

L'IMPACT DES LASERS DANS LA PRISE EN CHARGE DES PATHOLOGIES GYNÉCOLOGIQUES

LE CHOIX DES ARMES

30^e édition - 14/15/16 mars 2019

Marseille

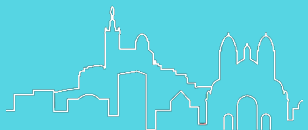


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LE CHOIX DES ARMES

L'auteur déclare n'avoir aucun conflit d'intérêt en rapport avec la présentation.

Pour quelles indications?



50%

of women experience **BLADDER LEAKAGE** also know as **URINARY INCONTINENCE (UI)**. 46% of these women say their symptoms impact their **SEXUAL FUNCTION** ¹



40%

of women suffer from **SEXUAL DYSFUNCTION** ¹



> 1/4

of collegiate female athletes who've never had children experience **URINARY INCONTINENCE** while participating in their sport ¹

Viveve

Treatments for Incontinence, Sexual Function, or Vaginal Laxity



Matmatech

LA SOLUTION INTIME

Un traitement innovant et sans douleur pour retrouver un confort au quotidien



SÉCHESSE ET INCONFORT INTIMES



Collagen isn't just for your face anymore.

The loss of vaginal collagen can lead to decreased sexual sensation and urinary incontinence. But now there is a comfortable, clinically-proven safe and effective treatment!

Ask us about it today!

TOP 6 REASONS WE LOVE THERMI VA!



Improves appearance of labia



Reduces vaginal dryness & atrophy



Reduces urinary leakage



Improves vaginal muscle tone



Improves orgasmic dysfunction



Improves sexual comfort & pleasure

Découvrez EVA™, la solution pour le bien-être intime de la femme...





Fotona
choose perfection

The Viveve Solution

Viveve® System utilizes internationally patented, cryogen-cooled monopolar RF energy (CMRF) technology



© 2014 Fotona LLC

VIVEVE



Matmatech

- 1 Sécheresse vaginale
- 2 Fuites urinaires
- 3 Relâchement cutané
- 4 Rapports douloureux



CO₂RE Intima
Women's Intimate Wellness

100% reported satisfaction with treatment and 100% would recommend it.

94% reported an improvement in vaginal laxity.

81% reported an improvement in overall appearance.



SYNERON CANDELA

New Zealand Restricts All Transvaginal Mesh Implants



from Radio New Zealand

Mesh Medical Device News Desk, December 12, 2017
~ Whether petitioning Parliament, partaking in on-camera interviews or newspaper stories, anti-mesh campaigners from around the world are seeing the results of their efforts.

The new restrictions on transvaginal mesh implants are the result of greater awareness on the part of the public and front-page news headlines.

New Zealand has gone one step further than any other country in its attitude toward the controversial polypropylene transvaginal mesh.

Early next year, New Zealand will restrict the use of all transvaginal mesh implants- those used to treat stress urinary incontinence (SUI) as well as pelvic organ prolapse (POP).

That means the small island nation is going one step further than its nearby neighbor, Australia, which announced last month, a ban on the use of mesh for POP only.

SIGN UP FOR MDND
NEWSLETTER

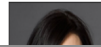
Email Address

Preferred Format

☐ HTML ☐ Text

Submit Form

CONTACT SHEILA
BOSSIER FOR ANY
TRANSVAGINAL MESH
CONCERNS



How safe are surgical mesh implants?

AUSTRALIA NEW ZEALAND NORTH AMERICA

Class Action Lawsuits against
some pelvic and hernia
mesh makers.

MORE VIDEOS

W5: How safe are surgical mesh implants?

Patients deserve better than this. Surgeon speaks of the 'Absolute disaster' of global approval systems for women's pelvic mesh kits



INDEPENDENT

News InFact Politics Voices indy/Life Business

The vaginal mesh scandal is the 'new thalidomide' – so where is the outcry?

MailOnline

'The day before my vaginal mesh surgery I ran 5k, now I wet myself and am in pain': Women reveal how their lives and marriages have been destroyed by contentious NHS implant

ABC NEWS

just in Australia World Business Sport

Vaginal mesh implants: Gynaecologist urges proactive response to health concerns

MORE VIDEOS

To alert patients and health care providers that the use of energy-based devices to perform vaginal "rejuvenation," cosmetic vaginal procedures, or non-surgical vaginal procedures to treat symptoms related to menopause, urinary incontinence, or sexual function may be associated with serious adverse events.

The safety and effectiveness of energy-based devices for treatment of these conditions has not been established.



The screenshot shows the U.S. Food & Drug Administration (FDA) website. The top navigation bar includes the FDA logo, the text "U.S. FOOD & DRUG ADMINISTRATION", and links for "A to Z Index", "Follow FDA", and "En Español". A search bar is located on the right. Below the navigation bar, a horizontal menu lists various FDA categories: Home, Food, Drugs, Medical Devices, Radiation-Emitting Products, Vaccines, Blood & Biologics, Animal & Veterinary, Cosmetics, and Tobacco Products. The "Medical Devices" section is highlighted. Below this, a breadcrumb trail reads: Home > Medical Devices > Medical Device Safety > Safety Communications. A sidebar on the left lists "Safety Communications" with links for "2018 Safety Communications" and "2017 Safety Communications". The main content area features the title "FDA Warns Against Use of Energy-Based Devices to Perform Vaginal 'Rejuvenation' or Vaginal Cosmetic Procedures: FDA Safety Communication". Below the title are social media sharing icons for Facebook, Twitter, LinkedIn, Pinterest, Email, and Print. The "Date Issued:" is listed as "July 30, 2018". The "Audience:" section lists two groups: "Patients considering any vaginal 'rejuvenation' or cosmetic vaginal procedure, or procedures intended to treat vaginal conditions and symptoms related to menopause, urinary incontinence, or sexual function" and "Health care providers who perform vaginal procedures using energy-based devices". The "Specialties:" section lists "Primary Care, Obstetrics and Gynecology, Plastic Surgery, General Surgery". The "Device:" section begins with "Energy-based devices - commonly radiofrequency or laser - that have received FDA clearance for general gynecologic tool indications, including, but not limited to, the destruction of abnormal or pre-cancerous cervical or..."

U.S. FOOD & DRUG ADMINISTRATION

Search FDA

Home Food Drugs Medical Devices Radiation-Emitting Products Vaccines, Blood & Biologics Animal & Veterinary Cosmetics Tobacco Products

Medical Devices

Home > Medical Devices > Medical Device Safety > Safety Communications

Safety Communications

2018 Safety Communications

2017 Safety Communications

FDA Warns Against Use of Energy-Based Devices to Perform Vaginal 'Rejuvenation' or Vaginal Cosmetic Procedures: FDA Safety Communication

SHARE TWEET LINKEDIN PIN IT EMAIL PRINT

Date Issued:
July 30, 2018

Audience:

- Patients considering any vaginal "rejuvenation" or cosmetic vaginal procedure, or procedures intended to treat vaginal conditions and symptoms related to menopause, urinary incontinence, or sexual function
- Health care providers who perform vaginal procedures using energy-based devices

Specialties:

Primary Care, Obstetrics and Gynecology, Plastic Surgery, General Surgery

Device:

Energy-based devices - commonly radiofrequency or laser - that have received FDA clearance for general gynecologic tool indications, including, but not limited to, the destruction of abnormal or pre-cancerous cervical or...



LE CHOIX DES ARMES

**LED LASER ET RF NE SONT PAS LES TRAITEMENTS DE
PREMIERE INTENTION** des pathologies gynécologiques
vulvovaginales: SGUM, IU, LSA, Vulvodynies, vaginisme etc...

**Mais doivent être intégrés dans une prise en charge
pluridisciplinaire après avoir établi un diagnostic
clinique rigoureux**

Œstrogénothérapie locale Lactobacilles

Rééducation pelvi périnéale+++

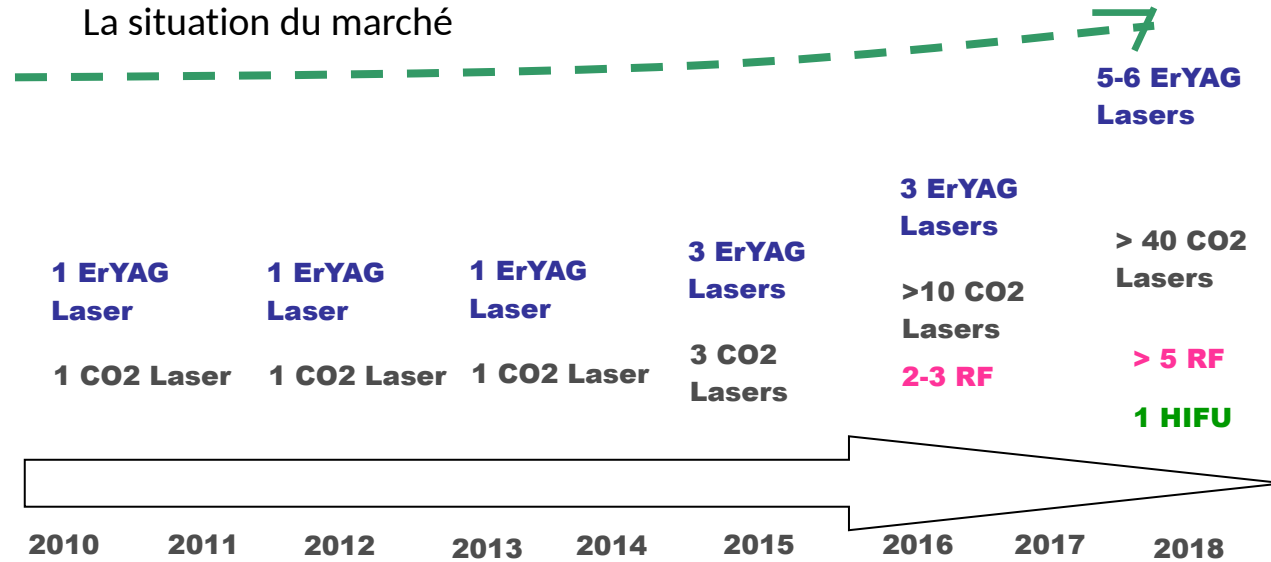
Biopsie

Dermocorticoïdes

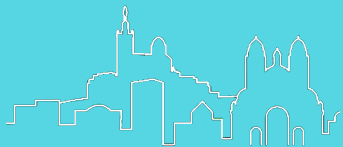




LA COMPÉTITION EST DE PLUS EN PLUS FORTE



Le marché des lasers vaginaux



LASER EN GYNÉCOLOGIE :INDICATIONS

Indications

- ☐ SGUM Syndrome génito-urinaire de la ménopause
- ☐ Incontinence urinaire, impériosité
- ☐ Béance (« syndrome de relâchement vaginal)
- ☐ Atrophie
- ☐ Chirurgie esthétique vulvo-vaginale
- ☐ HPV
- ☐ Blanchiment périnéal
- ☐ Cystocèle et rectocèle????



DÉFINITIONS

L.A.S.E.R. : Light Amplification by Stimulated Emission of Radiation

Il existe de multiples appareils qui permettent d'émettre un rayon lumineux visible ou invisible par l'œil humain.

On caractérise ces rayons de lumière en fonction **de leurs longueurs d'onde**.

Celles-ci s'étendent des rayons **ultraviolets** aux rayons **infrarouges** avec au milieu, les couleurs visibles de l'arc en ciel (**rouge**, **jaune**, **bleu**, **vert**, **violet**).

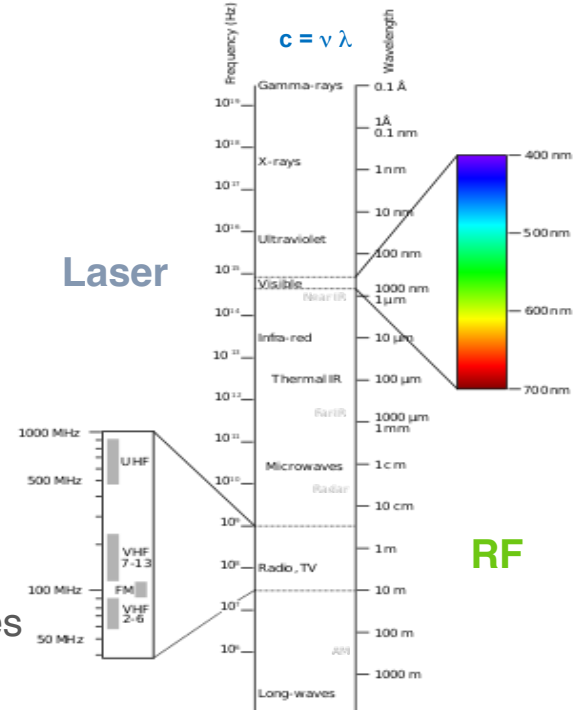
- *Si le rayon lumineux n'est composé que d'une longueur d'onde, il s'agit d'un laser.*
- Les L.E.D (light emitting diode) : dispositif lumineux permettant d'obtenir un faisceau de longueur d'onde unique mais d'énergie très inférieure au laser.

LE LASER ET LA RADIOFRÉQUENCE (RF) SE SITUENT SUR LE SPECTRE ÉLECTROMAGNÉTIQUE

- Toutes les différentes sources d'énergie passent à travers l'épithélium
- La profondeur et l'effet sur les tissus varient en fonction de la source d'énergie utilisée et de son mode d'application
- **Déterminer les zones à traiter, ainsi que les effets souhaités en terme de profondeur afin de choisir la source d'énergie**

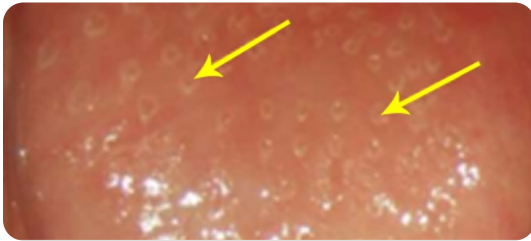
Lasers = Haute fréquence / Longueurs d'onde plus courtes

RF = Basse fréquence / Longueurs d'onde plus longues

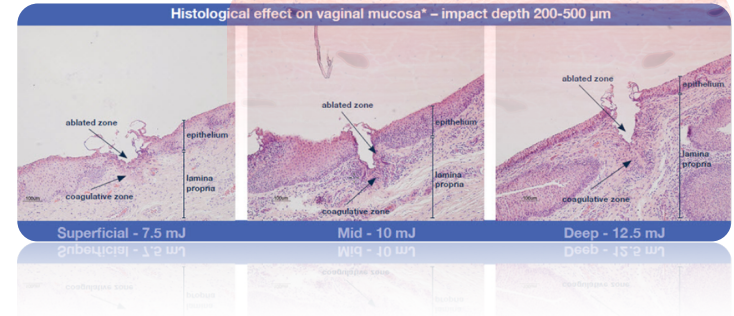
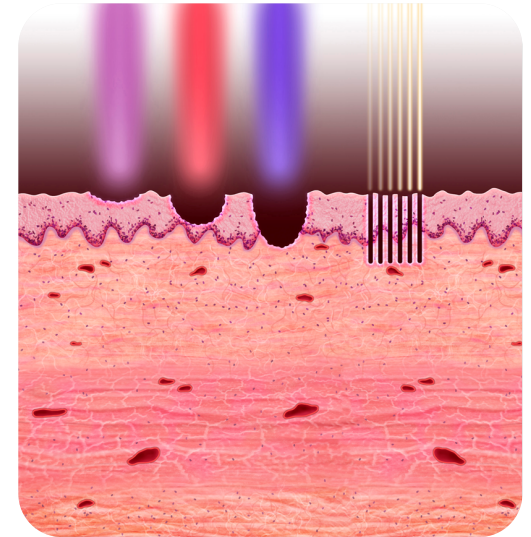


LES LASERS ONT UN EFFET ABLATIF PEU PROFOND

- Absorption de l'énergie par les tissus puis dispersion
- Effet direct sur la muqueuse
- Pénétration jusqu'à la partie supérieure de la lamina propria

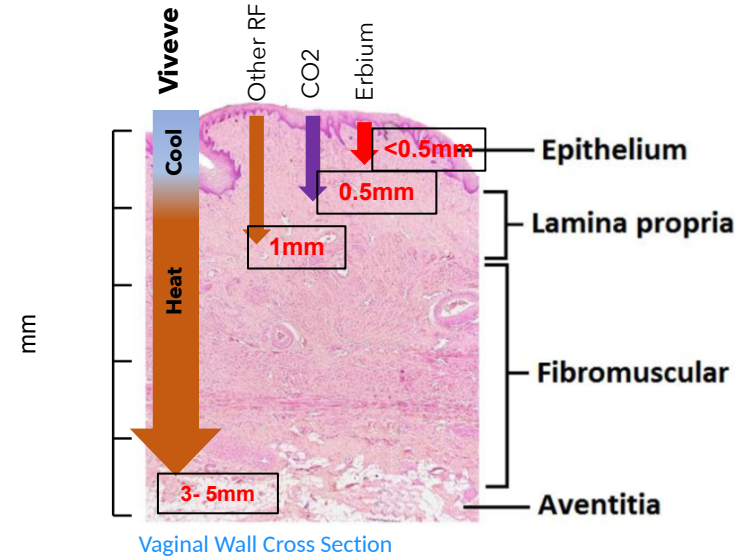


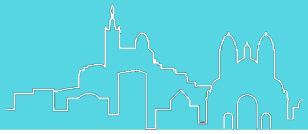
Impact sur le Tissu Muqueux



COMPARAISON DES PROFONDEURS DE PÉNÉTRATION: LASER - RF

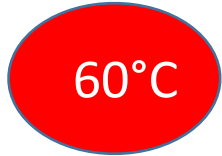
	Viveve CMRF	Other RF
Depth of penetration	3-5 mm	1mm
Safety	Reverse thermal gradient	Operator technique
Therapeutic temp	~50 c	~35 c
Power output	50 watts	20 watts
Time on tissue	~ 8-10 sec	





Principe physique des lasers

Thermique



Lésions thermiques aiguës
(48-72h)

Phase proliférative
(30 jours)

Phase de remodelage
du collagène
(>40 jours)

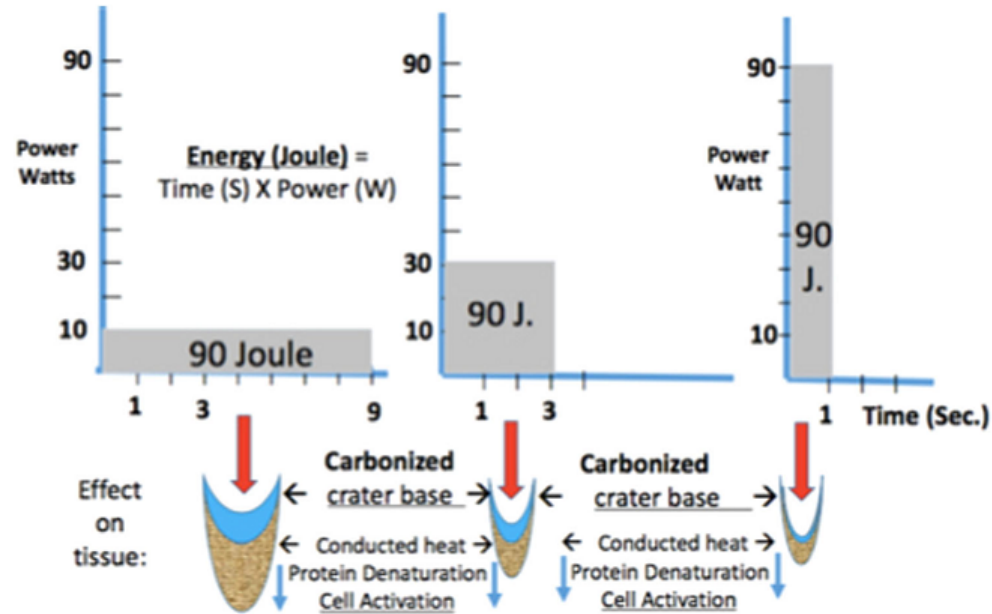
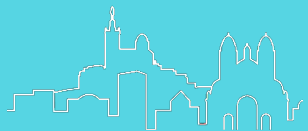


Fig. 4. Energy (Joule) = Power (Watt) $\times$ Time (Second). Effect on tissue is different even if the same energy is deposited depending on exposure time. Same energy may cause different effect, that is, crater shape, superficial carbonization, and thermal coagulation. Three examples of same energy, 90 J, will cause different effect on the tissue. (Courtesy: Tadir Y).



LASER CO2 fractionné : Mécanismes PHYSIQUES

Effets dermiques connus de longue date par stimulation collagénique et remodelage

Application de ces effets à la muqueuse vaginale

- Risques peu importants
- Suites simples
- Techniques peu ou pas douloureuses

Berlin et al. A prospective study of fractional scanned nonsequential carbon dioxide laser resurfacing: a clinical and histopathologic evaluation. Dermatol Surg 2009

Tierney et al. Ablative fractionated CO2, laser resurfacing for the neck: prospective study and review of the literature. J Drugs Dermatol 2009

Tierney et al. Fractionated carbon dioxide laser treatment of photoaging: prospective study in 45 patients review of the literature. Dermatol Surg 2011

Ong et al. Fractional laser resurfacing for acne scars: a review. Br J Dermatol 2012

Ingo et al. Laser skin rejuvenation: epidermal changes and collagen remodeling evaluated by in vivo confocal microscopy. Lasers Med Sci 2013



LASER CO2 fractionné: Mécanismes

- * Active les fibroblastes de la muqueuse vaginale par l'effet thermique spécifique provoqué par l'irradiation
- * Les fibroblastes retrouvent ainsi leur activité fonctionnelle et leur capacité de synthèse du collagène et de l'acide hyaluronique
- * Réactivation des fibrocytes en fibroblastes fonctionnels.

MODE D' ACTIONS DES LASERS VAGINAUX CO2

Etude d'échantillons de muqueuse vaginale de femmes post ménopausées non hormonalement traitées au microscope électronique après laser fractionné CO2

Restauration des couches épithéliales, Augmentation du glycogène dans les cellules Modifications du chorion : restauration des fibroblastes, du collagène
Angiogenèse des papilles épithéliales

Stefano Salvatore and col ., Histological study on the effects of microablative fractional CO2 laser on atrophic vaginal tissue: an ex vivo study Menopause: The Journal of The North American Menopause Society Vol.22, No. 8, pp. 000/000 2015 by The North American Menopause Society*

Stefano Salvatore, A. Calligaro, Use of CO 2Laser Therapy Against Vaginal Atrophy, Vaginal Laxity and Urinary Incontinence. San Raffaele Hospital in Milan, Italy. University of Pavia, Italy (Doc interne Deka)

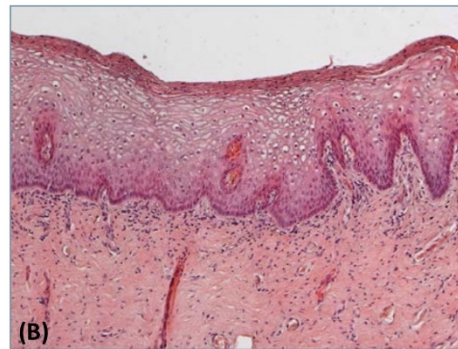
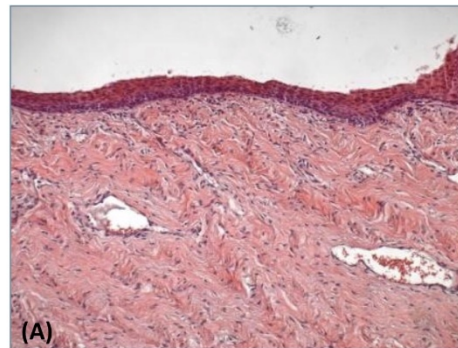
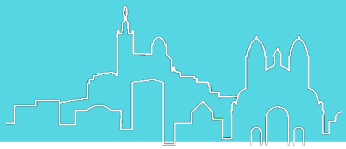


Figure 3.25 – Histological preparation of a section of the vaginal mucosa stained with haematoxylin and eosin (H&E). (A): Vaginal mucosa in the basal condition. This morphological picture indicates vaginal atrophy at an advanced stage with an epithelium formed by few cell layers and no papillae. (B): Vaginal mucosa of the same patient one month after the first session with the MonaLisa Touch® treatment. The much thicker epithelium and the larger diameter of epithelial cells rich in glycogen, demonstrate the restored metabolic trophism and dynamics of the whole epithelium.



LASER CO₂ FRACTIONNÉ

- Published 2018 Jan 19
- **Early Regenerative Modifications of Human Postmenopausal Atrophic Vaginal Mucosa Following Fractional CO₂ Laser Treatment**
- Biopsie vaginale 1 heure après la fin d'une séance: identification de l'action sur le tissu conjonctif par formation de nouveaux vaisseaux, de nouvelles papilles, de nouveau collagène et sur l'épithélium par desquamation des cellules de surface.

[Stefano Salvatore](#),¹ [Katlein França](#),² [Torello Lotti](#),³ [Marta Parma](#),¹ [Sonia Palmieri](#),¹ [Massimo Candiani](#),⁴ [Edoardo D'Este](#),⁵ [Simona Viglio](#),⁶ [Antonia Icaro Cornaglia](#),⁷ [Aurora Farina](#),⁷ [Federica Riva](#),⁷ [Alberto Calligaro](#),⁷ [Jacopo Lotti](#),^{8,*} [Uwe Wollina](#),⁹ [Georgi Tchernev](#),¹⁰ and [Nicola Zerbinati](#)¹¹

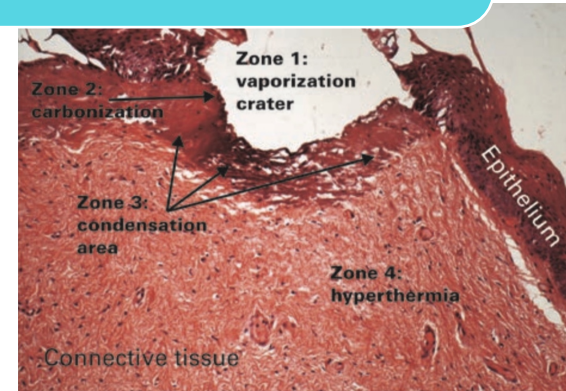
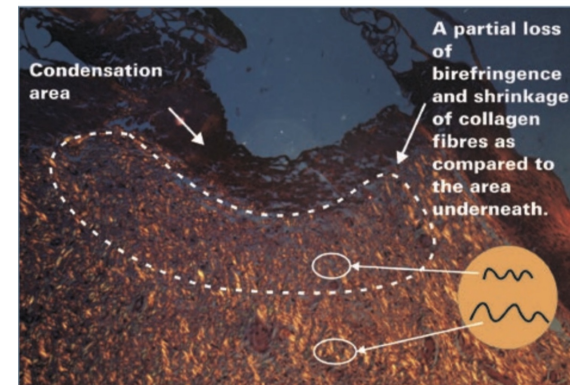
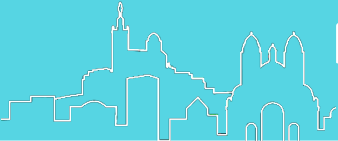


Figure 3.12 – Histological preparation of a section of the vaginal mucosa stained with haematoxy and eosin (H&E). As in figure 3.11, there are four different areas following the CO₂ fraction laser treatment SmartXide[®] VLR CO₂. The light microscope does not show significant structural modifications in zone 4. It is possible to see the characteristic scallop-shaped aspect typical of connective tissue of the vaginal mucosa.





MODE D'ACTION DES LASERS VAGINAUX ER:YAG

Samer Shamout, MD; Lysanne Campeau, Can Urol Assoc J 2017;11(6Suppl2):
S155-8. <http://dx.doi.org/10.5489/cuaj.46>₁₃

- L'action thermique du laser **provoque le rétrécissement de la muqueuse et du tissu de soutien sous-jacent** sans pour autant opérer leurs destruction.
- On pense également que cela entraîne **une attraction mécanique des couches de tissu plus profond** consécutives à cette attraction **et à l'activation de la voie de la néo-collagénogénèse: qui favorise davantage l'élasticité, l'épaisseur et la résistance de la paroi vaginale.**

Lapii GA, et al. Bull Exp Biol Med. 2017.

- Le **marqueur de prolifération Ki-67 augmente dans l'épithélium des biopsies vaginales de femmes souffrant d'IU traitées par erbium Fotona®: l'indice Ki67** des noyaux des cellules parabasales et basales de l'épithélium avant l'exposition au laser Er: YAG était de **19,05 ± 2,86%.**
- Après 1 à 2 mois de traitement au laser, l'indice des noyaux de l'épithélium a augmenté de manière significative et a atteint **31,79 ± 2,25%.**

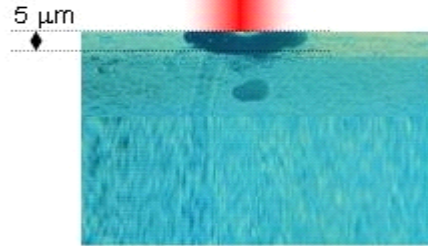
On estime que l'augmentation de l'activité proliférative de l'épithélium vaginal après exposition au laser Er: YAG est due



à la présence d'un niveau appréciable de fibroblastes actifs dans le stroma sous-épithélial

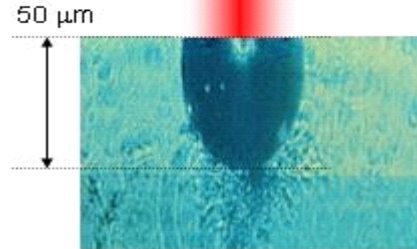
PROFONDEUR DE PÉNÉTRATION DANS L'EAU DES LONGUEURS D'ONDE ABLATIVES

Er:YAG
2.940nm



Absorption forte
Profondeur faible

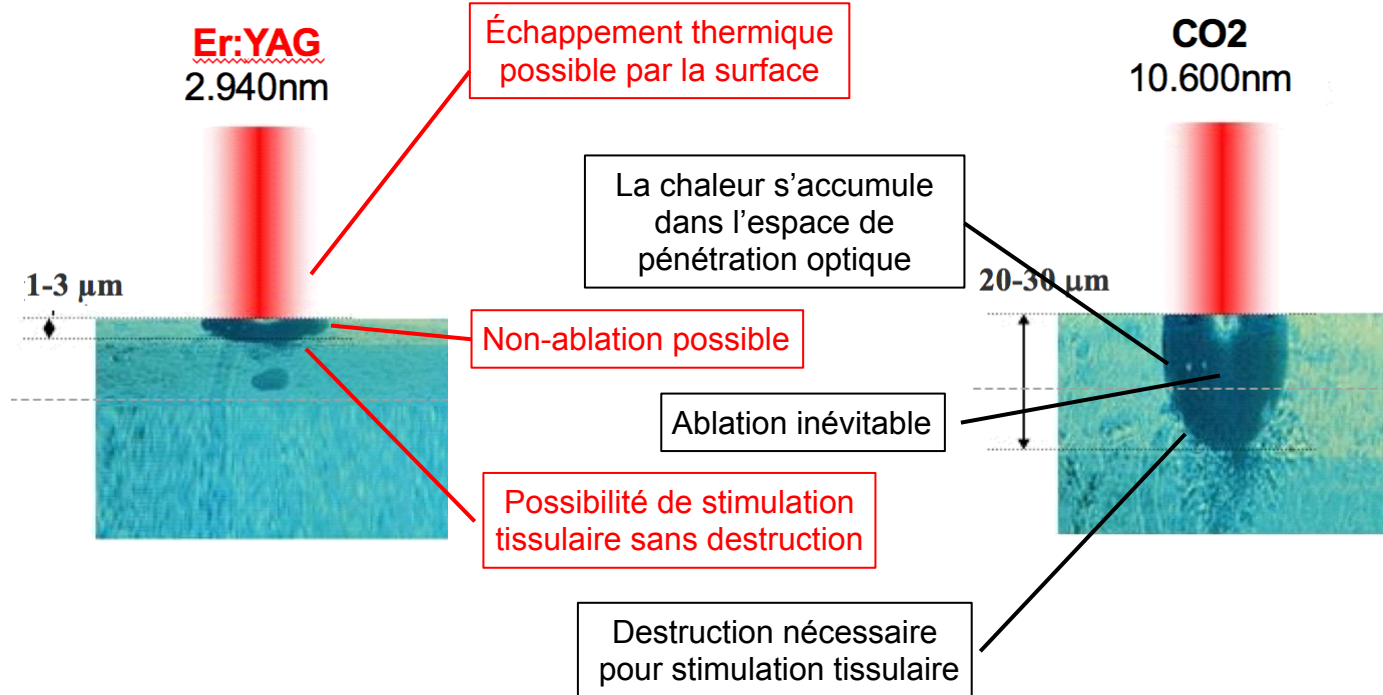
CO2
10.600nm



Absorption 10x moins forte
Profondeur 10x plus grande

EFFETS TISSULAIRES DES LONGUEURS D'ONDE ABLATIVES

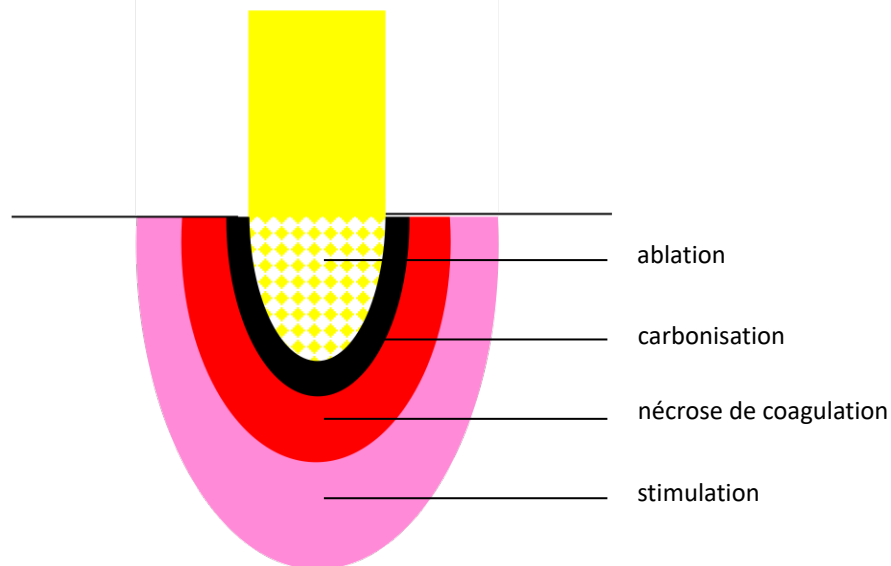
Il découle plusieurs conséquences des propriétés optiques de ces LO



L'Er: YAG peut chauffer sans ablater, le CO₂ ablate inévitablement



CO₂



Ablation : élimine du tissu immédiatement

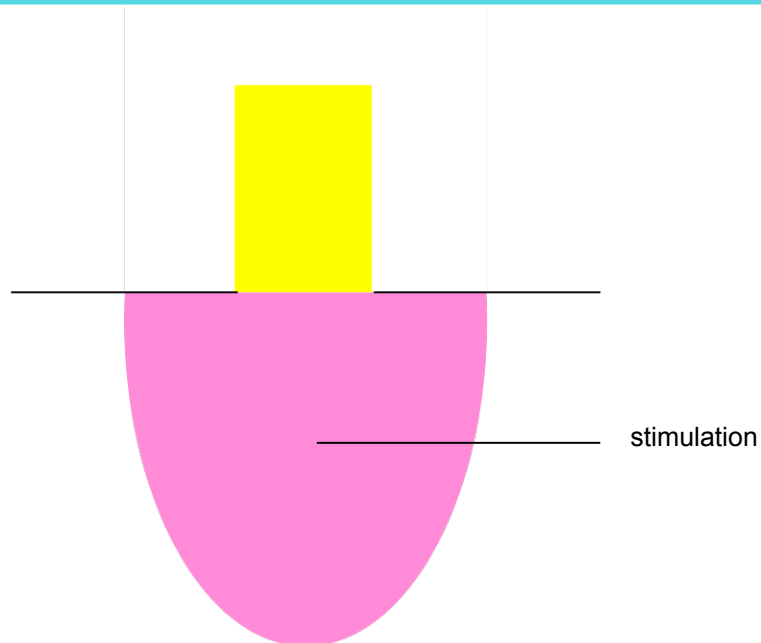
Carbonisation : une frange de tissu est fortement échauffée sans être vaporisée

Nécrose de coagulation : supplément de destruction cellulaire au-delà de l'ablation

Stimulation : régénère les tissus dans leur structure et leurs fonctions



Er:YAG FotonaSmooth[®]



En FotonaSmooth[®] Er : YAG, il y a stimulation pure sans ablation.



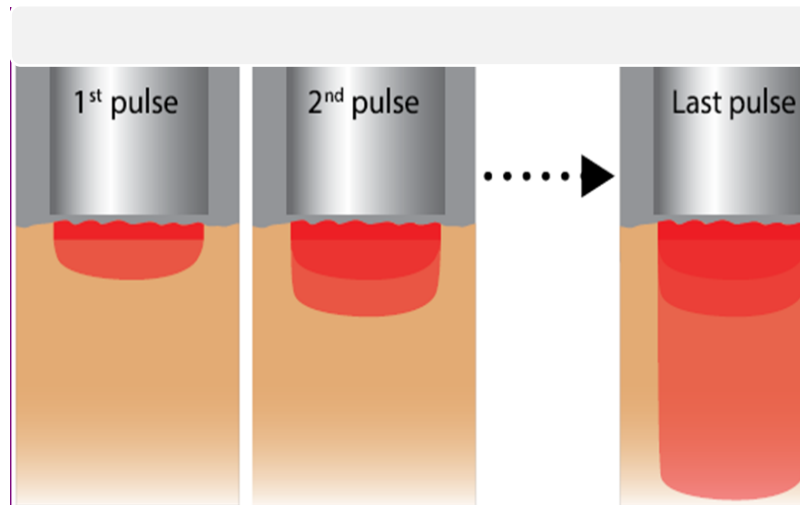
LE LASER ERBIUM:YAG FOTONASMOTH

La grande différence avec le CO2 vient du fait **que la chaleur qu'il dégage est moindre**, de sorte qu'il pénètre beaucoup moins profondément dans la muqueuse

FotonaSmooth™ délivre dans la muqueuse des parois vaginales des impulsions laser provoquant une distribution contrôlée et optimale de chaleur sur la muqueuse

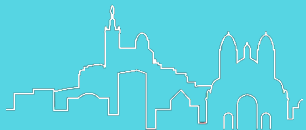
La longueur d'onde 2940 nm, associée à son mode de délivrance permet une procédure hautement contrôlée et sûre, sans impact sur une quelconque structure cruciale, notamment sans pénétration ni rupture de la paroi de la muqueuse.

ON PARLE de « PULSES SUB-ABLATIFS » au contraire des LASERS CO2 qui sont ablatifs



Les impulsions laser de l'exclusif mode séquentiel Er:YAG SMOOTH™ génèrent une structure optimale d'ondes de chaleur.

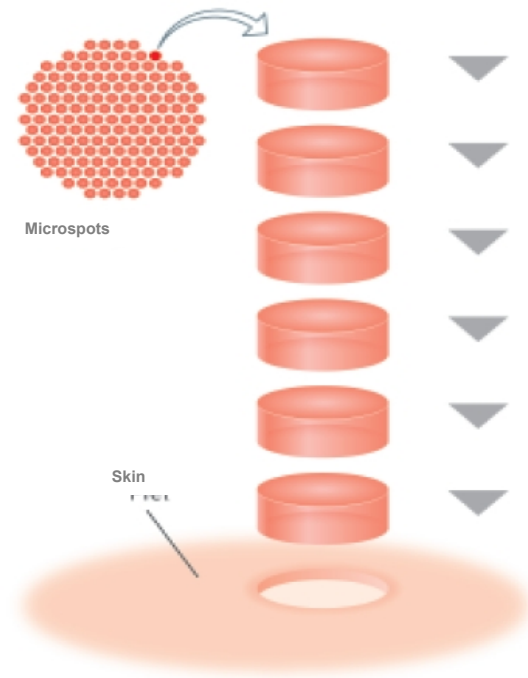
LA CLÉ DE L'ACTION MUQUEUSE DE L'ER : YAG, LES PULSES ULTRA-LONGS



Fotona Er:YAG
Qu'est ce que "Smooth Mode"

Le mode Smooth est une succession de six petits impacts non ablatifs (trains de micro-pulses) avec action purement chauffante.

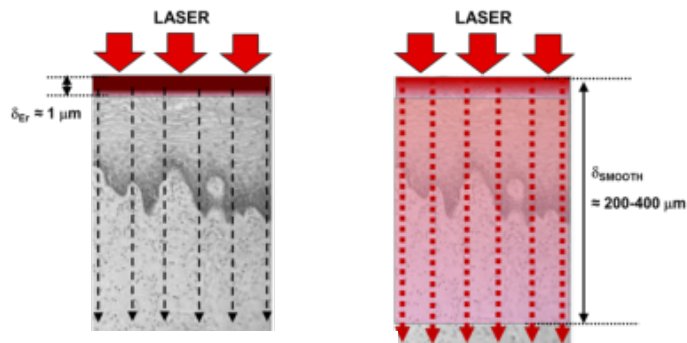
**Les micro-pauses de "rafraichissement"
du point d'impact permettent de faire
diffuser la chaleur vers la profondeur sans
léser la surface**





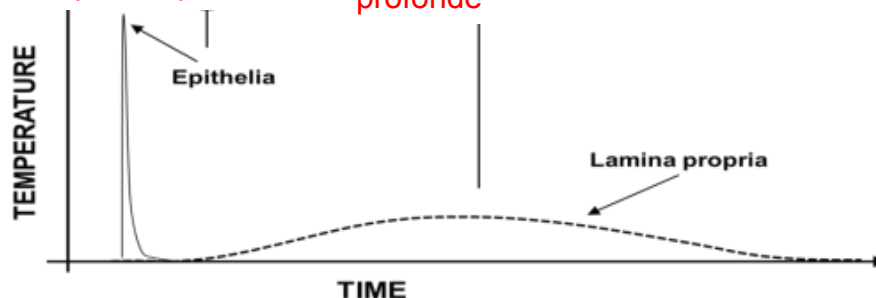
EFFETS THERMIQUE DU PULSE FOTONASMOOTH®

**Double mécanisme de
régénération tissulaire du
mode FotonaSmooth®**



1/choc thermique
rapide superficiel

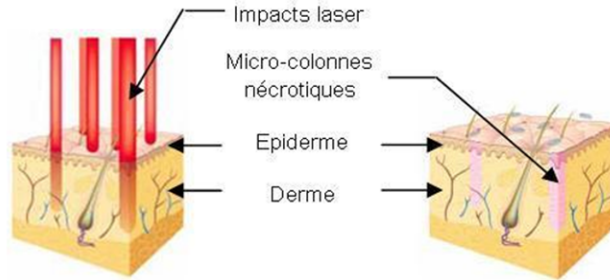
2/action tissulaire lente
profonde



Les chocs thermiques rapides de surface (250°C) génèrent des HSP (Heat Shock Proteins) qui stimulent les kératinocytes et les fibroblastes
La diffusion lente de la chaleur (gradient dégressif à partir de 60-65°C) vers la profondeur stimule les structures de la lamina propria.

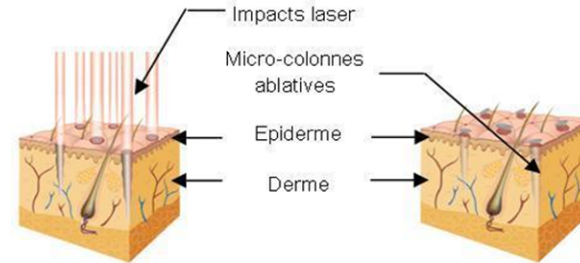


LASER FRACTIONNÉ : EFFETS TISSULAIRES D'UN IMPACT LASER NON ABLATIF OU ABLATIF



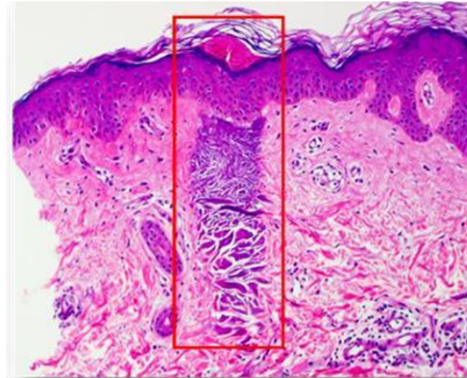
Mécanisme d'action Non Ablatif

Le tissu touché reste en place puis s'élimine en deux semaines

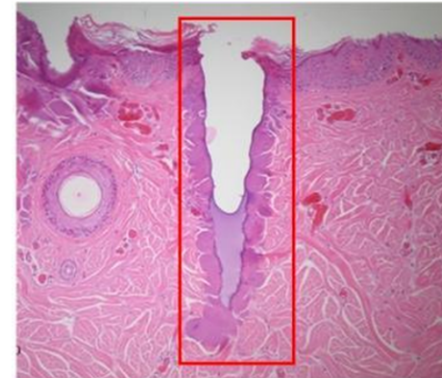


Mécanisme d'action Ablatif

Le tissu touché est immédiatement vaporisé



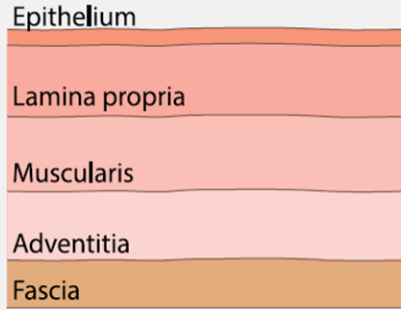
Fractionnel Non Ablatif



Fractionnel Ablatif

MÉCANISME D'ACTION

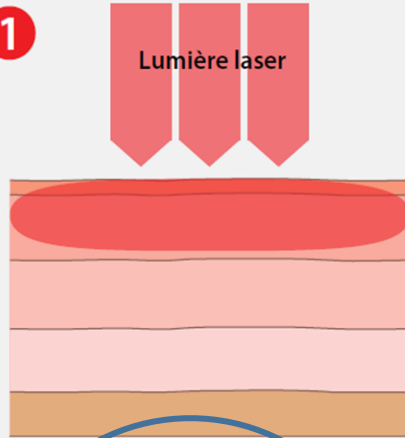
Avant



Structure de la paroi vaginale

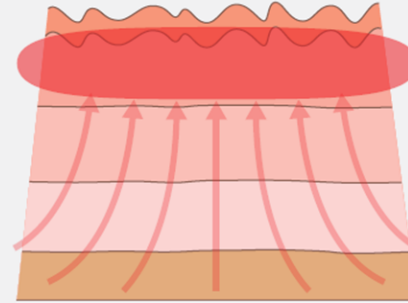
1

Lumière laser



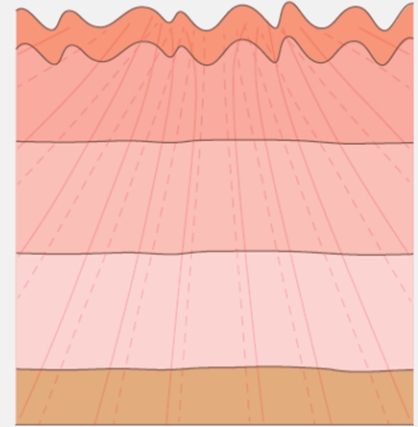
Ondes de chaleur photothermiques pénétrant jusqu'à 0,5 mm sous la surface de la muqueuse vaginale. Les fibres de collagène se raccourcissent et s'épaississent, conséquence du remodelage collagénique provoqué par la chaleur.

2



Les couches plus profondes du tissu sont tirées vers le haut et resserrées par la couche de tissu superficielle remodelée.

3



Les parois vaginales sont encore renforcées par le processus de néocollagénèse (formation de nouvelles fibres de collagène).

LASER CO₂ FRACTIONNÉ
VAGINAL

Pièce à main à 360°





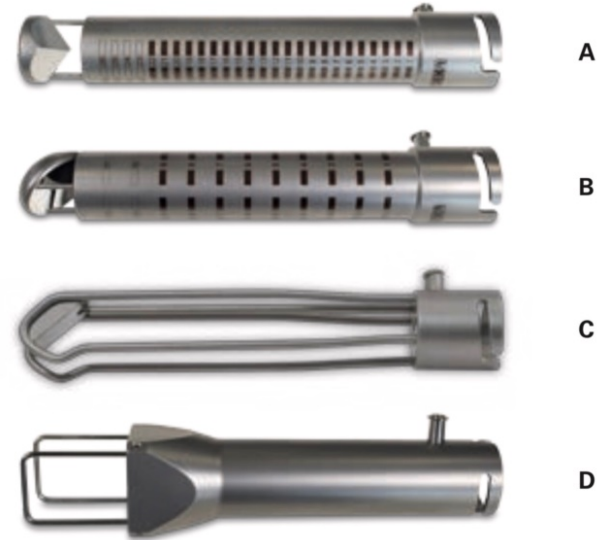
LASER CO2: les différentes pièces à main

Matériel :

Lunette de protection

Source LASER

Différentes PAM



A range of available probes for HiScan V²LR. Simply changing the probe is adapted to all patient's needs. (A): Full-angle vaginal probe emitting in 360° in one time. A single-use version will be ready in due course. (B): Single-use vaginal probe. 2 versions are available with different diameter. (C): Single-mirror probe for the treatment of vulvar and perineal area.

DÉROULEMENT D'UNE SÉANCE TYPE: LASER VAGINAL

TRAITEMENT AU LASER CO₂ FRACTIONNE

(Mona Lisa Touch - Deka)



Intervention au cabinet réalisée
par le Dr Christne LOUIS-VAHDAT

DÉROULEMENT D'UNE SÉANCE TYPE: LASER DE LA FOURCHETTE VULVAIRE



Dr CHRISTINE LOUIS-VAHDAT

TRAITEMENT AU LASER CO2 FRACTIONNE

Intervention au cabinet réalisée
par le Dr Chrisitne LOUIS-VAHDAT

ASPECT POST-TRAITEMENT



FOTONA ERBIUM YAG : les différentes pièces à main

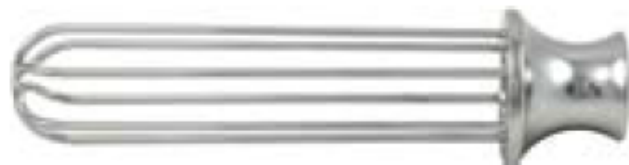
Spéculum en verre et en métal



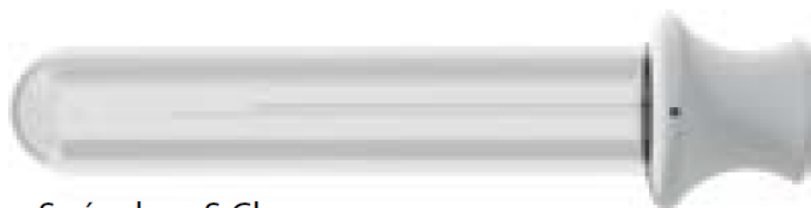
Speculums en métal ou en verre



Pièces à main 380 degrés ou seulement à 90



Spéculum laser métallique fileté



Spéculum S Clear

**SCANNER G-RUNNER™, POUR UN MODE
OPÉRATEUR AUTOMATISÉ**



- Délivrance automatique de l'énergie laser dans le canal vaginal
- Amélioration de l'exactitude et de la précision de la délivrance du rayon laser + couverture plus homogène de la muqueuse vaginale = meilleurs résultats !
- Optimisation du temps de traitement
- Plus grand confort et plus grande commodité pour l'opérateur

G-Runner™ - La technologie scanner exclusive de Fotona



Traitements IncontiLase® et ProlapLase®
Adaptateur en titane à miroir angulaire 90° en or



Traitements IntimaLase®, RenovaLase® et ProlapLase®: Adaptateur en titane à miroir circulaire 360° en or



Pièce à main en titane à rayon intégral R11

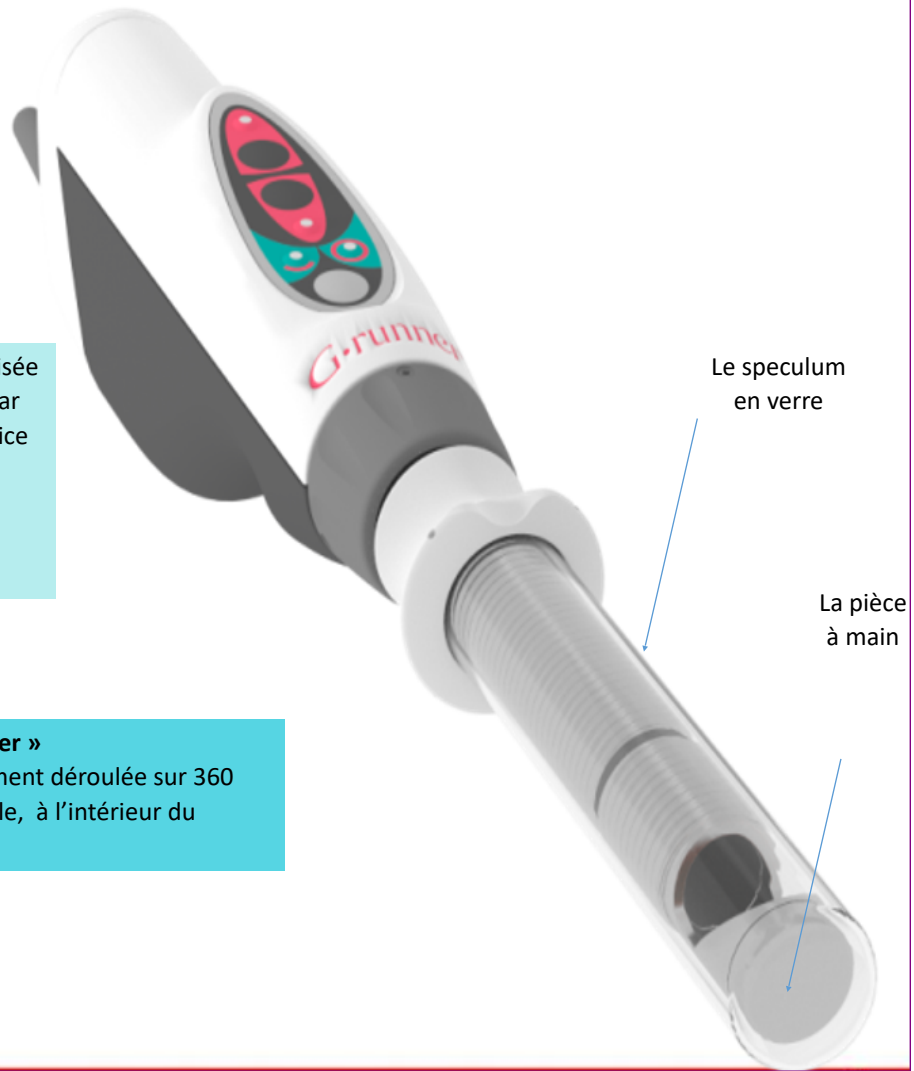


Pièce à main en titane fractionnelle PS03

La PAM peut être mobilisée
« à la main » demi cm par
demi cm du fond à l'orifice
vaginal
Mais aussi grâce au G-
Runner qui le fait
automatiquement

« Le G-Runner »

La pièce à main est automatiquement déroulée sur 360
degrés, du fond vaginal au vestibule, à l'intérieur du
« speculum en verre »

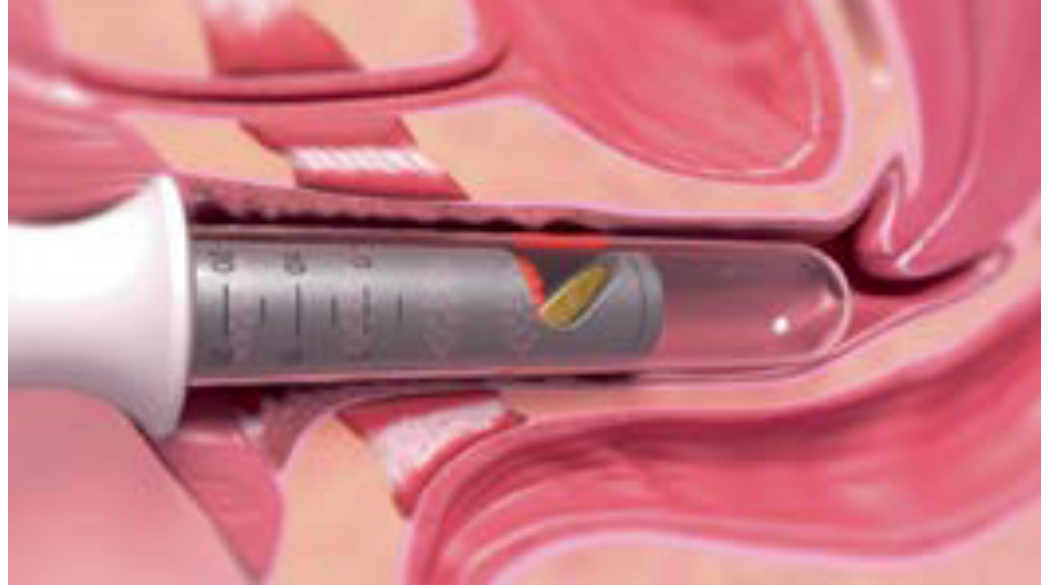


Le speculum
en verre

La pièce
à main

La procédure INCONTILASE®

Pour IUE et
Urgenturies



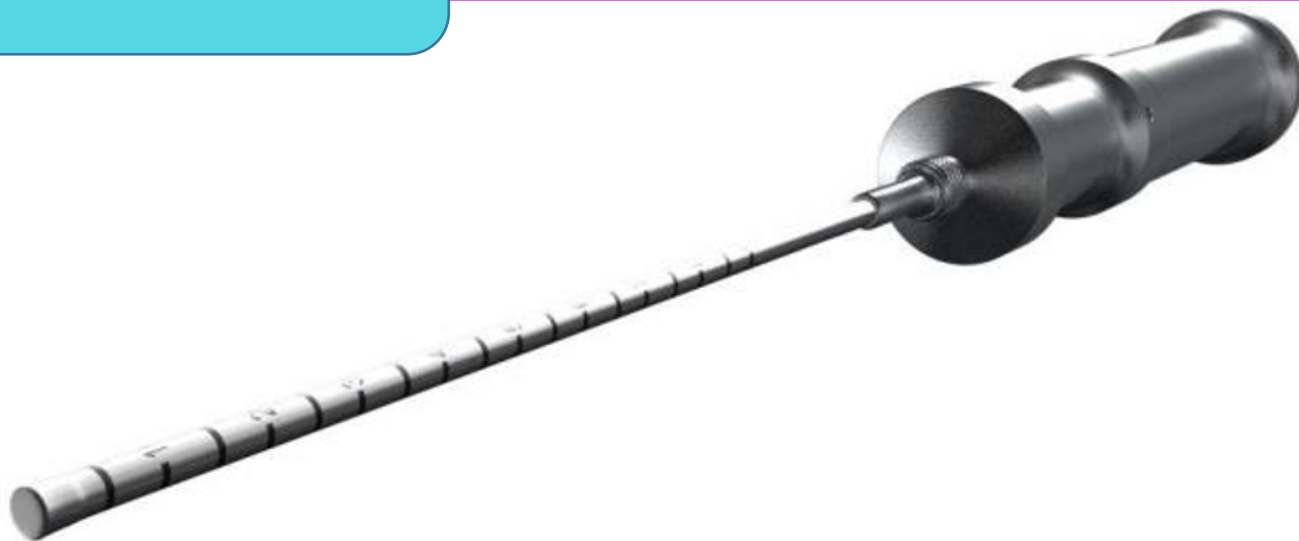
Insertion of the speculum
into the vaginal canal

IncontiLase

Stress urinary incontinence laser treatment



La sonde urétrale
de 4mm



Intraurethral Erbium:YAG Laser for the Management of Urinary Symptoms of Genitourinary Syndrome of Menopause: A Pilot Study

Adrian Gaspar,^{1,2*} Sandra Maestri,¹ Joaquin Silva,² Hugo Brandi,¹ Daniel Luque,¹ Neza Koron,³ and Zdenko Vizintin³

¹Esapacio Gaspar Clinic, Olascoaga 881, 5500 Mendoza, Argentina

²Uroclinica Mendoza, Paso de Los Andes, 5500 Mendoza, Argentina

³Fotona d.o.o., Stegne 7, SI-1000 Ljubljana, Slovenia

2018 Wiley Periodicals, Inc.

- 29 patientes GSM (moyenne 66 ans)
- < 5% de cellules vaginales superficielles + dysurie, fréquence, urgenteries et incontinence par atrophie de l'urètre
- Avec un VLPP («Valsalva Leak Point Pressure)inferieur à 60 cm H2O définissant l'insuffisance sphinctérienne
- 2 séances de laser intra urétral Er: YAG séparées de 3 semaines avec une canule de 4 mm d'épaisseur.
- Efficacité thérapeutique: ICIQ-SF, Pad test et EVA score
- Suivies à 3 et 6 mois



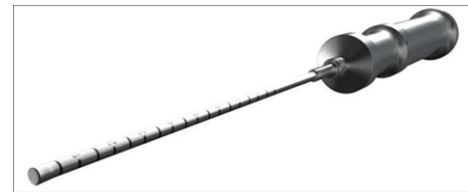
R09-2Gu, new handpiece for gynecology



Dr. Adrian Gaspar



April 2018



New Article

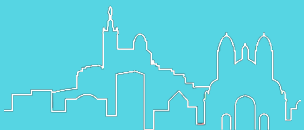
Intraurethral Erbium:YAG Laser for the Management of Urinary Symptoms of Genitourinary Syndrome of Menopause: A Pilot Study

Average Improvement Rates (%) from Baseline Values

	3-month FU	6-month FU
Dysuria	87 (12)	64 (25)
Urgency	79 (18)	44 (35)
Frequency	77 (18)	52 (23)
ICIQ-UI	64 (25)	40 (31)
1-h pad test (g)	59 (13)	42 (20)

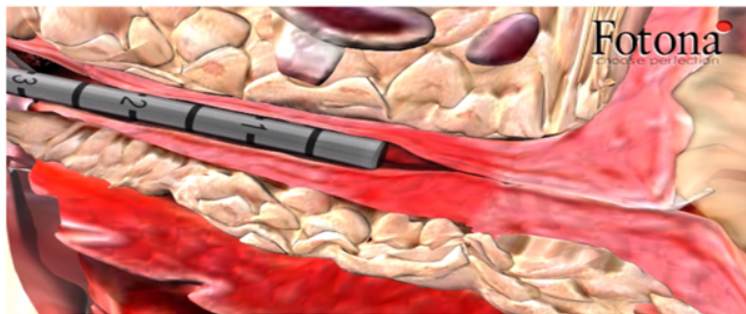
Results are presented as mean (SD)

GASPAR ADRIAN (SUITE)



Insuffisance sphinctérienne (accessoire urétral)

R09-2Gu, new handpiece for gynecology



Non-ablative, thermal only treatment of urethra

- Pas d'anesthésie nécessaire
- 1g de ciprofloxacine 1 heure avant et 1 g de vitamine C et 25 000 unités de vitamine A /J 60 jours *
- Chaque point reçoit 4 impulsions d'une fréquence de 1,4 Hz
- Taille des impulsions : 4 mm avec énergie de 1,5 J / cm².
- La canule retirée de 2,5 en 2,5 mm jusqu'à l'orifice urétral
- Le faisceau laser à une forme conique avec un angle de 22° permettant de traiter la paroi uréthrale à 360°

*La vitamine C = cofacteur des métaux ferreux (Fe [II]) et 2-dioxygénases dépendantes de l'oxoglutarate dans la synthèse du collagène

La vitamine A est un cofacteur important nécessaire au niveau de l'épithélium [25].



RÉSULTATS

TABLE 3. Average Improvement Rates (%) from Base-line Values

	3-month FU	6-month FU
Dysuria	87 (12)	64 (25)
Urgency	79 (18)	44 (35)
Frequency	77 (18)	52 (23)
ICIQ-UI	64 (25)	40 (31)
1-h pad test (g)	59 (13)	42 (20)

Results are presented as mean (SD).

TABLE 1. Effect of Intraurethral Laser Treatment During the Course of the Study

	Baseline (B) ^a	3-month FU ^b	6-month FU ^c	<i>P</i> [*]	<i>post hoc</i> test [#]
Dysuria (VAS 0-100)	66 (21)	8.3 (7.6)	20 (11)	<0.0005	a vs. b, c <0.0005
Urgency (VAS 0-100)	58 (28)	13 (12)	28 (15)	<0.0005	a vs. b, c <0.001
Frequency (VAS 0-100)	49 (20)	11 (8.4)	21 (8.8)	<0.0005	a vs. b, c <0.0005
ICIQ-UI	13 (4.1)	5.2 (3.6)	8.1 (4.8)	<0.0005	a vs. b, c <0.0005
1-h pad test (g)	42 (17)	16 (5.2)	23 (10)	<0.0005	a vs. b, c <0.0005

INCONTINENCE URINAIRE D'EFFORT ET ERBIUM YAG: UNE ÉTUDE RANDOMISÉE VS PLACEBO



Adolf Lukanovic

Eur J Obstet Gynecol Reprod Biol. 2018 May;224:153-158. doi: 10.1016/j.ejogrb.2018.03.038. Epub 2018 Mar 22.

Non-ablative Er:YAG laser therapy effect on stress urinary incontinence related to quality of life and sexual function: A randomized controlled trial.

Blaganje M¹, Ščepanović D¹, Žgur L¹, Verdenik I¹, Pašk F², Lukanović A³.



LASER THERMOTHERAPY IN PELVIC FLOOR DYSFUNCTION RANDOMISED PLACEBO CONTROLLED STUDY

Prof.dr. Adolf Lukanovič, dr.med., svetnik, Mija Blaganje, dr.med.

Viš. pred., mag. Darija Ščepanović, viš.fiziot., Lidija Žgur, viš.fiziot.

Departement of Obstetrics and Gynecology University Medical Center Ljubljana,
Slovenia



LASER THERMOTHERAPY IN PELVIC FLOOR DYSFUNCTION RANDOMISED PLACEBO CONTROLLED STUDY

APPROVAL OF NATIONAL MEDICAL ETHICS COMMITTEE

Randomisation

120 patients

Laser therapy

„Sham“ laser therapy

Full length article

Non-ablative Er:YAG laser therapy effect on stress urinary incontinence related to quality of life and sexual function: A randomized controlled trial



Mija Blaganje^a, Darija Ščepanović^a, Lidija Žgur^a, Ivan Verdenik^a, Franja Pajk^b, Adolf Lukanović^{a,*}

^a Department of Gynecology, University Medical Centre Ljubljana, Ljubljana, Slovenia

^b IAGHA-Laser and Health Academy, Stegne 3, Ljubljana, Slovenia

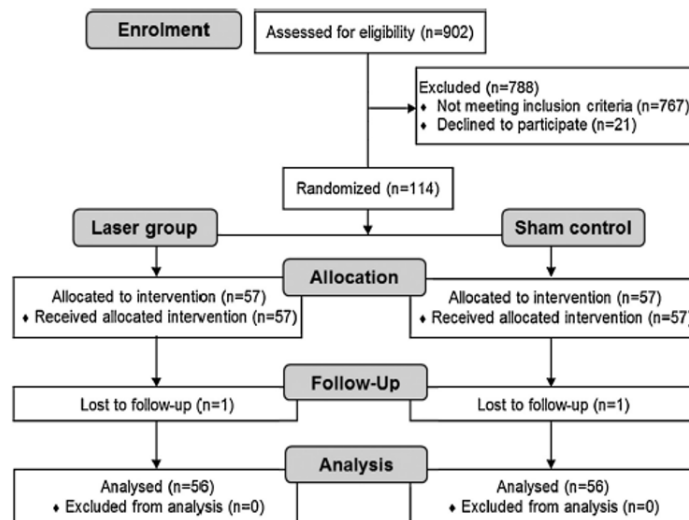
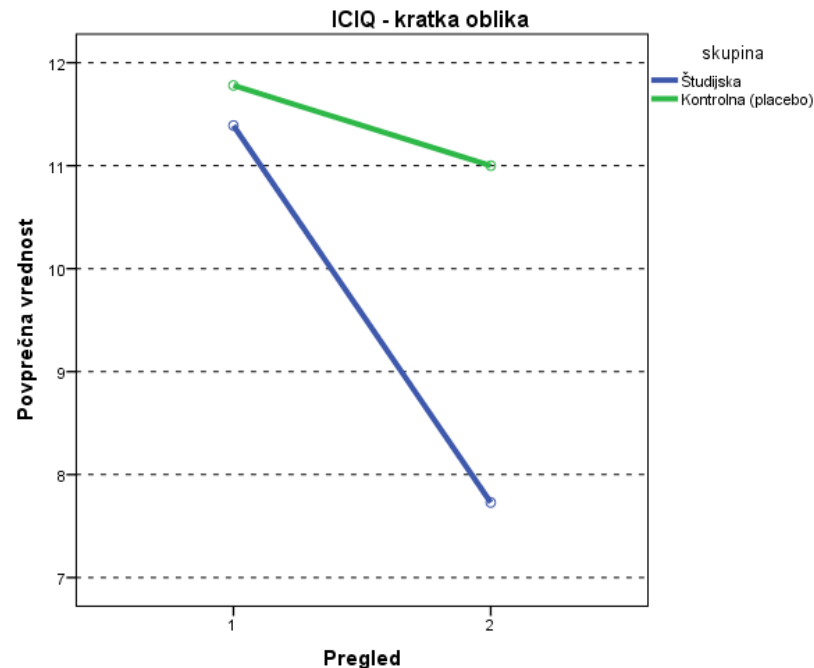


Fig. 1. CONSORT flow diagram of the progress of patients through the phases of this randomized controlled trial.

Randomized Placebo Controlled Study

University of Ljubljana, Slovenia



$p < 0,001$

L'amélioration du « groupe laser » est supérieure au « groupe placebo » et la différence est statistiquement significative *

* *Repeated measures ANOVA*

- 3 mois après le traitement, **les scores ICIQ-UI SF** ($p < 0,001$), **PISQ-12** ($p = 0,014$) et **FSFI** ($p = 0,025$) sont significativement plus améliorés dans le groupe laser que dans le groupe placebo.

- Toutes les variables du **BUD** sont améliorées dans le groupe laser.

- **21%** des patientes traitées au laser étaient continentes au score (ICIQ-UI SF = 0), contre seulement **4%** des patientes du groupe témoin. Aucun effet indésirable grave n'a été observé ou rapporté. Le traitement a été bien toléré par les patients.

INCONTINENCE URINAIRE / ERBIUM YAG: 9 études sur 13

[Int Urogynecol J.](#) 2017 A systematic review on vaginal laser therapy for treating stress urinary incontinence: Do we have enough evidence? Pergialiotis V¹, Prodromidou A², Perrea DN², Doumouchtsis SK^{2,3}.



Table 1 Methodologic criteria of included studies

Date; Author	No.	Type of Laser	Evaluation*	Therapy mode
2017; González Isaza	161	Fractional CO ₂ laser system (MonaLisa Touch™; Deka, Florence, Italy)	12–24/36	-
<u>2017; Lapii</u>	98	Er:YAG laser (SP Spectro, Fotona, Slovenia) SMOOTH Mode	1.5–2	3260 ± 368 pulses
<u>2017; Gaspar</u>	22	Er:YAG laser (SP Spectro, Fotona, Slovenia) -SMOOTH mode	3–6	2 mm spot size, 6.0 J/cm ² , 1.4 Hz
<u>2017; Tien</u>	35	Fotona Dynamis Er:YAG laser (2940 nm) system (XS Dynamis, Fotona, Slovenia) SMOOTH mode	3–6	N/A
2016; Pitsouni	53	CO ₂ Laser (SmartXide ² V ² LR, MonaLisa Touch, DEKA)	1	D-pulse mode, dot power, 40 W, 400 μs, dot spacing 1000 μm
<u>2016; Fistonic</u>	31	2940 nm Er:YAG laser (XS Dynamis, Fotona, Slovenia) -SMOOTH mode	1 to 6	300 μs pulses each 50 msec
<u>2016; Pardo</u>	42	2940 nm Er:YAG laser (Fotona Smooth™ XS, Fotona, Ljubljana, Slovenia)	3–6	6 J/cm ² 1.6 Hz
<u>2015; Gambacciani</u>	45	2940-nm Er:YAG laser (XS Dynamis, Fotona, Slovenia) SMOOTH mode	1–3–6	6 J/cm ² 1.6 Hz
<u>2015; Fistonic</u>	73	2940-nm Er:YAG laser, (XS Dynamis, Fotona, Slovenia) SMOOTH mode	2 to 6	2500–3000 J
2015; Elbia	50	IncontiLase™ procedure Fotona, Slovenia	6	N/A
<u>2015; Ogrinc</u>	175	2940 nm Er:YAG laser (SP Spectro, Fotona, Slovenia) set in smooth mode	2–6–12	10.0 J/cm ² 1.6 Hz
2013; Salvatore	34	Fractional CO ₂ laser	30–40 days	
<u>2012; Fistonic</u>	39	2940 nm Er:YAG laser (XS Dynamis, Fotona, Slovenia)	1–3–6	30 J



Photomedicine and Laser Surgery. – Vol. 35, No. 3, 2017.
Epub 2016 Dec 30– Vol. 26, No. 1, 2017. Epub 2016 Oct 09

Fractional CO₂ laser: from skin rejuvenation to vulvo-vaginal reshaping

Filippini M¹, Del Duca E¹, Negosanti F^{2,3}, Bonciani D⁴, Negosanti L⁵,
Sannino M², Cannarozzo G², Nisticò SP^{2,6}

1: Hospital State of Republic of San Marino - Republic of San Marino. 2: University of Rome Tor Vergata, Rome - Italy.
3: Dermatology Center, Bologna - Italy. 4: Pistoia Palagi University Hospital, Florence - Italy.
5: S.Orsola-Malpighi University Hospital, Bologna - Italy. 6: Magna Grecia University of Catanzaro - Italy.

386 patientes
ménopausées
3T
Résultat à 12 mois

Abstract

Background

The CO₂ laser has become the gold standard treatment in dermatologic surgery for the treatment of a large number of skin and mucosal lesions. The introduction of the fractional micro-ablative technology represented an integration to the ablative resurfacing technique, reducing the healing time and the side effects.

Objective

Vaginal rejuvenation performed with this technique is a minimally invasive procedure that stimulates internal tissues of the female lower genital tract to regenerate the mucosa, improving tissue trophism and restoring the correct functionality.

Methods

In our experience, 386 menopausal women affected with vulvo-vaginal atrophy (VVA) were treated with three sessions of fractional micro-ablative CO₂ laser.

Results

After three treatments, patients reported a complete improvement of the symptoms (59.94% dryness, 56.26% burn, sensation, 48.75% dyspareunia, 56.37% itch, 73.15% soreness, and 48.79% vaginal introitus pain).

Conclusions

Fractional micro-ablative CO₂ laser seems to reduce symptoms related to vaginal atrophy. The beneficial effects were reported just after the first session and confirmed 12 months after the last session.

Amélioration
60% Sécheresse
56% Diminution des brûlures
73% diminution des douleurs

Climacteric – Vol. 19, No. 5, 2016. Epub 2016 Aug 2

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

Athanasidou S¹, Pitsouni E^{1,2}, Antonopoulou S¹, Zacharakis D¹, Salvatore S¹, Falagas ME^{2,3,4}, Grigoriadis I⁵

¹: National and Kapodistrian University of Athens, Athens – Greece; ²: AIBS, Athens – Greece; ³: "G. Gennimatas" General Hospital, Athens – Greece; ⁴: San Raffaele Hospital, Milan – Italy; ⁵: MGS General Hospital, Athens – Greece; ⁶: Tufts University School of Medicine, Boston, MA – USA; ⁷: Alexandra Hospital, Athens – Greece.



Abstract

Objectives

To assess the effect of microablative fractional CO₂ laser (MFCO₂-Laser) therapy on the vaginal microenvironment of postmenopausal women.

Methods

Three laser therapies at monthly intervals were applied in postmenopausal women with moderate to severe symptoms of genitourinary syndrome of menopause, pH of vaginal fluid >4.5 and superficial epithelial cells on vaginal smear <5%. Vaginal fluid pH values, fresh wet mount microscopy, Gram stain and aerobic and anaerobic cultures were evaluated at baseline and 1 month after each subsequent therapy. Nugent score and Hay-ison criteria were used to evaluate vaginal flora.

Results

Fifty-three women (mean age 57.2±5.4 years) participated and completed this study. MFCO₂-Laser therapy increased Lactobacillus ($p < 0.001$) and normal flora ($p < 0.001$) after the completion of the therapeutic protocol, which decreased vaginal pH from a mean of 5.5±0.8 (initial value) to 4.7±0.5 ($p < 0.001$). The prevalence of Lactobacillus changed from 30% initially to 79% after the last treatment. Clinical signs and symptoms of bacterial vaginosis, aerobic vaginitis or candidiasis did not appear in any participant.

Conclusions

MFCO₂-Laser therapy is a promising treatment for improving the vaginal health of postmenopausal women by helping repopulate the vagina with normally existing Lactobacillus species and reconstituting the normal flora to premenopausal status.

53 patientes Augmentation des lactobacilles de 30 à 79%

Menopause – Vol. 23, No. 10, 2016

An assessment of the safety and efficacy of a fractional CO₂ laser system for the treatment of vulvovaginal atrophy

Sokol ER¹, Karram MM²

¹: Stanford University, Stanford, CA – USA; ²: The Ochs Hospital, Cincinnati, OH – USA.



Abstract

Objective

The aim of the study was to assess the safety and efficacy of a novel fractional CO₂ laser for the treatment of genitourinary syndrome of menopause (GSM).

Patients and Methods

Women presenting with GSM and meeting study criteria were enrolled. Examinations at baseline and follow-up (3 mo after final treatment) evaluated dilator tolerance and vaginal pH. Visual analog scales were used to assess pain, vaginal burning, vaginal itching, vaginal dryness, dyspareunia, and dysuria; Vaginal Health Index scores were completed before each treatment and at follow-up; Female Sexual Function Index and Short Form 12 questionnaires were also completed. Participant satisfaction was measured on a 5-point Likert scale (1=very dissatisfied, 5=very satisfied). Women received three laser treatments, 6 weeks apart.

Results

Thirty women participated (mean age 58.6±8.8 y). None withdrew or were discontinued due to an adverse event; three were lost to follow-up. Average improvement in visual analog scale scoring was 1.7±3.2 for pain, 1.4±2.9 for burning, 1.4±1.9 for itching, 6.1±2.7 for dryness, 5.1±3.0 for dyspareunia, and 1.0±2.4 for dysuria; improvement in average Vaginal Health Index and Female Sexual Function Index scores were statistically significant ($P < 0.001$). Twenty-five of 30 participants (83%) showed increase in comfortable dilator size at 3-month follow up. Before the second and third treatments, 86.6% (26 of 30) of women reported they were better or much better than at the previous treatment; 26 of 27 women (96%) were reportedly satisfied or extremely satisfied at follow-up.

Conclusions

In this sample, the data suggest that the fractional CO₂ laser is effective and safe for treatment of the symptoms associated with GSM.

Menopause. Epub 2017 Feb 6

Use of a novel fractional CO₂ laser for the treatment of genitourinary syndrome of menopause: 1-year outcomes

Sokol ER¹, Karam MM²

1: Stanford University, Stanford, CA - USA; 2: The Christ Hospital, Cincinnati, OH - USA.



Abstract

Objectives

To assess safety and efficacy of a fractional CO₂ laser therapy for the treatment of genitourinary syndrome of menopause (GSM) with follow-up to 1 year posttreatment.

Methods

Women presenting with GSM and meeting inclusion criterion were enrolled. Visual Analog Scales were used to grade vaginal pain, burning, itching, dryness, dyspareunia, and dysuria. Dilators were used to rate vaginal elasticity at baseline and at each follow-up visit. Before each treatment and at follow-up, Vaginal Health Index scoring and Female Sexual Function Index questionnaires were completed. Women received three vaginal laser treatments spaced 6 weeks apart. Participant satisfaction was measured on 5-point Likert scales (1=very dissatisfied, 5=very satisfied).

Results

Of 30 women (mean age 58.6±8.8 years), three were lost to follow-up at 3 months and six at 1 year. None were discontinued or withdrew due to an adverse event. Average improvement in Visual Analog Scale scores for all symptom categories was statistically significant at 3 months and remained so through 1 year, except dysuria. Differences between data at 3 months and 1 year were not statistically significant, indicating persistence of positive outcomes. Average overall improvement in pain was 1.9 (±3.4), burning 1.9 (±3.1), itching 1.4 (±1.9), dryness 5.9 (±2.8), dyspareunia 4.9 (±3.3), and dysuria 0.9 (±3.1). Improvement in average Vaginal Health Index and Female Sexual Function Index scores was also statistically significant (P<0.0001). Of 19 women undergoing dilator examination at 1 year, 18 (94.8%) were comfortable with the same or larger dilator size. Twenty-two of 24 women (92%) were satisfied or extremely satisfied with the treatment at 1 year.

Conclusions

Based on study data up to 1 year, the fractional CO₂ laser may be an effective and safe treatment for women suffering from symptoms of GSM, although additional studies with larger populations and placebo control is needed to confirm these results.

3 traitements à 6 semaines d'intervalle
30 patientes
92% satisfaites à 1 an
Evaluation de l'élasticité 94% à 1 an

European Journal of Obstetrics Gynecology and Reproductive Biology
Vol. 213, 2017. Epub 2017 Apr 2

Safety and long-term efficacy of fractional CO₂ laser treatment in women suffering from genitourinary syndrome of menopause

Behnia-Willison F^{1,2}, Sarraf S³, Miller J⁴, Mohammadi B⁵, Care A S^{6,7}

Lean A⁸, Willison N⁹, Behnia L⁷, Salvatore S⁴

1: FBM Gynecology Plus - Australia; 2: RMIT University - Australia; 3: The Prince of Wales Medical Centre - USA; 4: The University of Adelaide - Australia; 5: Robinson Research Institute - Australia; 6: Centre for Advanced Reproductive Endosurgery - Australia; 7: University of Tehran - Iran; 8: San Raffaele Hospital - Italy.



Abstract

Objective

To evaluate the safety and long-term efficacy of fractional CO₂ laser treatment in reducing the severity of symptoms of genitourinary syndrome of menopause (GSM) in menopausal women.

Study Design

102 women presenting with symptomatic GSM were treated with the fractional CO₂ laser (MonaLisa Touch, DEKA) system across a series of treatments delivered at intervals of six or more weeks. The Australian Pelvic Floor Questionnaire was used to gather data on sexual function and side-effects at three time-points across the study period (prospective panel design study). Wilcoxon signed-rank tests were used to detect statistically and clinically significant changes in sexual function and side-effects occurring from pre- to post-treatment. The primary outcome of this study was an improvement of the symptoms of GSM. The secondary outcome included bladder function and prolapse symptoms.

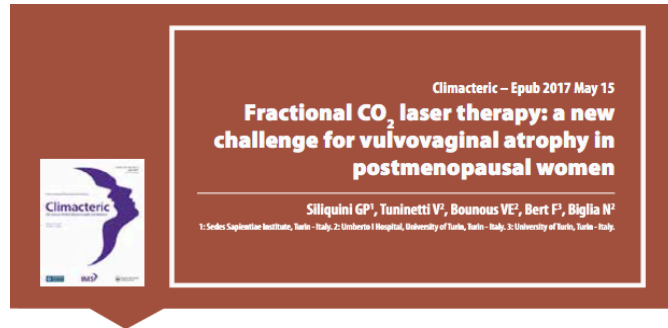
Results

A total of 102 women suffering from moderate to severe GSM were recruited. Eighty-four percent experienced significant improvement in their symptoms after CO₂ laser treatment. Scores on measures of sexual function, dyspareunia, and bothersomeness of sexual issues were improved from pre-treatment to long-term (12–24 month) follow-up. Furthermore, there were improvements on measures of bladder function (P = 0.001), prolapse (P = 0.001), vaginal sensation (P = 0.001), vaginal lubrication (P < 0.001) and urge incontinence (P = 0.003) from the pre-treatment assessment to the second assessment (i.e. after the third treatment).

Conclusions

In this study, fractional microablative CO₂ laser treatment was associated with an improvement in symptoms of GSM and sexual function.

102 patientes
évaluation de la fonction sexuelle
84% satisfaites entre T1 et T2



Abstract

Objectives

To evaluate the effects of CO₂ laser in the treatment of vulvovaginal atrophy (VVA) in postmenopausal women.

Methods

VVA was assessed in 87 postmenopausal women (mean age 58.6±6.9 years) before and after the treatment. The protocol consisted of three monthly treatments and included the treatment of vulva. Subjective measures included VAS (Visual Analog Scale) both for vaginal dryness and dyspareunia; DIVA (Day-by-day Impact of Vaginal Aging); a questionnaire on treatment satisfaction and one about the degree of pain during the procedure. Objective measures included VHI (Vaginal Health Index) and VVHI (Vulvo-Vaginal Health Index). Time points of the study were at the screening visit (T0), at baseline (T1), at week 4 (T2), at week 8 (T3), after 3 months since the last laser application (T4), after 6 months (T5), after 9 months (T6), after 12 months (T7) and after 15 months (T8).

Results

Treatment induced significant improvement in the VAS score. After treatment, VHI and VVHI indicated no VVA and this improvement was long lasting. Multivariate analysis showed that the time of follow-up was correlated with better VHI and VVHI ($p < 0.001$). DIVA improved over time ($p < 0.001$).

Conclusions

This study shows that CO₂ laser treatment induces a significant and long-lasting improvement of symptoms.

87 patientes

87 patientes âge moyen 58,6

3 Traitements à 1 mois avec traitement
vulvaire

A 12 et 15 mois

Amélioration significative de l'AVV

Evaluation VHI et VVHI / VAS (sécheresse et
Dyspareunie)



Maturitas - Epub 2017 Jul 21

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

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Abstract

Objectives

The aim of this prospective study was to assess the efficacy of 3, 4 or 5 CO₂-laser sessions for the management of the genitourinary syndrome of menopause (GSM).

Methods

Postmenopausal women with moderate to severe symptoms of dyspareunia, wanting to resume/retain sexual activity, were treated with 3–5 laser sessions depending on symptom severity/presence, sexual function, clinical findings and women's preference following the third laser application.

Main Outcomes

Severity of dyspareunia, dryness, sexual function, sexual satisfaction and frequency of sexual intercourse defined the primary outcomes. Vaginal Maturation Value (VMV) and Vaginal Health Index Score (VHIS) defined the secondary ones.

Results

Fifty-five women received three sessions, 53 an extra fourth and 22 an extra fifth. Following the third, fourth and fifth laser sessions, respectively: dyspareunia completely regressed in 15/55 (27%), 32/55 (58%) and 38/47 (81%) of participants; dryness completely regressed in 20/55 (36%), 36/55 (66%) and 44/51 (86%); normal sexual function resumed in 23/55 (41%), 37/54 (69%) and 41/49 (84%); VMV regained non-atrophic values in 29/55 (53%), 38/55 (69%) and 42/50 (84%); and VHIS regained non-atrophic values in 44/55 (80%), 53/55 (96%) and 55/55 (100%) of participants.

Conclusion

Results of this study indicate that CO₂-laser therapy may contribute to complete regression of dyspareunia and dryness and reestablishment of normal sexual function in postmenopausal women, in a dose-response manner. An extra fourth or fifth session may further increase the GSM symptom-free rate.

55 PATIENTES 3T

53 PATIENTES 4T

22 PATIENTES 5T

Dyspareunie 27%/58%/81%

Sécheresse 36%/66%/86%

VMV 53%/69%/84%

VHIS 80%/96%/100%

Menopause – Epub 2017 Jul 31

Randomized, double-blind, placebo-controlled clinical trial for evaluating the efficacy of fractional CO₂ laser compared with topical estriol in the treatment of vaginal atrophy in postmenopausal women



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ABC School of Medicine, São Bernardo do Campo, São Paulo – Brazil

Abstract

Objective

The aim of the study was to evaluate efficacy of fractional CO₂ vaginal laser treatment (Laser, L) and compare it to local estrogen therapy (Estriol, E) and the combination of both treatments (Laser + Estriol, LE) in the treatment of vulvovaginal atrophy (VVA).

Methods

A total of 45 postmenopausal women meeting inclusion criteria were randomized in L, E, or LE groups. Assessments at baseline, 8 and 20 weeks, were conducted using Vaginal Health Index (VHI), Visual Analog Scale for VVA symptoms (dyspareunia, dryness, and burning), Female Sexual Function Index, and maturation value (MV) of Meisels.

Results

Forty-five women were included and 3 women were lost to follow-up. VHI average score was significantly higher at weeks 8 and 20 in all study arms. At week 20, the LE arm also showed incremental improvement of VHI score ($P=0.01$). L and LE groups showed a significant improvement of dyspareunia, burning, and dryness, and the E arm only of dryness ($P<0.001$). LE group presented significant improvement of total Female Sex Function Index (FSFI) score ($P=0.02$) and individual domains of pain, desire, and lubrication. In contrast, the L group showed significant worsening of pain domain in FSFI ($P=0.04$), but FSFI total scores were comparable in all treatment arms at week 20.

Conclusions

CO₂ vaginal laser alone or in combination with topical estriol is a good treatment option for VVA symptoms. Sexual-related pain with vaginal laser treatment might be of concern.

Etude comparative Laser seul, Laser+Estriol et Estriol seul
45 patientes
L et L+E nette amélioration
E amélioration sécheresse seul symptôme

Lasers Med Sci - Epub 2017 Aug 2

Microablative fractional CO₂ laser for the genitourinary syndrome of menopause: power of 30 or 40 W?



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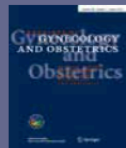
Abstract

This retrospective case-control study aimed to compare 30 versus 40 W power of CO₂ laser for the therapy of genitourinary syndrome of menopause (GSM). Postmenopausal women with severe intensity of dyspareunia and dryness were eligible to be included in this study. Primary outcomes were dyspareunia and dryness. Secondary outcomes were itching/burning, dysuria, frequency and urgency, Female Sexual Function Index (FSFI), vaginal maturation value (VMV), and Vaginal Health Index Score (VHIS).

One laser therapy was applied every month for 3 months. Outcomes were evaluated at baseline and 1 month following the 3rd therapy. Fifty (25 per group) women were included in this study. In the 30-W group, mean improvement of dyspareunia, dryness, itching/burning, FSFI, VMV, and VHIS was 6.1 ± 1.7 , 6.0 ± 1.9 , 5.9 ± 2.0 , 16.6 ± 6.7 , 29.9 ± 13.0 , and 11.0 ± 2.9 , respectively (within group comparisons all $p < 0.001$). In the 40-W group, mean improvement of dyspareunia, dryness, itching/burning, FSFI, VMV, and VHIS was 6.1 ± 1.7 , 6.5 ± 2.0 , 5.2 ± 2.5 , 14.8 ± 7.1 , 25.0 ± 13.4 , and 10.5 ± 4.1 , respectively (within-group comparisons, all $p \leq 0.001$).

Comparison between 30 and 40 W revealed that mean improvement or presence of all GSM symptoms and clinical signs was not statistically significant different. CO₂ laser therapy may improve GSM symptoms and clinical signs. This improvement did not seem to associate to power of 30 or 40 W.

50 patientes: 25 +30W 25+40W
Pas d'impact sur l'efficacité



Archives of Gynecology and Obstetrics – Epub 2017 Sep 2

Long-term reliability of fractioned CO₂ laser as a treatment for vulvovaginal atrophy (VVA) symptoms

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Abstract

Purpose

The aim of this study was to evaluate long-term effects of the fractional CO₂ laser for the treatment of vulvovaginal atrophy (VVA) symptoms.

Methods

Women presenting with VVA symptoms and meeting inclusion criterion were enrolled to fractioned CO₂ laser therapy. Patient's satisfaction was measured on five-point Likert scale at 4 weeks and 6, 12, 18, 24 months after treatment by interview and clinical examination for vaginal livability.

Results

184 patients constituted the final study group: 128 women were spontaneous menopause and 56 were oncological menopause. 117 women were nulliparous and 36 had previous hysterectomy. 95.4% (172/184) of the patients declared that they were satisfied or very satisfied with the procedure at 4 weeks after treatment. At 6 months 92% (170/184) patients were satisfied; at 12 months 72% (118/162) were satisfied; at 18 months 63% (60/94) were satisfied; at 24 months 25% (4/16) of patients answered they were still satisfied. We observed a decline in patient's satisfaction between 18 and 24 months after laser therapy. Data showed that the time interval from onset of menopause was a statistically significant factor ($p < 0.05$) for treatment satisfaction in oncological group.

Conclusions

Long-term data showed that the improvement of vaginal health may continue up to 24 months after fractional CO₂ laser treatment although between 18 and 24 months benefits decline, and approximately 80% of women decide to start a new treatment cycle of laser applications.

184 patientes

128 ménopausées

56 Cancer du sein hormono dépendant

Satisfaction des patientes à 6,12,18 et 24 mois +T3

95,4% T3+4 semaines

92% T3+6 mois

72% T3+12 mois

63% T3+18 mois

>18 mois 80% font un nouveau traitement



Lasers Surg Med. Epub 2017 Sep 7

Fractional CO₂ laser of the vagina for genitourinary syndrome of menopause: Is the out-of-pocket cost worth the outcome of treatment?

Lang P¹, Dell JR², Rosen L³, Weiss P⁴, Karram M¹.

1: The Christ Hospital, Cincinnati, OH - USA; 2: Institute for Female Pelvic Medicine, Knoxville, TN - USA; 3: Fairfax OB-GYN Associates, Gainesville, VA - USA; 4: Bonbury Surgical Center, Beverly Hills, CA - USA.

Abstract

Objectives

The purpose of this study is to assess patient's satisfaction treatment outcomes and out-of-pocket expense for the fractional CO₂ laser (SmartXide) in the treatment of genitourinary symptoms of menopause (GSM).

Materials and Methods

A multicenter retrospective cohort study of patients who completed a course of three vaginal treatments with the SmartXide Fractional CO₂ laser. Patients contacted via telephone and asked to participate in questionnaires to evaluate for adverse outcomes since last treatment, symptom severity before and after treatment, patient satisfaction with treatment, patient satisfaction with out-of-pocket expense, and sexual function.

Results

Of the 368 patients contacted, 122 agreed to be interviewed. No patients reported seeking emergent medical treatment. Patient reported vaginal dryness significantly improved following treatment ($P < 0.05$). The frequency of intercourse increased from "once a month" to "few times a month" ($P < 0.001$). The vast majority of patients reported being satisfied with their treatment results (86%) and with the cost of treatment (78%). Satisfaction with the out-of-pocket expense did not correlate with household income ($P = 0.07$).

Conclusions

The SmartXide Fractional CO₂ laser is a safe and efficacious treatment for GSM. This treatment is associated with a high level of patient satisfaction with both treatment results and out-of-pocket expense.

Aucune douleur pendant le traitement
Satisfaction 86%

- Patientes « Vessie hyperactive »: depuis ≥ 3 mois, ≥ 8 mictions/24H avec au moins 3 ou 4 épisodes d'urgence avec ou sans incontinence, pendant 3 jours
- Etude pilote observationnelle prospective de janvier 2014 à Janvier 2015 **avec 30 patientes**
- Evaluation de l'urgence : 0, pas d'urgence, urgence légère 2, urgence modérée; **3, urgence sévère; 4, incontinence par urgence** (Patient's Perception of Intensity of Urgency Scale)
- Seules les patientes **3 et 4** sont enrôlées dans l'étude
- Traitement :3 séances de Laser Mona Lisa(DEKA) espacées de 4 semaines

Pitsouni E, Grigoriadis T, Falagas ME, Salvatore S, Athanasiou S Laser therapy for the genitourinary syndrome of menopause.

A systematic review and meta-analysis. Maturitas. 2017 Sep;103:78-88.

- Cette revue systématique et méta analyse a pour but **de synthétiser tous les résultats** concernant l'efficacité des lasers concernant le GSM (avec ou sans I U) en date d'Octobre 2016 :**14** études ont été retenues incluant **542 patientes**
- **Sécheresse, dyspareunie, prurit, brûlure , dysurie, urgenteries, fréquence urinaire et IU** diminuent de façon de manière significative et constante dans toutes les publications disponibles.
- En conclusion la thérapie laser semble avoir un avenir prometteur pour ces femmes en ***réduisant la sévérité de leurs symptômes, en augmentant leur qualité de vie, en restaurant leur muqueuse vaginale au statut pré ménopausique.***

Cependant manquent encore les arguments "évidence base médecine"



Syndrome Génito-urinaire des femmes avec antécédents de cancer du sein

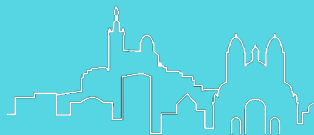
Cook ED, et al. Ménopause, 2017, Jun 19.

- Ces femmes prennent souvent **des inhibiteurs de l'aromatase** qui aggravent les symptômes du syndrome génito-urinaire de la ménopause (GSM) préexistants comme **la dysurie et l'incontinence urinaire**,
- Elles connaissent rarement le GSM et peu d'entre elles se voient proposer un traitement adéquat.
- Cette étude descriptive concerne 800 patientes ayant un GSM documenté consultant à la **Clinique de Survie du Cancer du Sein**(au sein du Centre de lutte contre le cancer) entre 1er juillet 2010 et le 1er Juillet 2011, au moins 5 ans après la fin du traitement pour un cancer du sein invasif ou au moins 6 mois après la fin du traitement pour le carcinome canalaire in situ.

Sur les **71 patientes** présentant des symptômes documentés **d'atrophie des voies urinaires**, seulement **33,8%** avaient reçu des documents ou avaient reçu un traitement ou une recommandation quelconque de traitement.

Il est urgent que les patriciens ayant en charge ces femmes:

- Prennent connaissance des progrès réalisés dans l'évaluation du GSM,
- Diffusent les documents destinés aux patientes,
- Prennent connaissance des nouveaux traitements permettant d'améliorer la qualité de vie de ces femmes



Traitement des femmes après un cancer du sein

*Revue de John Eden **ENDOCRINE DILEMMA: Managing menopausal symptoms after breast cancer.** Eur J Endocrinol 174 R71-R77. First published online 14 October 2015*



Treatment options for menopausal women with a personal history of breast cancer.	
Symptom	Treatment option
Hot flushes	Remifemin
	SSRIs
	Clonidine
	Gabapentin (Moderate-dose progestin) (HRT)
Vulvo-vaginal dryness	Soap-free washes
	Moisturizers
	Lubricants (CO ₂ laser)
Osteoporosis	Bisphosphonates
	Denosumab
	Tamoxifen/Raloxifene

« Parmi toutes les stratégies disponibles dans ce domaine, une thérapie d'apparition récente **est l'utilisation d'un laser vaginal**

« Dans une étude prospective non randomisée (*Salvatore S Climacteric 2015 18 219–225.77*), 77 femmes ménopausées ont été traitées avec le laser CO₂ fractionné. Une amélioration marquée et significative des symptômes a été observée après 12 semaines.

LASER FRACTIONNÉ CO₂ : Expérience

« Gynécologie, obstétrique fertilité et sénologie »

Christine Louis-Vahdat, Isabelle Jardin, Henri Azaïs

Service de chirurgie et oncologie gynécologique et
mammaire, Pitié-Salpêtrière, AP-HP, Médecine
Sorbonne Université, Paris, France

*Comment je fais... un traitement des sècheresses
vaginales induites par la ménopause par LASER
vaginal fractionné au CO₂*

- *En cours, étude multicentrique Service de
chirurgie et oncologie gynécologique et
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<http://dx.doi.org/10.1016/j.ejogrb.2017.07.008>

Re: "Safety and long-term efficacy of fractional
CO₂ laser treatment in women suffering from
genitourinary syndrome of menopause" [Eur. J.
Obstet. Gynecol. Reprod. Biol. 213 (2017) 39–44]



Dear Editor,

We read with interest the recent study by Behnia-Willison and colleagues [1] in your June issue, reporting their investigation of "the safety, feasibility and long-term efficacy (12–24 months) of fractional micro-ablative CO₂ treatment in a cohort of postmenopausal women suffering dyspareunia and/or other symptoms due to GSM [genitourinary syndrome of menopause]". Their study included 102 postmenopausal women (median age 61 years; range: 51–86) who had three fractional CO₂ vaginal laser treatments at intervals of six or more weeks because they "were not responding or not able to take conventional treatments (such as oestrogen therapy for postmenopausal women)". Each woman had a colposcopy before laser treatment to grade the vaginal atrophy. Before and after the treatment, the women completed the Australian Pelvic Floor Questionnaire [2]. All variables improved significantly, including sexual function, painful intercourse, vaginal dryness, and reduced libido.

The results of this single-centre study are very encouraging, especially in view of the scarcity of the literature about GSM treatment by vaginal laser. We would like to share our experience and difficulties and discuss some points raised by this study.

From December 2016 to May 2017, we treated 45 women in a similar but substantially narrower age bracket (median age 54 years; range 48–60). They all presented with very similar symptoms due to GSM; this is less likely to be entirely the case in a population aged from 51 to 86 years.

Our pre-laser clinical screening systematically included a gynecologic examination, a cervical (Pap) smear test followed by a colposcopy only in case of abnormalities, a transvaginal ultrasound examination to measure the endometrial thickness, and a vaginal pH

time of 1000 µs, DOT spacing 1000 µm, and SmartStak with parameter 2 for the first two treatments and parameter 3 for the third. The vaginal probe, introduced without lubricant, is used to treat the entire vaginal wall, then the vestibule, and the fourchette. Sexual intercourse is strongly discouraged during the three days after treatment.

After the first laser treatment, our patients had global improvement for urinary function, especially in terms of urge and stress incontinence, and a decrease of vaginal discharge. They reported an improvement of overall quality of intercourse after the third treatment. To date, we have not been faced with any complication. Moreover, the transvaginal ultrasound examination performed before each laser treatment did not reveal any increase of endometrial thickness in any of our cases.

Our patients are very motivated; none has been lost to follow-up. However, the use of laser treatment is still limited, perhaps because it is not yet widely known by women, but probably more because laser treatments are not currently covered in France by the national health insurance fund. Further research is needed to assess safety and effectiveness of this innovative treatment in correctly selected patients.

Conflict of interest

None.

Funding sources

None.

References

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Résultats sur le SGUM (laser CO₂)

Indication	15 Séries (n > 1200)	1 Etude comparative	1 ECR
SGUM / atrophie vulvo-vaginale (sécheresse, brulures, dyspareunies)	Salvatore et al, Climacteric, 2014 & 2015 50 puis 77 femmes en échec d'estrogénothérapie Perino et al, Maturitas, 2015 48 femmes ménopausées Pagano et al, Menopause, 2016 26 Femmes après traitement d'un cancer du sein Pitsouni et al, Maturitas, 2016 53 femmes Filippini et al, Photomedecine Laser Surg, 2017 386 femmes Behnia-Willison et al, Eur J Obstet Gynecol Reprod Biol, 2017 102 femmes	Pitsouni et al, Laser Med Sci, 2017 50 femmes Rétrospectif Cas / témoin 30 W vs 40W Pas de différence	Cruz et al, Menopause, 2017 45 femmes en 3 groupes ■ Laser ■ E2 loc ■ Laser + E2 loc

Amélioration significative

après 3 applications en 12

semaines

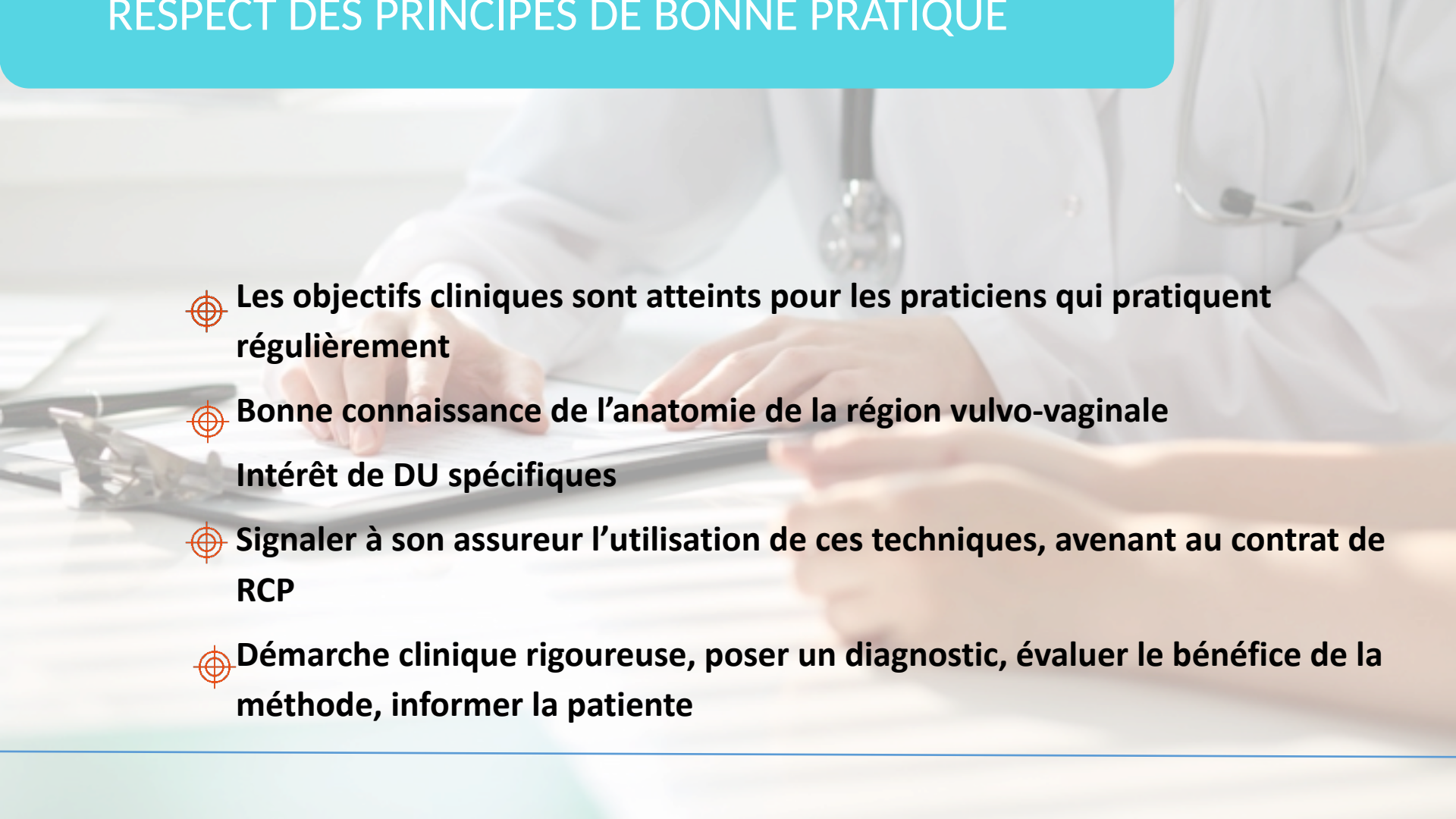


CONCLUSIONS

- Le manque d'étude randomisées rend difficile la méta-analyse des études et il n'y pas encore d'études force 1 concernant l'efficacité à long terme et les autres effets, négatifs ou positifs.

Des essais contrôlés randomisés comparant les traitements par laser par rapport au placebo aux médicaments ou aux hormones ou enfin à la chirurgie doivent être mis en place et sont nécessaires pour obtenir des preuves force 1

Pour atteindre l'EVIDENCE BASE MEDICINE, nécessité de nombreuses études randomisées vs placebo en double aveugle: elles sont en cours.

- 
- 🎯 **Les objectifs cliniques sont atteints pour les praticiens qui pratiquent régulièrement**
 - 🎯 **Bonne connaissance de l'anatomie de la région vulvo-vaginale**
 - Intérêt de DU spécifiques**
 - 🎯 **Signaler à son assureur l'utilisation de ces techniques, avenant au contrat de RCP**
 - 🎯 **Démarche clinique rigoureuse, poser un diagnostic, évaluer le bénéfice de la méthode, informer la patiente**



CONCLUSIONS

- Les Lasers vaginaux continuent de démontrer leur efficacité au sein des moyens thérapeutiques gynécologiques du SGUM
- Les lasers CO2 et ERBYUM :YAG se disputent aujourd'hui le marché en pleine expansion
- Les résultats sur l'atrophie vaginale du SGUM semblent comparables pour les deux techniques
- L'Erbyum:Yag accumule de plus en plus de preuves sur l'amélioration des symptômes urinaires et nous a livré cette année la première étude de force 1
- La Sonde intra urétrale se présente sous un jour très attractif
- Pour certains, l'Erbyum:Yag serait donc d'une sécurité d'utilisation appréciable

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About us

The Group for Research and innovation in genital restauration (GRIRG) is a scientific society of physicians. The objective of this association is to bring together gynecologists, plastic surgeons, dermatologists and sexologists around some specific pathologies of the female genital sphere.

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Je vous remercie



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