CIRCUMFERENCE REDUCTION BY TriPollar™ RF TECHNOLOGY USING THE apollo™ DEVICE

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Abstract:

**Background:** Aesthetic procedures aiming at circumference reduction are desired by both women and men worldwide. Non-invasive treatments using IR light, RF, laser or ultrasound are common practice but do not necessarily provide the optimal solution. apollo™ is the first medical grade non invasive system that uses cutting edge 3rd generation TriPollar™ RF technology, for the purpose of circumference reduction.

**Objective:** The Evaluation of the safety and efficacy of the apollo™ device for non invasive treatment of excess fat manifested by circumference reduction.

**Method:** 37 healthy female patients in three clinics underwent sessions of TriPollar™ treatments using the apollo™. The treatment was performed in the body at a week interval between sessions. Results were assessed using photographs and circumferential measurements.

**Results:** Significant reduction in body circumferences was observed following the treatment period. The average circumferences reduction in main body areas (abdomen, buttocks, thighs), was $3.6 \pm 2.4$ cm with a maximum reduction of up to 10.5 cm in the abdomen. No adverse events were recorded during the evaluation period.

**Conclusion:** The apollo™ powered by TriPollar™ technology is a safe and effective procedure for the treatment of excess f

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**Introduction:**

Excess fat and cellulite are caused due to the enlargement of hypodermal fat cells and the alteration of connective tissue. Although significant clinical improvement may be achieved through surgical procedures, these are not without risk, and there is a growing demand for pain-free, mild, non-invasive solutions. These technologies offer a gradual and cumulative solution for body shaping by affecting both the connective tissues and fat. Treatments result in increased collagen regeneration and stimulated fat metabolism in a safe, painless ‘lunch time’ clinical process.

**Technology:**

Several treatment options are currently available for non invasive fat reduction. These include professional devices based on optical energy or Radio Frequency (RF) electrical current, devices based on vacuum and massage, and devices based on a combination of the above mentioned technologies. Ultrasound is also used for the purpose of reducing circumference. The apollo™ powered by the TriPollar™ technology is a novel RF system developed and marketed by Pollogen™ Ltd. The technology is based on three or more electrodes designed to deliver focused RF current into the skin, thus generating heat through resistance in both the dermal and subcutaneous layers. Selective and focused electro-heating of the skin is intended to stimulate collagen remodeling and increased fat metabolism, resulting in non invasive treatment for cellulite, and circumference reduction.
Device Description:

The apollo™ device delivers RF current at a frequency of 1 MHz and a maximum power of 50 watts. The system consists of a main unit, three applicators, a foot switch and a bio-feedback control. The three applicators differ in size and configuration and are indicated for treatment of different body and facial areas. Applicator No. 1, which can treat an area of 9.4 cm² at a time, is indicated for the treatment of large body areas. Applicator No. 2 which covers a treatment area of 1.7 cm² is indicated for the treatment of medium sized body areas and various facial areas. Applicator No. 3 which covers a treatment area of 0.4 cm² is indicated for the treatment of very small areas and delicate facial areas such as around the eyes and lips.

The power level and the treatment time can be adjusted by the operator from the user interface on the Main Unit. No active cooling of the electrodes or the skin is required.

The apollo™ is indicated for non-invasive use in dermatologic procedures for treatment of wrinkles, skin tightening, and the reduction of cellulite.

Objectives:

The evaluation was intended to assess the safety and efficacy of the apollo™ for non-invasive fat reduction manifested by circumferences and cellulite reduction.

Methodology:

apollo™ treatments were conducted in 3 clinics during a period of 6 months (February – August 2008). Treatments were performed once a week following an in-service training session. Prior to treatment a medical history was taken to exclude any contraindication such as pregnancy, any implantable electronic device that could be disrupted by RF energy and any active dermatological or collagen-vascular disorder.

Treatment areas were first cleaned and then lubricated with medical grade Glycerin. Patients were provided with a ‘bio-feedback control’ which enabled them to stop the treatment should they experience significant discomfort. Applicators were applied with continuous circular or elliptical movements, with slight pressure. A non-contact, infrared thermometer (Newtech Sources Co. Ltd.) was used to monitor external skin temperature during treatment. The treatment endpoint was reaching a temperature of 40-42 C ° on the epidermis and maintaining it for the recommended typical exposure time.
Measures:

Treatment results were recorded by photographs and circumferential measurements taken at standard conditions.

- **Photographs:** Photos were taken using a digital camera of at least 8 mega pixels placed on a tripod. Photos were taken before (baseline) and immediately after the 1st treatment (for the evaluation of immediate results) and at the following visits (for long term results). Photos were taken under standard settings: distance, angle, position, background and lightening.

- **Circumference measurements:** Circumference measurements of body areas were taken before each visit at standard conditions: always at the same height from the floor or at the same distance from a defined anatomical point, constant distance between the subject’s feet (about the width of his/her pelvis), and arms crossed and positioned in front of the chest. In most cases, four marks of the same height at the front, back and sides of the anatomical area were made using a make-up pencil. Afterward, a measuring tape was placed across all marks. This procedure ensured a straight, horizontal and continuous line between the marks.

- **Safety and Adverse Events:** Adverse events, complications or side effects during or in between treatments were recorded. These included: excessive erythema or edema lasting longer than normal (more than 1-2 days), crusting, blistering, burn, hyper-pigmentation, hypopigmentation, scaring or pain.

- **Study demographics:**
  - A total of 37 patients, all females, were included in the evaluation. 33 patients completed a full treatment session, 4 patients withdrew after 2 treatments due to: incompliance with the protocol (2), herpes predisposition (1) and non-satisfactory results (1).
  - Patient Age: Average age 47 years (range: 23 - 82 years)
  - Treatment areas: 47 anatomical areas were treated:
    - Abdomen: 16, Buttocks: 5, Thighs: 9, Arms: 3, Hands: 3, Face: 9, Neck: 3

Results:

**Number of weekly treatments:**
The average number of weekly treatments was 7 (a range of 2-15). The number of treatments was determined according to the individual condition and specific needs of each patient.

**Circumferential Reduction:**
Significant circumferential reduction was measured (p <0.0001). The average circumference reduction in main body areas (abdomen, buttocks, thighs), was 3.6 ± 2.4 cm. In percentage reduction vs. baseline: 4.2 ± 2.7%.

**Improvements in specific anatomical areas:**
- **Abdomen** – The average circumference reduction was 4.5 ± 2.7 cm. Maximum reduction was 10.5 cm, P=0.000003
- **Buttocks** – The average circumference reduction was 3.1 ± 1.7 cm. Maximum reduction was 5 cm, P=0.0076
- **Thighs** – The average circumference reduction was 2.4 ± 2.0 cm. Maximum reduction was 6.4 cm, P=0.000019
- **Arms** treatment was performed on 3 patients. 2 patients experienced considerable reduction of 2.1 ± 0.7 cm, maximum reduction was 2.8 cm.
**Short-term Immediate effect:**
Slight erythema and/or edema were detected at the end of the treatment and generally lasted for a few hours and up to 1 day. This immediate effect contributes to an overall tightening and firming of the skin. Transient erythema and/or edema are indications of energy delivery to the tissue to stimulate the long term therapeutic effect.

**Weight:**
Patients’ average weight before the treatments was 66 Kg. At the end of the sessions, the average weight was 65 Kg.

**Adverse Events:**
No significant adverse effects were recorded during the evaluation period. Most patients reported that the treatment was pleasant and felt like a nice warm massage.
Summary:

The apollo™, powered by TriPollar™ technology, is a safe and effective device for the treatment of excess fat and body contouring. The treatment is painless and pleasant even when performed on sensitive areas with sagging and loose skin such as the inner thighs and the arms. The apollo™ treatment is suitable for patients following pregnancy, liposuction or dramatic weight loss who have excessive loose skin. Following a treatment session with the apollo™ device, most patients benefit from immediate as well as long term results.

Clinical Results:

Abdomen Immediate results: Patient post dramatic weight loss of ~40Kg. Before (left) and immediately After one treatment. (right)

Abdomen Immediate results : Before (left) and immediately After one treatment. (right)
Thighs: 4.2 cm reduction on left thigh, 4.3 cm reduction on right thigh. Before (left) and After 8 treatments. (right)

Thighs: cellulite and circumference reduction: Before (left) and After 3 treatments. (right)
Arms: 2 cm reduction. Before (left) and After 5 Treatments. (right)

Buttocks: 3 cm reduction. Before (left) and After 8 treatments. (right)