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 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:	15.3 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, Short−Form McGill Questionnaire International Pelvic Pain Society's form 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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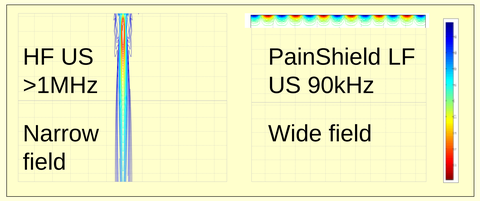
Therapeutic Ultrasound

- 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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