

Clinical evaluation of the effect of low frequency ultra sonic waves on localised fat. A new approach in body contouring and fat reduction.

Nazzareno Cammarota, MD

Department of Dermatological Sciences, University of Florence –Florence, Italy -

Summary

When it comes to reducing volume of adipose tissue and improving shape, besides a proper diet combined to appropriate regular exercise the approach has been so far the use of surgery involving obviously relatively invasive procedures.

Patients nowadays are more and more informed and a greater number of them are looking at the availability of efficient non invasive procedures capable to deliver results with comfort and no down time.

The following is the summary of our clinical evaluation of a non invasive treatment using Low frequency Ultra sounds to improve contour and silhouette by reducing circumference and volume of areas with localised fat.

The simplicity and time efficiency of the procedure added to its non invasive nature makes it very attractive to those patients in need of reshaping their silhouette and who are not ready for or simply do not desire the use of an invasive procedure.

Material and method

The apparatus used – Proslimmelt- emits low frequency ultrasound waves ranging from 30 khz to 70 khz through a transducer of 45 mm diameter at a power of 5 watts / cm² with an emission time capacity ranging from 3" to 30". In order for the transducer to transfer the ultra sound waves a conductive gel must be used.

The Proslimmelt is equipped with 2 alike transducers allowing the treatment of 2 areas at the same time but we actually used only one transducer and treated one area at a time.

The objective of our work was to evaluate the effectiveness and safety of such a non invasive apparatus and test a new method to improve the shape of treated areas by reducing the volume of the localised fat .

Indeed it is the adipose tissue which here is our target in which the low frequency ultrasound waves due to their nature end up creating a cavitation phenomenon.

The adipocyte membrane permeability is increased during the process leading to the liberation within the interstitial liquid of the stored Triglycerides .

The Triglycerides are then metabolized in Free Fatty Acid (FFA) and Glycerol (hydrosoluble molecule).

The FFA link themselves to albumin molecules and are transported to the liver.

Methods

Subjects

Healthy volunteers between 22 and 58 years old (mean value = 38,4years old) all females, participated in the study.

They were not required to change their lifestyle and all consented to the protocol.

The apparatus was tested on a patient population of n = 20.

For this study the patient population was divided according to the treated area.

- Hips
- Abdomen
- Buttocks
- Thighs (inner & outer)
- Knees (inner)
- Sub scapular area

Treatments

Each procedure was provided according to a defined protocol and each target area was treated according to its size for a minimum of 15 minutes per session and up to 45 minutes.

The evaluation period lasted 8 consecutive weeks at the frequency of 1 session a week for a mean total of 6,5 sessions:

Measurements

Objective and subjective evaluations were utilised.

Objective

Prior to the start of the treatment program each subject's age, height and weight were recorded along with a perimetric measurement of the area to be treated and photos of the subject.

The perimetric measurements and photos were taken using a standardized procedure.

- Perimetric measurements : with the subject standing up feet apart at always same distance
 - o Marking the height from the floor up to the area of concern
 - o Measuring just below the marking making sure the measuring tape is parallel to floor.

- Photos: with the subject standing up feet apart at always same distance.
 - o Digital Camera from Olympus : C 5050
 - o Camera distance from subject always the same
 - o Camera height always the same
 - o Camera angle always the same
 - o Camera focal always the same: 5,5
 - o Light always same with 4 flash lights in slave mode (2 behind the subject and 2 on either side of the camera)
 - o 4 photos taken at each evaluation period:
 - 1 photo of front
 - 1 photo of back
 - 1 photo of right side
 - 1 photo of left side

Subjective

- o self evaluating questionnaires with a scale from 0 to 5 were used addressing the skin compacted ness, volume appearance, treatment comfort, treatment satisfaction.

Outcome measurements

Tests and measurements were realised prior to start of treatment program, at mid program and at end of program.

Objective evaluation charts show values Before and After end of treatment program.

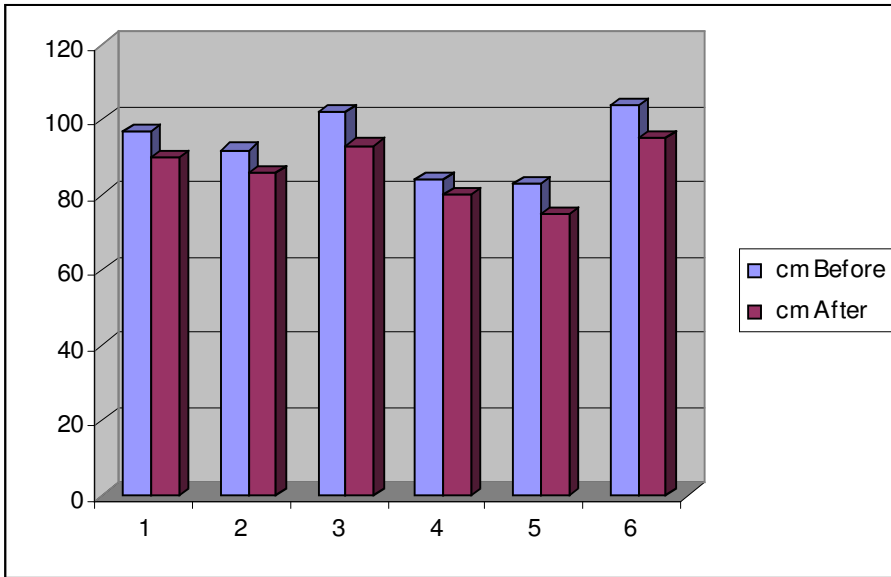
Subjective evaluations were performed at Day 0 and at end of treatment.

Results

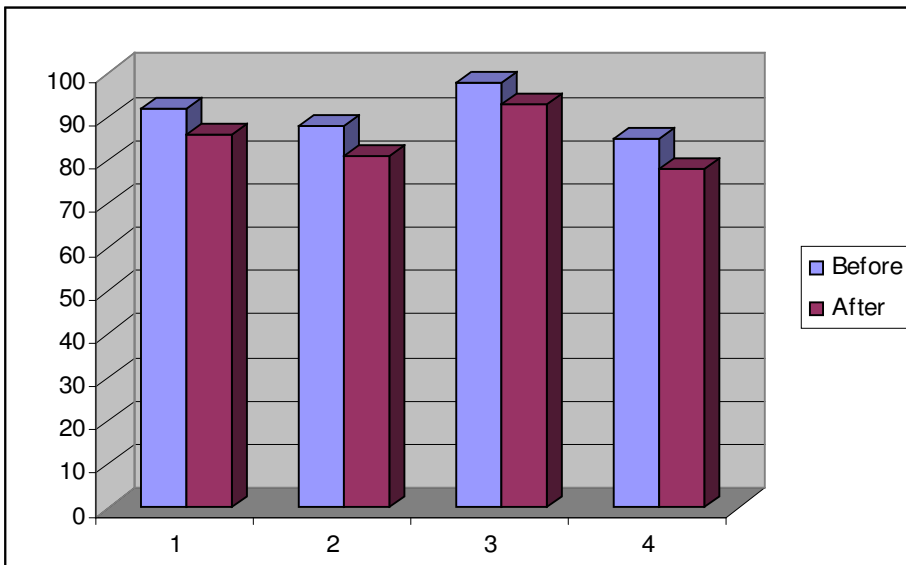
- Graphs below show evaluation Before start of treatment program and at end of program and represent mean values.
- Improvement is noticeable.

Perimetric measurements Before and after treatment program.

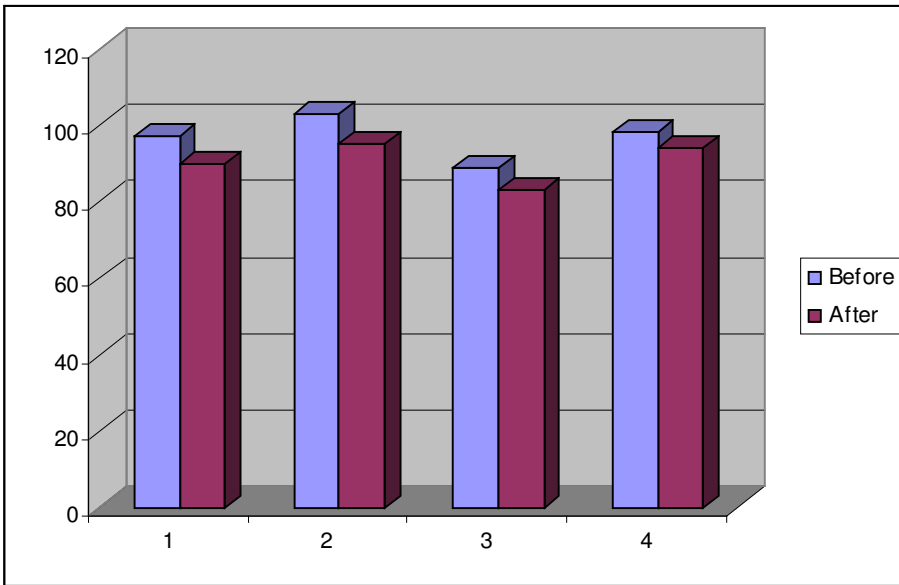
Hips



Abdomen

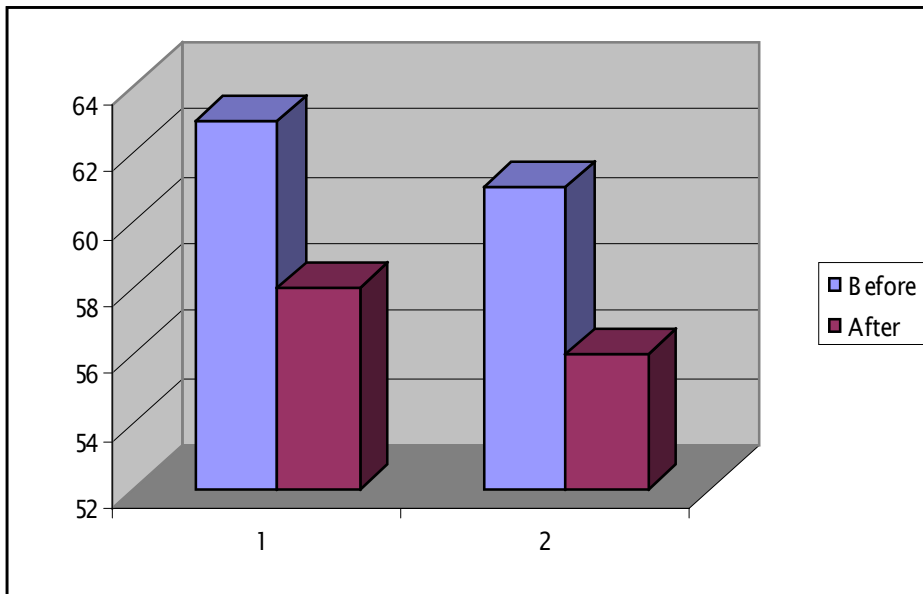


Buttocks

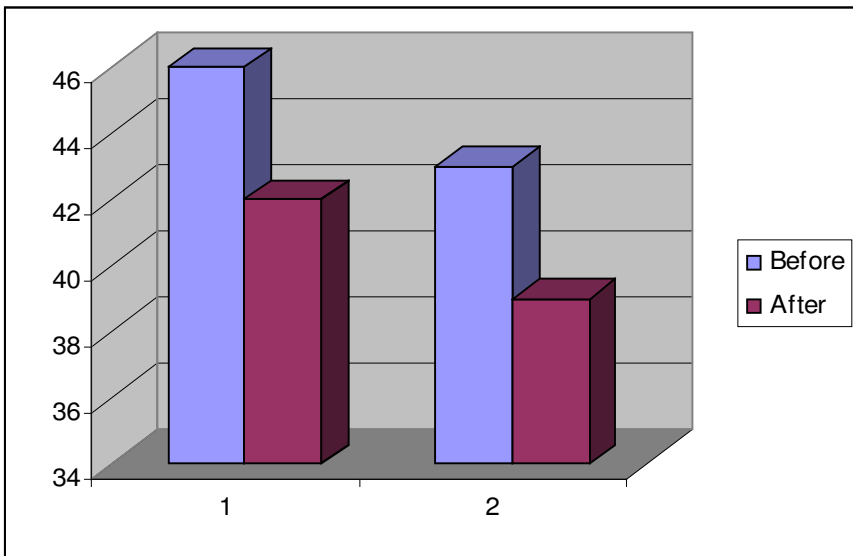


Thighs

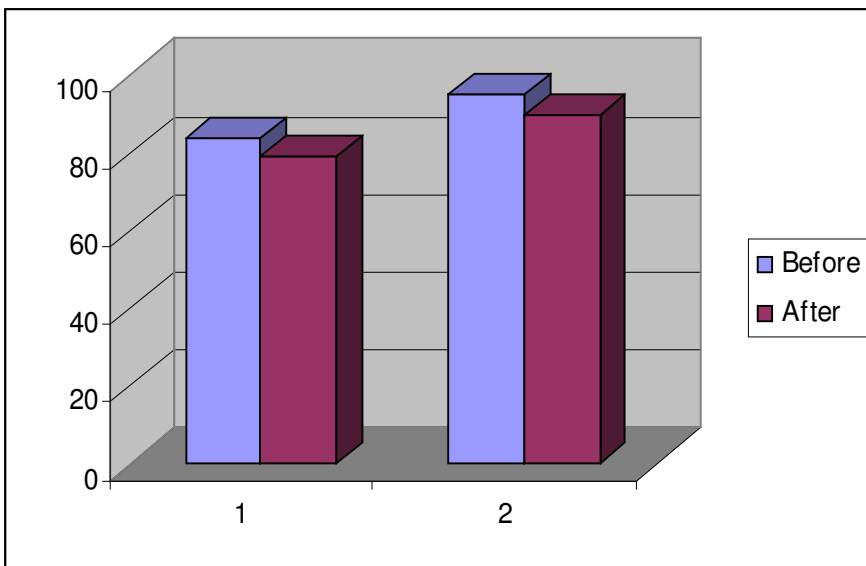
Outer perimeter & inner perime



Knees



Sub Scapular



Mean value cm loss:

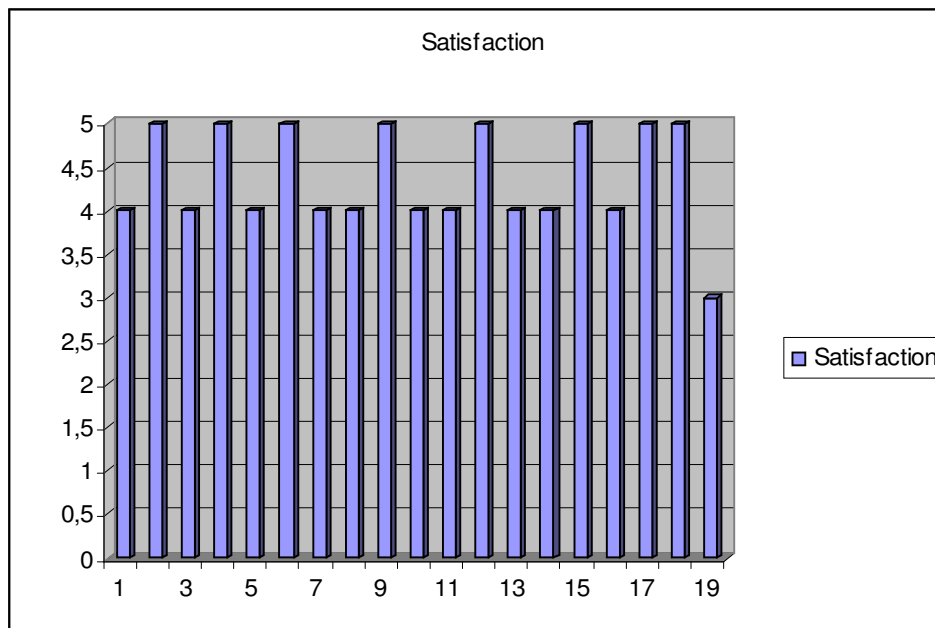
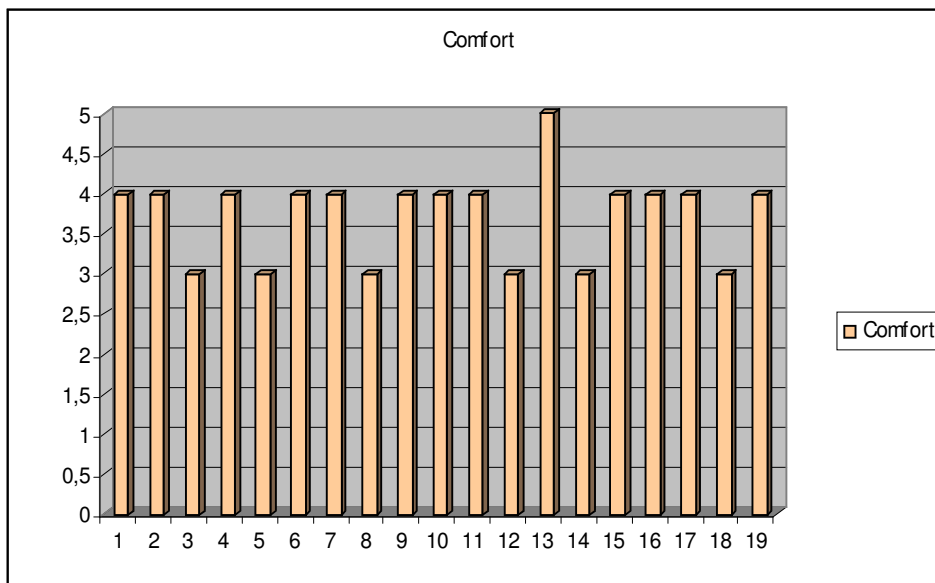
- Hips = 6,5
- Abdomen = 6,25
- Buttocks = 6,25
- Thighs = 5
- Knees = 4
- S Scapular = 5

There was no significant weight loss observed.

Subjective results

The charts below give an idea of the patients satisfaction. While most patients found the treatment comfortable, the significant improvements of the condition with the technology is translated more specifically in the subjective appreciation and satisfaction of the patients.

Patients self evaluation



Discussion

The corrections of volume linked to the accumulation of adipose tissue in certain areas of the body can be addressed using minimally invasive procedures.

In our observation all the patients treated with this low frequency ultra sound apparatus had substantial results in terms of centimetre reduction of the treated areas and all of them experienced comfort during the procedure and no collateral effects.

Consequently all the patients in this clinical evaluation were satisfied with the obtained results and most of them specially those with a weight surcharge expressed the desire to change their lifestyle by adding regular exercise and paying attention to their eating habits.

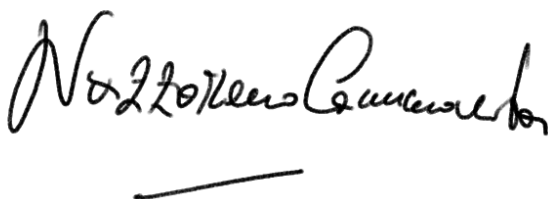
It is our objective to keep looking for safe and efficient solutions to help our patients experience wellness . Patients are now more and more educated and aware of the various treatment possibilities. A growing number of them are now asking for non invasive methods and formulas which can provide effects and long lasting results to improve their silhouette and consequently their confidence and self appreciation.

Beyond the aging process female patients have always been asking and today even more for the right treatment to keep them fit and good looking.

Even though today a number of possibilities can be chosen from, we can only find interesting the non invasive solution studied and presented here.

This study, in accordance with the scientific literature, points out the efficiency of a non invasive approach which appears to be a valid body contouring methodology free of observed collateral effects for the treatment of areas with localised fat .

Author Nazzareno Cammarota, MD

A handwritten signature in black ink, appearing to read "Nazzareno Cammarota", with a horizontal line underneath it.

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