New Approach in Body Contouring Non-Invasive Treatment

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INTRODUCTION

Effective body appearance modification through both invasive and non-invasive treatment methods has been demonstrated in numerous clinical studies. Liposuction and assisted liposuction are at present the most extensively utilized methods for reducing localized fat deposits [1]. Technological progress has also made the use of radiant energy in aesthetic medicine a feasible non-invasive treatment solution [2]. Ultrasound and high-frequency wave treatment are among the most promising non-invasive treatment methods, and are based on the principle of mechanical and thermal affectation stimulating physiological processes resulting in fat tissue reduction.

HIGH-FREQUENCY AND ULTRASOUND IN MEDICINE

The effectiveness of high-frequency (HF) wave therapy has been proven in several branches of medicine. For example, it has been used as a component in revolutionary oncologic treatments as a result of its effectiveness in stimulating a cytotoxic deep-tissue thermal response [3]. Ultrasound (US) has been used in physical medicine for over seventy years, and has been demonstrated effective in stimulating both an increase in metabolic rate and tissue regeneration [4].

THE TREATMENT DEVICE

The EXILIS™ device combines both high-frequency and ultrasound in one applicator head, resulting in a very promising new treatment method for aesthetic medicine. The continuously cooling applicator tip protects the skin of the treated area while allowing the sub-dermal fat layers to reach higher and therefore more effective temperatures. A LCD display on the hand-held applicator allows the user to monitor basic therapy parameters such as elapsed treatment time, energy level and surface temperature. Operational energy ranges from 5 W to 120 W and carrier frequency is 2 MHz (HF) and 2 MHz (US). Optimal settings are dependent on the specific treatment protocol and patient tissue parameters, such as the size of the area to be treated, fat thickness, water content, tolerability, etc.

BTL EXILIS™ EFFECTS

Redundant fat deposits are typically composed of metabolically near-inactive fat cells [5]. High-frequency energy initiates a targeted deep thermal heating, increasing metabolic activity and accelerating lipolysis in local fat tissues. The volume of the fat cells decreases and the fat layer is shrunken [6].

The combination of ultrasound and high-frequency energy allows access to and treatment of generally resistant fat tissues. High-frequency energy targets precisely defined deep fat layers, while constant cooling of the skin's surface maintains patient comfort and protects fine dermal structures. Meanwhile, the ultrasound waves interact with the tissue's fibrotic structure, stimulating the fat cells' formation called lobules transformation into separate units. At this point the fat cells are highly susceptible to the metabolic mechanisms.

BODY SHAPING TREATMENT PROCEDURE

Therapy was conducted by a medically educated specialist. Each participant has to cooperate regarding anamnesis to rule out possible contraindications and sign an informed consent form. Therapy protocol dictates that the patient be weighed, photographed and have treatment templates marked. To ensure optimal contact, the patient's skin is lubricated with mineral oil before the hand-held applicator tip is applied. A reference electrode is placed near the treated area. The EXILIS™ device's energy parameters range between 5 to 120 Watts (typically 60-80W) and can be adjusted during therapy by pressing the keys under the applicator's LCD display. It is recommended to begin at a lower power level (50W) and then gradually increase it until the optimal skin temperature is reached (surface ≈ 42 degrees Celsius). The applicator monitors the skin's surface temperature via an internal thermometer, cools the dermis throughout the therapy session and can be adjusted as needed. A maximum temperature of up to 42.5 degrees Celsius is recommended. The average treatment time for a standard area of 600 cm^2 is approximately 20 minutes. Additional pre- or post-therapy measures on the patient's part, such as anesthetic or modified diet, are not required.

CLINICAL EVALUATION

A total of 41 patients (35 female, 6 male) participated in the effectiveness evaluation trial of the EXILIS device, 37 com-

Fig. 1: The average score for the abdominal treatment was 4.3 points. 70% of patients gave 4 points (significant improvement) and 15 % gave 5 points (excellent improvement). Fig. 1 shows a case with a patient index of 4. The independent assessors scored it at 3.9.

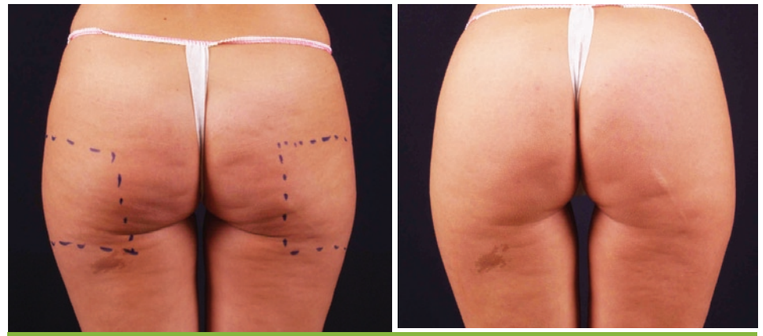

Fig. 2: 15 cases of treated thighs showed an average score of 3.9. The Fig.2 photograph depicts a patient with a score of 3 and an independent assessor score of 3.8.

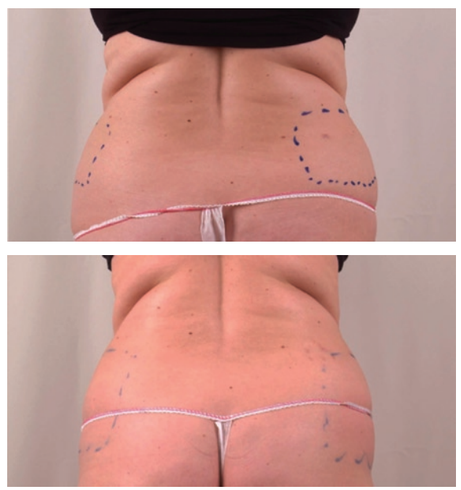

Fig. 3: The lowest satisfaction scores were recorded with treatment of the flanks (3.6). Independent assessors gave an average score of 3.0. The case in Fig. 3 represents a patient with a score of 4 and an independent assessor score of 3.

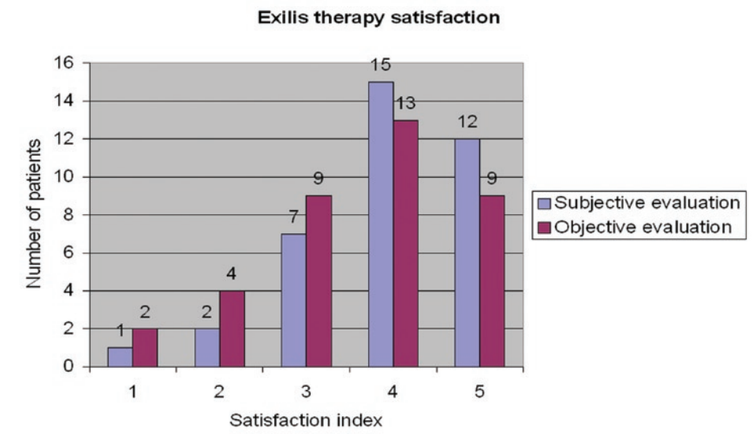

Fig. 4: Comparisons of objective and subjective evaluations show minimal deviation. The patient satisfaction index taken from all results was generally higher (4.0) than the objective assessment index (3.6). The majority of patients (73%) scored significant to excellent improvement compared with physicians (60%).

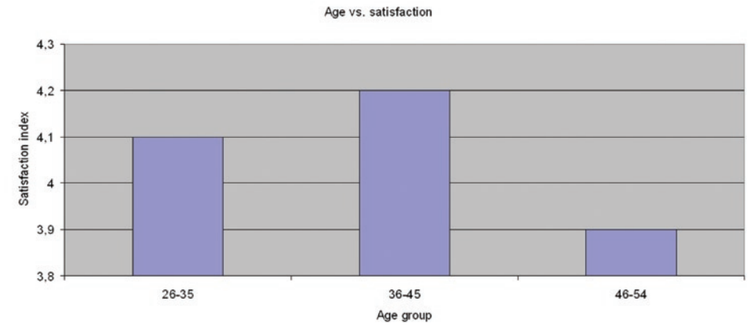

Fig. 5: The average satisfaction index was similar across all age groups. The most satisfied volunteers were between ages 36-45 and scored the treatment at 4.2 points. Overall, there was no significant difference between the three groups (0.3 points).

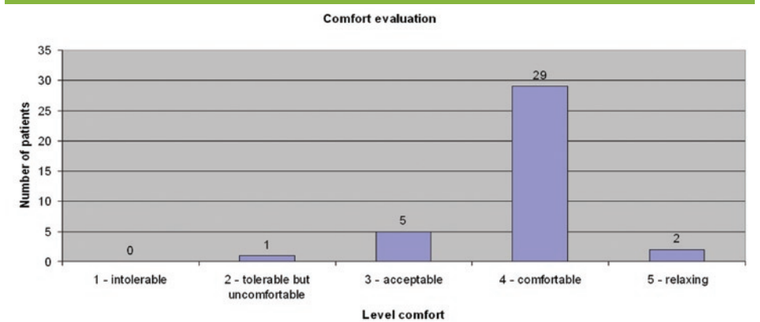

Fig. 6: In spite of mild redness visible on treated areas, no one described the therapy as intolerable or uncomfortable. 13.5% (n=5) of volunteers found it as acceptable, 80% (n=29) felt comfortable and 5 % (n=2) assessed the therapy course as relaxing. If compared the age related groups, there was no significant difference.

pleted the whole protocol. All patients were healthy and without any contra-indications. Treated areas of abdomen (n=25), thighs (n=15) and flanks (n=8) were photographed at the beginning and end of therapy and at a two-month follow-up (Fig.1-3). Number of other treated areas (upper back, upper arms, ...) were not statistically significant for further examination. Patients received 4 to 5 (avg. 4.5+-0.8) treatments at 10- to 14-day intervals, with each session lasting approximately 20 minutes, depending on the treated area location and size (avg. 600 cm^2).

Volunteers were divided into three age groups: < 35 years (n=9), 36-45 years (n=18), > 45 years (n=10). . A five-grade scale was used (1 - no improvement, 2 - mild improvement, 3 – good improvement, 4 – significant improvement, 5 - excellent improvement) for improvement classification. The volunteers rated their results according to the scale after their final therapy session and during the 2-month follow-up. To objectify the results, independent clinical specialists were asked to assess photographs taken before treatment (baseline) and at the 2-month follow-up.

CLINICAL REPORT

Given the data (Fig: 1, 2 and 3), the BTL EXILIS™ treatment brings the most significant results on abdominal areas.

The participants were also asked to evaluate heat sensation from the applicator during the therapy session. Active cooling was used at all times during the therapy session. The patients described the therapy as comfortable. Mild redness of the skin diminished a few minutes after completing the session. The heat sensation was usually rated higher by patients with a thinner fat layer.

No significant changes were observed in the patients' body weight. Average weight was 78kg +-2 SD before and 77 kg after therapy.
The comparison of post-treatment scores and those from follow-up visits showed no significant differences in patient satisfaction and objective evaluations by physicians. The long-lasting effects of the treatment were evident.

INDEX OF COMFORT

As was expected, 80% (n=29) of patients found the Exilis therapy very comfortable . We asked them, to classify the general therapy course on five grade scale (1-intorelable, 2 - tolerable but uncomfortable, 3 – acceptable , 4 – comfortable 5 - relaxing). The patients were asked to evaluate following aspects: side effects, feelings during the therapy of heat, cold and pressure etc.

CONCLUSION

This clinical study demonstrates that the EXILIS™ device is both safe and effective for body contouring. Combined high-frequency and ultrasound treatment is able to induce volume reduction of unwanted fat deposits. Further details of EXILIS treatment results ought to be examined in prospective studies.

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