Open-label Pain Study Comparing the Effects of the IceWave® Pain Patches to the Regular Treatment of Various Pain Medications

Comprehensive Data Analysis Report

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Approved by Institutional Review Board: Independent Investigational Review Board on 15 March 10

Introduction

The purpose of this open-label, dual-center, crossover study was to assess the effectiveness of the LifeWave IceWave patches in an elderly population who was on a regular regimen of pain medication. The study compared the efficacy of the IceWave patches vs. pain medications for pain management in two treatment groups (A and B) within a 10-day period. *This report is prepared based upon the data acquired as part of a protocol design carried out by* Dr Carl Rowe Pharm D. and Dr Dean Clark DC from March to September 2010*. The raw data collected by the researchers were digitized and tabulated, then quality-assured and analyzed by Homer Nazeran PhD, CPEng (Biomed.) to prepare the report in May-June 2013.*

The main aims of the study were as follows:

1. To determine the primary outcome variables for *pain* levels at different time points: 1-hour post-patch, 5 days post-patch and 5 days post-medications (post-meds) compared to baseline (pre-patch or pre-meds) using the Universal Pain Assessment Tool (UPAT) and Infrared (IR) Thermal Imaging.

2. To determine the secondary outcome variables for long-term (5 days) impact of IceWave patches and pain medications on quality of life by comparing the 5 days post-patch and post-med scores with pre-patch scores acquired using the Patient Specific Functional Scale (PSFS) and the Functional Activities Pain Checklist (FAPC) questionnaires.

3. To determine the overarching outcome variable by the evaluation of the safety and effectiveness of IceWave patches as a method of controlling pain compared to a second method involving the use of regular prescription and over the counter pain medications.

The UPAT was used for evaluation of perception of pain and Infrared (IR) Thermal Imaging was used as a quantitative measure of pain intensity in the painful areas at different time points: baseline (pre-patch or pre-meds), 10-minutes (min), 1-hour (hr), and 5 days post-patch as well as 5 days post-meds.

The impact of long-term pain management on quality of life was evaluated by comparing the pre-patch, 5 days post-patch and 5 days post-meds scores with baseline scores all collected on the Patient Specific Functional Scale (PSFS) and the Functional Activities Pain Checklist (FAPC) questionnaires.

Data were acquired in a population of 40 subjects residing in: 1) a Residential Care Facility for the Elderly (RCFE), an assisted living facility in Moreno Valley California, and 2) Moreno Valley Senior Center, after giving informed consent. After completion of data collection by the researchers, quality-assured IR Thermal Imaging data were available from 36 subjects (7 males and 29 females, age range: 59-95 years, weight range: 105-280 lbs, height range: 4 ft 10 in - 6 ft 8 in). The UPAT data were available for 35 of these subjects (7 males, 28 females), as one female dropped out from the study.

Quality of life data were available for 2 movements (activities) in the PSFS questionnaire and for 11 questions related to pain level when performing different tasks in the FAPC questionnaire in 34 subjects (7 males, 27 females), as another female in the study population did not complete these questionnaires.

Material and Methods

1. Study Population and Selection Criteria

Approximately 40 subjects of both sexes between the ages of 59 and 95 years of age, who resided at two aged-care facilities located in Moreno Valley, California, were recruited in 2011 to participate in the study. The following criterion was used for subject

inclusion in this study:

1. Male or female subjects of any race, between about 60 and 100 years of age with pain of at least 24 hours duration.

2. The ability to understand the requirements of the study and sign Informed Consent/HIPAA Authorization forms and the willingness to sign.

3. Individuals with musculoskeletal pain of at least 1 day in duration within the previous week.

4. A pain level of at least 3 (on a scale of 0 to 10) when evaluated and self-described on the Universal Pain Assessment Tool (UPAT).

5. Score of 5 or less on the Short Blessed Test cognition test.

6. Taking pain medication on a scheduled daily basis or as needed. Pain medications include: Tylenol, Advil, Motrin, morphine, fentanyl, codeine, vicodin, flector patch, aspirin, darvocet, tramadol, and naproxyn.

The following criteria were used to exclude subjects from participating in this study:

1. Allergy or sensitivity to medical adhesives.

2. Medical condition that, in the opinion of the investigators, contraindicated the subject's participation in the clinical study.

3. Wearing an implanted Pacemaker.

4. Use of pain medications on the day of the study, when assigned to the IceWave pain patch treatment group.

5. Pain that has resulted in litigation.

2. LifeWave IceWave (Pain) Patches

For this investigation, the IceWave patches (LifeWave, San Diego, California, USA) were used (Fig. 1). The IceWave patches are described as “passive nano-devices”. These are non-transdermal patches and no substance enters the body. "They only reflect energy back into the body and they do not generate energy. The organic molecules in the patches act like frequency specific mirrors or reflectors (narrow-band) as compared to the ceramic fibers found in infrared products, which are broad-band reflectors. These organic materials have liquid crystal properties similar to the liquid crystal properties of cell proteins” [1].

IceWave consists of a set of white and tan colored patches and are to be used together. Each patch contains a polyester pad, which is saturated with a patent pending solution of sugars, water and amino acids that is sealed within a polyethylene shell. The top-side of the patch is composed of water-resistant polyethylene film (Part No. A19-48G) sealed to the bottom portion that is composed of water-resistant single coated Medical-grade polyethylene tape (Part No. 1525L). The bottom side of the Medical-grade polyethylene tape that attaches the WHITE and TAN patches to the body is coated with a hypoallergenic pressure sensitive acrylate adhesive made by the 3M Company, which allows the patch to adhere to the body. *Because of the nature of construction **none** of the organic materials in the WHITE and TAN patches enter into the body making the IceWave device a non-transdermal patch system.*

“Placing a patch containing an organic liquid crystal on the skin will allow the organic materials to passively absorb wide-band energy and reemit narrow-band energy back into the body. Infrared wraps contain inorganic ceramic fibers. These inorganic fibers absorb infrared energy from the body and then reemit the energy across a wide energy band. LW patches contain organic materials, which only mirror back energy that the body is already emitting. The difference between LifeWave patches and infrared products is that LifeWave patches only mirror back a very narrow band of frequencies. In this context LW patches are not significantly different in mechanism of action from infrared wraps, socks, bandages, blankets, etc” [2].

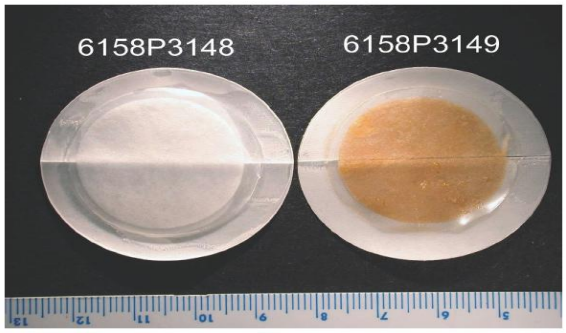


Fig. 1. The IceWave patches (Courtesy LifeWave LLC).

There are a number of recommended methods for efficient placement of IceWave patches on acupressure points by the manufacturer. For this study, application was based on the source of pain identified by infrared. Fig. 2 shows an example called the "*Bracketing Method*" [2].

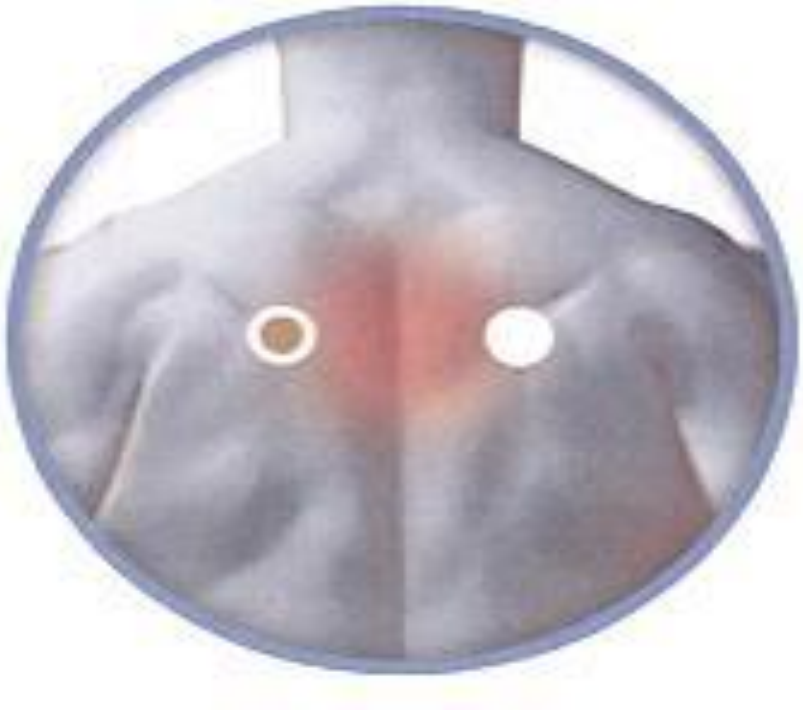


Fig. 2. Bracketing method of IceWave patch placement [2].

2. Prescription and Over the Counter Medication

Pain medications used in the study included: Tylenol, Advil, Motrin, morphine, fentanyl, codeine, vicodin, flector patch, aspirin, darvocet, tramadol and naproxyn.

3. The Universal Pain Assessment Tool (UPAT)

The *Universal Pain Assessment Tool* (UPAT) is a visual analog scale to assist healthcare practitioners to assess pain according to individual patient needs. This is basically a 10 cm long line with numerals from 0 to 10, marked 1 cm apart, and three descriptors (0 at the beginning designated as *No pain*: 5 in the middle designated as *Moderate pain* and 10 at the end designated as *Worst possible pain*). These numerical scales are enhanced with faces representing various pain levels when the patient cannot communicate his/her pain intensity. Figure 3 shows the UPAT.

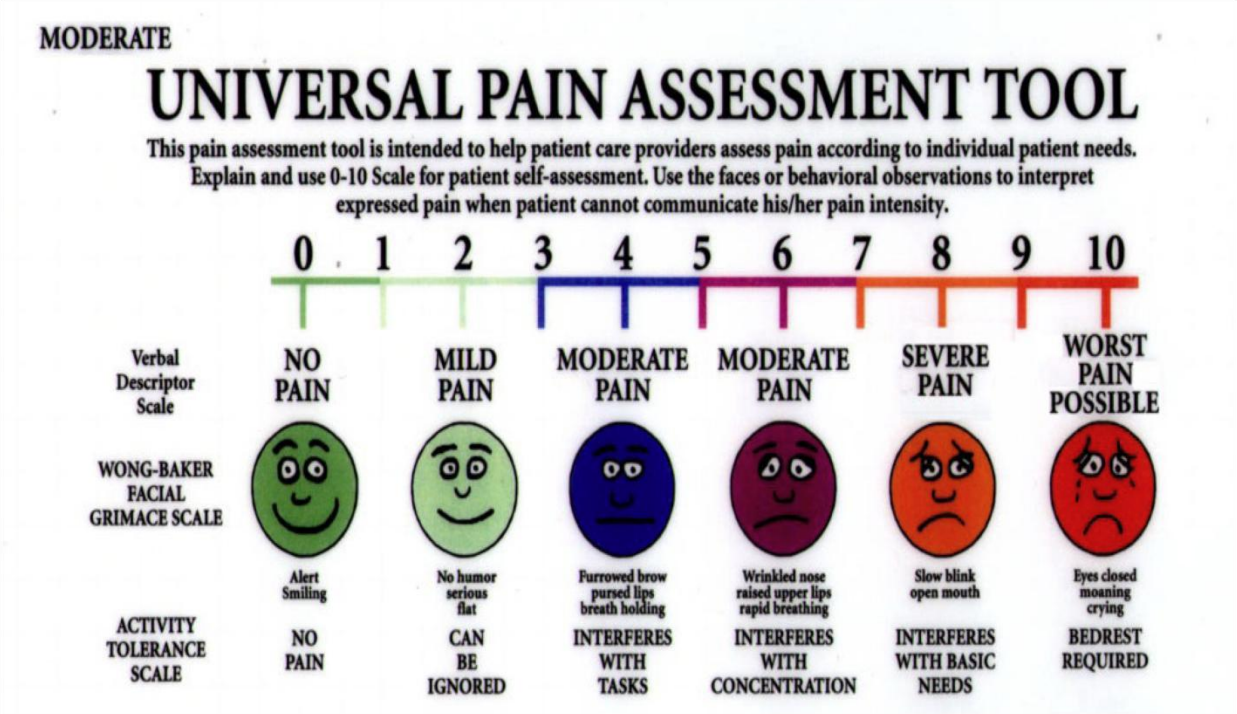


Fig. 3. The *Universal Pain Assessment Tool* (UPAT).

4. Infrared (IR) Thermal Imaging

Infrared Imaging was performed on subjects prior to IceWave usage to aid in determining patch placement. Infrared Thermal Imaging is a non-invasive diagnostic procedure, which detects and records surface skin temperatures by measuring the variations in the heat spontaneously emitted from body surfaces. The infrared imaging

system used in this study could measure infrared thermal differences to one-hundredth of a degree (0.01^{o} C resolution.) The surface skin temperatures are affected by the individual's physiological responses. Specifically, the autonomic nervous system (ANS) of the body controls the thermal response. The external skin temperature creates a thermal map that is an objective measure of normal as well as abnormal physiologic function. The infrared evaluation as a diagnostic procedure in evaluating normal physiologic function can be an *accurate and objective evaluation of pain*. In thermal skin readings, a 0.5 °C difference is considered significant.

Infrared Thermal Imaging is generally regarded as safe. It has been used for 20 years in diagnostic medicine. Whereas X-rays demonstrate anatomy, Thermal Imaging is unique in its *capability to show physiological change and metabolic processes*. It has also proven to be a very useful complementary procedure to other diagnostic modalities.

5. Patient Specific Functional Scale (PSFS) Questionnaire

The Patient Specific Functional Scale (PSFS) questionnaire (Please see Appendix) is an instrument used to assess the perception of pain by the subjects. This questionnaire can be implemented to quantify activity limitation and measure functional outcome for patients with any orthopedic condition.

6. Functional Activities Pain Checklist (FAPC) questionnaire

The *Functional Activities Pain Checklist* (FAPC) is a standardized questionnaire that is used to assess perception of pain while performing different tasks (Please see Appendix A.).

RESULTS

Table 1 shows the UPAT data for 35 subjects (28 females, 7 males) wearing IceWave patches and while taking pain medication during the study period.

Table 1a. UPAT data for all participants (N1 = 35, 28 Females and 7 Males) at different time points at baseline and during the 5-day IceWave patch application period (B represents Baseline, min represents minutes, hr represents hour, hrs represents hours).

	Day 1				Day 2				Day 3				Day 4				Day 5			
B	**10-min**	**1-hr**	**12-hrs**	**24-hrs**	**10-min**	**1-hr**	**12-hrs**	**24-hrs**	**10-min**	**1-hr**	**12-hrs**	**24-hrs**	**10-min**	**1-hr**	**12-hrs**	**24-hrs**	**10-min**	**1-hr**	**12-hrs**	**24-hrs**
5	3	**3**	2	2	2	3	2	2	3	3	2	1	2	2	1	0	2	0	2	**1**
10	6.5	**2**	0	5	5	5	0	0	0	1	0	0	0	0	0	0	0	0	0	**1**
7	4	**2**	1	1	0	0	0	0	1	1	1	1	1	1	1	1	1	1	0	**0**
6	4	**4**	4	6	4	3	5	5	4	3	4	4	4	3	4	4	4	3	4	**4**
3	4	**2**	5	4	4	2	2	2	0	0	2	2	2	2	2	2	2	4	2	**5**
5	0	**0**	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	**0**
4.5	1	**2**	2	2	0	1	0	0	0	0	1	2	1	1	1	2	0	1	0	**1**
8	2	**2**	2	2	3	3	5	3	1	1	1	1	1	1	1	1	2	2	2	**2**
4	1	**3**	0	0	0	0	0	0	0	1	3	2	0	2	1	0	0	0	0	**0**
3	4	**2**	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	**0**
9	9	**8**	9	8	8	8	7	8	8	8	7	6	7	7	7	6	7	7	7	**7**
8	6	**2**	2	6	8	8	3	3	4	5	5	6	6	6	7	7	7	8	7	**7**
3	8	**4**	3	1	1	1	1	1	2	2	2	2	2	2	2	3	3	3	3	**3**
6	4	**4**	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2.5	3	2.5	**3**
3	2	**2**	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	**2**
4	3	**3**	2	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	**3**
9	10	**2.5**	1	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	**2**
8	8	**7**	7.5	8	8	8	8	8	8	8	8	8	8	8	8	8	8	8	8	**8**
8	7	**6**	7	6	3	3	4	3	3	3	3	3	2	3	3	2	8	8	8	**8**
7	4	**4**	3	4	4	3	6	6	6	6	6	6	7	7	7	8	8	8	8	**8**
8	7	**6**	6	6	5.8	5.5	5.5	5	4.5	4.5	4.5	5	5.5	5.5	6	6	5	5	5	**4.5**
8	3	**4**	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	5	**5**
5	6	**3**	3	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	**0**

4	0	**1**	1	1	1	2	1	2	0	0	0	1	1	1	0	0	0	1	0	**0**
8	7.5	**5**	2.5	5.5	5.5	8.5	7.5	5.5	6.5	7.5	5.5	5	4.5	4	5	5.5	5.5	5.5	6.5	**6**
3	7	**0**	0	2	1	0	0	1	1	1	1	1	1	1	1	1	1	1	1	**1**
6	8	**2**	2	4	2	2	2	3	1	2	2	1	2	2	2	6	4	4	3	**4**
6	9	**1**	3	2	1	1	1	1	1	1	1	3	1	1	1	1	1	1	1	**1**
4	1	**0.5**	0	1	0	0	0	0	0	0	0	0	0	0	0	1	1	1	0	**1**
8	5	**5**	5	6	6	6	6	6	6	6	6	7	6	6	6	6	6	6	6	**6**
4	8	**4**	4	3	4	8	10	6	8	8	8	6	6	6	6	6	6	6	6	**6**
2	3	**2**	2	2	2	2	3	2	1	2	2	1	2	2	1	1	2	2	1	**1**
4	4	**4**	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	**4**
4	5	**5**	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5	**5**
4	6	**5**	4	5	4	4	4	3	2	2	2	2	2	3	3	3	4	3	2	**2**
6	3	**3**	2	2	2	3	2	2	3	3	2	1	2	2	1	0	2	0	2	**1**

Table 1b. UPAT data for all participants (N1 = 35, 28 Females and 7 Males) at different time points at baseline and during the 5 days while taking pain medication (B represents Baseline, min represents minutes, hr represents hour, hrs represents hours).

	Day 1				Day 2				Day 3				Day 4				Day 5			
B	**10-min**	**1-hr**	**12-hrs**	**24-hrs**	**10-min**	**1-hr**	**12-hrs**	**24-hrs**	**10-min**	**1-hr**	**12-hrs**	**24-hrs**	**10-min**	**1-hr**	**12-hrs**	**24-hrs**	**10-min**	**1-hr**	**12-hrs**	**24-hrs**
5	3	3	3	3	2	3	3	2	4	4	3	3	2	2	2	2	2	2	2	**2**
10	1	1	0	4	2	0	0	2	4	4	2	6	6	4	0	3	2	6	4	**2**
7	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	**0**
6	3	3	3	3	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	**2**
3	4	2	4	4	4	4	4	4	2	2	4	4	4	4	0	2	2	2	1	**1**
5	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	**0**
4.5	6	4	2	3	4	3	2	4	2	1	5	4	3	3	6	6	3	3	4	**4**
8	9	9	8	9	9	9	8	8	8	9	9	9	8	8	8	7	7	7	7	**7**
4	0	1	1	2	0	1	3	2	2	4	4	2	1	2	2	4	1	2	2	**2**
3	3	3	3	3	2	2	3	3	4	4	4	4	4	4	4	4	4	4	4	**4**
9	7	7	7	7	8	7	6	7	8	7	8	8	8	8	7	8	7	7	6	**6**
8	6	6	8	8	4	5	5	5	6	4	5	6	4	6	6	5	6	6	5	**4**

3	2	3	3	2	2	2	3	3	3	3	3	3	3	3	3	3	2	2	2	**2**
6	2	2	3	3	3	3	3	3	3	3	3	3	4	4	4	4	4	4	4	**4**
3	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	**0**
4	5	5	5	5	4	5	5	4	5	4	4	5	5	5	5	5	5	8	6	**6**
9	3	6	6	9	10	10	8	8	8	8	9	7	2	5	8	8	7	8	6	**6**
8	8	8	8	8	7	7	7	8	8	8	8	7	8	8	8	7	7	7	7	**7**
8	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	**3**
7	8	8	7	6	5	5	5	5	5	5	4	4	5	5	4	6	5	5	4	**4**
8	5.5	5	5	5	6	6	6	6	7	7	7	7	9	9	9	9	9	9	9	**9**
8	5	5	5	4	4	4	4	5	5	5	5	5	5	5	5	5	5	5	5	**4**
5	4	4	4	4	4	4	4	4	0	0	0	0	0	4	4	4	4	4	4	**10**
4	2	2	2	2	2	3	3	2	2	2	3	3	3	4	5	5	4	4	6	**0**
8	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	**5**
3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	**6**
6	5	5	5	4	4	4	4	5	5	5	5	5	5	5	5	5	5	5	5	**5**
6	4	4	4	4	4	4	4	4	0	0	0	0	0	4	4	4	4	4	4	**4**
4	2	2	2	2	2	3	3	2	2	2	3	3	3	4	5	5	4	4	6	**2**
8	5	5	5	4	4	4	4	5	5	5	5	5	5	5	5	5	5	5	5	**4**
4	4	4	4	4	4	4	4	4	0	0	0	0	0	4	4	4	4	4	4	**4**
2	2	2	2	2	2	3	3	2	2	2	3	3	3	4	5	5	4	4	6	**6**
4	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	**2**
4	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	**3**
4	6	6	6	6	6	6	6	6	6	5	5	5	5	5	6	6	6	6	6	**6**
6	3	3	3	3	2	3	3	2	4	4	3	3	2	2	2	2	2	2	2	**2**

Table 2 shows the IR Thermal Imaging raw data obtained for all participants (including

their demographics).

Table 2. IR Thermal Imaging data (Temperature in ^{o}C) for all participants (N2 = 36, 29 Females and 7 Males) along with their demographics.

Sub No	Pre-patch (Baseline) Temp (^{o}C)	1- hour post-patch Temp (^{o}C)	5 Days post-patch Temp (^{o}C)	5 days post-med Temp (^{o}C)	***Age***	***Gender*** ***Male***	***Female***	***Weight (lbs)***	***Height (in.)***	***Race***
1	32.23	30.8	31.08	29.04	75		X	170	64	Caucasian
2	28.51	27.46	26.49	26.21	89		X	126	62	Caucasian
3	31.08	29.95	29.73	30.2	82	X		193	71	Caucasian
4	31.73	31.6	32.14	31.75	67		X	157	59	Filipino
5	30.63	30.31	30.59	31.36	79	X		155	66	Filipino
6	31.2	30.96	30.58	30.19	59		X	115	61	Asian
7	30.36	30.74	32.1	32.09	80		X	110	58	Filipino
8	32.83	31.26	33.38	32.15	65	X		178	63	Hispanic
9	32.08	32.54	32.03	32.03	94		x	124	60	Caucasian
10	32.23	32.31	31.86	32.61	78		X	141	65	Caucasian
11	27.33	25.02	28.75	27.45	95		X	110	65	African-Amer
12	32.26	33.54	33.21	32.85	87		x	91	5’	Asian
13	33.025	32.225	32.675	34	--			--	--	Caucasian
14	32.975	32.963	32.76	33.263	85		X	114	60	Filipino
15	31.688	31.4	31.625	33.4	65		X	175	60	Hispanic
16	32.6	32.125	30.825	33.225	73	X		150	67	Hispanic
17	32.15	32	31.188	32.338	89	X		189	70	Caucasian
18	31.225	29.675	31.225	32.125	68		X	184	60	Hispanic
19	32.75	33.35	32.938	32.85	71		X	124	67	Caucasian
20	32.338	32.275	32.875	31.525	89		X	140	65	Caucasian
21	31.888	32.862	31.675	30.625	77		X	130	64	African-Amer
22	29.712	30.375	30.375	29.95	76		X	185	60	Caucasian

23	31.763	31	29.363	31.9	74		X	255	67	Caucasian
24	31.113	31.913	31.975	33.14	88		X	171	64	Caucasian
25	33.638	31.775	33.038	33.338	82		X	180	62	African-Amer
26	32.325	32.35	31.45	32.588	87		X	125	60	Caucasian
27	32.088	30.875	32.85	33.85	66	X		200	67	Caucasian
28	30.613	31.25	30.425	30.8	61	X		180	66	Hispanic
29	31.6	31.375	31.163	31.712	--		X	124	60	Caucasian
30	30.375	30.888	30.263	30.988	60		X	205	68	Caucasian
31	30.7	31.4	29.975	31.65	65		X	195	64	Caucasian
32	30.813	29.513	29.9	30.962	60	X		258	80	Hispanic
33	30.638	29.425	30.438	31.513	78		X	119	62	Filipino
34	29.813	30.025	29.45	28.875	--		X	176	60	Caucasian
35	31.038	31.063	30.4	31.925	71		X	164	65	Caucasian
36	30.75	32.838	32.175	30.775	63		X	195	66	African-Amer
37	31.888	32.75	31.15	31.738	65	X		280	67	Caucasian

Figure 4 a shows an example of IR thermal images at baseline.

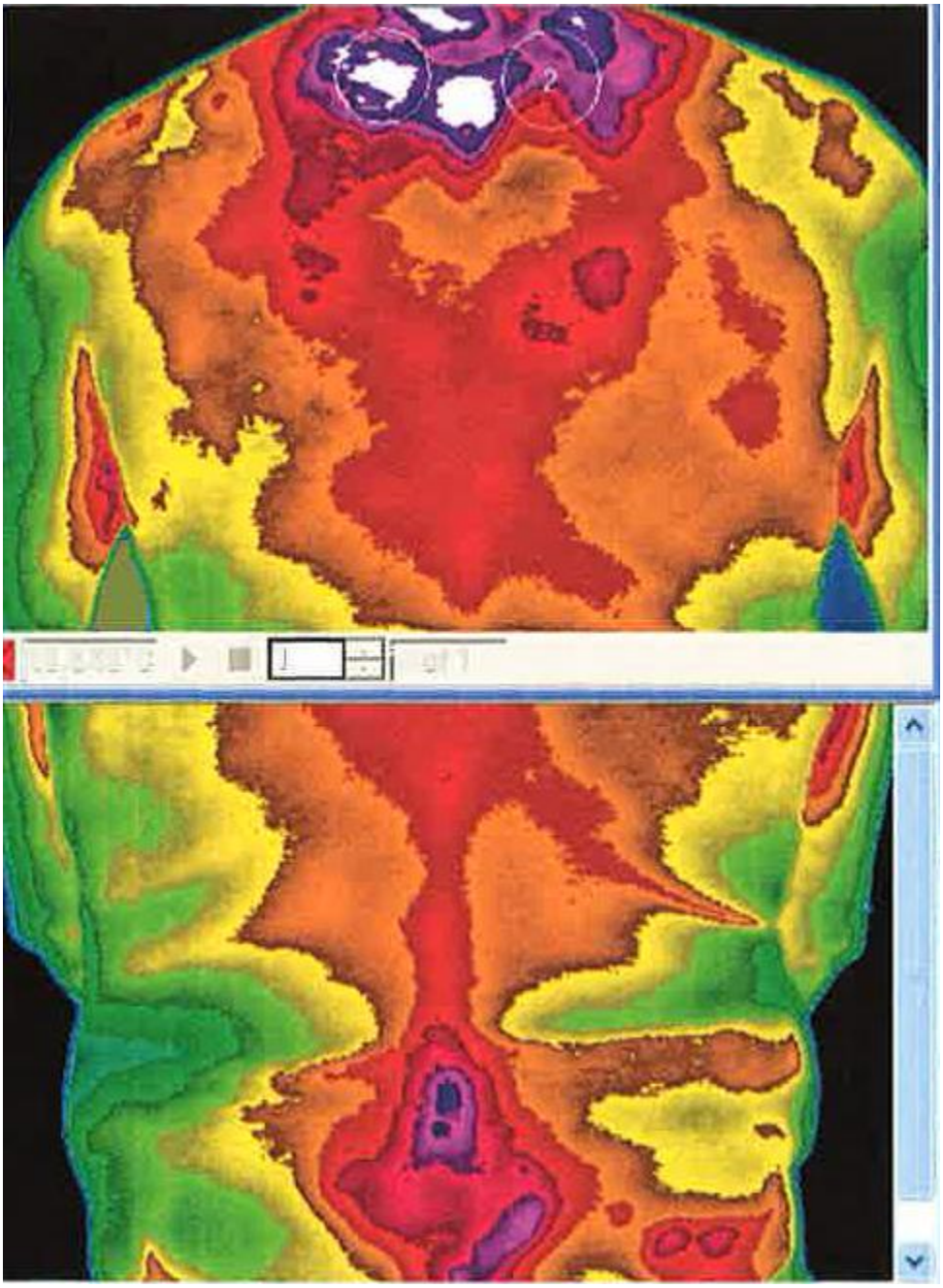


Figure 4a. An example of a thermal image at baseline.

Figure 4b. An example of a thermal image at 1-hour post-patch.

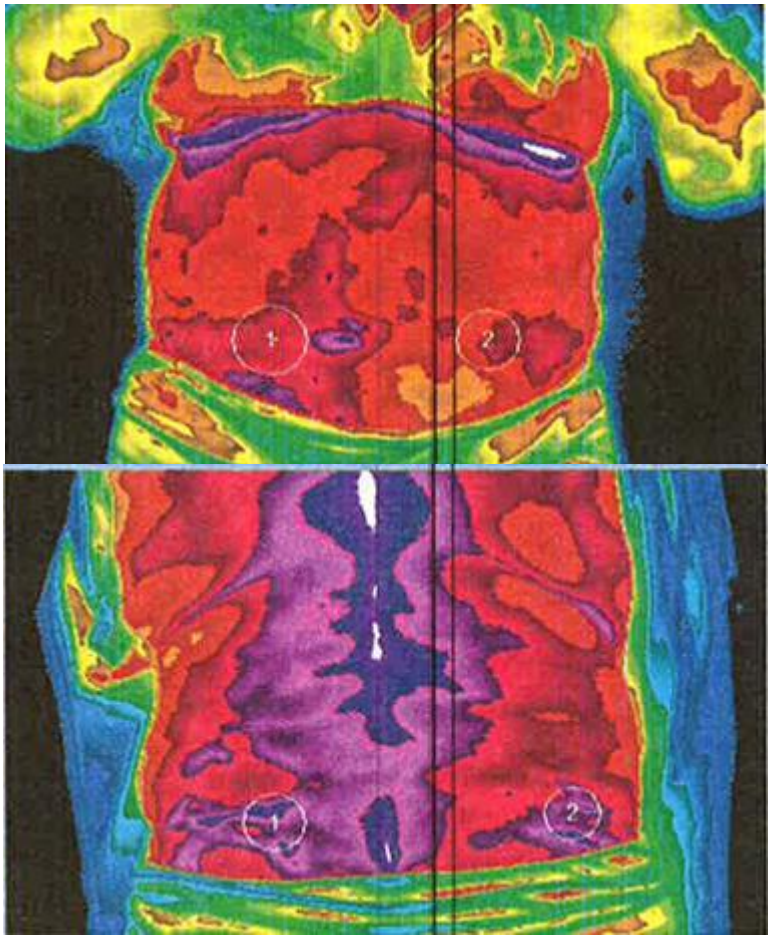
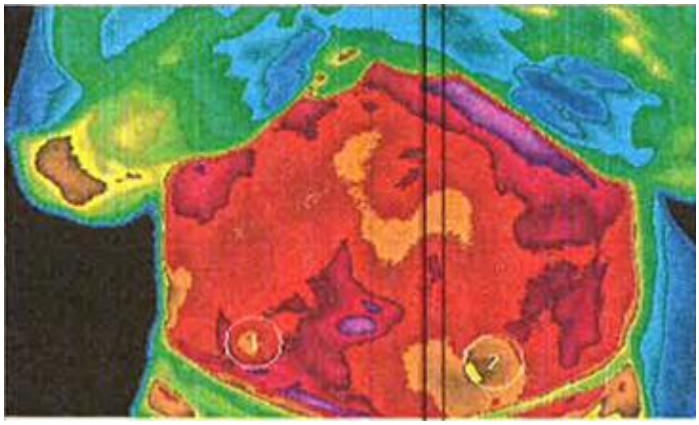


Figure 4c. An example of a thermal image at 5 days post-patch and beginning of taking pain medication.



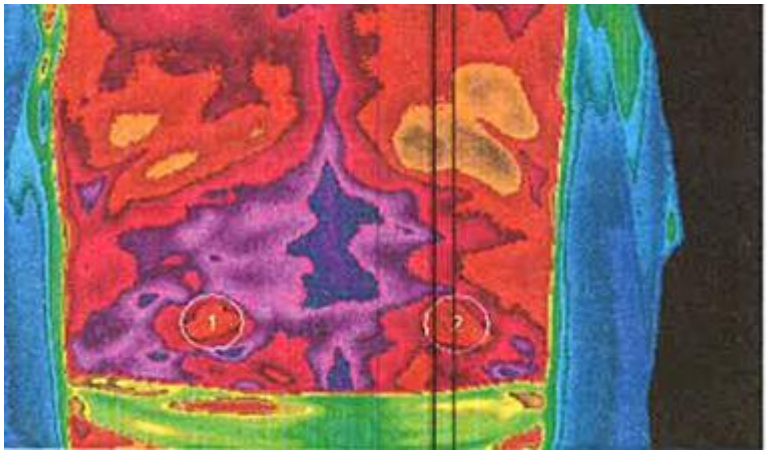


Figure 4d. An example of a thermal image at 5 days post-medication (Please See Appendix B in a separate file).

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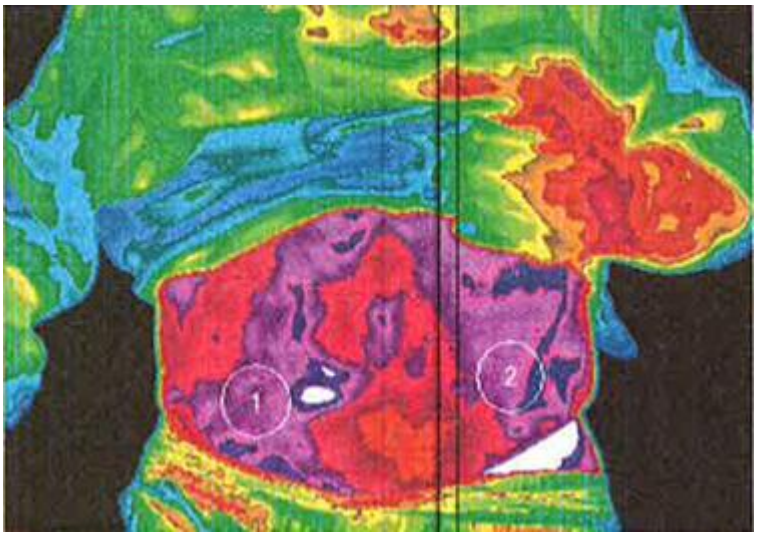

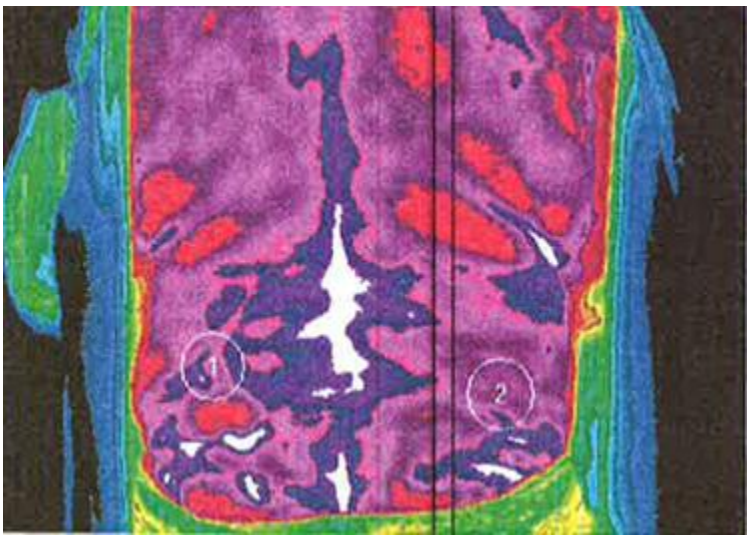

Table 3 shows the PSFS results for 2 activities (movements) carried out by 34 subjects (27 Females and 7 Males) at baseline and while wearing the IceWave patches or taking their pain medications for 5 days.

Table 3. PSFS data for all participants (N3 = 34, 27 Females and 7 Males) at different time points: baseline, 5 days post-patch, and 5 days post-meds.

Baseline		5 days Post-patch		5 days Post-patch	
Activity 1	Activity 2	Activity 1	Activity 2	Activity 1	Activity 2
7	6	9	8	5	5
4	3	7	6	8	6
7	7	9	10	6	7
7	5	7	5	9	7
6	7	8	8	7	7
6	7	9	10	8	9
6	4	5	4	9	9
2	4	2	5	9	8
8	7.5	8	7.5	9	10
5	6	5	9	9	10
3	2	4	6	4	4
8	8	10	8	8	6
2	2	9	9	8	8
4	7	8	10	8	8
5	5	10	5	10	5
8	8	4	4	8	9
0	0	10	10	7	7
8	8	0	0	5	5
9	9	3	8	10	10
3	3	2	2	3	3
2	3	4	5	3	4
3	2	5	5	4	5
6	6	5	10	10	10
9	8	9	8	1	0

2	2	8	2	6	5
3	2	9	1	5	7
2	2	3	4	9	9
0	0	8	8	4	4
4	3	10	10	8	10
1	1	8	9	3	2
5	7	5	6	6	7
5	6	5	6	7	7
0	0	0	0	0	3
2	4	2	4	9	4

Table 4 shows the FAPC results for 13 questions (Q1-Q13) that 34 subjects (27 Females and 7 Males) answered while performing a variety of tasks at baseline and at the end of the 5-day intervention period post-patch and post-medication.

Table 4. FAPC data for all participants (N3 = 34, 27 Females and 7 Males) at different time points: baseline, 5 days post-patch, and 5 days post-meds, providing answers to questions related to perceived level of pain while performing a variety of tasks (Please see Appendix for these questions.)

Baseline											**5 days post-patch**											5 days post-medication										
Questions: level of pain while performing tasks											**Questions: level of pain while performing tasks**											**Questions: level of pain while performing tasks**										
1	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**	1	2	3	4	5	6	7	8	9	10	11
6	*0*	*4*	*0*	*0*	*0*	*0*	*8*	*0*	*0*	*0*	*3*	*0*	*0*	*0*	*1*	*3*	*0*	*4*	*0*	*2*	*2*	*5*	*2*	*2*	*1*	*1*	*5*	*2*	*5*	*2*	*3*	*3*
9	*9*	*5*	*5*	*10*	*0*	*6*	*10*	*7*	*7*	*10*	*9*	*9*	*5*	*5*	*10*	*0*	*6*	*0*	*7*	*7*	*10*	*0*	*4*	*2*	*5*	*2*	*3*	*2*	*5*	*3*	*3*	*2*
0	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*1*	*1*	*1*	*1*	*0*	*0*	*0*	*1*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*
4	*8*	*7*	*7*	*2*	*4*	*5*	*5*	*8*	*0*	*0*	*0*	*2*	*0*	*2*	*0*	*0*	*3*	*0*	*2*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*
4	*2*	*0*	*0*	*0*	*5*	*0*	*4*	*0*	*0*	*2*	*4*	*2*	*0*	*0*	*0*	*5*	*0*	*4*	*0*	*0*	*2*	*4*	*3*	*0*	*4*	*0*	*0*	*4*	*0*	*0*	*0*	*0*
0	*0*	*0*	*5*	*5*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*4.5*	*4.5*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*
0	*3*	*0*	*0*	*0*	*2*	*1*	*1*	*3*	*0*	*1*	*0*	*3*	*0*	*0*	*0*	*2*	*1*	*1*	*3*	*0*	*1*	*0*	*1*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*
10	*3*	*3.5*	*2*	*0*	*6*	*0*	*10*	*3*	*1*	*2*	*3*	*1*	*0*	*0*	*0*	*3*	*1*	*9*	*5*	*1*	*2*	*10*	*4*	*1*	*0*	*0*	*10*	*4*	*10*	*5*	*2*	*2*
2	*4*	*0*	*1*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*5*	*0*	*0*	*5*	*0*	*0*	*0*	*0*	*0*	*1*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*
0	*0*	*2*	*0*	*0*	*0*	*2*	*4*	*0*	*0*	*0*	*0*	*0*	*2*	*0*	*0*	*0*	*2*	*4*	*0*	*0*	*0*	*0*	*0*	*1*	*0*	*1*	*0*	*0*	*0*	*1*	*0*	*0*
0	*1*	*1*	*8*	*9*	*0*	*8*	*2*	*10*	*0*	*1*	*9*	*7*	*8*	*1*	*1*	*9*	*9*	*8*	*2*	*5*	*8*	*10*	*2*	*9*	*4*	*4*	*9*	*9*	*9*	*3*	*9*	*9*
0	*3*	*4*	*10*	*4*	*2*	*2*	*2*	*0*	*3*	*5*	*0*	*3*	*0*	*8*	*1*	*1*	*1*	*2*	*4*	*0*	*0*	*1*	*33*	*1*	*9*	*1*	*1*	*2*	*2*	*2*	*2*	*1*
1	*3*	*1*	*1*	*1*	*1*	*2*	*2*	*1*	*1*	*1*	*9*	*3*	*9*	*8*	*8*	*4*	*4*	*4*	*3*	*8*	*4*	*9*	*4*	*9*	*6*	*6*	*6*	*7*	*5*	*7*	*7*	*6*
4	*5*	*1*	*9*	*9*	*6*	*6*	*4*	*1*	*6*	*7*	*10*	*9*	*10*	*10*	*10*	*10*	*4*	*8*	*9*	*8*	*10*	*8*	*7*	*8*	*6*	*6*	*8*	*8*	*7*	*5*	*7*	*5*
0	*0*	*0*	*1*	*0*	*0*	*0*	*1*	*0*	*0*	*0*	*10*	*9*	*9*	*10*	*10*	*9*	*9*	*8*	*10*	*10*	*10*	*10*	*10*	*10*	*10*	*10*	*10*	*10*	*10*	*10*	*10*	*10*

6	6	6	6	5	6	7	6	5	6	6	10	10	0	3	3	3	3	3	10	6	6	9	9	9	9	9	9	9	9	9	9	9
8	9	9	9	9	9	8	7	8	9	9	10	10	10	10	10	10	10	10	10	10	8	4	2	4	4	2	4	2	5	5	4	4
0	6	0	8	7	0	6	0	3	3	0	10	3	10	3	3	10	4	10	7	0	0	5	5	5	5	5	5	5	5	5	5	5
3	5	4	8	4	8	1	4	1	2	2	1	5	10	5	3	4	10	3	10	2	5	2	1	2	2	1	0	0	1	1	5	2
0	2	0	5	5	3	3	7	9	2	5	9	7	10	5	3	7	6	4	2	8	3	10	6	10	5	5	10	4	8	1	10	5
7	8	3	7	6	10	9	10	5	10	9	2	2	4	3	9	3	8	2	8	2	2	3	3	9	5	7	2	9	2	9	2	2
3	3	3	3	4	3	3	2	3	3	3	3	3	3	3	4	3	3	2	3	3	3	4	4	4	3	4	4	4	0	4	4	4
10	1	10	6	5	7	8	4	5	0	0	10	1	10	6	5	7	8	4	5	0	0	10	10	10	10	10	10	10	10	10	10	10
10	7	10	5	10	10	7	7	7	10	10	10	7	10	5	10	10	7	7	7	10	10	0	1	0	0	0	0	0	0	1	0	0
10	3	2	3	5	1	4	0	1	5	5	10	3	2	3	5	1	4	0	1	5	5	8	4	3	2	4	3	4	2	2	4	4
10	2	10	6	10	8	10	10	2	10	10	10	2	10	6	10	8	10	10	2	10	10	10	5	10	7	5	10	10	10	0	10	5
5	6	7	3	8	6	3	4	5	10	10	5	6	7	3	8	6	3	4	5	10	10	10	10	10	9	10	10	10	10	9	10	10
9	0	6	0	4	9	7	4	0	9	9	9	0	6	0	4	9	7	4	0	9	9	10	5	8	2	6	9	5	8	3	9	9
10	6	10	10	3	10	8	9	10	10	10	10	6	10	10	3	10	8	9	10	10	10	10	10	10	9	10	10	10	10	10	10	10
10	7	10	7	7	8	7	6	6	8	7	10	7	10	7	7	8	7	6	6	8	7	10	10	10	9	9	10	10	10	9	10	10
10	0	5	5	5	5	9	10	2	9	4	10	0	5	5	5	5	9	10	2	9	4	5	5	5	5	7	5	5	5	5	5	5
7	10	10	7	10	8	10	9	10	4	3	7	10	10	7	10	8	10	9	10	4	3	10	9	10	10	10	10	10	9	10	10	9
10	4	8	5	6	10	10	7	8	8	8	10	4	8	5	6	10	10	7	8	8	8	10	10	4	7	8	8	10	10	7	0	3
9	9	10	8	9	10	9	10	6	9	10	9	9	10	8	9	10	9	10	6	9	10	9.5	6	10	7	9	8	9	9	8	10	10
6	0	4	0	0	0	0	8	0	0	0	3	0	0	0	1	3	0	4	0	2	2	5	2	2	1	1	5	2	5	2	3	3
9	9	5	5	10	0	6	10	7	7	10	9	9	5	5	10	0	6	0	7	7	10	0	4	2	5	2	3	2	5	3	3	2

DISCUSSION

Statistical analyses of the qualitative measure of pain were carried out by comparing the participants' average UPAT scores calculated at 1-hour post-patch, 5 days post-patch and 5 days post-medication with the corresponding (pre-patch) baseline scores. *On average there was a 44.1% reduction (from 5.72 to 3.20) in the average UPAT scores at 1-hour post-patch compared to pre-patch application*. This showed that there was a *highly statistically significant ($p < 0.001$)* reduction in the perception of pain in the painful areas as reflected in the UPAT scores when IceWave patches were applied to these areas 1-hour *post-patch* compared to baseline (pre-patch) with a statistical power of at least 98%. There was also a *highly statistically significant* (*$p < 0.001$*) reduction (an average of 44.4%, *from 5.72 to 3.18*) in the perception of pain in the painful areas 5 days *post-patch* application compared to baseline with a statistical power of 72%. The UPAT scores also indicated that there was a *statistically significant* (*$p < 0.05$*) reduction (an average of 32%, *from 5.72 to 3.88*) in the perception of pain in the painful areas 5 days *post-medication* compared to baseline with a statistical power of 86%. *These outcomes clearly demonstrate the more effective means of pain management as perceived by the participants who wore IceWave patches compared to the pain relief experienced when taking regular prescription and over the counter medications. As*

such, IceWave patches may prove a safe and effective alternative to these medications with superior performance for controlling pain.

Statistical analyses of the quantitative measure of pain were carried out by comparing the average infrared (IR) temperature reduction (hypothermic effect of IceWave patches) in the painful areas acquired at 1-hour post-patch, 5 days post-patch and 5 days post-medication with the corresponding (pre-patch) baseline IR values in the Thermal Imaging data. *On average there was a 2.5% reduction at 1-hour post-patch compared to baseline (from 31.5 ^{o}C to 30.1 ^{o}C) in the Thermal Imaging* data. This showed that there was a *statistically significant ($p < 0.05$)* reduction in IR temperature when IceWave patches were applied to the painful areas, at 1-hour post-patch compared to baseline (pre-patch) with a statistical power of at least 98%. There was *no statistically significant* (*$p < 0.15$*) reduction in the IR temperature in the painful areas 5 days post-patch application compared to pre-patch application, *even though on average there was a 1.5% reduction in IR temperature.* There was also *no statistically significant* (*$p < 0.5$*) reduction in the IR temperature in the painful area 5 days post-medication compared to pre-patch application. However, it is remarkable to note that there was not any reduction in the IR temperature for this condition as expected, but there was a 0.05% *increase* in the IR temperature in the painful areas 5 days after taking pain medications.

Statistical analyses of 2 movements (activities), carried out by the participants while wearing the IceWave patches or taking their pain medications for 5 days and based upon the data acquired from the PSFS questionnaire, revealed that there were *very significant differences* ($p<0.01$) between the level of pain while performing the movement and the baseline pain in the painful area (an *increase* of ~ 27 % in pain level for patches, and an *increase* of ~31% in pain level for pain medications compared to baseline due to moving the painful area.). This simply means that *movements exacerbated* the perceived pain level, regardless of applying IceWave patches or taking pain medicines for 5 days, even though wearing the patches made it slightly less painful (by 4%).

Statistical analyses of the answers to the 11 questions on the FAPC questionnaire related to the perceived level of pain by the participants in performing different tasks while wearing the IceWave patches or taking their pain medications for 5 days revealed that in general there were *no statistically significant differences* between the level of pain *while performing these* tasks compared to the baseline pain in the painful areas. This simply means that applying IceWave patches or taking pain medications for 5 days *did not improve the* perceived level of pain compared to baseline while performing these tasks. This could be interpreted as the ability of the IceWave patches and pain meds to ameliorate the qualitative and quantitative measures of pain even though they could *not eliminate the cause of pain while participant performed demanding tasks*.

CONCLUSION

The UPAT and IR Thermal Imaging results in this open-label, dual-center, crossover investigation clearly demonstrate the more effective means of pain reduction in painful areas achieved by the IceWave patches compared to regular prescription and over the counter medications. As such, IceWave patches may prove a safe and effective alternative to these medications with superior performance for controlling pain.

The PSFS results showed that *movements exacerbated* the perceived pain level, regardless of applying IceWave patches or taking pain medicines for 5 days, even though wearing the patches made it slightly less painful (by 4%).

The FAPC results revealed that in general there were *no statistically significant differences* between the level of pain *while performing a variety of demanding* tasks and the baseline pain in the painful areas. This could be interpreted as follows: usage of IceWave patches and pain meds could *not eliminate the cause of pain*; however, they were effective in ameliorating the qualitative and quantitative measures of pain.

References:

[1] http://www.lifewave.com. Retrieved July 2010.

[2] *The LifeWave Handbook: A Guide to Basic and Advanced Patch Use*. Page 11.

Appendix A

Patient-Specific Functional Scale (PSFS)

This useful questionnaire can be implemented to quantify activity limitation and measure functional outcome for patients with any orthopedic condition.

Clinician to read and fill in below: Complete at the end of the history and prior to physical examination.

Initial Assessment:

I am going to ask you to identify up to three important activities that you are unable to do or are having difficulty with as a result of your _____ problem. Today, are there any activities that you are unable to do or having difficulty with because of your_____ _____ problem(s)? (Clinician: show scale to patient and have the patient rate each activity).

Follow-up Assessments:

When I assessed you on (state previous assessment date), you told me that you had difficulty with (read all activities from list at a time). Today, do you still have difficulty with: (read and have patient score each item in the list)?

Patient-specific activity scoring scheme (Point to one number):

0 1 2 3 4 5 6 7 8 9 10

Unable to perform activity

Able to perform activity at the same level as before injury or problem

(Date and Score)

Activity	Initial					
1.						
2.						

3.						
4.						
5.						
Additional						
Additional						

Total score = sum of the activity scores/number of activities

Minimum detectable change (90%CI) for average score = 2 points

Minimum detectable change (90%CI) for single activity score = 3 points

PSFS developed by: Stratford, P., Gill, C., Westaway, M., & Binkley, J. (1995). Assessing disability and change on individual patients: a report of a patient specific measure. Physiotherapy Canada, 47, 258-263.

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Functional Activities Pain Checklist (FAPC)

CIRCLE the number that signifies your level of pain when you perform the tasks below:

1. What is the level of pain that you have when you scratch the top of your head?

0 1 2 3 4 5 6 7 8 9 10

2. What is the level of pain that you have when you bend over to touch your toes?

0 1 2 3 4 5 6 7 8 9 10

3. What is the level of pain that you have when you crumple this piece of paper?

0 1 2 3 4 5 6 7 8 9 10

4. What is your level of pain when you stand for 5 minutes?

0 1 2 3 4 5 6 7 8 9 10

5. What is your level of pain when you sit for 5 minutes?

0 1 2 3 4 5 6 7 8 9 10

6. What is your level of pain when you lift this book above your head?

0 1 2 3 4 5 6 7 8 9 10

7. What is your level of pain when you lean over into the position as if you spit tooth paste into the sink or wash your dishes?

0 1 2 3 4 5 6 7 8 9 10

8. What is your level of pain when you put your hand behind you to scratch your back?

0 1 2 3 4 5 6 7 8 9 10

9. What is your level of pain when you cross you leg to take off your shoe, stocking or sock?

0 1 2 3 4 5 6 7 8 9 10

10. What is your level of pain when you touch your chin to your chest?

0 1 2 3 4 5 6 7 8 9 10

11. What is your level of pain when you turn your head to the right and left?

0 1 2 3 4 5 6 7 8 9 10