

Experimental Group Based Study of topical oil treatment - Niavin

Author Dr. Dirk Wiedbrauck, Gran Canaria, Spain

Introduction

Pain reducing medications such as acetaminophen, non-steroidal anti-inflammatory drugs (NSAIDs), and COX-2 inhibitors have been common treatments for osteoarthritis in the growing elderly population. However, these medications often have painful side effects or do not react well with other medications. Accordingly, there is a need for alternative treatments for the osteoarthritis patient.

Today, patients have a variety of treatment options for managing their pain. Topical pain relief products are not only gaining in popularity, but medical science is discovering innovative ways to broaden their use. Scientists from the University of Strathclyde and University of Glasgow stated (1),

Advantages:

- Oil base makes application easy and controllable.
- Onset of symptom relief is faster than oral preparations (3-8).
- Symptoms are alleviated at a steady rate and relief may last longer (3-8).
- Drugs delivered topically may need to be applied less frequently and in smaller amounts (3-8).
- Formulations diffuse through the skin and enter into the bloodstream, thereby initially bypassing the liver, stomach, and digestive system (called 'first pass'). Many systemic (whole body) side effects, such as irritated stomach lining, may be diminished or eliminated.
- Studies have shown that when formulations are delivered topically - as much as 95% reach the target cells (e.g. muscle). Results from oral preparations delivered to a targeted site of pain are less than 5% (2).

Topical application of drugs directly to pathological sites offers potential advantages over systemic delivery by producing high drug concentration in the affected tissue while avoiding unwanted side-effects due to high systemic drug levels. Topical preparations of NSAIDs are commonly used as analgesics and anti-inflammatory agents to treat various disorders such as arthropathies and myalgias. Many topical formulations employ chemical penetration enhancers to improve dermal penetration of drugs. Chemical enhancers, which are usually organic solvents, may cause skin irritation and sensitization. An advantage of NIAVIN is that it is composed of natural lipids and oils designed to minimize irritation.

References:

1. Uchegbu IF, Schätzlein AG. "Generics Manufacturers Should Exploit Drug Delivery Technologies for Improved Therapeutics." Business Briefing: Pharmagenerics 2002.
2. Department of Pharmacology, University of Dublin.

Objectives

To study pain management with topical oil treatment substance: NIAVIN in an outpatient rehabilitation center for 8 weeks.

Study Design

Double blind randomized trial

Randomized selected patients from a holistic orientated outpatient clinic for rehabilitation, specialized in chronic pain relief. (Primarily: Physiotherapy, Osteopathy, Acupuncture, Electrotherapy, Neural Therapy, Carbon Dioxide Therapy and Chiropractics.)

The study consisted of a block of 8 weeks. Subjects were reassessed after one, two, four, six and eight weeks. The assessments were done consistently by the same study consultant, including goniometer measurements, pain questionnaire evaluation and treatment response with the Lanier Scale.

Treatment

Topical **NIAVIN** oils were supplied to the test group and placebo oil to the control group, who were instructed by a blinded consultant (nurse) as to appropriate use. Instructions included applications three times a day on the pain region and surrounding trigger points.

Placebo oils, identical in smell and appearance to the active oils were supplied to the control group.

If subjects encountered any side effects while using the product, they were instructed to notify the study personal immediately.

Methodology

All subjects were required to complete a pain questionnaire and a numerical rating scale for pain. Measurements included goniometer measurements for epicondylitis, knee arthritis and achilles tendon pain.

Subjects also rated their response to treatment using the seven points Lanier scale.

Numeric Pain Assessment Scale

On a scale of 0 to 10 (0=no pain, 10=most pain), my pain is:

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

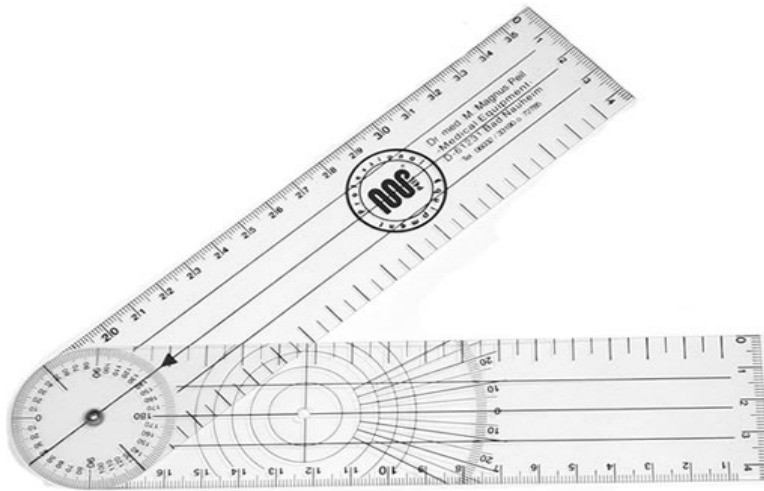
Response to treatment with the Lanier Scale

1 markedly worse	5 mildly better
2 moderately worse	6 moderately better
3 mildly worse	7 markedly better
4 no change	

Range of Motion Measurement

Joint flexibility is defined as the range of motion (ROM) allowed at a joint. A joint's ROM is usually measured by the number of degrees from the starting position of a segment to its position at the end of its full range of the movement. The most common way this is done is by using a double-armed goniometer. A stationary arm holding a protractor is placed parallel with a stationary body segment and a movable arm moves along a moveable body segment. The pin (axis of goniometer) is placed over the joint. When anatomical landmarks are well defined, the accuracy of measurement is greater. If there is softer tissue surrounding the joint area, measurement error can be more frequent.

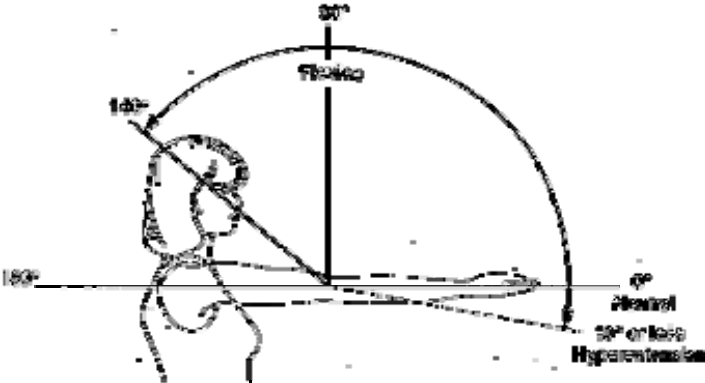
Goniometer



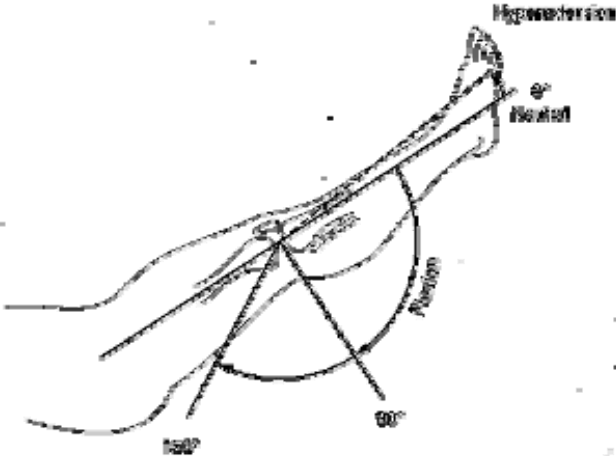
Normal Range

Joint/Segment	Movement	Source 3*
Elbow	Flexion	145
	Hyperextension	0
Knee	Flexion	140
Ankle	Plantar flexion	45

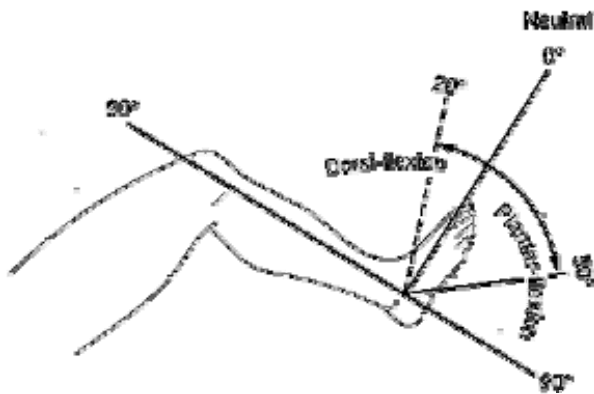
Elbow Joint



Knee Joint



Dorsal and Plantar Flexion Ankle Joint



Assessment of a trigger points (TPs)

TPs are assessed primarily by palpation with the fingers, although Electromyographical (EMG) studies and Thermography also are valid procedures for locating them since altered nerve signals and increased temperature can be detected with some trigger points. Research using instrumentation which reads the level of pain associated with a particular pressure (Pressure algometry) has proven that therapists can be quite consistent in locating trigger points, showing that those familiar with trigger points can reliably identify the same trigger point in the same spot again at a later time. Interestingly, the same research has also shown that different therapists will often not point to the same spot as the location for a trigger point. There is, therefore, a certain subjective 'feel' element in assessing and treating trigger points. So while the art of palpation is important for locating more specialized or subtle trigger points, anybody can stick their own fingers into their sore muscle and feel around for a trigger point

How to find your own trigger points

Make sure the patient and the affected muscle are completely relaxed, not on stretch. One of the following techniques can be used to palpate the trigger point:

Flat Palpation involves simply moving the fingertip(s) transversely across the muscles fibers with some pressure until a 'taut band' is located. Having found this tight section of the muscle, explore along its length to locate the spot of maximum tenderness with minimum pressure: that is the trigger point. With some practice it doesn't take long to find the taut bands in a muscle.

To determine whether the trigger point is 'active' or 'latent' (ATP/LTP) apply some firm pressure to the sore area - an ATP will be extremely tender compared to a LTP, but more importantly, an ATP should refer pain to another area in the body. While different trigger points refer to different areas, the referred pain pattern is quite similar from person to person. Sometimes a trigger point needs to be pressed or flicked over for up to 10 seconds before the referred pain becomes evident.

Test Group

Twelve patients having epicondylitis, fourteen experiencing finger polyarthritis, twenty test results were obtained for patients with knee arthritis and sixteen measurements were taken with patients diagnosed with Achilles tendon pain. Each patient received substance NIAVIN.

Control Group

Twelve patients having epicondylitis, fourteen experiencing finger polyarthritis, twenty test results were obtained for patients with knee arthritis and sixteen measurements were taken with patients diagnosed with Achilles tendon pain. Each patient received a placebo.

Demographic Charts

Chart 1: Treatment Group

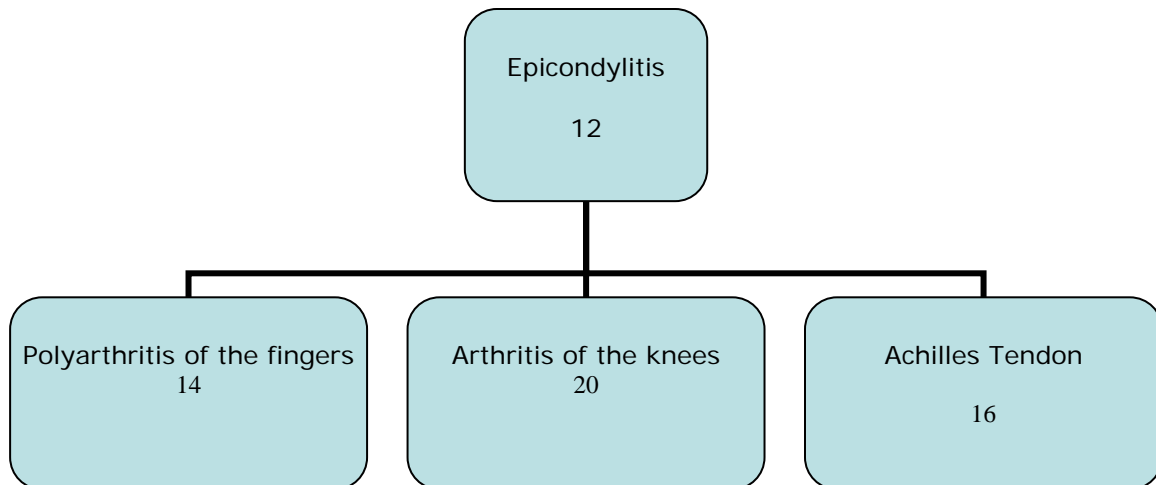


Chart 2: Placebo Group

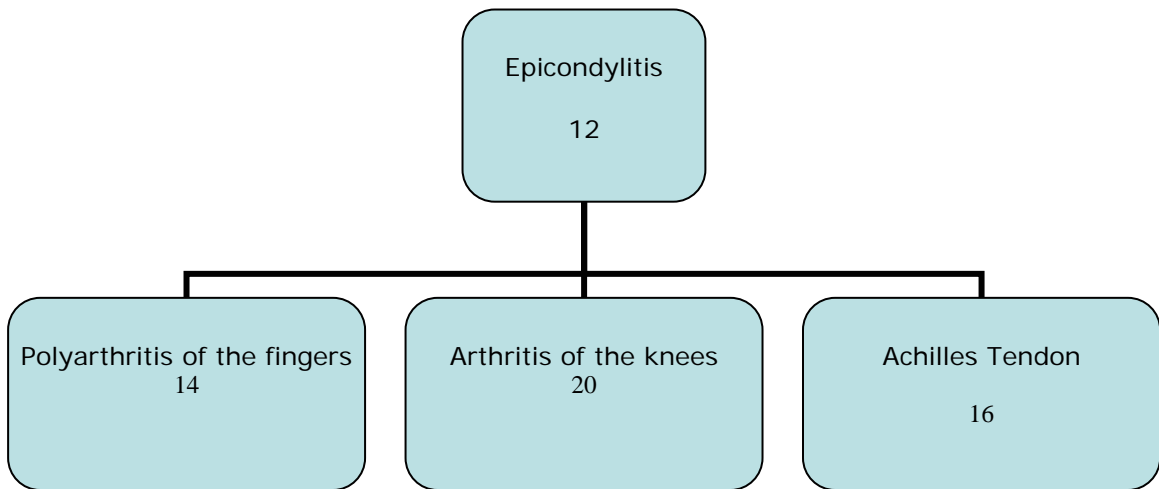


Chart 3: Mean Age Distribution treatment group

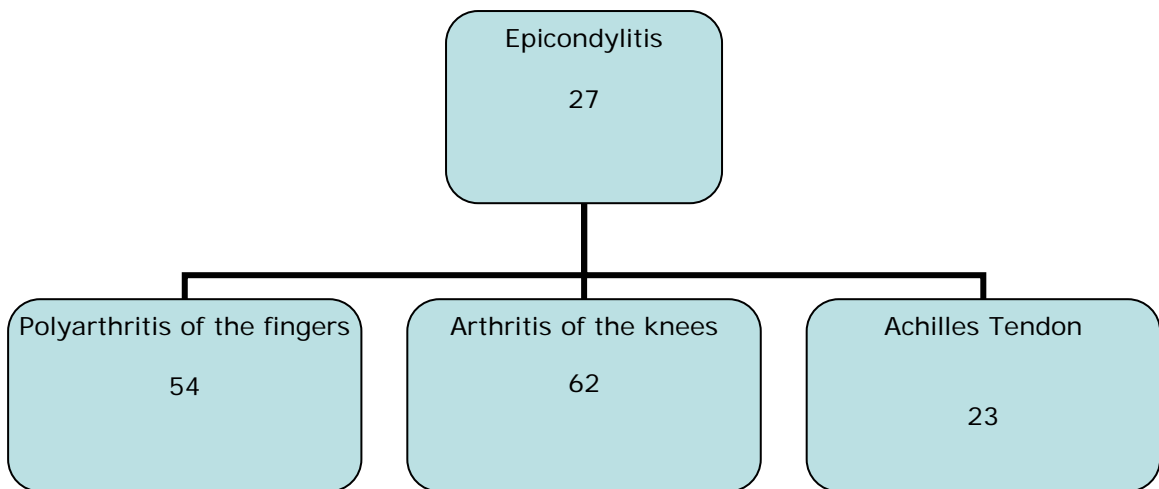


Chart 4: Mean Age Distribution placebo group

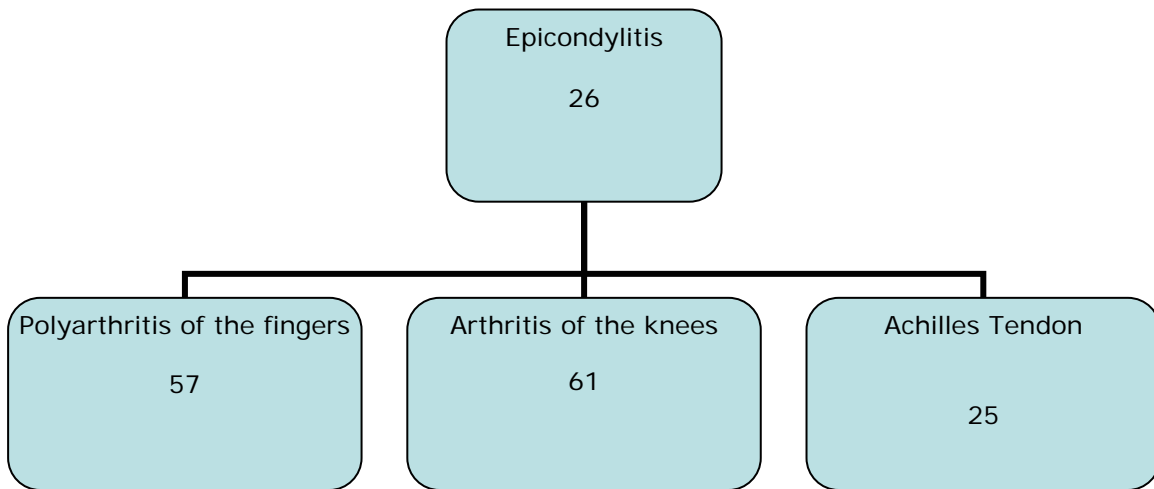


Chart 5: Gender treatment group

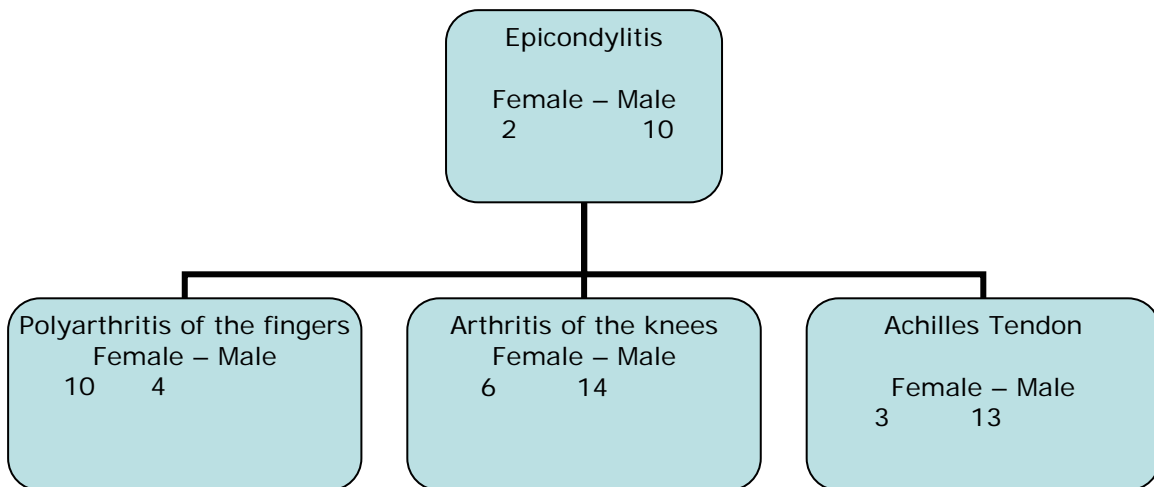
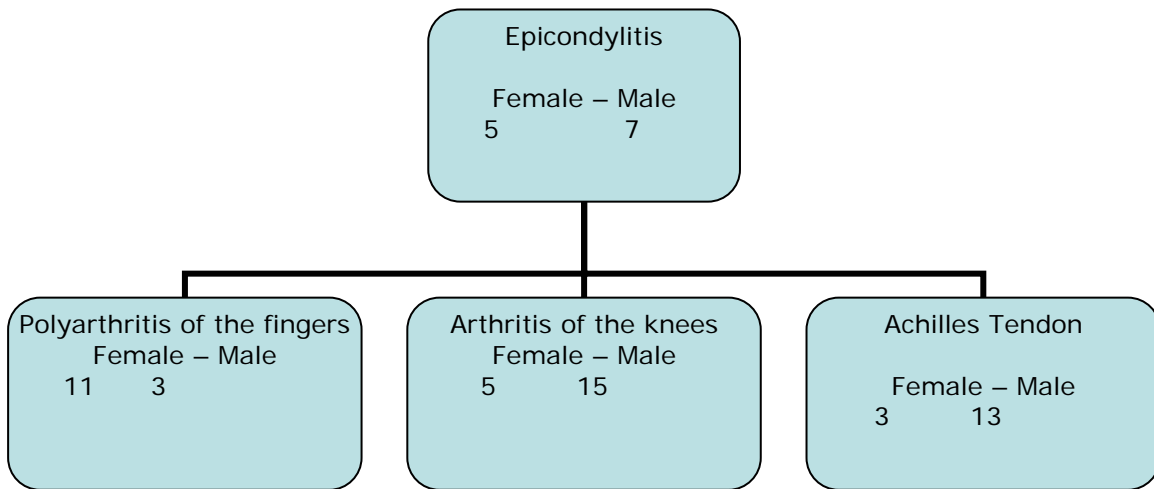


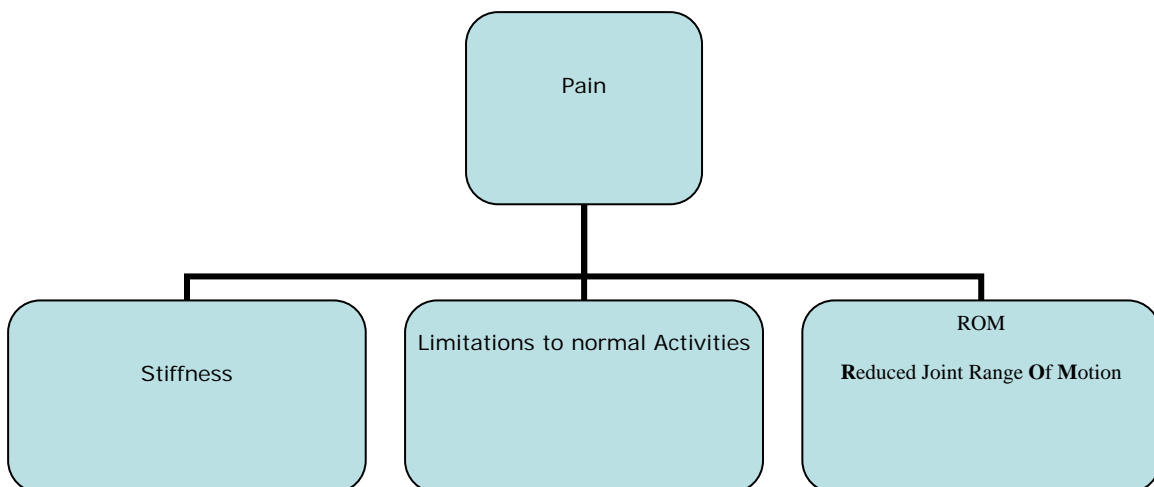
Chart 6: Gender placebo group



Symptoms

The most common symptoms are pain, stiffness, reduced joint range of motion (ROM), and limitations to normal activities of daily living such as getting up from a chair, walking, ascending and descending stairs for knee patients. Achilles tendon pain patients mostly experience pain and difficulties of plantar flexion in the affected foot.

Chart 7: Symptoms treatment and placebo group



Author:

Dr. med.Dirk Wiedbrauck
Gran Canaria
Spain

Results

Of the initially 124 participants assessed, all participants completed the necessary post treatment and finished the evaluation completely. Over the eight weeks, 62 participants used substance NIAVIN and 62 used placebo treatment.

Methodology

The study consisted of a block of 8 weeks. Subjects were reassessed after one, two, four, six and eight weeks. The assessments were done consistently by the same study consultant, including goniometer measurements, pain questionnaire evaluation and treatment response with the Lanier Scale.

Demographics

The study included 38 men (61.3%) and 24 women (38.7%) in the placebo group. The treatment group included 41 men (66.1%) and 21 women (33.9%).

Diagnosis

The diagnosis in the treatment group was twelve patients having epicondylitis (19.2%), fourteen experiencing finger polyarthritits (22.6%), twenty test results were obtained for patients with knee arthritis (32.5%) and sixteen measurements were taken with patients diagnosed with Achilles tendon pain (25.7%).

The diagnosis in the placebo Group was twelve patients having epicondylitis (19.2%), fourteen experiencing finger polyarthritits (22.6%), twenty test results were obtained for patients with knee arthritis (32.5%) and sixteen measurements were taken with patients diagnosed with Achilles tendon pain (25.7%).

Treatment

Topical **NIAVIN** oils were supplied to the test group and placebo oil to the control group, who were instructed by a blinded consultant (nurse) as to appropriate use. Instructions included applications three times a day on the pain region and surrounding trigger points.

Placebo oils, identical in smell and appearance to the active oils were supplied to the control group.

In both groups no adverse reactions were reported.

Results

The results of the study were based on the response of the treatment with the Lanier scale and the range of movement measurement (ROM), after eight weeks.

After the first week 54 patients reported no change of symptoms in the placebo group (87.2%), 4 patients felt worse (6.4%), 4 patients felt mildly better (6.4%).

In the treatment group 9 patients reported no change of symptoms (14.5%), 2 patients felt worse (3.2%), 11 patients were mildly better (17.7%) and 41 patients were moderately better (66.2%).

After eight weeks 42 patients reported no change of symptoms in the placebo group (67%), 3 patients felt worse (4.8%), 4 patients were mildly better (6.4%), 7 patients were moderately better (11.2%) and 6 patients were markedly better (9.6%).

In the treatment group 4 patients reported no change of symptoms after eight weeks (6.4%), 2 patients were worse (3.2%), 6 patients were mildly better (9.6%), 4 patients were moderately better (6.4%) and 46 patients were markedly better (74.4%).

Five post functional testing sessions were taken for all four groups, after one, two, four and six weeks. Across the four groups the test measurement revealed that the use of topical oil, applied to the trigger points in a range of three centimeters of the affected joint produced significant improvements in pain relief, range of motion, physical performance and plantar/dorsal flexion in the achilles tendon pain group.

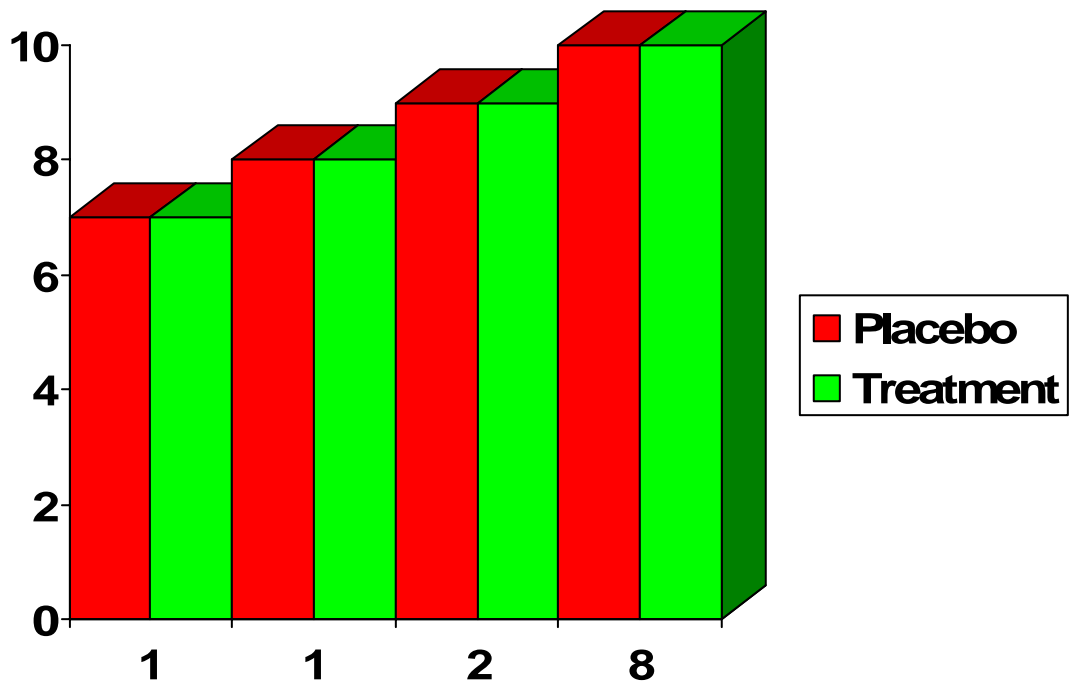
74.4% of the treatment group were markedly better after eight weeks of treatment and only 6.4% in the placebo group were markedly better.

Conclusion

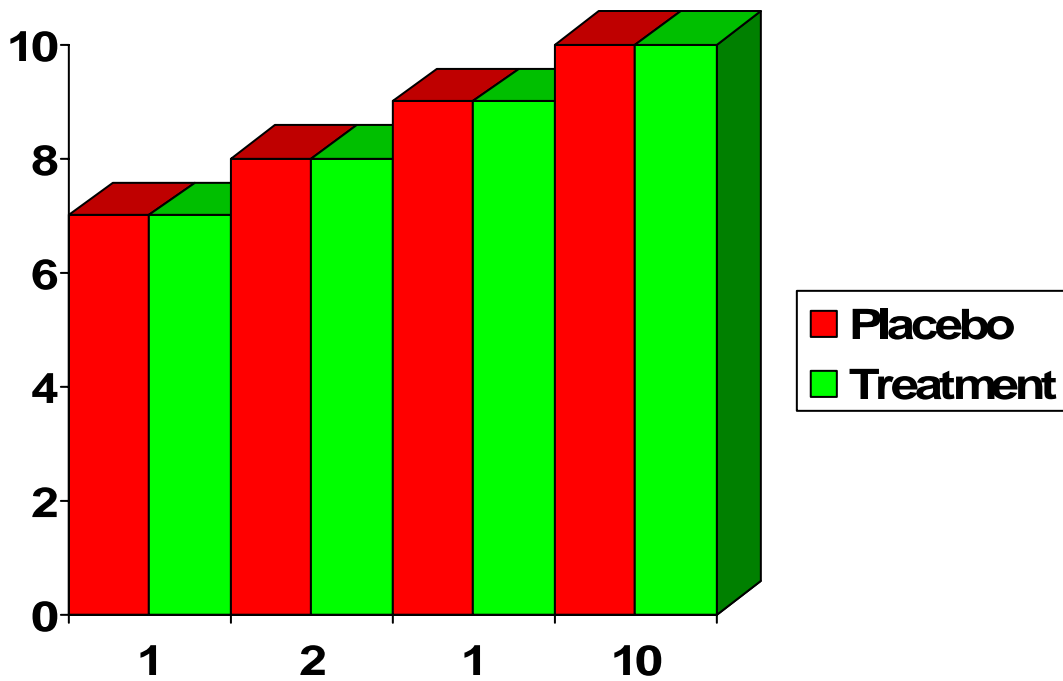
The study clearly pointed out the effectiveness of Niavin topical oil in the treatment of epicondylitis, knee arthritis, finger arthritis and achilles tendon pain.

Appendix: Charts

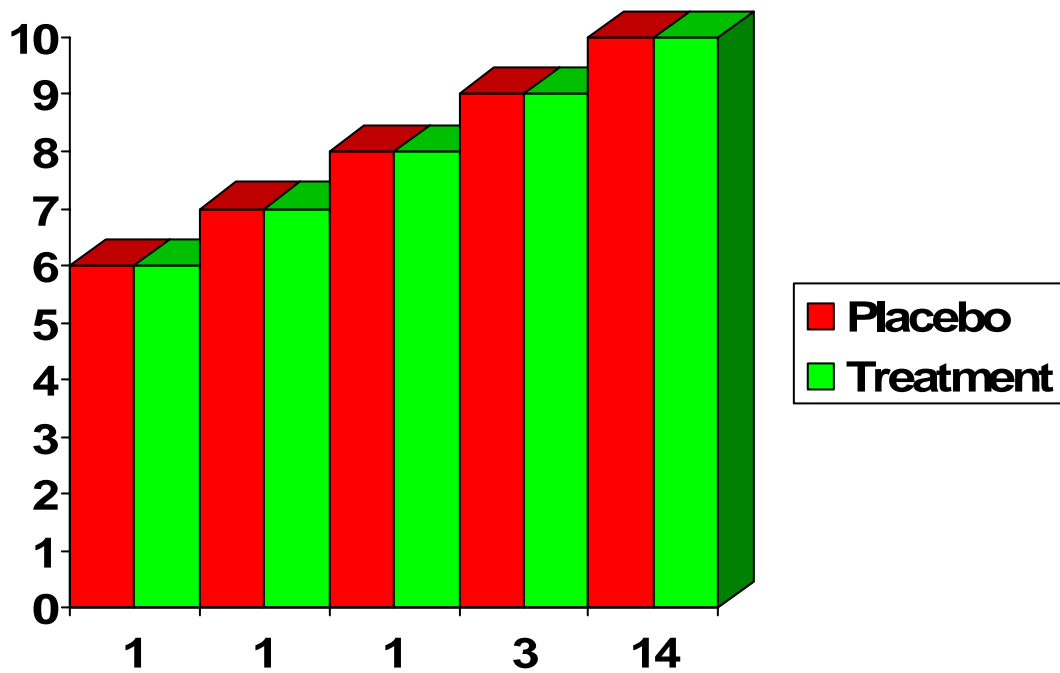
Outcome measures of the Numeric Pain Scale



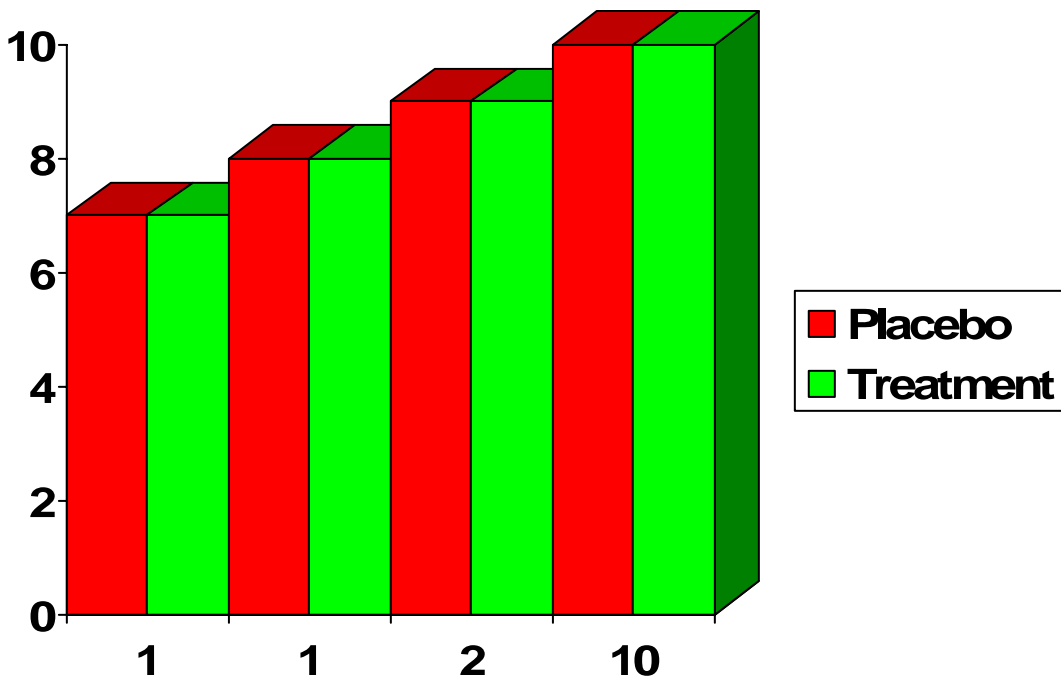
Outcome measures Numeric Pain Scale: Epicondylitis



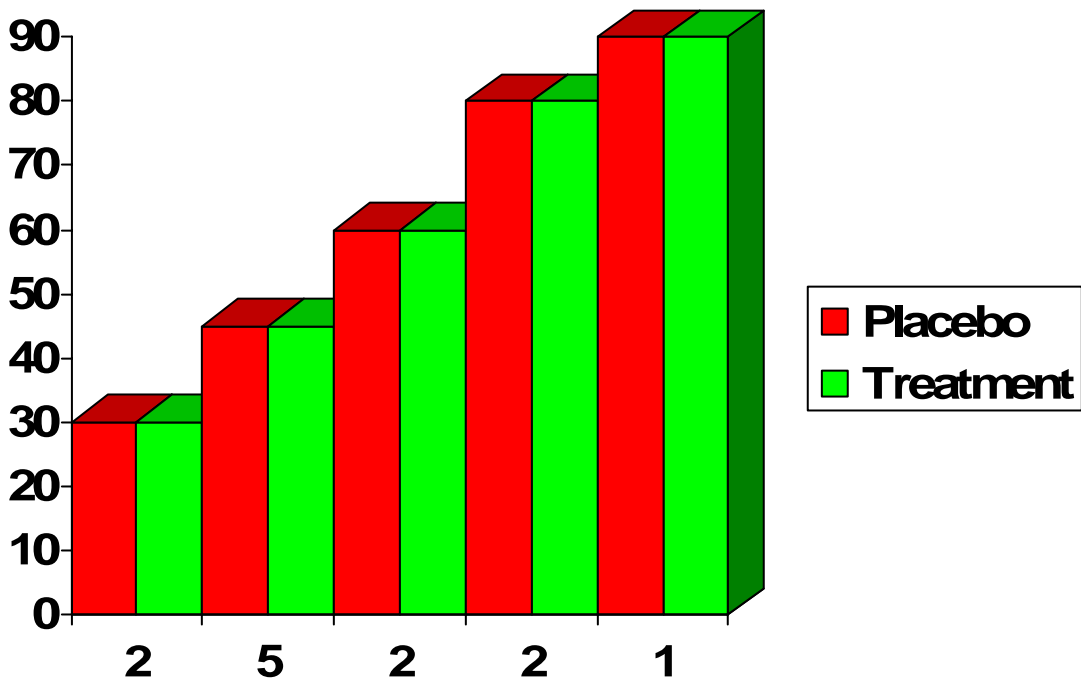
Outcome measures Numeric Pain Scale: Arthritis Fingers



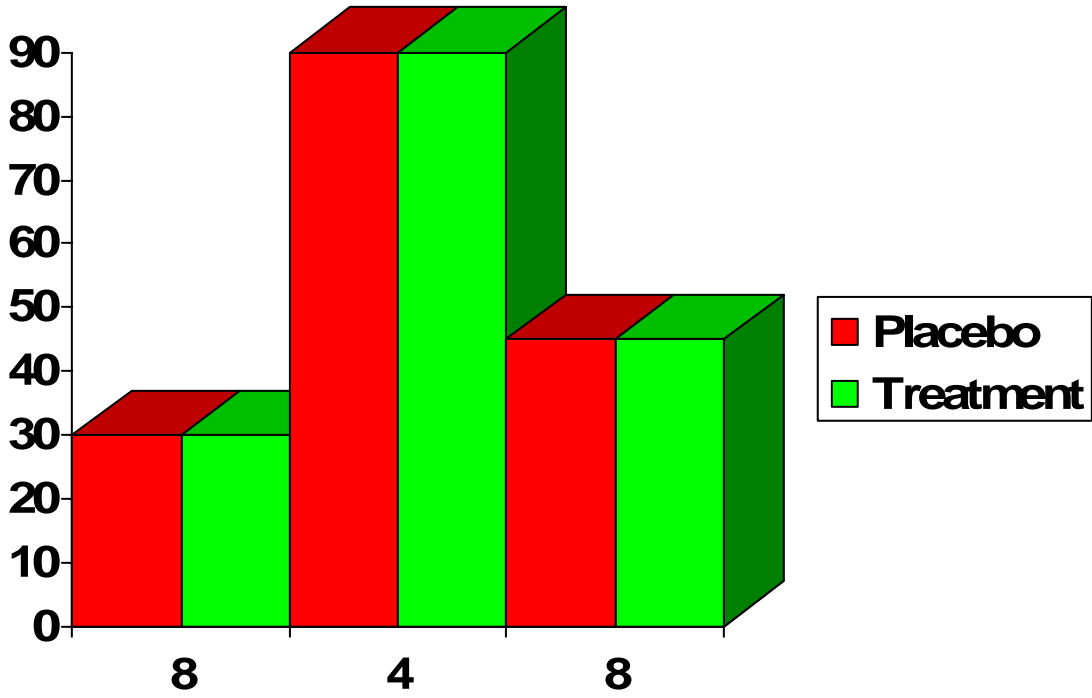
Outcome measures Numeric Pain Scale: Arthritis knees



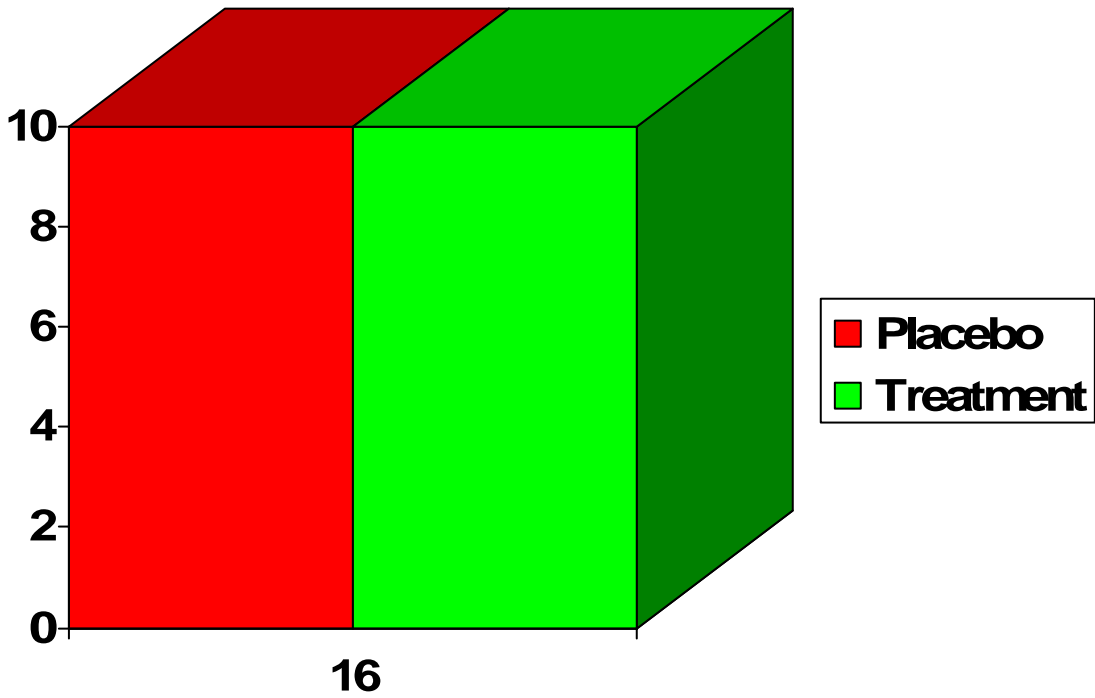
Outcome measures Numeric Pain Scale: Achilles Tendon
 Outcome measures Range Of Movement (ROM)



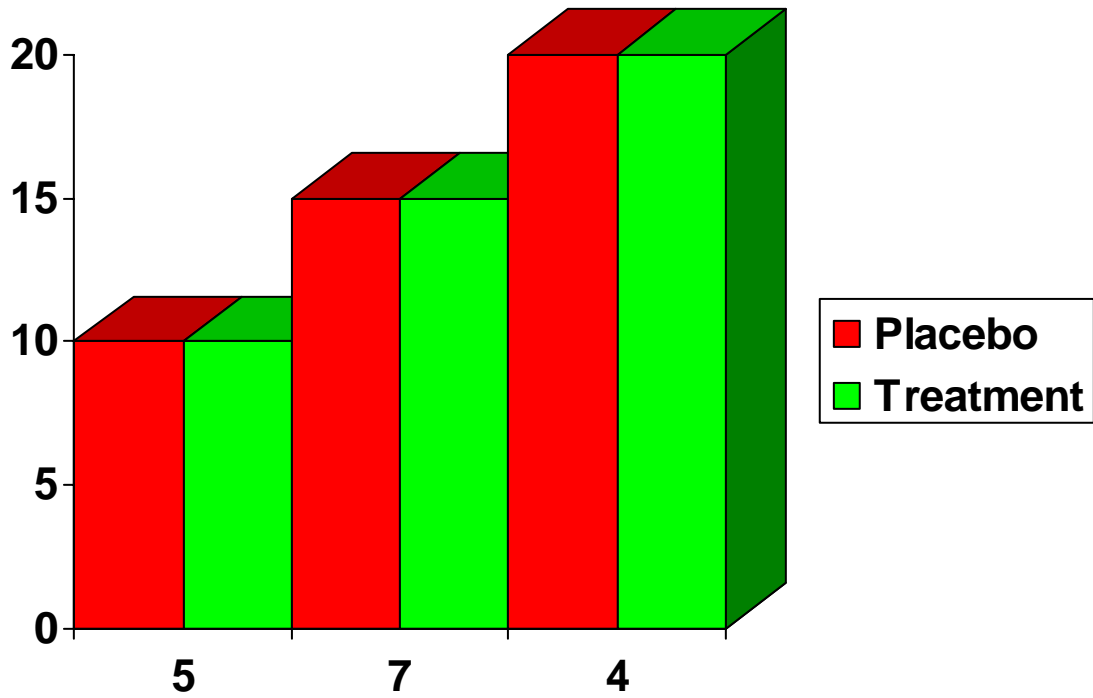
Epicondylitis: Pain-Free-Flexion in Degrees



Knee Arthritis: Pain-Free-Flexion in Degrees



Achilles Tendon: Pain-Dorsal-Flexion in Degrees



Achilles Tendon: Pain-Plantar Flexion in Degrees
Response to treatment with the Lanier Scale

Lanier Scale Rating	Number of Subjects	Percentage of Subjects
1	1	1.6%
2	2	3.2%
3	1	1.6%
4	54	87.2%
5	4	6.4%
6	0	0
7	0	0

Placebo Group after one week (n=62)

Lanier Scale Rating	Number of Subjects	Percentage of Subjects
1	0	0
2	0	0
3	1	1.6%
4	9	14.5%
5	11	17.7%
6	41	66.2%
7	0	0

Treatment Group after one week (n=62)

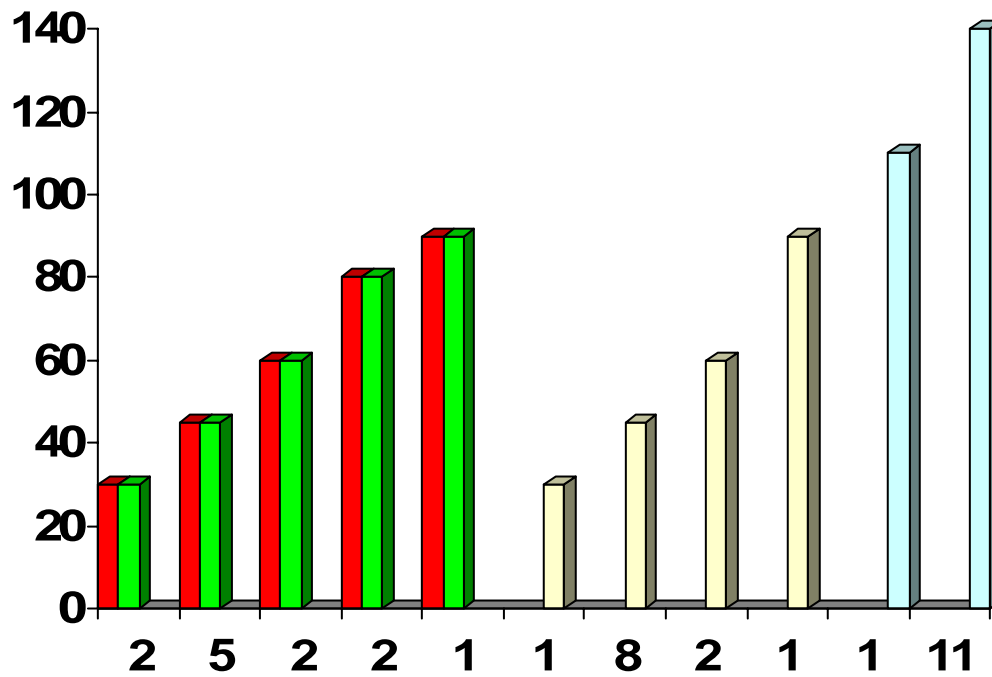
Lanier Scale Rating	Number of Subjects	Percentage of Subjects
1	1	1.6%
2	1	1.6%
3	1	1.6%
4	42	67.0%
5	4	6.4%
6	7	11.2%
7	6	9.6%

Placebo Group after eight weeks (n=62)

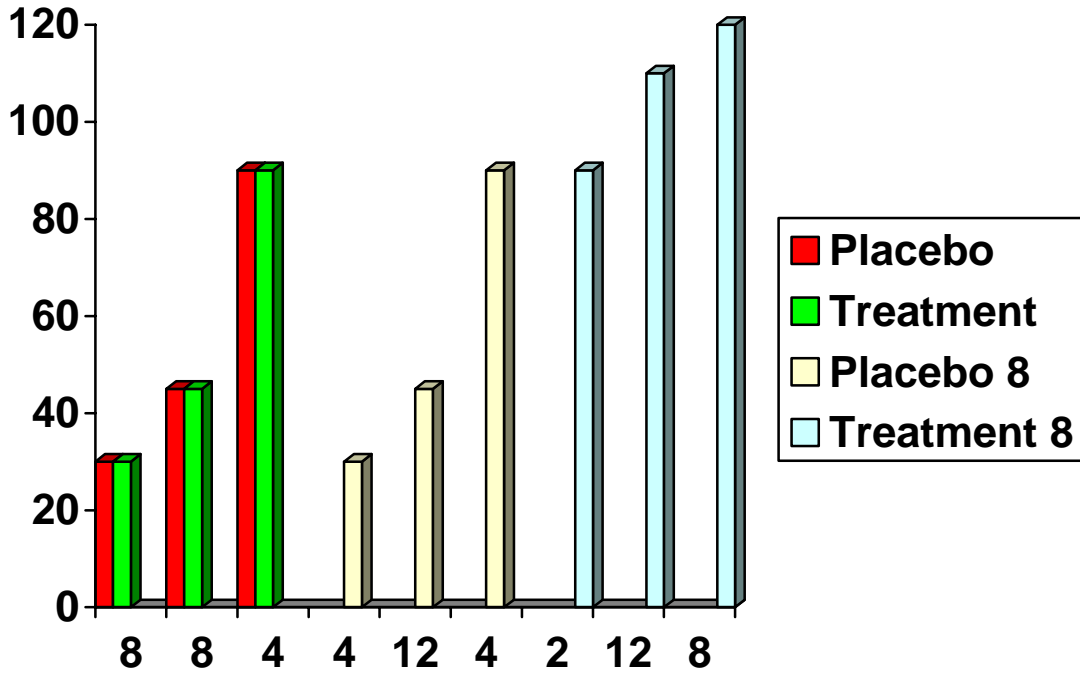
Lanier Scale Rating	Number of Subjects	Percentage of Subjects
1	0	0
2	1	1.6%
3	1	1.6%
4	4	6.4%
5	6	9.6%
6	4	6.4%
7	46	74.4%

Treatment Group after eight weeks (n=62)

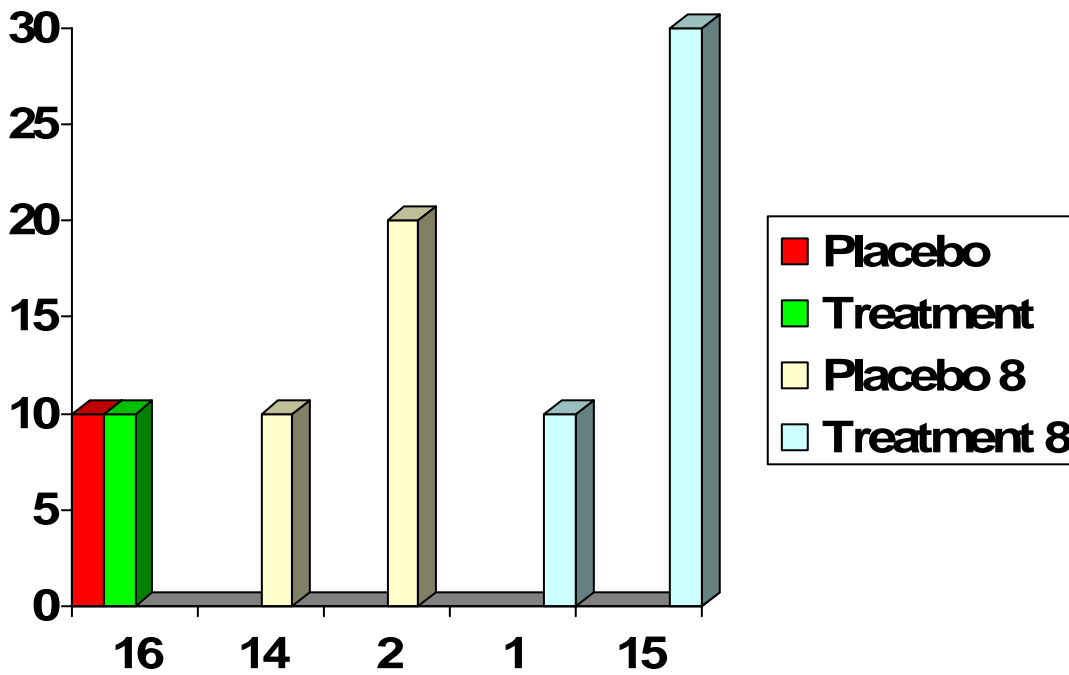
Outcome measures Range Of Movement (ROM) after 8 weeks



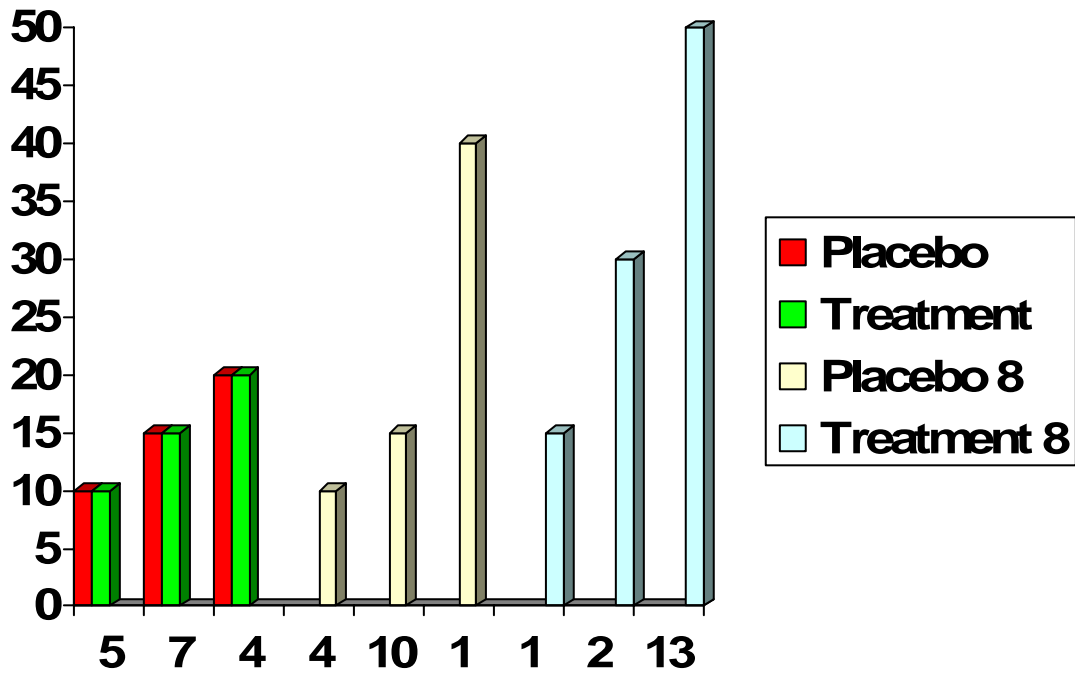
Epicondylitis: Pain-Free-Flexion in Degrees after 8 weeks



Knee Arthritis: Pain – free flexion in degrees after 8 weeks



Achilles Tendon: Pain-Dorsal-Flexion in Degrees after 8 weeks



Achilles Tendon: Pain-Plantar Flexion in Degrees after 8 weeks

© Study results copyright 2007 Jungle Pharmaceutical Company