

Topical composition of rh-Polypeptide-17 (Dermatopietin™) and Hexapeptide-18 for cosmetic anticellulite treatments: randomized, double-blinded, placebo-controlled anti-cellulite study

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Background: Cellulite is an important aesthetic problem that affects 85% of post-adolescent women. Cellulite is characterized by an irregular, dimpled skin surface of thighs, abdomen, and buttocks. Human visual perception of cellulite significantly relates to skin roughness characteristics, i.e. deviations of a real skin surface from its ideal form. Cellulite severity is best correlated with the percent of fat in the subregion and irregularity in the architecture of the dermal-subcutaneous border. Thus, consumer-oriented approach to the cellulite treatment must be directed toward decreasing roughness of cellulite-affected skin through improvement of regularity of dermal-subcutaneous border and/or decrease in the percent of fat in cellulite-affected subregions.

Objective: The purpose of the study was to evaluate the anti-cellulite efficacy of a topical cosmetic formulation comprising combination of rh-Polypeptide-17 and Hexapeptide-18, wherein rh-Polypeptide-17 (Dermatopietin™) is an activator of dermis remodeling and Hexapeptide-18 is an activator of cutaneous microcirculation.

Design: Twenty female volunteers (43.6 ± 8.8 years of age; BMI mean 24.9; and BFI mean 32.6) presenting visual signs of cellulite participated in a randomized double-blinded, placebo-controlled trial. Forty thighs from 20 subjects were randomly assigned to receive topical application of either the Test Article or the Placebo. The Test Article or the Placebo was applied onto a skin of thighs twice-a-day (morning and evening) for eight weeks. Anthropomorphic and ultrasonography measurements were performed at baseline, within 8 weeks of the treatment period, and two weeks after the treatment was stopped.

Statistics: Non-parametric, exact statistical test for small groups: Permutation test for paired samples, StatXact® V.5.0.3, Microsoft Excel 2003.

Results: No irritation, itching, or other side effects were observed during the topical treatment with the Test Article or the Placebo. These results suggest that the cosmetic formulation comprising combination of rh-Polypeptide-17 (Dermatopietin™) and Hexapeptide-18 is well-tolerated on skin.

Ultrasonography measurements. The Number of Dark Pixels (NDP) in epidermis plus dermis area on ultrasonograms of thighs was progressively decreased in the Test group during the observation period (8 weeks of treatment plus 2 weeks after stop of the treatment) See Fig. 1A.

Significant differences in NDP evolution were observed at days 14, 28, 56, and 70 between the Test group and the Placebo group ($p < 0.05$).

There were statistically significant differences in NDP in the Test group between mean values at baseline level (day 0, D0) and those at D28 (-12.9%, $p=0.03$), D56 (-25.9%, $p=0.006$), and D70 (-36.8%, $p=0.0001$).

The Number of Dark Pixels in dermis on ultrasonograms corresponds to low echogenic depositions, e.g. fat and water, in the dermal fibrous protein network. These results suggest that that a topical treatment with a cosmetic formulation comprising combination of rh-Polypeptide-17 and Hexapeptide-18 is effective for reducing fat and water deposition in dermis and, thus, improving regularity of dermis fibrous network composed by collagen and elastin.

Dermis-hypodermis Junction Distance (JD) decreased in the Test group during the observation period (8 weeks treatment plus 2 weeks after treatment stop).

Significant differences in Junction Distance (JD) evolution were observed at D14, D28, 56, and D70 between the Test and the Placebo group ($p < 0.05$, Fig. 1B).

There were statistically significant differences in the Test group between JD mean values at baseline level (day 0) and those at days 28 (-21.5%, p=0.0001), 56 (-17.7%, p=0.0001), and 70 (-21.1%, p=0.0001).

Dermis-hypodermis junction distance is a measure of the subcutaneous dermal border irregularity, which is related to the irregularity of skin surface and to the human perception of cellulite severity. These results suggest that topical treatment with cosmetic formulation comprising combination of rh-Polypeptide-17 and Hexapeptide-18 is an effective for improving regularity of dermal-subcutaneous border, and thus reducing cellulite severity.

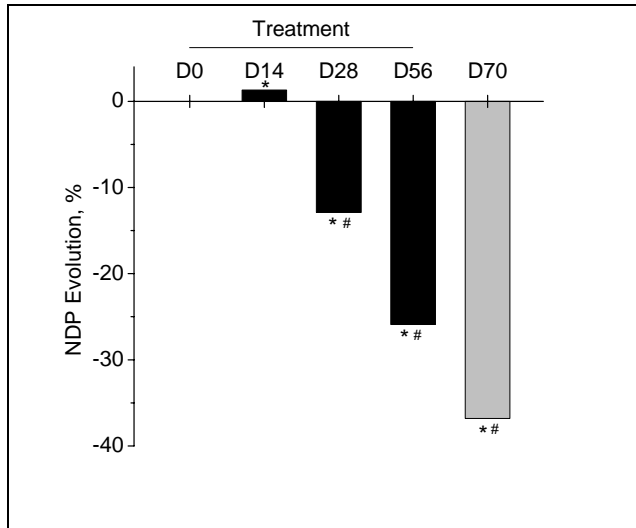


Fig.1. NDP Evolution.

Evolution of Number of Dark Pixels (NDP) on ultrasonograms of thighs in subjects presenting visible cellulite on thighs topically treated with topical cosmetic formulation comprising combination of rh-Polypeptide-17 and Hexapeptide-18. *Differs significantly from Placebo (p<0.05). #Differs significantly from the baseline (D0; p<0.05).

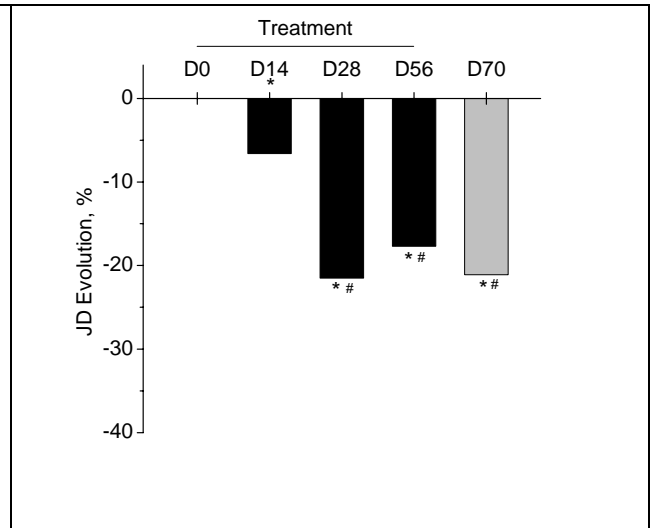


Fig. 2. JD Evolution.

Evolution of hypodermis-dermis Junction Distance (JD) in subjects presenting visible cellulite on thighs topically treated with topical cosmetic formulation comprising combination of rh-Polypeptide-17 and Hexapeptide-18. *Differs significantly from Placebo (p<0.05). #Differs significantly from the baseline (D0; p<0.05).

Anthropometric measurements. There were no significant (p>0.05) BMI differences (24±3.0 vs. 24.1±3.0) and BFI differences (32.1±5.3 vs. 32.6±4.7) between its levels at baseline (day 0) and those after 56 days of the cosmetic treatment.

There were no significant (p>0.05) thigh girth differences between the Placebo and the Test group during the treatment period.

Conclusion

These results demonstrated that a cosmetic combination of rh-Polypeptide-17 (Dermatopoin™) and Hexapeptide-18 represents an effective and well-tolerated topical anticellulite treatment with focus on dermis-hypodermis regularity improvement, and may have an importance in the consumer-oriented management of the cellulite.