The Treatment of Chronic Musculoskeletal Pain with PainPause

Abstract

Background

There is currently a lack of effective over the counter (OTC) pain relief products that address the challenges of treating serious and long-lasting pain referred to as chronic pain. The current study was a single arm Phase 2 clinical trial designed to test the efficacy and safety of PainPause, a novel OTC pain relief device to treat chronic musculoskeletal pain.

Objective

The objective of the study was to provide data on the clinical efficacy and safety of PainPause for treating chronic musculoskeletal pain including low back pain and sciatica, knee pain, and thoracic and shoulder pain.

Methods

Each Subject was treated with PainPause, which consists of arrays of miniature structures referred to as Micro-Points that are attached to an adhesive backing. Two devices were applied on the skin and intended to remain in place for 7 days.

The level of pain was measured using the VAS Scoring System where level of pain is scored from 0-10. Subjects reported their pain scores before treatment on Day 0 and then on Days 1, 3, 5, and 7. On Day 7, they also reported their average pain score for the week of the study. A determination was made whether Subjects achieved more than a 30% reduction in their pain score which is considered clinically significant and often used to measure the efficacy of pain treatments.

Statistical analysis was performed using a Student's t test.

Subjects were monitored for adverse events during the study.

Results

Thirty-seven (37) elderly Subjects enrolled in the study – 20 Subjects with low back pain and /or sciatica, 11 with thoracic or shoulder pain, and 6 with knee pain. The mean baseline pain score at Day 0 was 5.8+/-1.8. The Day 1 median score was 2.4+/-2.0 representing a 59% decrease. Pain scores decreased by a range of 47-48% on Days 3, 5, and 7. Compared to Day 0, the reduction in pain scores was highly significant ($p<0.001$) at all time points, and for the average score that Subjects rated for the week of the study. In the study, 67-75% of Subjects on Days 1, 3, 5, 7 demonstrated clinically significant pain relief, while 81% met this endpoint for their average pain level over the week on the study.

There were four minor adverse events in the study including 2 Subjects complaining of pinching, one with discomfort, and another with itching.

Conclusion

PainPause was demonstrated to be a safe and effective product to treat chronic pain due to multiple musculoskeletal conditions. It provided durable pain relief for the one-week duration of the study in most Subjects. It was also shown to be effective in treating severe pain, common in patients with chronic pain. Clinical results were highly significant ($p<0.001$) for all measurable endpoints and the effectiveness of the product was demonstrated to be superior to other treatments for chronic pain.

Background

Chronic pain is a major clinical problem that affects one in five Americans amounting to over 50 million people.[1-5] The pain affects nearly all aspects of a person's life, including their quality of life, mental and emotional well-being (over 80% suffer from depression), and disability.[1-7] Musculoskeletal disorders comprise 80% of people with chronic pain.[1] The leading causes are back pain followed by knee pain which together comprise the majority of Americans with chronic musculoskeletal pain.[1,2,8]

Most people with chronic pain have failed multiple healthcare treatments (surgery, steroid injections, opioids, PT, etc.) and suffer with long-standing pain for many years.[9-18] Many make attempts to treat their ongoing pain themselves using over the counter (OTC) consumer products. However, these products only provide temporary pain relief for a few hours and are unable to treat the severe pain experienced by many people with chronic pain.[19-27]

It was recently discovered that the microMend® wound closure product (KitoTech Medical, Seattle, WA) was able to provide pain relief in people with musculoskeletal pain. microMend was originally designed as a product to close wounds.[28] microMend is applied just like a bandage. They are able to anchor the device to the skin for 7-10 days. microMend has been tested in the clinic where it was been demonstrated to be safe and effective in closing wounds.[23] The device is available in both the consumer and medical markets and has an excellent safety record with no reported serious adverse events.

The same microMend product was discovered to provide pain relief. It was previously tested in over 50 people with a variety of acute and chronic musculoskeletal conditions. These included back pain and sciatica, neck pain, knee pain, shoulder pain, trigger points (myofascial syndrome), osteoarthritis, carpal tunnel syndrome, and tennis elbow. Significant pain relief was reported in all of these conditions after treatment with microMend. The results of these studies led to the development of microMend as a pain relief product which is referred to as PainPause (KitoTech Medical, Seattle, WA).

PainPause was recently introduced onto the consumer market as a non-prescription over the counter (OTC) product to treat painful musculoskeletal disorders. In the current Phase 2 clinical study, we evaluated the safety and efficacy of PainPause to treat people with chronic pain due to musculoskeletal disorders.

Materials and Methods

Materials

PainPause is an identical device to microMend. It incorporates arrays of miniature metal Micro-Points which are incorporated into an adhesive backing for application to skin (Figure 1). The device is similar in shape and dimensions to a butterfly closure bandage. PainPause is applied to the skin just like a patch. The Micro-Points are 1 mm in length and reach the upper dermal skin layer. When microMend is applied, the Micro-Points penetrate the skin where they provide force on mechanical receptors which are located in this layer. Force activates the receptors which stimulate nerves that block pain signals and prevent them from reaching the brain. In addition, the Micro-Points act to provide secure attachment of the device to the skin which allows it to remain in place for 7-10 days.

Methods

Thirty-seven (37) Subjects with chronic low back pain and / or sciatica, knee pain, thoracic pain, and shoulder pain were entered in the study. On Day 0, each Subject received a single treatment with 2 PainPause devices (Figure 1) which were applied on the skin. A cover was then placed over them which was to remain in place while the devices remained on the skin. For Subjects with spinal pain (lower back pain, sciatica, and thoracic back pain), the devices were applied adjacent to the spine on the side with pain. For pain at other locations, the device was applied over the painful area (e.g., shoulder). The study was intended to have the devices remain in place for 7 days. All devices were applied by the clinical staff and removed by the Subjects. The study duration was one week.

Subjects were required to rate their pain level between 0 and 10 using the Visual Analog Scale VAS), a standard system used to measure pain.[24,25] A higher pain score indicates a higher level of pain with 0 being no pain and 10 being the worst pain imaginable. Subjects reported their baseline pain prior to treatment at Day 0 (day of treatment) and then on Days 1, 3, 5, and 7. On the last day of the study (Day 7), Subjects reported their average pain score during the week on the study.

In addition to determining whether Subjects experienced any pain relief, an assessment was made whether Subjects achieved a more than 30% decrease in their pain score at each timepoint and for the week on the study. This is an important endpoint referred to as clinically significant pain relief. It is used by the FDA and pain management specialists to measure the efficacy of treatments for pain.[26-31]

Statistical analysis using a Students t-test was used to determine differences in pain scores at different time points in Subjects. Adverse events were monitored during the study including local effects on the skin at the site of application as well as any other effects related to treatment with the devices.

Results and Discussion

Of the 37 Subjects with chronic musculoskeletal pain, there were 20 with low back pain and / or sciatica, 11 with thoracic or shoulder pain, and 6 with knee pain. Subjects were elderly (mean of 72 years old) and there were 20 female and 17 male Subjects. They had longstanding pain averaging 5 years in duration. PainPause was worn by Subjects for an average of 6 days. Out of the 37 enrolled Subjects, 36, 33, 30, and 30 reported their pain scores and were evaluable on Days 1, 3, 5, and 7, respectively. Thirty-six (36) reported their average scores for the week on the study.

On Day 0, baseline VAS scores before treatment ranged from 4 to 10 indicating Subjects had moderate to severe pain. The mean VAS score on Day 0 was 5.8+/-1.8 (Figure 2 and Table 1). The Day 1 score was 2.4+/-2.0 representing a 59% decrease in the average pain score. On Days 3, 5, and 7, pain scores were 3.1+/-2.2, 3.1+/2.2, and 3.0+/-2.9, respectively, corresponding to average decreases of pain that ranged from 47-48%. Compared to Day 0, the reduction in pain scores was highly significant ($p<0.001$) at all time points (Days 1, 3, 5, and 7). There was no statistically significant difference between pain scores at Days 1, 3, 5, and 7. Subjects rated their average pain score for the week at 2.6+/-2.0 which was also significantly lower than Day 0 ($p<0.001$). This translated into a 55% decrease in pain score. Ninety percent (92%) of Subjects reported a reduction in their average pain score for the week on the study (data not shown).

An important clinical endpoint in studies of pain is clinically significant pain relief which is defined as more than a 30% decrease in pain scores with treatment.[29-36] This level of pain reduction correlates with improved quality of life and decreased disability. It is an endpoint used by the FDA and pain management specialists to determine the efficacy of treatments for pain. In the current study, 67-75% of the Subjects at Days 1,3, 5, and 7 demonstrated clinically significant pain relief (Figure 3). These results demonstrated that pain relief does not dissipate over time which indicates that the effects are durable and suggests that tolerance does not develop to treatment. Consistent with the results described above, 81% of Subjects rated their average pain score during the week on study that demonstrated clinically significant pain relief (Figure 3).

The fraction of Subjects achieving clinically significant pain relief compares favorably with current healthcare treatments for treating chronic pain. A recent publication summarized data on the efficacy of a variety of treatments including surgery, steroid injections, physical therapy, opioids and other prescription drugs, and non-steroidal anti-inflammatory drugs.[17] Clinically significant pain relief was demonstrated in a range of only 5-25% of patients with these treatments, much lower than the percent of Subjects treated with PainPause in the current study.

There were no significant differences in any of the endpoints of the study between Subjects with low back pain / sciatica, thoracic and shoulder pain, and knee pain (data not shown). There was no relationship between the severity of pain prior to treatment at Day 0 and pain relief. Eighty two percent (82%) of Subjects (9 out of 11) with severe pain (pain score: ≥ 7) demonstrated clinically significant pain relief during the week on treatment compared to 84% of Subjects (21 out of 25) with moderate pain (pain score: <7) (data not shown). There was also no correlation between the duration of chronic pain and clinically significant pain relief (data not shown).

The study results are especially noteworthy given that the Subjects were elderly, and many suffered with severe pain. The elderly population have the highest frequency of chronic pain.[1] They are difficult to treat due to co-morbid conditions preventing use of many treatments and they respond poorly to most therapies.[37-40]

Four (4) out of the 37 Subjects reported minor adverse events. They included two Subjects with two complaints of pinching of the Micro-Points, one with discomfort and one with itching at the site where the PainPause was on the skin. There were no other reported adverse events.

PainPause provides several benefits over currently available over the counter (OTC) consumer pain relief products used to treat pain.[19-27] Current products provide only modest analgesic effects and are primarily used to treat mild pain. In contrast, PainPause is effective in treating severe pain which is experienced by many people with chronic pain. In the current study, a single treatment with PainPause provided pain relief in the majority of Subjects for a week. In contrast, other OTC treatments including topical products and non-prescription drugs are only able to provide pain relief for a few hours. This makes them of limited use for treating long-term pain.

Most OTC pain relief products contain drugs or chemicals which are associated with safety risks.[41-50] Many people self-medicate and take excess amounts of these agents that can be harmful to them.[45] Non-steroidal anti-inflammatory drugs (NSAIDs) are the most common pain relief medications (e.g., Aleve®, Advil®). They carry many safety risks which include gastrointestinal bleeding, hypertension, renal insufficiency, cardiac complications and others.[46-48] These risks increase significantly with long-term use of these drugs for even a few weeks.

Topical products including skin patches (e.g., Salonpas®, Icy Hot®), gels (e.g. Voltaren Gel®), and creams and ointments (e.g., Bengay®, Aspercreme®). Local skin reactions occur with several topical products that can be severe in some cases.[49] Of more concern is the systemic risks of these products. For example, several contain NSAIDs, which can cause the same problems observed with these drugs when orally administered. As with the oral formulations, long-term use of topical products containing NSAIDs and other drugs is contraindicated making it problematic to use them for treating chronic pain. Recently, Lidocaine, one of the common drugs in topical products including skin patches, ointments and creams has been the subject of FDA warnings due the dangers of using it especially with long-term use.[50] In contrast, PainPause contains no drugs or chemicals and is a safe and well-tolerated product as demonstrated in the current study.

Summary

This clinical study provides strong evidence of the safety and efficacy of PainPause in treating chronic musculoskeletal pain. Clinically significant pain relief (>30% decrease in pain score) was demonstrated in the majority of the Subjects (67-75%) at each measured time point as well as the average over the week of the study (81%). Results were highly significant ($p<0.001$), similar at all time points, and pain relief did not decrease over the one-week study. In the study, similar pain relief was demonstrated in several different musculoskeletal disorders and independent of duration of pain or its severity. In addition, PainPause contains no drugs or chemicals and was

demonstrated to be safe in the study. With all of these attributes, it has the potential to treat many people who suffer from chronic musculoskeletal pain.

Additional studies are planned to confirm the findings in this study and test the product in other painful musculoskeletal conditions.

References

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Figures and Table

Figure 1

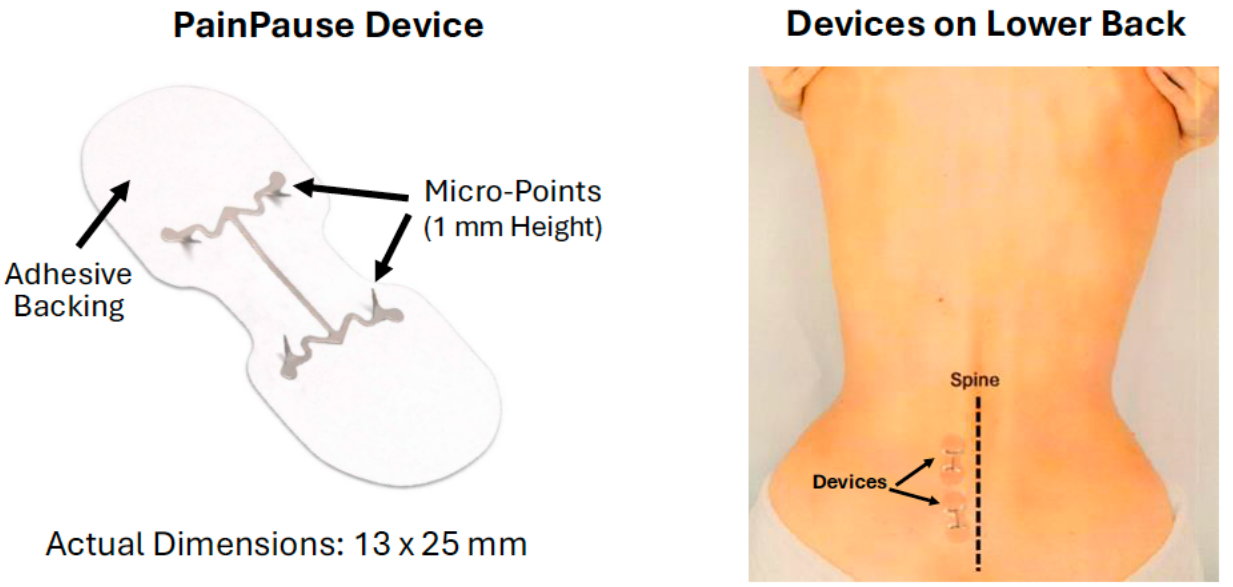


Figure 2

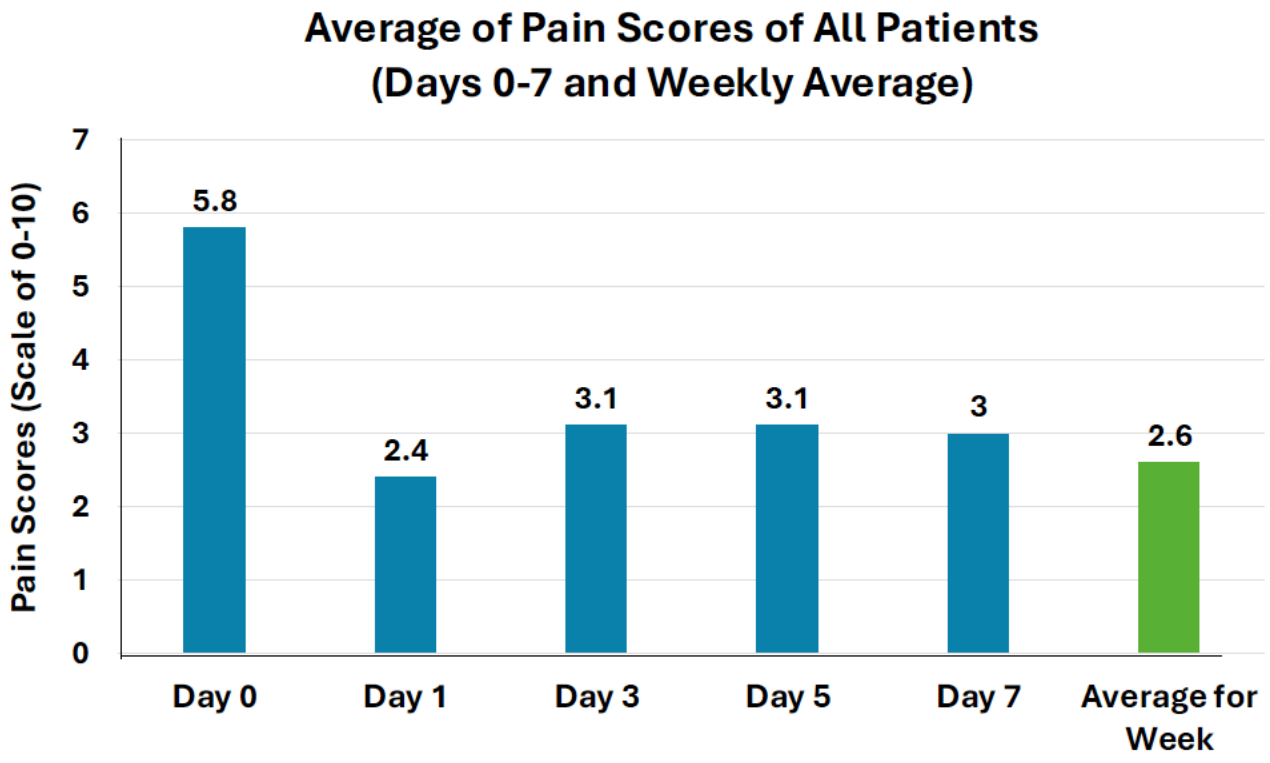


Figure 3

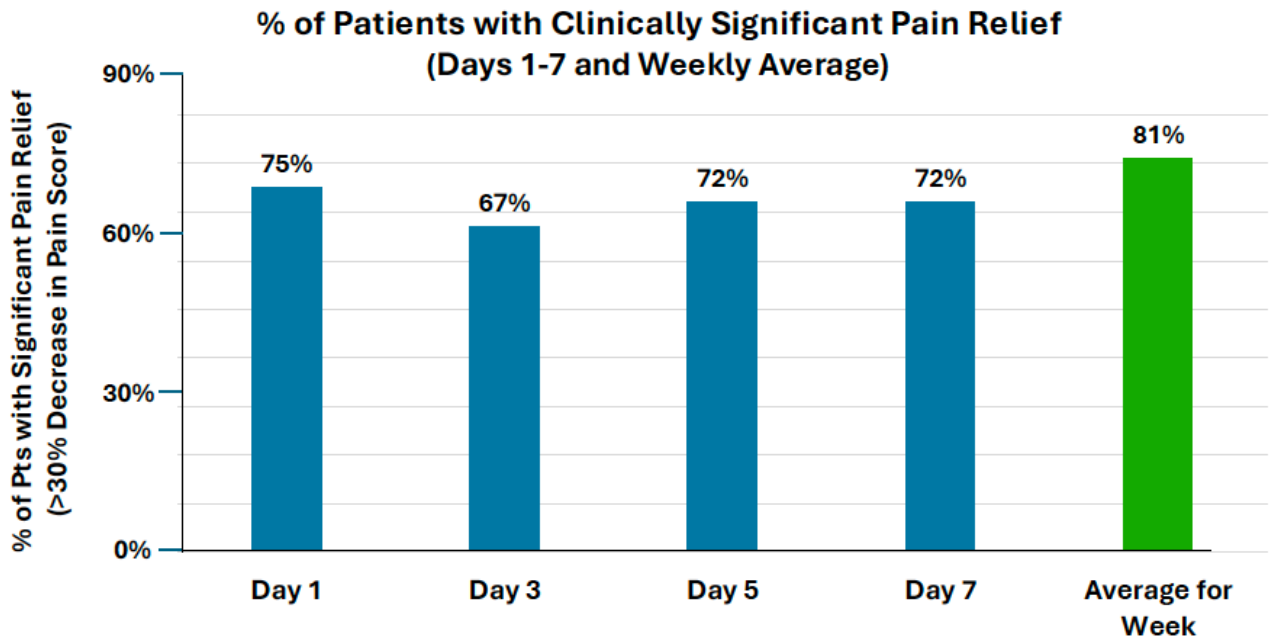


Table 1. Median and % Decrease in Pain Scores (Days 0-7 and for Week)

	Day 0	Day 1	Day 3	Day 5	Day 7	Average for Week
Mean (% Decrease)	**5.8** +/-1.8	**2.4** +/-2.0 **(-59%)** P<0.001	**3.1** +/-2.2 **(-47%)** P<0.001	**3.1** +/-2.2 **(-47%)** P<0.001	**3** +/-2.9 **(-48%)** P<0.001	**2.6** +/-2.0 **(-55%)** P<0.001