

A SINGLE-CENTER, PROSPECTIVE, CONTROLLED, DOUBLE BLIND AND RANDOMIZED STUDY FOR EVALUATION OF THE EFFICACY AND SAFETY OF INVEL® ACTIVE GLOVE WITH INVEL® TECHNOLOGY.

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Introduction

Repetitive movement related disorder (RSI: repetitive strain injury / WRMD: Work related musculoskeletal disorder) of the hand and the wrist is associated with extended absenteeism from work, therefore, associated with the greater productivity loss ⁽¹⁾.

More than 90% of patients with RSI / WRMD prevented musculoskeletal pain and strong association with Myofascial Pain Syndrome (MPS)⁽²⁾ was observed.

Myofascial Pain Syndrome is one of the most common causes of musculoskeletal pain and functional incapacity. It is little recognized by health professionals, since the diagnosis depends exclusively on clinical history and physical examination findings. MPS is a regional neuromuscular dysfunction, with trigger points in the tense bands of muscle fibers and when stimulated mechanically it presents local or referred pain in distant areas. Myofascial pain can be silent, in intense heat and stabbing sensation. It can become extremely strong that it can be confounded with a bone pain, which hampers diagnosis.⁽³⁾

Myofascial trigger point (TP) can cause a tingling sensation and numbness. In this situation, the electroneuromyographic examination and the neurological examination are normal. Many of the myofascial TPs are referred pain, that is, they are far from the stricken site.⁽⁴⁾

Treatment is clinical and consists in medication, physical means, kinesiotherapy, ergonomic orientations, use of orthosis, and postural hygiene for improvement of pain and functional incapacity. The use of long-wave infrared radiation emitted by Biocerâmica® incorporated in Invel® Active Glove can be another coadjuvant treatment option for alleviating pain and aiding in rehabilitation.⁽³⁾

Objective

Primary objective:

- To verify the efficacy of Invel® Active Glove in muscular pain inpatients with myofascial pain syndrome in the wrists.

Secondary objective:

- To evaluate functional capacity of upper limbs of patients with myofascial pain syndrome;
- To evaluate safety in the use of the product.

Methodology

A single-center, prospective, controlled, double blind and randomized study was performed, approved by the independent ethics committee on research, including a sample of 60 subjects suffering from muscular pain (MPS) caused by repetitive strain on the upper limbs.

Investigational product:

Invel® Active Glove.

Methodology

Sixty (60) subjects from both genders were selected and, after signing the informed consent form, randomized into two groups: Group A (group that used Invel® Active Glove) and Group B (placebo, which used the glove of the same fabric, however with the incorporation of Biocerâmica® MIG3®). The subjects used for 6 hours daily for 28 days. For the two groups, A and B, four (4) visits were planned in the course of 2 months.

V0	V1 (14 days)	V2 (28 days)	V3 (56 days)
Randomization	Evaluation after 2 weeks of use	Evaluation after 4 weeks of use	Evaluation after 4 weeks WITHOUT the glove
Period WITH glove			Period WITHOUT glove

Means of evaluation:

- Pain by the Visual Analog Scale - VAS;
- DASH (Disabilities of the arm, shoulder and hand) Functional Assessment;
- Assessment of the TPs (by the Fischer algometer)
- JAMAR (grip dynamometer)
- Clinical assessment

Results

Intensity of Pain:

Pain reduction was evaluated in the course of time through the Visual Analog Scale - VAS and a drop was confirmed in the right arm by 12% in V2, 28% in V3, in Group A (group that used Invel® Active Glove) and variation of 11% in V2, 14% in V3 in Group B (placebo). There were significant differences in the absence of pain in the times of 14, 28 and 56 days compared to the presence of pain in the basal time, in the elbow and wrist, at a significance level of 5%. The average percentage of the lack of pain in the wrist was 55.55% in group B and 33.33% in group P, being higher in group B.

Clinical Assessment of the Pain:

The location and reduction of pain were assessed and we observed significant differences in their absence at times of 14, 28 and 56 days compared to the baseline time, at the elbow and wrist, with 5% significance level.

Functionality:

There was decrease of DASH scores, suggesting improvement of functionality in the two groups ($p < 0.0001$).

Safety:

No clinically significant adverse event was verified in the studied population.



55% reduction in wrist pain

Conclusion

This study showed clearly that Invel® Active Glove leveraged the analgesic effect. Mild compression exercised by the gloves aids in muscular stabilization and reduces vibration resulting from impact with movements. This product can be used as coadjuvant treatment in pain of the forearms and wrists.

ANVISA, National Health Surveillance Agency, recognized the efficacy and safety of this product and granted the registration ANVISAMS N° 80104760006 on April 25, 2011.

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