

A Double-Blind Study using Novaped Golf Prodynamic Magnetic Pads to Demonstrate Therapeutic Benefit in Heel Pain Symptomatology

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OBJECTIVE: To determine the effectiveness of permanently magnetized pads for the treatment of heel pain syndrome. A double-blind study was performed on patients who have had symptoms in the above areas for at least two weeks. Permanently magnetized and demagnetized pads will be applied to the symptomatic feet without the patient or the clinician able to differentiate due to identical appearing pads. Only an impartial referee is aware of the true identity of each pad.

Characteristics of the Material to Be Tested

1. The Novaped Golf Prodynamic pads to be used are rectangular and are 53 mm x 83 mm and produce about 300 gauss of magnetic current. The magnetic coils inside each pad are arranged in concentric circles and are not visible or palpable.
2. An identical number of factory demagnetized pad of identical dimensions were also used for the study.
3. All pads were provided by Novaped Golf Prodynamic Corporation and in Germany by Novaped Golf Prodynamic.
4. All pads have cotton covering on the inside, which faces the skin during application and an aluminium cover on the outside for insulation. Again, all pads appear identical.

Patients to Be Tested

1. Twenty patients were initially studied using the Novaped Golf Prodynamic pads on their symptomatic feet. All patients were seen at the foot clinics of the Barry University School of Podiatric Medicine. The age of patients varied from age 21 to age 78. The sex of the patients was noted, but not thought to be a significant factor in the study.
2. The patients tested had either heel spur or acute plantar fasciitis symptoms such as, aching, burning or sharp pain on the heel area.
3. All patients have local symptoms without neurological damage to their back or lower extremities.
4. Patients who underwent foot surgery within the past year were not included.
5. Patients who had metallic implants, such as screws or wires in their feet were excluded.
6. All patients underwent two weeks of therapy and two weeks of minimum follow-up after the treatment.

Method of Double-Blind Procedure:

1. All magnetized and demagnetized pads were randomly mixed before starting the clinical trial.

2. All pads were placed on a flat surface next to each other so that there would be no means of differentiating magnetized from demagnetized pads.
3. Each pad was taken randomly for placement on the perspective patient in the study.
4. Patients were told that they must use their pads as instructed for the entire two-week trial period to optimize therapeutic benefit.
5. Each patient was made aware of possible side effects and possible reactions to local magnetic therapy.
6. Patients were advised to keep pads away from all credit cards, computer discs and sensitive electronic equipment.
7. A medical history and podiatric physical examination were performed on each patient with a questionnaire and consent to medical treatment prior to starting therapy.
8. All pads were attached to the skin of the painful area using non-allergic tape or non-adhesive elastic wrap. Additional tape was provided for each patient reapplication during the two-week period.
9. Each patient was reappointed for an evaluation in 7 days.
10. The second stage of the evaluation began after the first 7 days when the patient was reappointed in one more week. The patient was questioned after each seven-day period concerning compliance, improvement or worsening of symptoms and side effects during the treatment periods.
11. The clinical trial was concluded on the fifteenth day following the start of treatment.
12. Examination of the treated foot was performed. Results were documented according to the study guidelines.
13. The pads were removed and decoded by the referee using a magnetic detecting film. These results were then recorded along with each patient's medical information taken during the study. The decoding of the pads was done in the absence of the patient. All pads were then filed and secured by the referee.
14. The clinical staff during the study monitored each patient's compliance.

Criteria for Test Documentation

1. Criterion A: Subjective pain sensation.
2. Criterion B: Ability to ambulate without pain.
3. Criterion C: Need for pain or anti-inflammatory medication.
4. Criterion D: Accompanying therapy.

The Effective Comparison Index

The effectiveness comparison index is used to compare the therapeutic effectiveness of magnetized and demagnetized pads between the groups in the trial population. With reference to the same differentiation category within the indication group, this corresponds to the quotient of the sums of the percentage values describing the clinical effectiveness of magnetized or demagnetized pads of all criteria.

p= Percentage of efficiency with reference to the number of patients of a trial criterion treated with magnetized pads.

n= Percentage of efficiency with reference to the number of patients of a trial criterion treated with demagnetized pads.

A,B,C & D = Trial Criteria

WVI - $p(A) + p(B) + p(C) + p(D) \%$

$n(A) + n(B) + n(C) + n(D) \%$

A WVI of 1.0 is equal to an equivalent effect of magnetized and non-magnetized pads. A factor of less than 1.0 represents higher participation of the magnetized pads in the obtained result. The higher the obtained count factor beyond 1.0, the stronger the assumption that the therapeutic effect is due to the magnetized pad for particular symptoms. The WVI in all categories showed a high count factor beyond 1 in all four criteria in the clinical trial. The WVI was greater the 0.5 in all differentiation categories.

Discussion of Results of Clinical Trials of Twenty Patients

Criterion A: Subjective relief of symptoms.

1. Magnetized pads: Fourteen patients

Excellent = Five
Good = Three
Fair or no = Six
better

2. Demagnetized pads: Six patients

Excellent = One
Good = None
Fair or no = Five
better

Criterion B: Ability to ambulate without pain.

1. Magnetized pads: Fourteen patients

Excellent = Seven
Good = Four
Fair or no = Three
better

2. Demagnetised pads: Six patients

Excellent = one
Good = one
Fair or no = Four
better

Criterion B and C = All patients in the study did not need medications or physiotherapy.

Percentage of Improvement with Magnetized Pads

Criterion A: Subjective relief of pain = 57.2%

Criterion B: Improvement in walking = 77.1%

Criterion C: Need for medication = 0%

Criterion D: Need for physiotherapy = 0%

Percentage of Improvement with Demagnetised Pads

Criterion A: Subjective relief in pain = 16.6%

Criterion B: Improvement in walking = 16.6%

Criterion C: Need for medication = 0%

Criterion D: Need for physiotherapy = 0%

Discussion of Results

The indication groups for all trial criteria showed a significantly higher therapeutic effectiveness with the magnetized pads than the control groups (demagnetized pads). The best results were achieved with reduction in subjective pain in the heel spur syndrome category. 57.2% of all test persons in this category treated with magnetized pads expressed significant relief of symptoms. The patients who showed increase in ability to walk without pain after treatment represented a 77.1% improvement rate with the magnetized pads versus a 16.6% improvement reported by those with the demagnetized pads. This percentage represented a placebo effect.

Conclusion

1. The patient group in all criteria showed a higher percentage of favourable results with the magnetized pads than the demagnetized pads.
2. The application of the pads to the treatment areas produced no side effects or skin irritation.
3. Patients showed compliance and remarked about the ease of pad application.
4. The patients showed a willingness to try alternatives to their pain and anti-inflammatory medications.
5. The patients were excited about their therapy and eager to continue with biomagnetic therapy.

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