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, experimental 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 NanoviBrionx, Inc. (Neshoba, Israel) for providing PainShield units at no cost.

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 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 up to 4 cm below the surface and therapeutic action reaching up to 20 cm from the device

Results

<table>
<thead>
<tr>
<th>Symptom</th>
<th>Pain or symptom score Before Tx</th>
<th>After Tx</th>
<th>% of pain/symptom</th>
<th>N</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pain on full bladder</td>
<td>5.0’/3.0</td>
<td>2.5 / 0.0 *</td>
<td>4.5 / 1.0 *</td>
<td>83 / 38 *</td>
</tr>
<tr>
<td>Dysuria</td>
<td>4.5 / 2.0</td>
<td>0.0 / 0.0</td>
<td>2.5 / 1.0</td>
<td>78 / 41</td>
</tr>
<tr>
<td>Pelvis or abdominal pain</td>
<td>9.5 / 6.5</td>
<td>2.0 / 0.0</td>
<td>5.5 / 3.0</td>
<td>84 / 61 *</td>
</tr>
<tr>
<td>Dyspareunia, during</td>
<td>10.0 / 5.0</td>
<td>2.0 / 2.0</td>
<td>4.0 / 3.0</td>
<td>92 / 68</td>
</tr>
<tr>
<td>Dyspareunia, after</td>
<td>7.0 / 2.5</td>
<td>1.0 / 0.5</td>
<td>4.5 / 1.5</td>
<td>100 / 70 *</td>
</tr>
<tr>
<td>Dyschezia</td>
<td>7.0 / 3.5</td>
<td>0.0 / 0.0</td>
<td>3.0 / 2.0</td>
<td>84 / 52 **</td>
</tr>
<tr>
<td>Abdominal bloating</td>
<td>83 / 59</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Rectal pain</td>
<td>10.0 / 6.0</td>
<td>3.0 / 0.0</td>
<td>6.0 / 3.0</td>
<td>53 / 18</td>
</tr>
<tr>
<td>SI-Joint pain</td>
<td>9.5 / 5.5</td>
<td>3.0 / 0.5</td>
<td>6.0 / 3.0</td>
<td>87 / 40 *</td>
</tr>
<tr>
<td>Sitting pain</td>
<td>8.5 / 6.0</td>
<td>1.0 / 1.5</td>
<td>4.5 / 5.0</td>
<td></td>
</tr>
<tr>
<td>Other muscle/joint pain</td>
<td>8.0 / 5.5</td>
<td>2.0 / 1.0</td>
<td>6.0 / 5.0</td>
<td>77 / 63</td>
</tr>
<tr>
<td>Frequency, day</td>
<td>21.7 vs 12.2</td>
<td>4.0 / 2.4</td>
<td>2.4 / 1.2</td>
<td>13</td>
</tr>
<tr>
<td>Frequency, night</td>
<td>1.8 vs 0.2 + 1.2 *</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sitting tolerance</td>
<td>28 + 12.2 vs 68 + 38 minutes</td>
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<td></td>
<td></td>
</tr>
</tbody>
</table>

* p < 0.05  ** p < 0.10

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:

* KevMed Living beyond the pain* www.kevmed.com