# Reduction of Chronic Abdominal and Pelvic Pain, Urological and GI Symptoms Using a Wearable Device Delivering Low Frequency Ultrasound

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## Summary

PainShield®, a portable, wearable ultrasound device was found to reduce pelvic, urological pain and related symptoms in 19 patients presenting with long−standing and refractory symptoms.

## Objective

To assess the efficacy of Painshield for pelvic and related pain.

## Methods

| | | |
|---|---|---|
| Design: | Open−label, prospective, experiential study | |
| Patients: | 16 women and 3 men (age 46, range 33−62) | |
| 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: | 15.3 years, range 1−33 years | |
| Diagnoses: | Adhesions | 63% |
| | Bowel obstruction | 42% |
| | Endometriosis | 26% |
| | IBS | 32% |
| | Interstital Cystitis | 32% |
| | Other Chronic Pelvic Pain | 63% |
| Scoring based on: | Brief Pain Inventory,<br>Short−Form McGill Questionnaire<br>International Pelvic Pain Society's form<br>Scores collected before and up to 51.4 (range 1-207) days after treatment started. | |
| Comparison: | Maximum scores for each type of pain from before and after treatment were ranked and compared (t 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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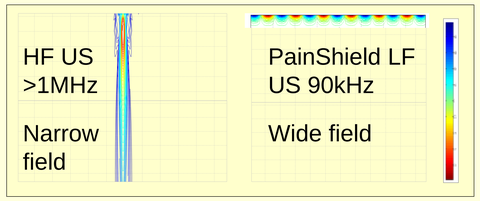
## Therapeutic Ultrasound

- 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

- 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 US energy of up to 4 cm below the surface and therapeutic action reaching up to 20 cm from the device

## Results

| Symptom | Maximum pain or symptom score | | N | P |
|---|---|---|---|---|
| | Before Tx | After Tx | | |
| Bladder pain before urination | 6.1 | 4.3 | 12 | 0.021 |
| Pain on urination | 6.0 | 2.0 | 7 | 0.001 |
| Urinary urgency (% of time) | 100% | 54% | 6 | 0.060 |
| Urination frequency (/day) | 21 | 14 | 11 | |
| Difficulty urinating (% of time) | 100% | 60% | 6 | 0.080 |
| Other Chronic Abdominal or Pelvic Pain | 8.3 | 5.9 | 12 | 0.042 |
| Dyspareunia, during | 7.8 | 5.5 | 12 | |
| Dyspareunia, after | 6.6 | 4.3 | 8 | |
| Dyschezia | 7.7 | 3.6 | 10 | 0.001 |
| Abdominal bloating (% of time) | 83% | 53% | 10 | 0.049 |
| Rectal Pain | 9.3 | 6.0 | 4 | |
| SI-Joint Pain | 8.5 | 6.5 | 6 | 0.081 |
| Sitting tolerance time (mins) | 36.3 | 90.8 | 12 | |
| Other muscle/joint pain | 7.4 | 5.2 | 18 | 0.030 |

## Results

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

| | |
|---|---|
| Negative | 2/19 |
| Mild | 4/19 |
| Moderate | 3/19 |
| Good | 10/19 |

- Improvements in pain or related symptoms noted for all symptoms:

Exceeding Significance (<0.05)
- Bladder pain before urination
- Pain on urination
- Dyschezia
- Abdominal bloating
- Other muscle/joint pain
- Other chronic pelvic or abdominal pain

Approaching Significance (<0.10)
- Urinary urgency
- Difficulty urinating
- Sacroiliac joint pain

Numerical Reductions
- Urination frequency
- Dyspareunia (during or after)
- Rectal 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 maximum score mirrored for minimum & average scores, and longer term follow-up
- Delayed return of symptoms after discontinuation of treatment in several patients with return of effect after resumption

## Adverse events

The two patients responding negatively reported a rapid onset (< 1 day) of pain and/or swelling which subsided from 1 to several days later. One patient responding well experienced some abdominal discomfort after using the device. Two of these patients reported similar reactions to conventional office-based ultrasound.

## Conclusion

Further evaluation of Painshield for CPP is warranted.

## 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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