



TRATTAMENTO LASER DELL' ATROFIA VAGINALE

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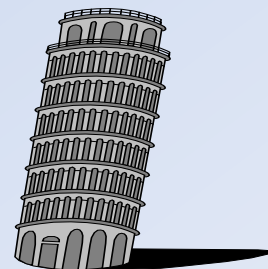
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SINDROME GENITO-URINARIA DELLA MENOPAUSA

Sindrome Genito Urinaria (GSM): è definita da un insieme di sintomi e segni associati alla riduzione di estrogeni e degli altri ormoni sessuali e che determina cambiamenti a livello di:

- Grandi e piccole labbra
- Clitoride
- vestibulo/introito
- Vagina
- Vescica e uretra

GSM può includere:

◆ Sintomi genitali

secchezza, bruciore, irritazione

◆ Sintomi sessuali:

mancanza di lubrificazione, discomfort o dolore ai rapporti

◆ Sintomi urinari :

urgenza, disuria, infezioni urinarie ricorrenti (UTIs).

I sintomi della GSM possono avere un effetto negativo sulla qualità di vita

SINDROME GENITO-URINARIA DELLA MENOPAUSA

- 75% delle donne in menopausa
- 20% o meno viene trattata



- Under-reported
- Under-recognized
- Under-treated



SINDROME GENITO-URINARIA DELLA MENOPAUSA

TRATTAMENTO DELL' ATROFIA VAGINALE

- **Lubrificanti/sostanze idratanti vaginali non ormonali**
- **Estrogeni vaginali a basse-dosi**
- **HRT (se coesistono sintomi vaso-motori)**
- **Ospemifene (SERM)**

– **Laser vaginale**

- CO₂ LASER
- ERBIUM LASER





Rationale for the Vaginal Erbium Laser as a second generation thermotherapy for GSM

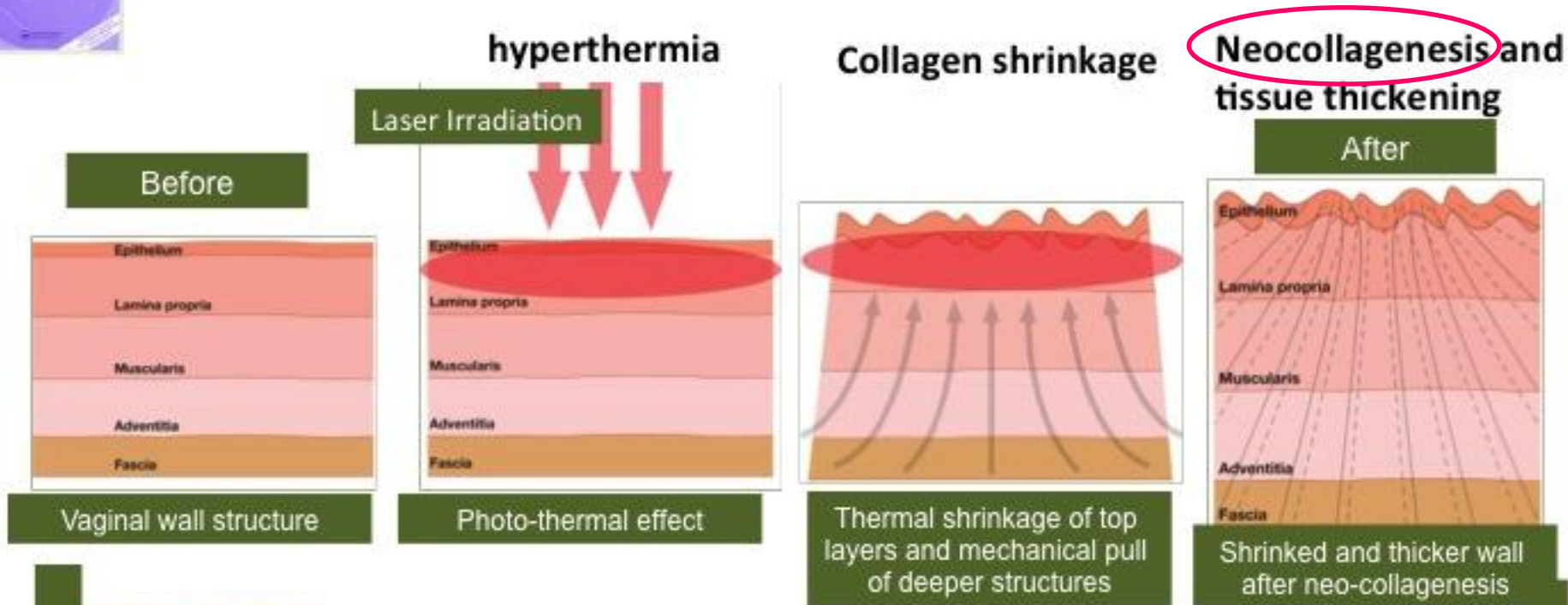
Not all lasers are created equal

Lasers with different physical characteristics can share some applications, perhaps diverging in their clinical outcomes and side- and/or adverse effects

Table 1 Differences between CO₂ and Er:YAG lasers in the treatment of genitourinary syndrome of menopause (GSM) (A. Gaspar, as presented at FIGO 2012, personal communication)

	CO ₂	Er:YAG
Absorption in water	15 × less than Er:YAG	15 × more than CO ₂
Optical penetration	50 μm	3–5 μm
Mechanism of action	ablation	thermal diffusion
Aggressiveness of treatment	always partial necrosis and associated adverse effects	surface of mucosa is not ablated (damaged)
Depth of penetration	3 mm or more	200–500 μm
Operative time (min)	20	15
Pain level during treatment on scale of 0–10	5	0
Pain level post treatment on scale of 0–10	3–5	0
Treatment zone	vaginal canal	vaginal canal and introitus
Tissue-healing phase	20 days	2 days
Return to normal sexual activity	10 days	3 days
Laser release	operator-dependent	uniform and controlled

Photo-Thermal -Mechanical Interaction



M. Rivera measured an average shrinking of vaginal canal of 12 mm (or 17%)

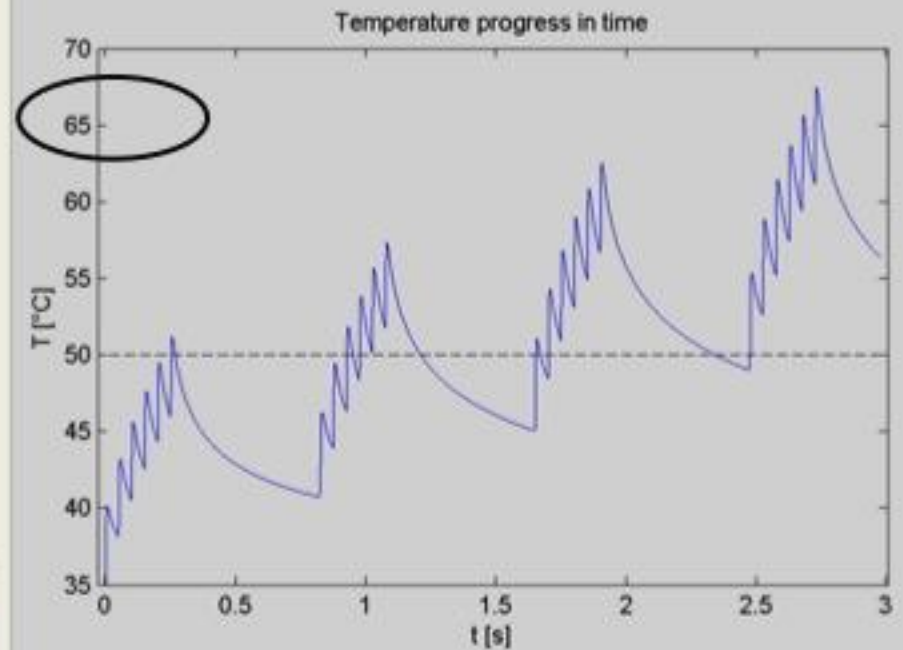
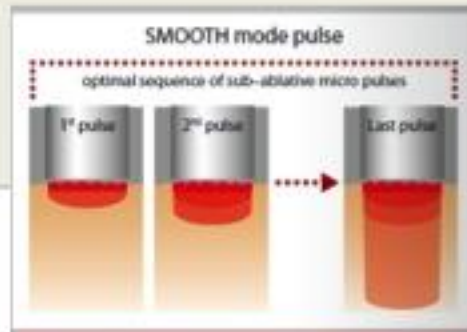
A.A. Bezmenko measured an average thickening of vaginal wall of 1.5 mm (or 56%)



SMOOTH mode controlled Tissue Heating Process

Er:YAG optical laser SMOOTH non-ablative mode

- Sequence of short pulses temporally spaced
- Prevent sharp temperature rise
- Homogeneous heating of the tissue within a several-hundred-microns
- Controlled temperature increase in the range for collagen remodeling: 50 - 70 C
- Vasodilation
- **No ablation**
- **No bleeding**
- **No tissue necrosis**

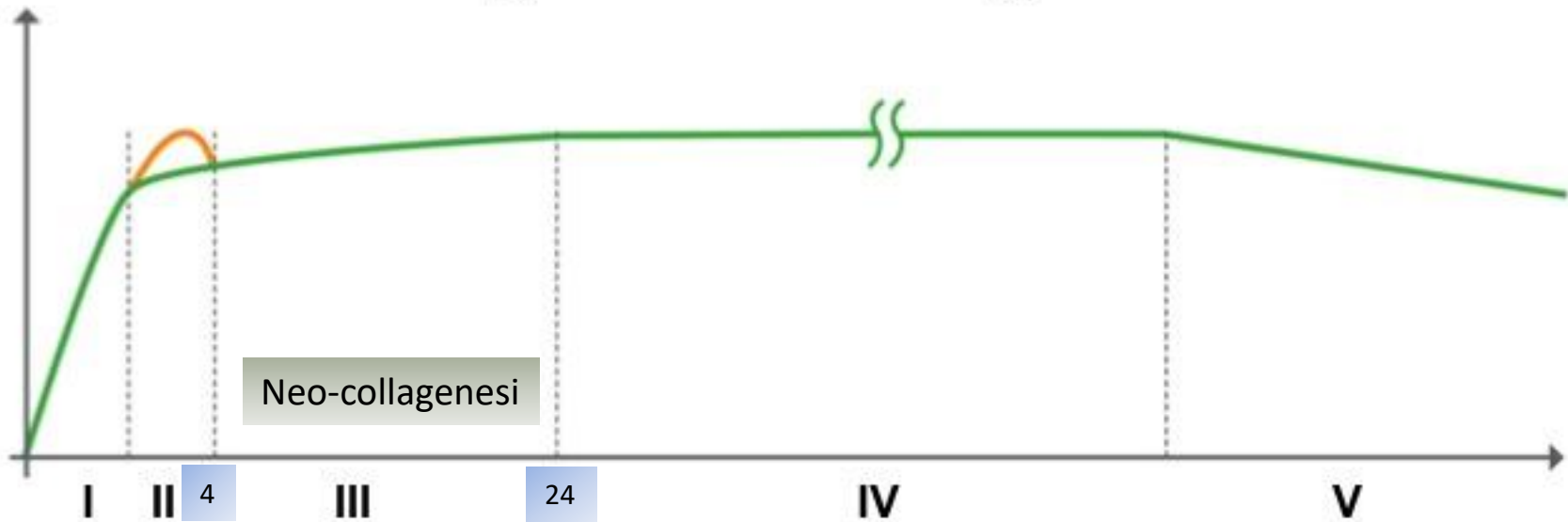


An example of four SMOOTH mode pulses delivered in a full beam manner with fluence of 3 J/cm²



Treatment regime

Collagen Remodeling Process

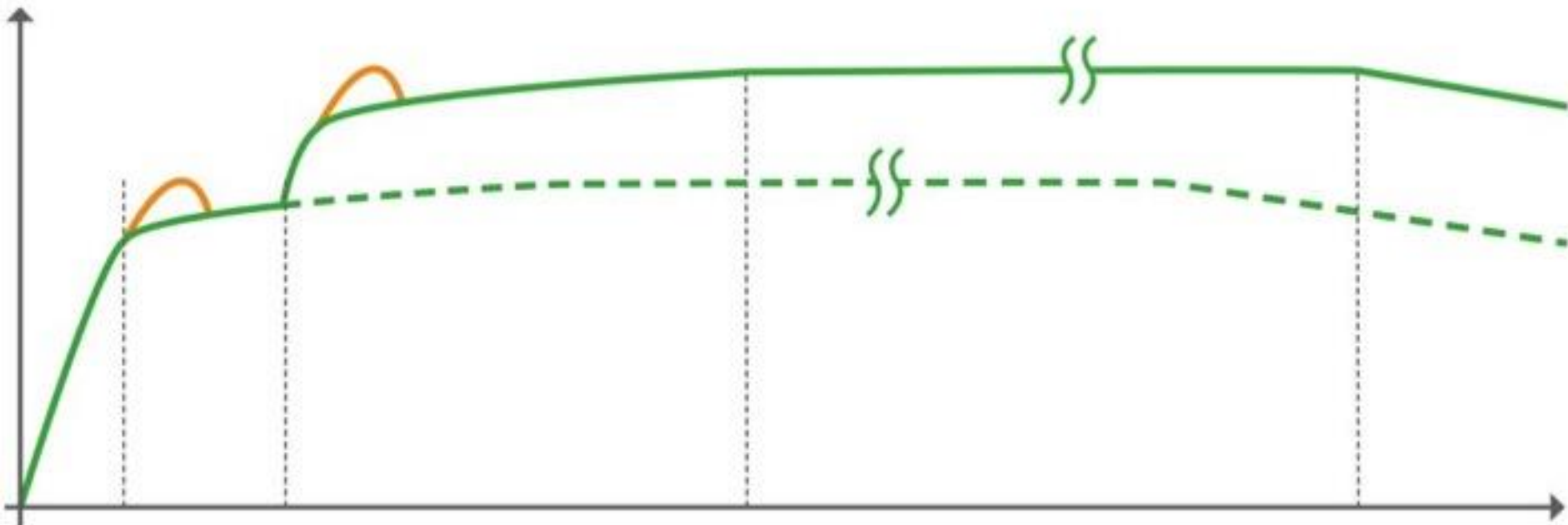


- I** phase: immediate shrinkage after laser irradiation (up to 30%)
- II** phase: short-term edema recession (1-2 days after)
- III** phase: neo-collagenesis, generation of new fibers (4 up to 24 wks after)
- IV** phase: steady state (1 year or more)
- V** phase: gradual decrease of the collagen firmness

Treatment regime



Collagen Remodeling Process

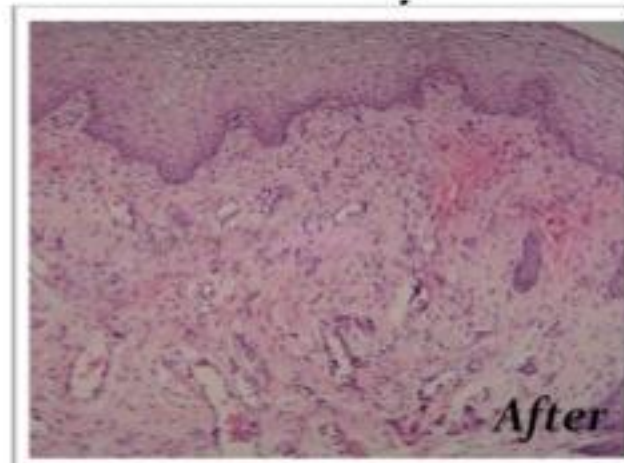
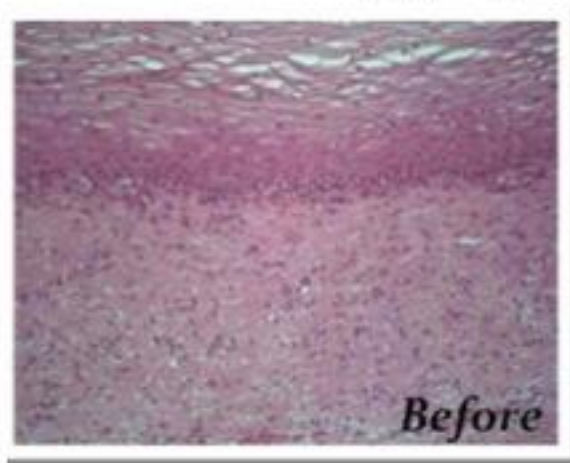


2-3 TRATTAMENTI OGNI 4-6 SETTIMANE

Subsequent treatment is done after 4-6 weeks when the process of neo-collagenesis is well on its way, so with the further session recruits additional collagen fibers, to reach the patient CRC (Collagen Remodeling Capacity)

MINIMALLY INVASIVE LASER TREATMENT FOR VAGINAL ATROPHY

Vaginal mucosa biopsies before and after RenovaLase treatment with increases in epithelial thickness, glycogen content and vascularization



Changes in Epithelial Tissue

- Treatment significantly increased superficial and intermediary cells and decreased parabasal cells
- Glicogen increase

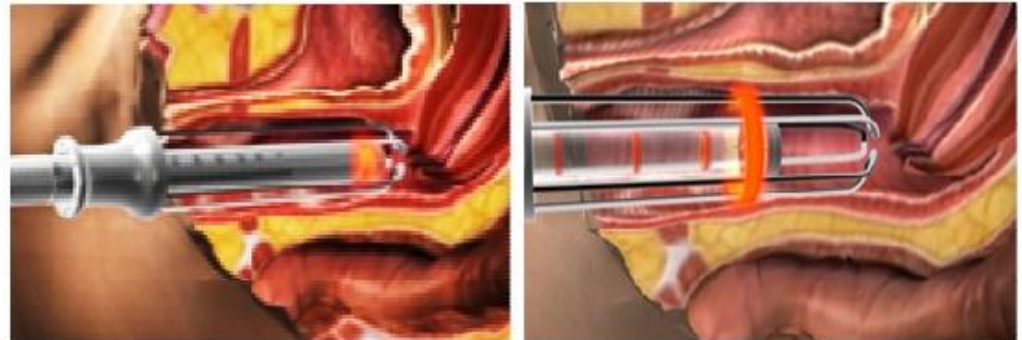
Changes in the Lamina Propia

- Marked Angiogenesis.
- Major Congestion (red blood cells in the lumen of neovessels)
- Collagenesis
- Increase in the Cellularity of the Extracellular Matrix. (Blasts of G0 to G1 phases)
- Papillomatosis

ERBIUM-LASER: INDICAZIONI

- ATROFIA VAGINALE
- WIDE VAGINA
- IUS LIEVE-MODERATA

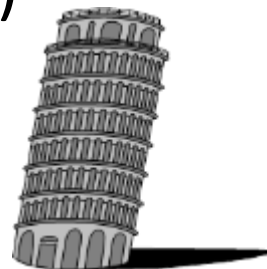
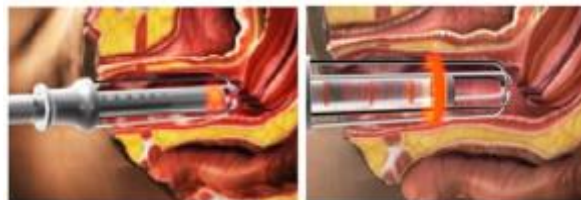
- Trattamento minimamente invasivo/ non ablativo
- Senza incisioni
- Non è necessaria alcuna anestesia
- Trattamento ambulatoriale, sicuro, veloce
- Elevato tasso di successo e di soddisfazione della paziente





I: TRATTAMENTO DELL' ATROFIA VAGINALE CON ERBIUM-LASER : LA NOSTRA ESPERIENZA

- STUDIO PROSPETTICO LONGITUDINALE SU DONNE IN MENOPAUSA AFFETTE DA GSM (N: **105**)
- VALUTAZIONE DELLA SECCHENZA VAGINALE E DELLA DISPAURENIA (**VAS**) E DELLO STATO VAGINALE (**VHIS**)
- TRATTAMENTO CON **ERBIUM-LASER** (3 SEDUTE)





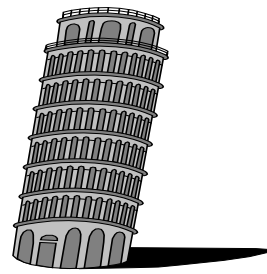
Pisa VEL PROTOCOL



- Prospective, longitudinal study performed in PMW suffering from GSM, attending the outpatient Menopause Clinic of Pisa University Hospital.
- The VEL procedures were performed in an outpatient clinical setting @ the Casa di Cura San Rossore
 - without any specific preparation, anesthesia, or post treatment medications.
 - Before the procedures the vagina was cleaned with disinfectant solution and dried with a swab.
 - Patients were treated with **3 laser applications, (L 1, L2, L 3) every 30 days**, with screening visit 2 to 4 weeks prior the first laser treatment (Baseline)



Pisa VEL PROTOCOL



- **Inclusion criteria**

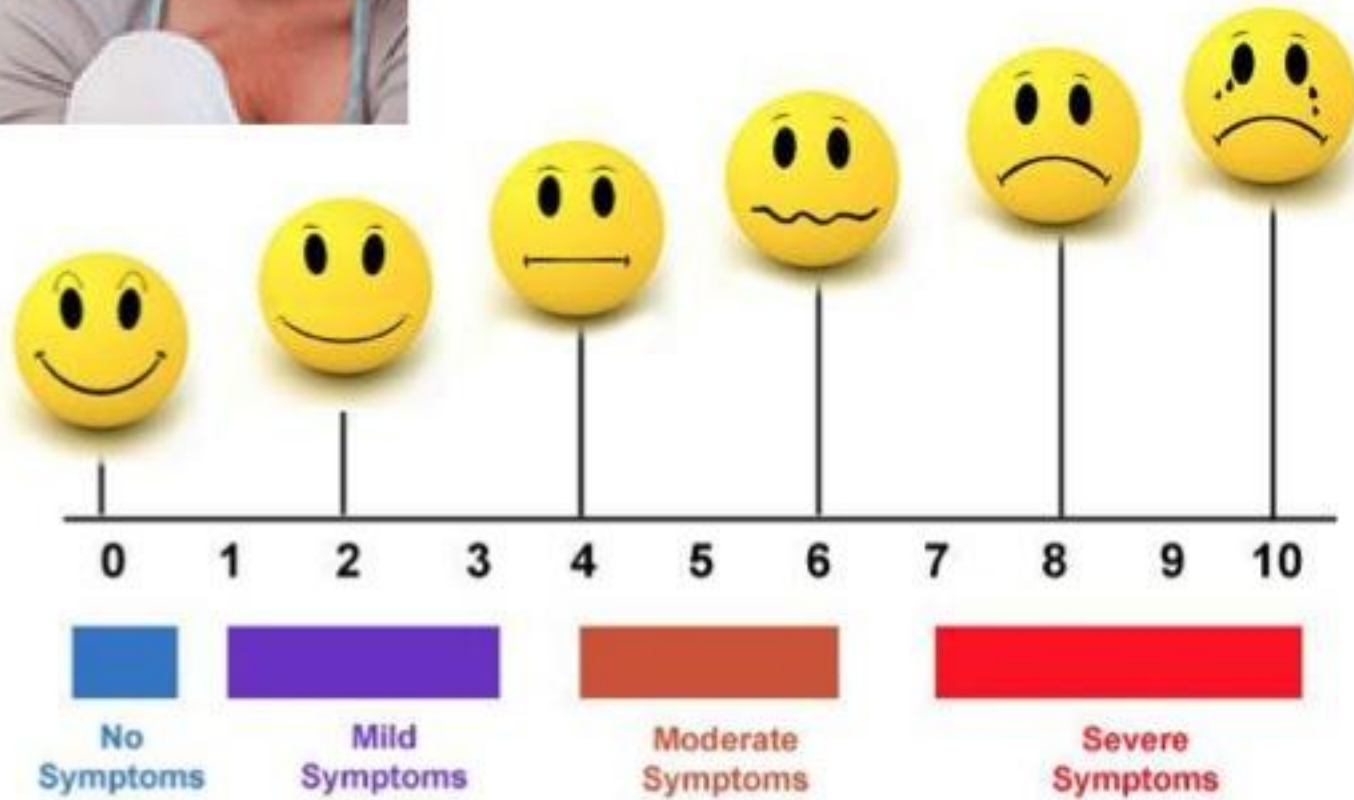
- **the presence of GSM** in healthy PMW (at least 12 months since LMP or bil.OVR)
- plasma gonadotropin and E2 levels in the PMW range (FSH >40 U/L; E2 <25 pg/ml)
- negative PAP smear.

- **Exclusion criteria**

- vaginal lesions, scars, active or recent (30 days) of the genitourinary tract infections
- abnormal uterine bleeding
- **use of lubricants or any other local preparations**, within the 30 days prior to the study
- history of photosensitivity disorder
- use of photosensitizing drugs
- genital prolapse (grade II-III according to the Pelvic Organ Prolapse Quantification, POP-Q, system classification)
- serious or chronic condition that could interfere with study compliance
- **treatment with hormones** or other medicines to relieve menopausal symptoms in the 12 month before the study



VAS



Vulvo Vaginal Atrophy

Severity classification / assessment

Bachmann Vaginal Health Index

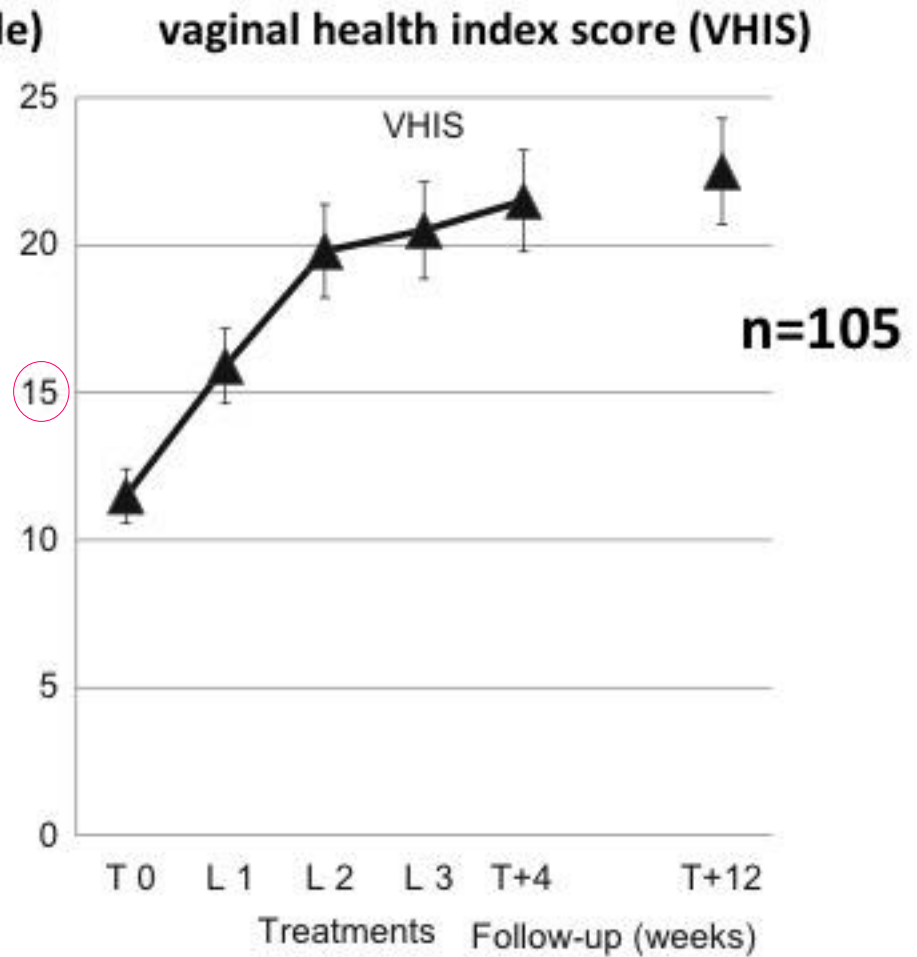
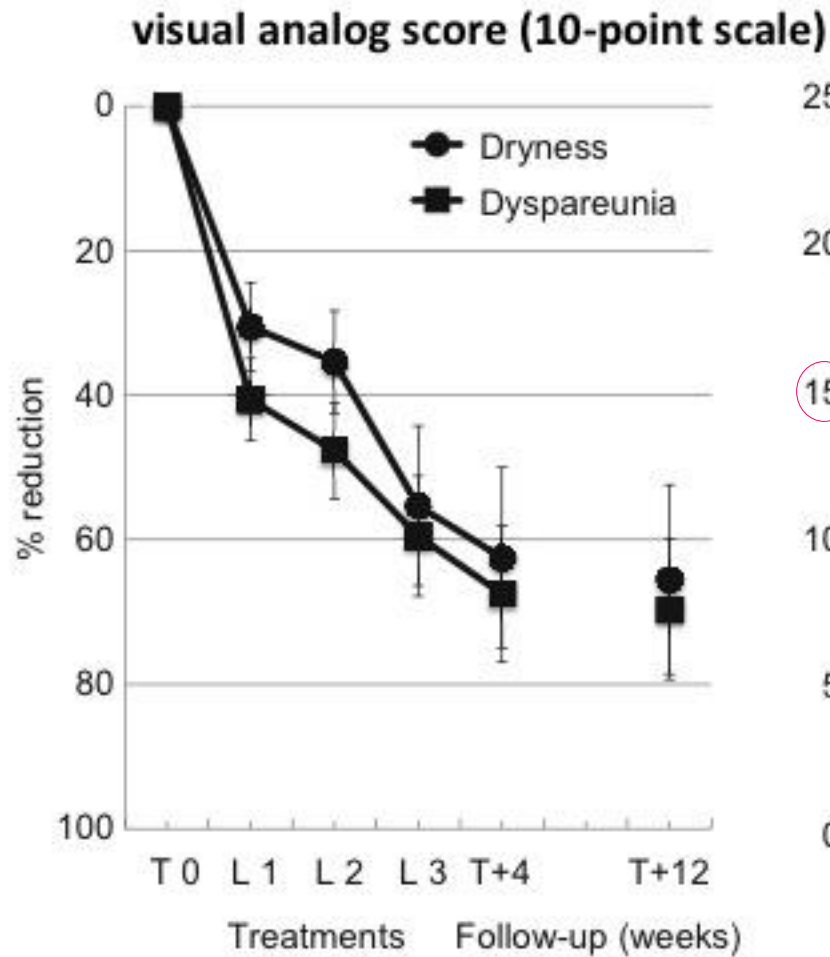
Score	1	2	3	4	5
Elasticity	none	poor	fair	good	excellent
Fluid Volume (Pooling of Secretion)	none	Scant amount, vault not entirely covered	superficial amount, vault entirely covered	moderate amount of dryness (small areas of dryness on cotton tip applicator)	normal amount (fully saturates on cotton tip 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).

VHIS < 15 → ATROFIA



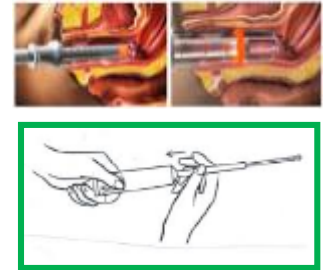
Vaginal dryness and dyspareunia in patients suffering from GSM.



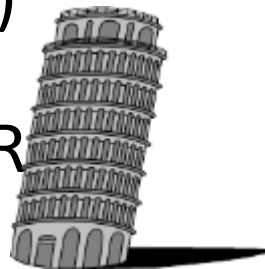
II: TRATTAMENTO DELL' ATROFIA VAGINALE CON ERBIUM-LASER : LA NOSTRA ESPERIENZA

- STUDIO **COMPARATIVO** SU DONNE IN MENOPAUSA AFFETTE DA GSM

TRATTAMENTO LASER
vs
ESTROGENI LOCALI
(Estriolo 50 mcg)



- VALUTAZIONE DELLA SECCHENZA VAGINALE E DELLA DISPAURENIA (**VAS**) E DELLO STATO VAGINALE (**VHIS**)
- TRATTAMENTO CON **ERBIUM-LASER** (3 SEDUTE)
- FOLLOW UP A 6 MESI DAL TRATTAMENTO LASER





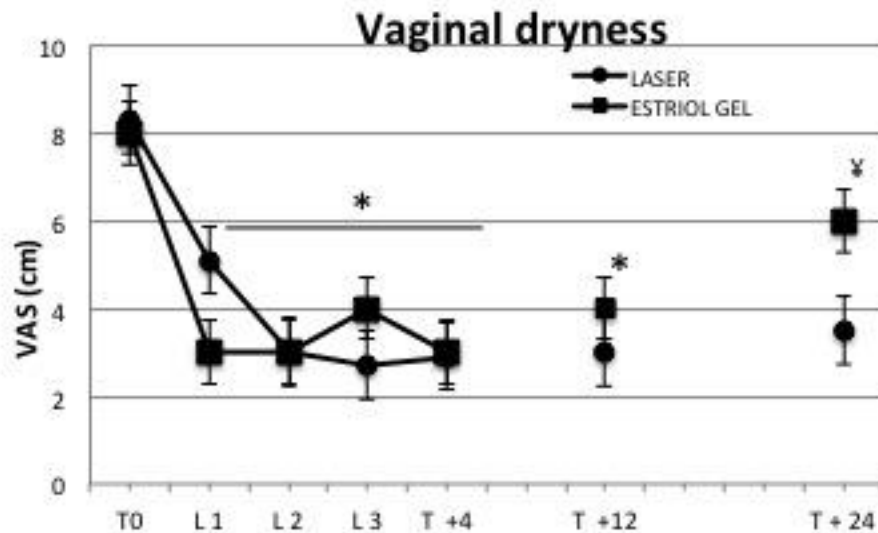
Baseline characteristics of participants who completed the 6 months study

Data are expressed as a Mean \pm SD, (min-max). VEL: Vaginal Erbium Laser; Estriol Group: women receiving vaginal estriol gel supplementation

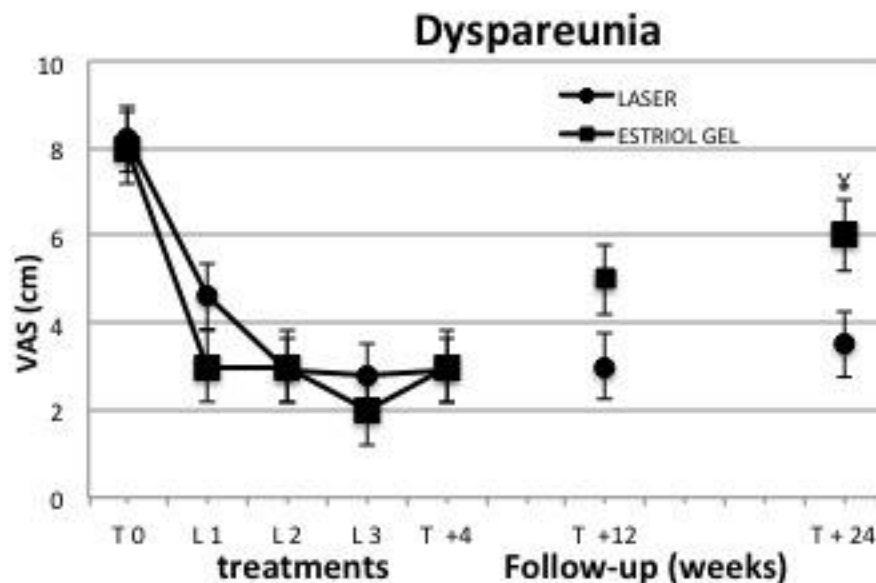
	VEL group	Estriol group
	N= 43	N=19
Age (years)	60.9 \pm 8.1	63 \pm 4.5
Age at Menopause	49.3 \pm 4.1	51.7 \pm 3.3
Years since menopause	12.5 \pm 5.8	11.8 \pm 3.1
Body mass index (kg/m²)	26.1 \pm 3.3	25 \pm 3.0
FSH (IU/L)	85.4 \pm 7.8	81.5 \pm 4.5
Estradiol (pg/mL)	18.4 \pm 2.3	20.2 \pm 3.4



Effect of second-generation laser thermotherapy on vaginal dryness and dyspareunia



Laser group n=43
Estriol group n=19



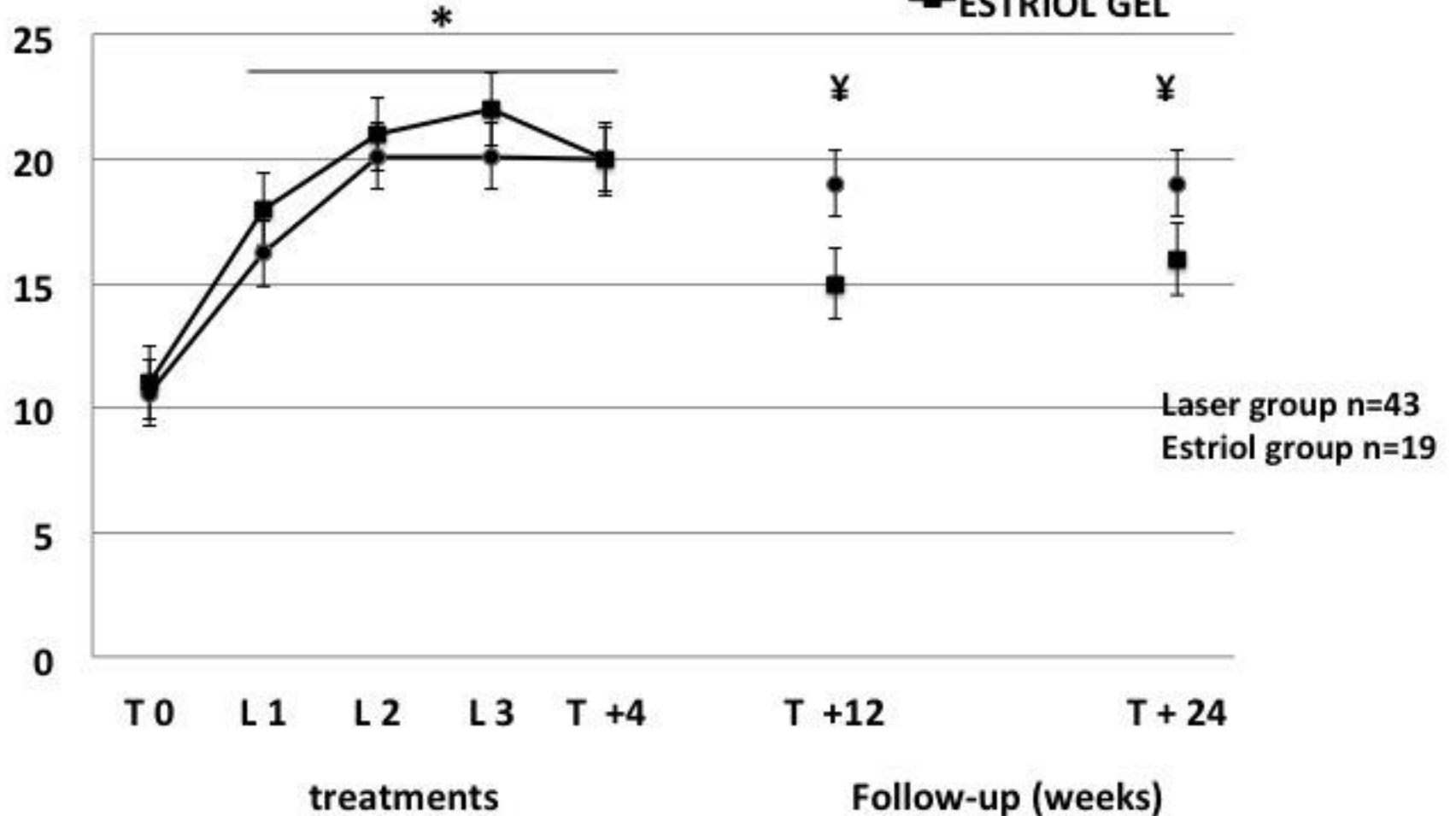


Effect of second generation laser thermotherapy on VHIS

VHIS

● LASER

■ ESTRIOL GEL

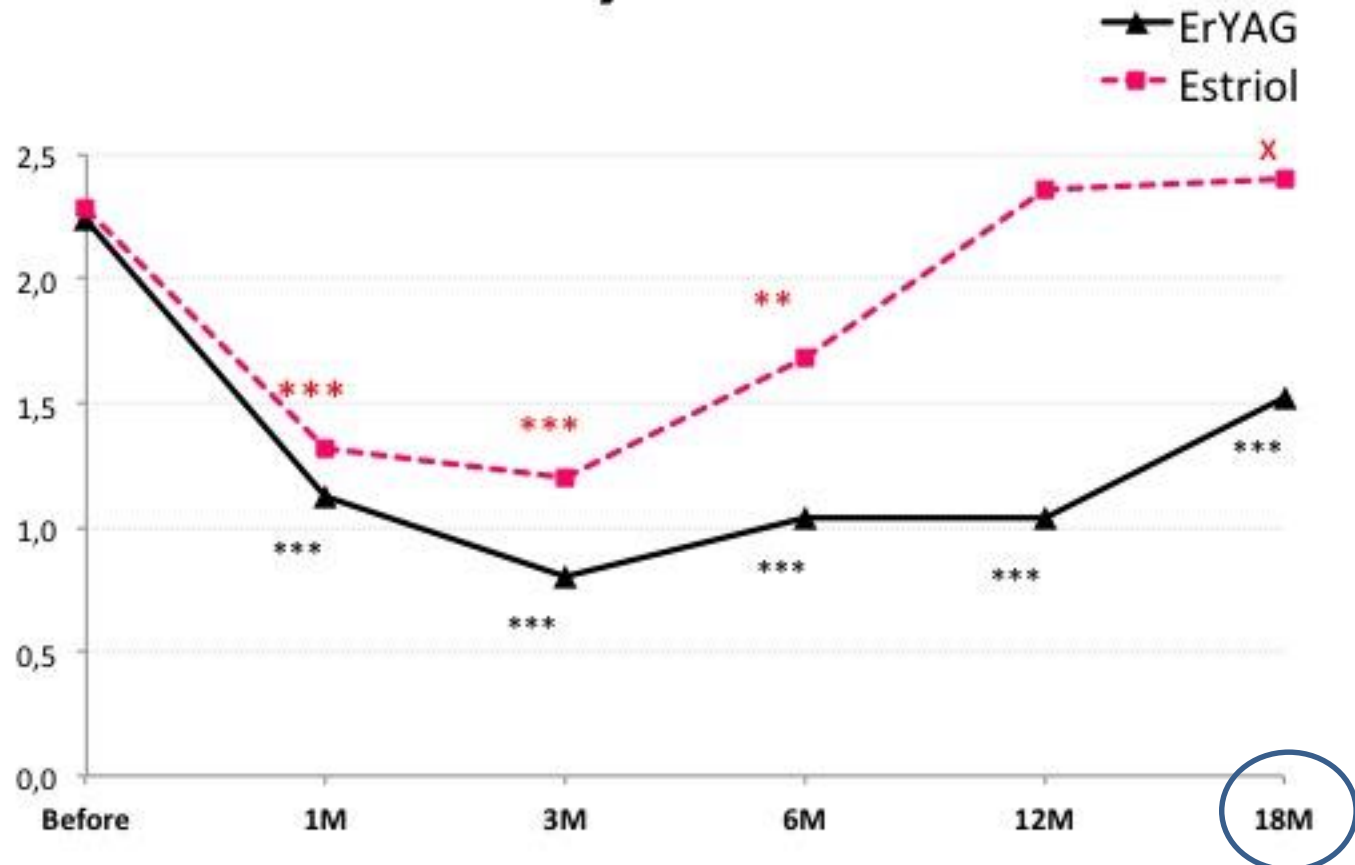


Laser group n=43
Estriol group n=19

Improvement of Atrophy symptoms

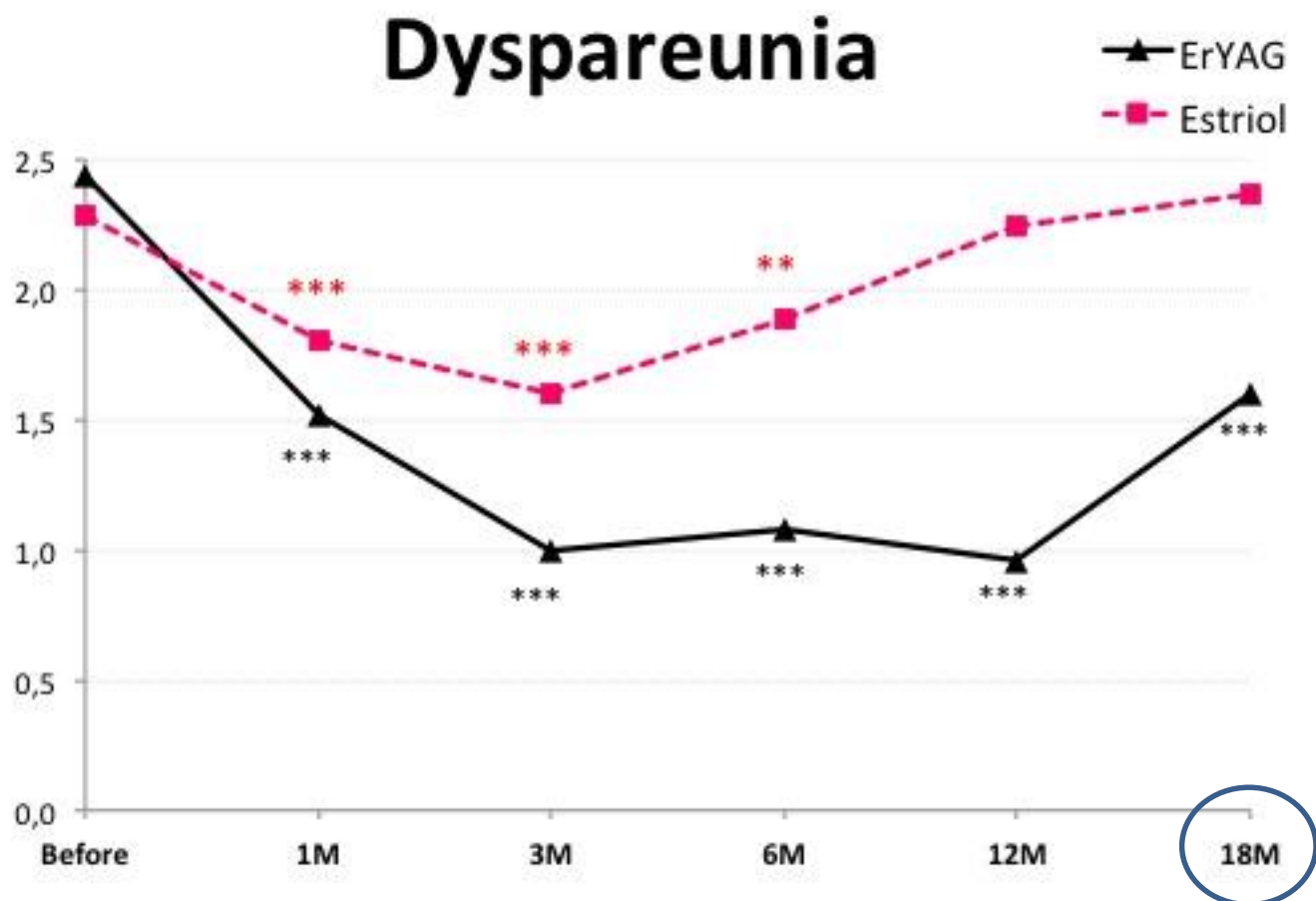
- Open label, prospective, randomized control trial
- 50 PMW randomly divided into two groups

Dryness



Improvement of Atrophy symptoms

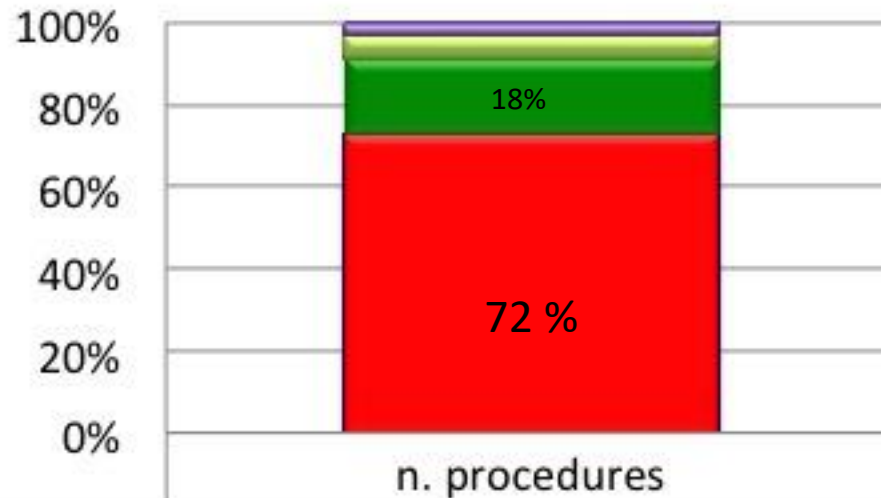
- Open label, prospective, randomized control trial
- 50 PMW randomly divided into two groups





ERBIUM LASER: SODDISFAZIONE DELLE PAZIENTI

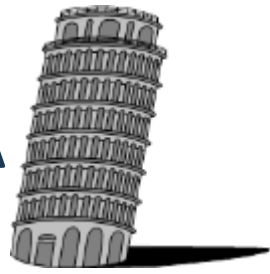
as expressed by the patients in 622 procedures



	n. procedures
■ unacceptable	1
■ bad	20
■ acceptable	36
■ good	115
■ excellent	450



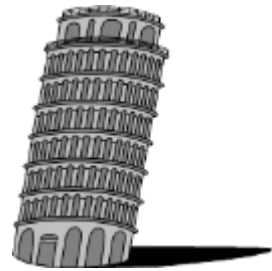
TRATTAMENTO ERBIUM-LASER DELL' ATROFIA VAGINALE: LA NOSTRA ESPERIENZA



CONCLUSIONI:

- ➔ IN DONNE IN MENOPAUSA IL TRATTAMENTO CON **ERBIUM-LASER** HA DETERMINATO UN **MIGLIORAMENTO** DELL' ATROFIA VAGINALE (VALUTAZIONE SOGGETTIVA E OGGETTIVA).
- ➔ SI E' DIMOSTRATO **BEN TOLLERATO** DALLE DONNE.

TRATTAMENTO ERBIUM-LASER



CONCLUSIONI:

- TRATTAMENTO AMBULATORIALE
- TRATTAMENTO MINIMAMENTE INVASIVO ➔ NON ABLATIVO, NON INCISIONI, NON SANGUINAMENTO
- TRATTAMENTO SICURO
- INDOLORE, NON È NECESSARIA ALCUNA ANESTESIA
- ELEVATO TASSO DI SUCCESSO E DI SODDISFAZIONE DELLA PAZIENTE





Level of evidence of treatments for genitourinary syndrome of menopause

<i>Treatments</i>	<i>Level of evidence</i>
<i>Lifestyle</i>	
Sexual activity	II-2B
Obesity	III-C
Exercise	III-C
Smoking	II-3B
<i>Vaginal moisturizers 2–3 times/week for improvement of symptoms</i>	I-A
<i>Vaginal lubricants for sexual activity</i>	II-2B
<i>Other treatments</i>	
Homeopathy	III-D
Phytotherapy	III-D
Phytoestrogens	II-3D
<i>Systemic and local hormonal therapy</i>	
Improvement of symptoms	I-A
Tropism	I-A
<i>Vaginal laser for improvement of symptoms and tropism</i>	I-A



Vaginal Laser treatment

CO2

Er-Yag

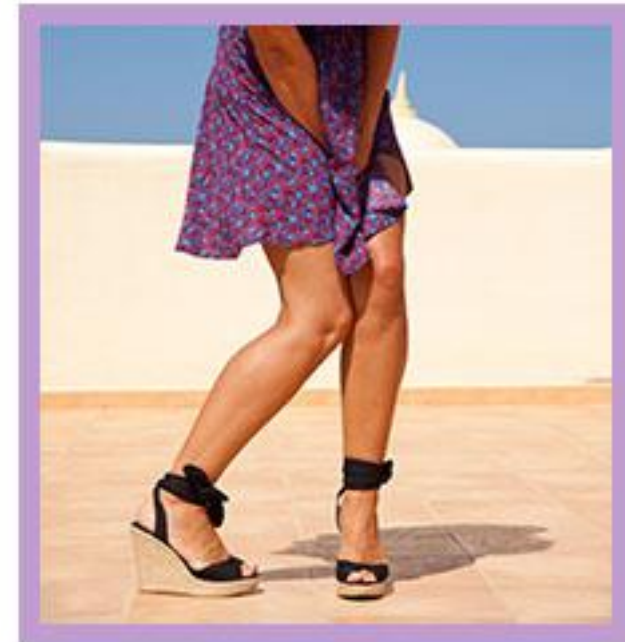
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VEL: The Second Generation Thermotherapy for the GSM

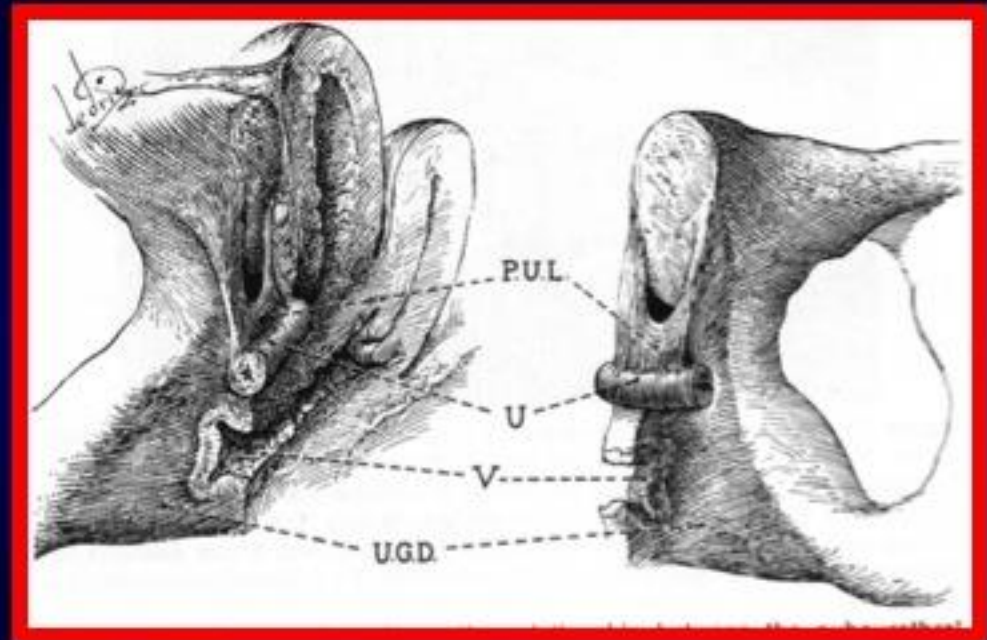


- **Stress Urinary Incontinence**



The female urethral sphincter

- **Connective tissue 56%**
- Smooth muscle 30%
- Blood vv 11%
- Striated muscle 2%
- Nerves 1%



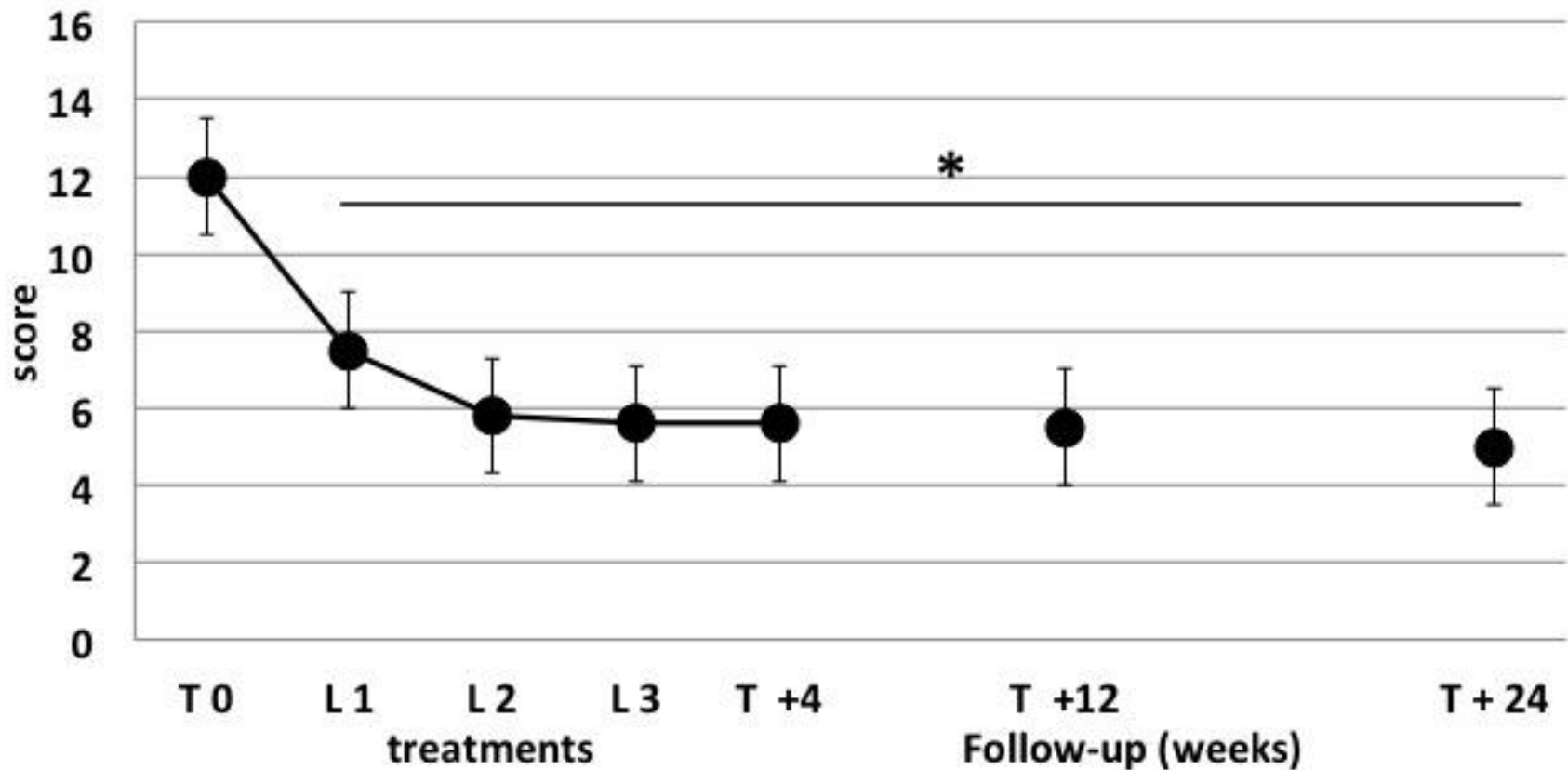
- No difference along length of urethra
- Reduced CT & Blood vv in post menopausal women



Effect of second generation laser thermotherapy on International Consultation on Incontinence Questionnaire

ICIQ- SF

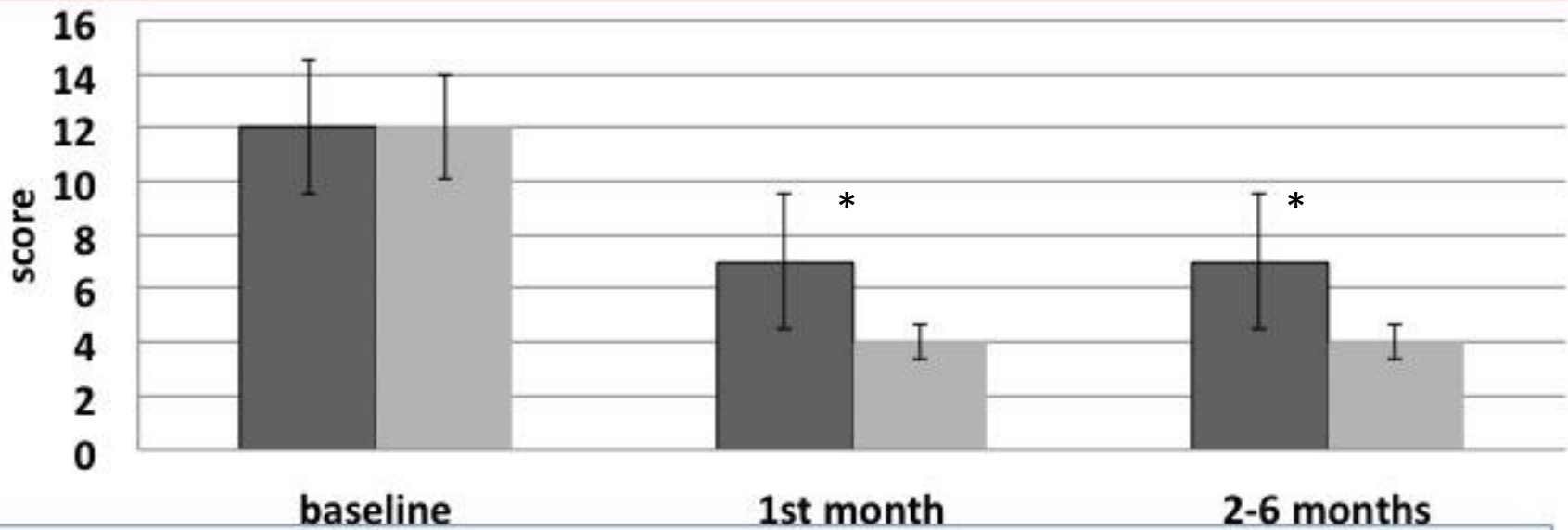
n=19





ICIQ-UI score

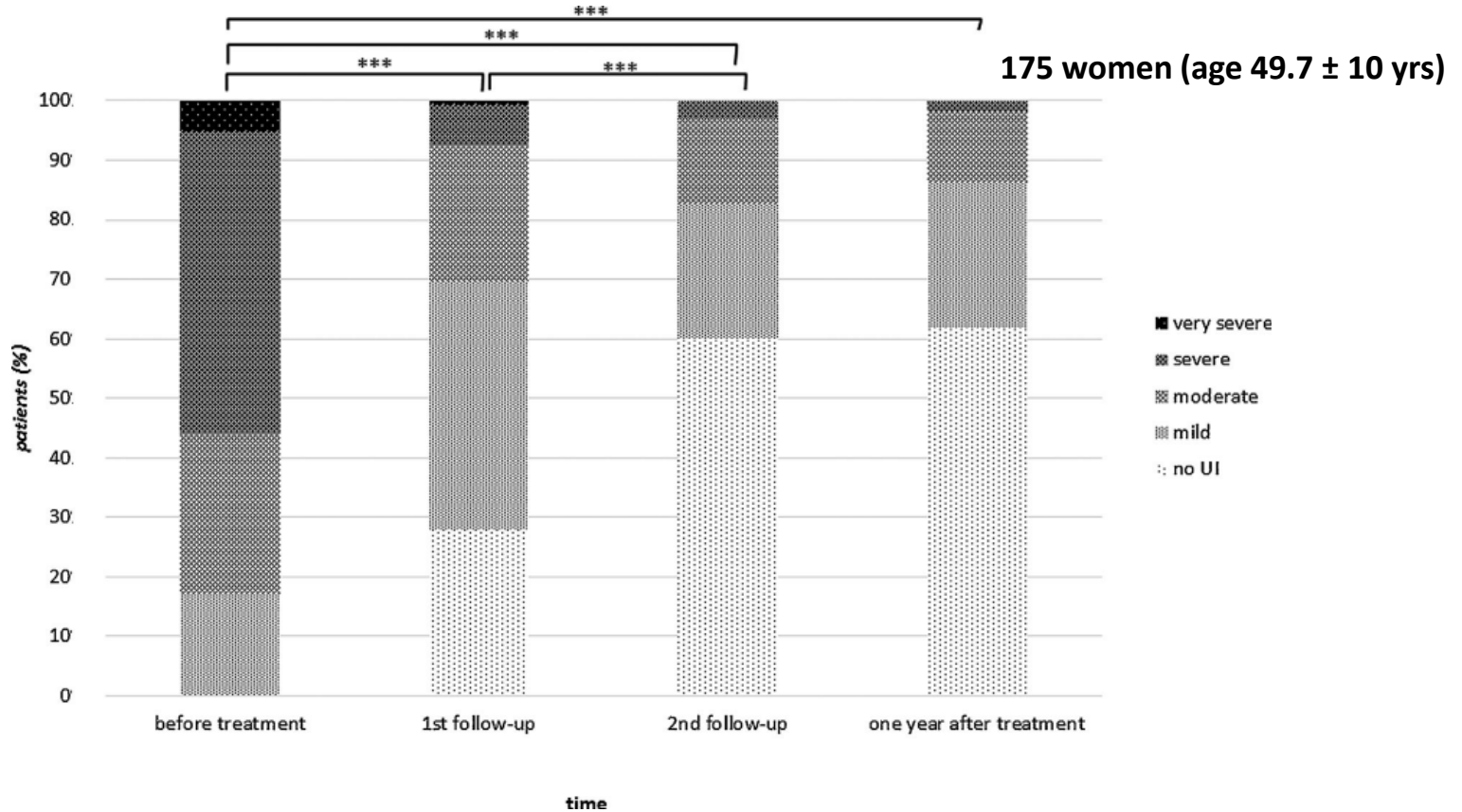
	Baseline (n = 73)	Follow-up		p	Rd	Ad	95% CI
		1st month (n = 52)	2-6 months (n = 47)				
ICIQ-UI	12.0 (6.0-16.0)	4.0 (0.0-10.8)	4.0 (0.0-11.0)	<0.001	46%	-5.5	33-67%
ICIQ-UI sensitivity analysis	12.0 (6.0-16.0)	7.0 (0.0-15.0)	7.0 (0.0-13.0)	<0.001	43%	-5.0	36-72%



ICIQ-UI sensitivity analysis was done under the assumption that the second follow-up values for all those that were lost for follow-up were the same as at baseline, indicating no effect

Rd, median relative difference between baseline and at 2-6-month follow-up; Ad, median absolute difference between baseline and 2-6-month follow-up; 95% CI, 95% confidence interval of the median difference between baseline and at 2-6-month follow-up

The effect of Er:YAG laser therapy on the improvement of the grade of SUI



Incontilase: long term effects on stress incontinence

Int Urogynecol J

Table 2 Clinical outcomes at 6 months after treatment based on changes in pad weights

Variables	6 months after treatment [<i>n</i> (%)]
Baseline pad weight >1 g (<i>n</i> = 28)	
Cure	11 (39.3)
Improvement	11 (39.3)
Failure	6 (21.4)
Baseline pad weight 1–10 g (<i>n</i> = 18)	
Cure	9 (50)
Improvement	5 (27.8)
Failure	4 (22.2)
Baseline pad weight ≥10 g (<i>n</i> = 10)	
Cure	2 (20)
Improvement	6 (60)
Failure	2 (20)

Cure = < 1 g pad weight at 6 months; improvement = >50 % pad weight reduction from baseline at 6 months; failure = ≤50 % pad weight reduction from baseline at 6 months

GRAZIE PER L'ATTENZIONE



JACK VETTRIANO



TRATTAMENTO LASER DELL' ATROFIA VAGINALE

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