



AGL 2022

51st GLOBAL CONGRESS ON MIGS

December 1–4, 2022 | Gaylord Rockies Resort and Convention Center | Aurora, Colorado

SYLLABUS

Panel 2: Vaginal Laser / Photobiomodulation Therapy: Examining the Evidence and Controversy

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Georgine Lamvu, MD, MPH AbbVie; SoLa Pelvic Therapy

Eric R. Sokol, MD*

PANEL 2: Vaginal Laser / Photobiomodulation Therapy: Examining the Evidence and Controversy

Chair: Georgine Lamvu, MD, MPH

Faculty: Charles W. Butrick, MD, Eric R. Sokol, MD

Course Description

This learning activity will review the evidence and controversy surrounding the use of vaginal lasers / photobiomodulation for vaginal atrophy, pain, incontinence, and prolapse. It will provide an overview of how lasers work, as well as indications and contraindications for use. The lecture will focus on evidence-based recommendations and factors that clinicians need to consider before integrating laser technology into their clinical practice.

Learning Objectives

At the conclusion of this course, the participant will be able to: 1) Describe the biomechanics and biological effects of laser therapy; 2) Recognize the gynecologic conditions that may benefit from vaginal laser therapy; and 3) List the main benefits and risks of vaginal laser therapy.

Course Outline

2:00 pm	Welcome, Introduction and Course Overview	G. Lamvu
2:05 pm	What is a Laser and What are the Biological Effects of Laser Therapy?	G. Lamvu
2:20 pm	Non-Ablative Laser Therapy for Pelvic Pain	C. Butrick
2:35 pm	Should Vaginal Lasers be Used for Genitourinary Symptoms of Menopause?	E.R. Sokol
2:50 pm	Questions & Answers	All Faculty
3:05 pm	Adjourn	



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Non-Ablative Laser Therapy For Pelvic Pain

Charles 'Chip' Butrick, MD, FPMRS
Urogynecology of Kansas City

Past President of the International Pelvic Pain Society

Disclosures



Director of Professional Education; Uroshape LLC

- maker of device used for the treatment of pelvic pain

Consultant: Axonics, Inc.

- maker of sacral neuromodulation system

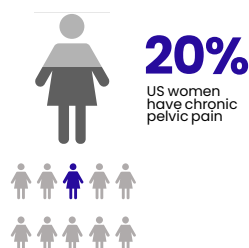


Objectives

- 1 Review the impact and prevalence of chronic pelvic pain (CPP) and pelvic floor myalgia (PFM) as a common contributor to CPP
- 2 Discuss the mode of action of photobiomodulation in the treatment of pain
- 3 Introduce a novel trans-vaginal delivery of photobiomodulation to the pelvis for the treatment of various CPP disorders



Impact of CPP



IMPACT
CPP is more prevalent than breast cancer (13%), diabetes (14%), and asthma (8%).

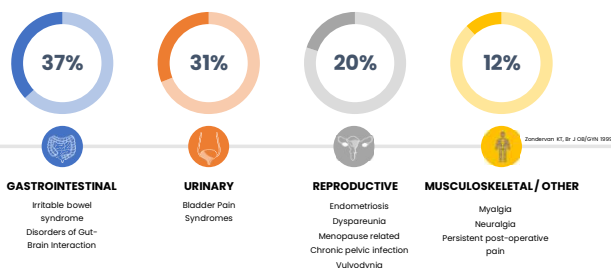
ACCESS
Less than 5% of persons living with chronic pain in US have access to a pain specialist; CPP is the most common indication for referral to gynecology

ECONOMIC COSTS
Individual: direct \$1367 - \$7043 per woman per year; indirect \$4216 - \$12,789 per woman per year; \$2.8 Billion.



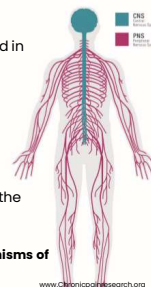
Causes of Chronic Pelvic Pain

Among women with CPP, 40-60% have more than one associated diagnoses



Pathophysiology of Chronic Pain

- Original peripheral **NOCICEPTIVE insult** (injury, surgery, infection, endometriosis) that does not heal, or is propagated in an environment that promotes progression to central sensitization
- Active peripheral or central neurons that repetitively send signals into the brain, without nociceptive injury, or after the peripheral injury has healed: **NEUROPATHIC, PERIPHERAL SENSITIZATION**
- The brain 'over interprets' the pain or cannot down regulate the pain: **CENTRAL SENSITIZATION**



The mechanisms that lead to chronic pain are distinct from mechanisms of acute pain, i.e. chronic pain is not just acute pain that lasts longer.

www.ChronicPainResearch.org



Pelvic Floor Hypertonicity A Component of Chronic Pelvic

- **85%** of all patients evaluated with pelvic floor disorders have pelvic floor myalgia¹
- **80%** of patients with CPP have central sensitization; the majority will also have pelvic floor myalgia and hypertonicity²
- **50-87%** of patients with IC/BPS have pelvic floor pain and dysfunction (5-6.8% of all women have IC/BPS)
- **87%** of women with endometriosis and pain have central sensitization and pelvic floor myalgia³
- **80-90%** of women with vulvar pain have pelvic floor myalgia
- **24%** of women with incontinence or prolapse have pelvic floor pain or hypertonic dysfunction⁴

¹McIntyre, Ann J Gyn 2009
²Butrick, Pelvic Pain: Diagnosis and Management, Phil PA, Lippincott 2009
³Stratton P, et al. Obstet Gynecol. 2005;105(3):759-768
⁴Adams, Int J Urogyn 2013



Myofascial PT for Chronic Pelvic Pain Summary of the evidence

- Fitzgerald MP, 2009, Randomized multicenter trial¹, n=48 women with IC/BPS
 - Pelvic myofascial PT vs. global massage therapy; improved 59% vs. 26%
 - Global pain and O'Leary Sant reduced by 36%
 - 62% with adverse events (most involved pain)
 - Poor follow-up allowed no determination of duration of benefit

Outcome is highly dependent on access and physical therapist skill

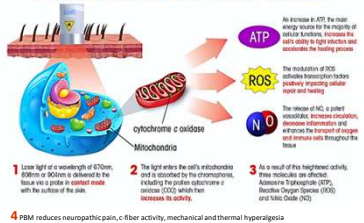
- van Reijl-Baggen DA², 2022, systematic review
 - 10 studies (5 RCTs, 5 prospective studies)
 - PT efficacious in patients with chronic pelvic pain, vulvodynia, and dyspareunia. Smaller effect in patients with IC/BPS
 - Studies of poor methodologic quality

¹Fitzgerald MP. J Urol 2009; ²Woodburn, K.L., et al. Female Pelvic Med Reconstr Surg. 2018; ³van Reijl-Baggen DA, et al. Sex Med Rev. 2022



Photobiomodulation (PBM) Non-ablative Therapeutic Laser

A MECHANISM OF LASER THERAPY IN TISSUE



- Indicated for acute and chronic pain
- Multiple RCTs showing benefit for myofascial pain
- Over 1000 laboratory studies describe the effects of PBM on living tissue
- IASP recommends PBM as first line therapy for Myofascial Pain in 2010
- Only FDA cleared device to treat myofascial pain and spasm
- Response typically last 6-12 months after therapy in other MF pain disorders



Probes that deliver PBM are not currently designed for pelvic pain



www.lightforcemedical.com



Novel Transvaginal Delivery of Photobiomodulation



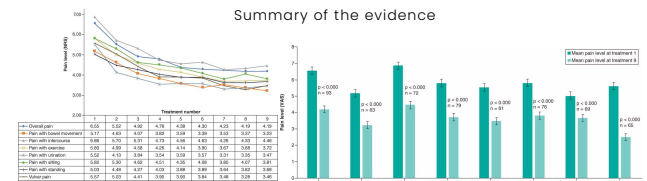
- Developed first in ovine pelvic model¹
- Non-ablative laser therapy for CPP associated with pelvic myalgia^{2,3}
- FDA 510k exempt for temporary reduction of muscle pain, spasms, and temporary improvement of circulation^{2,3}
- Recommended treatment 9 sessions (3-5 minutes each)²
- VAS and PGIC collected on every patients & treatment^{2,3}

With permission from Solis Pelvic Therapy, Unishape, LLC.

¹Zipper R, Pryor B. Lasers in Medicine, 2022
²Kohl N, et al. J Comp Eff Res. 2021
³Lamm G, Zipper R. J Comp Eff Res. 2022



Trans-Vaginal Photobiomodulation (TV-PBM) for Chronic Pelvic Pain Summary of the evidence



- Observational studies, from clinical settings where CPP is treated
- 60% achieved the success criteria of MCID ≥ 2 (mean reduction $\geq 30\%$)¹
- 93-73% completed 4-9 recommended treatments
- No reported SAEs¹
- Effect may last as long as 6 months²

¹Kohl N, et al. J Comp Eff Res. 2021
²Lamm G, Zipper R. J Comp Eff Res. 2022



Slide 9

GL1 Where did this image come from?

Georgine Lamvu, 8/9/2022

GL2 We need references for at least some of these comments

Georgine Lamvu, 8/9/2022

MOU1 I think this is Hamblin et al, modified.

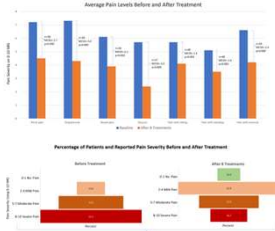
Microsoft Office User, 8/9/2022

MOU2 You may want to use the image from our science page of our provider website..which is our image and more detailed.

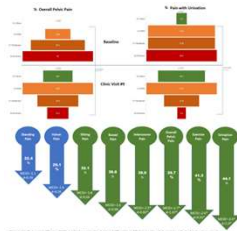
Microsoft Office User, 8/9/2022

TV -PBM for Endometriosis and IC/BPS Preliminary evidence

ENDOMETRIOSIS N=48



IC/BPS N=89



Agarwal C, Carillo J, Lemos G. Transvaginal Photobiomodulation for Treatment of Chronic Pelvic Pain Associated with Endometriosis. International Pelvic Pain Society Annual Meeting 2022.

Burck C, Lemos G. Transvaginal Photobiomodulation for Treatment Associated Interstitial Cystitis/Bleeder. Pain Societies International Pelvic Pain Society Annual Meeting 2022.

Acceptability of TV-PBM

Preliminary evidence, survey of 423 women with CPP



Agarwal C, Carillo J, Lemos G. Acceptability of Transvaginal Photobiomodulation Among Women with Chronic Pelvic Pain. International Pelvic Pain Society Annual Meeting 2022.

LASERS AND PELVIC PAIN: KEY POINTS



KEY POINT #1

Pelvic myalgia is a major pain generator for almost every patient with chronic pelvic pain

KEY POINT #2

Physical therapy, while certainly considered the gold standard, is limited by availability, access, tolerability, length of therapy, reproducibility, and lack of data on duration of pain relief.

KEY POINT #3

Non-ablative laser therapy, photobiomodulation (PBM), is well studied and effective for tissue inflammation, wound healing, and reduction in pain. Transvaginal PBM is novel and may be effective for multiple causes of pelvic pain; preliminary data is promising.

CULTURAL AND LINGUISTIC COMPETENCY & IMPLICIT BIAS

The California Medical Association (CMA) announced new standards for Cultural Linguistic Competency and Implicit Bias in CME. The goal of the standards is to support the role of accredited CME in advancing diversity, health equity, and inclusion in healthcare. These standards are relevant to ACCME-accredited, CMA-accredited, and jointly accredited providers located in California. AAGL is ACCME-accredited and headquartered in California.

CMA developed the standards in response to California legislation ([Business and Professions \(B&P\) Code Section 2190.1](#)), which directs CMA to draft a set of standards for the inclusion of cultural and linguistic competency (CLC) and implicit bias (IB) in accredited CME.

The standards are intended to support CME providers in meeting the expectations of the legislation. CME provider organizations physically located in California and accredited by CMA CME or ACCME, as well as jointly accredited providers whose target audience includes physicians, are expected to meet these expectations beginning January 1, 2022. AAGL has been proactively adopting processes that meet and often exceed the required expectations of the legislation.

CMA CME offers a variety of resources and tools to help providers meet the standards and successfully incorporate CLC & IB into their CME activities, including FAQ, definitions, a planning worksheet, and best practices. These resources are available on the [CLC and IB standards page](#) on the CMA website.

Important Definitions:

Cultural and Linguistic Competency (CLC) – The ability and readiness of health care providers and organizations to humbly and respectfully demonstrate, effectively communicate, and tailor delivery of care to patients with diverse values, beliefs, identities and behaviors, in order to meet social, cultural and linguistic needs as they relate to patient health.

Implicit Bias (IB) – The attitudes, stereotypes and feelings, either positive or negative, that affect our understanding, actions and decisions without conscious knowledge or control. Implicit bias is a universal phenomenon. When negative, implicit bias often contributes to unequal treatment and disparities in diagnosis, treatment decisions, levels of care and health care outcomes of people based on race, ethnicity, gender identity, sexual orientation, age, disability and other characteristics.

Diversity – Having many different forms, types or ideas; showing variety. Demographic diversity can mean a group composed of people of different genders, races/ethnicities, cultures, religions, physical abilities, sexual orientations or preferences, ages, etc.

Direct links to AB1195 (CLC), AB241 (IB), and the B&P Code 2190.1:

[Bill Text – AB-1195 Continuing education: cultural and linguistic competency.](#)

[Bill Text – AB-241 Implicit bias: continuing education: requirements.](#)

[Business and Professions \(B&P\) Code Section 2190.1](#)

CLC & IB Online Resources:

[Diversity-Wheel-as-used-at-Johns-Hopkins-University-12.png \(850×839\) \(researchgate.net\)](#)

[Cultural Competence In Health and Human Services | NPIN \(cdc.gov\)](#)

[Cultural Competency – The Office of Minority Health \(hhs.gov\)](#)

[Implicit Bias, Microaggressions, and Stereotypes Resources | NEA](#)

[Unconscious Bias Resources | diversity.ucsf.edu](#)

[Act, Communicating, Implicit Bias \(racialequitytools.org\)](#)

<https://kirwaninstitute.osu.edu/implicit-bias-training>

<https://www.uptodate.com/contents/racial-and-ethnic-disparities-in-obstetric-and-gynecologic-care-and-role-of-implicitbiases>

<https://www.contemporaryobgyn.net/view/overcoming-racism-and-unconscious-bias-in-ob-gyn>

<https://pubmed.ncbi.nlm.nih.gov/34016820/>