

Reduction of Chronic Pelvic, Urological and GI Pain Using Wearable Therapeutic Ultrasound in Women with Extended Follow-Up to 17 Months

Summary

The reduction of pelvic, urological and GI pain by PainShield® MD, a wearable ultrasound device, persisted in this follow-up to 541 days in 16 women with long-standing and refractory symptoms.

Objective

To assess the efficacy of a wearable low-frequency, low-intensity ultrasound device in treating pelvic and related pain up to 17 months.

Methods

Design: Open-label, prospective, experiential study
Patients: 16 women (age 47, range 33–62)
 Patients part of cohort that included 3 male patients previously followed up to 207 days.
Inclusion criteria: Age > 18 years
 Doctor or PT prescription/order
 History of chronic pelvic, urological or related pain or symptoms, refractory to other treatment
Exclusion criteria: Malignancy, known sensitivity to ultrasound
Time from first Dx: 15.6 years, range 1–33 years
Diagnoses:
 Adhesions 69%
 Bowel obstruction 44%
 Endometriosis 31%
 IBS 31%
 Interstitial Cystitis 25%
 Other Chronic Pelvic Pain 63%
Scoring based on: Brief Pain Inventory, Short-Form McGill Questionnaire, International Pelvic Pain Society's form. Scores collected before and up to 190 (range 1-541) days after treatment.
Comparison: Worst, Least and Average scores (0–10) from before and after treatment were compared by the Wilcoxon Signed Rank test.
Treatment: 1-2 sessions/day each consisting of 12 alternating periods (30 minutes) of active and inactive ultrasound energy delivery.

Acknowledgement

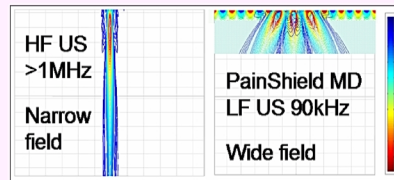
We thank NanoVibronix, Inc. (Nesher, Israel) for providing PainShield units at no cost.

Citation

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Therapeutic Ultrasound

- Ultrasound widely known for effects in pain relief, muscle spasm and wound healing
- Low-frequency, low-intensity ultrasound shown to reduce pain & biofilm formation, increase wound healing via possible effects on nerves, blood vessels and nitric oxide formation



PainShield Driver and Patch

PainShield MD

- Thin 3cm transducer in self-adhering, portable and wearable patch
- Efficacy shown in trigeminal neuralgia and other pain conditions
- Conventional units limited by cost, size, portability and availability to offices
- Penetration of ultrasound energy of up to 4 cm below the surface and therapeutic action reaching up to 20 cm from the device

Results

Symptom	Pain or symptom score Before Tx /After Tx			% time with pain/symptom	N
	Worst	Least	Average		
Pain on full bladder	5.0 / 3.0	2.5 / 0.0 *	4.5 / 1.0 *	83 / 38 *	10
Dysuria	4.5 / 2.0 *	0.0 / 0.0	2.5 / 1.0 *	78 / 41	6
Pelvic or abdominal pain	9.5 / 6.5 *	2.0 / 0.0	5.5 / 3.0 *	84 / 61 **	10
Dyspareunia, during	10.0 / 5.0 *	2.0 / 2.0	4.0 / 3.0	92 / 68	11
Dyspareunia, after	7.0 / 2.5 *	1.0 / 0.5	4.5 / 1.5 *	100 / 70 *	8
Dyschezia	7.0 / 3.5 *	0.0 / 0.0	3.0 / 2.0 *	84 / 52 **	8
Abdominal bloating				83 / 59 **	10
Rectal pain	10.0 / 6.0	3.0 / 0.0	6.0 / 3.0	53 / 18	3
SI-Joint pain	9.5 / 7.5 *	3.0 / 0.5 *	6.0 / 3.0 *	87 / 48 *	10
Sitting pain	8.5 / 8.0	1.0 / 1.5	4.5 / 5.0		10
Other muscle/joint pain	8.0 / 5.5 *	2.0 / 1.0	6.0 / 5.0	77 / 63	13
Frequency, day	21 ± 7.4 vs. 12 ± 2.4 times				10
Frequency, night	1.8 ± 0.2 vs 1.2 ± 0.2* times				12
Sitting tolerance	28 ± 12.2 vs 68 ± 38 minutes				9

* p < 0.05 ** p < 0.10

Results

- Onset of relief often within hours or days after starting treatment
- Patients rated their overall response as:

Negative	1/16
Mild	4/16
Moderate	2/16
Good	9/16
- Improvements in pain or related symptoms noted for all symptoms:

Exceeding Significance (<0.05) Approaching Significance (<0.10)

- Bladder pain on urination
- Dyschezia
- Other muscle/joint pain
- Dyspareunia (during & before)
- Sacroiliac joint pain
- Frequency, night
- Other chronic pelvic or abdominal pain

Numerical Improvements

- Pain on full bladder
- Rectal pain
- Sitting pain
- Sitting tolerance
- Anecdotal reports of clinically significant:
 - reductions in analgesic and medication usage and cost
 - improvements in sleep due to less pain
- Effects seen for worst score mirrored for least & average scores
- Delayed return of symptoms after discontinuation of treatment in several patients with return of effect after resumption

Adverse events

The one patient responding negatively reported a rapid onset (< 1 day) of pain which subsided rapidly. One patient responding well experienced some abdominal discomfort after using the device. These patients reported similar reactions to conventional office-based ultrasound.

Conclusion

This study confirms and extends the previous findings of a beneficial effect of PainShield® MD in patients with severe and persistent CPP.

Disclosure

At the time of the study, neither author had a financial interest in the evaluated product. Subsequently, DW has formed a company (KevMed) to distribute PainShield for pelvic pain and related conditions.

For full prescribing information please contact: