



Obstetrics and Gynaecology Unit
Functional Unit of Urogynaecology
Vita-Salute San Raffaele University and San Raffaele Hospital
Milan – Italy



*Laser CO2: una terapia ambulatoriale
innovativa nel trattamento delle
disfunzioni sessuali femminili*

Stefano Salvatore

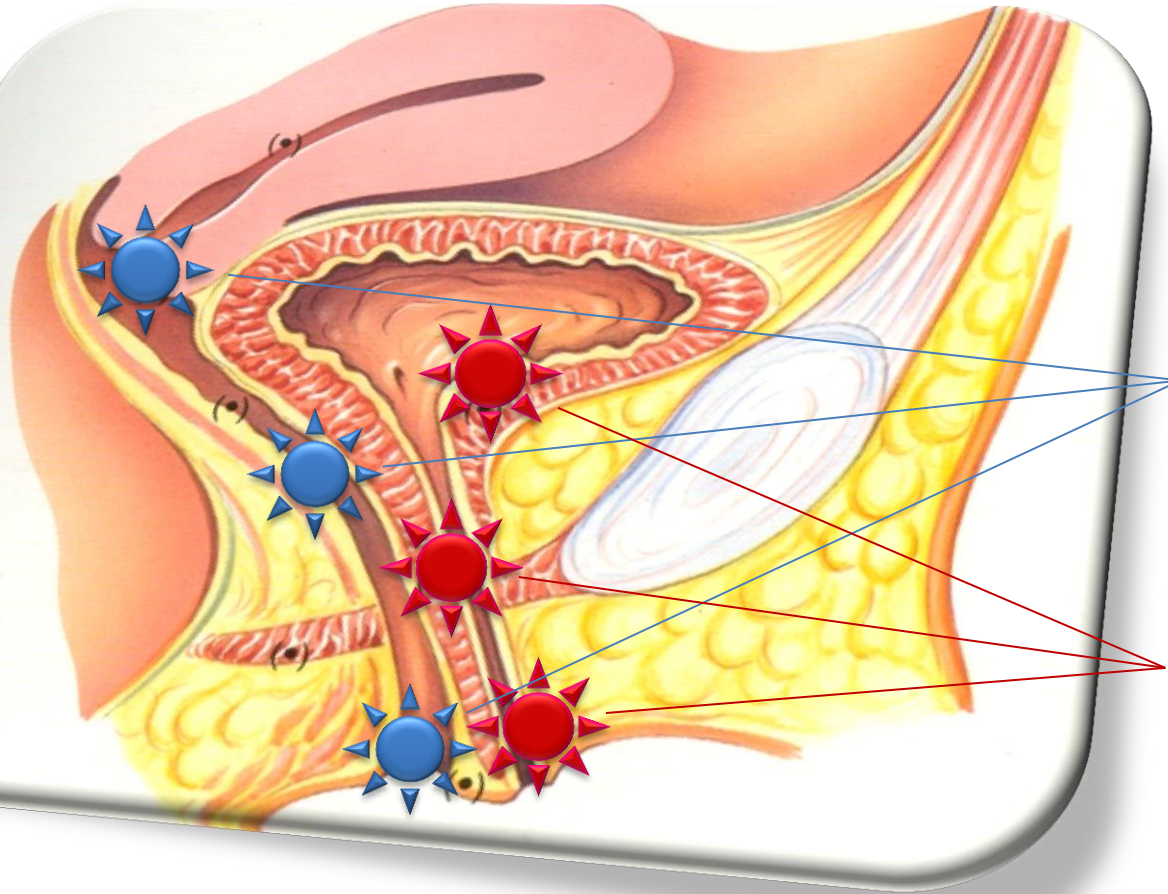
Vaginal changes after menopause

Senile changes in the vagina involve:

- Reduced vaginal blood flow
- Vaginal walls become thinner, less elastic, with loss of rugation
- Vaginal surface becomes friable with petechiae, ulcerations, and bleeding often occurring after minimal trauma.
- Shortening and narrowing of the vaginal canal
- Loss of glycogen content
- Loss of Lactobacilli easily replaced by pathogenic bacteria
- Increase of vaginal pH from 4.5-5.5 to 7.0-7.4
- Changes in the quantity and quality of vaginal secretions



VVA & LUTS



**DECREASE IN
ESTROGEN LEVELS**

**VULVO-VAGINAL
SYMPTOMS**

**URINARY
SYMPTOMS**

- ✓ Urinary frequency
- ✓ Urgency
- ✓ Urge incontinence
- ✓ Dysuria
- ✓ Recurrent UTIs

Background To The Health Issue



- During 1881-1890, the average life expectancy of a woman in Australia was 50.8 years, ie., The end of their childbearing years
- Now life expectancy is 84.3 years. The average age for menopause is 51 years old. Women now have 30+ years to live after menopause

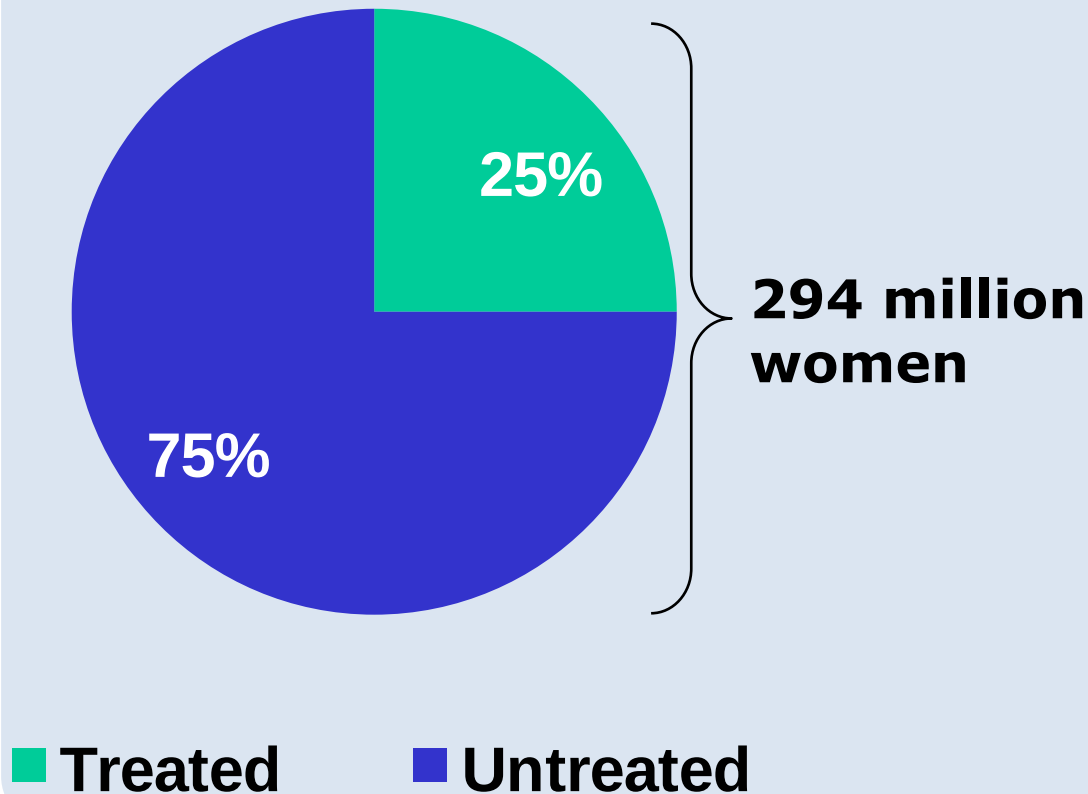
Managing a woman with GSM

Treatment options:

- Moisturizers and lubricants
- Estrogen therapy
- Selective estrogen receptor modulator (SERM)
- Laser therapies
- Synthetic steroid (tibolone)
- Oxytocin gel
- Intravaginal dehydroepiandrosterone
- Homeopathic remedies (black cohosh, dong quai, phytochemicals, nettle, comfrey root, motherwort, soy foods, chaste tree extract, etc.)
- Lifestyle modifications (increased sexual activity, stress reduction therapy and psychological counseling, cessation of smoking, etc.)

An almost untreated condition...

Postmenopausal women with vaginal atrophy worldwide¹



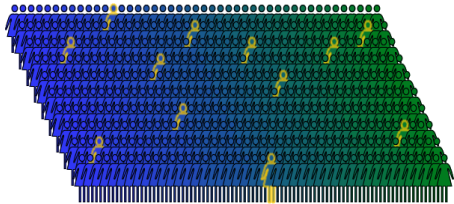
Key trends

- 294 million women worldwide with symptoms of VA
- 221 million women untreated worldwide
- Average duration of treatment: 43% > 1 year²

1. The World Bank

2. Market Research: Market Landscape & Pricing; Hall & Partners Healthcare, 2008

The VIVA (Vaginal Health: Insights, Views & Attitudes) - online survey



- 80% considered it to negatively affect their lives
- **75% reported negative consequences on sex life**
- **68% reported that it makes them feel less sexual**
- 36% reported that it makes them feel old
- **33% reported negative consequences on marriage/ relationship**
- 26% reported a negative effect on self-esteem
- 25% reported that it lowers QOL

Vulvo

Table 2 Self-reported reasons fo

Reason	La
Embarrassment	“It em “I a Em pro
Belief that nothing can be done	“It’ “Th do
Belief that it is an inappropriate topic to discuss with an HCP	“I c to “It cor “It to

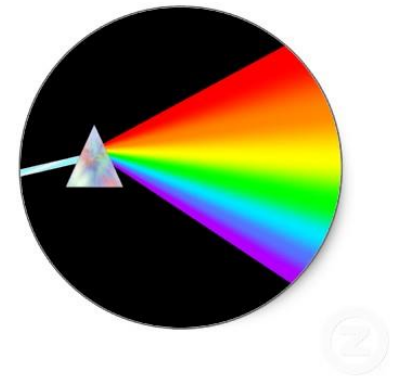
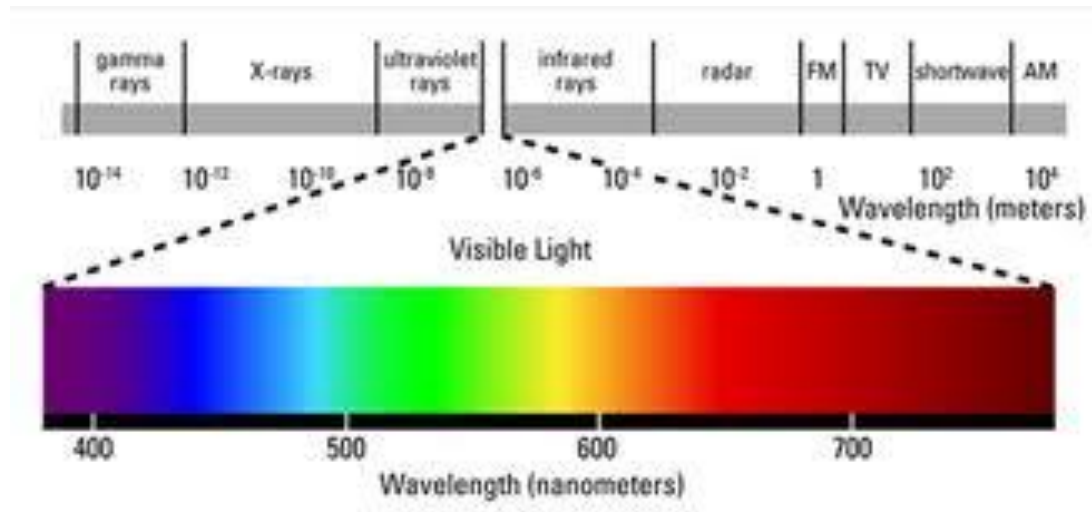
Abbreviations: HCP, health care provide
and Determinants of Treatment Seeking str
Parish SJ, Nappi RE et al In



Reference
Women's Voices in the Menopause ⁷
REVEAL ⁶
PRESIDE ³⁵
Women's Voices in the Menopause ⁷
REVEAL ⁶
Women's Voices in the Menopause ⁷
Women's Voices in the Menopause ⁷
REVEAL ⁶

blems Associated with Distress

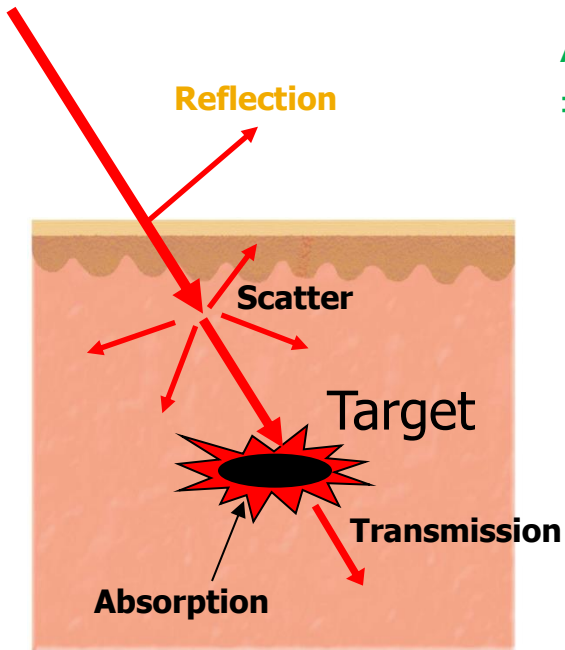
Wavelength: expressed in nanometer (nm)



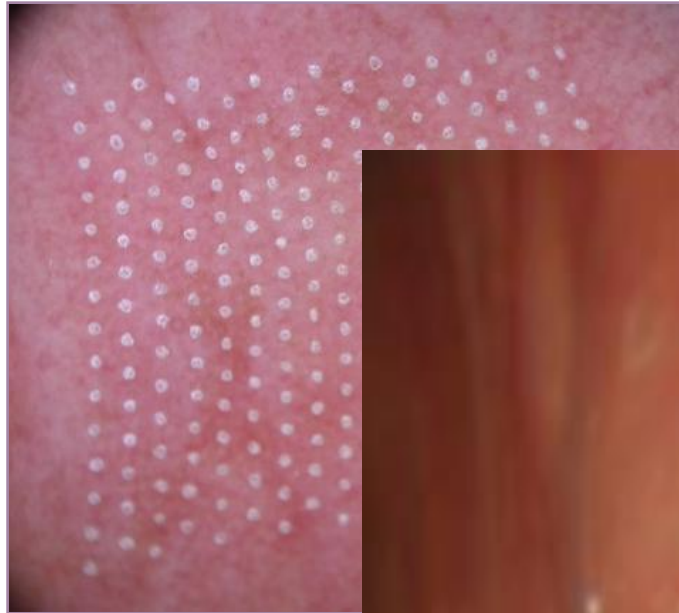
Wavelengths of medical lasers
UV – Visible– 10600nm (IR)

Laser basics (3/5)

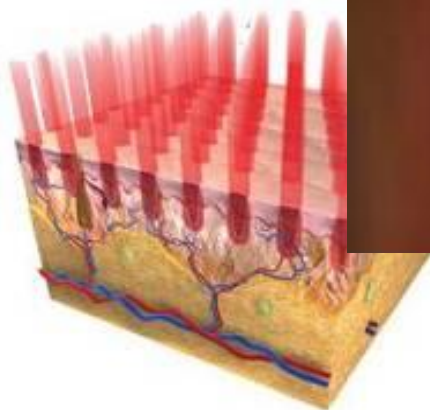
Absorption: light is transformed in heat
=> Selective Photothermolysis



FRACTIONAL CO₂ LASER



Spacing 1000 μ m

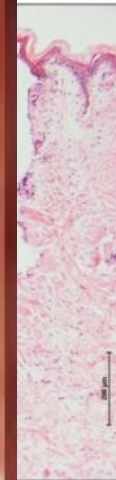


SmartXideDOT 30 W - 1000 μ s - 800 μ m - SmartTrack

Stack 1 (')

Stack 3 (")

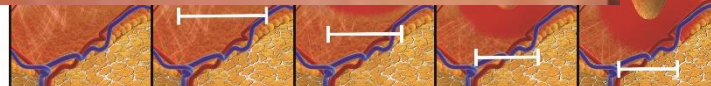
Stack 5 (")



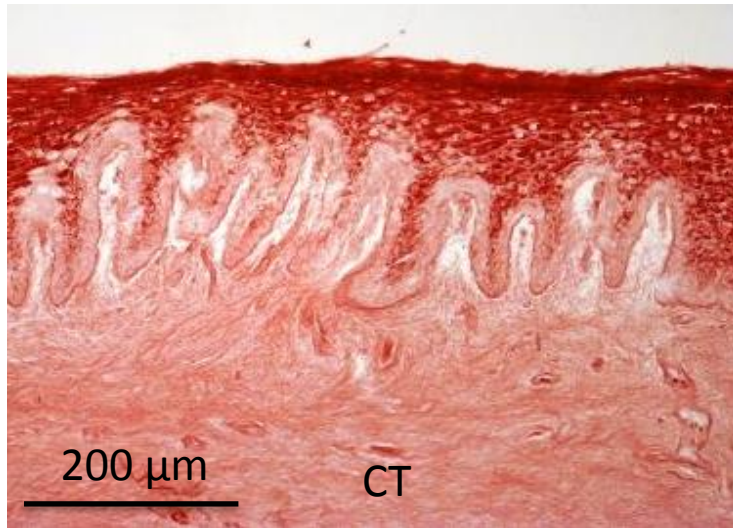
1000 μ m
900 μ m
800 μ m
700 μ m
600 μ m
500 μ m
400 μ m
300 μ m
200 μ m
100 μ m
0

Ingrandimento "10 x"

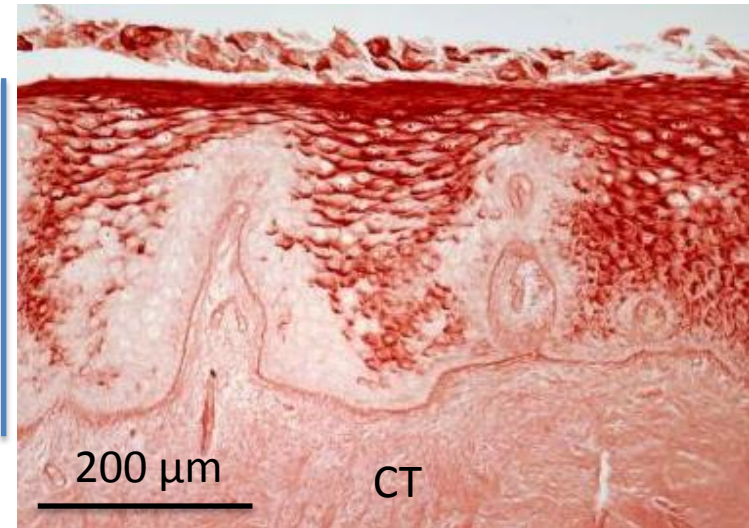
SmartStack 5



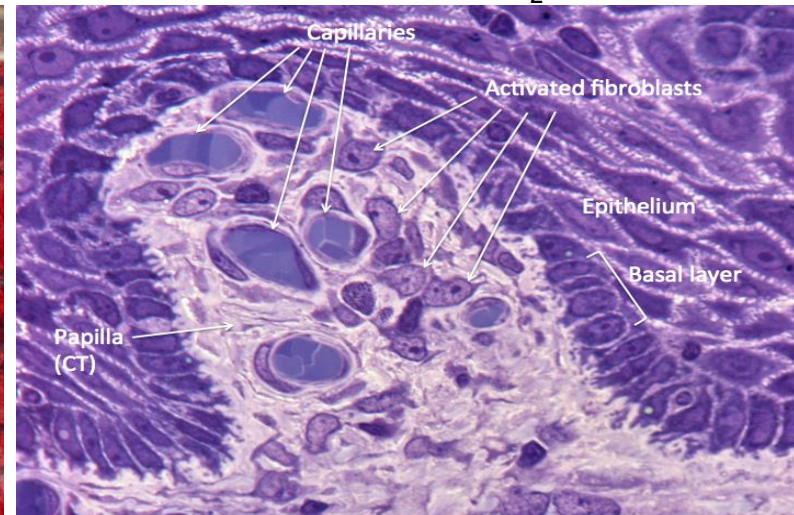
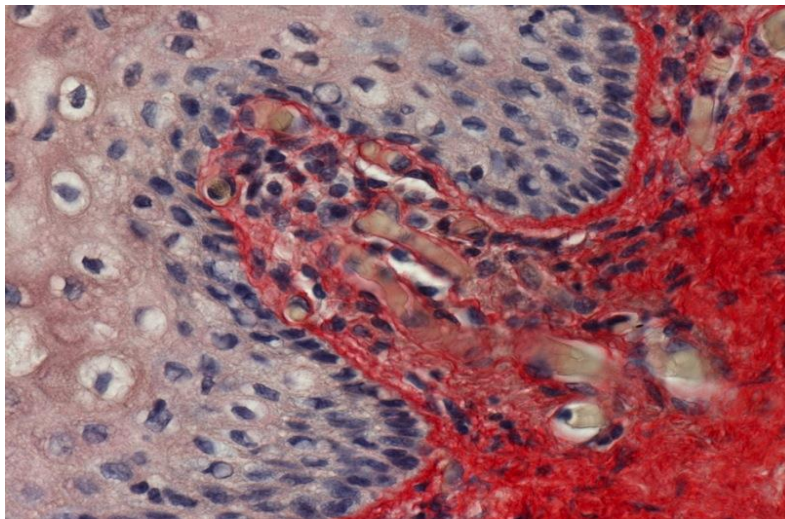
MICROABLATIVE FRACTIONAL CO₂ LASER



Postmenopausal vaginal mucosa



Postmenopausal vaginal mucosa
1 month after fractional CO₂ laser treatment



Treatment Applicators



360°
probe

Standard 90°
probe

Narrow 16mm
90° probe

[Climacteric.](#) 2014 Feb;17(1):3-9.

Impact of vulvovaginal atrophy on sexual health and quality of life at postmenopausal age



● Efficacy?

➤ Vulvovaginal Atrophy (VVA)



➤ Sexual Dysfunction



➤ Lower Urinary Tract Symptoms (LUTS)



GSM

- Vaginal dryness
- Dyspareunia
- Itching
- Burning

 **Efficacy?**
 **VVA**

 Visual analogue scale (VAS)



0

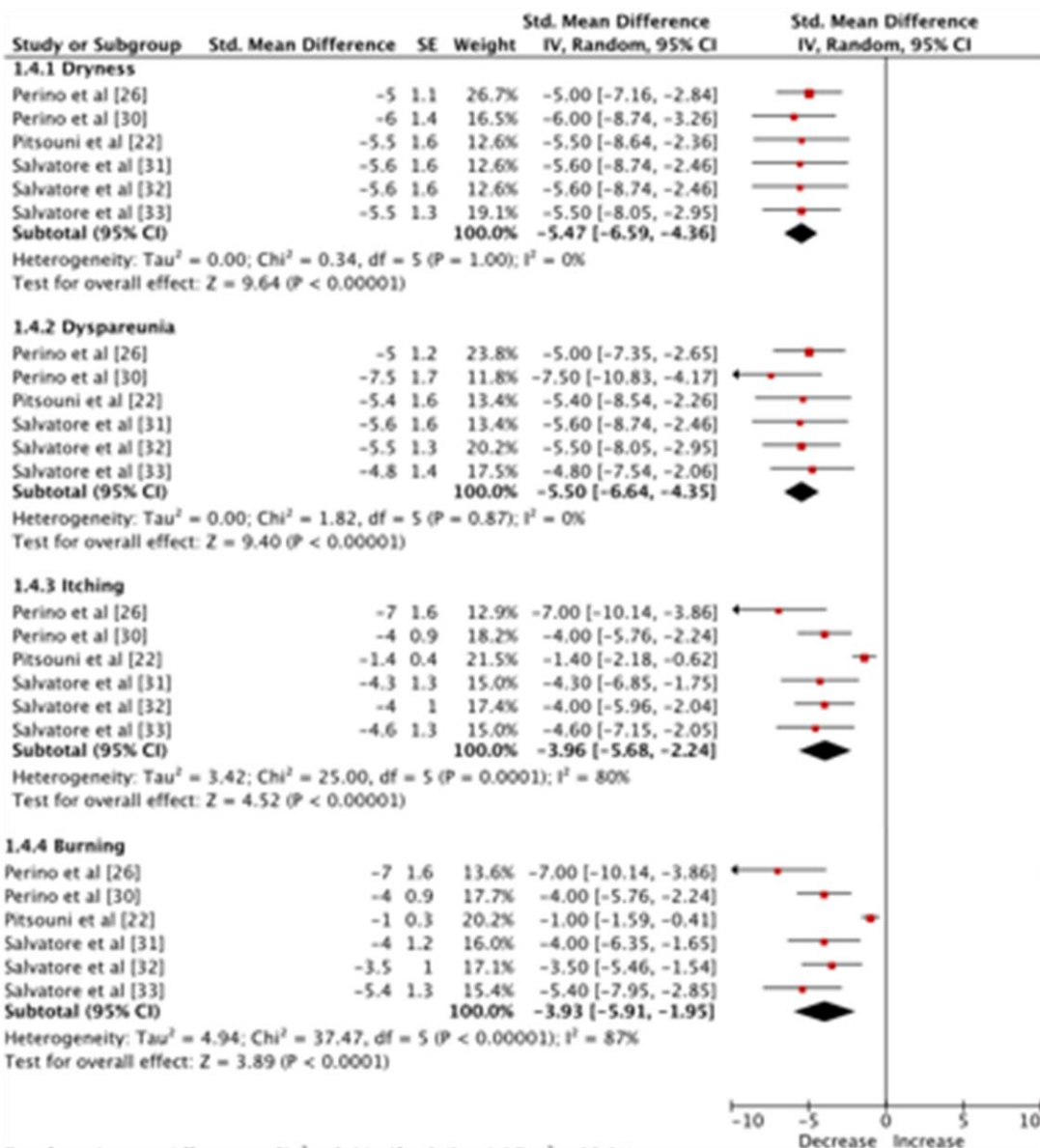
Absence of
symptoms

10

Worst possible

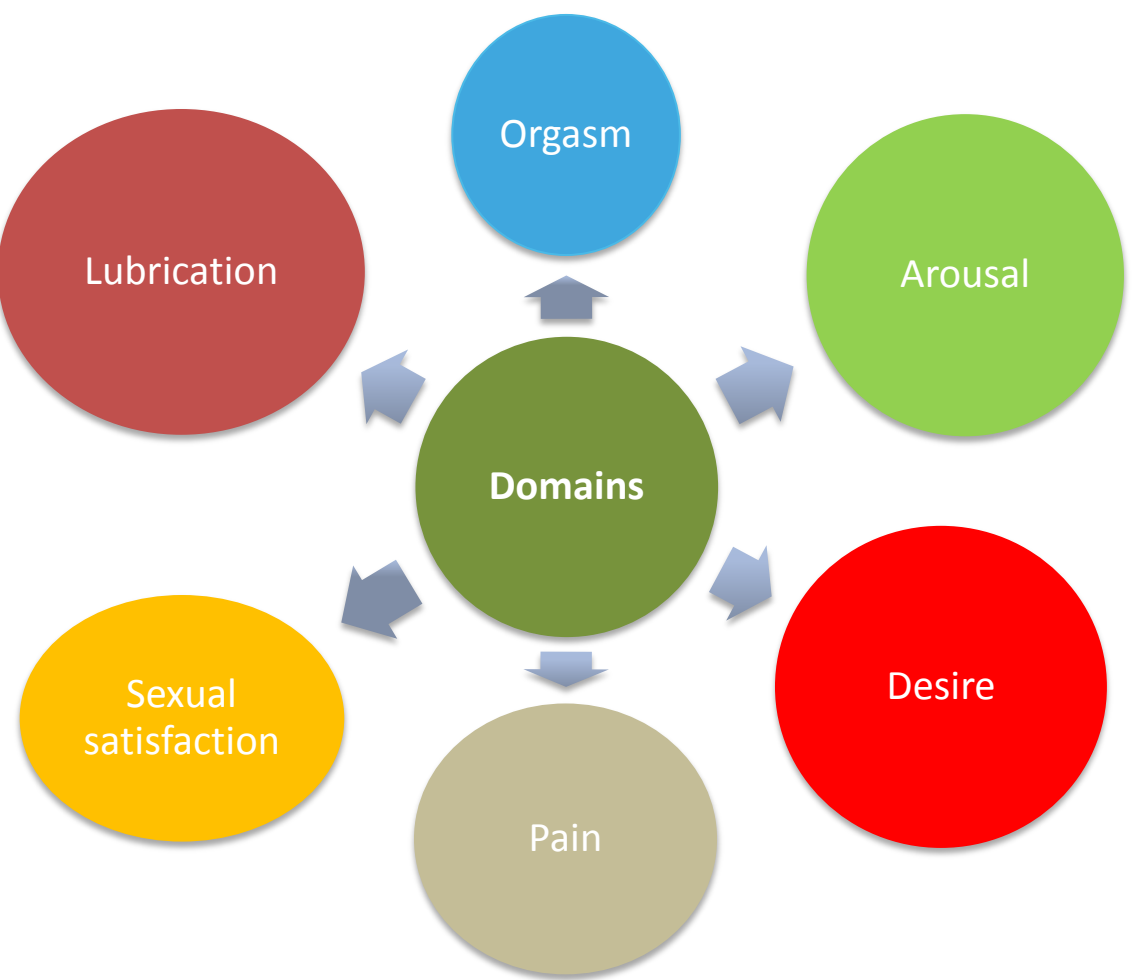
Laser therapy for the genitourinary syndrome of menopause. A systematic review and meta-analysis

Eleni Pitsouni^a, Themios Grigoriadis^a, Matthew E. Falagas^{b,c,d}, Stefano Salvatore^{e,f}, Stavros Athanasiou^{a,*}



- Observational studies
- 1-month after **3** laser sessions (1 session/month)
- n= 255

- Female Sexual Function Index (FSFI)



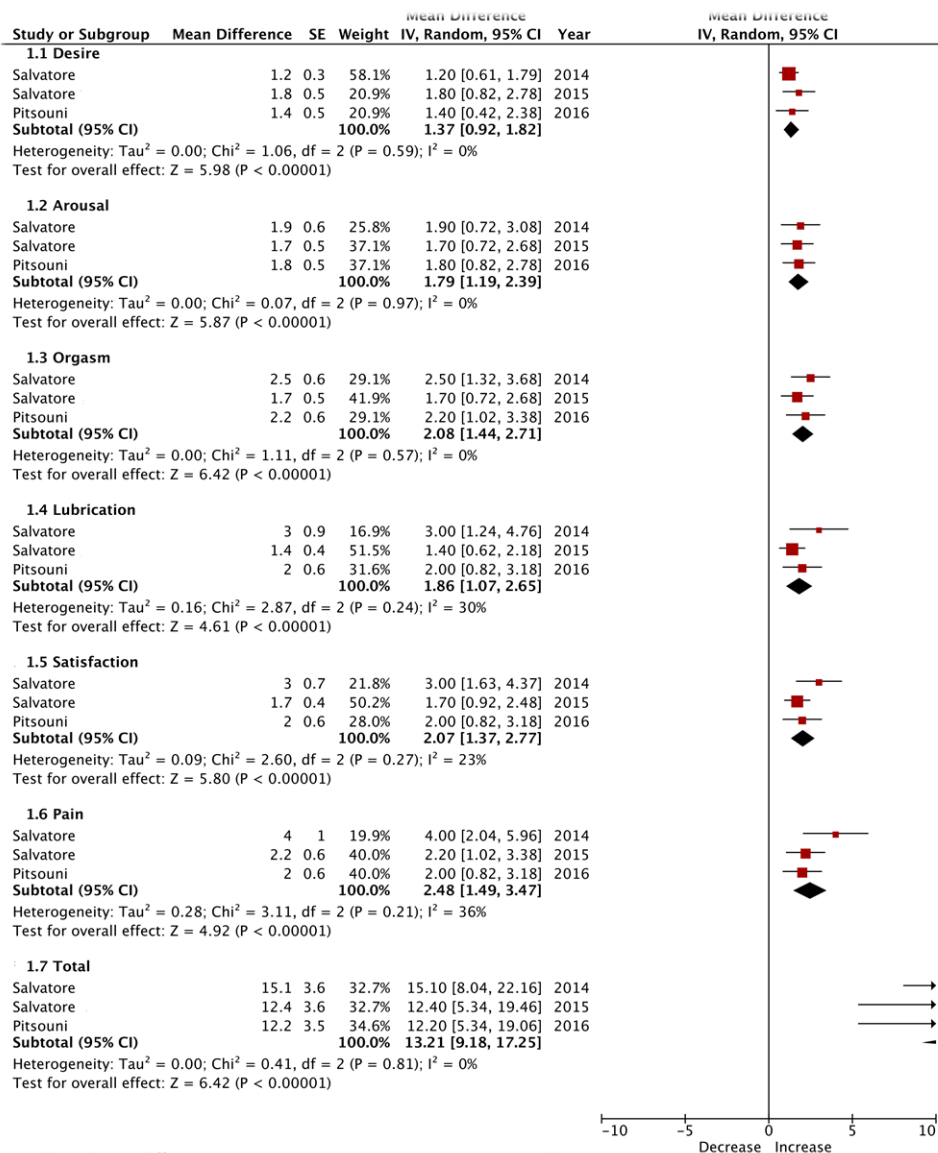
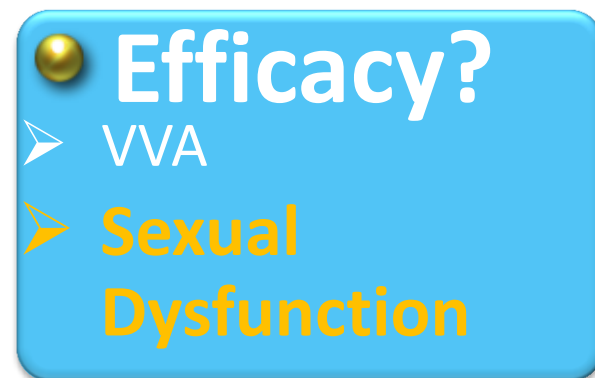
Efficacy?

- VVA
- Sexual Dysfunction

- Dyspareunia (VAS 0-10)
- Overall sexual satisfaction (VAS 0-10)

Sexual Function in Women Suffering From Genitourinary Syndrome of Menopause Treated With Fractionated CO₂ Laser

Stefano Salvatore, MD,¹ Eleni Pitsouni, MD,² Fabio Del Deo, MD,¹ Marta Parma, MD,¹ Stavros Athanasiou, MD,² and Massimo Candiani, MD¹



- Observational studies
- 1-month after **3** laser sessions (1 session/month)
- n= 273

Sexual Function in Women Suffering From Genitourinary Syndrome of Menopause Treated With Fractionated CO₂ Laser

Stefano Salvatore, MD,¹ Eleni Pitsouni, MD,² Fabio Del Deo, MD,¹ Marta Parma, MD,¹ Stavros Athanasiou, MD,² and Massimo Candiani, MD¹

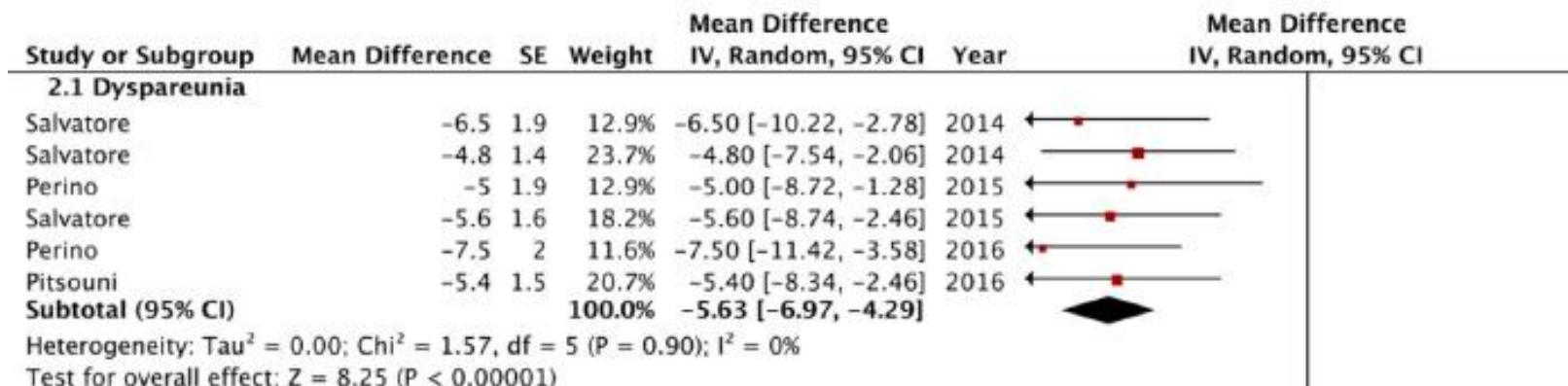


Efficacy?

VVA

Sexual Dysfunction

Dyspareunia



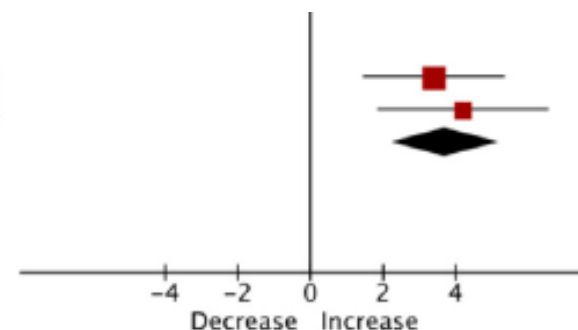
Overall satisfaction

2.2 Overall Sexual Satisfaction

Salvatore	3.4	1	59.0%	3.40 [1.44, 5.36]	2015
Pitsouni	4.2	1.2	41.0%	4.20 [1.85, 6.55]	2016
Subtotal (95% CI)			100.0%	3.73 [2.22, 5.23]	

Heterogeneity: $\tau^2 = 0.00$; $\chi^2 = 0.26$, $df = 1$ ($P = 0.61$); $I^2 = 0\%$

Test for overall effect: $Z = 4.85$ ($P < 0.00001$)



HOW MANY LASER SESSIONS?

● Efficacy?

- Resumption of sexual intercourse?
- Improvement of symptoms?
- Complete resolution of symptoms?



HOW MANY LASER SESSIONS?

Sexual function after fractional microablative
CO₂ laser in women with vulvovaginal
atrophy

2014

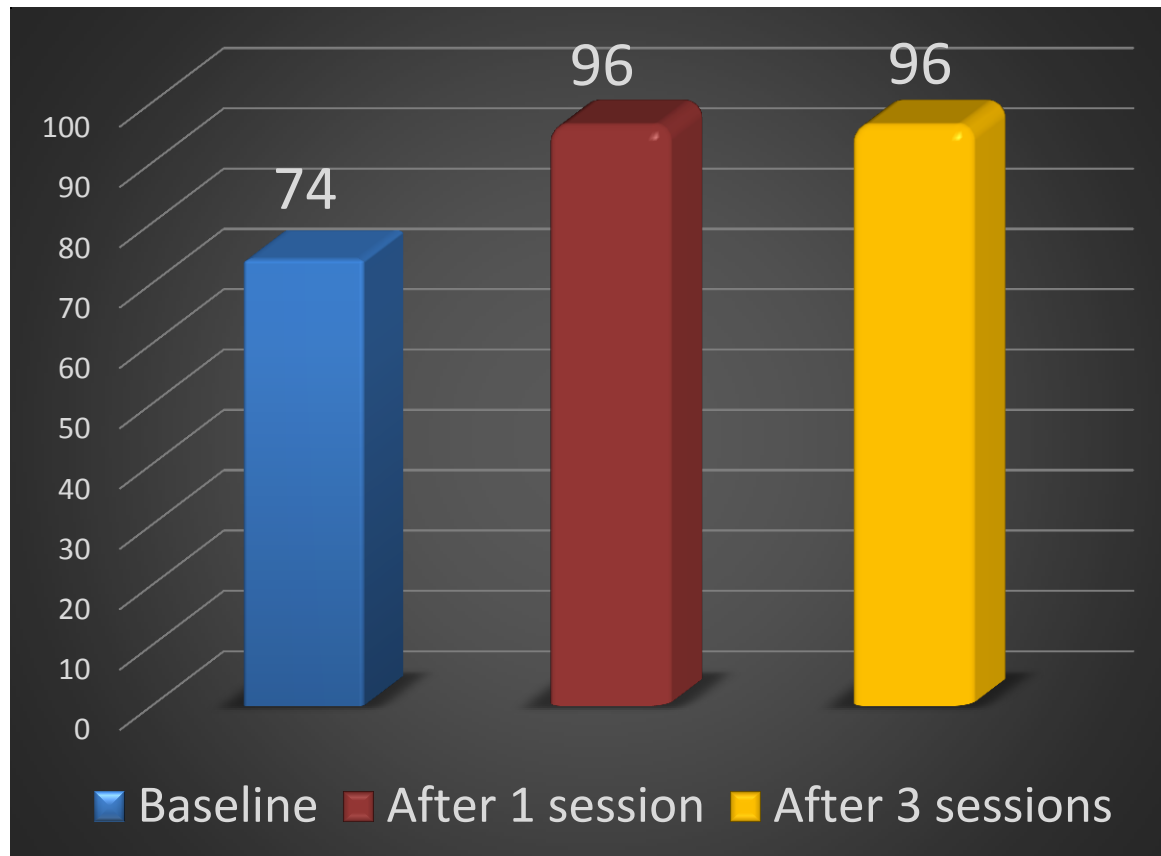
S. Salvatore, R. E. Nappi, M. Parma, R. Chionna, F. Lagona, N. Zerbinati†, S. Ferrero‡, M. Origoni,
M. Candiani and U. Leone Roberti Maggiore*



● Efficacy?

● Resumption
of sexual
intercourse?

1
SESSION?



HOW MANY LASER SESSIONS?

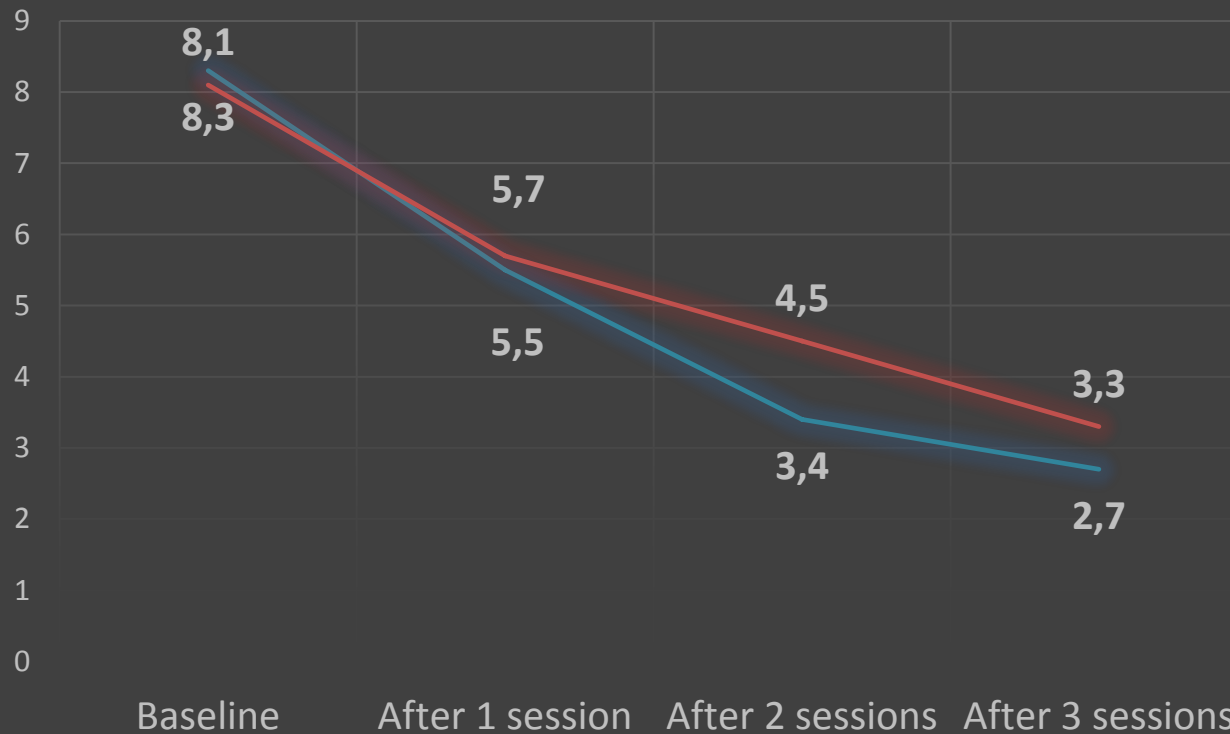
A 12-week treatment with fractional CO₂ laser for vulvovaginal atrophy: a pilot study

S. Salvatore, R. E. Nappi*, N. Zerbinati†, A. Calligaro‡, S. Ferrero**, M. Origoni, M. Candiani and U. Leone Roberti Maggiore

2014



— Dryness — Dyspareunia



● Efficacy?

● Improvement of symptoms?

HOW MANY LASER SESSIONS?

CO₂-laser for the genitourinary syndrome of menopause. How many laser sessions?

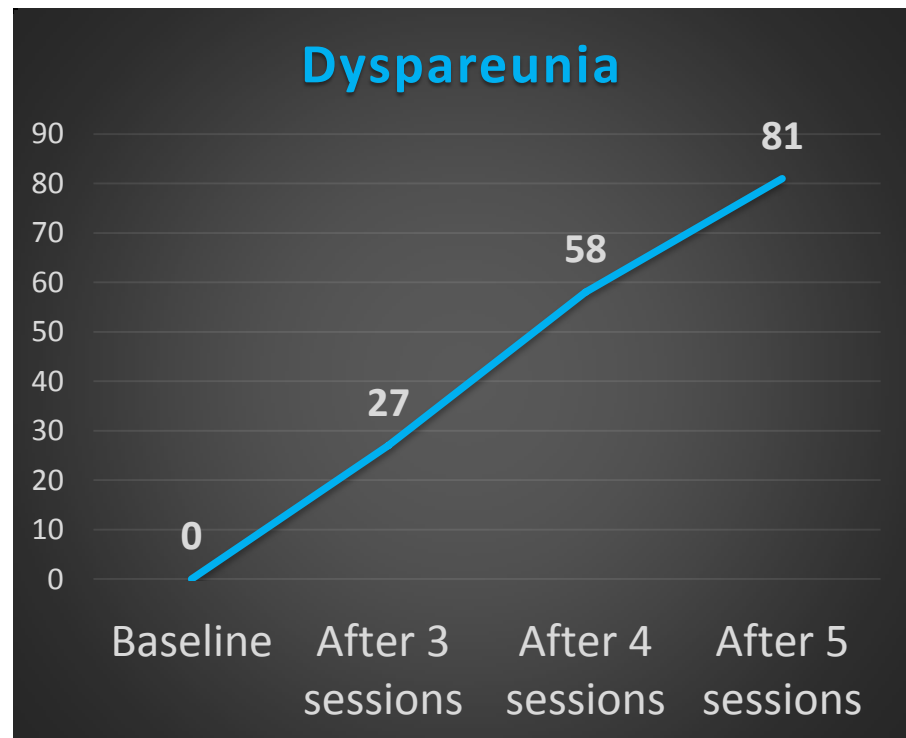
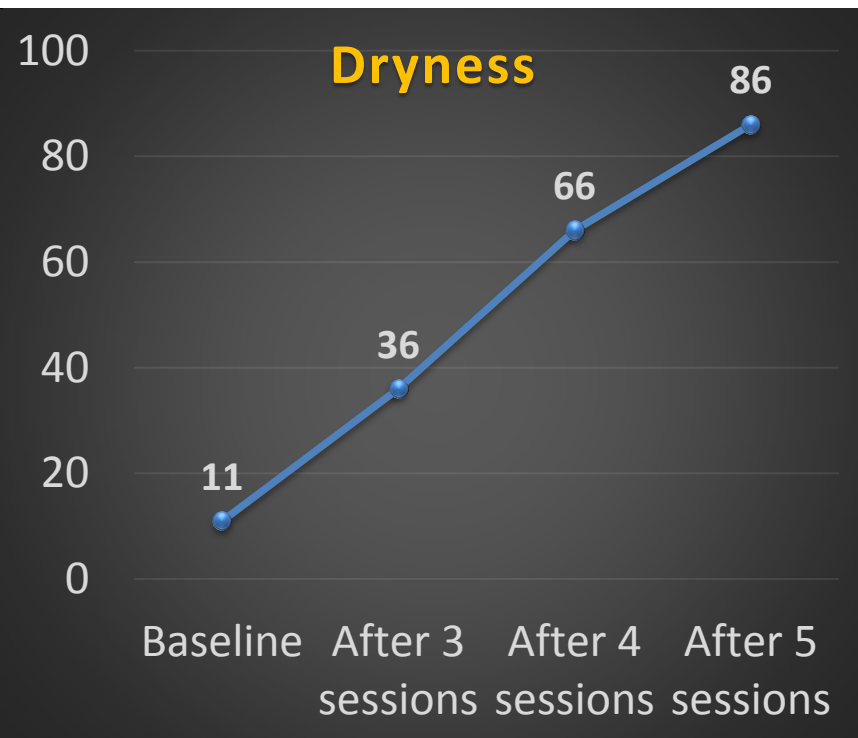
Stavros Athanasiou^{a,*}, Eleni Pitsouni^a, Matthew E. Falagas^{b,c,d}, Stefano Salvatore^e, Themis Grigoriadis^a

2017



3-5 SESSIONS?

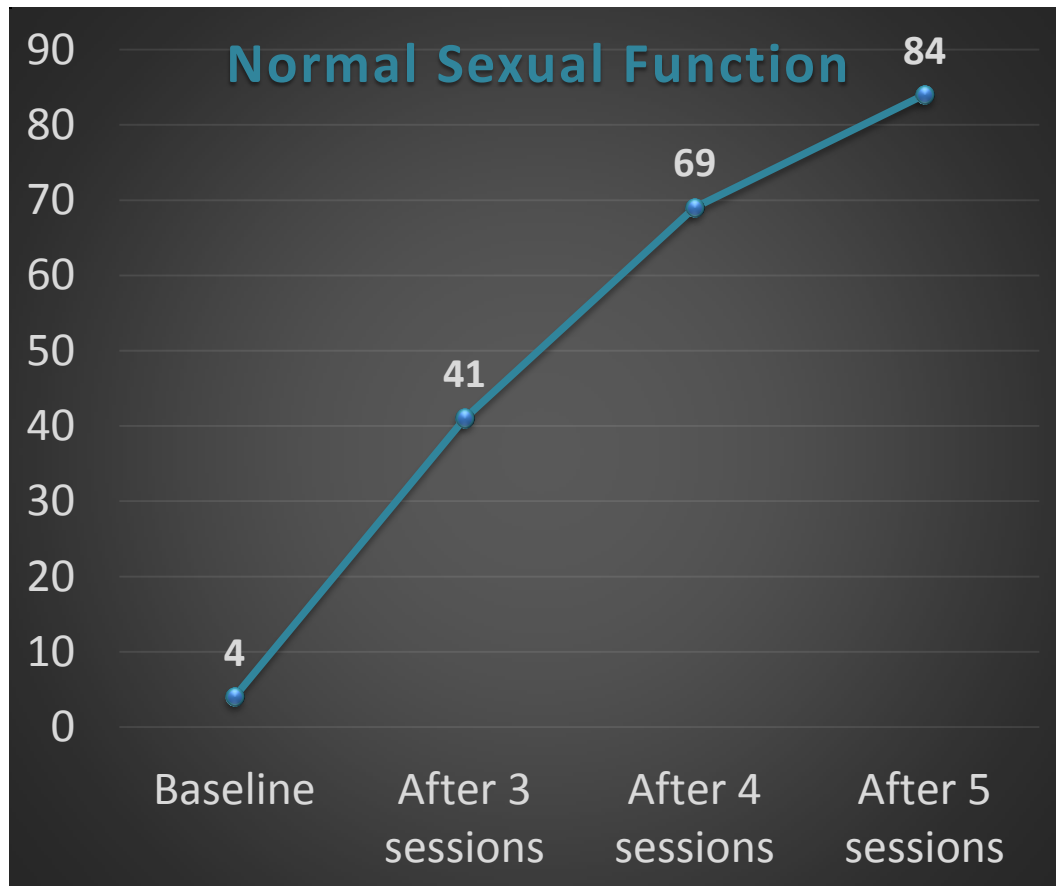
● Complete resolution of symptoms? (VAS zero)



HOW MANY LASER SESSIONS?

CO₂-laser for the genitourinary syndrome of menopause. How many laser sessions?

Stavros Athanasiou^{a,*}, Eleni Pitsouni^a, Matthew E. Falagas^{b,c,d}, Stefano Salvatore^e,
Themos Grigoriadis^a



● **Efficacy?**

● Normal Sexual
Function?
(Total FSFI > 26.55)

3-5 SESSIONS?

- **Postmenopausal women**

- Decrease in Lactobacilli
- Increase pH
- Loss of vaginal defense mechanisms
- Predisposition to infections
- High incidence of UTIs (8%) and recurrence

● **Efficacy?**

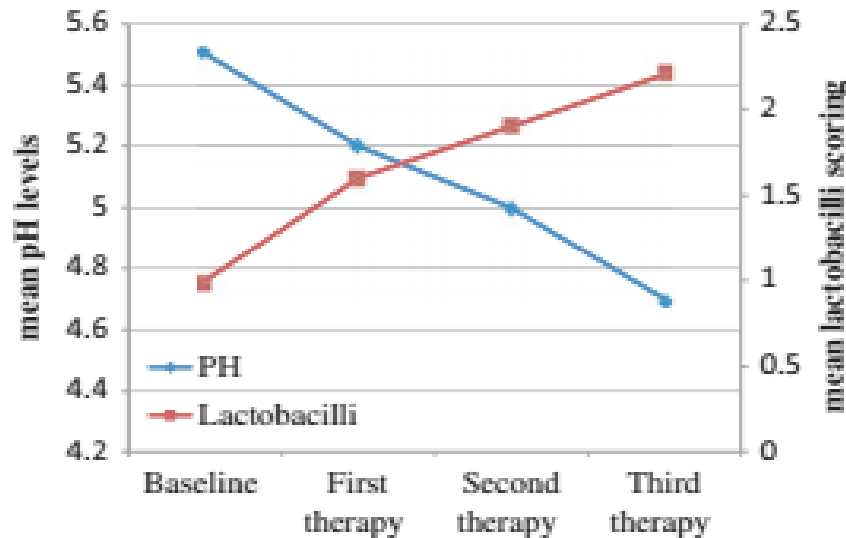
- VVA
- Sexual dysfunction
- **LUTS (UTIs)**

The effect of microablative fractional CO₂ laser on vaginal flora of postmenopausal women

2016



S. Athanasiou^a, E. Pitsouni^{a,b}, S. Antonopoulou^c, D. Zacharakis^a, S. Salvatore^d, M. E. Falagas^{b,e,f} and T. Grigoriadis^a



Efficacy?

- VVA
- Sexual dysfunction
- LUTS (UTIs)

- Observational study
- 1-month after 3 laser sessions (1 session/month)
- n=53

Table 2. Presence of microorganisms in the vaginal fluid of the women included in this study. Data are given as n (%)

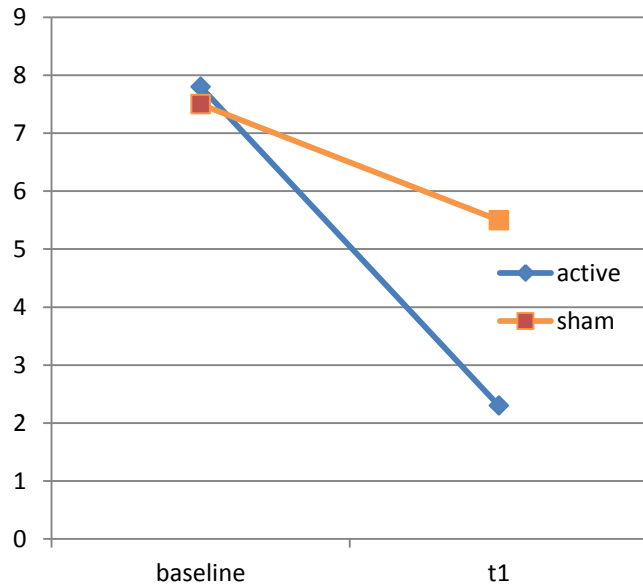
Microorganisms ^a	Baseline (n = 53)	After 1 laser therapy (n = 52)	After 2 laser therapies (n = 53)	After 3 laser therapies (n = 53)	p Value ^b
<i>Lactobacillus</i>	36 (67.9)	45 (86.5)	46 (86.8)	53 (100)	<0.001
<i>Gardnerella vaginalis</i>	5 (9.4)	2 (3.8)	4 (7.5)	4 (7.5)	0.7
<i>Bacteroides</i>	5 (9.4)	5 (9.6)	4 (7.5)	2 (3.8)	0.2
<i>Mobiluncus</i>	4 (7.5)	2 (3.8)	2 (3.8)	0 (0)	0.04
<i>Streptococcus agalactiae</i>	5 (9.4)	2 (3.8)	1 (1.9)	2 (3.8)	0.2
<i>Enterococcus faecalis</i>	12 (22.6)	8 (15.1)	7 (13.2)	6 (11.3)	0.1
<i>E. coli</i>	20 (37.7)	10 (19.2)	6 (11.3)	9 (16.9)	0.02
<i>Klebsiella</i>	3 (5.7)	2 (3.8)	1 (1.9)	0 (0)	0.08
<i>Proteus</i>	1 (1.9)	2 (3.8)	3 (5.7)	1 (1.9)	1
<i>Candida spp.</i>	1 (1.9)	1 (1.9)	1 (1.9)	1 (1.9)	1



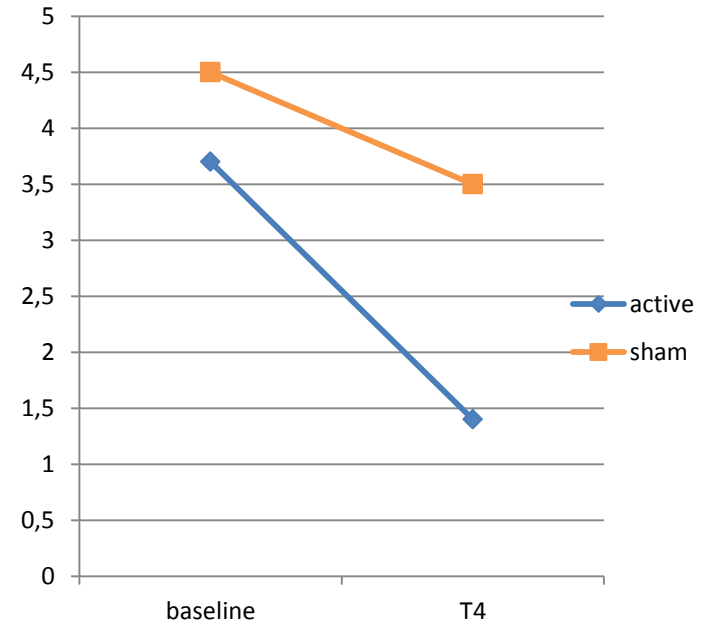
**A double-blind randomised controlled trial of
microablative fractional CO₂ laser vs sham
therapy on patients with
vaginal dryness linked sexual function
limitations: an interim analysis**

*S. Girardelli, E. Pitsouni, E. Marotta, M. Parma,
M. Candiani, S. Athanasiou,
S. Salvatore*

Vaginal Dryness



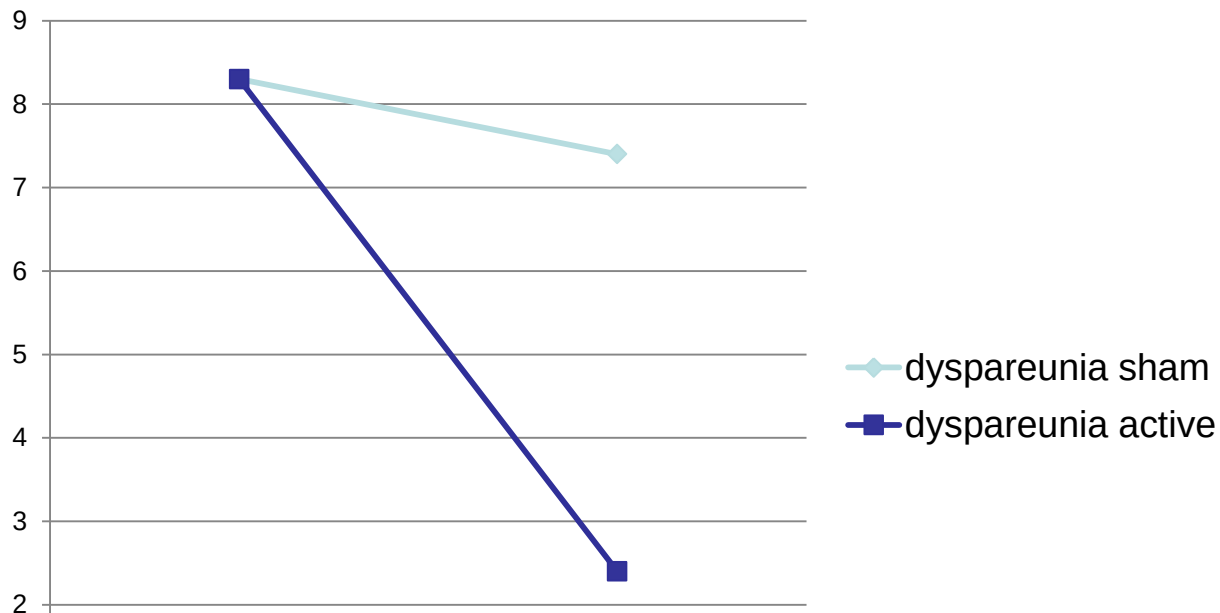
Burning



Vaginal Dryness	Baseline	T4	p - value
Active	7.8	2.3	< 0.05
Sham	7.5	5.5	> 0.05

Changes in dyspareunia

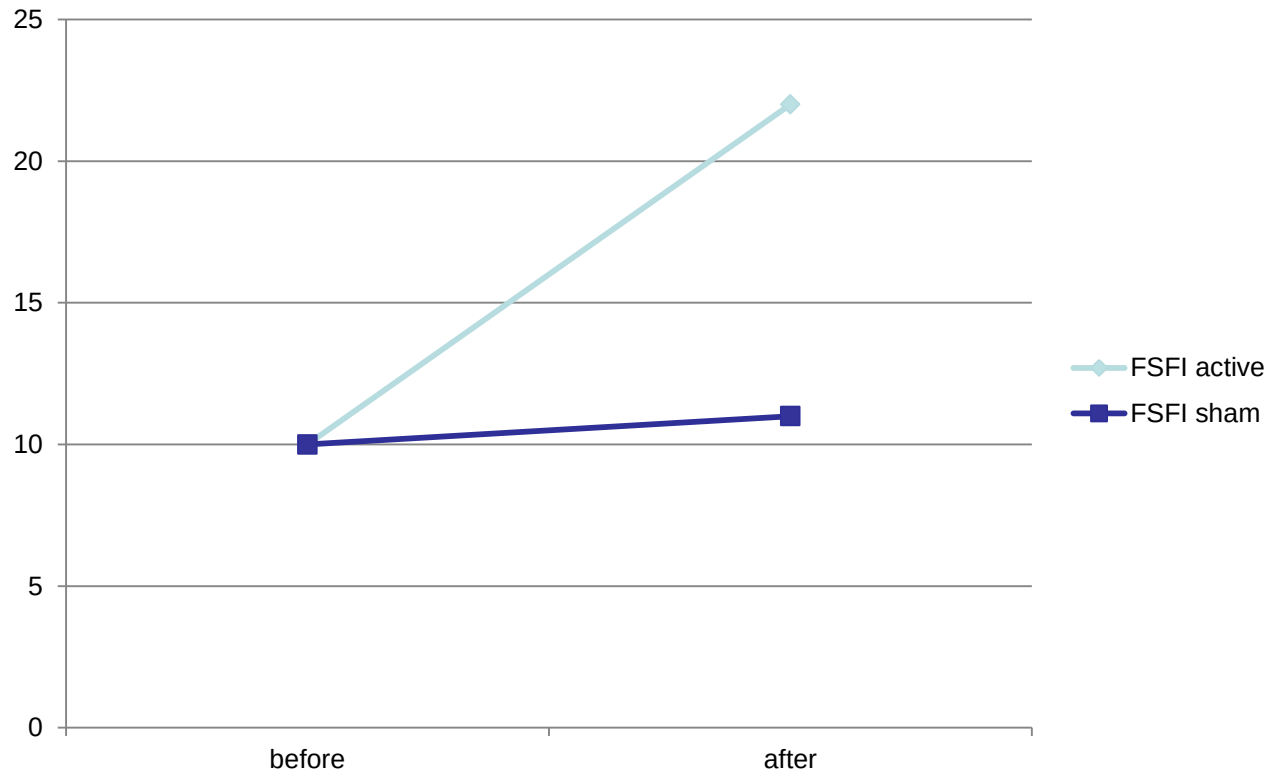
VAS dyspareunia before and after treatment



Dispareunia	before	After	p - value
Sham	8.3	7.4	> 0.05
active	8.3	2.4	< 0.05

Changes in FSFI

FSFI changes before and after treatment



Safety?

- No serious adverse events
 - Pain at the probe insertion
 - Mild irritation of the vulva and introitus
 - Mild to moderate lower pelvic pain
 - Minor bleeding
 - Vaginal discharge
 - Recommendation to avoid intercourse for 3 days

- CO₂-laser improves all GSM symptoms
- Persistence of positive effect on long-term follow-up
- 3-5 laser sessions
- No serious adverse events

Take Home Messages





*Thank you for
your attention!*



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