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T-Shape 2 Clinical Study Review

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INTRODUCTION

T-Shape 2 Technologies

T-Shape 2 is an FDA-approved Class II multifunctional face and body shaping system equipped with various technologies.

- Low-level Laser Therapy (LLLT)
 - Promotes regeneration and vasculature of the skin to aid in the decreased circumference of the desired area(s)
- Bipolar Radio Frequency
 - With three different levels, the T-Shape RF technology works to stimulate the production of collagen to provide lifting effects
- Electroporation
 - Allows for increased hydration and overall health of the skin
- Endodermic Massage with Vacuum Suction
 - With 4 different modes of suction, the endodermic massages aid in redistributing oxygen to increase blood circulation and allow for skin-firming and improved physique
- Mesospheric Deep Therapeutic Massage
 - Designed to improve the body's natural processes to improve circulation



Report # 2315F19F-1

Clinical Study Overview

Primary Objective:

The primary goal was to assess the safety and tolerability of the T-Shape 2/Proshape Med device, focusing on adverse events (AE), adverse device effects (ADE), and incidents related to device deficiency (DD).

Secondary Objective:

Secondary objectives included evaluating the device's efficacy in reducing localized fat deposits and improving skin firmness, as well as assessing customer satisfaction.

Study Design:

- 20 female subjects aged 18-60 with localized adiposity on the abdomen
- Each subject underwent 10 T-Shape 2 treatment sessions twice a week
- During the study the subjects did not alter their diet or exercise habits

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Clinical Study Highlights

Endpoints:

- Primary endpoints focused on safety and tolerability, these were recorded qualitatively by assessing the type, frequency, and severity of adverse events.
- Secondary endpoints included:
 - Quantitative measurements such as waist circumference, volume changes of the abdomen, skin compactness, thickness of subcutaneous adipose tissue, muscle ratio, and thickness of the rectus abdominis muscle.
 - Clinical evaluations of visibility of fat deposits and silhouette reshaping were also conducted.
 - Subjective assessments of customer satisfaction were measured using numerical rating scales.

Data Analysis:

Quantitative data were analyzed using measures of central tendency and dispersion, along with appropriate statistical tests to compare measurements at different time points. Qualitative data were summarized using frequencies.

Results:

- *No subjects experienced adverse events or breached inclusion/exclusion criteria.*
 - Therefore, all 20 subjects completed the study.
- The T-Shape 2 demonstrated safety, tolerability, and efficacy in reducing localized fat deposits and improving skin firmness. Additionally, subjects reported excellent pleasantness and perceived effectiveness of the treatment.
- In conclusion, the study confirmed the safety, efficacy, and acceptability of the T-Shape 2 device for targeted fat reduction and skin firming, as well as high customer satisfaction.

5 Key Findings



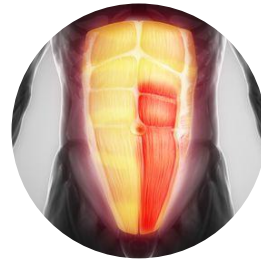
No adverse events related to the use of T-Shape 2 were reported among the 20 subjects during the 10 treatment sessions



Quantitative analysis revealed a significant reduction in waist circumference and volume changes of the abdomen



Instrumental analysis demonstrated an increase in skin compactness, suggesting an improvement in skin firmness



Evaluation of the muscle-to-fat ratio in the abdominal area showed material improvements



Subjective assessments using numerical rating scales indicated excellent pleasantness and perceived effectiveness

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Clinical Data



- 80% of patients experienced improvements in their body.
- An increase in muscle tissue: fat ratio of 23 % after 10 treatments
- 10% Improvement of skin tone and laxity after 10 treatments
- Abdomen circumference reduction on 2 cm average after 10 treatments
- Decrease in the abdomen area volume of 1481.19 cm³ average after 10 treatment
- Decrease of the thickness of total subcutaneous adipose tissue of 8% after 10 treatments
- Increase of thickness of the rectus abdominis muscle tissue of 14 % after 10 treatments

HOW IT WORKS

Several Mechanisms:



- It has effects that reduce swelling (anti-edematous), improve circulation, and promote skin health which helps with cellulite and connective tissue issues.
- It influences fat cells (adipocytes) to release fatty acids more easily. These fatty acids can then be broken down by the body, primarily through a process called lipolysis, which is promoted by certain hormones.
- The device also seems to affect muscle thickness in the abdomen, making the muscles stronger and increasing the ratio of muscle to fat tissue. This was confirmed by ultrasound measurements.
- Lastly, the device uses vibrations, radiofrequency, and laser stimulation to activate specific receptors in muscles, which improves muscle tone locally.

In simpler terms, this study found that the T-Shape 2 device is safe and can help reduce belly fat and improve skin firmness. It does this by affecting fat cells, improving circulation, and strengthening the muscles in the abdomen through various mechanisms.

Safety Study

FINDINGS & INTERPRETATION



REPORT #2315A24F-1_REV.01

Introduction



- The study evaluated the effect of professional treatment by observing temperature changes in subjects after 10 minutes of treatment. It involved 35 female volunteers aged 18-60 years who met specific eligibility criteria, ensuring good health and absence of designated contraindications and medical considerations.
- Participants received radiofrequency treatment with the multipolar handpiece on the arms and legs. 8 minutes were performed for the arm and the leg for 10 minutes, both at 100% intensity using different handpieces. The treatment aimed to maintain skin temperature within the range of 40°C-45°C, measured with a FLIR TG165 Imaging IR Thermometer.

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Study findings + interpretation.

- To achieve skin tightening, the skin's temperature must be in a range of 41-43°C. With this targeted level of heat, the dermal layer can release proteins that actively stimulate collagen production.
- The results obtained show that T-SHAPE 2 can maintain, on average, skin temperature in the range of 40°-45°C after 10 minutes of treatment.

Clinical interpretation:

- To achieve skin tightening, the skin's temperature must be in a range of 41-43°C. With this targeted level of heat, the dermal layer can release proteins that actively stimulate collagen production.
- No adverse effects or dropouts occurred during the trial, affirming the safety and feasibility of the treatment protocol performed.
- The study's findings support the incorporation of the treatment protocol into clinical practice, offering a safe and feasible option for the targeted intervention without concerns about adverse effects or participant non-compliance.

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CLINICAL FINDINGS

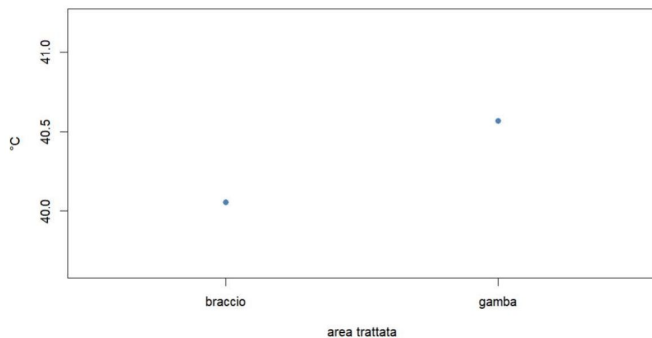
Temperatura cutanea - Skin temperature

Descriptive analysis

Treated area	Survey times	Mean	±	Standard deviation	Median	IQR	
Braccio	T10	40,1	±	1,2	39,9	39,2	- 41,0
Gamba	T10	40,6	±	1,9	39,9	39,2	- 41,9

Descrizione della variabile temperatura cutanea nelle due aree trattate
Description of the variable skin temperature in the two treated areas

Temperatura cutanea - Skin temperature

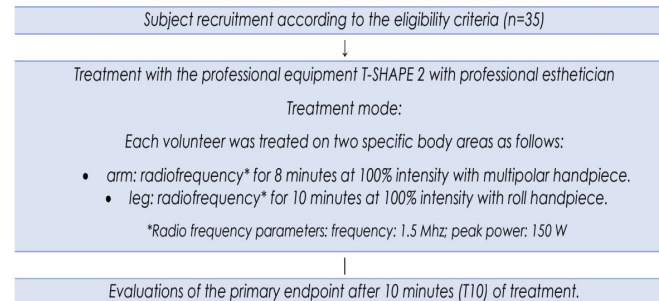


Andamento della variabile temperatura cutanea nelle due aree trattate
Trend of the variable skin temperature in the two treated areas

Dalla tabella in cui è riportata l'analisi descrittiva si osserva che per entrambe le aree trattate la temperatura cutanea rilevata rientra, in media, nel range stabilito di 40°-45°C dopo 10 minuti di trattamento.

The table displaying the descriptive analysis, shows that in both treated areas the detected skin temperature is, on average, within the established range of 40°-45°C after 10 minutes of treatment.

Trial scheme



Criteria for the subject withdrawal

The following rules were imposed on a possible subject withdrawal which may occur during the trial:

- breach of one of the inclusion/exclusion criteria;
- development of adverse effects;
- non-compliance.

Thank you!

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