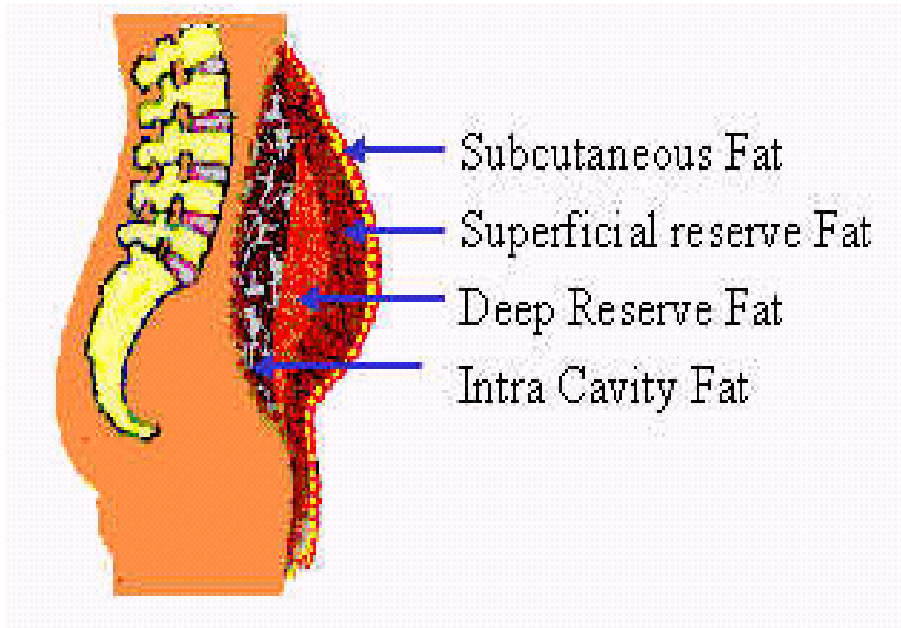


A NEW TREATMENT FOR CELLULITE



Fat and Cellulite

Cellulite results from sub-cutaneous fat (Hypodermis)



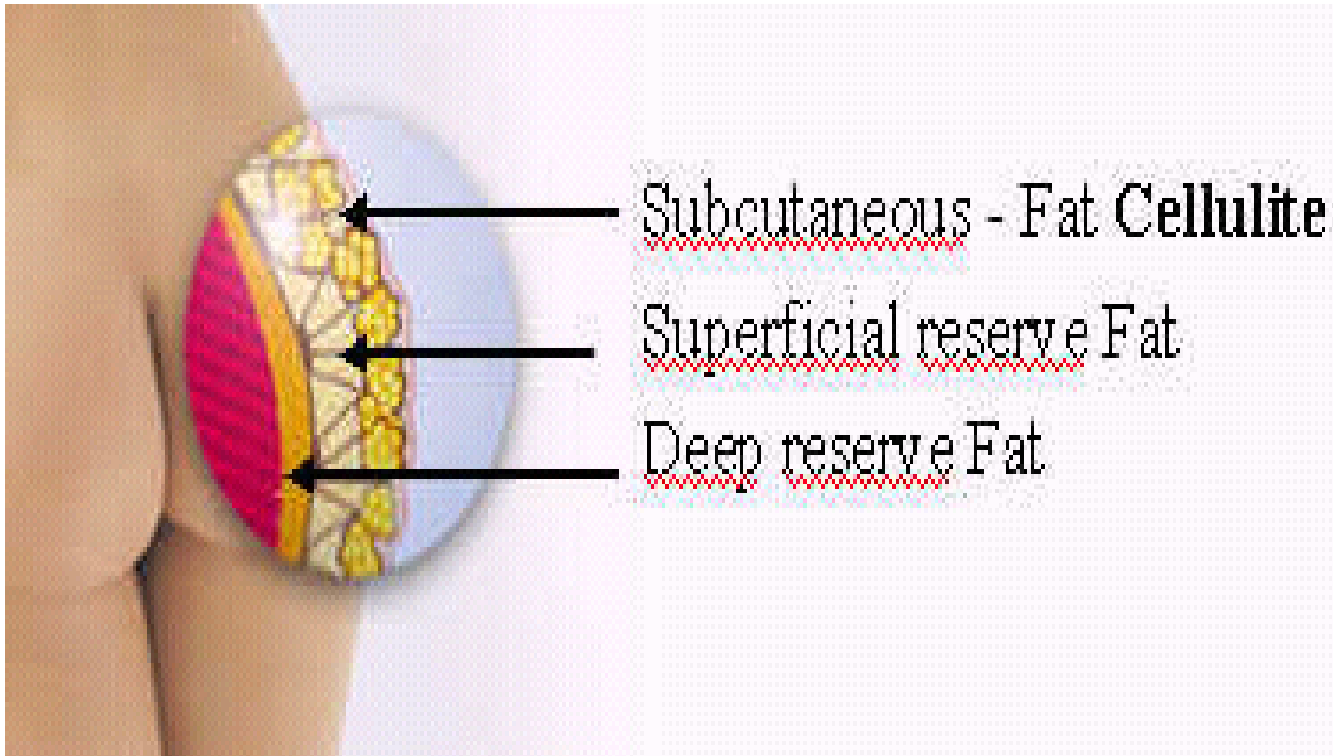
All fat is not cellulite!

Weight and Cellulite Management are completely separate issues

Cellulite Myths

- Cellulite can **NOT** be eliminated by dieting and exercise alone
- Diet and exercise affect deep fat but fail to reach the superficial tissue of the skin
- Weight and fat may be reduced but cellulite remains
- Even women who exercise regularly and follow low-fat, nutritious diets may still have cellulite

Sub-cutaneous Fat

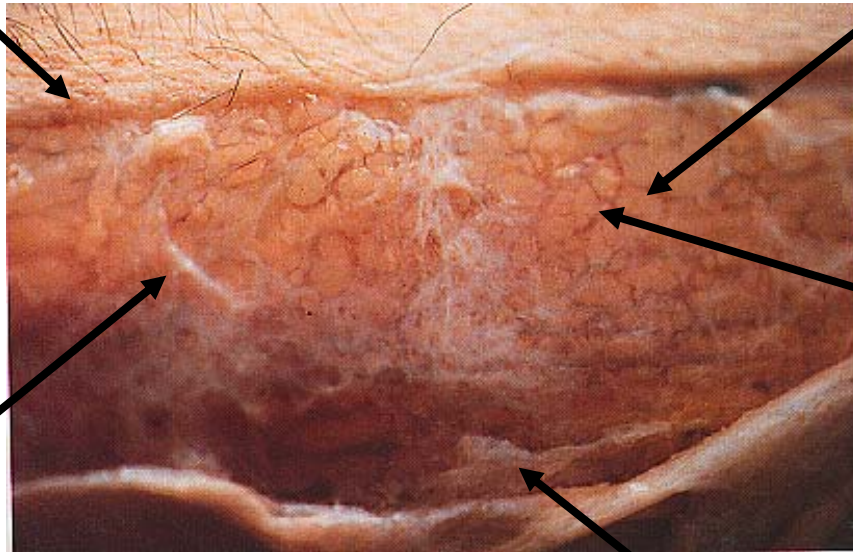


Fat lobes are organized into chambers by strands of connective tissue

The Hypodermis

Skin (epidermis + dermis)

Fat cell chambers



*Vascular and lymphatic
(supply + drainage)*

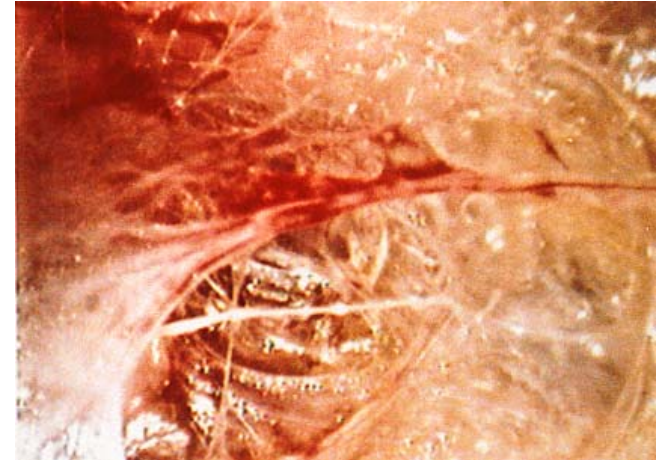
*Connective tissue
(Fibrous Septae)*

Fascia

The Connective Tissue

A mesh-like structure

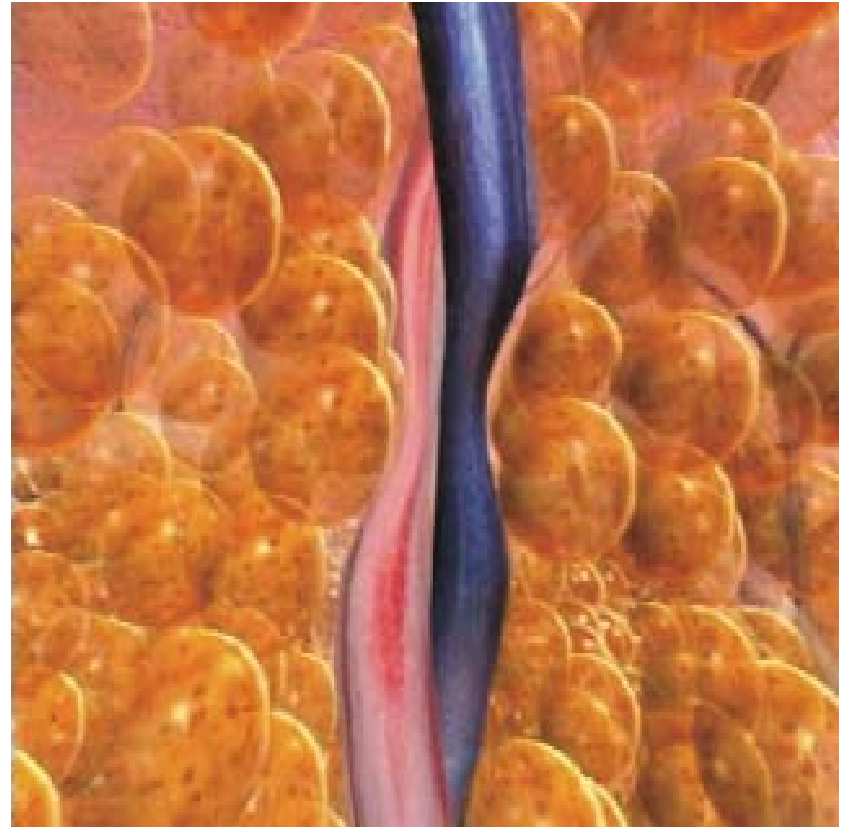
- *Holds skin to muscle*
- *No particular color (creamy)*



Good exchanges are critical to its structure and function

The Circulatory System

- **Arteries provide**
 - *clean water*
 - *nutrients*
 - *oxygen*
- **Veins eliminate**
 - *Salted water*
 - *CO²*
 - *Small toxins*
- **Lymphatic system**
 - *Eliminates water, larger toxins*
 - *Ensures circulation of lymphocytes*



Formation of Cellulite

Lipids accumulate in fat cells of the hypodermis



Cells increase in size



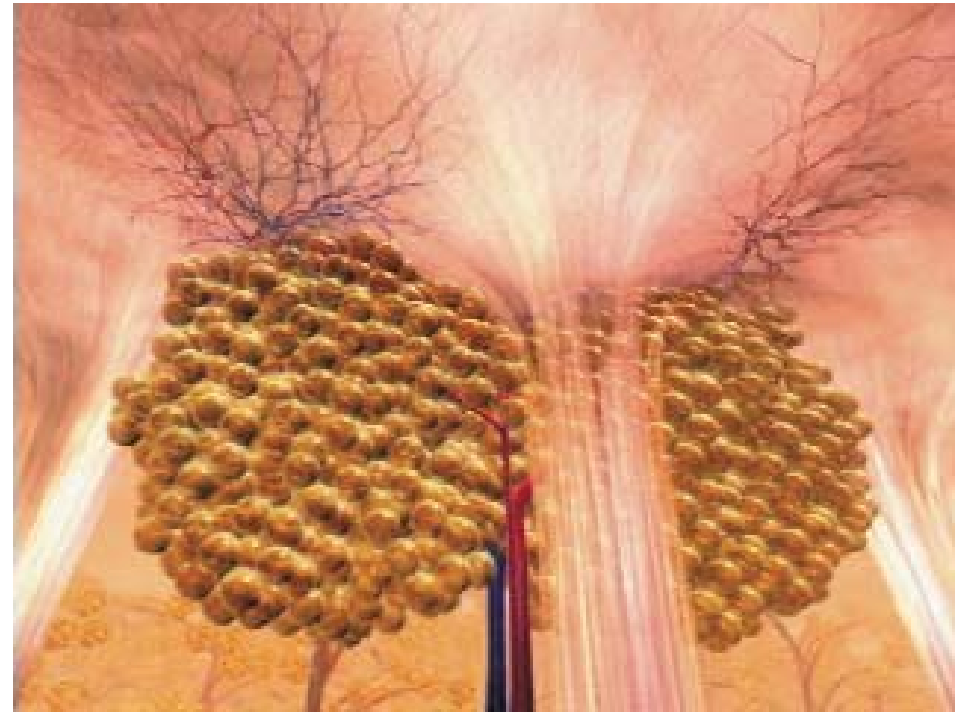
Pressure reduces circulation



Metabolism is reduced

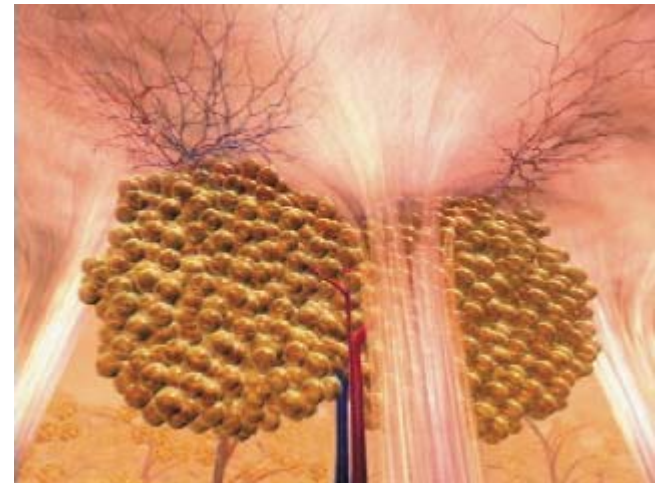


Connective tissue stiffens, pulling down the skin



Cellulite Affects Women

- *Their connective tissue is vertical (90° angle)*
- *80% of women have cellulite*
- *The remaining 20% often think they do!*



Causes of Cellulite

General Factors

- *Genetics*
- *Hormones*
- *Organ Disorders*
- *Lifestyle*
- *Stress*
- *Clothes*



Causes of Cellulite

Localized Factors

- *Poor vascular function*
- *Poor lymphatic drainage*
- *Stiff connective tissue*



Stages of Cellulite

Stage 0: *No cellulite:* The skin on the thighs, buttocks and stomach are smooth while standing or lying down.

•**Stage 1:** *Slight dimpling of the surface of the skin:* “pinch test” is positive.

•**Stage 2:** *Dimpling and skin depressions:* skin is smooth while lying down but shows “orange peel” look when standing.

•**Stage 3:** *Dimpling and severe depressions:* “orange peel” look when both standing and lying down.

Acoustic Wave Therapy

Basic Principle

Acoustic Pulses can be generated in different ways:

- ***Pneumatically generated pulses:***
 - *ballistic pulses (radial waves)*
- ***Electromagnetically generated pulses:***
 - *Electromagnetic pulses (planar waves)*

Acoustic Wave Therapy

Basic Principle

Acoustic Pulses initiates different tissue reactions:

- Analgesic effect (nerve over stimulation)
- Increased blood flow (blood vessels dilatation and revascularization)
- Increased cell wall permeability
- Initiation of metabolic processes, like fat dissolution, collagen genesis etc.

Ballistic Pulses

Traditional Indications

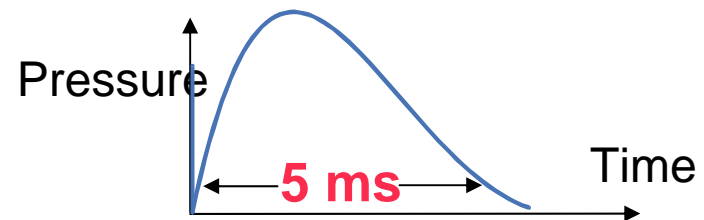
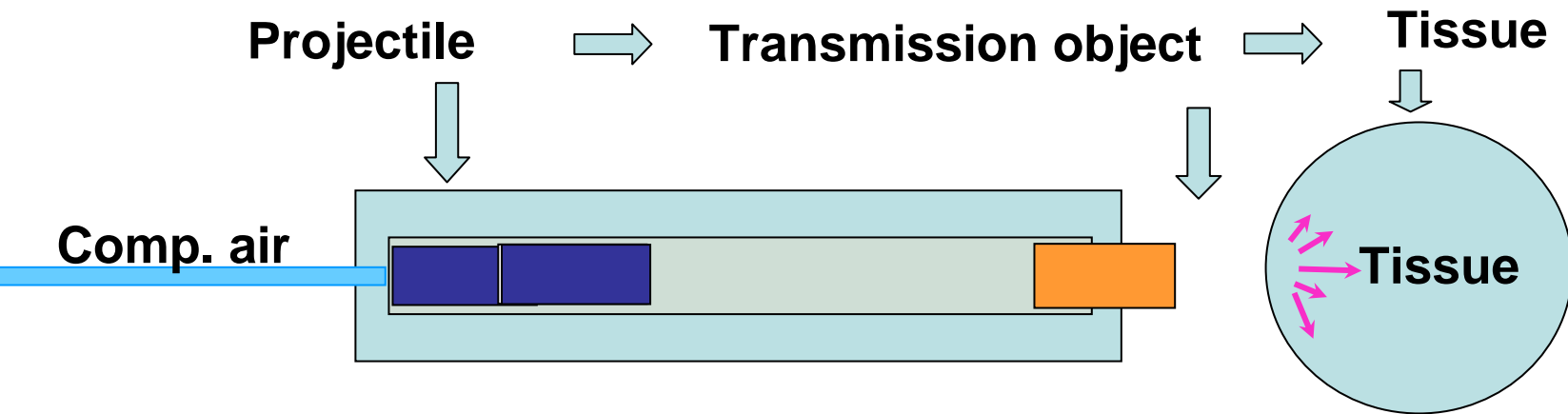
- *Muscle and tissue pulse massage*
- *Stimulation of micro circulation*
- *Therapy of trigger related superficial muscle pain*
- *Muscle tension increase*



Ballistic Pulse Generation

Pulse transmission:

projectile impact



CLINICAL EVALUATION

Use of Acoustic Wave Therapy (AWT) in Treating the symptoms of Cellulite

Methods

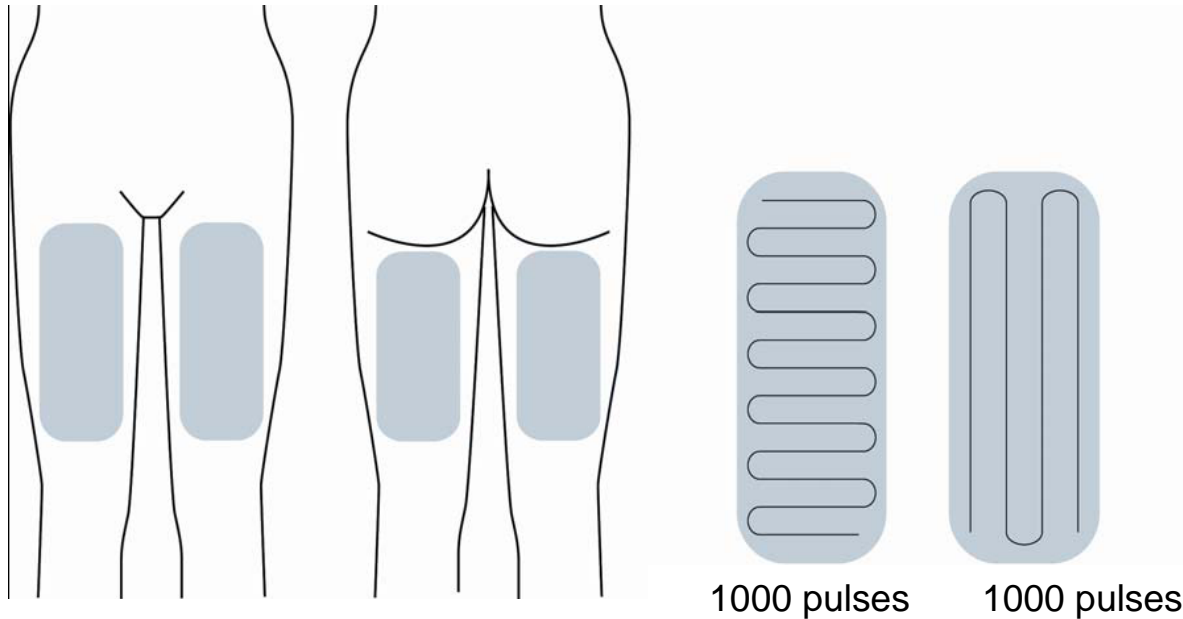
Treatments

- *Patients recruited from phone calls at a medical practice office.*
- *Treatments based on regions of complaint.*
- *20x30 cm area (front or back of one thigh).*
- *Per area:*
 - *2 treatments a week*
 - *Three weeks total*



Treatment Pattern

- *Treatments consisted of 1,000 vertical and 1,000 horizontal pulses.*



Photos and Surveys

- *B/A Photographs and circumference measurements*
- *B/A Weight and electrical impedance measurements*
- *Patient satisfaction survey post treatment*



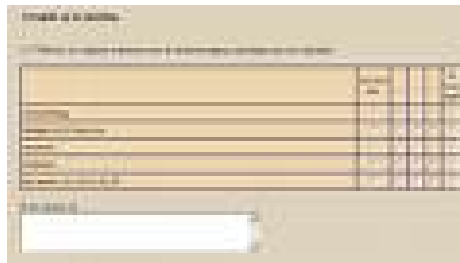
Patient Numbers

- *167 patients expressed interest and were treated*
- *All were women*
- *Average age was 42.8 yrs, (range 14-65 yrs)*
- *102 agreed to inclusion*
 - *completed weight,*
 - *percentage body fat*
 - *electrical impedance data*



Patient Numbers

- *Circumference on 147 thighs*
 - 72 right
 - 75 left
- *To date 19 patient satisfaction have been completed*



A screenshot of a data entry form. The form has a header section with a title and a sub-header. Below this is a table with several columns and rows. The table appears to be for recording patient data, with columns for patient ID, date, and other variables. The data is mostly obscured by a light beige background, but the structure of the table is visible.

Results

Photographs

- *Reviewed by staff & patients*
- *No standardized photographic evaluation*



Results

Weight

- *Average weight loss 0.19 lbs (0.08 kg) - $p=0.21$*
- *No additional weight loss recommendations or techniques*
- *Percentage body fat decreased by 0.02% - $p=0.45$*

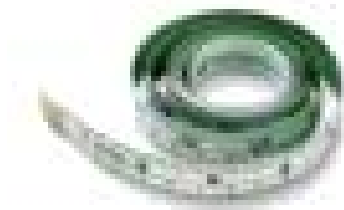


Results

Circumference

- *Thigh circumference decreased 0.45 cm*
- *Statistically significant with $p=0.025$*

Any significant decrease in thigh circumference over a three week period is a worthwhile improvement.



Results

Patient Satisfaction

- *Ratings on a scale of 0-100*
 - *0 being extremely disappointed*
 - *100 being extremely pleased*
- *Posterior thigh treatment rated at 84%*
- *Anterior thigh treatment rated at 52%*



Results

Patient Satisfaction

- *68% of patients were more comfortable in revealing clothes*
- *74% were more comfortable with their bodies*
- *73% stated the treatment area was closer to the appearance desired*
- *In all three areas, the same 2 patients (11%) responded negatively*



Results - Photographs

- *Before and after photographs ranged from:*
 - *Significant after initial treatment*
 - *Improvement noted 2 weeks after treatment*
 - *Mild improvement in small dimpling and texture*
 - *No patients saw worsening*
 - *Continued improvement was seen photographs taken at the 2-3 week follow-up appointment*
 - *Patients saw continued improvement throughout follow-up (maximum of 6 weeks)*
 - *Response to the photographs was positive from researchers, patients and independent observers.*



Results



Before – May 5, 2006



After – May 25, 2006

Results



Before – May 5, 2006



After – May 25, 2006

Results



After 6 treatments– May 5, 2006



3 weeks after 6th treatment – May 30, 2006

Results



After 6 treatments– May 5, 2006



3 weeks after 6th treatment – May 30, 2006

Results



Before – April 25, 2006

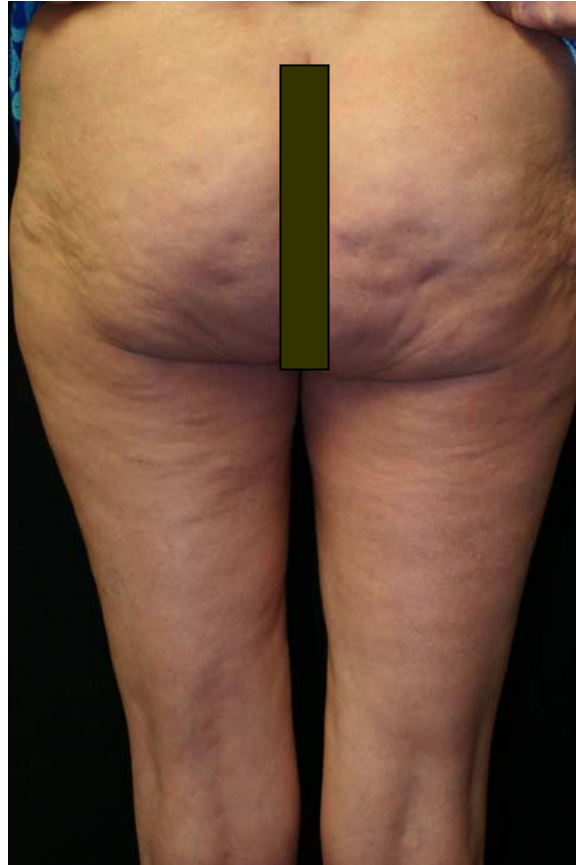


After – May 12, 2006

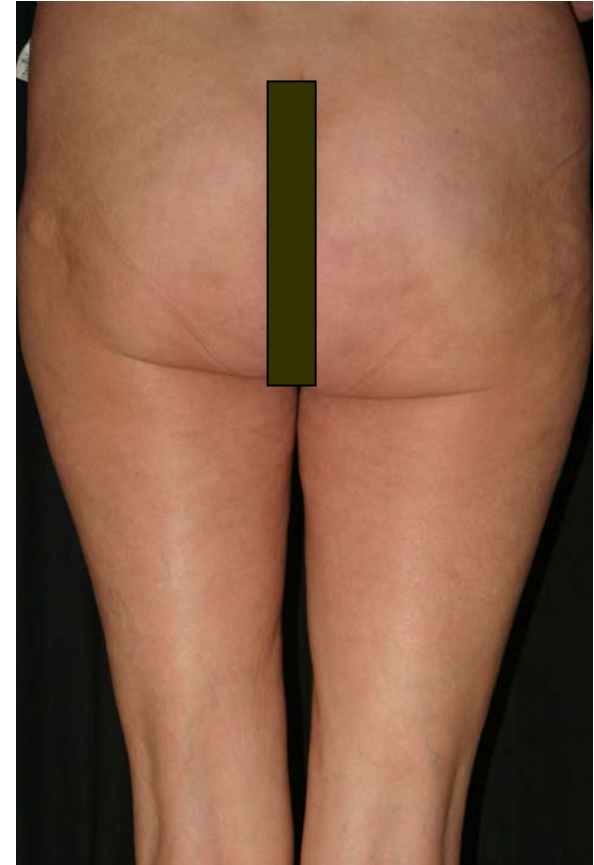
Results



Before – April 20, 2006



After – May 10, 2006



3 wks – June 1, 2006

Results

Side Effects

- *Patients reported no significant pain or discomfort*
- *Two patients received mild bruising. This appeared to be a calibration error on the pressure settings of one of the D-Actors. After adjustment, no further bruising was reported.*

Pricing

- Initial pricing - \$50 per area per treatment
 - Area received 2,000 pulses
 - Back of both thighs – 2 areas, \$600 both thighs 6 treatment
- Currently charging \$75 per area per treatment during further protocol development
- Initial market charge should be \$75-\$100 per area per treatment



Pricing - Packaging

- *D-Actor packages well with other procedures on the legs*
 - *Leg veins*
 - *Permanent laser hair reduction*
 - *IPL on legs*
- *Give further discounts for additional procedures*



Conclusion

- *AWT delivered by a using a ballistic head and pulsed mode (D-Actor) was effective for improving the appearance of cellulite*
- *Patients reported minimal side effects during and after treatment*
- *Appearance of cellulite continued to improve throughout the 3-6 week follow-up period*
- *Improvement is most apparent in the before and after photographs*
- *A small decrease in thigh diameter is also seen*

THANK YOU