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

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## 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)<br>Patients part of cohort that included 3 male patients previously followed up to 207 days. |
| Inclusion criteria: | Age > 18 years<br>Doctor or PT prescription/order<br>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%<br>Bowel obstruction 44%<br>Endometriosis 31%<br>IBS 31%<br>Interstitial Cystitis 25%<br>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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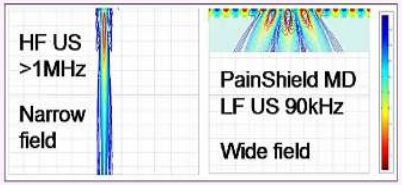
## Therapeutic Ultrasound

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

*Approaching Significance (<0.10)*
- Time with pelvic/ abdominal pain
- Occasions with dyschezia
- Time with abdominal bloating

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:

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