The Peer Review

SoLa Pelvic Therapy Peer Reviewed LIterature Synopsis

The SoLá Pelvic Therapy

laser collects data from every patient at every treatment. All personally identifiable information is removed and the data is analyzed. The following is a summary of both the SoLa Pelvic Therapy pre-market and post-market analyses as published in the peer reviewed literature.

An observational cohort study of pelvic floor photobiomodulation for treatment of chronic pelvic pain

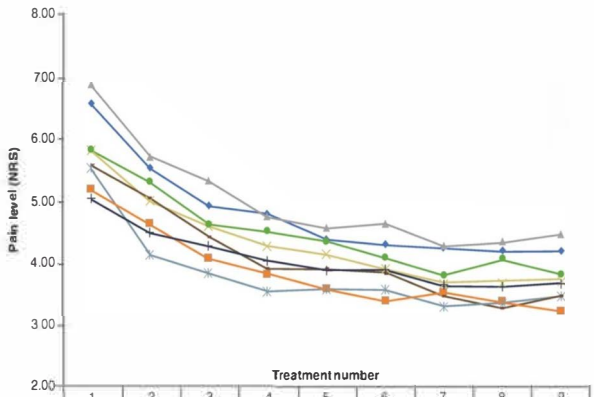
Kohli N, Jarnagin B, Stoehr AR, Lamvu G. An observational cohort study of pelvic floor photobiomodulation for treatment of chronic pelvic pain. J Comp Eff Res. 2021.

Aim: This research is the first to evaluate the effectiveness of trans-vaginal photobiomodulation therapy (TV-PBMT) for chronic pelvic pain. **Materials & methods:** Observational analysis of 128 women, undergoing TV-PBMT for chronic pelvic pain. Minimal Clinically Important Difference, defined as 2::2-point drop on a 0-10 numeric pain rating scale (NPRS), and effect size Cohen d coefficient, was calculated over nine treatments for overall pain, and pain with activities.

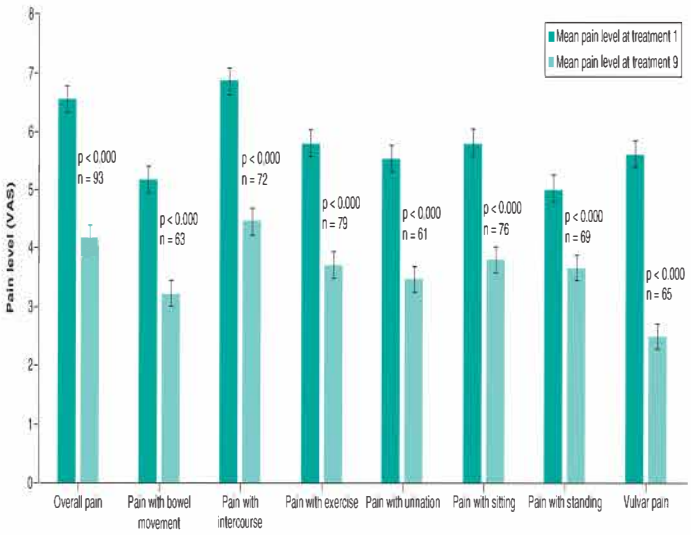
Results: Compared with baseline, 64.5% of women showed improvement in overall pain, pain with bowel movement, intercourse, exercise,urination, sitting and vulvar pain (Minimal Clinically Important Difference = -2.4, -2.0, -2.4, -2.1, -2.1, -2.0, -3.1; d = 0.9, 0.7, 0.9, 0.7, 0.7, 0.7, 0.9) by treatment 9.

Conclusion: In this cohort, TV-PBMT (delivered by the SoLá Pelvic Therapy System) resulted in improvement of pelvic pain without serious adverse events.

The standard measure of "minimal clinically important difference or MCID" in the published pain literature, is a 10 point drop in pain (0-100 VAS scale) or a 1 point drop in pain (0-10 point NRS or Wong Baker scale). The paper reports the mean drop in pain among the entire cohort, not just those who met this very high benchmark of ≥ 2-point drop. **Of those who met this benchmark, mean decrease in pain was >50% and and 2/3rds described minimal or no pain follow completion of therapy.**



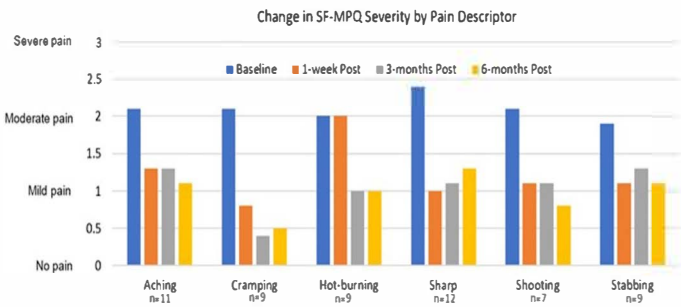
	1	2	3	4	5	6	7	8	9
Overall pain	6.55	5.52	4.92	4.78	4.38	4.30	4.23	4.19	4.19
Pain with bowel movement	5.17	4.63	4.07	3.82	3.59	3.39	3.53	3.37	3.23
Pain with intercourse	6.86	5.70	5.31	4.73	4.56	4.63	4.26	4.33	4.46
Pain with exercise	5.80	4.99	4.58	4.26	4.14	3.90	3.67	3.68	3.72
Pain with urination	5.52	4.13	3.84	3.54	3.59	3.57	3.31	3.35	3.47
Pain with sitting	5.82	5.30	4.62	4.51	4.35	4.08	3.80	4.07	3.81
Pain with standing	5.03	4.48	4.27	4.03	3.88	3.89	3.64	3.62	3.68
Vulvar pain	5.57	5.03	4.41	3.90	3.90	3.84	3.48	3.28	3.46



Transvaginal Photobiomodulation for the Treatment of Chronic Pelvic Pain: A Pilot Study

Zipper R, Pryor B, Lamvu G. Transvaginal Photobiomodulation for the Treatment of Chronic Pelvic Pain: A Pilot Study. Womens Health Rep (New Rochelle). 2021;2(1):518-527.

Background: Chronic pelvic pain (CPP) is a common and debilitating condition that affects millions of U.S. women. Most treatments are ineffective and innovative new therapies are desperately needed. Large, controlled studies show that photobiomodulation (PBM) can reduce pain in patients with other chronic pain conditions, such as low back pain, neck pain, and fibromyalgia. The objective of this pilot study was to determine if transvaginal PBM (TV-PBM) can reduce pain in women with CPP. **Methods**: We conducted a before and after, observational, pilot study. Patients completed the Short Form-McGill Pain Questionnaire (SF-MPQ) at baseline, 1 week, 3 months, and 6 months after nine treatments of TV-PBM. Clinicians completed the Clinical Global Impression Scale (CGI) assessing patient illness severity at the same time. **Results:** Thirteen women completed 9 treatments, and 10 women were successfully followed to 6 months. At baseline, the mean SF-MPQ score was 19.7 (standard deviation [SD] – 5.9). Compared with baseline, 60% improved; the mean SF-MPQ score decreased to 10.0 (SD –7.5, p = 0.004, d = 1.6) at 1 week after treatment, to 9.7 (SD –7.9, p=0.005, d=1.7) at 3 months, and 8.2 (SD –8.1, p=0.002, d=1.9) at 6 months.



Pain Descriptors*, Mean (±SD)	Baseline	1-week Post	3-months Post	6-months Post	P-value
Aching	2.1 (0.9)	1.3 (0.9)	1.3 (1.0)	1.1 (1.1)	<0.01, <0.05, <0.05
Cramping	2.1 (1.0)	0.8 (0.8)	0.4 (0.8)	0.5 (0.9)	<0.02, <0.01, <0.03
Hot-burning	2.0 (0.9)	2.0 (1.1)	1.0 (1.1)	1.0 (1.2)	<0.05, NS, NS
Sharp	2.4 (0.5)	1.0 (1.1)	1.1 (1.2)	1.3 (1.1)	<0.01, <0.01, <0.02
Shooting	2.1 (1.0)	1.1 (1.1)	1.1 (1.5)	0.8 (0.7)	NS, <0.03, <0.02
Stabbing	1.9 (0.9)	1.1 (1.1)	1.3 (1.4)	1.1 (1.2)	<0.03, <0.2, NS

*Participants may have selected more than one descriptor

NS- no significant, p>0.05

Analysis of variance (ANOVA), including all symptoms for the entire cohort demonstrated a significant improvement (p<.001).

Conclusion: Transvaginal PBM provided significant and sustained pain relief to women with CPP up to 6 months. Further controlled studies are needed to confirm these findings, however, in this initial pilot, TV-PBM shows promise

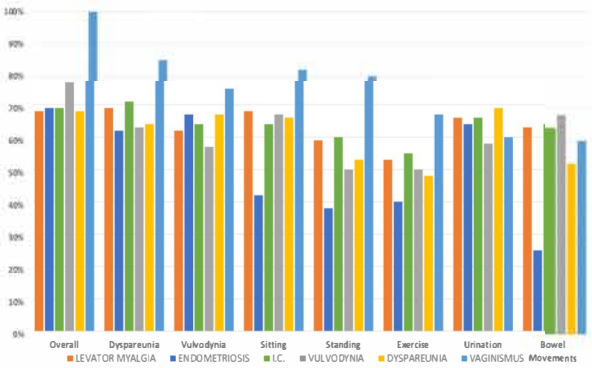
Treatment of Myofascial Pelvic Pain with a Novel Transvaginal Photobiomodulation Laser

Kohli N, Jarnagin B, Stoehr A. Treatment of Myofascial Pain with a Novel Transvaginal Photobiomodulation Laser. Neurourol Urodyn. 2021;40:S6-S242.

Introduction: The prevalence of myofascial pelvic pain amongst women with chronic pelvic pain likely exceeds fifty percent.1-4 This paper provides an analysis of real-world patient reported outcomes, following treatment of female myofascial chronic pelvic pain with a novel photobiomodulation therapy. The standard therapy involves 9 three-minute treatments over 3- 4 weeks. **Methods:** The SoLá Therapy near Infra-red Photobiomodulation laser (Uroshape, LLC) touch screen user interface queries patients using validated medical questionnaires (NRS/Wong Baker and PGIC). A coded, limited data set was analyzed. An additional analysis of Clinical Global Impression was also performed. The primary objective of this analysis is to determine the effects of a proprietary deep tissue transvaginal photobiomodulation laser system (TV-PBMS) on the overall pain score (NRS). The secondary objective of this analysis is to determine the effects of this novel TV-PBMS on specific pelvic pain symptoms. Analysis was performed on the first 101 consecutive patients treated with this novel TV- PBMS. As this is an analysis of real-world evidence, patient recorded outcomes, no patients are excluded from this analysis.

Results: Mean overall pain NRS reduction of ≥1 and ≥2 points was achieved by final treatment for 80% and 68% of patients (p<.0001, p<.0004). These patients experienced a mean decrease in overall pain of 50% and 55% respectively (NRS ≥1, NRS ≥2). By treatment number nine, NRS reductions of ≥1 and >2 were achieved in 78% and 67% of those with levator myalgia, 82% and 71% with interstitial cystitis, 75% and 69% with endometriosis, 83% and 77% with vulvodynia, 80% and 68% with dyspareunia, and 100% and 100% with vaginismus, respectively. All changes reached statisticalsignificance (p < .05). 47% of all women completing therapy were reduced to mild or no overall pain (0-3 NRS).

The mean number of treatments to maximum pain reduction was 4.3 +/- 3.7 treatments. Clinician Global Impression of Change at a mean of six months found 87 percent of patients to be improved. **Conclusion:** Women with myofascial pelvic pain, undergoing treatment with a proprietary transvaginal photobiomodulation laser system achieved significant reduction in multiple pain symptoms. This benefit was achieved regardless of associated pelvic pain diagnosis.



Percentage with Diagnosis Achieving NRS Decrease of ≥ 2 (Approx. 55% decrease in pain)

Evaluation of a novel deep tissue transvaginal near-infrared laser and applicator in an ovine model

Zipper R, Pryor B. Evaluation of a novel deep tissue transvaginal near-infrared laser and applicator in an ovine model. Lasers Med Sci. 2021.

This study was undertaken to determine if this device is capable of delivering therapeutic levels of irradiance to the pelvic muscles and to identify the surface irradiance required to achieve this goal. This live ovine lab included the implantation of NIR sensors at the surface and within the belly of the levator ani muscles and within the bladder. **Results.** The SPT laser deliverer therapeutic irrandiance to the pelvic musculature and bladder and rectum at powers ≥ 0.5W The 360 degree beam of SPT Laser delivered therapeutic irradiance simultaneously to all areas.

Power (W)	Surface irradiance (mW/cm2)	Irradiance inside levator ani (mW/cm2)
1	166	4.95
2	388	11.57
3	522	15.56
4	643	19.17
5	738	22.00
6	998	29.75

Conclusion: A novel class IV near-infrared laser and transvaginal applicator delivered therapeutic irradiance to the levator ani muscle and bladder of an anesthetized ewe at a power setting of 5 W. A power setting of 0.5 W failed to deliver therapeutic energy into either the levator ani muscle or bladder. Clinical applications targeting deeper tissues such as the pelvic muscles and or the bladder should consider power settings that exceed 0.5 W and or irradiance of ≥ 75 mW/cm2.

Transvaginal photobiomodulation for vulvodynia: A pilot report from real-world clinical settings.*

Georgine Lamvu, MD, MPH1; MD1; Neeraj Kohli, MD; Barry Jarnagin, MD; Angela Stoehr, MD; Ralph Zipper, MD. *Proceeds of the 2021 Internataional Pelvic Pain Society Meeting. A Poster Presentation,.*

Aim: Our goal was to determine if PBM can lead to significant pain relief in women with vulvodynia. This research is the first to evaluate the effectiveness of trans-vaginal photobiomodulation therapy (TV-PBMT) for vulvodynia in real-world clinical settings. **Methods:** Observational analysis of women with vulvodynia who received TV-PBM with SoLa Pelvic Therapy in 13 geographically diverse U.S. clinics.. The device has a touch screen interface that allows for collection of patient demographics, symptoms, and pain severity. Chi 2, Fisher's Exact test, paired t-test, and Wilcoxon ranked sum t-test were used for descriptive analysis. Minimal Clinically Important Difference (MCID) was defined as ≥ 2-point drop on a 0-10 NPRS. **Results:** 99 women who had completed at least their first two treatments were eligible to participate; 61 (61.6%) had completed their 9th treatment by the time of this analysis. The mean pre-treatment score of vulvar pain was 6.5 (SD± 2.6). Compared to baseline, pain scores at treatment 9 changed as follows (Fig 1): vulvar pain from 6.5 (SD±2.6) to 4.5(SD±2.5), MCID= -2, d=0.8; dyspareunia from 6.6 (SD±2.5) to 4.9 (SD±3.1), MCID-1.7, d=0.6; overall pelvic pain 6.5 (SD±2.3) to 4.5 (SD±2.5), MCID=-2, d=0.8. **Conclusion:** In this cohort of women with vulvodynia, significant improvement in vulvar pain, dyspareunia, and overall pelvic pain was observed after 9 TV-PBM treatments.

Women with Pelvic Muscle Tenderness and Interstitial Cystitis/Bladder Pain Syndrome: A Preliminary Observational Study

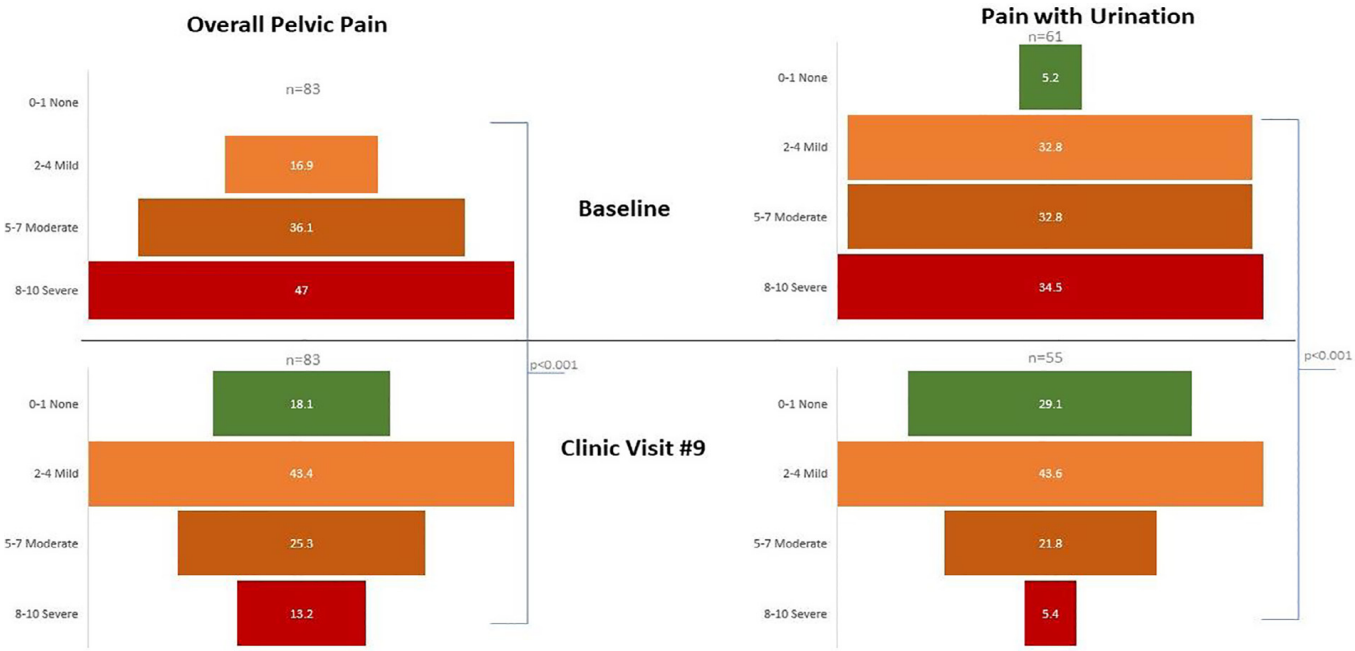
Butrick CW, Lamvu G. Transvaginal Photobiomodulation Improves Pain in Women with Pelvic Muscle Tenderness and Interstitial Cystitis/Bladder Pain Syndrome: A Preliminary Observational Study. Urology. 2022.

Purpose: Interstitial Cystitis/ Bladder Pain Syndrome (IC/BPS) is characterized by pelvic/bladder pain, associated with pelvic muscle tenderness, urgency, frequency, and dysuria. Prior stud- ies show that transvaginal photobiomodulation (TV-PBM) reduces pain in women with chronic pelvic pain (CPP). Our objective was to obtain preliminary data on treatment effect and adherence, in women with IC/BPS who selected TV-PBM therapy for manage- ment of pelvic pain.

Materials and Methods: Before-and-after observational cohort study of women with IC/BPS who received TV-PBM in 17 US practices. Pain was measured using a 0-10 numeric rating scale (NRS). The pri- mary outcome was a minimal clinical important difference (MCID); reduction of overall pelvic pain severity by ≥2 NRS points from baseline compared to after 8 treatments. Cohen d coefficient measured effect size (low effect size d<0.2, medium 0.2<d<0.8, and high d>0.8).

Results; Of 140 patients with IC/BPS who self-selected to start TV-PBM therapy, 89.3% (n=125) completed 4 treatments and 59.3% (n=83) completed 8. Improvement ≥1 NRS point was reported by 73.5% (n=61) and meaningful improvement (≥2 points) was reported by 63.9% (n=53) after 8 treatments. In this group, patients with severe / moderate pain decreased from 83.1% (n=44) to 38.5% (n=20); p<0.001. Pain levels decreased as follows: overall pelvic pain MCID=-2.7, d=1.07, pain with urination MCID=-2.6, d=1.0; pain with exercise MCID=-2.6, d=0.91, pain with intercourse MCID=-2.5, d=0.82.

Conclusion: In real-world clinical settings, 2/3 women with IC/BPS who opted to undergo TV-PBM therapy reported significant decrease in pelvic pain and dysuria. These findings are promising; however, controlled studies are needed.



Changes in moderate / severe overall pelvic pain and urinary pain before and after 8 treatments.