

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

## 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%  
 Interstitial 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

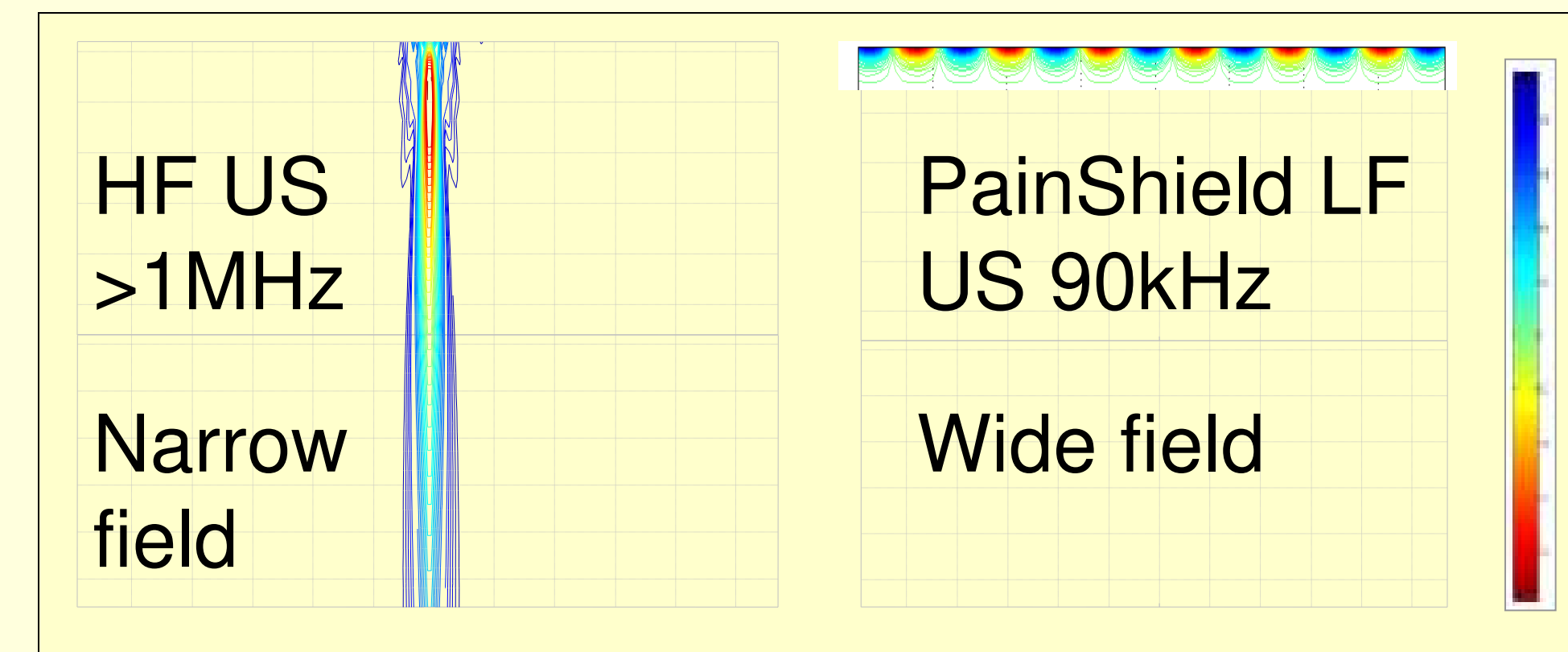
We thank Nanovibronix, Inc. (Nesher, Israel) for providing Painshield units at no cost.

## 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

- 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



PainShield Driver and Patch

## 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)      Approaching Significance (<0.10)

- Bladder pain before urination
- Pain on urination
- Dyschezia
- Abdominal bloating
- Other muscle/joint pain
- Other chronic pelvic or abdominal pain
- 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: