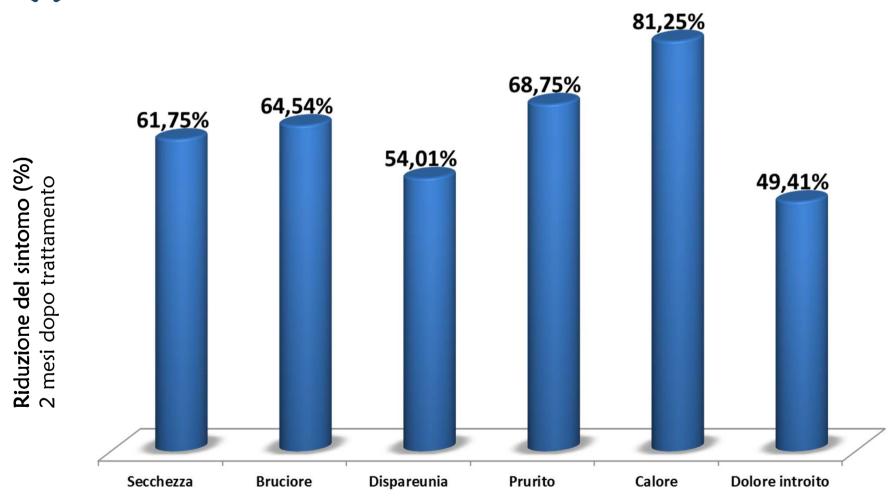
Maurizio Filippini- Ospedale di Stato della Repubblica di Sun murmo



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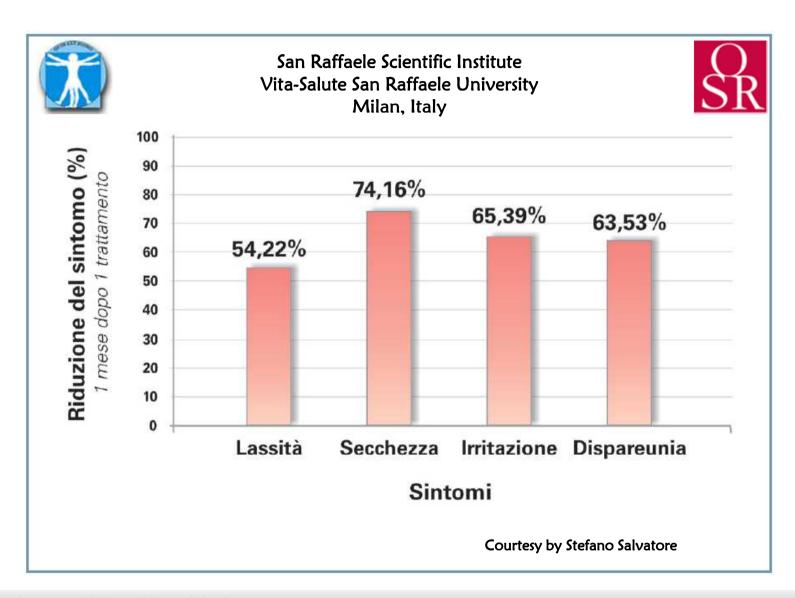


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### RIDUZIONE IN PERCENTUALE DI OGNI SINTOMO





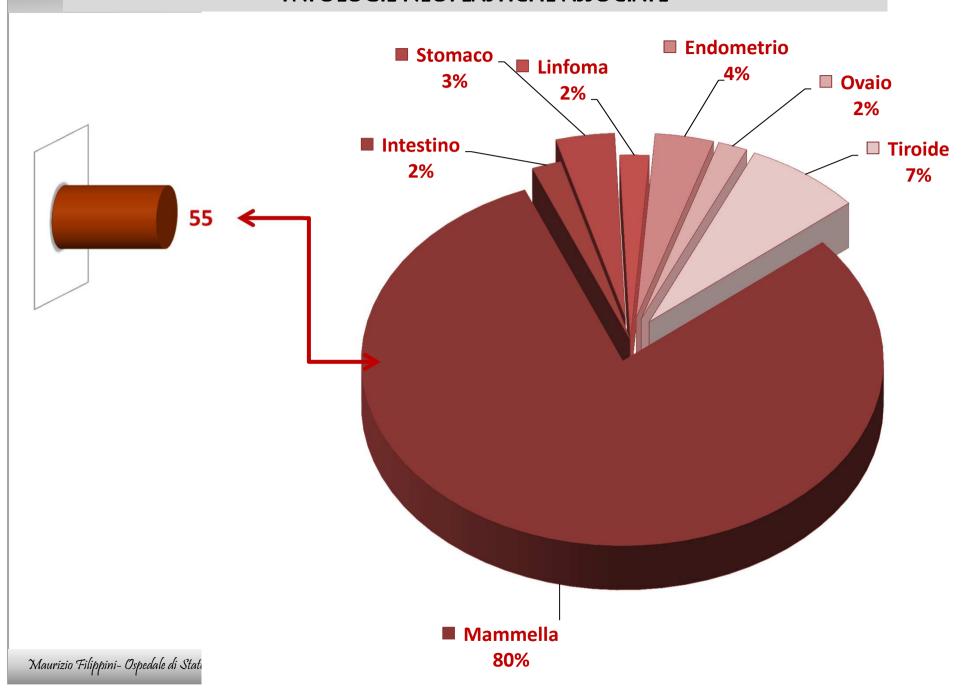


# PATOLOGIA NEOPLASTICA

Maurizio Filippini- Ospedale di Stato della Repubblica di San Marino



## PATOLOGIE NEOPLASTICHE ASSOCIATE

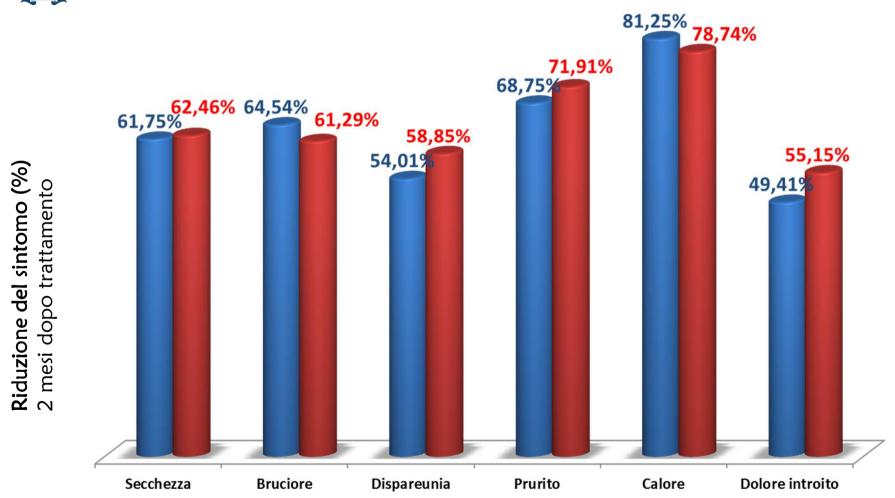




### RIDUZIONE IN PERCENTUALE DI TUTTI I SINTOMI DOPO 3 TRATTAMENTI



Ospedale di Stato della Repubblica di San Marino



## Risultati del trattamento Monna Lisa Touch nell'esperienza dell'Ospedale della Repubblica di San Marino





**NOVEMBER 2014** 

#### Use of the MonaLisa Touch® Treatment on Cancer Patients

Maurizio Filippini, M.D. - Miriam Farinelli, M.D. Gynaecological Endoscopy Functional Unit of the Republic of San Marino State Hospital

Objectives: This pilot study aimed to assess the efficacy in treating atrophic vaginitis symptoms in those women who cannot receive local or systemic hormone-based therapies, since they have had a hormone-sensitive tumour.

Materials and methods: 46 treatments with the MonaLisa Touch® were performed from 01/23/2013 to 10/31/2014 at the Republic of San Marino State Hospital involved patients with neoplasias. The intensity of atrophic vaginitis symptoms was recorded for each patient.

Results: About two months after the first treatment the percent reduction of the individual symptoms was very significant. not unlike that obtained from patients who received the treatment but without neoplastic pathologies. Furthermore, after the treatment, a significant improvement in quality of life was shown

Conclusions: Considering the absence of complications and especially the absence of contraindications, the MonaLisa Touch® laser treatment is a valuable and irreplaceable aid for all patients who cannot and prefer not to receive hormone replacement therapy.

Key words: vaginal atrophy, oestrogen-sensitive tumour, induced menopause, laser

#### INTRODUCTION

Vaginal atrophy, also called atrophic vaginitis, affects many women throughout the world, occurring almost always after menopause, but also in all cases where there is a lack of oestrogen, such as after childbirth, during the breastfeeding stage when ovulation is blocked or after an oestrogen-sensitive tumour (such as in the breasts, endometrium or the ovaries) where a chemotherapeutic or surgical "castration" of the This new therapeutic opportunity is an excellent menstrual cycle occurs. In these cases the use of chance for all women who suffer from these disorders. hormone replacement therapies, even local or at low dosage, are therefore absolutely contraindicated1.

The symptoms related to vaginal atrophy normally begin to appear between the ages of 45 and 55. Unlike other symptoms of menopause, such as the hot flashes which often decrease over time, these usually continue and can worsen as time progresses.

This condition can cause dryness, irritation, burning or pain during sexual intercourse, affecting up to 40% of MATERIALS AND METHODS postmenopausal women1,2.

Until now, treatment for this condition involved the CO<sub>2</sub> laser system SmartXide<sup>2</sup> (DEKA - Florence, Italy) prescribing of vaginal oestrogens in the form of were performed from 01/23/2013 to 10/31/2014 at the tablets. ovules or creams to insert into the vaginal Republic of San Marino State Hospital; 46 of these

that have a stimulating or revitalizing action such as natural hyaluronic acid.

Borrowing from dermatological treatment for collagen stimulation which has been done for many years using CO, fractional laser scanning systems, scientific research has come up with a very effective therapeutic solution to improve the symptoms of vulvo-vaginal

especially women who do not want to take hormones for personal or psychological reasons, believing that they are the cause of the pathology

The importance of this treatment is all the more reason to be considered for those women who cannot receive local or systemic hormone-based therapies, since they have had a hormone-sensitive tumour78.

359 treatments with the MonaLisa Touch® using the canal using an applicator, infiltrations with substances treatments involved patients with neoplasias (36

STATE HOSPITAL - REPUBLIC OF SAN MARINO

Via Scialoja, 20 - 47893 Borgo Maggiore (RSM) el. +378 (0549) 994220







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