

Effectiveness of Invel® Active Insole in Reducing Muscular Pain and Physical Fatigue in Guarulhos Municipal Guard Collaborators: A Study

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Introduction

The demanding nature of the Civil Guards' work, which involves long periods of walking and maintaining static postures, can lead to physical discomfort and necessitates adequate preparation and physical strength. In addition to other factors such as wearing inappropriate footwear and the stress associated with facing danger and threats, these conditions can contribute to the development of chronic pain in the lower limbs. Also, The collaborators carry out their daily duties while being burdened with additional weight due to the presence of a bulletproof vest, combat boots, guns, and batons. The combined weight of these essential job tools can range from 17 to 26 lbs. The pain, according to STERNBACH (1968), can be translated as personal and particular sensation of physical suffering that involves real or potential tissue damage. It is a pattern of responses that act to protect the body against damage and are related to psychosocial, behavioral and psychophysiological processes, being a multifactorial disease. It is known that in the lower limbs, no form of therapy alone is quite effective. The debilitating impact of chronic pain in the lower limbs necessitates the exploration of new procedures that offer a low-risk solution. The infrared phototherapy constitutes a therapeutic tool noninvasive which should be incorporated into guidelines for those suffering from pains. (RAMOS et al, 2006; MACHADO, 2005). In order to promote the quality of the life of these workers, the Secretary for Public Security Subjects of the General Office of Guarulhos, introduced in their program "Quality of Life for Public Safety Services" the Invel® Active insole.

Objective

Assess the effects of using insoles during daily activities on the prevention and alleviation of pain, fatigue, and leg swelling reported by the user, collaborators of the Municipal Guard of Guarulhos. Evaluation conducted before and after the utilization of Invel® Active insoles.

Secondary : Evaluate the changes in the aspects related to the quality of life of the collaborators of Municipal Guard of Guarulhos during treatment by completing a questionnaire before and after using the product. Evaluate the safety in the use of the product by reporting type, intensity and frequency of adverse events and the satisfaction regarding the quality of the product.

Methodology

Execution place of the clinical trial :

General Office of Public Safety of the Prefecture of Guarulhos

Number of Volunteers :

Participated of the visit of Pre-valuation a total of 758 persons. However, the study was conducted with 548 volunteers.

Form of valuation : Pain according to Visual Analogue Scale – VAS.

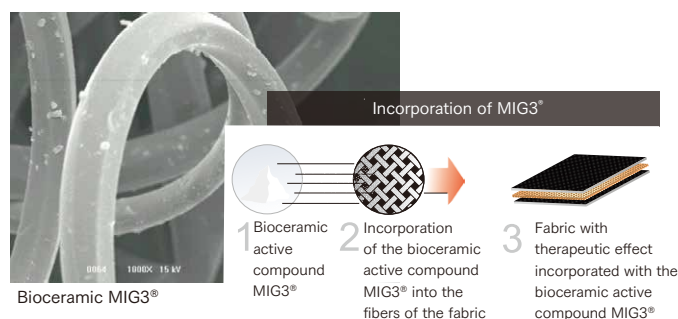
Visit of Pre-valuation : Volunteers were selected according to inclusion and exclusion criteria. After receiving information on the product and methodology used, signing the TCLE. At the same day, they answered the pre-valuation questionnaire and were orientated to:

1. How to place the Invel® Active Insole inside their combat boots;
2. To use Invel® Active Insole during 30 consecutive days in their work journey;

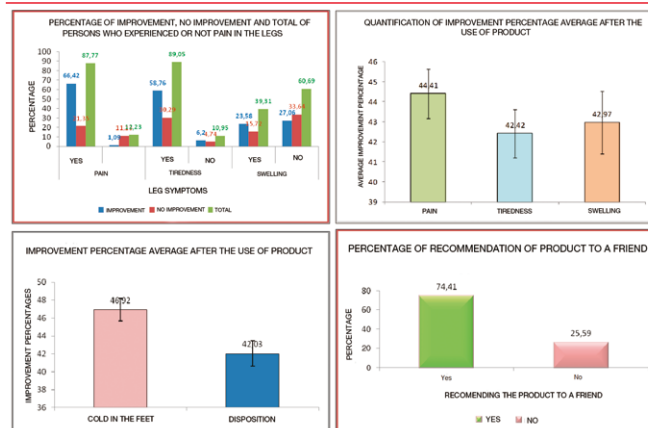
Visit of Post-valuation : 30 days after starting the use of Invel® Active Insole consecutively, the persons were again valued with a Post-valuation questionnaire regarding the percentage of improvement in pain, tiredness and swelling and also regarding to the satisfaction with the product.



Figure 1 : Investigational Product :
Invel® Active Insole (100% Polyester fabric
incorporated with MIG3® Invel®)



Results



Safety : No adverse event was observed in the studied population

Conclusion

Among the various symptoms experienced, including leg pain, tiredness, swelling in the legs, and cold feet, the use of insoles demonstrated significant results. Specifically, there was a remarkable reduction in leg pain intensity, with a 76% decrease as assessed by the VAS scale in the post-evaluation period compared to those who reported pain in the pre-evaluation period. Additionally, there was a 61% improvement in leg swelling observed in the post-evaluation compared to the pre-evaluation. The product received a high recommendation rate, with 74.51% of participants stating they would recommend it to a friend. The product performs a photochemical and a cutaneous vascular effect, without risk. Therefore can be used in the treatment of pain, tiredness and swelling of the lower limbs.

ANVISA, National Agency for Sanitary Vigilance, recognized the efficacy and safety of this product and granted on March 18th, 2013 the ANVISA / MS register No. 80104760011.

References

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