The Mona Lisa Touch, a microablative fractionated CO2 laser for vaginal atrophy

- VVA
- Lasers basics
- The MLT treatment
- Evidence
- Indications ,cautions etc
- Summary

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Vulvovaginal Atrophy

- The new term is GSM- Genitourinary Symptoms of Menopause.
- Due to lack of oestrogen
- Affects vulva, vagina, lower urinary tract
- Most common cause is natural menopause, average age 51.
- Usually develop 3-4 years after menopause
- Life expectancy 85 years, ie. women may live 30+ years in a post menopausal state,
- Symptoms affect at least 40% of women but 70% don't discuss the problem.
- Higher incidence in woman treated for breast and pelvic cancers, the onset can be more rapid, and symptoms may appear more severe.

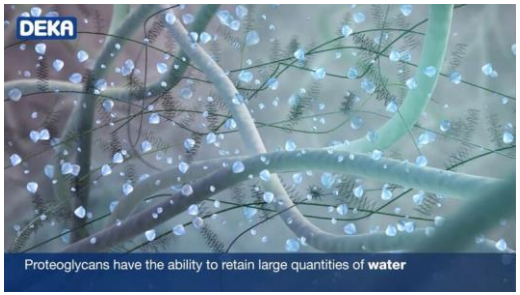
Causes of VVA

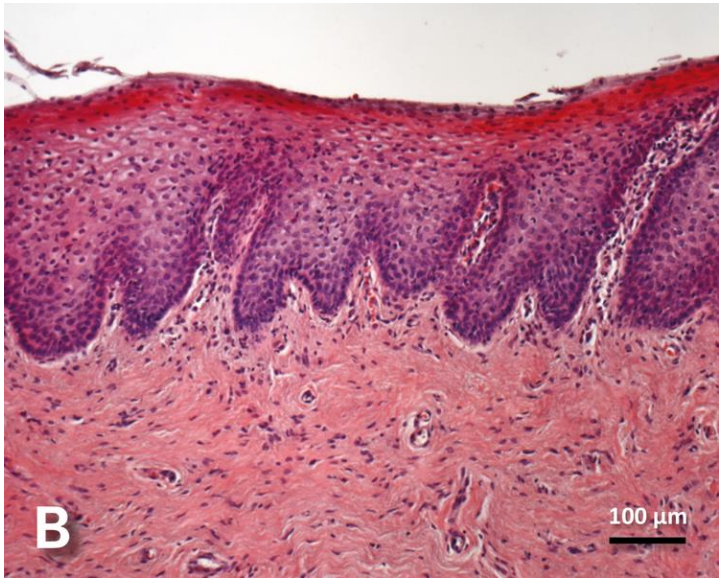
- Natural menopause
- Spontaneous premature ovarian failure
- Bilateral oophorectomy, often for breast and pelvic cancers
- Ovarian failure due to radiation therapy, chemotherapy: this may be temporary or permanent
- Drugs used for breast cancer eg Tamoxifen, which is an anti-oestrogen, and Femara which blocks post menopausal production of oestrogen.

- Other drugs which block ovarian activity, eg Danazol
  Postpartum state, especially during breast feeding
- Prolactin elevation due to hyperprolactinemia, pituitary ademomas,
- Hypothalamic amennorhea, eg excess exercise or anorexia

A Healthy Vagina

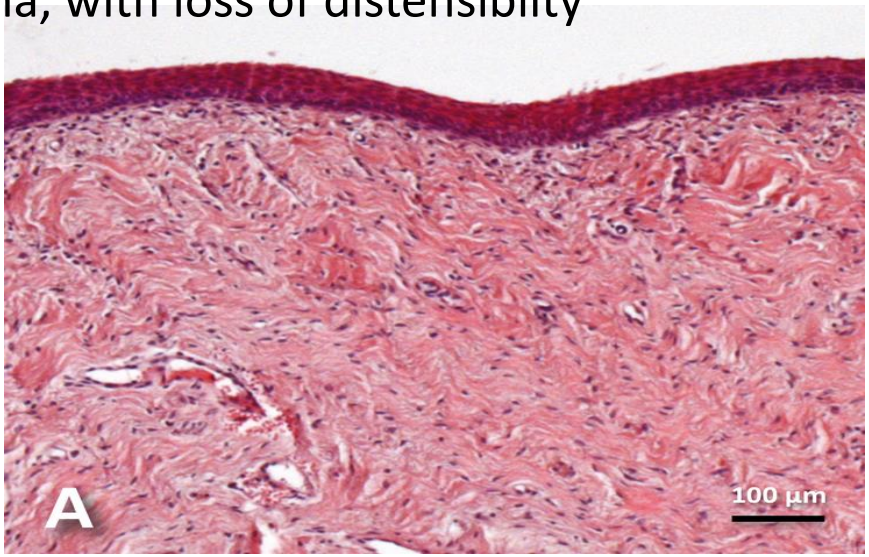
- The presence of oestrogen promotes a thick, non-keratinized stratified squamous epithelium, which is rugose and rich in glycogen. Glycogen from sloughed surface cells is the substrate for lactobacilli, which convert glucose to lactic acid and maintains an acidic vaginal environment.
- The lamina propria is rich in fibrocytes which create and align collagen and elastin.
- The fibrocytes produce acid mucolpolysaccharides and hyaluronic acid which keep the tissue, including the epithelium , moist.
- Oestrogen maintains optimal genital blood flow





Changes caused by oestrogen deficiency

- Thinning of the top layer of superficial epithelial , with surface abrasions, petechiae and bleeding after minimal contact.
- Loss of elasticity and collagen matrix
- Loss of rugae.
- Shortening and narrowing of the vagina, with loss of distensibilty
- Reduction in vaginal secretions
- Increase in vaginal pH due to loss of lactobacilli and glycogen.
- Increased pathogens on surface
- Reduced vascularity
- Small inactive fibrocytes
- Can be a narrow, rigid tube.



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Symptoms of VVA

- Vulval and vaginal dryness
- Vulval and vaginal burning or irritation
- Decreased vaginal lubrication during sexual activity
- Dyspareunia, including vulvar or vaginal pain (at the introitus or within the vagina)
- Vulvar or vaginal bleeding (eg, post coital bleeding, fissures)
- Vaginal discharge (leukorrhea or yellow and malodorous discharge)
- Pelvic pressure or a vaginal bulge
- Urinary tract symptoms (eg, urinary frequency, dysuria, urethral discomfort,)

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Other causes of Symptoms of VVA

- Vaginal infections (candidiasis, bv, herpes)
- Chronic skin conditions (Lichen sclerosus, Lichen planus, Sjogrens syndrome)
- Sensitivities to local agents
- Vulvodynia, PVD
- Genital tract ulcers, malignancy
- Causes of bleeding eg uterine/Cx Ca

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Treatments

- Vaginal moisturizers, eg Replens. Use 2-3 times a weeks.
- Vaginal lubricants can be waterbased, oils, silicone based,.
- Sexual activity, with or without a partner, maintains elasticity and vascularity.
- Vaginal dilators can gradually increase vaginal dimensions
- Vit E cream or capsules inserted vaginally.
- Stopping smoking.
- HRT only if menopausal symptoms. Often not effective.

Treatments

- Vaginal oestrogens are available in form of tablets and creams. Dosage is daily for 2 weeks then twice a week. Creams are initially more effective, but are messy.
- Both are probably safe use in the long term because the serum levels achieved are low, but no studies beyond 12 months.
- Vagifem tablets now 10ug rather than 25ug. Less effective and 4 tabs/week required.
- Long term data on risks of VTE not available, but probably very low risk. Data in high risk women lacking.

- But compliance poor.
- Need for prescription and doctor's visit.
- Effect on mucosa probably limited.
- Patient preference

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Vaginal oestrogens and breast cancer

- Absorption is low.
- If patient on Tamoxifen, is safe, but no long term studies. Not if patient on aromatase inhibitor (Femara).

- May be considered if patient has failed non-hormonal treatments, has a low grade malignancy, is not on aromatase inhibitors, and her oncologist is happy.
- .
- But patients are usually wary.

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Not new!

- CO2 laser for skin resurfacing and skin thickening/rejuvenation .
- Other laser treatments for hair reduction, removal of tattoos, redness of the face, excess scarring.
- Studies +++ been done on cellular changes, methods of laser working and risks are well understood.
- Vaginal laser is new!

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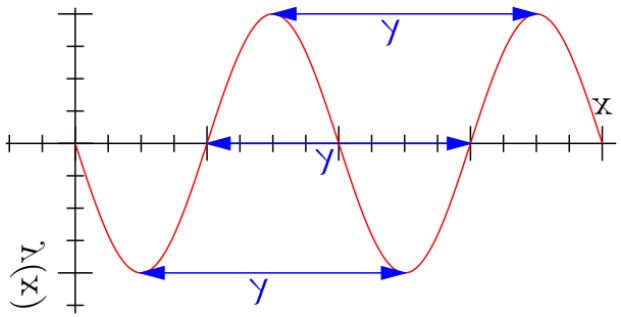
Lasers in a nutshell

- LASER = Light amplification by stimulated emission of radiation
- Light is optical radiation
- Light is not always visible.
- Intense, high energy light beam.



Gamma rays	X-rays	Ultraviolet*	Visible	Near infrared	Far infrared	Microwaves and radiowaves
<0.1 nm	0.1-10 nm	10-400 nm	400-760 nm	760-1000 nm	1000-100,000 nm	>100,000 nm

*** Ultraviolet spectrum divisions and wavelengths (nm)**

Vacuum ultraviolet	10-200
UVC	200-290
UVB	290-320
UVA2	320-340
UVA1	340-400

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Laser concepts

- Some materials when stimulated by sufficient energy will produce a coherent beam of light (CO2, Ruby, Nd:YAG , Argon)
- Different materials produce light of different wavelengths. Shorter wavelengths penetrate less deeply than longer wavelengths.
- Different tissues (chromophore) respond to light of different wavelengths, which explains the different types of laser available.
- Shorter wavelength treats shallower lesions, eg tattoos. Longer wavelengths penetrate deeper for dermal rejuvenation.

- Laser beams can be continuous or pulsed. Pulsed beams are delivered at a rate =/< the thermal relaxation time, ie the time taken for at issue to be treated, then cooled. Continuous beam more destructive, eg used for laser cutting.
- Fractionated laser is delivered in narrow beams to reduce the surface damage. Treatment of a larger area is ablative. Spacing of the beams is important.
- The power of the beam can be varied. Fluence = w/cm2, must be sufficient to treat but not damage collateral structures.

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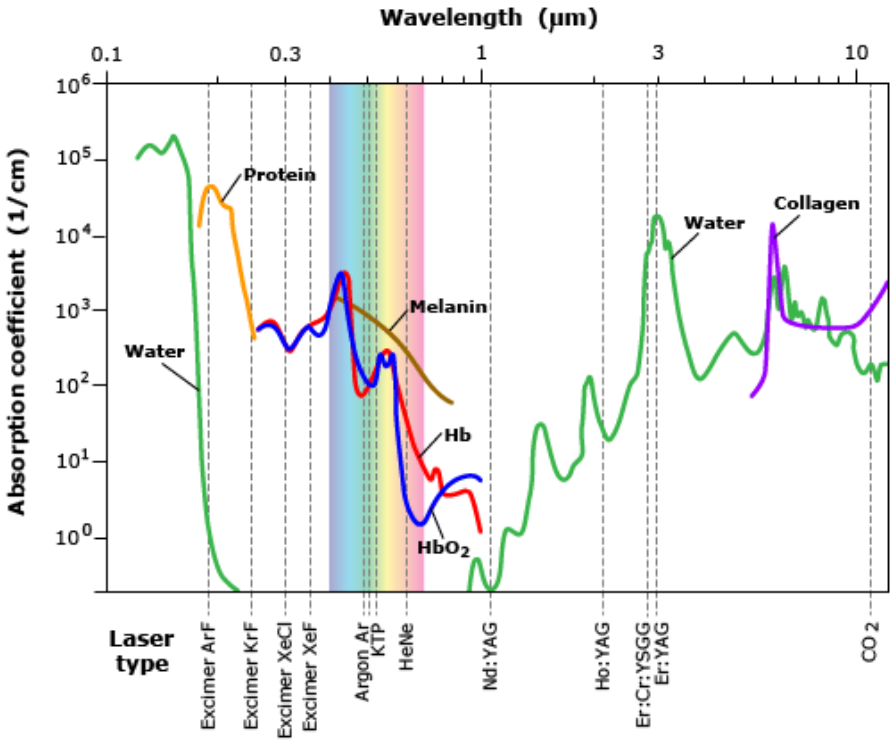
Wavelengths



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How does CO2 laser treatment regenerate skin?

CO2 laser induces a heat shock response (HSP 70 and 47)

Production of heat shock proteins

Activation of growth factor-B (collagen production)

Activation of basic fibroblast GF (angiogenetic activity)

Epidermal GF (Re-epithelialization)

Platelet derived GF(extracellular matrix)

Vascular endothelial GF (Vascularization)

Activation of fibroblasts

Production of collagen and extracellular matrix.

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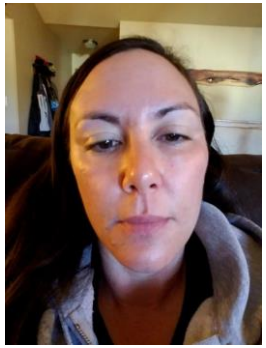
Phases of laser regeneration of skin

- Acute Thermal damage phase (48-72hrs)
- Oedema
- Release of chemical mediators
- Collagen shrinkage

- Proliferation phase (30 days)
- Fibroblast recruiting
- New dermal matrix molecules
- New collagen fibres

- Remodelling phase
- Extinction of inflammatory infiltration
- Matured collagen fibres
- Increase of collagen fibre strain
- New elastic fibres



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MLT

- Doctors from Milan used laser principles to design a treatment for vaginal atrophy.
- Would it work.
- Risks involved.
- Skin thicker and moister, vagina thinner and drier.
- How do you get it in?

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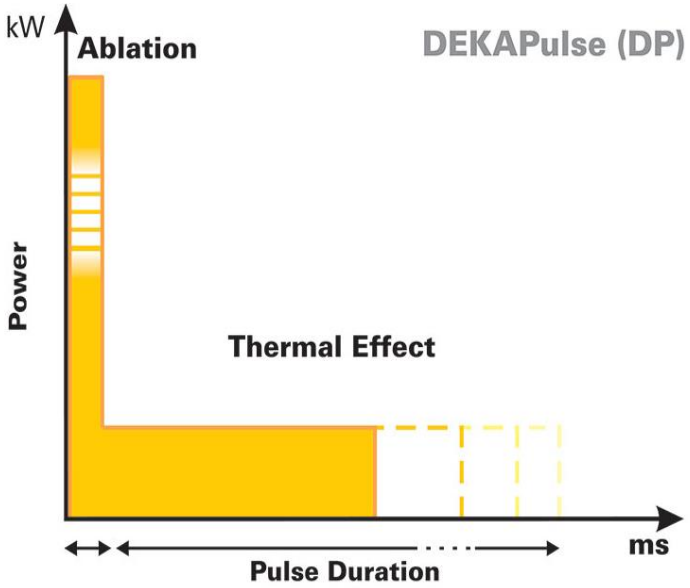
New technique of delivery of laser energy to the genital tract to treat vulvovaginal atrophy.

- Special features of this treatment are:

A) D-pulse. An initial part with a high energy peak power for rapid removal of the epithelial component of the mucosa which has a low water content, lasting 60us, followed by a low peak power and longer emission time that allows the laser energy heat to penetrate the mucosa and stimulate synthesis of collagen and ground substance.



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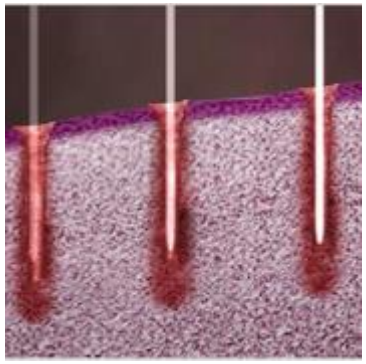
- Dot therapy is the delivery of fractionated laser deployed in small dots of 200 microns, treating only a small percentage of the vaginal tissue. The tissue is ablated in these microthermal zones (MTZ) leading to minimal surface damage and rapid re-epithelialization. The use of the CO2 laser allows for deeper penetration of energy and thermal response.



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- Smart Stack
- Special scanner system to deliver fractioned laser energy to vaginal mucosa
- Special probes-
- 360 degree
- 90 degree
- Vulvar probe
- Easy to use computerised interface.

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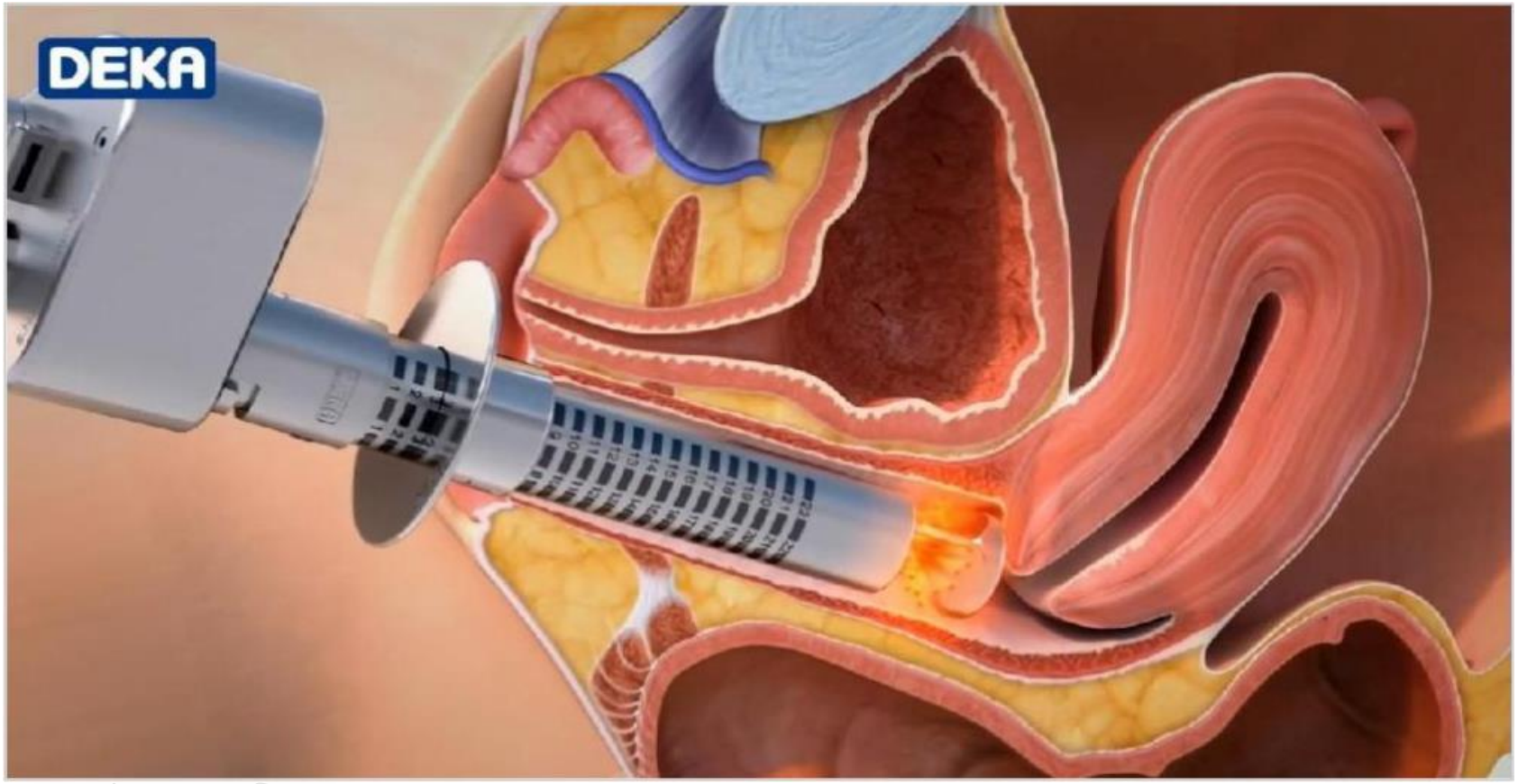
360 degree probe



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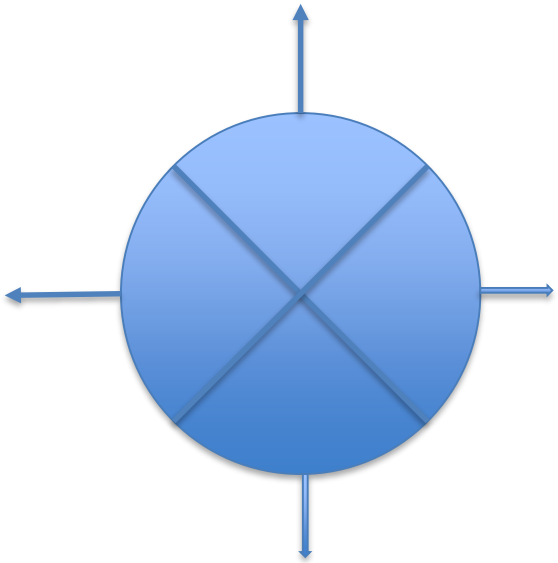
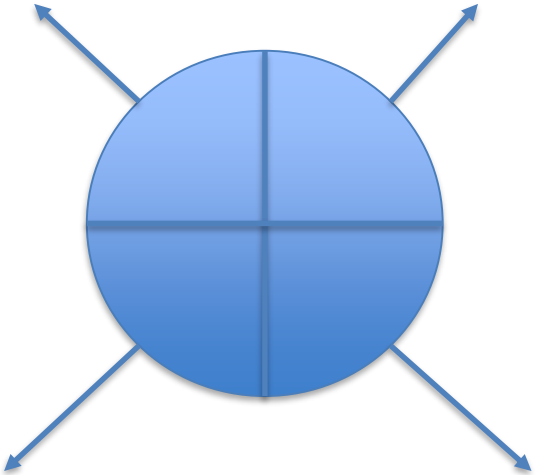
360 degree probe





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

Nicola Zerbinati et al. Laser Med. Science. 2014

Methods: 5 women between the ages of 54 and 63, who reached menopause between the age of 44 and 53 years, with severe atrophic symptoms who have not used systemic or local oestrogens for 12 months, who do not use vaginal moisturizers, and who have no genital infections. One treatment.

Biopsies were taken before treatment and one month after Rx on L vaginal wall, 20mm apart. Biopsy taken from R vaginal wall 2 months after Rx.

Tissue examined by light and electron microscopy.

Results after treatment:

- Thicker epithelium with basal layer of closely packed proliferating cells.
- Significant glycogen storage in intermediate and superficial cells.
- High degree of epithelial exfoliation with glycogen shedding.
- Fibroblasts with active cellular activity for collagen and ground substance .
- Rich supply of blood vessels in CT and papillae on epithelium.

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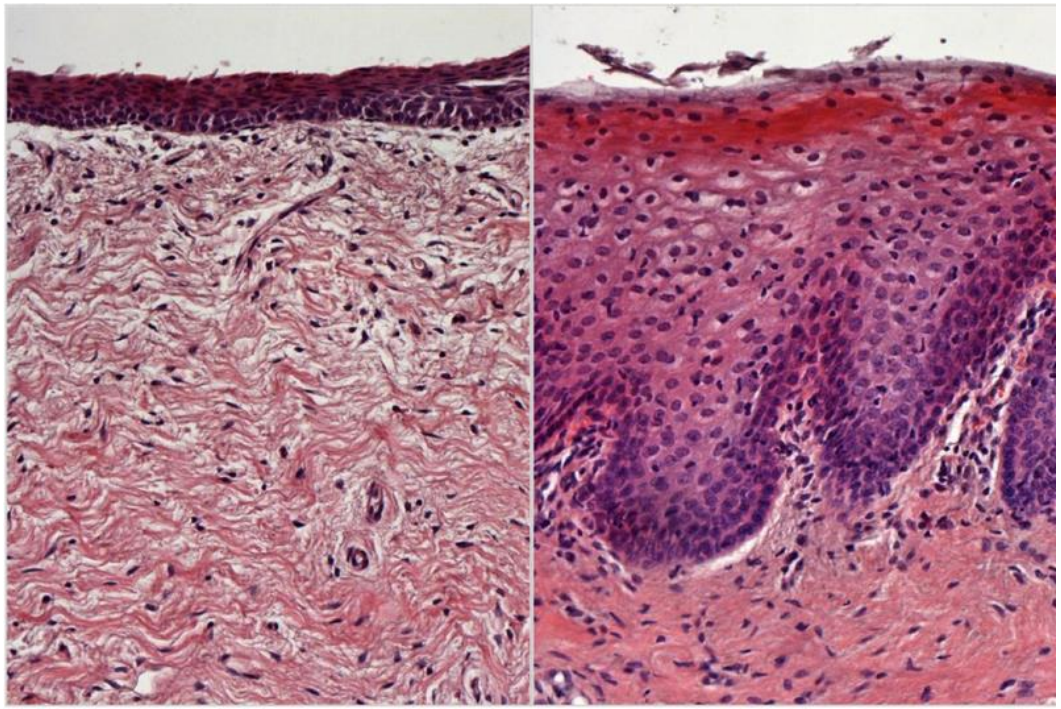
Findings support a metabolic reactivation of the CT components of the vaginal mucosa due to a photobiomodulation effect with remodelling of collagen as a result of fractional laser nonablative photothermolysis as see in skin.



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Histological study on the effects of microablative fractional CO2 laser on atrophic vaginal tissue: an ex vivo study

Salvatore et al. Menopause. Journal NAMS. Vol 22, No 8.

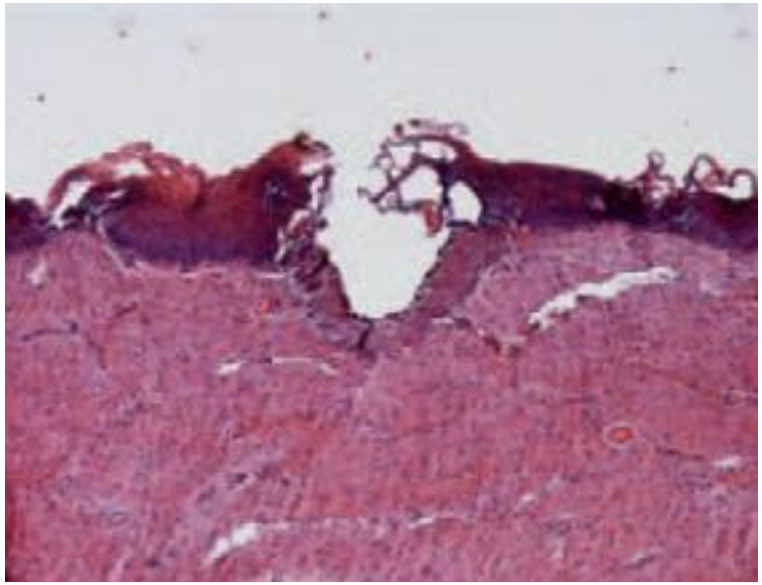
Aim of study to evaluate effects of laser.

Methods: 5 women referred for prolapse surgery. Post menopausal, Stage 2+ anterior vaginal wall descent, non-oestrogenised.

30 mins before trimming excess vaginal tissue, one side treated with MLT, other side not treated. 5 different treatment protocols applied, varying spacing and stacking.

All biopsies sent away for histological evaluation, electron microscopy and qualitative analysis of collagen and elastin.

Analysis showed that microablative fractional CO2 laser was immediately associated withinitial tissue remodelling (activation of fibroblasts and neocollagenesis) without damage to surrounding tissues.



Vaginal mucosal histological preparations stained with haematoxylin and eosin (H&E). The effect produced by a D-Pulse on the epithelium is a superficial vaporization and the formation of a band of denatured collagen. Below this area, laser stimulation produces a controlled temperature gradient which induces the activation of a specific Heat Shock Protein (HSP47) capable of promoting the synthesis of new collagen fibroblasts.

Inclusion criteria

- Symptoms of VVA, rated as moderate/severe
- Age > 50 years
- Absence of menstruation for > or equal to 12 months.
- Not responding to local oestrogen therapies.

Exclusion criteria

- Any use of systemic or local oestrogen in last month
- Use of vaginal moisturizers within last 30 days
- Acute or recurrent UTI
- Active genital infections eg candidiasis or herpes
- Prolapse > stage 2
- Previous pelvic surgery
- Any serious or chronic disease that would interfere with compliance
- Psychiatric disorders preventing informed consent.

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

Salvatore et al. Climacteric 2014:17:1-7

- VVA symptoms assessed in 50 women before and after 3 applications of laser treatment over 12 weeks.
- Subjective (visual analogue scores- vaginal burning, itching, dryness, dyspareunia and dysuria) and objective (Vaginal Health Index Scores – assesses elasticity, fluid volume, pH, epithelial integrity and moisture) were used to assess VVA. QOL assessed using SF-12. A subjective scale VAS) to assess pain and difficulty of the procedure was performed.

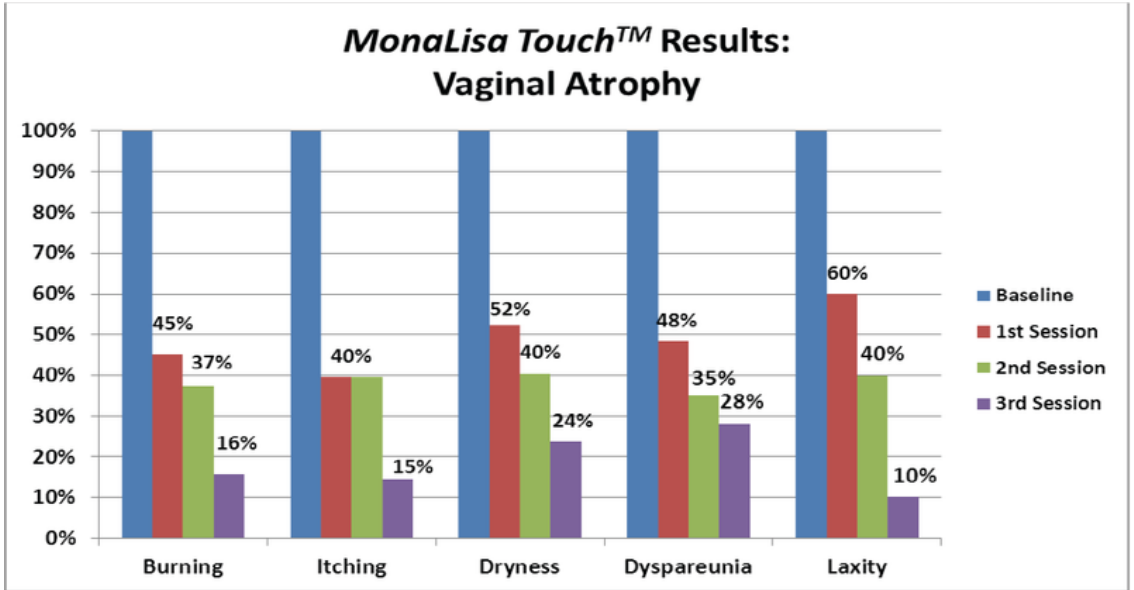

Table 2 Vaginal Health Index Score (VHIS) and intensity of vulvovaginal symptoms during the study period with the fractional microablative CO_2 laser system. Data are given as mean ± standard deviation (*n*)

	Baseline (T1) (first laser)	*4-week follow-up (T2) (second laser)*	*8-week follow-up (T3) (third laser)*	*12-week follow-up (T4)*
VHIS	13.1 ± 2.5	17.1 ± 1.9†	22.1 ± 1.9†,‡	23.1 ± 1.9†,‡
Vaginal dryness (cm)*	8.3 ± 2.1 (43)	5.5 ± 2.9† (42)	3.4 ± 2.5†,‡ (42)	2.7 ± 1.9†,‡ (42)
Vaginal burning (cm)*	6.4 ± 2.7 (45)	4.7 ± 2.2 (44)	3.8 ± 2.5 (44)	2.9 ± 2.4 (44)
Vaginal itching (cm)*	6.1 ± 3.0 (40)	3.3 ± 3.1† (39)	2.1 ± 2.8†,‡ (39)	1.5 ± 1.7†,‡ (39)
Dyspareunia (cm)*	8.1 ± 2.8 (45)	5.7 ± 3.2† (44)	4.5 ± 3.0†,‡ (44)	3.3 ± 2.3†,‡ (44)
Dysuria (cm)*	5.0 ± 2.4 (37)	2.8 ± 1.3† (36)	2.0 ± 0.9†,‡ (36)	1.1 ± 1.1†,‡,** (36)

*, Measured on a 10-cm VAS scale (range 0–10); †, statistical significant difference with T1; ‡, statistical significant difference with T2; **statistical significant difference with T3

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Table 3 Pain related to fractional microablative CO_2 laser application and degree of difficulty to perform the procedure. Data are given as mean ± standard deviation or *n* (%).

	Baseline (T1) (first laser)	*4-week follow-up (T2) (second laser)*	*8-week follow-up (T3) (third laser)*
Pain experienced			
During insertion of probe (cm)	4.7 ± 1.6	2.6 ± 1.5*	0.4 ± 0.5*,†
Due to movements of probe (cm)	2.6 ± 1.5	1.0 ± 0.8*	0.2 ± 0.4*,†
During laser application (cm)	0.6 ± 0.8	0.3 ± 0.5*	0.1 ± 0.4*
Degree of difficulty encountered in laser procedure			
Very easy	41 (82.0%)	49 (100%)	49 (100%)
Easy	8 (16.0%)	0 (0%)	0 (0%)
Neutral	0 (0%)	0 (0%)	0 (0%)
Difficult	0 (0%)	0 (0%)	0 (0%)
Very difficult	1 (2.0%)	0 (0%)	0 (0%)

*, Statistical significant difference with T1; †, statistical significant difference with T2

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Microablative fractional CO2 laser improves dyspareunia related to vulvovaginal atrophy: a pilot study Salvatore et al. J of endometriosis and pelvic pain. 2014

15 patients with same inclusion/exclusion criteria as before.

All women were sexually active and reported dyspareunia at baseline. 3 treatments and assessed before, after each treatment and at 12 weeks. Not responsive to vaginal oestrogen.

Women were assessed, using the VHIS objectively, VAS to assess severity of vaginal symptoms, QOL, and FSFI (Female sexual Function Index – desire, arousal, lubrication, orgasm, and satisfaction and pain)

TABLE II - VHI SCORES, PREVALENCE AND INTENSITY OF SYMPTOMS RELATED TO VULVOVAGINAL ATROPHY DURING THE STUDY

	Baseline (T1) (First laser)	4-week follow-up (T2) (Second laser)	8-week follow-up (T3) (Third laser)	12-week follow-up (T4)
VHI (mean ± SD)	12.9 ± 3.0	17.8 ± 2.0*	19.0 ± 2.2*,†	22.1 ± 2.3*,†,‡
Dyspareunia§ (no., mean ± SD)	8.7 ± 1.0 (n = 15)	3.5 ± 0.8* (n = 15)	2.1 ± 1.0*,† (n = 15)	2.2 ± 1.0*,† (n = 15)
Vaginal dryness§ (no., mean ± SD)	7.2 ± 1.1 (n = 13)	2.8 ± 0.7* (n = 13)	1.5 ± 1.1*,† (n = 13)	1.7 ± 0.9*,† (n = 13)
Vaginal burning§ (no., mean ± SD)	6.9 ± 2.7 (n = 13)	2.5 ± 0.9* (n = 13)	1.9 ± 2.3*,† (n = 13)	1.5 ± 1.9*,† (n = 13)
Vaginal itching§ (no., mean ± SD)	5.6 ± 1.3 (n = 11)	2.5 ± 0.9* (n = 11)	1.8 ± 0.8* (n = 11)	1.6 ± 0.7*,† (n = 11)
Dysuria§ (no., mean ± SD)	5.1 ± 0.9 (n = 9)	2.9 ± 0.7* (n = 9)	1.6 ± 0.8*,† (n = 9)	0.8 ± 1.0*,† (n = 9)

Data are presented as means ± standard deviation.
VAS = visual analog scale; VHI = vaginal health score index.
*Statistical significant difference with T1.
†Statistical significant difference with T2.
‡Statistical significant difference with T3.
§Measured on a 10-cm VAS scale (range: 0-10).

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TABLE III - FSFI TOTAL AND DOMAIN SCORES

	Baseline (T1) (First laser)	12-week follow-up (T4)
Desire	2.2 ± 0.7	3.4 ± 0.7*
Arousal	2.2 ± 0.4	4.1 ± 0.4*
Lubrication	1.4 ± 0.2	4.4 ± 0.6*
Orgasm	2.4 ± 0.7	4.9 ± 0.8*
Satisfaction	2.5 ± 0.5	5.0 ± 0.3*
Pain	1.5 ± 0.2	5.5 ± 1.1*
Total score	12.2 ± 1.0	27.3 ± 0.9*

Data are presented as means ± standard deviation.
FSFI = female sexual function index.
*Statistical significant difference with T1.

Sexual function after fractional microablative CO 2 laser in women with vulvovaginal atrophy Salvatore et al. Climacteric 2015:18:219-225

- To assess effects of MFL on sexual function and overall satisfaction in postmenopausal women with VVA.
- 77 women, 3 treatments.
- Assessed by FSFI and SF-12 at 12 weeks, VAS for symptoms

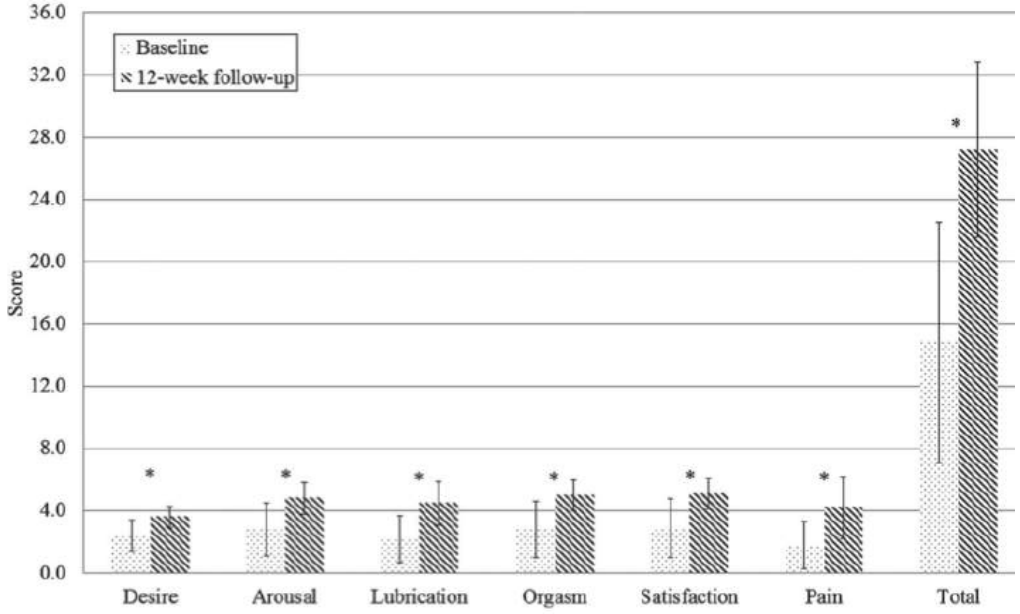

Figure 1
Female Sexual Function Index scores at baseline and at 12-week follow-up

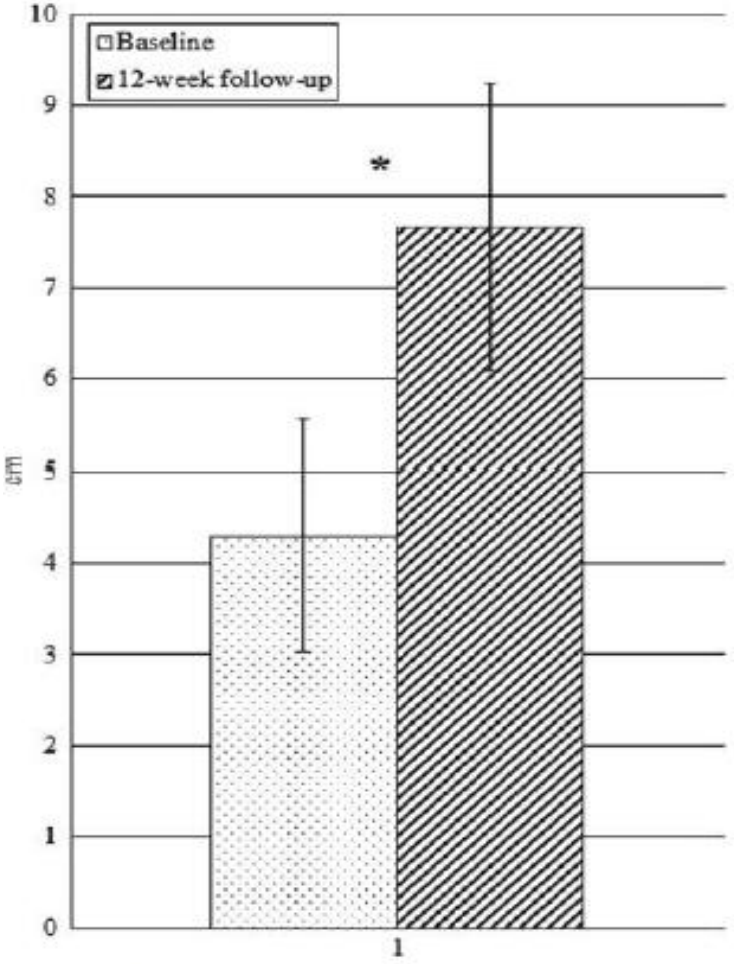

Figure 2 Overall satisfaction with sexual life (expressed as cm) at baseline and at 12-week follow-up

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An added benefit

- The treatment was designed for vaginal atrophy.
- In the initial studies an improvement in bladder function was noted. These symptoms included urgency, urge and stress incontinence, and dysuria and UTI. (Non-published data)
- It may treat symptoms dependent on the integrity of the anterior vaginal wall and lower urinary tract.
- If woman's symptoms worsen after menopause, or are improved by vaginal oestrogens, the MLT may be effective.
- It seems to treat mild symptoms.
- It is possible to provide added treatment specifically to the anterior vaginal wall by using the 90 degree probe.

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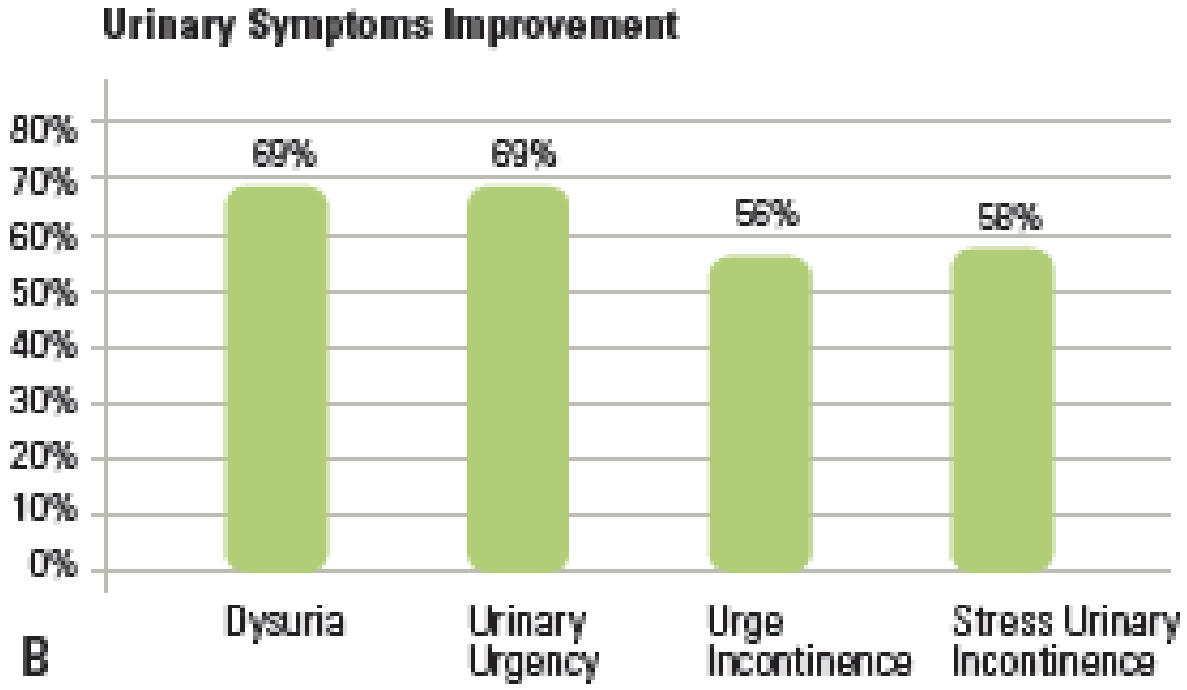

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Other studies

- Pieralli et al. 2016. Treated 50 breast cancer survivors, with one year follow up. 76% satisfied after 3 treatments. After 12 months 52% still very satisfied or satisfied, and 22% weren't satisfied but were happy to have more treatment. 26% weren't satisfied but were not happy to have more treatment.
- Pagano et al. 2016. Improvements after 3 treatments. Pain with intercourse 78%, dryness 80%, itching/stinging 75%.
- Behnia-Willison et al . 2017. Improvements after 3 treatments. Prolapse symptoms, 82%, Vaginal sensation 63%, Vaginal lubrication 36%, Bladder function 77%, urge incontinence 53%. Improvements appeared to be maintained at 24 months, but high attrition rate.
- Siliquini et al 2017. Improvement in QAL in daily living, emotional wellbeing, sexual functioning, self concept and body image 3 months after treatment. Women felt more attractive and desirable.

Effective.

Safe.

Patient satisfaction.

Easy to use.

But

Most studies are short lasting.

No placebo studies.

No RCT cf MLT to vaginal oestrogen.

Studies needed in women with breast and pelvic Ca.

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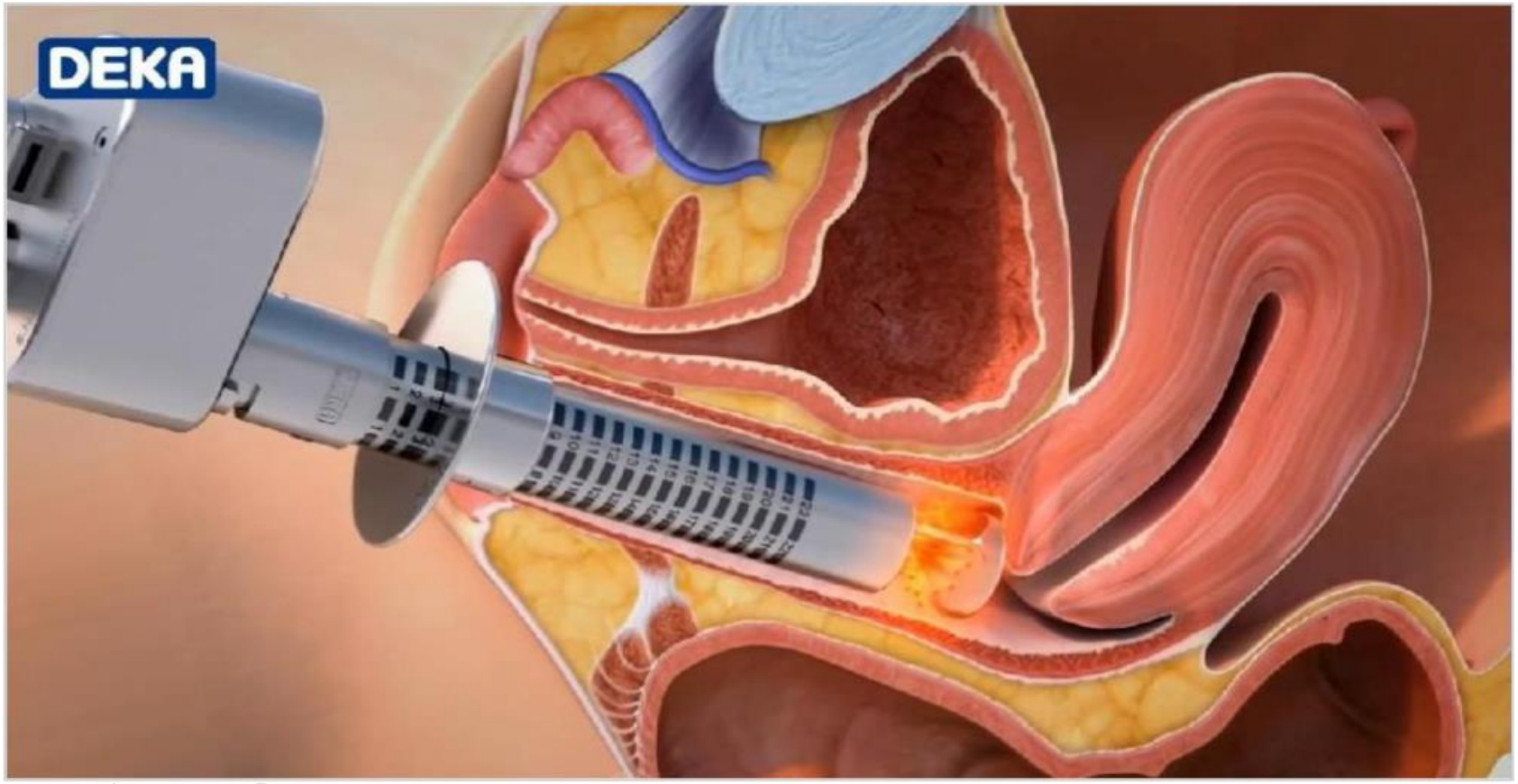
Ongoing studies

- Long term results (Italy – Milan)
- Vaginal Microbiota (Italy – Milan)
- RCT treatment vs sham (Italy – Milan)
- Women with history of breast cancer and VVA-Milan
- Prospective longitudinal cohort study (US)
- RCT treatment vs local oestrogens (US)
- Vaginal cytology and vaginal flora (Greece – Athens)
- Long term histology (Greece – Athens)
- Vaginal tightening results (US, this study will be presented next August at the IUGA Congress in South Africa)

360 degree probe



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The treatment!

- Pre-treatment assessment is essential.
- Vaginal drying is painful, not treatment itself.
- Treatment lasts 5-10 minutes.
- LA may be used which prolongs appointment.
- Can treat vagina, vulva, bladder neck, and wider areas of vulval skin.
- 3-5 days rules afterwards (No sex, swimming, bathing)
- Discomfort 2-48 hrs, rarely longer.
- May have small blood loss.
- Complications few.

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Who to treat?

- Women with VVA- either peri- or post-menopausal.
- Woman having treatment for breast Ca.
- Post pelvic irradiation.
- Before vaginal surgery.
- Vaginal laxity, mild symptomatic prolapse.
- Recurrent UTI, stress or urge incontinence, urgency, frequency
- Post-partum atrophy.
- Dyspareunia due to perineal scarring.
- Recurrent thrush or discharge.
- Lichen sclerosus, Sjogren's syndrome, other skin conditions.???
- Vulval make-over- cosmetic. Whitening.

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Cautions

- If PH genital herpes, needs pre and post-treatment antivirals
- Wait for 6 months after chemotherapy or irradiation
- Women on immunosuppressant drugs
- Be careful if patient taking anticoagulants, b/c bleeding
- Large prolapse
- Wait 3-6 months after vaginal repair
- Suburethral mesh
- Some women will need a smaller probe
- Remember that it is a gynaecological procedure and not one for plastic surgeons and GPs

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Contra-indications

- Pregnancy
- Active cancer in genital tract.
- Untreated CIN changes
- Bladder symptoms need to be assessed before treatment.
- Active pelvic infections.
- Patients with mesh erosion in vagina.
- Patients with > Grade 2 POP ??

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Unknowns

- When is ideal time to repeat treatment. How long will effects last?
- How many treatments?
- Does age mean need more treatments?
- Do aromatase inhibitors mean more treatments.?
- What is the ideal age to start?

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Happy Patients

I had three Mona Lisa Touch Treatments in 2016. It has helped my marriage immensely and I am still enjoying the benefits 12 months later!- M.B, 64 years.

- Treatment made a huge difference to pain with sex, and my bladder.
- My partner has noticed the difference, and I hadn't even told him about the treatment!
- After my first treatment I was able to have sex without pain.
- My husband would like to buy you flowers!

Summary

- New treatment, based on known principles.
- Safe treatment.
- Non-hormonal.
- Relatively painless.
- Easy to do.
- Itsounds too good to be true, but the evidence is stacking up in its favour!

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