

Technology Investment Corporation P/L (TIC)

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Report

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The Effect of Emu Oil on Muscle Soreness

Further information relating to this study and report remains confidential pending ongoing related research.
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Aim of Trial

To investigate the effectiveness of pure Emu oil for relieving muscle soreness in a human model and to compare the effectiveness of Emu oil with a conventional anti-inflammatory “over the counter” (OTC) product.

Scope of Trial

A human trial was undertaken to investigate the effect of Emu oil on induced muscle soreness which included Emu oil, a control (no treatment) and a conventional anti-inflammatory OTC product as a positive control, Piroxicam (NSAID).

The Model

A recognised and suitable model of inducing muscle soreness was adopted to assess the efficacy of Emu oil in response to the symptoms produced. The Delayed Onset Muscle Soreness (DOMS) model was the preferred protocol as it is often used as an experimental means for assessing the efficacy of anti-inflammatory products. Muscle soreness was induced in the quadriceps (upper thigh) on a given number of human subjects. Over a defined period of time, the subjects were treated with the Emu oil, a control (no treatment) or a conventional anti-inflammatory product.

Objective

There is currently limited research to support any established treatment for the effects and discomfort associated with DOMS therefore, a treatment to minimise such discomfort and speed recovery would be highly beneficial. Given the documented anti-inflammatory benefits of Emu oil and the anecdotal use of Emu oil for DOMS and similar applications, the objective was to demonstrate Emu oil as a legitimate natural treatment for such conditions, without the adverse side effects produced by alternative treatments of non-steroidal anti-inflammatory drugs (NSAID) such as Piroxicam and Ibuprofen.

Emu Oil

Emu oil has been subjected to a number of scientific studies. These studies have demonstrated that Emu oil possesses anti-inflammatory properties. One of these studies has shown Emu oil to possess pain relieving benefits comparable to Ibuprofen, one of the most powerful non-prescription anti-inflammatory preparations. Some Emu oil products have been compared to Prednisolone, a powerful steroidal anti-inflammatory drug, and were found to provide comparable reductions in swelling.

Emu oil is now commonly recognised as an anti-inflammatory product for conditions including arthritis, joint and muscle conditions, aches, pains, bruising and swelling. Emu oil is a natural product which does not produce any unwanted side effects and has very low irritation levels to the skin. Emu oil is recognised as having excellent skin penetrating properties, due to its unique combination of components. This provides Emu oil with the ability to transport bioactive compounds through the skin. Emu oil can be applied topically and/or taken orally. In 2002, the Australian Regulatory Body, The Therapeutics Goods Administration (TGA) recognised Emu oil as a therapeutic active ingredient, and listed Emu oil on the Australian Register of Therapeutic Goods. The Emu Industry has been conducting scientific research since 1995 in order to validate the range of benefits associated with Emu oil.

DOMS

Delayed onset muscle soreness (DOMS) is the pain, tenderness and stiffness that occurs 24 to 48 hours after unaccustomed exercise and is particularly associated with eccentric contractions. The soreness has been reported to be most evident at the muscle/tendon junction initially, and then spreading throughout the muscle. DOMS is thought to result from a combination of microscopic tearing of the muscle fibres and an inflammatory reaction within the muscle.

Pain is not the only factor associated with this condition. There is also an associated loss of strength, loss of motion and swelling of the involved musculature. Muscle fibre damage seen post eccentric muscle activity is thought to cause an inflammatory response. Eccentric activity is characterised as the muscle lengthening as it develops tension and contracts to control motion under load. Examples of eccentric muscle contractions include going down stairs, running downhill, lowering weights and the downward motion of squats and push-ups.

There are a number of opinions for treating the effects of DOMS after exercise including:

- Avoid any further vigorous exercise that may increase pain.
- Perform some low impact aerobic exercise to increase blood flow which may diminish soreness.
- Some research has found that gentle massage is effective in alleviating DOMS by approximately 30%, but it has no demonstrated effect on muscle function.
- Use the RICE (Rest, Ice, Compression and Elevation) method.
- Use a non-steroidal anti-inflammatory medication (such as aspirin or ibuprofen) to temporarily reduce soreness, though they don't actually speed healing.
- Although research hasn't found any evidence that gentle stretching reduces soreness, some people indicate it feels good.
- Or simply wait for up to 10 days for the discomfort to diminish.

Methodology

A group of sedentary subjects was recruited and baseline measurements recorded to evaluate muscle soreness using a visual analogue scale (VAS) and range of motion (ROM) of the knee joint by extending the lower leg back towards the buttocks. Subjects underwent a strenuous and repetitive leg extension exercise under a controlled environment to induce muscle damage. After a 24 hour period, VAS and ROM values were again recorded prior to application of treatment.

Treatment

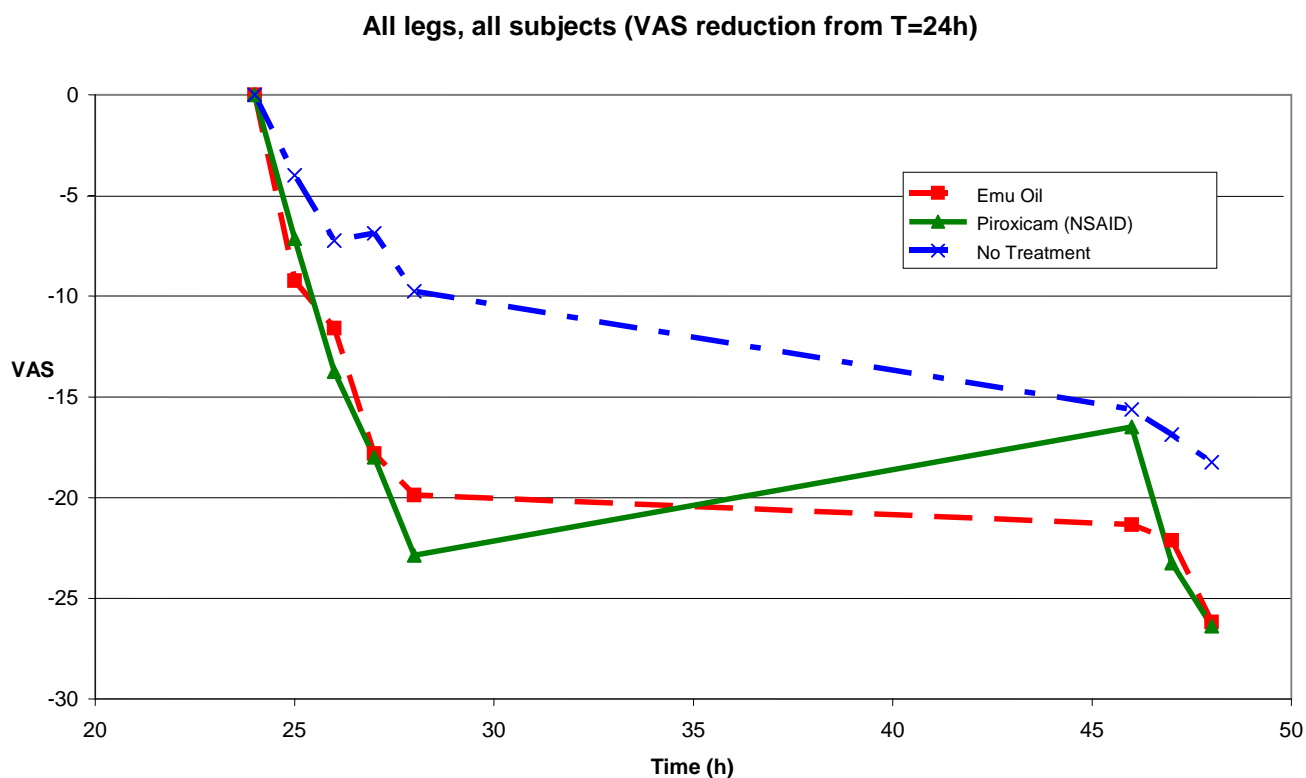
It was intended to compare the effects of Emu oil to a topical NSAID and Piroxicam was selected as the positive control as previous studies have shown Piroxicam to be effective in reducing muscle soreness, stiffness and range of mobility.

A pre-determined quantity of either the Emu oil or Piroxicam (NSAID) was applied to the quadriceps in a randomised order and the application was conducted under double-blind conditions. Once the treatment was applied, VAS and ROM were again measured hourly over a 4 hour period.

Subjects returned at the 46 hour point for a second application of the same treatment with VAS and ROM being monitored for a further 2 hours.

Evaluation

The following chart plots the rate of reduction in muscle soreness (VAS) for all subjects from the time point of when the first treatment is applied (24h).



Conclusion

It was concluded that both Emu Oil and Piroxicam (NSAID) displayed a significant reduction in pain and soreness over the first 3 hours of application compared to when 'no treatment' was applied. Emu oil is shown to provide a more immediate response within the first hour of application compared to the NSAID.

Emu oil displayed a more sustained and continued benefit throughout the period prior to re-application, whereas the effect of the NSAID immediately diminished after 3 hours and continued to reduce in effectiveness until re-application at the 46 hour mark. It was concluded from the chart that Emu oil was equally effective in the reduction of muscle soreness and inflammation to the NSAID while exhibiting a more prolonged and continued treatment without the potential adverse side effects of the NSAID (see next page). Furthermore, it was concluded that Emu oil provides substantial benefit compared to no treatment at all.

Non-Steroidal Anti-Inflammatory Drugs (NSAIDs)

Piroxicam

Piroxicam is in a group of drugs called non-steroidal anti-inflammatory drugs (NSAIDs). They are available in both oral and topical form. NSAIDs are commonly prescribed orally to relieve the symptoms of rheumatoid arthritis, osteoarthritis, menstrual cramps and spondylitis by reducing pain, swelling, and inflammation. They are available in topical form without prescription, as 'over the counter' (OTC) products and are recommended for aches, pains, strains, muscle and joint conditions. Approximately 30% of all patients receiving daily doses of 20 mg of Piroxicam experience side effects.

Other NSAIDs

There is a significant number of NSAIDs marketed under a variety of trade names. Other commonly recognised NSAIDs include; ibuprofen, aspirin and methyl salicylate (oil of wintergreen). Methyl salicylate is frequently incorporated as a rubefacient (a substance that causes redness to the skin by dilating the capillaries) in liniments and balms.

In pure form, methyl salicylate is toxic, especially when taken internally. The lowest published lethal dose is 101 mg/kg body weight in adult humans. It has proven fatal to small children in doses as small as 4ml. A 17 year-old cross-country runner at Notre Dame Academy on Staten Island, died on April 3, 2007, after her body absorbed high levels of methyl salicylate through excessive use of topical muscle-pain relief products.

Side Effects of NSAIDs

The comprehensive and serious side effects of NSAIDs are well documented.

- NSAIDs can increase the risk of life-threatening heart or circulation problems, including heart attack or stroke.
- NSAID's cause an increased risk of serious gastrointestinal (GI) adverse events including inflammation, bleeding, ulceration, and perforation of the stomach or intestines, which can be fatal. These events can occur at any time during use and without warning symptoms. The risk of GI effects may be increased for people who have poor health, drink large amounts of alcohol or in older adults.
- NSAIDs can lead to the onset of hypertension or worsening of pre-existing hypertension.

<u>Serious side effects include:</u>	<u>Other side effects include:</u>
<ul style="list-style-type: none">• heart attack• stroke• high blood pressure• heart failure from body swelling (fluid retention)• kidney problems including kidney failure• bleeding and ulcers in the stomach and intestine• low red blood cells (anemia)• life-threatening skin reactions• life-threatening allergic reactions• liver problems including liver failure• asthma attacks in people who have asthma	<ul style="list-style-type: none">• stomach pain• constipation• diarrhoea• gas• heartburn• nausea• vomiting• headache• dizziness• rashes, hives & itching• difficult or painful urination• tinnitus• tiredness & energy loss

Skin Reactions

NSAIDs, including Piroxicam, can cause serious adverse skin reactions such as rashes or blistering, hypersensitivity and itching, exfoliative dermatitis, Stevens-Johnson Syndrome (SJS), and toxic epidermal necrolysis (TEN), which can be fatal. These serious events may occur without warning.

NSAIDs may cause skin to become more sensitive to sunlight.

The Regulatory Agencies

The United States FDA (Food & Drug Administration) asserts that Piroxicam may be harmful to an unborn baby. The European Medicines Agency (EMA) has recommended restrictions on the use of piroxicam-containing medicinal products because of the risk of gastrointestinal side effects and serious skin reactions. The Agency's Committee for Medicinal Products for Human Use (CHMP) concluded that Piroxicam should no longer be used orally for treatment of short-term painful and inflammatory conditions.