

## Thermal-Aid Use for the Treatment and Management of Pain: A Four-Month Study

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### Abstract

**Background:** **Thermal-Aid** is an effective therapeutic modality that can both administer cold and heat therapy. More specifically it is four pounds of an all natural corn product packaged within a cotton twill bag that can be placed in the freezer for cold therapy applications or heated in a microwave for three minutes for heat therapy applications. Two objectives were assessed. The first measured objective was whether the use of **Thermal-Aid** was a more effective pain reliever than the hydrocollator. The second measured objective was the quantitative use of pain medications by the study participants who were using **Thermal-Aid** therapy.

**Objective:** In this study the effectiveness and safety of Thermal-aid was assessed for the treatment and management of pain in the extended care facility.

**Methods:** 96 adults with mild, moderate, and severe osteoarthritis were randomized for twice daily treatment with **Thermal-Aid**, acetaminophen, and NSAIDS or hydrocollators, acetaminophen, and NSAIDS. Treatment was given as needed for 24 weeks. A patient survey monitoring pain control on a five point scale (1, very good; 2, good; 3, moderate; 4, poor; 5, very poor), and the percentage of days with decreased use of pain medications were the outcome measures.

**Results:** The **Thermal-Aid** group reported a 35.3% improvement in pain control, a 21.8% decrease in acetaminophen usage, and a 21.3% decrease in the use of NSAIDS.

**Conclusions:** **Thermal-Aid** is an effective, well-tolerated, and cost-effective treatment for varying degrees of osteoarthritis in adults. Based on self-assessment surveys, pain control was better with **Thermal-Aid** leading to an improvement in quality of life. Also, it substantially reduced the need for pain medications when compared to conventional therapy.

### Introduction

Since the 1960s, treatment of osteoarthritis has combined the use of hydrocollators and pain medications. Hydrocollators and pain medications are effective in the treatment of osteoarthritis. However, hydrocollators are used primarily in physical therapy departments. They are bulky, require constant maintenance, can cause cutaneous burns, and are not patient friendly, especially to the geriatric population. In addition, pain medications are becoming more costly and many have multiple side effects which make some patients and doctors hesitant to use them for the long-term. Difficulty of use, cost, and side-effects are legitimate concerns of patients and doctors.

**Thermal-Aid** offers a novel, portable, safe, cost-effective approach to the long-term future management of osteoarthritis. It can be used as mono therapy or in conjunction with other prescribed modalities. It is an all natural corn product packaged within a malleable cotton twill bag that conforms to all body regions. It can be placed in an ordinary microwave and heated for 3 to 4 minutes. Upon removal from the microwave its average temperature is 158 degrees Fahrenheit. It maintains its heat capacity for greater than one hour with an average temperature of approximately 140 degrees Fahrenheit. Upon removal from a household freezer its average temperature is 14 degrees Fahrenheit. It maintains its cold capacity for greater than one hour with an average temperature of approximately 30 degrees Fahrenheit. Its mode of action is the delivery of a deep penetrating heat or cold to soft-tissue structures and body joints. It safely and comfortably transfers heat and cold without causing cutaneous burns or frostbite.

This study investigated whether **Thermal-Aid** was more effective at pain relief than the conventional hydrocollator. Also, measured was the decreased percentage of acetaminophen and NSAID usage.

## Participants

### Study Design

This was a randomized, parallel-group, multi-center study in 4 extended care facilities. Patients were recruited from July 2003 to December 2003, and in total, 96 adult patients, ages 58 to 96, with a clinical diagnosis of osteoarthritis, were randomized, 1:1, to receive treatment as needed over 16 weeks with either **Thermal-Aid**, acetaminophen, and NSAIDS, or hydrocollator, acetaminophen, and NSAIDS.

### Inclusion Criteria

Patients were required to have osteoarthritis affecting at least two major joints or one joint and the spine.

### Exclusion Criteria

Patients with dementia or other vascular insults that inhibited their ability to understand and complete the pain quantification survey. Patients with previous GI bleed or kidney disease.

### Planned Interventions

Patients applied the **Thermal-Aid** pack or the hydrocollator pads to the affected areas twice daily for 20 to 30 minutes. Acetaminophen and NSAIDS were used in conjunction and given as per patient request. If a patient requested twice daily NSAID and thrice daily acetaminophen for three consecutive days they were then given the medications routine for one week. Their pain was re-evaluated and the patients were then placed back on the P.R.N. schedule. If for a second time they requested the full dose of acetaminophen and NSAIDS for three consecutive days they were then maintained on a routine medication schedule for the remainder of the study. Patients were given pain surveys upon entering the study thus establishing their baseline. The patients completed additional pain surveys at 4, 8, and 16 weeks.

### Primary and Secondary Outcome Measures

The primary efficacy endpoint was the percentage decrease in pain of the **Thermal-Aid** group. This endpoint reflected the design of the study in which the principal aim was to assess the

efficacy of **Thermal-Aid** in comparison to the hydrocullator. Secondary outcome measures included the quantification of decreased use of acetaminophen and NSAIDS.

## **Results**

### **Patients**

Of the 96 patients from the 4 extended care facilities who were randomized for treatment, 48 were randomized to the **Thermal-Aid** group and 48 to the hydrocullator control group. Each patient had 2 major joints or one major joint and the spine affected by osteoarthritis. The first table shows the study demographics. The second table shows the pain survey results. The third table shows the medication usage.

### **DEMOGRAPHICS**

		Thermal-Aid	Control
Age, Years	Median	73.4	72.6
	Range	60-95	58-96
Sex	Male	15	18
	Female	33	30

**PAIN CONTROL SURVEY:** Please rate how well controlled your arthritis pain is?  
Scale (1, very good; 2, good; 3, moderate; 4, poor; 5, very poor)

	Thermal-Aid	Control
Baseline	3.12	3.34
Week 4	2.34	2.98
Week 8	2.10	2.85
Week 16	2.02	2.82

**MEDICATION USAGE:** Acetaminophen numerator 0-3 / denominator 3  
NSAID numerator 0-2 / denominator 2

		Thermal-Aid	Control
Baseline	Acetaminophen	78%	74%
	NSAIDS	75%	80%
Week 4	Acetaminophen	64%	71%
	NSAIDS	65%	76%
Week 8	Acetaminophen	62%	70%
	NSAIDS	62%	74%
Week 16	Acetaminophen	61%	71%
	NSAIDS	59%	73%

### **Efficacy**

Treatment with **Thermal-Aid** was associated with a significant reduction in pain as quantified by a 35.3% measured improvement on the pain survey. The hydrocullator control group showed a mild 15.6% improvement.

Medication usage significantly dropped in the **Thermal-Aid** group. There was a 21.8% decline in the use of acetaminophen vs. a 4.1% decline in the hydrocollator control group. There was a 21.3% decline in the use of NSAIDS in the Thermal-aid group vs. a 8.8% decline in the hydrocollator control group.

### Safety

**Thermal-Aid** treatment was well tolerated. There were no side-effects. Several of the study participants requested to use the **Thermal-Aid** pack more than twice daily, but for study conformity were denied.

### Discussion/Conclusion

The results of this 4 month study demonstrate conclusively that **Thermal-Aid** is more effective for pain management than conventional hydrocollator treatment for osteoarthritis. Treatment with a **Thermal-Aid** pack reduced and in some cases eliminated the need for pain medications. Over 20 % of the patients in this study reduced or eliminated the use of their pain medications. The **Thermal-Aid** group noted a 35.3 % improvement in pain reduction.

The **Thermal-Aid** pack offers a portable, safe, and effective alternative for the management of pain caused by osteoarthritis.

### Time Study for Temperature Retainment

**Duration:** Four-month study (2004).

**Testing devices:** standard hydrocollator, microwave (900 watt) and 12 degree Fahrenheit freezer.

\* A five-minute equilibration period for base line temperature stabilization.

\* Application 3 times daily.

\* All measurements recorded in degrees Fahrenheit.

\*\*\*Note: Comparable heating and cooling products consist of hydrocollator, gel pack, herb pack, grain/rice pack and seed pack. All products similar in size. **The brand names of the products tested have been omitted. All products tested were purchased at the following retail locations: Walgreens, Wal-Mart, Rite-Aid, Save-On, Eckerd, Target and others.**

**Study performed by:** Dr. David E. Toomey DO, Toomey & Toomey Medical Group, Lancaster, PA.

#### **Thermal Aid- 3.5 lbs. Engineered grain:**

**Heat:** 3 minutes in microwave. The products' initial temperature was 158 degrees after heating, and slowly dropped to 142 degrees after one hour.

**Cold:** A minimum of 4 hours in a 12-degree freezer. The products' initial temperature was 13 degrees and rose to a temperature of 29 degrees after one hour.

The product is easily applied and effective for all areas, including soft tissue and large, medium and small joints. Outer cotton pouch allows comfortable hot and cold transference. The product is easy to use, readily conforms to all body parts and is an effective moist heating agent as well as a cooling agent. There are no frostbite or burn issues. A wrap is not necessary between product and patient. **Product cleanable and reusable.**

#### **Hydrocollator- 7 to 10 lbs:**

**Heat:** Pre-heated water for one hour, to a temperature of 160 degrees. Pad requires a one-

hour heat-up time. The temperature of pad went from 160 degrees to 140 degrees in 30 minutes, and then became ineffective as a therapeutic heating agent.

**Cold:** Chilled water to 40 degrees. Pad requires a two-hour immersion to reach optimum application temperature. The pad temperature rose from 40 degrees to 50 degrees in 30 minutes, and then became ineffective as a therapeutic cooling tool.

Product effective for large areas only. Produces moist heat, which is more effective for large areas. Limited usefulness for soft tissue, small and medium joints. Uncomfortable both hot and cold when in direct contact with patients' skin. Requires wrapping in towel prior to application, which increases bulkiness and impedes hot and cold transference.

Required: Prep time, cleaning and regular maintenance for 2 to 2.5 hours monthly.

Note: mold/fungi issues present. **Product washable/cleanable and reusable.**

### **Gel pack- .5 lbs. (large pack):**

**Heat:** 105 seconds (three X 35-second intervals, per instructions). The initial product temperature was 165 degrees, and quickly dropped to a temperature of 129 degrees after one hour.

**Cold:** A minimum of 4 hours in a 12-degree freezer. The products' initial temperature was 3 degrees and only rose to a temperature of 12 degrees after one hour.

Product is effective for large and small areas. It's uncomfortable hot and cold when in direct contact with patients' skin. Very lightweight and can pinpoint small and large joints as well as soft tissue, however, the product needs to be strapped on and/or pressure to be applied for application success. The extreme hot and cold of this product makes the use of a wrap necessary between patient and product. The Product does not readily conform when cold. May cause frostbite (cold) and/or burn (hot and cold). **Washable/cleanable and reusable.**

### **Herb Pack- 1.5 lbs. scented and unscented:**

**Heat:** 1.5 minutes in microwave as directed by instructions. The products' initial temperature was 178 degrees and dropped to a temperature of 136 degrees after one hour.

**Cold:** 12 degrees for a minimum of 4 hours. The products' initial temperature was 12 degrees and rose to a temperature of 36 degrees after one hour.

Product not effective. Heat process over 160 degrees not recommended. Product also became dried out after the 6th heating session. An oven mitt was required when removing this product from the microwave due to extreme heat. The product did not heat or cool uniformly. On the 6th day the product began to have a bad aroma. The product was opened after the 11th day and the herbs had become brown/black. Visible fungi was prevalent throughout the inner contents on the 20th day. It was then determined that testing on the herb pack should terminate. **Product not washable/cleanable.**

### **Rice pack- 3 lbs:**

**Heat:** 3 minutes. The products' initial temperature was 165 degrees and dropped to a temperature of 121 degrees after one hour.

**Cold:** 12 degrees for a minimum of 4 hours. The products' initial temperature was 12 degrees and rose to a temperature of 39 degrees after one hour.

The product was effective for a very short period of time, and did not heat or cool uniformly. The product became dried out after 6th heating session, and began to have a bad aroma after 7th day. The product was opened after the 9th day and visible fungi was prevalent throughout the inner contents. It was then determined that testing on the product should terminate.

**Product not washable/cleanable.**

#### **Oat pack- 2 lbs:**

**Heat:** 3 minutes. The products initial temperature was 169 degrees, and dropped to 129 degrees after one hour.

**Cold:** 12 degrees for a minimum of 4 hours. The product initial temperature was 8 degrees, and rose to a temperature of 36 degrees after one hour.

The product did not heat or cool uniformly, was very dry, and was ineffective. After 4 days the product began to have a bad aroma, and after 6th day it began to turn brown. The product was opened on the 8th day and visible fungi was prevalent throughout the inner contents. It was then determined that testing on the product should terminate. **Product not washable/cleanable.**

#### **Barley pack- 3 lbs:**

**Heat:** 3 minutes. The products' initial temperature was 140 degrees and dropped to a temperature of 115 degrees after one hour.

**Cold:** 12 degrees for a minimum of 4 hours. The products initial temperature was 17 degrees and rose to a temperature of 38 degrees after one hour.

The product was not effective. The product was very dry, did not heat uniformly and on the 10th day the product began to have a bad aroma. On the 15th day the product was opened, and had begun to turn brown/black. On the 16th day visible fungi was prevalent throughout the inner contents. It was then determined that testing on the product should terminate.

**Product not washable/cleanable.**

#### **Corn (feed corn, Indian corn, cracked corn)- 3.5 lbs:**

**Heat:** 3 minutes. The products' initial temperature was 160 degrees and dropped to a temperature of 130 degrees after one hour.

**Cold:** 12 degrees for a minimum of 4 hours. The products' initial temperature was 16 degrees, and rose to a temperature of 35 degrees after one hour.

The product was effective for all areas including soft tissue and large, medium and small joints. Slight aroma of corn. The product did not heat uniformly. Easy application, patient friendly and conforms to all body parts. Outer cotton pouch allows comfortable hot and cold transference. Effective when heated. Dry cold. No frostbite or burn issues. No wrap necessary. Occasional popping will occur. On the 20th day the product was opened and visible fungi was prevalent in the cracks of the corn. It was then determined that testing on the product should terminate. **Product not washable/cleanable.**

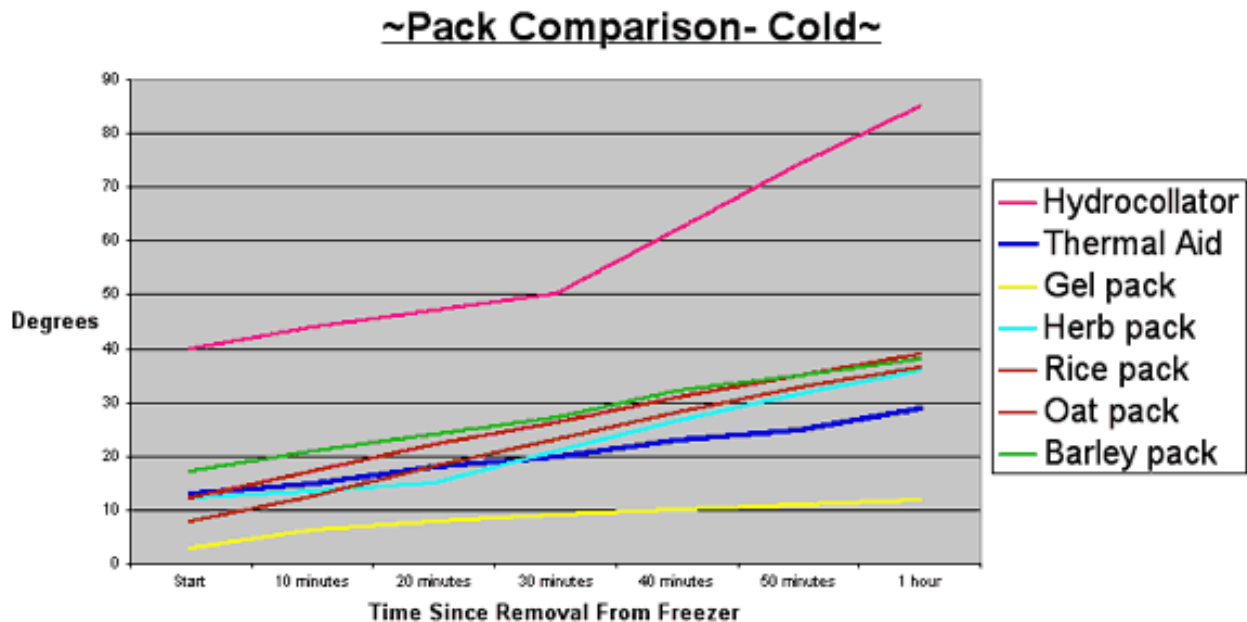
## Conclusion of Product Testing

After four months of testing, it was concluded that most products on the market today are not only sub-standard but are also dangerous to the patient. Testing on the herb pack, rice pack, oat pack, barley pack and corn pack was terminated prior to completing the four-month term due to in-effectiveness, temperature safety and fungi growth. Only three products in the test group are suitable to be used on patients. These three products are:

**Thermal Aid**- This 100% natural product is effective for all areas, including soft tissue and large, medium and small joints. The product maintained heat and cold within the therapeutic range, longer than any of the other products tested. This product performed better overall than all the other products tested, is very economical, was the most patient-friendly and had no apparent drawbacks.

**Hydrocollator**- Unlike all the other products this one has a very high initial expense. Is stable in regards to temperature retainment for 30-minute treatments. Product is effective for large areas or large joints. The product has its drawbacks, including its lack of conformity, its heavy and bulky and is too large to be used effectively on soft tissue, and small and medium joints. This product is outdated and requires prep time as well as regular maintenance.

**Gel pack**- This product is economical and effective for all areas but caution must be exercised when application is initiated. This product is more effective when a delay (10-minute for hot; 15-minute for cold) is initiated prior to applying, and when direct pressure is applied during the treatment. This product must not be in direct contact with the patients' skin, and a required wrap significantly reduces the product's effectiveness.



### ~Pack Comparison- Hot~

