



New Energy-Based Devices for Vaginal treatments

Update 2021

פרופ' חיים קריסי

מנהל מחלקת נשים והיחידה האופרטיבית

מרכז פסואי רבין

מה קורה נכון ל 2021

מטפלים עצמאיים
גינקולוגים פלסטיקאים
אורולוגים רפאי עור
ואחרים



**מכשירי אנרגיה לא
מבוססים מחקרית**



קופות חולים בתי חולים
כללית, מכבי, אסותא, HMC,
מדיקה, רפאל, ועוד


Is it interesting ?

Why it is interesting ?

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MY NCBI FILTERS 201 results

RESULTS BY YEAR



Filters applied: Review, Systematic Review. Clear all

1 **CO2-Laser therapy and Genitourinary Syndrome of Menopause: A Systematic Review and Meta-Analysis.**
Cite Filippini M, Porcari I, Ruffolo AF, Casiraghi A, Farinelli M, Uccella S, Franchi M, Candiani M, Salvatore S.
J Sex Med. 2022 Jan 28:S1743-6095(21)00830-4. doi: 10.1016/j.jsxm.2021.12.010. Online ahead of print.
Share PMID: 35101378
AIM: We aimed to systematically review the current literature on CO2-Laser therapy efficacy for the treatment of GSM. METHODS: MEDLINE and Embase databases were systematically queried in December 2020. Studies included women with a diagnosis of Vulvo-Vaginal Atrophy ...

2 **Low-Level Laser Therapy: Potential and Complications.**
Cite Arjmand B, Khodadost M, Jahani Sherafat S, Rezaei Tavirani M, Ahmadi N, Hamzeloo Moghadam M, Okhovatian F, Rezaei Tavirani S, Rostami-Nejad M.
J Lasers Med Sci. 2021 Aug 4;12:e42. doi: 10.34172/jlms.2021.42. eCollection 2021.
Share PMID: 34733765 [Free PMC article.](#) Review.

TEXT AVAILABILITY

- Abstract
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ARTICLE ATTRIBUTE

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Current Treatments are not optimal to all women !

- **GUSM** – Estrogen, creams
- **USI** – PFP, MUS
- **OAB** – Anti-cholinergic, Beta agonist

אוכלוסייה פוטנציאלית לטיפול בלייזר וגינלי

- **GSM** - נשים אחרי ממאירות / לא מעוניינות בטיפול הורמונלי
- **USI** - כל גיל - דליפה קלה שלא רוצות/יכולות/הצליחו בפיזיותרפיה

לא מעוניינות בניתוח

- **OAB** - כל גיל - לא מגיבות לטיפול תרופתי/אסור/לא מעוניינות

תופעות לוואי קשות

SAFETY

Vaginal laser treatment of GUSM: does the evidence support the FDA safety communication 2018 ?

Urology, Cedars-Sinai Medical Center, Los Angeles, CA.
Los Angeles School of Law, Los Angeles, CA.

- **MAUDE database** – Only 30 AE (22 pain or burning)
- **Bloomberg law database** - no claims
- No evidence for significant patient risk

* FDA Manufacturer and User Facility Device Experience

What is Being Reported About Vaginal "Lasers"?

An Examination of **Adverse Events Reported to the FDA** on Energy-Based Devices

OBGYN Pittsburgh USA.

- **MAUDE database** - 18 manufacturers, 43 products,
- **Only 39 AEs**
- 32 injuries (21 local reaction)
- 6 cases - device malfunction
- 1 case - improper maintenance

New Arguments Against vaginal laser

Vaginal Er:YAG laser in the menopausal **ewe model**: a randomized **estrogen** and **sham**-controlled trial

Belgium, Italy BJOG 2021

3 groups (n=24): Er:YAG laser, Sham manipulations, Estrogen+sham

Vaginal wall biopsies for thickness

Laser & sham - significant increase vaginal thickness ($P < 0.0008$)

Estrogen – X2 increase from **Laser & sham** ($P < 0.0001$)

Effect of **CO2 Laser vs Sham** Treatment on Symptom Severity in Women With Postmenopausal Vaginal Symptoms

A **Randomized Clinical Trial** (Australia) JAMA. 2021

2016- 2020

232 participants, only 78 (**40** vs **38**) evaluated at 12 month

Clinically difference defined > 50% decrease in severity scores

No significant difference >50% found between the groups

No severe adverse events

New Arguments For vaginal laser

Vaginal CO2 Laser Treatment and Changes in Vaginal Biomechanical Parameters

Lior Lowenstein Israel, Lasers Surg Med 2021

- Prospective study, 25 women , 2018-2020
- **Objective tissue parameters** using **VTI technology**, VHI, FSFI
- Laser increased vaginal elasticity, tightening, FSFI, VHI ($P < 0.027$)

* VTI Instruments characterizes the physical integrity of materials

Vaginal collagen I and III changes after CO2 laser application in postmenopausal women with the GUSM: a pilot study

obgyn-Spain. Climacteric 2021

14 postmenopausal women with vulvovaginal atrophy

Histological studies - increases epithelial layers & collagen fibers ($p < 0.05$)

Immunohistochemical studies - increase in collagen type III ($p < 0.005$)

GUSM & Sexual Function

The Efficacy of Vaginal Laser and Other Energy-based Treatments on GUSM: A **Systematic Review and Meta-analysis**

Australia, J Minim Invasive Gynecol 2021

2678 women , 3 randomized, 16 prospective, 7 retrospective studies

Vaginal laser & topical Estrogen:

- significantly improvement in GUSM & sexual function
- equal efficacy

Vaginal laser therapy for GUSM - **systematic review**

BGYN, Spain, Maturitas 2021

- **64 studies**, 10 controlled intervention, 7 observational, 47 before-after studies

Vaginal Rejuvenation: A Retrospective **Review** of Lasers and Radiofrequency Devices

Dermatology, Irvine , California. Review Dermatol Surg . 2021

- **59 studies** (3,609 women)

- Significant improvement in GSM & sexual function
- High patient satisfaction

The Efficacy and Safety of CO₂ Laser Treatment for **Sexual Function** and Vaginal Laxity Improvement in **Pre-Menopausal Women**

Lior Lowenstein, Ilan Grinwald, Israel. Case Reports Lasers Surg Med 2021

- Prospective study, 84 pre-menopause women, mean age 47.7 years
- **VHI & FSFI increased significantly but decreased at 6 months**
- **Rate of sexual intercourse doubled during the study** ($P < 0.0001$)
- No serious adverse events

Cancer Survivors

Fractional CO₂ vaginal laser for GUSM in **breast cancer survivors**

Public Health, OBGYN, Italy. Breast J 2021

- Retrospective study, 135 PM women (45 BCS and 90 healthy women)
- **Objective** (VHI) & **Subjective outcomes** (VAS for dyspareunia, dryness and pain questionnaire)
- **Both improved significantly**
- Improvement **last up to 12 months**
- No severe adverse events

Use of a vaginal CO₂ laser for the management of **GUSM** in **gynecological cancer survivors**: a systematic review

OBGYN , Oncology, Mount Sinai Hospital, Toronto, Canada. Climacteric 2021

- 269 studies, Only 4 met their inclusion criteria
- **lack of literature to recommend** laser to manage GSM in gynecologic cancer patients

Urinary disorders

Fractional CO₂ Laser Treatment in Patients With Urodynamic Stress Urinary Incontinence: 1-Year Follow-Up

Menachem Alcalay (Sheba, Kaplan, Tiberias). Lasers Surg Med 2021

- **Prospective study, 52 women, Urodynamic SUI mild/moderate**
- 1-hour pad test, Pelvic Floor Distress Inventory 20 (PFDI-20), Pelvic Floor Impact Questionnaire (PFIQ),
- Patient Global Impression of Improvement (PGI-I), and a 3-day urinary diary.
- **Pad test - significant reduction, 6.3 ± 1.6 g vs. 3.7 ± 1.4 g, $P < 0.05$**
- **PGI-I** showed 75.0% and 64.3% improvements at 3 and 12 months
- **Urodynamic at 6 months - 41.4% no stress incontinence !**

Comparison of urethral sling surgery and non-ablative vaginal Erbium:YAG laser treatment in 327 patients with **stress urinary incontinence**: a case-matching analysis

Urology, Japan. Lasers Med Sci 2021

Retrospective study, 327 women

TVT, VEL, and control groups

Pad test, Incontinence Questionnaire-Short Form (ICIQ-SF) and the OAB Symptom Score (OABSS)

TVT & VEL groups – similar significant improvement Compared control

OAB - significantly greater improvement in VEL than TVT group

Safety and efficacy of vaginal laser therapy for stress urinary incontinence: a **meta-analysis**

Dermatology, Urology, China. Ann Palliat Med 2021

- 16 clinical studies, 899 patients with SUI
- 1-hour pad test, ICIQ-SF, PISQ-12 score
- **SUI improved significantly at 6 & 12 months from last treatment**
- No significant adverse events

שאלות פתוחות

- האם בכל סוג לייזר וכל מבצע התוצאות זהות ?
- האם לכל אישה מתאים פרוטוקול אחיד של 3 טיפולים ?
- אותה עוצמה ?
- כיצד להתאים טיפול לאישה ?
- כל כמה זמן לבצע טיפול מתחזק ?

סיכום

- טכנולוגיה ניתוחית חלופית חדשה לטיפול ב GUSM ו Mild SI

- בטיחות ויעילות גבוהים אך יתכנו תופעות לוואי וסיבוכים

- המטפל צריך להיות רופא מיומן בתחום

- חשיבות למחקרים גדולים השוואתיים לטיפולים הקיימים ומעקב ארוך טווח



פרופ' חיים קריסי

האם באמת אפשר לקבל נתונים ממחקרים גדולים השוואתיים כפולי סמיות לטווח רחוק מטכנולוגיות חדשות שנכנסות לשוק ?

- משך הזמן לפיתוח טכנולוגיה חדשה
- משך הזמן והעלות לעריכת מחקרים מהסוג הנ"ל
- מהו מחקר ארוך טווח ?
- תוצאות המחקרים ?
 - טיפולי בסוג האוכלוסיה (נשים גברים ילדים משקל מחלות רקע וכו)
 - מינון –עוצמת לייזר, מספר מחזורים וכו
 - מיקום הטיפול
 - מטפלים שונים
 - ההתוויות (וגינה, שופכה, שלפוחית, וולווה, פורשט)
- משך הזמן שהטכנולוגיה תתקיים בשוק

Effects of Fractional CO₂ Laser Treatment on Patients Affected by Vulvar **Lichen Sclerosus**: A Prospective Study

Laser and Plastic Surgery, Florence, Italy. obgyn Republic of San Marino, Photobiomodul Photomed Laser Surg 2021

Significant improvement ($p < 0.001$)

The beneficial effects of CO₂ laser on perineal changes during **lactation and puerperium** : a multicentric retrospective study

Multicenter retrospective study , ObGyn, San Raffaele Hospital, Milan, Italy, Lasers Med Sci 2021

Significant improvement in dyspareunia, pain, dryness, itching and burning ($p = 0.01$)

Strategy for vaginal rejuvenation: **CO₂ laser or vaginoplasty?**

Department of Plastic Surgery, Shanghai, China. Ann Transl Med 2021

Female Sexual Function Index (FSFI) questionnaire significantly improved in mild vaginal laxity ($P < 0.05$)

Can POP in postmenopausal women be treated with laser ?

OBGYN , Greece. Climacteric 2021, Randomized trial, level 2 prolapse, stage 2-3, Er:YAG laser Vs. waiting

No participants had POP-Q stage 0 or 1 at 4 months.