Angelini Pharma

ThermaCare®
HEATWRAPS

In Partnership With

Irish Society of Chartered Physiotherapists
The Voice of Physiotherapy in Ireland

Key Facts & Clinical Data

for all Healthcare Professionals (HCPs)

Thermacare the pioneers of heal cell technology.

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Contents

Part 1

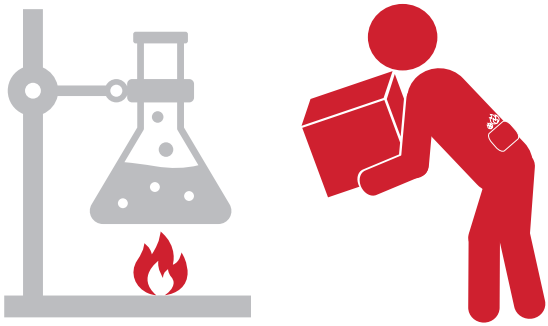
Mechanism of action of Thermacare

Mechanism of action of Thermacare device

1. In every cell of every patch of Thermacare there is a mixture (called **FUEL** by technicians) of compounds that includes: iron, carbon, water and several salts.[1]

2. When the pouch of any Thermacare wrap is opened, oxygen in the air reacts with **FUEL**, causing an exothermic reaction, based on the oxidation of iron.[1]

3. The exact composition of **FUEL** (tested over years) allows the device to provide a constant temperature of 40 degrees for 8 hours on the applied region of the body[2]



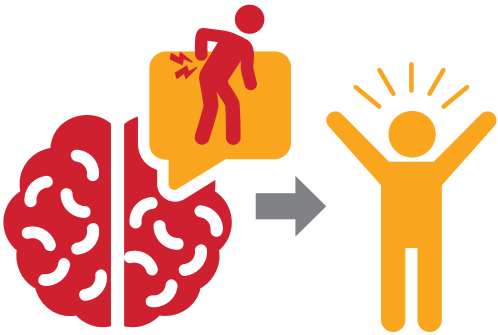
1. *Procter and Gamble company: "Development report -Issue #2- Thermacare" 2002*
2. *Pfizer Company: "Clinical Evaluation Report Thermacare Heat-wrap Version 3.0" 2019*

Mechanism of action of heat therapy

1. The constant application of a source of heat is able to modulate the transmission of the nervous impulse to the brain, reducing the perception of pain.
   Stimulation of thermoceptors interferes and reduces pain signalling of nociceptors to the brain (direct analgesic action) [1,2]

2. The modulation of the pain-signalling causes a muscle relaxation improving the pain relief.
   Less pain from muscles to brain = less contraction from brain to muscles = more pain relief (indirect analgesic action) [1]

3. A source of constant heating is able to cause a vasodilation, which allows and speeds up the elimination of many molecules produced by inflammation process, which are responsible for part of the painful feeling (indirect analgesic action) [2,3]



1. *Nadler F., Weingand K., Kruse R.J: "The physiologic basis and clinical applications of cryotherapy and thermotherapy for the pain practitioner". Pain Physician 2004; 7:395-299*
2. *Petrofsky J.S., Bains G., Raju C., Lohmann E., Berk L., Prowse M., Gunda S., Madani P., BattJ.: "The of the moisture content of a local heat source on the blood flow response of the skin". Arch Dermatol Res 2009; 301:581-585*
3. *Lepak V.: "Localized Inflammation" in "Physical Rehabilitation" 1st edition 2007, cured by Cameron M., Monroe L. edited by Saunders-Elsevier*

Part 2

Clinical data of Thermacare in Lower Back Pain

Clinical data of Thermacare in Lower Back Pain

Lower back pain

Lower back pain (LBP) has been described as a 20th century medical disaster. LBP commonly occurs in the general population, with an annual incidence of 5% and a lifetime prevalence of 60% to 90%. Approximately one half of the patients seen in the primary care setting self-treat for a given episode of lower back pain before their first visit.(1)

CLINICAL TRIALS

1). Nadler 2002 – Thermacare compared to Ibuprofen and Acetaminophen (Paracetamol) in non-specific lower back pain

Thermacare provides significantly greater pain relief than Acetaminophen (Paracetamol) and Ibuprofen, up to 16 hours of pain relief

2). Nadler 2003 - Thermacare in non-specific lower back pain

Thermacare provides significantly greater pain relief than placebo, up to 16 hours of pain relief

3). Nadler 2003 – Thermacare used overnight in non-specific lower back pain

Thermacare provides significantly greater pain relief than placebo, up to 16 hours of pain relief

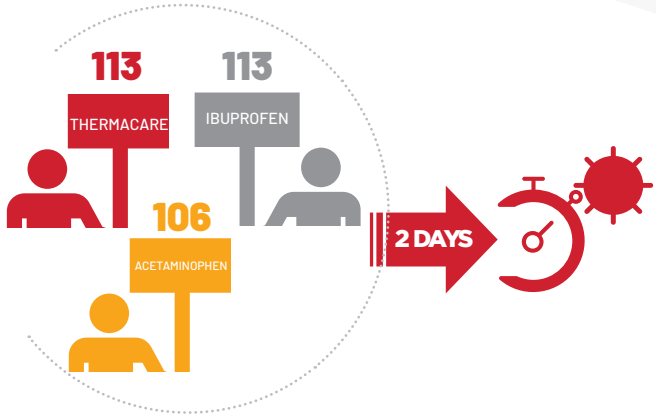
CLINICAL TRIALS (detailed presentation)

1). Nadler S.F., Steiner D. J., Erasala G.N., Hengehold D.A., Hinkle R.T., Goodale M.B, Abeln S.B, Weingand K.W.: "Continuous Low-Level Heat Wrap Therapy Provides More Efficacy Than Ibuprofen and Acetaminophen (Paracetamol) for Acute Lower Back Pain" *Spine 2002; 27(10): 1012-1017*

113 patients treated with **Thermacare** (1 wrap per day), 113 patients treated with Ibuprofen (1200 mg per day), 106 patients treated with Acetaminophen (Paracetamol) (4000 mg per day). All treatments were administered for 2 days with 2 days of follow up.

RESULTS:

- The Day 1 mean pain relief score for the heat wrap was significantly higher than Acetaminophen (Paracetamol) (P=0.0001) and higher than Ibuprofen (P=0.0007).
- Significant differences (P 0.05) were observed at every individual hourly time points of Day 1.
- The Day 2 main pain relief score for the heat wrap was significantly higher than Acetaminophen (Paracetamol) (P=0.0001) and higher than Ibuprofen (P=0.0001).
- The mean "extended" pain relief score for Days 3 to 4 for the heat wrap was significantly higher than Acetaminophen (Paracetamol) (P=0.0009) and higher than Ibuprofen (P=0.0001).



1. *Nadler S.F., Steiner D. J., Erasala G.N., Hengehold D.A., Hinkle R.T., GoodaleM.B, Abeln S.B, Weingand K.W.: "Continuous Low-Level Heat Wrap Therapy Provides More Efficacy Than*

Clinical trials (detailed presentation)

2). Nadler S.F., Steiner D. J., Erasala G.N., Hengehold D.A., Abeln S.B, Weingand K.W.: "Continuous low-level heat wrap therapy for treating acute nonspecific lower back pain". *Arch Phys Med Rehabil 2003; 84:329-334.*

95 patients treated with **Thermacare**, 96 patients with placebo. All treatments were administered for 3 consecutive days with 2 days of follow-up.

RESULTS:

- On day 1, the heat wrap group had greater pain relief than placebo (P<0.001).
- Pain relief over days 1 through 5 was significantly greater for the heat wrap (P=0.04).
- "Extended" pain relief scores, calculated from evaluations taken approximately 24 and 48 hours after treatment ended, were also significantly higher for the heat wrap (P<0.0001).

3). Nadler S.F., Steiner D. J., Petty S.R., Erasala G.N., Hengehold D.A., Weingand K.W.: "Overnight use of continuous low-level heat wrap therapy for relief of back pain". *Arch Phys Med Rehabil 2003; 84:335-342.*

33 patients treated with **Thermacare**, 34 patients with placebo. All treatments were administered for 3 consecutive night with 2 days of follow-up.

RESULTS:

- Morning pain relief from day 2 to day 4 (after three nights of treatment) was significantly greater for the heat wrap (P=0.00005).
- Pain relief for the heat wrap was significantly higher than for placebo at each of the 20 individual points collected throughout days 2 through 5 (P≤0.03 for each).
- Mean daytime pain relief from day 2 to day 4 was significantly greater for the heat wrap (P=0.00005).
- Extended pain relief, after the final treatment day, was also significantly higher for the heat wrap (P<0.0001).

Part 3

Clinical data of Thermacare in “add on” therapy

Clinical data of Thermacare in 'add on' therapy

1). Lurie-Luke 2003 – Thermacare in workers with lower back pain

Thermacare provides a significant reduction in both pain intensity and the impact of pain on everyday activities

2). Mayer 2005 – Thermacare and exercise for lower back pain

Thermacare + exercises provide significantly greater pain relief than exercises alone, heat wrap alone and education alone

3). Tao 2005 – Thermacare combined with education program vs education program only

Thermacare + education program provide significantly greater pain relief than education program alone

4). Petrofsky 2014 – Thermacare as an adjunct to physical therapy

Thermacare + physiotherapy and physical exercises provide significantly greater pain relief than physiotherapy and physical exercises alone

5). Petrofsky 2015 – Thermacare as add on therapy in rehab

Thermacare + physiotherapy and physical exercises provide significantly greater pain relief than physiotherapy and physical exercises alone

6). Freiwald 2018 – Thermacare as supplemental therapy in multimodal treated chronic low back to enhance bio-mechanical parameters

Thermacare + physiotherapy and physical exercises provide further improvement of strength parameter.

Detailed presentation of clinical trials

1). Lurie-Luke E., Neubauer G., Lindl C., Breitkreutz H., Fischer P., Hitzeroth S.: "An exploratory workplace study to investigate the perceived value of continuous low-level heat wrap therapy in manual workers". *Occupational Medicine 2003; 53:173-178*

This study was carried out at the Opel Plant in Germany. **52** respondents fulfilled the inclusion criteria and were recruited. Each participant was given **2** heat wraps (Thermacare) to be worn for **~8 h on two separate/consecutive days during a lower back pain attack**. *Prescription tablets and professional treatments (physiotherapy, massage, infra-red treatment, etc.) were admitted*. Among the participants, **~20% did not use any pain treatment, ~30% used only one type of treatment and ~50% used a combination of different treatments**.

RESULTS:

- **Use of the heat wrap therapy provided a statistically significant reduction in both pain intensity and the impact of pain on everyday activities most affected by pain** (ability to lift things, ability to do your job, ability to drive) and quality of sleep.

2). Mayer J.M., Ralph L., Look M., Erasala G.N., Verna J.L., Matheson L.N, Mooney V.: "Treating acute lower back pain with continuous low-level heat wrap therapy and/or exercise: a randomized controlled trial". *The Spine Journal 2005; 5:395-403*

100 individuals (age 31.2±10.6 years) with lower back pain of less than 3 months duration were included. **25** participants used heat wrap therapy alone; 25 were instructed to do directional preference-based exercise alone; **24** used heat wrap (Thermacare) and did exercise; 26 only read a booklet for pain management (control group). **Treatment was administered for 5 consecutive days. Visit at day 2, day 4 and at day 7 (2 days after the end of treatment).**

RESULTS:

- Significant differences appeared at day 4 and at day 7.
- Pain relief: At day 4, heat wrap + exercise and heat wrap were greater than booklet (P≤0.001 and P≤0.026, respectively).
- At day 7, heat wrap + exercise was greater than exercise and booklet (P≤0.007 and P≤0.0001, respectively).
- Also, in functional improvement and in disability reduction, heat wrap + exercise provide significant greater result than heat wrap alone, exercise alone and booklet.

3). Tao X., Bernacki E.J.: "A Randomized Clinical Trial of Continuous Low-Level Heat Therapy for Acute Muscular Lower Back Pain in the Workplace". *J Occup Environ Med. 2005; 47:1298 -1306.*

43 patients suffering with non-specific lower back pain were included. **18** individuals enrolled in the education-only group: they received only education regarding back therapy and regarding pain management with pain medication (paracetamol, NSAIDs). **25** in the treatment group: they received same educational program of the other participants and also Thermacare heat wrap. Education has been conducted at day 0 for all the participants, **then "treatment" group wore Thermacare heat wrap from day 1 to day 3. Visits were made until day 14.**

RESULTS:

- Heat wrap treatment had significantly reduced the pain intensity from the first day of treatment (day 1) to the last day of the follow up (day 14).
- Heat wrap treatment had significantly improved pain relief during the 3-day treatment period and during the day immediately after the treatment period.

4). Petrofsky J., Laymon M., Alshammari F., Khowailed I.A., Lee H.: "Use of Thermacare heat wraps as an adjunct to physical therapy". *International Journal of Therapy and Rehabilitation, 2014:21(9)*

144 people with acute, non-specific back pain underwent 45 minutes to 1 hour of physiotherapy, 2 days a week for 2 weeks. Participants were instructed to accomplish 30 minutes of therapeutic exercise at home daily. **Half of the participants used Thermacare heat wraps for 6 hours before home therapy when they were not being treated in the clinic. A total of 10 heat wraps per patient were used during the study.**

RESULTS:

- Roland-Morris Disability Index: heat group had over twice the loss of disability score compared to the control group. This difference in loss was significant ($p<0.01$).
- OSWESTRY disability index: the loss in disability in the heat group was significantly greater than that seen in the control group comparing the data at the start to at the end of week 2. ($p<0.01$).
- Pain: at the end of the 2-week period, the pain in the heat group was significantly lower than the pain at the end of the 2 weeks in the control participants. This reduction in the heat group was significant ($p<0.01$).

5). Petrofsky J., Laymon M., Alshammari F., Khowailed I.A., Lee H.: "Continuous Low-Level Heat Wraps; Faster Healing and Pain Relief during Rehabilitation for Back, Knee and Neck Injuries" *World Journal of Preventive Medicine 2015; 3(3):61-72*

248 subjects participated. There were **3 control groups** and **3 investigational groups**. 2 groups had diagnosed back pain, 2 with knee pain and 2 with neck pain. Subjects were followed for 2 weeks with 2 therapy sessions per week in clinic. Participants were also instructed to accomplish 30 minutes of therapeutic exercise at home daily. **Participants in investigational groups used Thermacare heat wraps for 6 hours before home therapy when they were not being treated in the clinic. A total of 10 heat wraps per patient were used during the study.**

RESULTS:

- Neck groups – **improvements** in all considered parameters **were significantly greater in investigational group than in control. Respectively: strength (p<0.01), range of motion (p<0.01), disability score (p<0.05), pain relief (p<0.01).**
- Back injuries groups – **improvements in all considered parameters were significantly greater in investigational group than in control. Respectively: strength (p<0.01), range of motion (p<0.01), disability score using Roland-Morris Disability Index (p<0.01), disability score using OSWESTRY disability index (p<0.01), pain relief (p<0.01).**

6). Freiwald J., Hoppe M.W., Beermann W., Krajewski J., Baumgart C.: "Effects of supplemental heat therapy in multimodal treated chronic lower back pain patients on strength and flexibility". *Clinical Biomechanics 2018; 57: 107-113*

Within a **Multimodal Treatment Concept (MTC)** based on training and physiotherapy exercises, **176** patients (**88 per arm**) were treated either **with or without supplemental heat wrap therapy**. There were **2 sessions of MCT per week, per 12 weeks**. Patients in Thermacare supplemental group, used **a heat wrap just after the session of MCT and one the day after**. Total amount of heat wraps: 4 per week, per 12 weeks.

RESULTS:

- Patients receiving additional thermotherapy to basic multimodal treatment showed a further improvement of strength parameters.
- No group differences were detected in flexibility.

ThermaCare HEATWRAPS

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Angelini Pharma

Thermacare products are CE marked products. CE 1639

Thermacare heat wraps for lower back and hip.

Thermacare heat wraps for neck, shoulder and wrist.

Notes

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