

# CLINICAL TRIAL OVERVIEW

*Marc Winter, M.D., Laguna Hills, CA*

*Yoni Iger, Ph.D., Israel*

# VelaShape™

FDA Cleared for Circumferential\* & Cellulite Reduction

## BACKGROUND

### **What is body shaping?**

Body shaping is demarcated alterations of different anatomical zones of the body by affecting the structure and function of superficial connective tissues. This leads to the phenotypic result of circumferential and cellulite reduction with overall reshaping of the treated area.

### **What is the etiology of the condition?**

Atrophic degeneration of the hypodermal and dermal zones, including:

- Significant hypertrophic and minor hyperplastic changes of fat cells
- Mal-performance of the venous and lymphatic system
- Disturbed blood perfusion
- Glycation of collagen and hypertrophic septae

*Resulting in:*

- Suboptimal tissue condition giving advantage to fat cells having a relatively low metabolism
- Cyclic atrophy of the tissue as the fat cells further increase in size promoting increased circumference and a bumpy appearance on the skin's surface

### **What is needed to improve this condition?**

To initiate anabolic processes in the dermis, together with catabolic processes in the hypodermis, the aims are:

- To increase blood circulation
- To enhance fibroblast activity
- To improve lymphatic and venal drainage
- To accelerate metabolism of fat cell activity

All of these processes result in a smoother appearance of the skin and reduced circumference.

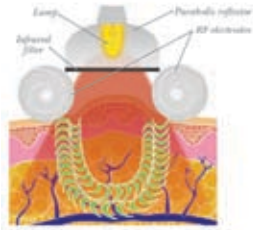
### **What is the challenge?**

To use a combination of technologies to perform two opposite activities in two different tissue depths – the dermis and the hypodermis.

# VelaShape™

## Circumferential Reduction\* & Cellulite Treatment

### HOW VELASHAPE MEETS THE CHALLENGE



#### Synergistic Use of Energies

The VelaShape device employs four modes of treatment:

- Infrared light heats the tissue up to 3mm depth.
- Radio Frequency heats tissue from 2 to ~20mm depth.
- Vacuum +/- massage mechanisms enable precise targeting of energy to the tissue, among other things.

**Biological Impact of Treatment** – Increased metabolism leading to anabolic and catabolic alterations at predetermined skin depths.

#### • Mechanical Manipulation (Vacuum +/- Massage)

- Stimulates lymphatic drainage and blood perfusion
- Facilitates fibroblast activity
- Reduces viscosity of fat cells clusters
- Promotes vasodilation and extravasation of oxygen and nutrients
- Enables heating at different pre-determined depths

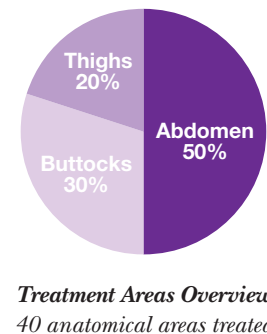
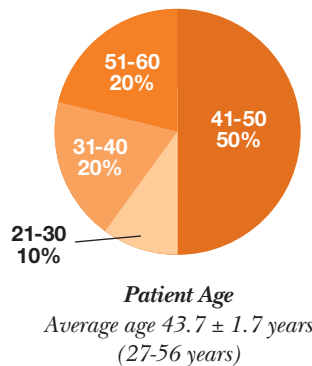
#### • Heating (Infrared + Radio Frequency Energies)

- Enhances blood perfusion and increases oxygen dissociation from oxy-hemoglobin
- Facilitates fibroblast activity
- Increases metabolism of fat cells
- Tightens the skin (septae and overall collagen)



### VELASHAPE STUDY: DEMOGRAPHICS

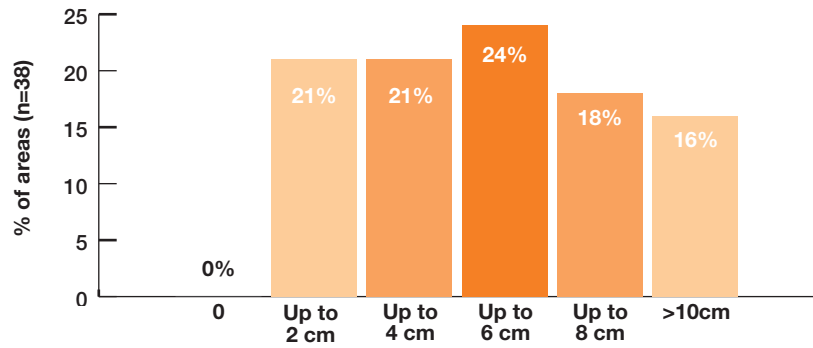
- 1 clinical site, U.S.
- 20 patients, all females
- Regular exclusion criteria, including no obesity
- All patients treated on abdomen were pregnant before (on average 11 years earlier)



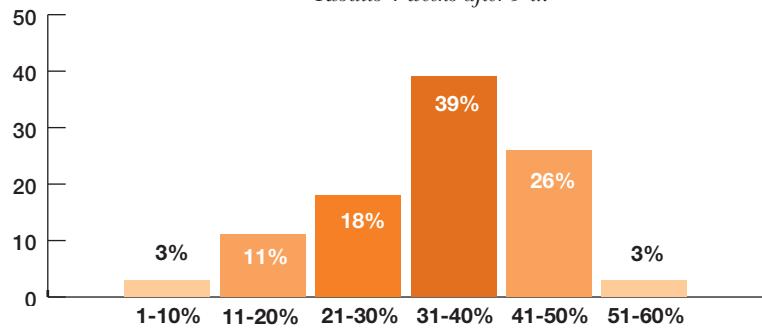
**RESULTS:**  
**CIRCUMFERENTIAL REDUCTION**

- Following 5 weekly treatments, the average circumferences reduction was  $5.93 \pm 0.79$  cm.
- In percentage reduction vs. baseline:  $6.07 \pm 0.69\%$ .
- Anatomical Areas of Improvement
  - Abdomen responds the best –  $7.37$  cm reduction
  - Buttocks –  $5.93$  cm reduction
  - Thighs –  $2.50$  cm reduction
- Patients' weight did not change significantly ( $167.9$  vs.  $167.7$  lb).
- Up to 60% overall skin texture improvement (including skin laxity and skin tone) was apparent after five sessions.

*Circumferential Reduction*  
 Results 4 weeks after 5 tx



*Skin Texture*  
 Results 4 weeks after 5 tx

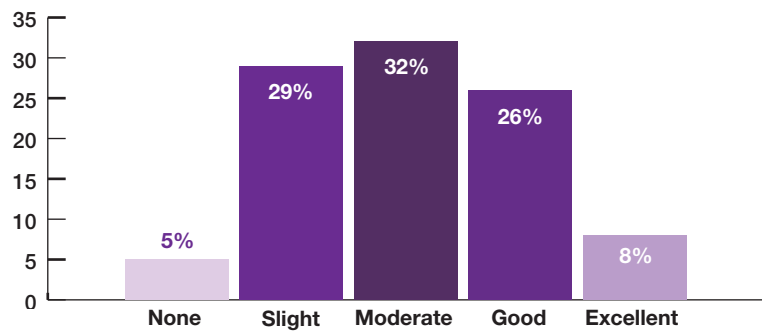


**ASSESSMENT OF IMPROVEMENT & SATISFACTION**

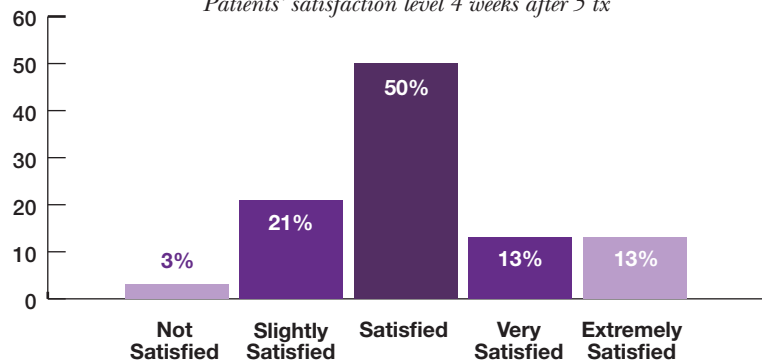
*Additional Data*

- More than 97% of the patients were from extremely satisfied to slightly satisfied with the treatment results after five sessions.
- 83% correlation between patients' assessment of improvement and their satisfaction, including patients' comfort.
- More than 92.5% of the patients found the treatment to be somewhat to very comfortable, the rest felt some discomfort.
- Response to treatment was limited to erythema and edema that lasted several hours. These phenomena are derived from the delivery of energy to the tissue and are considered treatment end point indicators.

*Assessment of Improvement*  
 Patients' assessment of improvement 4 weeks after 5 tx



*Patient Satisfaction*  
 Patients' satisfaction level 4 weeks after 5 tx



## CLINICAL RESULTS



*Before*



*After*

*Photos courtesy of Marc Winter, M.D., USA  
Post 2 treatments*



*Before*



*After*

*Photos courtesy of Marc Winter, M.D., USA  
Post 2 treatments*



*Before*



*After*

*Photos courtesy of Marc Winter, M.D., USA  
Post 2 treatments*

### **North America**

Syneron Inc.  
3 Goodyear, Suite A  
Irvine, California  
United States 92618  
Toll Free: 1-866-259-6661  
Fax: 949-716-8287  
Email: info@syneron.com

[www.syneron.com](http://www.syneron.com)

**Syneron**<sup>TM</sup>  
Powered by elōs

### **International**

Syneron Medical Ltd.  
Industrial Zone  
Tavor Building  
P.O.B. 550 Yokneam Illit  
20692 Israel  
Tel: +972 73 244 2200  
Fax: +972 73 244 2202  
Email: infois@syneron.com