

TREATMENT OF GYNOID LIPODYSTROPHY (CELLULITE) WITH HIVAMAT® 200: A PILOT CLINICAL STUDY

Korkina L, Reinhold J¹, Rota L, Primavera G, and Raskovic D

Istituto Dermopatico dell'Immacolata (IDI IRCCS) Rome, Italy

¹ Physiomed Elektromedizin AG, Schnaittach, Germany

Gynoid lipodystrophy (cellulite) is a common condition in 85% of post-adolescent women for which treatment is frequently required. There are numerous treatments offered to female population concerned by unsightly appearance of the cellulite-affected thighs, buttocks, and hips. All treatment modalities attempt either to attenuate the aggravating factors (obesity, bad habits, and the lack of physical exercise), or to induce lipolysis, or to disrupt altered fibrous septa, or improve microcirculation, or diminish the local inflammation. The physical and mechanical methods including massage, pulsative suction, radiofrequency fields, infrared heat and laser light, and pharmacological agents applied topically or by intradermal injections are among the most popular although low efficient treatments of cellulite. A very high concern has been raised recently about the safety and efficacy of unreasonably expensive methods for the cellulite treatment. A pilot open randomized clinical trial was carried out in the Department of Dermatology, Cosmetology, and Skin Pathophysiology of the Dermatology Institute to prove both safety and clinical efficacy of the HIVAMAT® 200 method (Physiomed Elektromedizin AG, Germany). The physiotherapeutic method is based on the use of intermittent electrostatic fields of low intensity ($U = 100-400V$; $I = 500\mu A$) and extremely low frequency ($F = 5-200Hz$) which create deep oscillation in the underlying tissues (epidermis, derma, subcutaneous layer, and myofibrils). Thoroughly studied molecular and cellular mechanisms of HIVAMAT® 200 method allowed us to develop several protocols focused on pathophysiological features of cellulite: (1st protocol) to improve microcirculation in the dermal and subcutaneous layers; (2nd protocol) to diminish inflammation and edema; (3rd protocol) to disrupt or/and prevent the formation of fibrous septa; and (4th protocol) to diminish number of estrogen receptors on the skin cells. Thirty women (age = $39.0\pm 9.6y$; weight = $58.0\pm 6.1 kg$; BMI = 1.63 ± 0.007) with clinical features of cellulite of I-III grade (Grade I – 14; Grade II – 12; and Grade III – 4) were recruited after their informed consent and approval of the local Ethical Committee. They were treated with the HIVAMAT® 200 anti-cellulite protocols twice a week for three months (the total duration of the treatment was 500-540 minutes). The clinical features were assessed by three independent dermatologists using high resolution digital photographs. The instrumental assessment included repeated measurements of circumferences (upper third of thigh, lower third of thigh, and upper third of leg), cutometry (the measurement of skin elasticity), ultrasound determination of microcirculation and fibrous tissue presence.

CONCLUSIONS: The pilot study confirmed the absolute safety of the method (there were not any immediate or remote adverse effects or complaints from the participants), its high efficacy in 93% (n=28) of the women (the circumferences diminished from 59.0 to 57.1 cm, upper thigh, $p<0.0002$; from 51.4 to 49.8 cm, lower thigh, $p<0.0001$; from 40.7 to 38.5 cm, upper leg, $p<0.0003$). The elasticity characteristics were improved in 48% (n=14) of the patients; the edema, lymphostasis, and fibrous heterogeneity of subcutaneous layer were improved remarkably in 80% (n=24) of the patients. The general conclusions of the experts were that the HIVAMAT® 200 method was efficient in more than 80% of the cases with moderate (grade I-II cellulite).