

Histological and Ultramicroscopic Clinical Study of the Skin with the Use of Tank Top Invel[®], Incorporated with MIG3[®], Radiator of the Far Infrared Ray in the Range of 3,0 to 14,8 mm: Analysis of Collagen Fibers, Elastic Fibers and of the Mitochondria

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Introduction

As the outermost barrier, the human skin is in direct contact with numerous environmental factors, including sunlight. The solar spectrum that reaches the earth's surface is composed by ultraviolet radiation (UVA and UVB) visible radiation and infrared radiation.

The harmful effects of ultraviolet radiation in the human skin were the great interest of photobiological research in the past. According to epidemiological and experimental data reported by KRUTMANN et al. in 2003, chronic exposure to UVA and UVB radiation not only causes acute reactions such as sunburns and immune suppression but also poses a significant risk for premature skin aging, known as photoaging, and the development of skin cancer, referred to as photocarcinogenesis.

In contrast to the detailed analysis of this response, the literature is scarce regarding the correlation of the infrared light with alterations in the tissues. HEE LEE, et al. 2006, praises a fibroblastic induction with an effective activation of the synthesis of new collagen and extracellular matrix with the use of therapies using infrared light.

However, with the increasing application of infrared rays for cosmetic purposes and the improvement of the quality of skin, there is still a considerable amount of research that needs to be conducted in this area, especially the real effects on the production of collagen and elastin by dermal fibroblasts.

Objective

Primary objective:

To assess whether the Invel[®] Tank Top has the potential to induce tissue changes, such as the proliferation or loss of collagen fibers and elastic fibers in the dermis, impairment of the epidermis, and potential mitochondrial dysmorphisms.

Secondary objective:

Evaluate if the product would stimulate benign proliferation of these same collagen and elastic fibers, in addition, the production of a new extracellular matrix which would benefit the tonus and elasticity of human skin.

Methodology

Study Draft:

An open study, unicentric, national, where the women volunteers received two Invel[®] Tank Tops for night use, for 8 hours, during 60 consecutive days. We included 12 healthy women volunteers aged between 21 and 35 years, anthropomorphically normolíneas and with healthy cutaneous skin.



Figure 1 - Invel[®] Active Tank Top

Investigational product: Invel[®] Active Tank Top (anti cellulite) - ANVISA/MS register No. 80104760008.

Collect of Samples:

After 60 days of using the product, the collection of samples was performed using the Punch Biopsy technique - a biopsy done by a round circular blade down through the epidermis and dermis, reaching the subcutaneous tissue and producing a cylindrical piece of tissue with minimal bleeding.

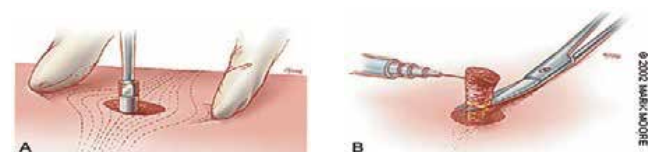


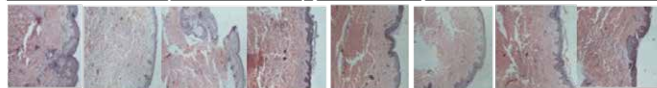
Figure 2 - Illustration of Punch Biopsy Technique.

Analysis of samples:

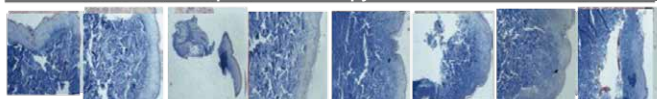
The cylindrical fragments obtained were parted in the middle with the assistance of a microtome and forwarded to the inclusion in formalin for optical microscopy (with the use of stainings of Masson's, Verhoeff and Picrosirius trichromes) and glutaraldehyde for electron microscopy. We evaluated the ultrastructure of the matrix, the membrane and mitochondrial cristae, with emphasis on the quantity and quality of collagen fibers and elastic fibers of the dermis, as well as the quality and morphology of mitochondria.

Results

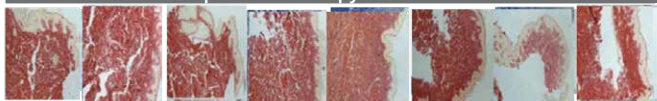
Optical Microscopy – Hematoxylin-Eosin:



Optical Microscopy – Masson:



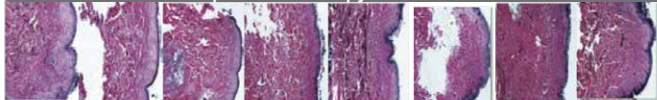
Optical Microscopy - Picrosirius:



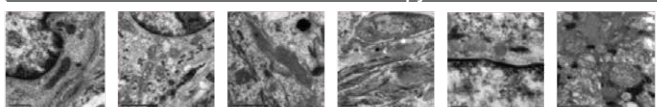
Optical Microscopy - Reticulin:



Optical Microscopy - Verhoeff:



Electronic Microscopy:



Conclusion

- 1 - The histological substrate of the skin biopsies under the special stains (Masson Trichrome, Reticulin, Verhoeff, Picrosirius, Hematoxylin eosin), show the epidermis and over all the and dermal collagen preserved. No evidence of inflammatory infiltrate and / or degenerative signs;
- 2 - The ultrastructural study in turn, showed the mitochondria with membranes and cristae intact as well as the mitochondrial matrix typically osmiophilic;
- 3 - The use of the Invel[®] Tank Top for 60 days/8hours a day, manufactured with fabric incorporated with MIG3[®], radiator of far infrared rays in the range of 3,0 to 14.8 µm, proved to be safe.

References

1. LEE, JH; ROH, MR; LEE, KH. Effects of Infrared Radiation on Skin Photo - Aging and Pigmentation, Yonsei Med. J, 2006; 47(4): 485-490.
2. SCHIEKE, S.M, SCHROEDER, P.; KRUTMANN, J. "Cutaneous effects infrared radiation: from clinical observations to molecular response mechanisms". Journal Photodermatol Photoimmunol e Photomed, 2003; 19(5): p.228-234.