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A Single-Center, Prospective, Controlled, Double Blind and Randomized Study for Evaluation of the Efficacy and Safety of Invel® Actiive Glove with Invel® Technology

Helena Hideko Seguchi Kaziyama[1], Manoel Jacobsen Teixeira[1], Ricardo Bocatto de Oliveira[1], Carina Mamy Nishimura[1], Vivian Massayo Kaziyama[1], Rosa Alves Targino de Araujo[1], Karine A. S. Leao Ferreira[1], Cidlia Yuko Wada[2], Roberta Pessoa Simoes[3]
[1]Pain Group of the Hospital das Clfnicas, School of Medicine, University of Sao Paulo - USP; [2]Statpharm Assessoria Cientifica; [3]INVEL

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 fictional 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, with intense heat and stabbing sensation. It can become extremely strong that it can be misdiagnosed with bone pain, which hampers diagnosis.[(3)]

Myofascial trigger point (TP) can cause a tingling sensation and numbness. In this situation, the electroneurographic examination and the neurological examination are often 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 Bioceramica® incorporated in Invel® Actiive Glove can be another coadjuvant treatment option for alleviating pain and aiding in rehabilitation.[(3)]

Objective

Primary objective: To assess the effectiveness of the Invel® Actiive Glove in reducing muscular pain specifically in patients diagnosed with myofascial pain syndrome in the wrists.

Secondary objective: To evaluate functional capacity of upper limbs of patients with myofascial pain syndrome and to evaluate the safety of using the product.

Methodology

A single-center, prospective, controlled, double blind and randomized study was perfonned, 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® Actiive 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® Actiive Glove) and Group B (placebo, which used the glove of the same fabric, however with the incorporation of Bioceramica® 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:

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

Results

Intensity of Pain:

The reduction in pain was assessed over time using the Visual Analog Scale (VAS). In Group A (those using Invel® Actiive Glove), a 12% drop in pain was observed in V2, followed by a 28% drop in V3. In Group B (placebo), there was a variation of 11% in V2 and 14% in V3. Significant differences were found in the absence of pain at 14, 28, and 56 days compared to the baseline, specifically in the elbow and wrist, at a significance level of 5%. The average percentage of pain relief in the wrist was 55.55% in Group B and 33.33% in Group P, with the former experiencing a higher level of pain reduction.

Clinical Assessment of the Pain:

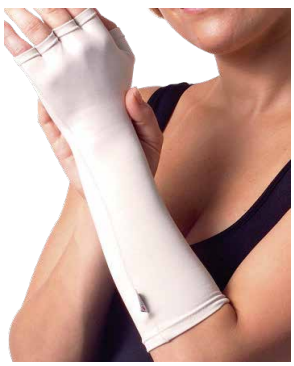
The assessment of pain location and reduction revealed significant differences in the absence of pain at 14, 28, and 56 days compared to the baseline, specifically in the elbow and wrist, with a significance level of 5%.

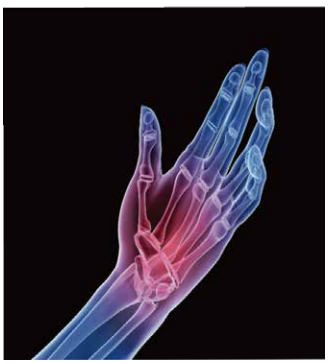
Functionality:

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® Actiive 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.

References

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