

Face & Body Contouring Station

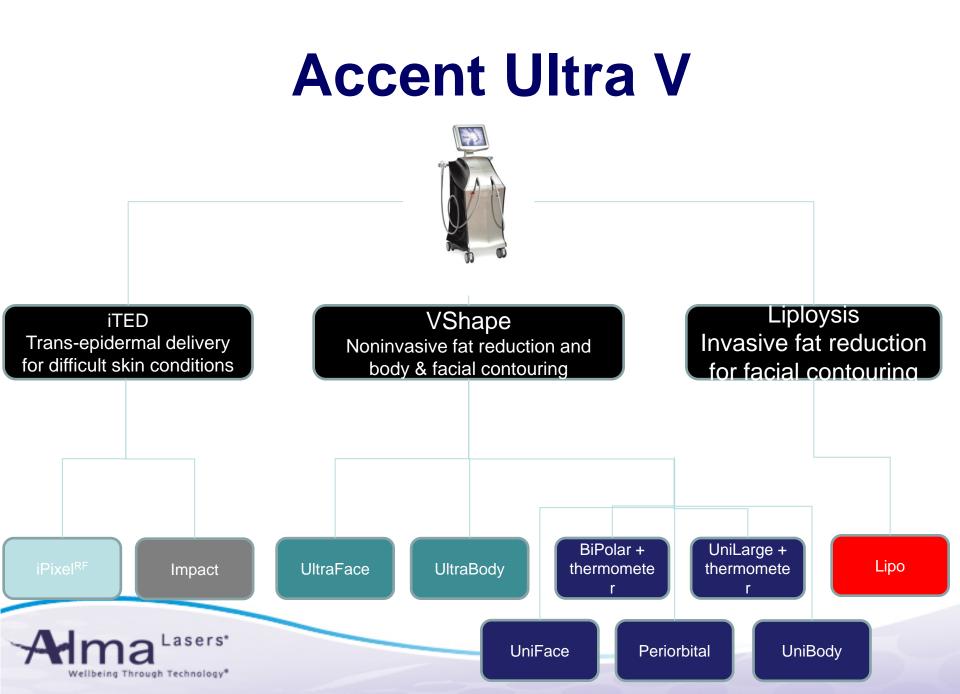
Clinical Overview

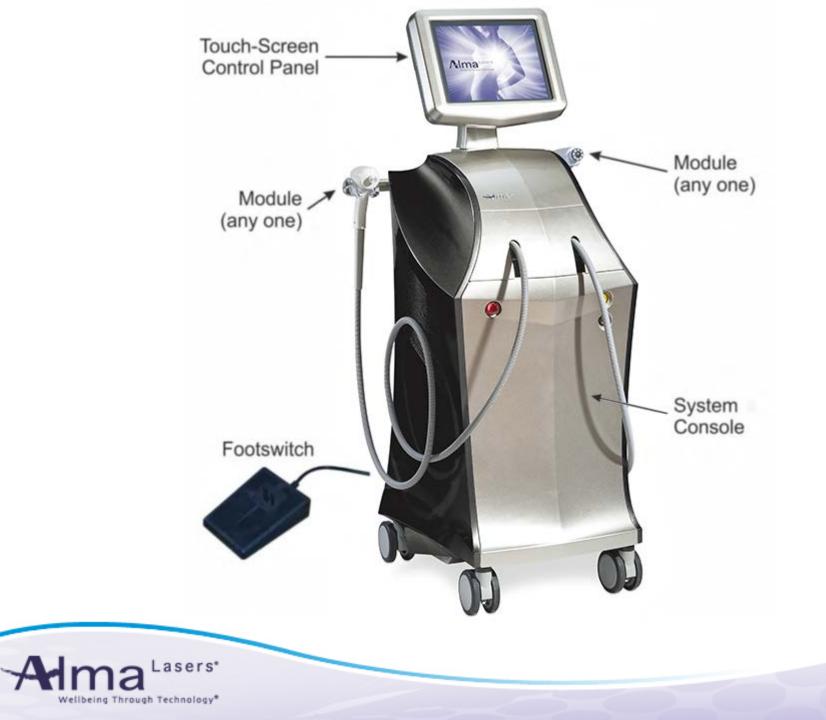
Dr. Joseph Lepselter VP, Clinical Affairs Alma Lasers Ltd. Caesarea, Israel

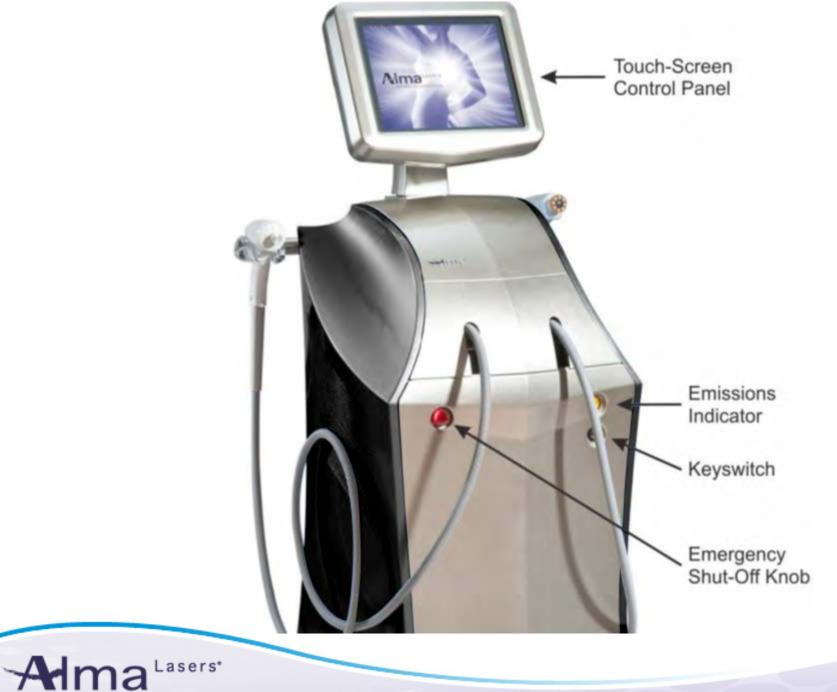












Wellbeing Through Technology*

Modules & Indications



RF UniLarge and Bipolar





Internal thermometer preset to C° or F° Every 1.5 seconds



Thermometer Display

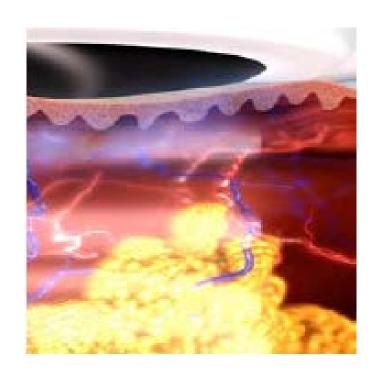


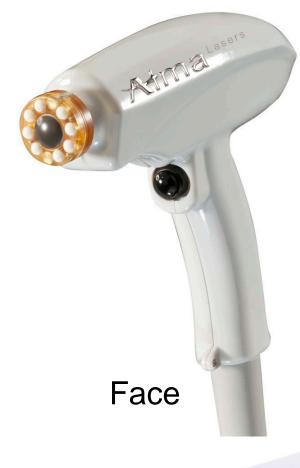
Indications

- Adiposis
- Skin tightening
- Cellulite



RF Handpieces





Body



Mannan Manna



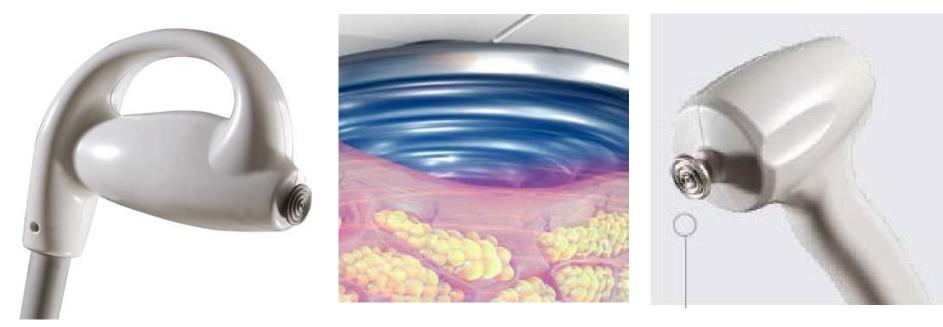


Indications

- Adiposis (non-invasive)
- Skin tightening
- Cellulite



US Handpieces



Body

Face



Indications

 Body & face adiposis (noninvasive)







Laser Lipolysis































RF Pixel (Roller)











RF Pixel (Stationary)











UltraFace



Min





UniFace









01:20 Min













Select Area

V-shape hand pieces

 the ultrasound frequency was doubled, and its output power decreased by half. <u>frequency</u> Output power

	frequency	Output power
Ultra Face	100~160kHz	20W
Ultra Body	60~70kHz	40W

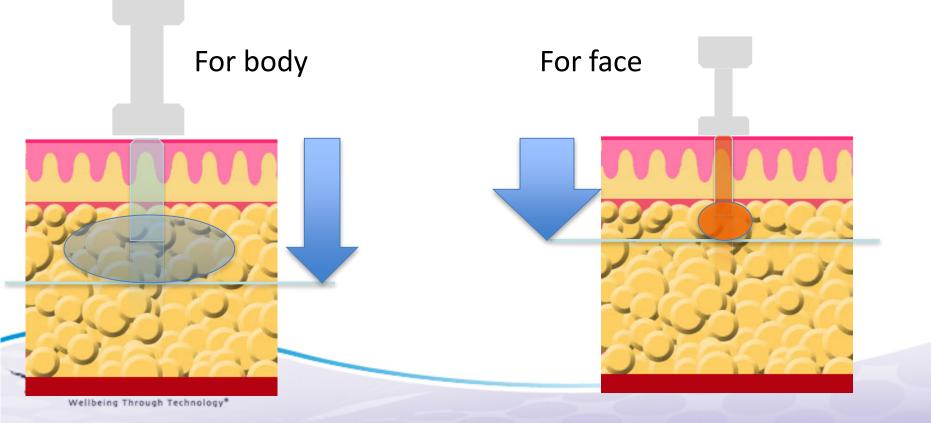
• The head size of both ultrasound and radiofrequency hand-pieces were reduced to fit the face.



Mechanism of ultrasound on face

- In High frequency
- The ultrasound focuses on small area & attenuate just below the surface. That means
- ultrasound vibrates strongly

small superficial layer.



The result is

- Damage by ultrasound is only beneath the skin, but does not affect deep fatty tissue.
- Thermal damage by RF causes skin tightening.

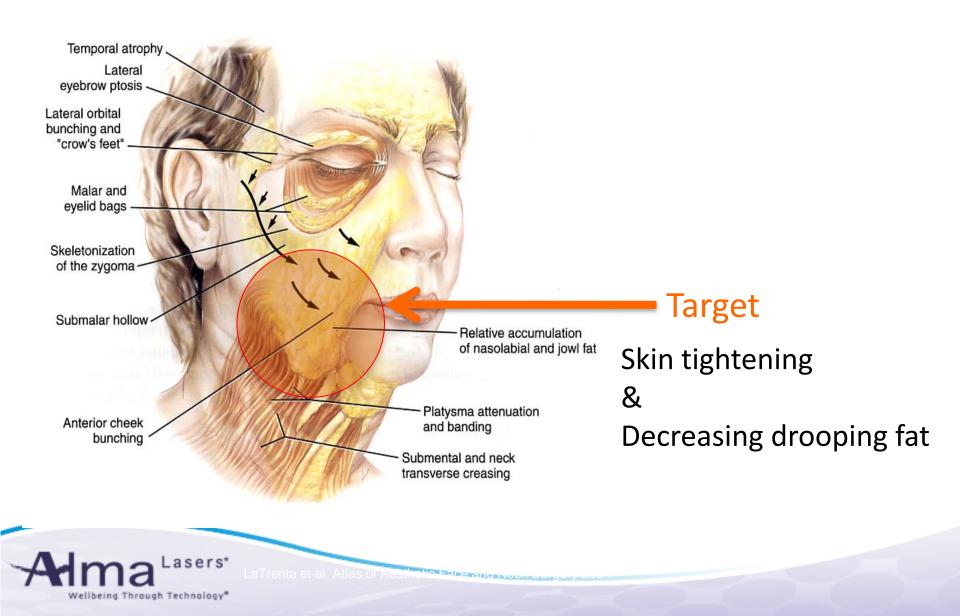
Synergetic tightening effect

by decreasing fat and collagen contraction

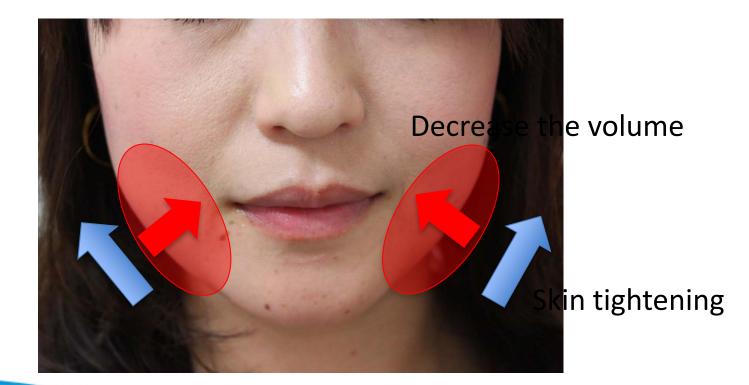




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Clinical effect





Clinical Evidence - Face







Before

1 Month After 3 Treatments

Dr. J. Lepselter, Alma Lasers Clinical Department







before

29 y/o female



Nariaki Miyata M.D. Miyata Plastic Surgery & Skin Clinic Tokyo, Japan







After 4 Treatments





Before Alma Lasers* Wellbeing Through Technology*

After 3 Treatments





After 4 Treatments



Ultraface + Uniface

- Age: 42 year-old
- 2 Tx with Ultraface + Uniface
- U/S COLD 8 minutes
- RF 90W 30kJ at each side
- 1 Tx with UniFace
- RF 90W 40kJ at each side





before

2 weeks after 3 Tx





before





UniFace/UNILARGE+UltraFac e

UltraFace COLD MODE ONLY-8 min at each side (7.5x5cm) UniFace/UNILARGE – 30KJ at each side







Before



After 5 Tx

Scott Scherer, MD

Renaissance Clinic Stockholm, Sweden



Case Report

- A general practitioner w/diabetes
- Patient has had nerve damage on her left side, where they did a fat transplant 10 years ago.
- Because of gravity the fat pocket fell.
- Treatment on left side of the face only; Ultra treatment (32min) with cold mode only to reduce the fat, and RF treatment 80-90 W temperature up to 45 to pull the face upwards.
- Diet and niacin.













before





2wks after 4 Tx



Courtesy of Dr. Scott Scherer, MD, Stockholm, Sweden



Courtesy of Dr. Fernando Urdiales, Aesthetic Medicine, Instituto Médico Miramar, Málaga, Spain



Courtesy of Dr. Rafael Nunes , plastic surgeon, Slim Clinique, Rio De Janeiro, Brazil



Courtesy of Dr. Tania Aparecida Meneghel, Dermatologist, Clínica Renaissance, São Paulo, Brazil



Courtesy of Maria Angelo-Khattar, PhD, Aesthetica Clinic, Dubai



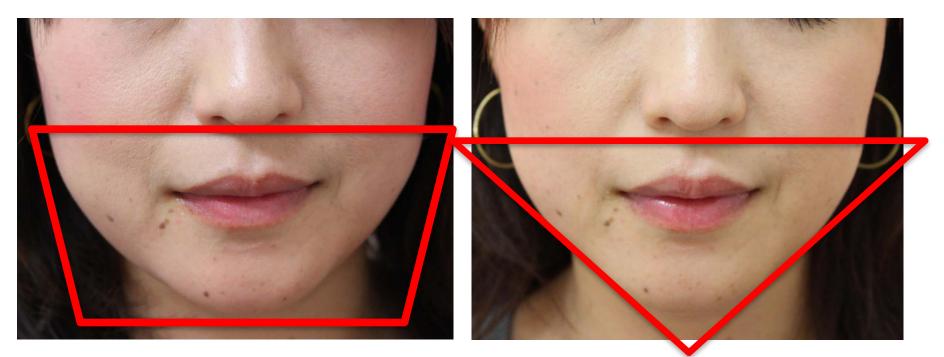
Courtesy of Dr. Fernando Urdiales, Aesthetic Medicine, Instituto Médico Miramar, Málaga, Spain



Case 1

Pre

Post 2 Tx



Nariaki Miyata M.D. Miyata Plastic Surgery & Skin



Case 2

Post 3 Tx





Nariaki Miyata M.D. Miyata Plastic Surgery & Skin





Pre

Post 2Tx



Nariaki Miyata M.D. Miyata Plastic Surgery & Skin



Dr. Maria Angelo-Khattar Dermatology & Plastic Surgery Clinic Dubai



Accent for Lower Face Volume Reduction and Rejuvenation







Immediately After One Session

Reduction of Lower Face with Ultrasound and Unipolar and Bipolar radiofrequency.





COMBINED APPROACH

Volume Reduction of Lower Face Restoration of Volume in Upper Face



After 2 sessions for Volume Reduction



A.V. 26 years old



Before Rectangular

After more oval



After Radiesse and Lip Augmentation for Total Facial Contouring

A.V. 27 years old





Cheek Enhancement





Volume Reduction of Lower Face and Radiesse for Cheeks

Y.Z. 26 years old



Before Rectangular

After more oval



Radiesse for Infraorbital Hollows



I.N. 28 years old









Radiesse for Infraorbital Hollows



D.I. 34 years old









Accent for Lower Face Volume Reduction and Rejuvenation





Volume Reduction of Lower Face and Radiesse for Cheeks



Before Heavy Lower face

After more oval



Advantage of Accent ultra "Vshape"

- Compared with other devices for fat reduction (cool sculpting & focused ultrasound), Accent ultra is the only one that able to use for face.
- Compared with other devices for facial rejuvenation, Accent ultra is the only one that able to reduce adipose tissue.



Conclusion

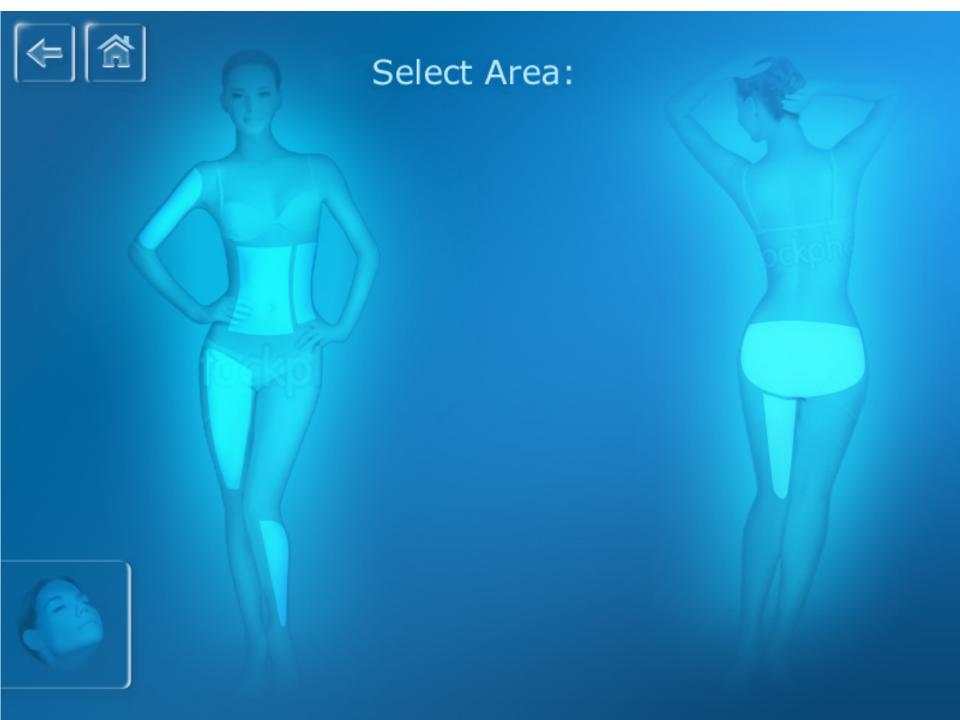
 "Sagging" is caused by loose skin and drooping subcutaneous tissue. So, not only tightening the skin but also reducing the subcutaneous tissue is most important to get a good result.

These hand-pieces, especially the one designed for the "V shape" concept, are ideal tools for tightening the face with no down time, pain, or disposables.







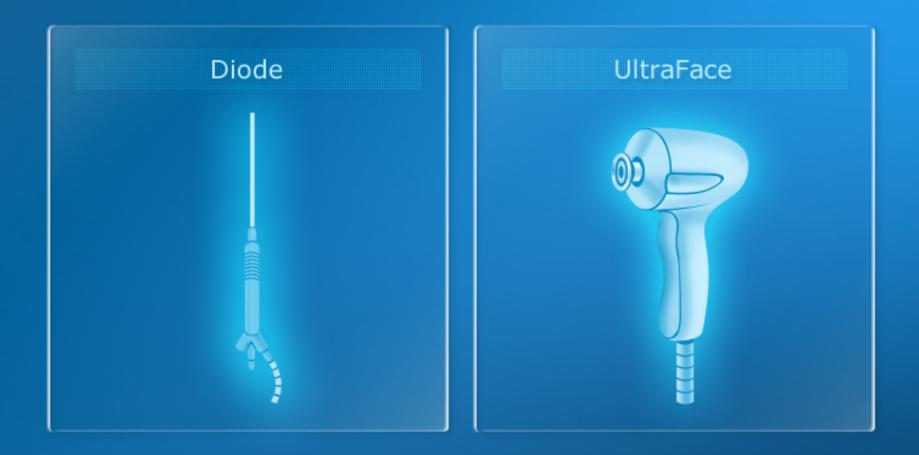


Handpiece Selection





Select Handle:

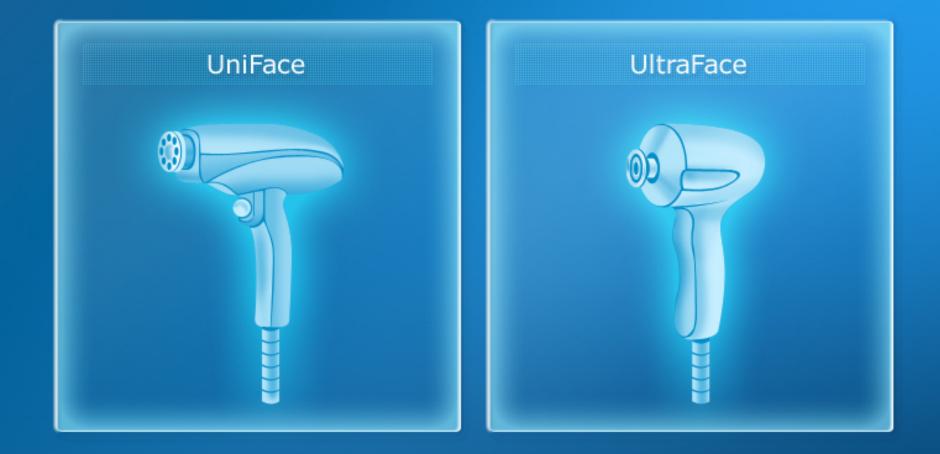


Handpiece Selection





Select Handle:



Handpiece Selection



Select Handle:



UltraBody Screen









30 KJ / Grid







RF Handpieces

- Unipolar electrode 19mm Ø (high power)
- 50/25 mm diameter massage wheel (Body/Face)
- 10/5 mm diameter massaging Balls (5/8 Body/Face)
- 150 turns/minute

asers'

Through Technology



US Technology

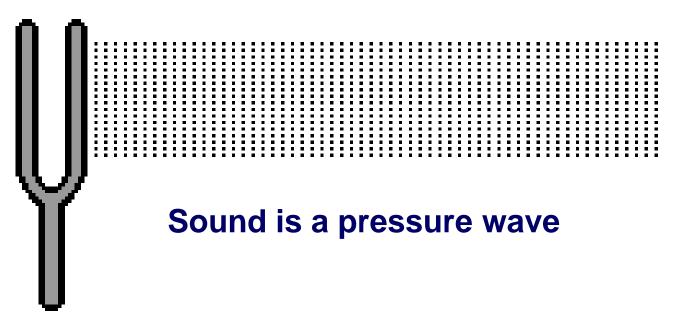


Sound - Definition

- Sound is a form of mechanical energy that is propagated from one point to another by the interaction between neighboring oscillating particles.
- The direction of propagation is parallel to the direction of oscillation and, hence, sound is defined as a longitudinal wave.



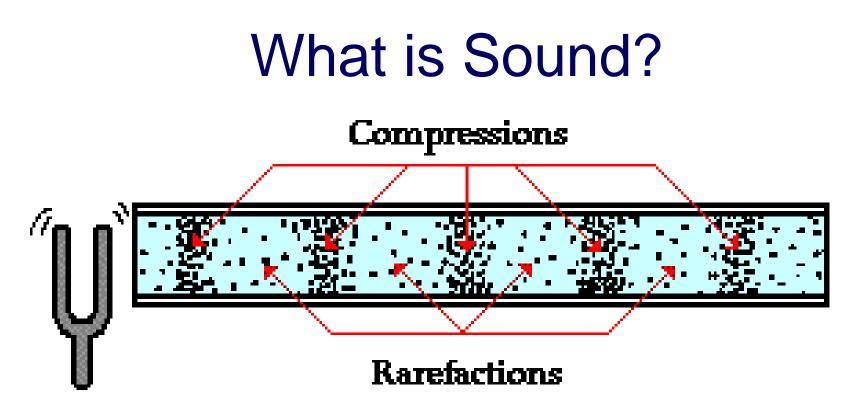
What is Sound?



 As the tines of the fork vibrate back and forth, they push on neighboring air particles

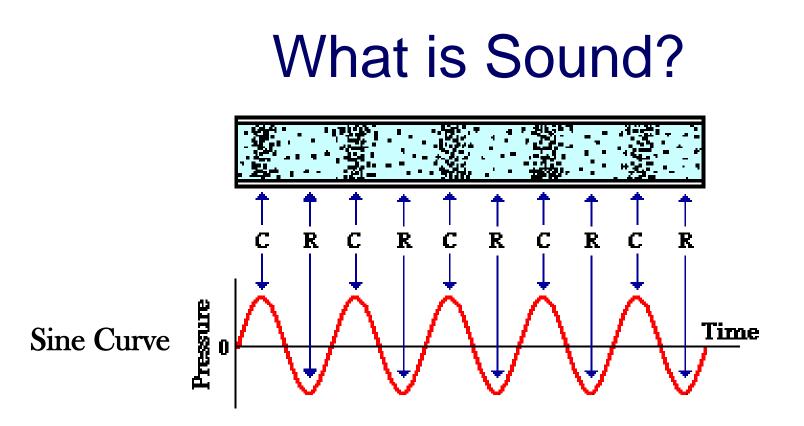
Through Technology*

• The forward motion of a tine pushes air molecules horizontally to the right and the backward *retraction* of the tine creates a low pressure area allowing the air particles to move back to the left.



- There are regions in the air where the air particles are compressed together (high pressure) and other regions in the air where the air particles are spread apart (low pressure)
- These regions are known as compressions and rarefactions





NOTE: "C" stands for compression and "R" stands for rarefaction

- Crests correspond to compressions (peak pressure points)
- Troughs correspond to rarefactions (low pressure points)
- One cycle is measured crest to crest (or trough to trough)



Modes of Sound Waves Propagation

Wave Types in Solids

- Longitudinal ——
- Transverse (Shear) → •
- Surface Rayleigh —
- Plate Wave Lamb

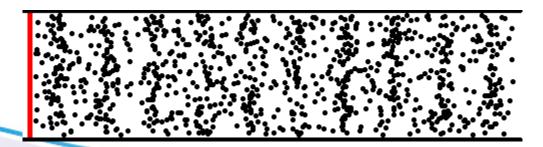
Particle Vibrations

- Parallel to wave direction
- → Perpendicular to wave direction
 - Elliptical orbit symmetrical mode
 - Component perpendicular to surface (extensional wave



Longitudinal Ultrasonic Wave

- 1. In longitudinal waves, the oscillations (or particles displacements) occur in the direction of wave propagation.
- Since compressional and dilational forces are active in these waves, they are also called <u>compression</u> <u>waves.</u>





Transverse (Shear) US Wave

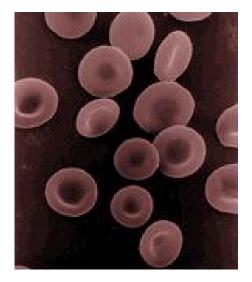
• ULS shear wave is a specific wave with mechanical oscillations perpendicular to the propagating longitudinal US wave.

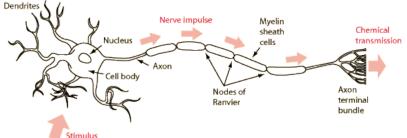




Human Cells Size

- Red Blood Cell ~ 6-8microns
- Muscle cell ~10 microns
- Bone cell ~15 microns
- Nerve cell ~ 4 microns

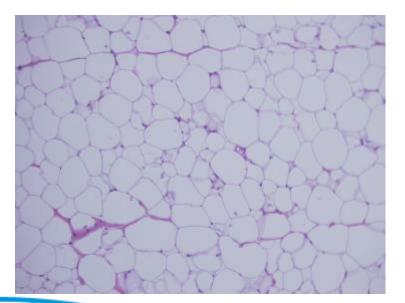


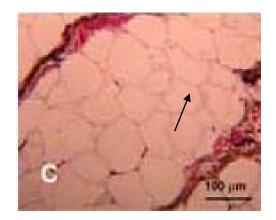




Adipocytes

- Fat cells are composed of 90% triglycerides and free fatty acids.
- They are "large" cells, 50-150 microns: easy to vibrate.





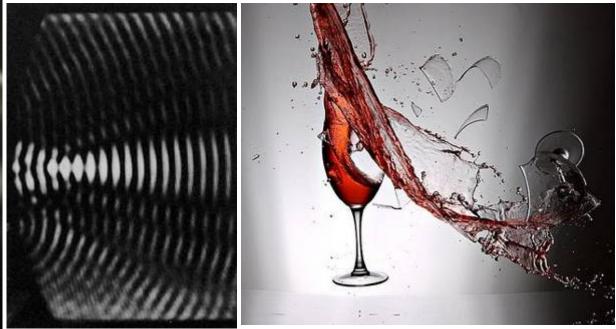


(van Gieson's Stain, Bar= 100 µm)

Self Resonance







Maria Callas

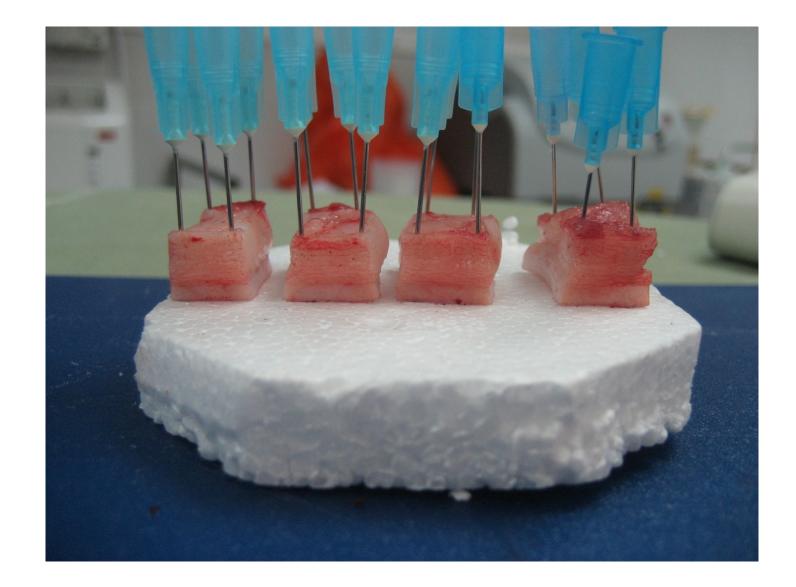


Broken Glass Movie



Selective Lipolysis by Acoustic Energy: A Dose Response Feasibility Study with a Novel Technology in an In-Vivo Porcine Model

















Selective Lipolysis by Ultrasound: A Dose Response Feasibility Study with a Novel Technology in an In-Vivo Porcine Model

Guy Nahmany, MD, Prof. Arie Orenstein, MD

Plastic Surgery Department, Sheba Medical Center, Israel

Objectives:

in-vivo feasibility assessment and dosimetry study with a novel selective ultrasound lipolysis system (Alma Lasers Ltd. Caesarea, Israel).

Methods:

Crossbreed (Landers & Large white) domestic female pigs were divided to the following groups: acute, 3 days, 7 days and 14 days. Each animal was marked with grids of treatment areas differ in energy level and duration of treatment. Samples were harvested and histological sections were prepared using H&E stain. Histopathological analysis of the samples was made and effects for each energy level and treatment duration were characterized through the time scale described above.

Results:

Well noted effects from membrane alteration through complete tysis were observed in the sub outaneous fat. A specific parameter combination of power level and treatment duration as well as a unique frequency window enabled a highly selective damage to the adipose tissue with no epidermal and dermal damage

Damages:







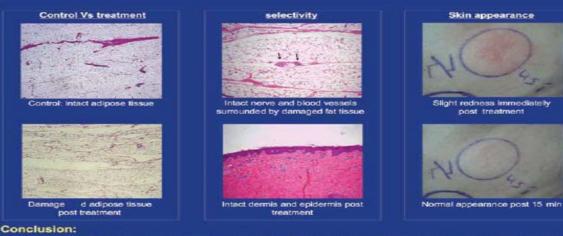
Membrane shape alteration





Ruptured adipocytes

Area of lysis



Non invasive selective ultrasound assisted lipolysis is feasible through use of specific parameters composition with no epidermal and dermal damage. This can be performed in a very simple procedure, high efficiency and low complications rate This highly selective ultrasound technology might be a solution for fat remodeling and sculpturing in the human body

ge: ASLMS Annual Conference, April 2009

and Armusi Conference, April 2001



Conclusion:

post treat

inted dermis and epidermis po

Normal appearance post 15 min

Histology

Normal Skin



Skin Layers

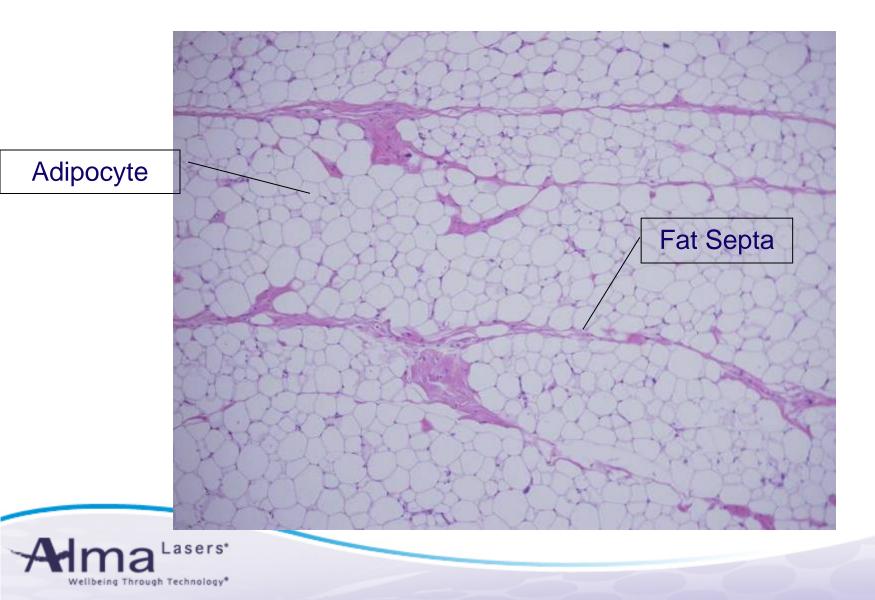


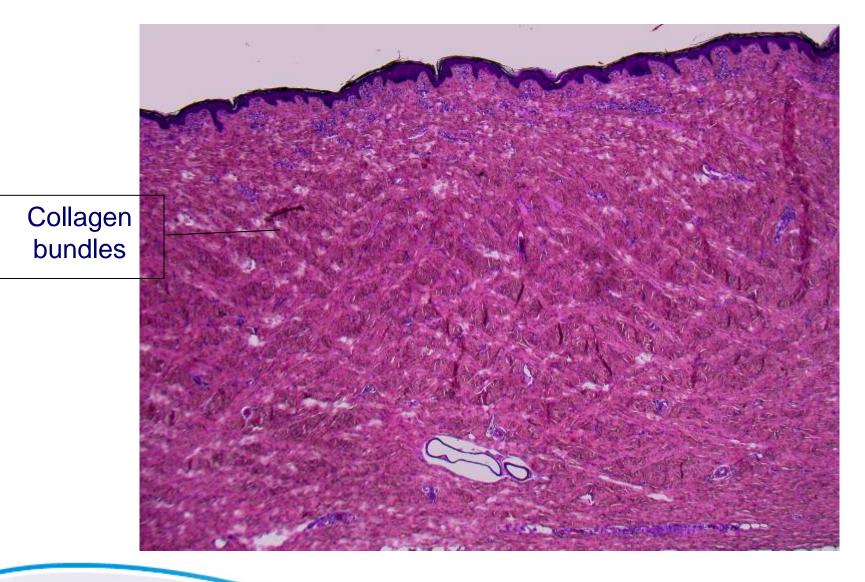






Normal Adipocytes





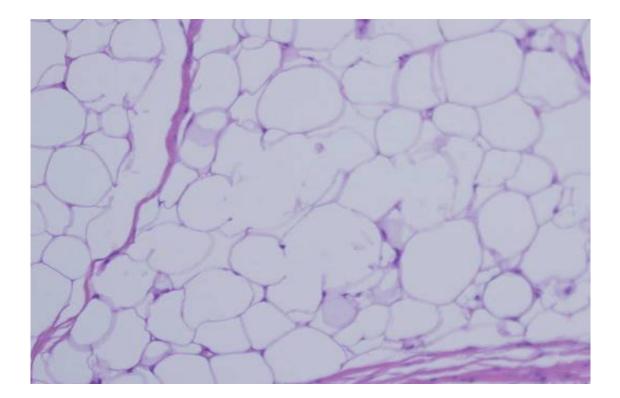


Histology

Types of Damage to Fat Cells

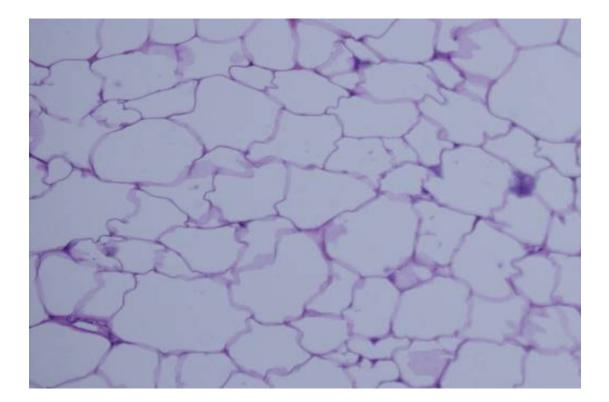


Destruction of fat cell membrane



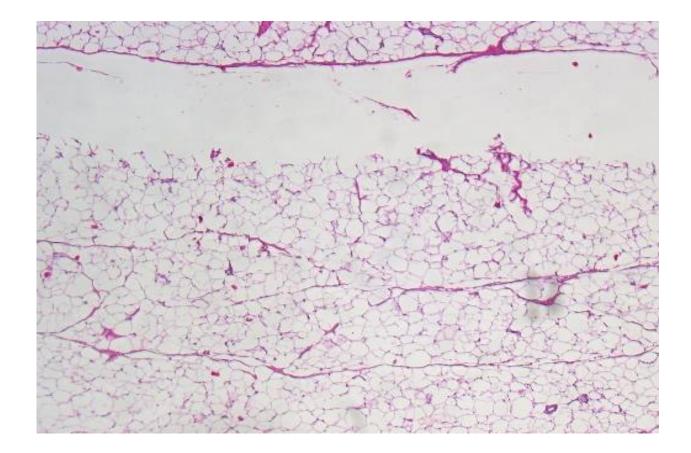


Change of fat cell membrane appearance



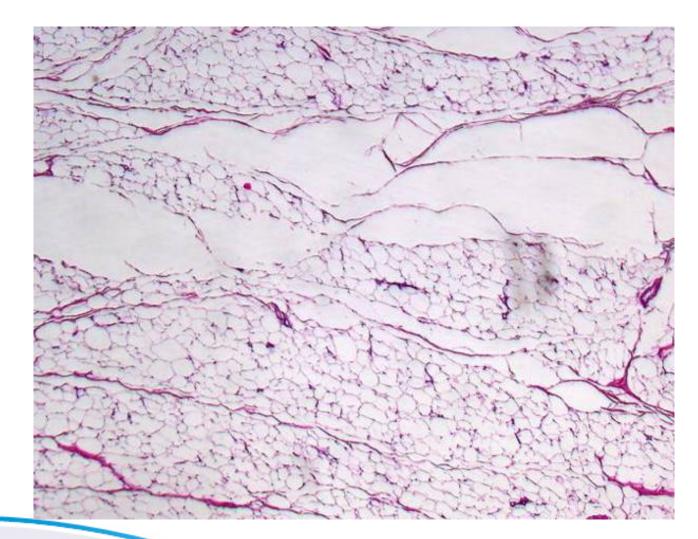


Septa Separation



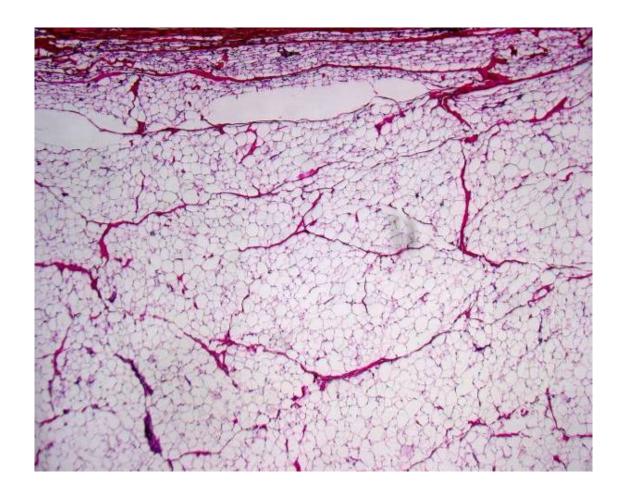


Acute



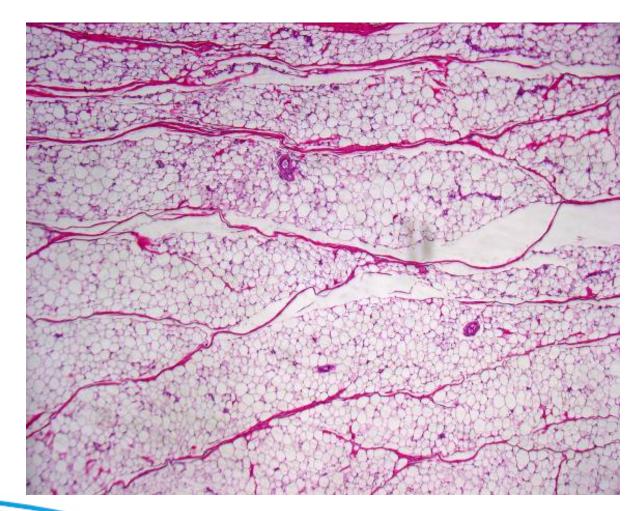


3 Days



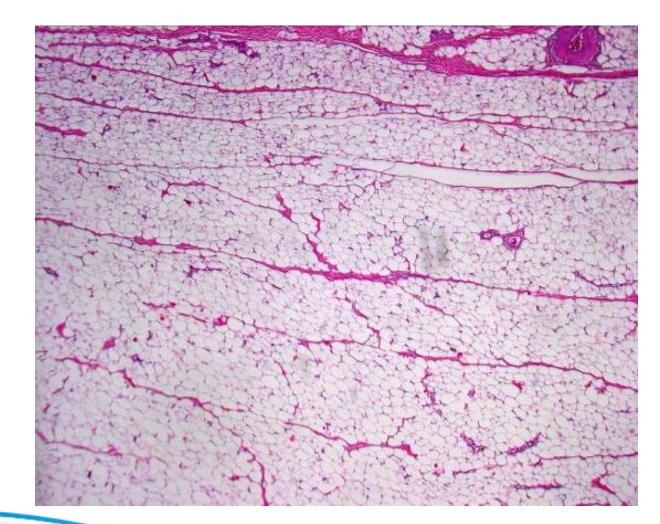


7 Days



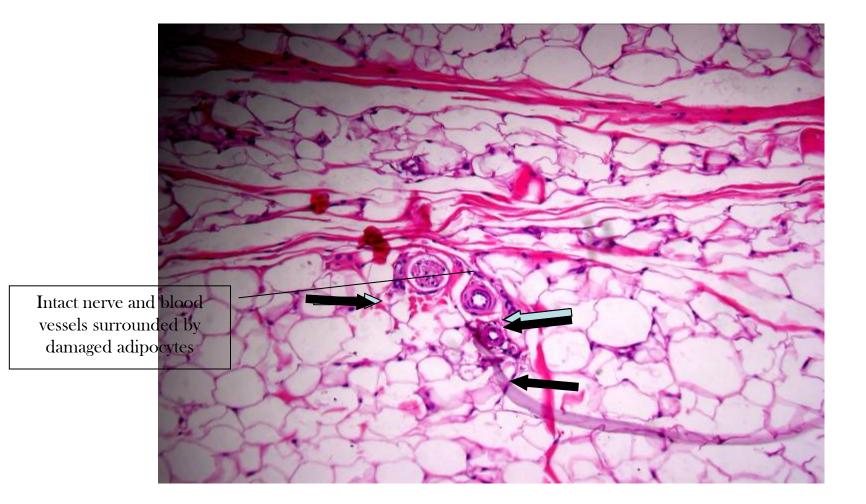


14 Days



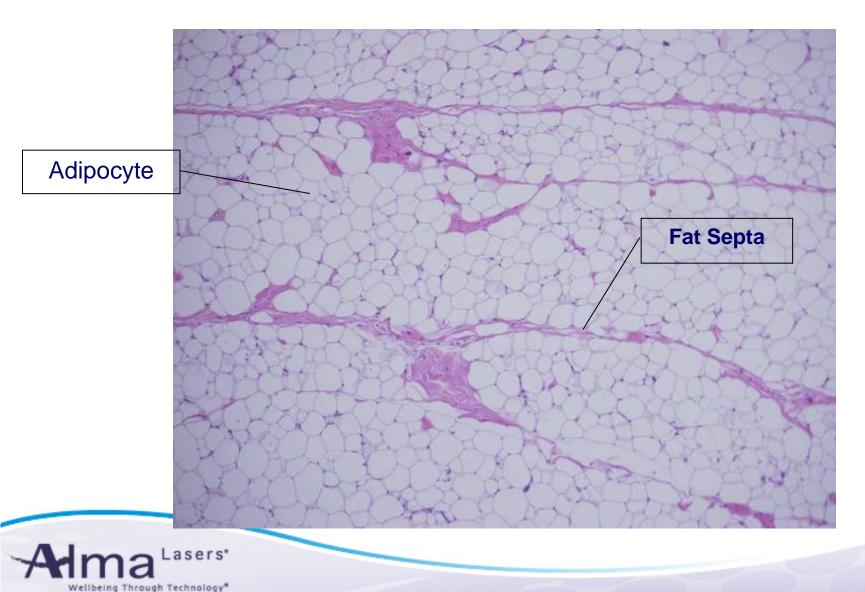


Selectivity

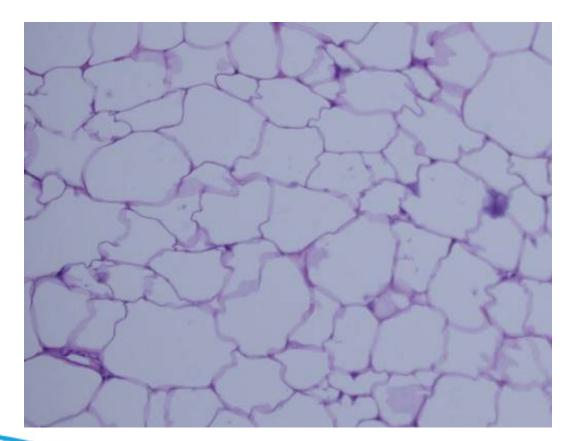




Normal Adipocytes

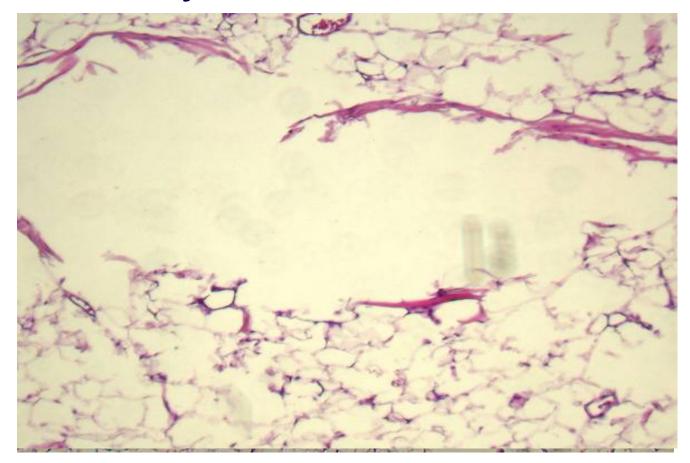


Deformation in fat cell membrane appearance





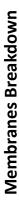
Lysis of fat cells





Histology

Cell Volume Reduced

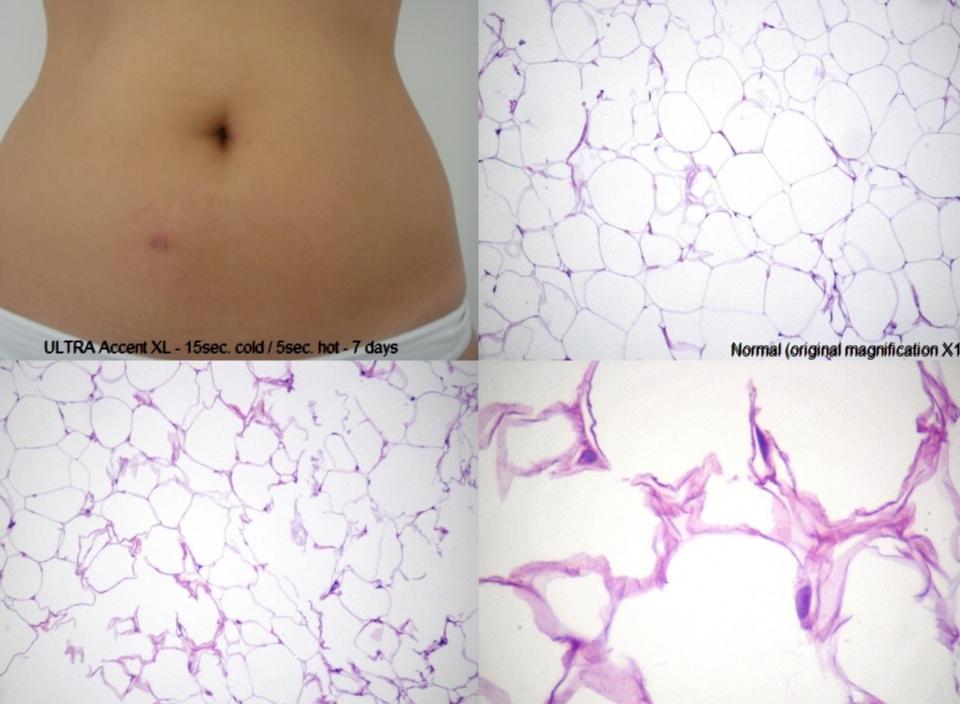


Cells Eliminated

Membranes Disrupted







parently there is rupture of adipocytes which are rolled and mimic

Apparently there is rupture of adipocytes which are rolled and min

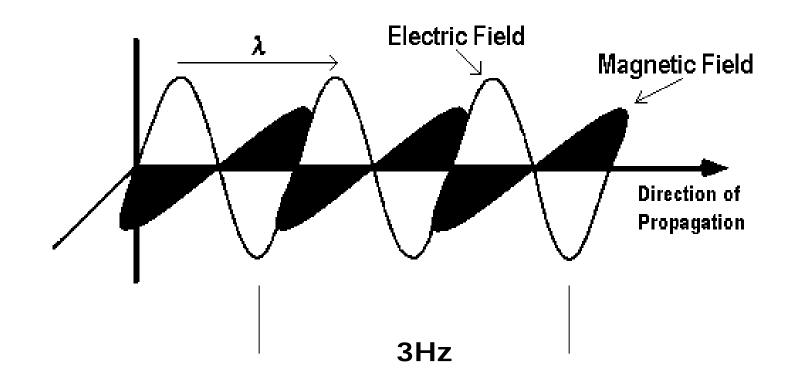
ULTRA Accent XL - 15sec. cold / 5sec. hot - 15 days

There are large cavities, apparently as a result of the breakdown of membranes of adipocytes and some small adipocytes (ruptured' rolled, forming thicker septa. (original magnification X100)

RF Technology

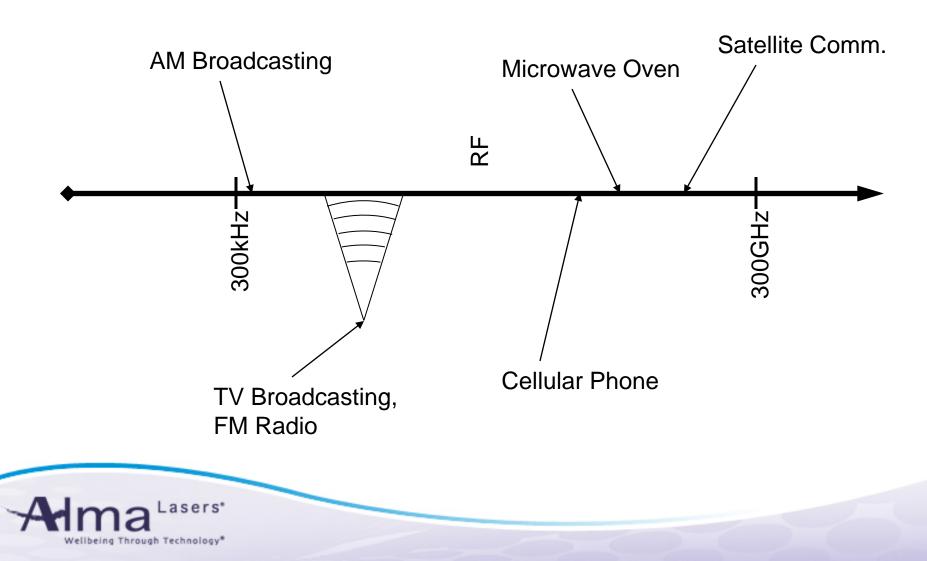


Electromagnetic Wave

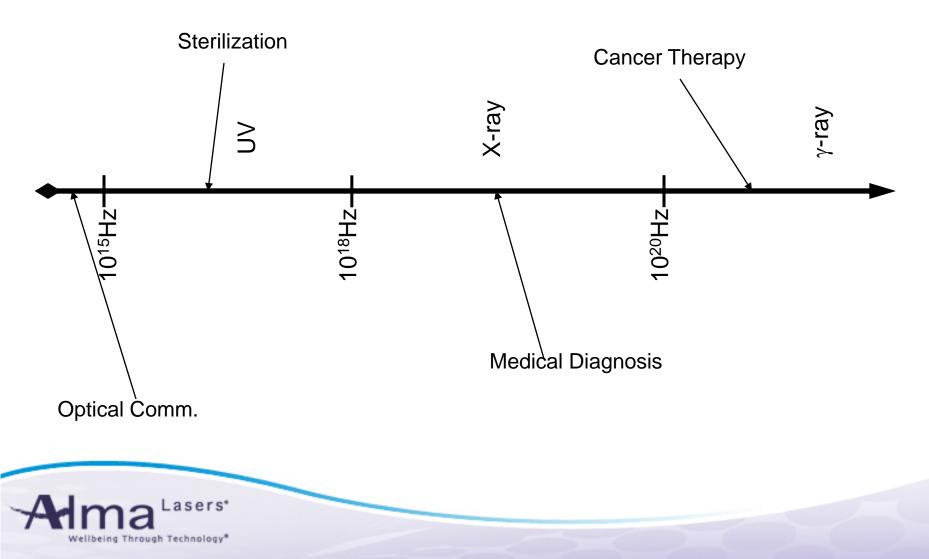




Radio Frequencies

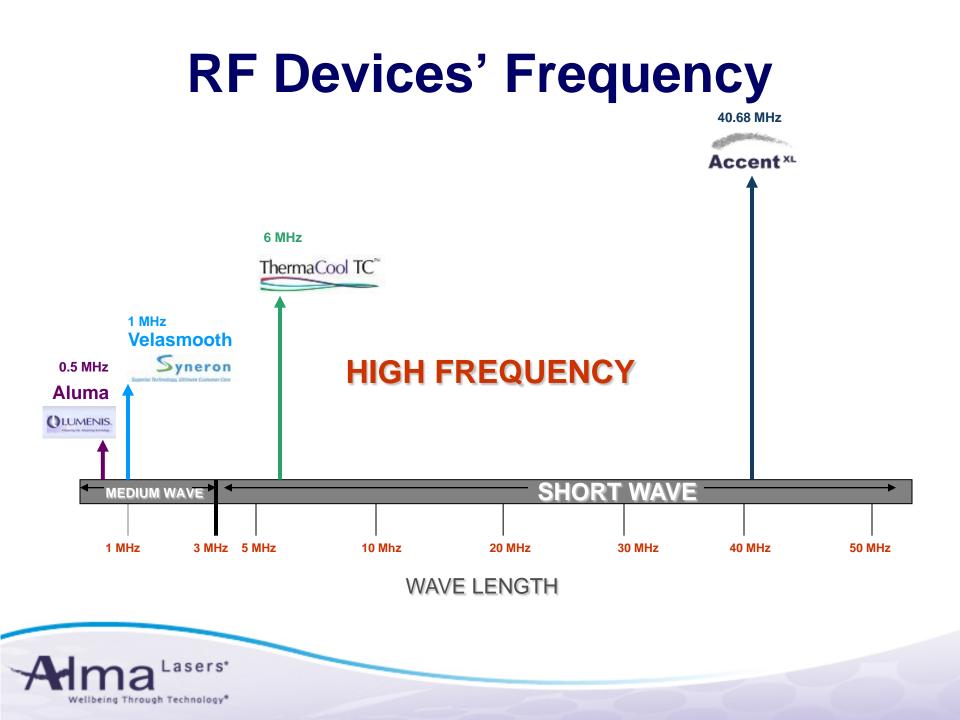


Ionizing radiation



The E	NON - IONIZING -		s Sp	
	Rediofrequencies>I	Visible Light		
Power Lines	Radio and Microwaves	Infra-red Ultra-viol	et X-raeys	G a mm a Ra ys
	Cellular Radio			
Frequency				
^(Hertz) 10 10 ² 10 ³ 10 ⁴	10 ⁵ 10 ⁶ 10 ⁷ 10 ⁸ 10 ⁹ 10 ¹⁰ 10	10 ¹² 10 ¹³ 10 ¹⁴ 10 ¹⁵ 10 ¹⁶	10 ¹⁷ 10 ¹⁸ 10 ¹⁹ 1	10 ²⁰ 10 ²¹ 10 ²² 10 ²³ 10 ²⁴ 10 ²⁵ 10 ²⁶
Energy (eV) 10 ¹³ 10 ¹² 10 ¹¹ 10 ¹	 10 ^{°°} 10	$\vec{0}^{3}$ $\vec{10}^{2}$ 0.1 1 10 $\vec{10}^{2}$	10 [°] 10 [°] 10 [°]	່ 10 ^{°°} 10 ^{7°} 10 ^{°°} 10 ^{°°} 10 ^{°°} 10 ^{°°}





RF Thermal Concept

- To deliver RF energy to the dermis, deep dermis and sub-dermal layers while protecting the epidermis.
- To heat these areas causing microscopic changes and collagen contraction, with subsequent collagen remodeling and micro-strucural changes in adypocytes (lipolysis).



RF + Mechanical Effect

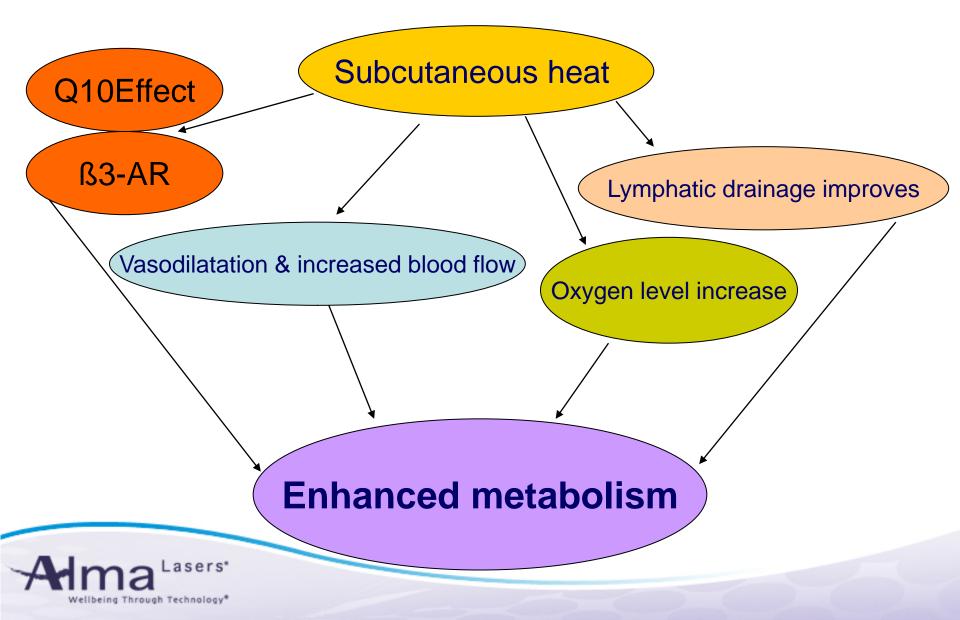
- Contraction of collagen fibers; firming and improving laxity;
- Deep heat reaches adipocytes; hypermetabolism
- Improves blood and lymphatic circulation and drainage
- Smother skin appearance

 Shrinkage of the subcutenous layer and overall skin





RF + Massager



RF Heat MOA

- Evacuating, enhancing, and augmenting the natural egress of triglyceride out of the fat cell, resulting in a diminishment of the convex distension.
- Release of dermal fibroblasts to stimulate and promote neocollagenesis.
- Increase vascular perfusion, which further enhances lipid turn over owing to the increase in oxygen content.
- Lymphatic circulation & drainage contribute to lipid turnover and fat cell redistribution



Heat and Catecholamines

- Elevation of catecholamines
 - Induce lipolysis in fat via ß-adrenergic receptors



ß-ARs Adipocytes' Receptors

B₃-AR	1:150		
B_2	1:1		
ß ₁	1:3		
Sub type	Ratio		



$m \ S_3$ -adrenergic receptors ($m \ S_3$ -AR)

- ß₃-AR receptor is key regulator of lipid metabolism in adipose tissue
- ß₃-AR mediates agonist-induced lipolysis in adipocytes



ß3-ARs Mediated Lipolysis

- Legand bound ß3-AR activates G proteins and induces cAMP accumulation
- Increase level of cAMP leads to activation of protein kinase A (PKA).
- cAMP-dependent PKA phosphorolates and activates hormone sensitive lipase (HSL)
- HSL catalyzes the breaks down of triglyceride (TG) to FAA and glycerol.



Non- ß-ARs mediators in Lipolysis

- Tumor necrosis factor (TNF)
- Interleukin-1 (IL-1)
- Interferon α
- Interferon γ

Decrease activity of lipoprotein lipase (LPL) and increase lipolysis in adipocytes

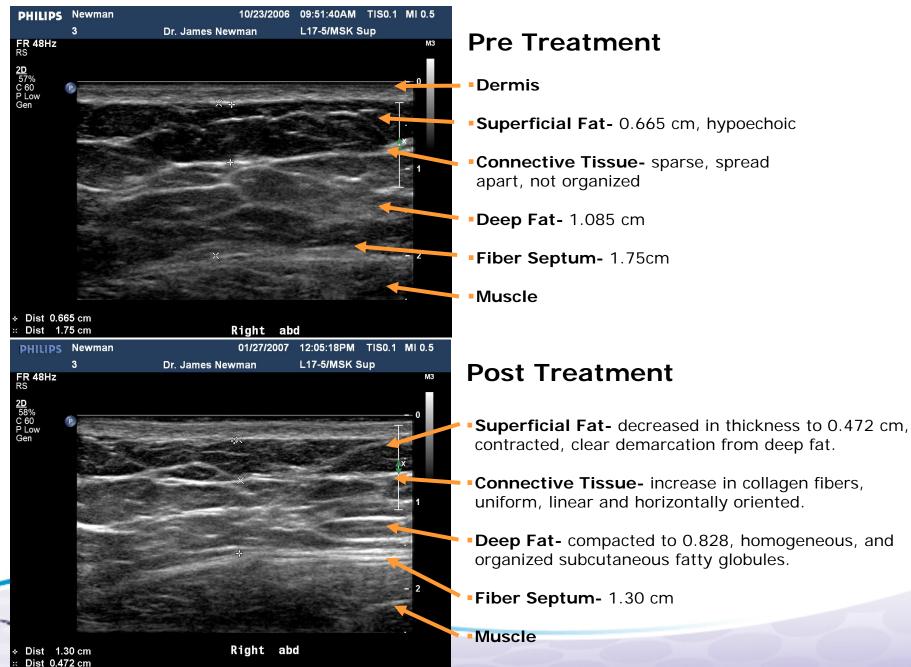


Skin Lymphatics

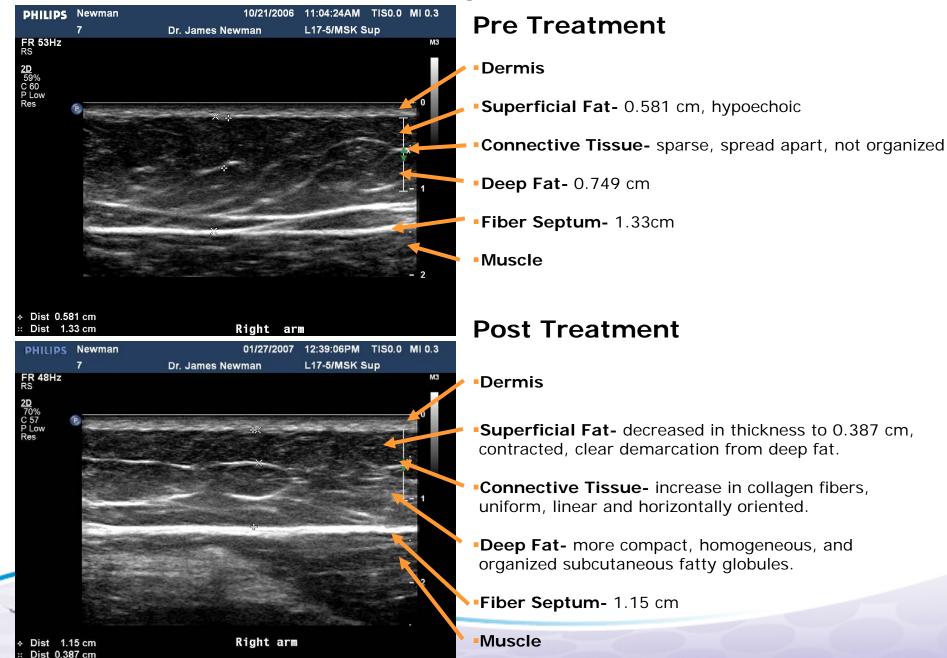
- Skin lymphatics parallel the blood supply and function to conserve plasma proteins and scavenge foreign material, antigenic substances, and bacteria.
- Blind-ended lymphatic capillaries arise within the interstitial spaces of the dermal papillae.
- These unvalved, superficial dermal vessels drain into valved deep dermal and subdermal plexuses.
- These then coalesce to form larger lymphatic channels, which course through numerous filtering lymph nodes on their way to join the venous circulation near the subclavian vein internal jugular vein junction bilaterally.



RF Accent - Abdomen



Accent through ULS – Arm



Accent-Ultra MOA Summary

- ULTRA: Shear wave ultrasound
 - Noninvasive selective fat cell deformation & destruction & compacting fat layers.
- RF: UniLarge radiofrequency + Massager
 - Contraction of collagen fibers
 - Deep heat reaches adipocytes; hypermetabolism
 - Improves blood and lymphatic circulation and drainage
 - Shrinkage of the subcutaenous layer and overall skin firming...Smoother skin appearance

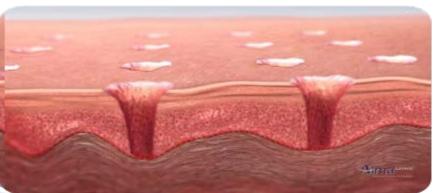


RF Micro-Plasma Technology











Plasma 1

- In physical sciences, "plasma" refers to the forth state of matter next to solids, liquids and gases; while in medicine and biology "plasma" is known as the noncellular fluid component of blood.
- The term "plasma" itself comes from Greek ("something molded").



Plasma 2

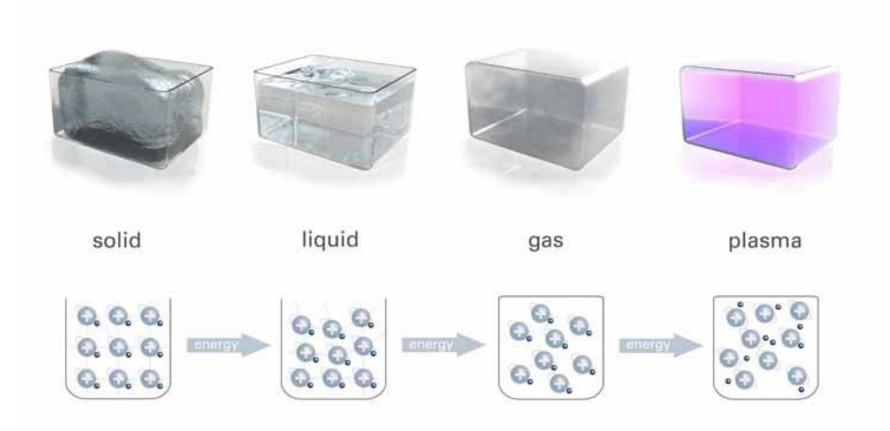
 Plasma denotes a partially ionized gas that consists to a large extent of charged particles such as ions and electrons, free radicals, molecules and also of neutral atoms.



Plasma 3

 In all plasmas supported by electric field, electrons receive the external energy much faster than the much heavier ions and have the opportunity to heat up to several thousands of degrees before their environment heats up.





•Plasma is a state of matter in which electrons are tripped from atoms to form an ionized gas.



Plasma Classes

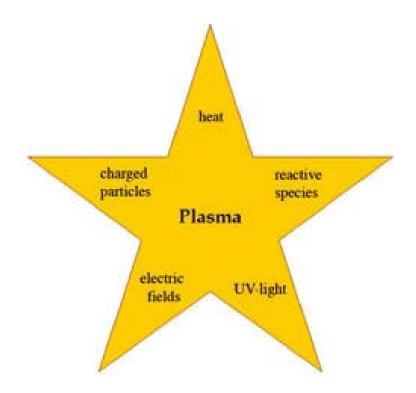
 It is important to differentiate between hot (thermal) and cold (nonthermal or low-temperature) plasma depending on the relative temperatures of electrons, ions and neutral gas.



Plasma Applications

- Heat and high temperature have been exploited in medicine for a long time for the purpose of tissue removal, sterilization and cauterization (cessation of bleeding).
- The thermal properties of plasmas (> 80°C) is utilized for cauterization, sterilization of heat-resistant, instruments or for cosmetic, reconstructive procedures.







Plasma – MOA 1

- When adding energy to a gas, the electrons separate from the nucleus and move around freely.
- Plasma is thus a (partially) ionized gas, which shows, as an electroconductive gas.
- Plasmas generate reactive species and radicals, such as atomic oxygen, hydroxyl, nitric oxide (NO), superoxides, etc.
- It is these short lived chemical species that play a major role in the plasma interaction with biological cells.



Plasma – MOA 2

 Decisive for the action is the flow of active, charged particles (electrons, positive and negative ions, e. g. Ar⁺, Ag⁻) and uncharged atoms and molecules (such as O3, OH, H2O2, NO, OH radicals etc.).



Thermal Plasma

 In thermal plasma, energy flux from electrons to heavy particles equilibrates the energy flux from heavy particles to the environment only when temperature of heavy particles becomes almost equal to the electron temperature.



MOA 1

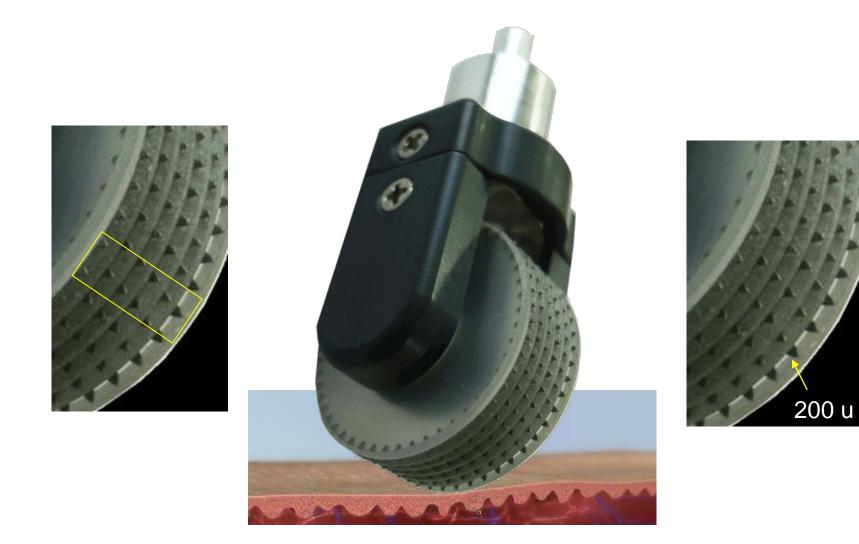
- The principle of operation of the Pixel RF roller tips relies on the formation of microplasma ('sparks') at the surface of the skin leading to the ablation and coagulation of the skin at the contact/treatment site.
- The ablative effects occur in the immediate vicinity of the interaction between the 'micro sparks' from each 'pin' of the Pixel RF roller and the surface of the skin in the treatment area when the pins come into close proximity to the skin.



MOA 2

- The electromagnetic RF energy stimulates micro-sparks between the skin surface and the RF electrode.
- These sparks ablate and perforate the skin.
- This produced micro-channels, their depth and diameter depend on duration of pulse of RF-energy and RF-power.
- The micro-channels pores produce holes of 100-150 µm in depth with diameter of 80-120 µm.





2 rows x 6 pins = 12 pins 50 W/12 = 4.75 W per pin



RF Pixilation

- Formation of multiple micro-ablative channels at the surface of the skin.
- The ablative/evaporative effects occur in the immediate interaction of the RF Pixel with the skin.
- Each of these small micor-channels is surrounded by untreated/unaffected tissue.
- The thermal effects include the zone of vaporization as well as the residual lateral coagulative damage.



Background

- The pixel RF hand piece is a Unipolar RF-based technology.
- The pixel RF applicator delivers electromagnetic energy that is creating multiple controlled, micro-perforations (channels) surrounded by thermally injured zone, into the skin layers depth.
- The hand piece can be used in stationary and inmotion modes.



Basics in RF Fractional Ablation

Fractional ablative RF is similar to fractional

ablative lasers in that both have a pattern of

microscopic ablated/coagulated tissue channels.



RF Pixilation

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- Each of these small micor-channels is surrounded by untreated/unaffected tissue.
- The thermal effects include the zone o vaporization as well as the residual lat coagulative damage.

Through Technology*

Advantages of RF Pixel

- Ablative effect: Micro-injury stimulate tissue regeneration. Improve skin color and texture.
 - Thermal effect: RF micro-plasma technology reaches dermis stimulates fibroblast and causes collagen regeneration Scar improvement.
 - Very efficient procedure
 - Only 10 minutes to treat the entire face with unique roller design
 - No extra supplies, no nitrogen refills required, NO Limitations.
 - Short healing time
 - Low complications rate.



Mechanism

- The principle of operation of the Pixel RF roller tips relies on the formation of microplasma ('sparks') at the surface of the skin leading to the ablation and coagulation of the skin at the contact/treatment site.
- The ablative effects occur in the immediate vicinity of the interaction between the 'micro sparks' from each 'pin' of the Pixel RF roller and the surface of the skin in the treatment area when the pins come into close proximity to the skin.



Clinical Applications

- Post-Acne Scars
- Stretch Marks
- Inflammatory Acne
- Pore reducing
- Skin Rejuvenation
- Tightening, firming skin
- Reducing rhytides



Pre-Clinical Study

Histology



Histology

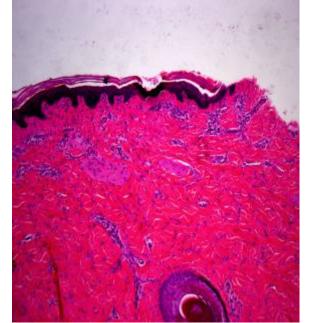
Day 0

Day 3

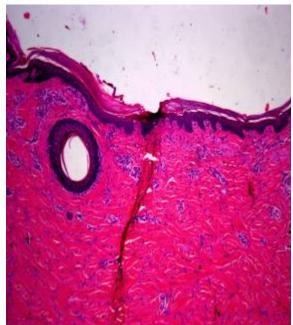
Day 14



A crater caused by the ablative effect of single Pixel RF spike at 45 Watts



Re-epithelializarion of the Crater



closer of the Crater and healing /rearrangement



Plasma Skin Interaction

- When plasma effect is induced in-vivo, various effects can be achieved from vaporization to local tissue heating as well as compressional waves.
- Just as with lasers, longer exposure times at lower energies allow for more thermal diffusion and tissue heating, while shorter exposures at high energies can produce vaporization or ablation, and less coagulation.



Clinical Application



Application technique

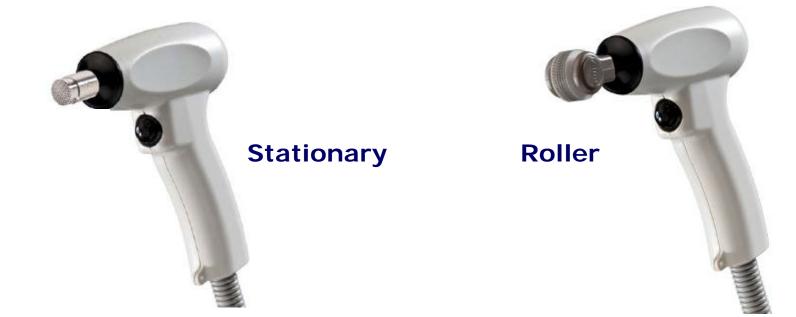
- The treatment technique involves moving the RF pixel handapplicator on the skin surface
- Two types of technique :
 - In-motion with a rotative tip
 - 2. Stationary technique non-gauged & gauged tip







Tip Applicators





Pixel RF Tips





Technique – Roller Tip

- The Pixel ^{RF} should be moved with brief roll-up and down strokes on the treatment area. This in-motion technique requires fine touch of the RF pixel on treatment area (skin)
- The Pixel ^{RF} tip should be in a non-tight contact with the skin in order to achieve an ablative effect along with the thermal effect.



Settings – Roller Tip

Skin Type	Tip Size	Energy (Watts)	Exposure Time (sec)	Number of Passes*
I-III	Narrow	45-60	Up to 30 (multiple strokes)	2-3
IV-VI	Narrow	40-50	Up to 30 (Multiple strokes)	2-3

* The number of passes depends on the desired level of penetration i.e., the greater the number of passes the greater the penetration.



Technique – Stationary Tip

- 1. Perpendicular position of the tip and contact between the pixel RF tip and the surface of the skin.
- 2. RF energy in one point; useful in the periorbital area.
- 3. The tip should be in a non-tight contact with the skin, to achieve an ablative effect along with the thermal effect.
- 4. Alma's new stationary tip



Settings - Stationary

Skin Type	Tip Size	Energy (Watts)	Exposure Time (sec)	Number of Stacks**
I-III	Small diameter; Medium grate	45-60	0.1	2-3
IV-VI	Small diameter; Medium grate	40-55	0.1	1-2

*The tip with the smaller diameter and lower number of pins (larger grate) is used for a more aggressive effect.

** The number of stacks depends on the desired level of penetration i.e.,

the greater the number of stacks the greater the penetration.



Advantages of RF Pixel

- Ablative effect: Micro-injury stimulate tissue regeneration → Improve skin color and texture.
 - Thermal effect: RF micro-plasma technology reaches dermis stimulates fibroblast and causes collagen regeneration → Scar improvement.
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Clinical Applications

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- Stretch Marks
- Inflammatory Acne
- Pore reducing
- Skin Rejuvenation
- Tightening, firming skin
- Reducing rhytides



Contraindications

- bacterial and viral infections
- impaired immune system
- isotretinoin in the past 6-9 months
- skin type VI
- cancer
- active collagen and vascular disease
- diabetes
- pregnancy
- metal implants near the treatment area
- pacemaker and defibrillator



Pre-Treatment Considerations

Anesthesia

- sedation
- zimmer
- analgetics
- EMLA
- ice pack



Ttreatment Considerations

- Adjust the energy parameters and recommended exposure time
- The down time: 12-24 hours until 3- 5 days with some flaking
- After the treatment the skin becomes red or appears sunburned



Patient Preparation

• Emla cream with occlusion for thirty minutes

• Nerve blocks

Infiltration anaesthesia



Acute Post Op Care

- Ice packs, zimmer
- Local corticosteroids
- Analgetics
- Open wound technique with emollients or
- Soak the skin and gently clean the skin to remove the skin fragments
- Avoidance of sun exposure with regular use of sun protection creams
- Discontinue local retinoids and peelings 7 to 10 days after the treatment



Treatment Sequale - Acute

- Erythema (up to 24 hours)
- Itching/tickling
- Mild-moderate burn sensation



Post Treatment Sequelae

For 5-7 Days

•Redness

•Swelling

•Crusting

Prolonged Erythema following aggressive treatments (> 60W < 100W)



General Post Treatment Care

- 1. Antiviral Medication: Valciclovir 1gm every 12 hours for one day
- 2. Topical Antibiotics: Fucidic acid (Fucidin) cream twice daily for two days
- 3. Topical Steroid:
 - 1% Hydrocortisone cream twice a day Or
 - 0.1% Hydrocortisone butyrate twice a day
- 4. Depigmenting and Vitamin C cream as of Day 4 for four weeks in all cases



Precautions

- Do not use the Micro Plasma Technology technology over Botox or Restylane for two weeks post injection.
- Use an antiviral before treatments if there is a history of cold sores.
- Make sure skin is clean and dry before



Treatments & Intervals

- Number of treatments: 4 6
- Intervals: 2-4 weeks

Face 3-4 wks Body 2-3 wks



Clinical Studies



Clinical Studies



Dr. Halachmi Shlomot & Dr. Lapidot Moshe



Journal of Commic and Later Therapy, 2010; 12: 208-212.

info



A novel fractional micro-plasma radio-frequency technology for the treatment of facial scars and rhytids: A pilot study

SHLOMIT HALACHMI¹, ARIE ORENSTEIN², TANIA MENEGHEL³ & MOSHE LAPIDOTH⁴

Later Unit, D Chain Shibu I Grand Ameri

Abstract Introduction: Pt due to their off or non-ablative treatment of faintervals. These centrion of tre months after tr onstrated reduc by all participals effectiveness of a and factal rives? Key Words: Av Introduction Fractional sk 22 and carbon o an effective till efficacy-to-do to a grid of a energies can surrounding e

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Phone is Histohysial damps following Find RF preliming of some effective literal in the patients and particle dimen-ing a single path of 44 mars 2.0, Day 2 mounts before a full decision path of 44 mars 2.0, Day 2 mounts before a

Figure). Find 10" sty, denotes the grandes due little the small half of senses with the same, in the value and grandes (347 and in range from two to treatme in depth and from sec to the same in diameter (Figure 4). The suchrosing improves upon conventional RF by lowering de-generation of planeas to gateries forcing higher condecivity and thately eligening micro-sparks and high semperatures in micros for. We report here the initial operations of masking field areas soon underlights.

Materials and methods

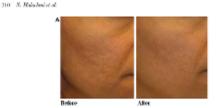
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Refue-Figure 5. Treatment of some source (A) Across source bet Cares Englangeds

Recubs

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A total of 16 patients were treated (five female). The clinical endpoint for commanment was moderate orythems. Owi rapid motion of the roller tip over large area passes over the face were swift and well tele total treatment time for the fall-face was mately 10 minutes. All facial treatments tolerated with no adverse events. Mild-tocrythena was present for 1 day after tree pale pixel-pattern grid was evident for 3 de background of fine existance acale.

Eight patients with some sours were to mean upe was \$4.5 years (range 23-57). Patie went one to four treatments (mean 3.1). scars demonstrated cumulative improven public improvement after three treatments (B The effect was maintained at 3 months' (Figure 3B). Of interest, patients with mild a

experience a reduction in active aeneiller during the treatment and follow-up interval. Eicht patients underwent treatment rhytics. The mean age was 58.8 years (rang) Patients underwent two to four treatments () Wrinkles were sighly reduced after two to

visual skin texture after four treatments i



with norable improvement in wrinkle appea





Afres

in discharge inter-

Clinical Studies

Pixel^{RF} - Fractional Micro-Plasma Radio-Frequency Technology for Ablative and Non-Ablative Skin Resurfacing, Skin Remodeling and Acne Scars

Joseph Lepselter, PhD¹, Alexander Dverin, M.Sc.² ¹Clinical Department & ²RF Research & Development Laboratory Alma Lasers Ltd. Caesarea, Israel

ABSTRACT

Various techniques and devices are known for medical treatment of skin layers by application of electromagnetic energy, and in particular radio-frequency (RF) energy. Recently, fractional ablative technology using ER:YAG, CO₂, or radiofrequency (RF) ablative technologies became commercially available and are gaining clinical recognition and popularity in procedural dermatology.

The Accent^{XL} (Alma Lasers Ltd., Caesarea, Israel) is a Unipolar- based, RF-energy delivery device with novel Fractional Micro-Plasma Radio-Frequency (Pixel^{RF}) technology. The Pixel^{RF} technology of the Accent^{XL} creates microscopic treatment zones included controllable depth perforations with small volumes of thermal damage or within the skin to produce focal resurfacing micro-wound patterns over the background of largely unaffected surrounding healthy skin. The Accent^{XL} Pixel^{RF} with the indications are skin tightening; skin resurfacing; treatment of fine lines and wrinkles; improvment of acne scars; stretch marks; chicken pox scars, rejuvenation (photoaged skin); combinations with other ablative procedures and photorejuvenation procedures.

INTRODUCTION

temperature substantially higher than when they are in



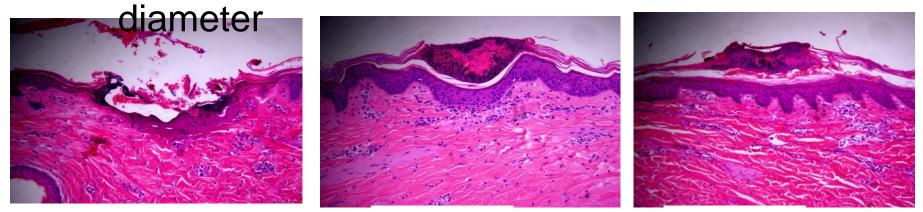
Pre-Clinical Study

Histology



Pre-Clinical Studies

- Procine Skin
- Depth and diameter depend on Power and Pulse duration
 - 100-150 μm in depth and 80-120 μm in



Day 3

Day 14



Day 0

Acute

The histology shows a crater caused by ablative effect of a single Pixel RF spike @56Watts



Photo Courtesy: Arie Orenshtein, M.D, Department of Plastic and Reconstructive Surgery, Sheba Medical Center, Tel Hashomer, Israel





The histology shows re-epithelialization of the crater 3 days after Pixel RF

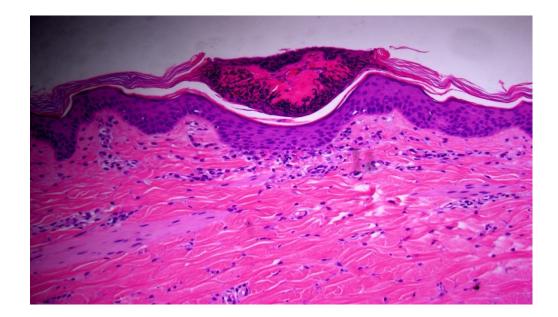


Photo Courtesy: Arie Orenshtein, M.D, Department of Plastic and Reconstructive Surgery, Sheba Medical Center, Tel Hashomer, Israel



14 days

The histology shows closure of the crater and healing/ rearrangement of the rate ridges area 14 days after Pixel RF.

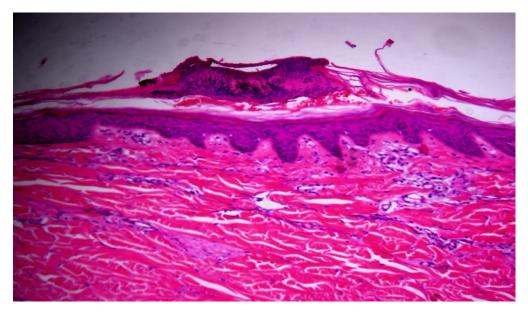


Photo Courtesy: Arie Orenshtein, M.D, Department of Plastic and Reconstructive Surgery, Sheba Medical Center, Tel Hashomer, Israel



Clinical Results



Acne



Before



1.5 months After 3 Treatments

Acne



Before



3 months After 3 treatments



Before



1 month after 2 treatments



Before



1 month after 4 treatments



Before



3 month After 3 treatments



Before



3 month After 3 treatments

Atrophic Scars



Post-Acne Scars



Asian skin treated with RF Pixel 2wks interval, total 6 txs



Post-Acne Scars



Before

After 6 tx











the second se





2 tx of 40W



Before

3 tx of 55W





4 tx of 50W





3 tx of 45W





5 tx of 50W



3 tx of 45W





3 tx of 45w

2 tx of 45W





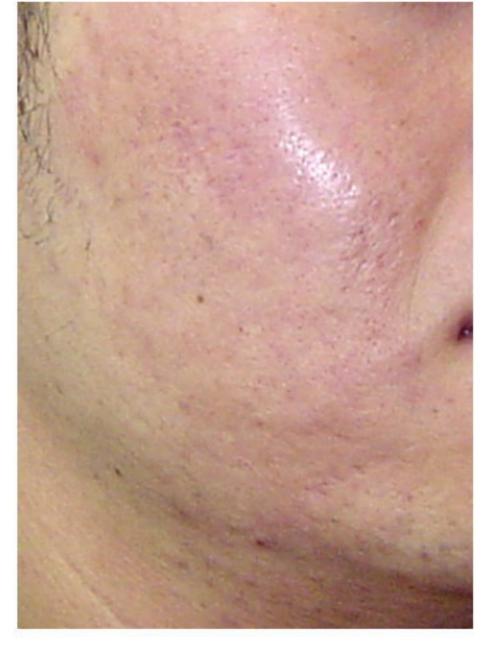


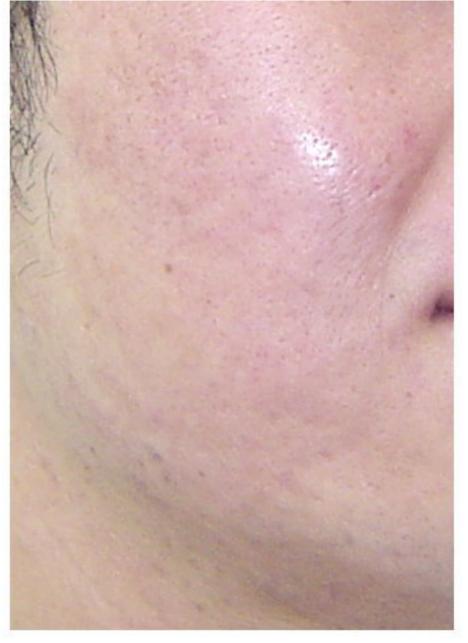
5 tx of 50w

the second s









5 tx of 45W

Treatment Practice



Patients Selection

- Motivated patients with realistic expectations
- Normal-moderately overweight:
 - -BMI <30kg/m²
 - -Localized fat deposits
 - -At least 1.5 cm of fat thickness as determined by a skin caliper



Treatment Areas

- Abdomen
- Flanks
- Thighs
- Knees
- Arms
- Face
- Calves









Biometric Measurements



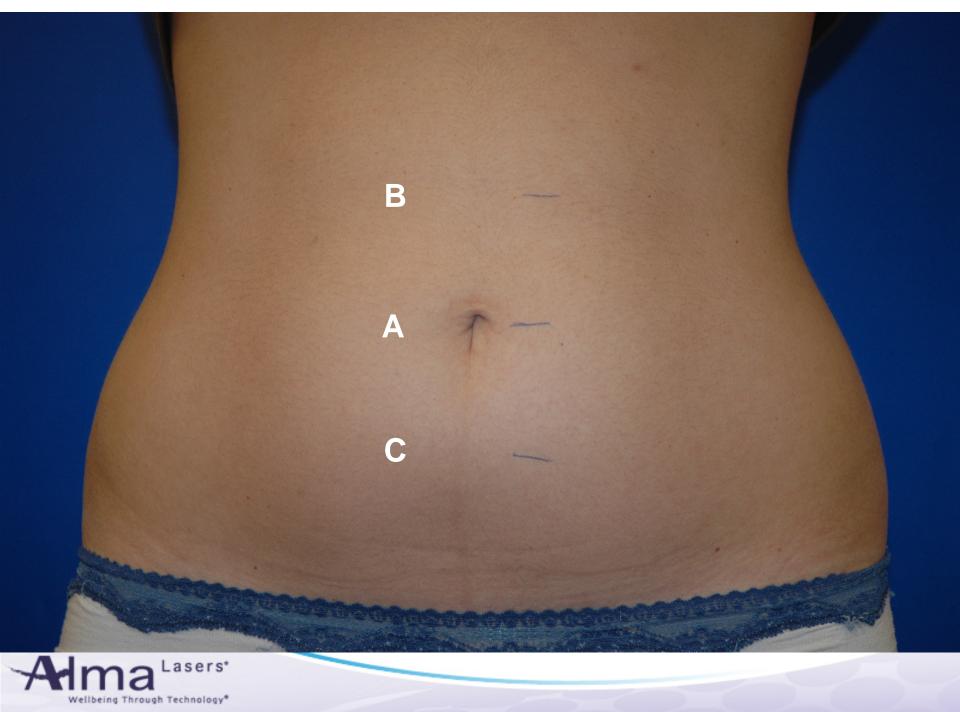
Measurements

- Circumference (abdomen)
- Skin fold ("pinch test")
- Photography

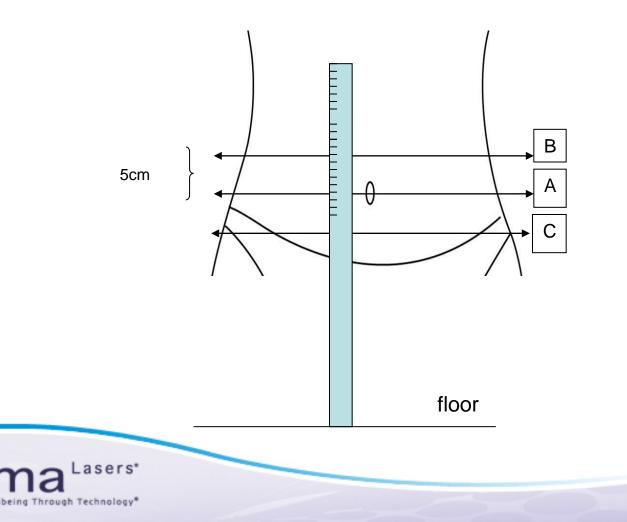








Circumference Measurements





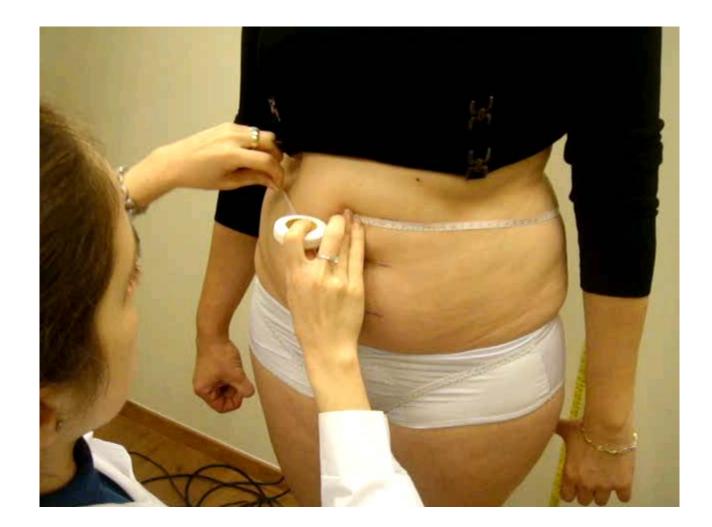














Skin-Fold (Caliper)







Abd Landmark



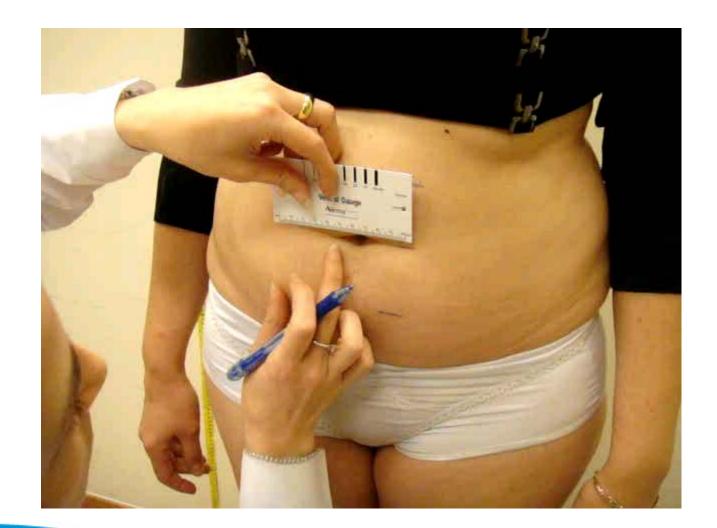
a mark is made 5 cm adjacent to the umbilicus (belly-button), to the right side.



Abd Pinch













Iliac Crest Landmark



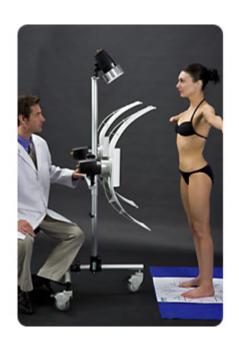


Iliac Crest Landmark

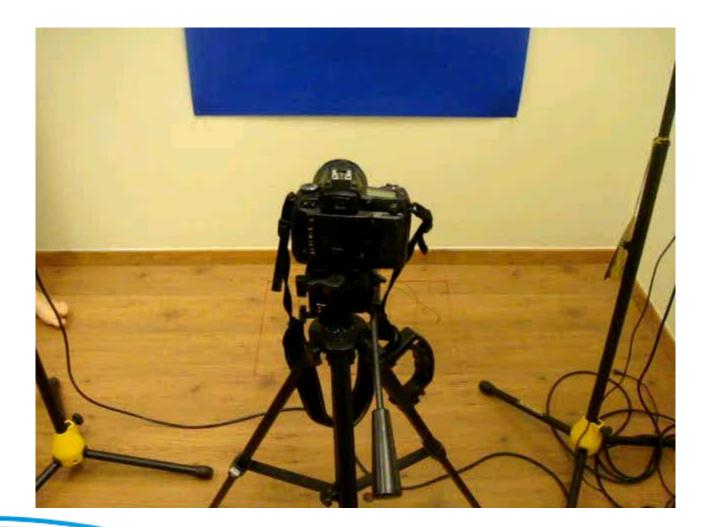




Photography









"Hands-On"



Ultra Handpieces

- Output acoustic frequency matched to resonance frequency of fat
- Operative modes
 - -"Hot" mode compression wave
 - -"Cold" mode transverse/shear wave





UltraFace

 A non invasive Selective Ultrasound, using shear wave technology



 Indications: for volume reduction (facial adiposis), pronounced jaw line and Face Contouring



UniFace

- Unipolar technology with eight focused lymphatic rings, to lift and tighten loose skin on the cheeks, and neck to give a younger slimmer look.
- Indications: wrinkles reduction, skin tightening, collagen remodeling and improvement of skin texture.



Hand Pieces

Clinically proven Impact sonotrode

Acoustic waves and air pressure Push and pull effect within the microchannels

Variable energy settings Quick makeover Single-use tips

Impact



Treatment Areas

- Abdomen
- Flanks
- Thighs
- Knees
- Arms
- Face
- Calves









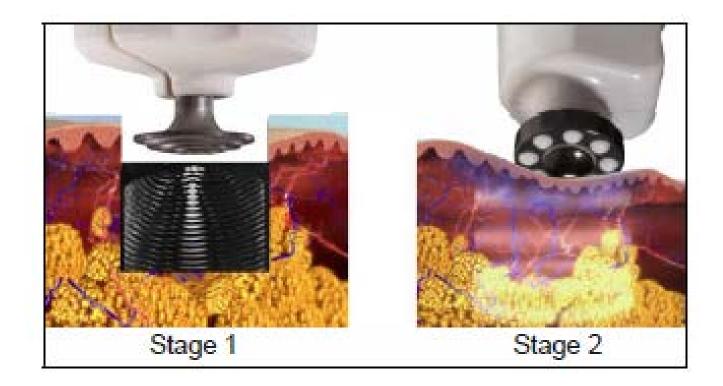
Treatment Areas (Face)

- Mandibles
- Jaw line
- Submental
- Chin
- Cheeks

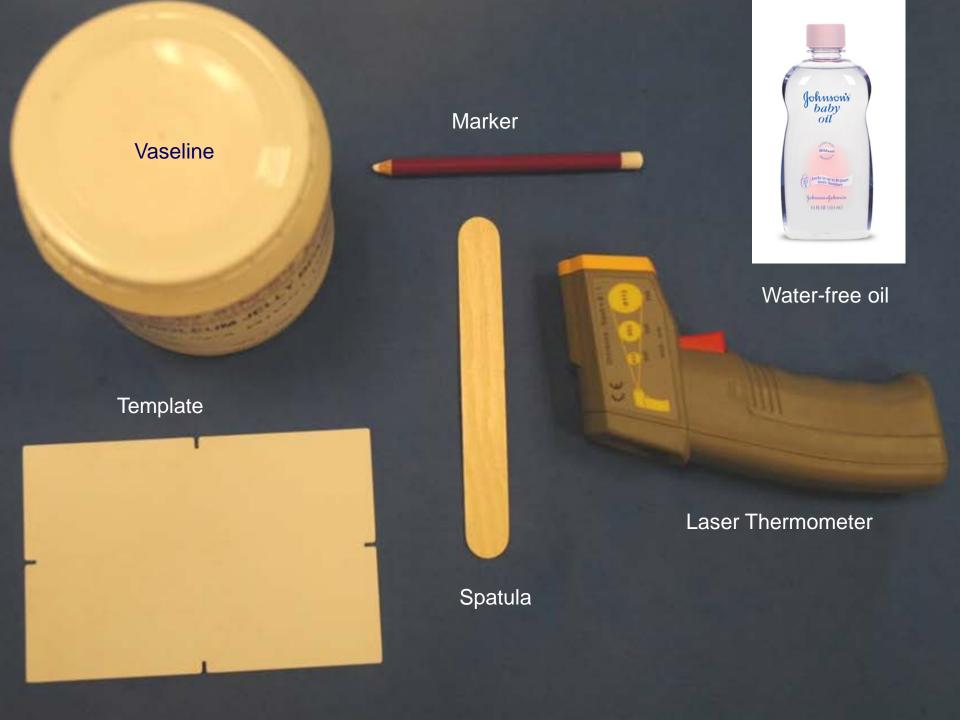




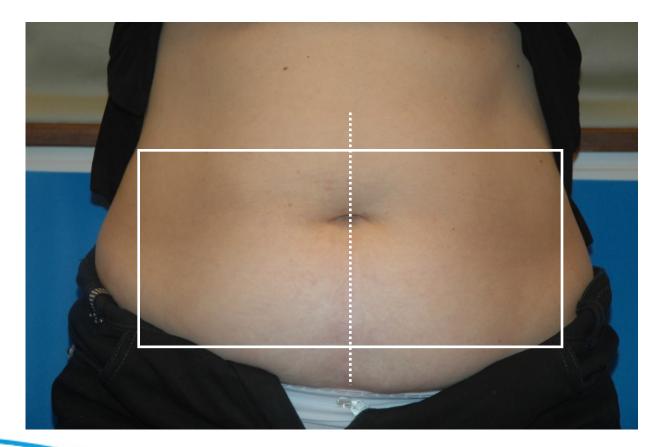
Treatment Regimen





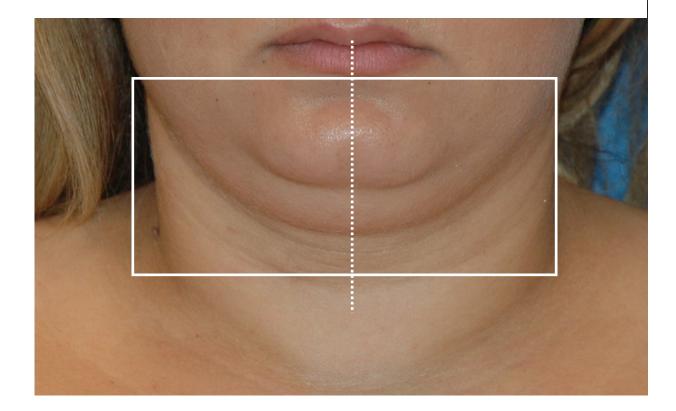


Treatment Area

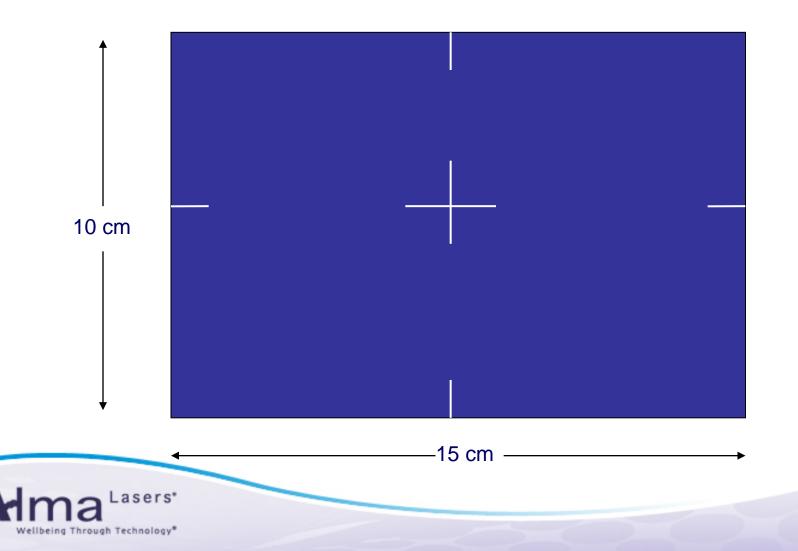


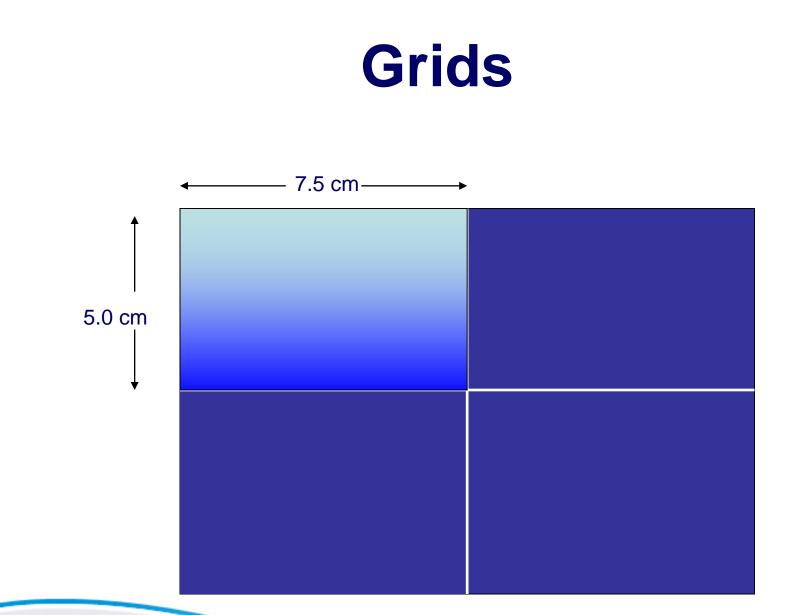


Treatment Area



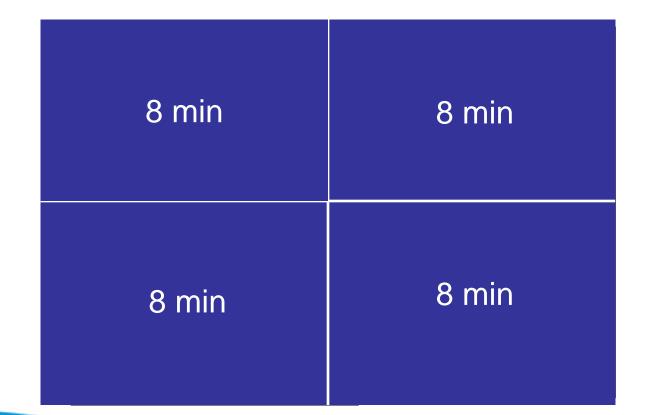








Treatment Time





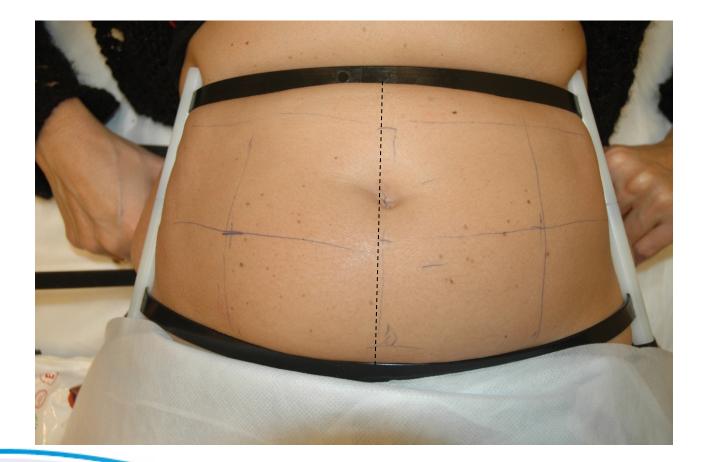








Treatment Area

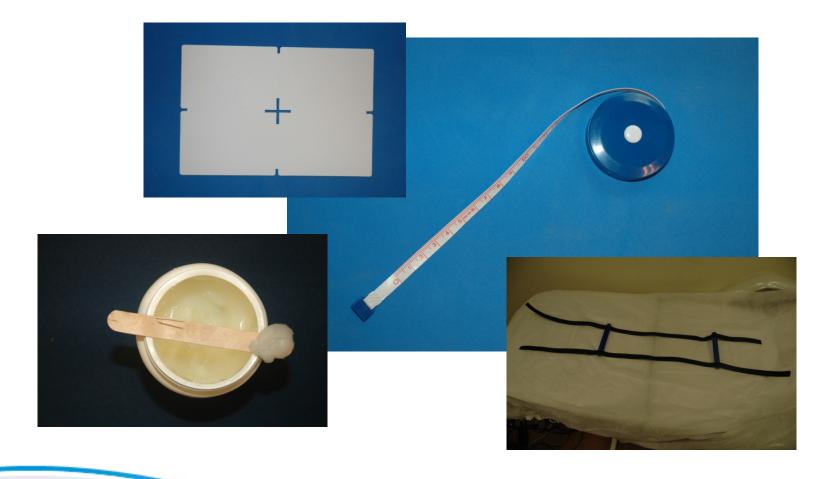








Accessories - Ultra





U/S Treatment

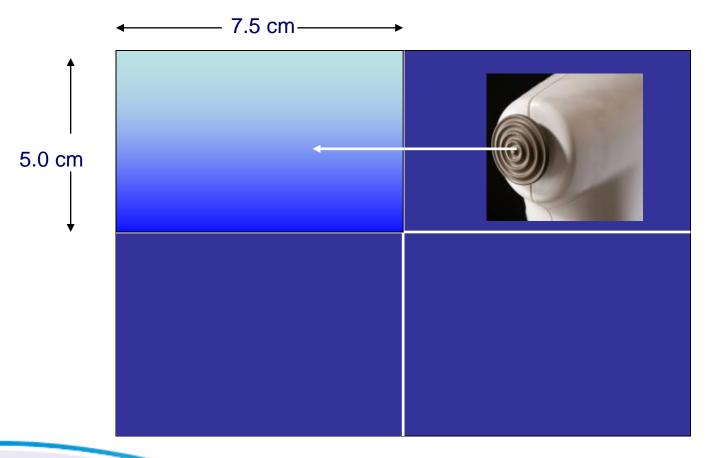


Ultra

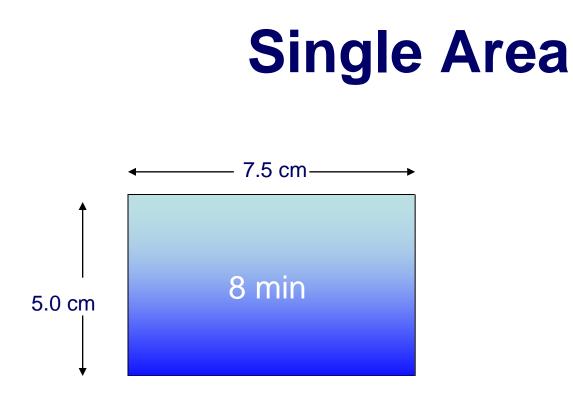




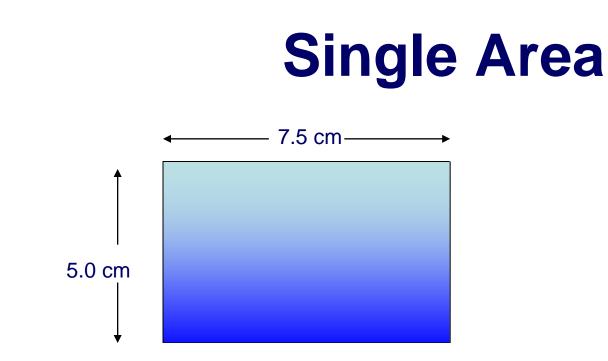
Treatment Areas





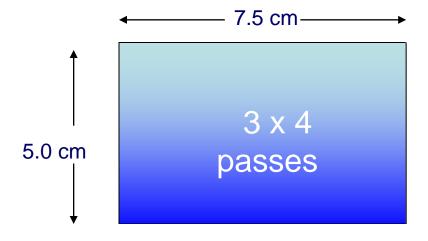






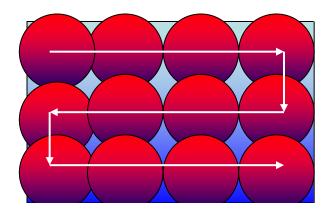


Handpiece Movement





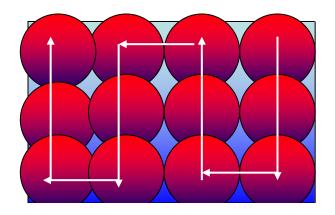
Handpiece Movement



- •Horizontal passes (3)
- •"In-Motion" technique
- Slow-moderate pace



Handpiece Movement

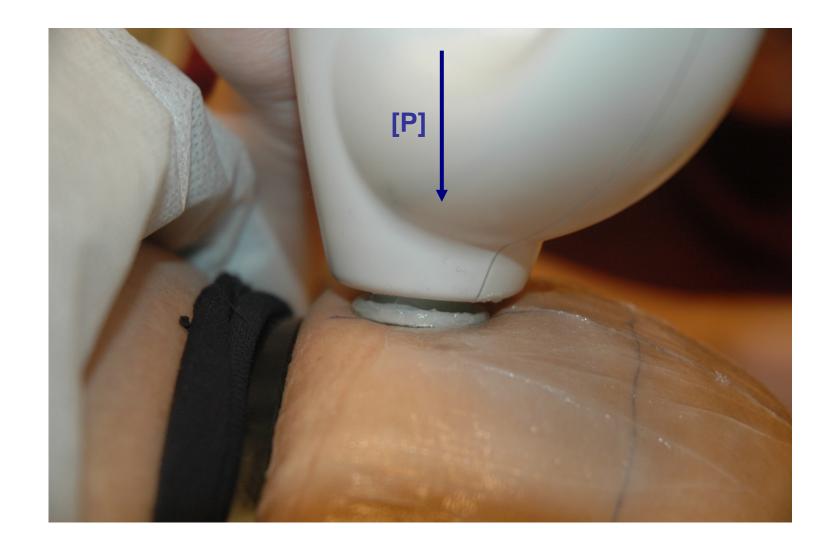


- Vertical passes (4)
- •"In-Motion" technique
- Slow-moderate pace















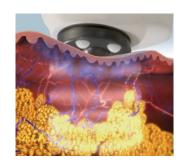
End-Points





Number of Treatments







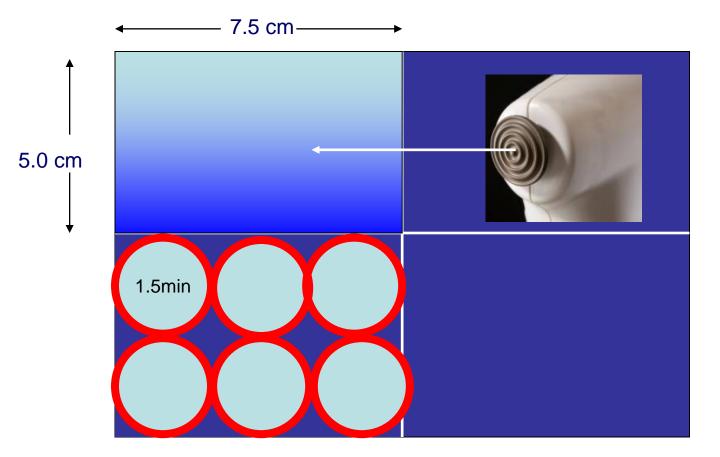
4



Treatment Intervals

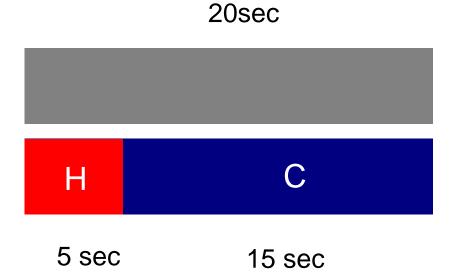


US Module Treatment Areas





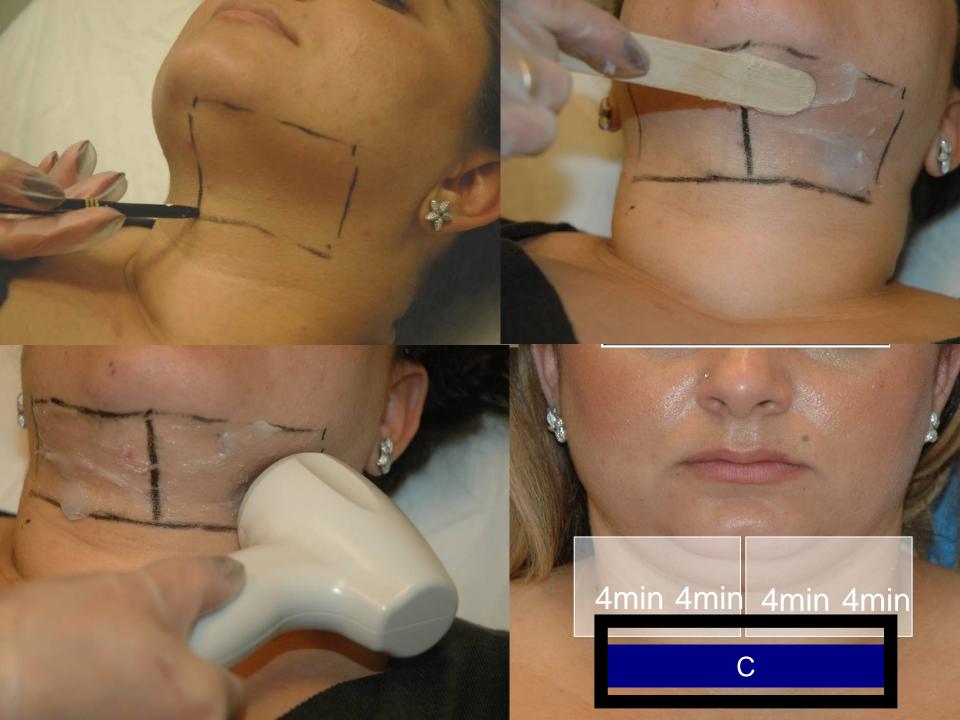
U/S Operation Cycle







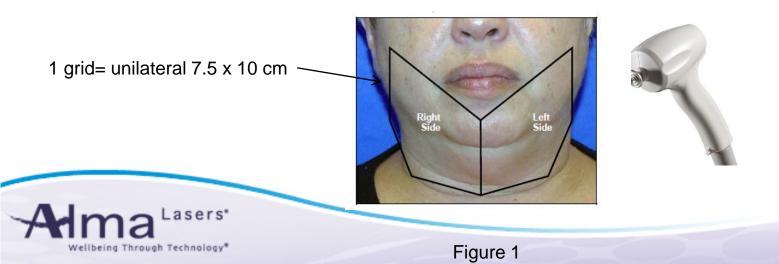




Treatment Protocol

• UltraFace (Ultrasound) Module

- 1. Mark the treatment grids (approximately 7.5 x 10 cm) on each unilateral side of the area to be treated (see Figure 1).
- 2. Cover the entire area with a coat (1-2mm) of Vaseline using a wooden spatula.
- 3. Turn the system on and select the UltraFace module from the control panel.
- 4. Inspect the entire module, giving special attention to the tip to identify any damage, and clean off any leftover Vaseline or other materials.
- 5. Adjust the timer to 8 minutes. This time interval should be applied on each and every unilateral grid (approximately 7.5 x 10 cm).



Treatment Objectives

UltraFace (Ultrasound) Module

To ultrasonically irradiate each area for a fixed amount of time/energy in **Cold mode.**

UniFace (RF) Module

To maintain the treatment area temperature at 104-111.2°F (40-44°C) until the recommended total energy (expressed in **kJ) is invested in the treatment area.**



RF + Massager Handpiece

















Right Single Area

70-90 W 30kJ

Left Single Area

70-90 W 30kJ



End-Point



erythema

41°-43°C

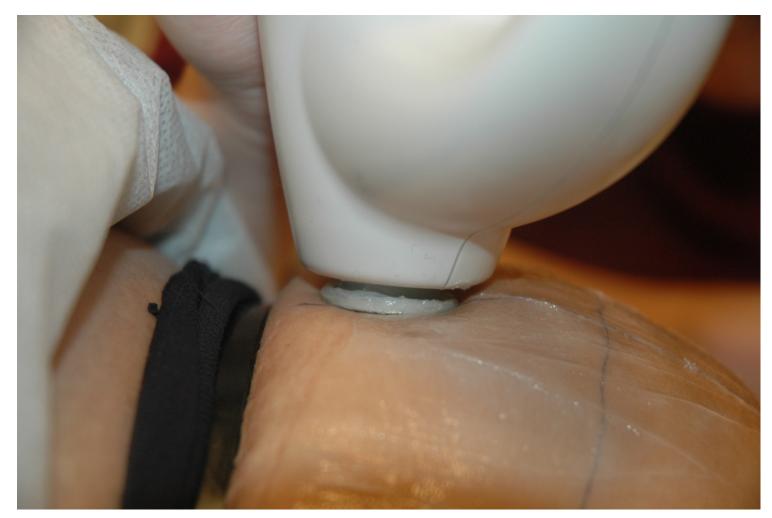


Ultra Handpiece



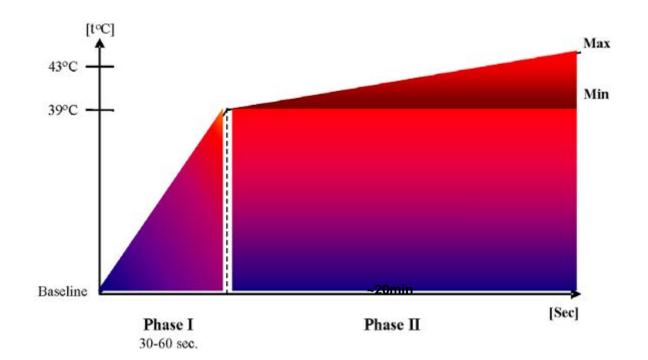


Vaseline





RF + Massager



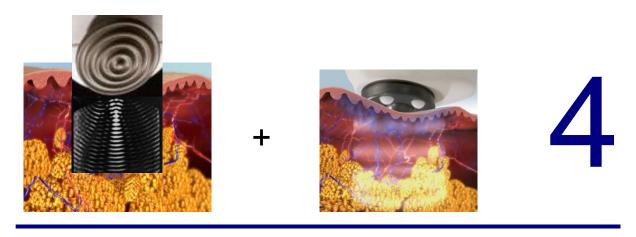
Ama Lasers' Wellbeing Through Technology*

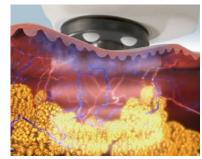
Recommended Total RF Energy - UniFace

Treatment Area	Power [W]	Total Energy [kJ] *
Rt./Lf. Cheek	70 – 90	15 – 30
Rt./Lf. Jaw Line	70 – 90	15 – 30
Rt./Lf. Submental (Chin)	70 – 90	15 – 30



Number of Treatments





2



Pre Treatment considerations-UltraFace

 Before commencing the ultrasound treatment, set the "Hot" mode duration (displayed on the system's screen) to 1-3 seconds in the Combo mode, depending on the patient's sensitivity to heat. The system will automatically complete the 20 seconds cycle with the "Cold" mode (i.e. 2 sec "Hot" with 18 sec "Cold", or 3 sec "Hot" with 17 sec "Cold"). The option of working only with Cold mode also available (full cycle of 20 sec Cold).



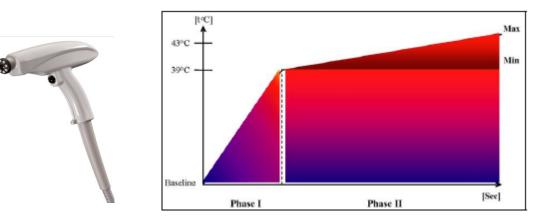
Pre-Treatment Considerations-UltraFace

 The ultrasonic tuning occurs automatically every 180 seconds and also when the system transitions from Standby to Ready mode (the tuning phase will take about 25-30 seconds). That will result in some heat sensation, moving the UltraFace handpiece faster at the tuning phase will help to reduce the patient heat sensation.



Pre Treatment considerations-UniFace

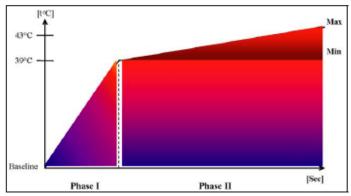
•The RF treatment includes two distinct phases: pre-therapeutic (Phase I) and therapeutic (Phase II); the goal of the pretherapeutic phase is to raise the basal (ambient) skin temperature from ~88-89.5°F (~31-32°C) to 102-104°F (39-40°C) within 60 seconds (max).





Pre-Treatment Considerations UniFace

•Once reaching to the desired temperature, the overall goal of the treatment is to maintain the skin temperature in the therapeutic temperature range of 104-111.2°F (40-44°C). The goal of the therapeutic phase (Phase II) is to increase and maintain the skin temperature of 104-111.2°F (40-44°C), without causing any patient discomfort. The therapeutic phase (Phase II) may last 20-30 minutes per treatment area.





Number of Treatments and Intervals:

Recommended number of treatments is 4-6 at 14day intervals (one treatment every 14 days).



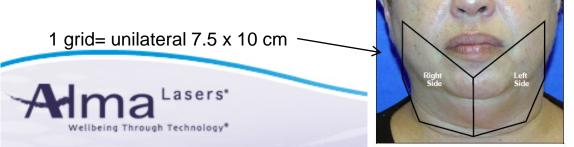
• UltraFace (Ultrasound) Module - continue

- 6. Press Stby (green) and activate Ready mode (red).
- 7. Allow the system to conduct its Resonance Tuning routine (this will take about 25 seconds).
- 8. Apply the transducer on the first treatment side (marked grid); the module/tip should be perpendicular to the surface of the skin and slightly pressed into the skin.
- 9. Press the footswitch once to enable the transmission of ultrasound energy. Press it again to stop transmission.
- 10.Treat in 20 sec COLD mode: move the module continuously (In-Motion) in slow, small circular movements inside the entire grid area.
- 11.Repeat the above protocol for each and every grid.
- 12.Upon completion of the first treatment side (7.5 x 10 cm grid), move to the second adjacent side (adjacent marked grid) and repeat the protocol as above.



• UniFace (RF) Module

- 1. Thoroughly wipe clean and dry the area from the Vaseline used during the Ultrasound treatment.
- 2. The treatment with the UniFace RF module should be used and applied on the same bilateral 7.5 x 10 cm grid areas treated previously with the UltraFace module.
- 3. Cover the entire area with a coat of mineral oil.
- 4. Select the UniFace option from the control panel.
- 5. Check the tip of the UniFace module to ensure that the cooling mode is on (this might take 2-3 minutes; touch the tip with your hand).
- 6. Set the power.
- 7. Press the Ready softkey; this will activate the module's massager component.
- 8. Position the module in the intended treatment area and start the module's movement prior to pressing the foo



• UniFace Module - continue

- 9. Press the footswitch to emit RF energy; this should be done only after the module is initially applied to the skin and while the tip is moving on the skin (In-Motion).
- 10.The motion should be circular within the enclosed area of the grid for the duration of the preset exposure time.
- 11.Use the infrared thermometer to measure and record the baseline temperature of the area to be treated by applying three (3) random measuring points inside the grid.
- 12.Monitor the temperature of the treated area using the IR thermometer at the end of every 30 seconds.
- 13.If the therapeutic temperature is not achieved within 30-60 seconds, increase the power by 5-10%.
- 14.Once the therapeutic temperature is achieved, start the recommended total KJ counting. The power level can be decreased by 5-10% (since less power is now required to maintain the temperature).



Protocol

- 3-4 treatments
- 2 wks intervals







Mechanism of Action

- 980 diode laser converts light to heat delivered through an optical fiber
- Heat is absorbed by the tissue
- Thermal chemical denaturization of the tissue composition
- Destruction of the fat cells without damaging the surrounding tissue (depth of penetration in fat is 2-3 mm)
- Causing simultaneous collagen stimulation for skin tightening and contouring

Clinical Manifestations

Thermal energy rising in the dermis leads to:

- Stimulation of fibroblasts
- Production of collagen
- Tightening of tissue
- The adipose tissue concentrates the thermal effect caused by the laser due to its high absorption coefficient.



Advantages of Adding Laser to Liposuction

- Procedure done under local anesthetic
 - Increases procedure safety
 - Greater patient appeal
- Improved collagen stimulation for skin tightening
 - Tuck and lift is less necessary after laser lipo
- Faster and less traumatic aspiration process
 - Requiring less physician exertion
 - Less downtime and bruising for a quick recovery (up and around in 24-48 hrs)
- Patients are asking for laser lipo
- Fuels other laser procedures
- Procedure produces high revenue



Accent 980 Specs

- Wavelength: 980 nm
- Power: up to 20 Watts
- Pulse length: 1 ms to cw
- Pulse interval: 2 ms to 1 sec
- Fiber size: 400 microns
- Aiming beam: 640 nm, 2 mW



Supplies and Medication

- Oral medication- pre treatment
- Patient forms
- Photography equipment
- Surgical pen, scalpel, wound dressing
- Tumescent fluid
- Aspiration/suction equipment
- Compression garment
- Pain medication- post treatment
- Antibiotics



Treatment Protocol & Parameters

- Patient selection
- Clinical history
- Patient consent form
- Pre-treatment picture
- Pre-treatment preparation:
 - Medication

Aspiration of fat

- Marking the treatment site
- Preparing the sterile table
- Tumescent fluid
 - 150 cc to 500 cc for a 10 x 10 cm area
- Incision at several access points

Fiber and cannula use in fat

Treatment Energy and Time

- Plan to employ approximately 3000 Jules per 5 x 5 cm area or until the laser passes through all areas will no resistance.
- The treatment time at 10 watts in the continuous wave setting is approximately 8-13 minutes to treat a medium sized body part.



Prep Treatment Site







Inject Tumescent Fluid







Insert and Move Fiber







Fiber in Abdomen





Aspiration







Suction



Post Treatment Protocol

- Wound dressing
- Relative hemostasis
- Compression garments
 - Wear continuously for 1 week and regularly for 2nd week
- Medication





















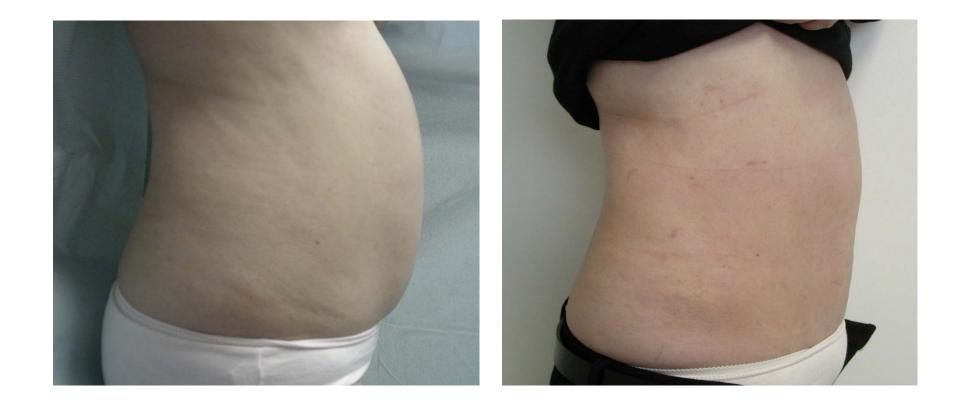












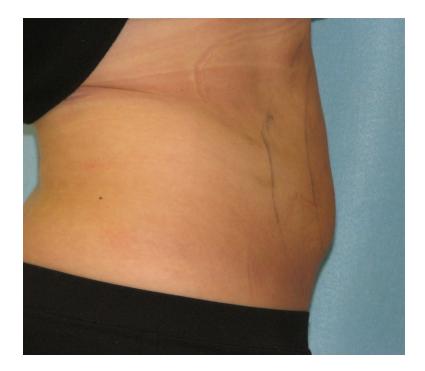




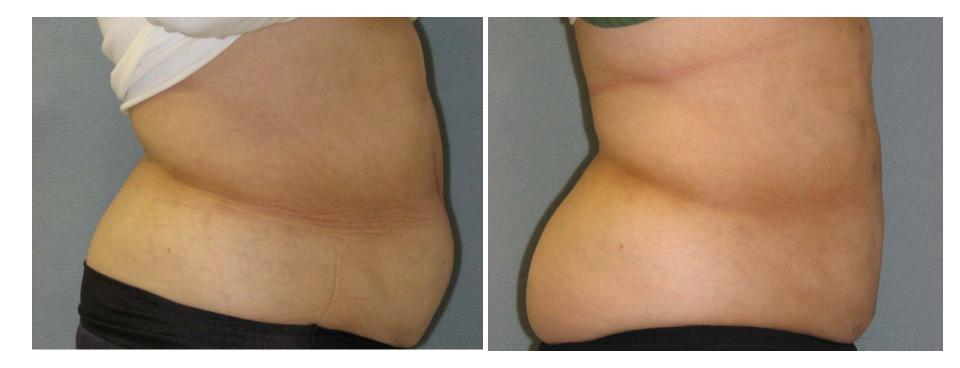




























Summary

- Single session treatment
- Internal tightening of tissue
- Less traumatic procedure with fast hemostasis
- Can be done with or without suction
- Very safe procedure when properly performed
- Popular treatment areas: abdomen, inner and outer thighs, arms, flank and chin/jowls
- May combine with Accent-Ultra package, 3 weeks post treatment



Periorbital

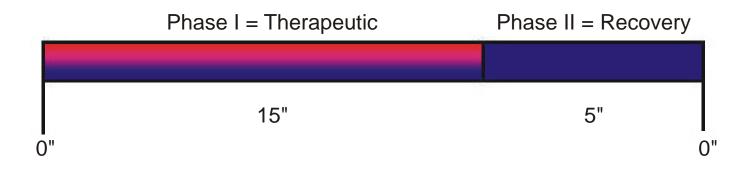


Periorbital Handpiece



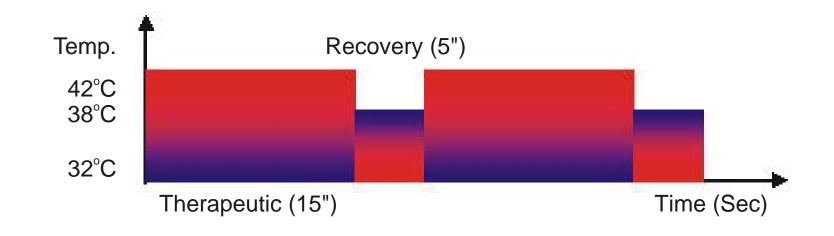


Each cycle = 20 seconds



15 sec of heating followed by 5 sec of cooling







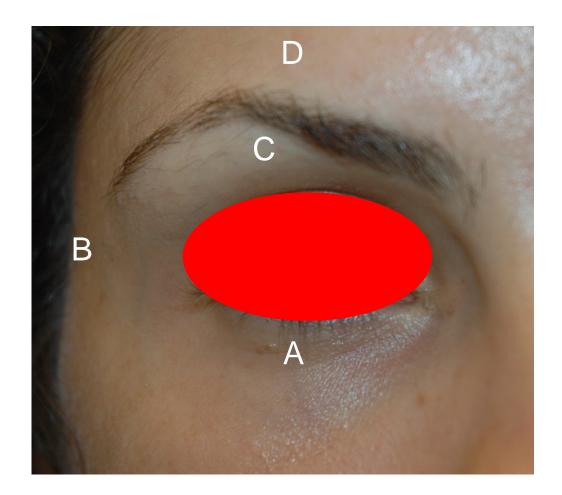




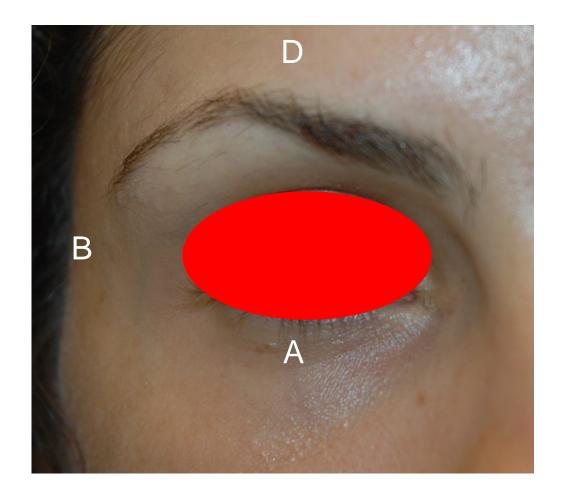


Do not Treat in the Red Area!









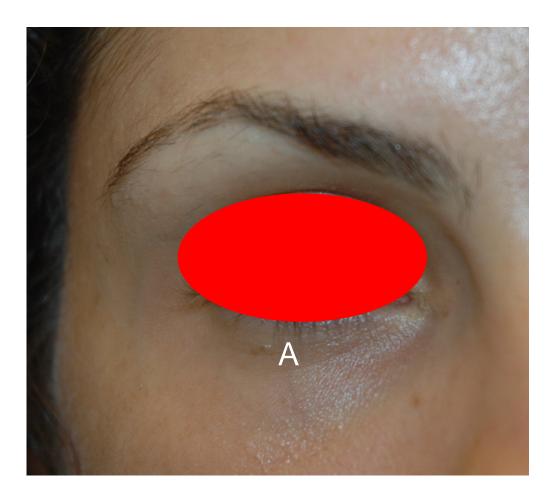


Periorbital Area

Energy [Watts]	Exposure Time [Sec]	Number of Passes	Total Energy [kJ] *
45 - 55	20	10 -15	10 - 12

Areas A,B,D





A = Infraorbital/lower eye lid

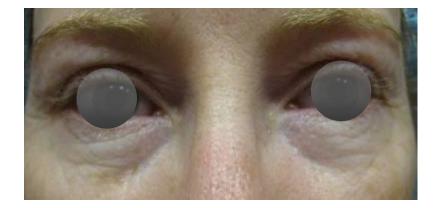


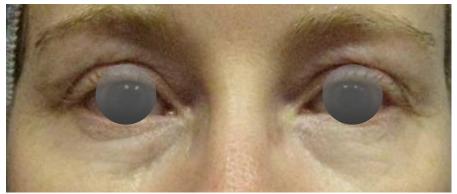
Lower Eye Lid/Infraorbital Area

Energy [Watts]	Exposure Time [Sec]	Number of Passes	Total Energy [kJ] *
40 - 50	20	6-8	4.0 - 6.0

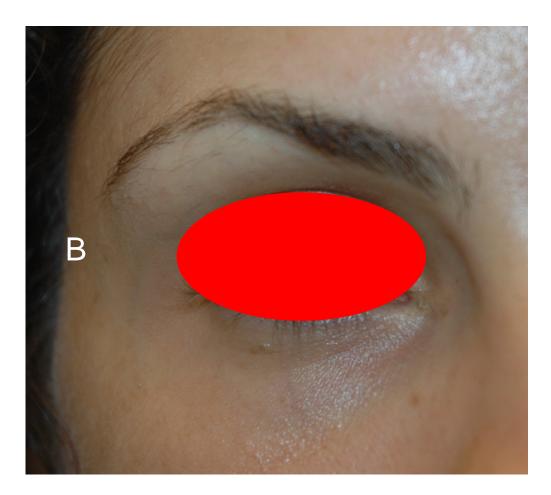
Lasers*

Ibeing Through Technology*









B = Lateral/Crow Feet

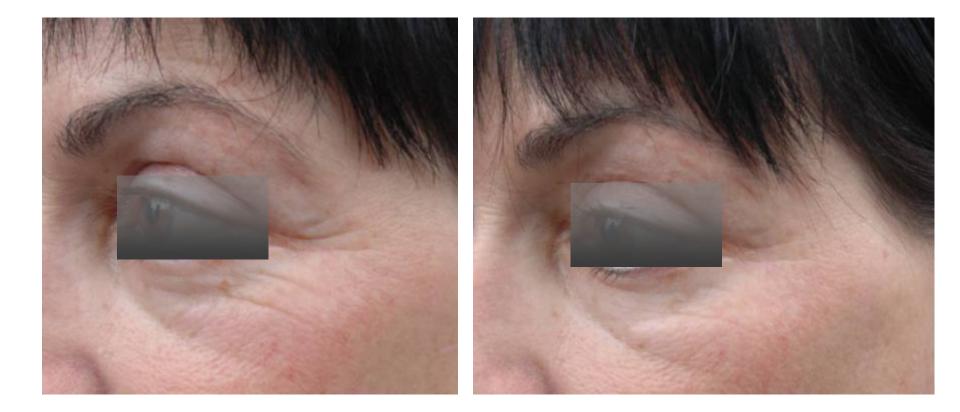


Crow's Feet Area

Energy [Watts]	Exposure Time [Sec]	Number of Passes	Total Energy [kJ] *
40 - 50	20	8 -10	6.0 - 8.0

Area B













C= Upper eye lid

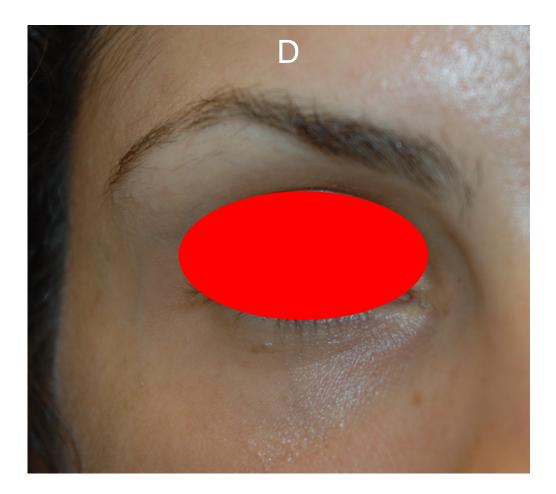


Upper Eyelid Area

Energy [Watts]	Exposure Time [Sec]	Number of Passes	Total Energy [kJ] *
40 - 50	20	8 -10	6.0 - 8.0

Area C





D = Upper eye brow



Upper Eye Brow Area

Energy [Watts]	Exposure Time [Sec]	Number of Passes	Total Energy [kJ] *
40 - 50	20	8 -10	6.0 - 8.0

Area D







Clinical Evidence - Face







Before

1 Month After 3 Treatments

Dr. J. Lepselter, Alma Lasers Clinical Department







before

29 y/o female



Nariaki Miyata M.D. Miyata Plastic Surgery & Skin Clinic Tokyo, Japan







After 4 Treatments





Before Alma Lasers* Wellbeing Through Technology*

After 3 Treatments





After 4 Treatments



Ultraface + Uniface

- Age: 42 year-old
- 2 Tx with Ultraface + Uniface
- U/S COLD 8 minutes
- RF 90W 30kJ at each side
- 1 Tx with UniFace
- RF 90W 40kJ at each side





before

2 weeks after 3 Tx





before





UniFace/UNILARGE+UltraFac e

UltraFace COLD MODE ONLY-8 min at each side (7.5x5cm) UniFace/UNILARGE – 30KJ at each side







Before



After 5 Tx

Scott Scherer, MD

Renaissance Clinic Stockholm, Sweden



Case Report

- A general practitioner w/diabetes
- Patient has had nerve damage on her left side, where they did a fat transplant 10 years ago.
- Because of gravity the fat pocket fell.
- Treatment on left side of the face only; Ultra treatment (32min) with cold mode only to reduce the fat, and RF treatment 80-90 W temperature up to 45 to pull the face upwards.
- Diet and niacin.













before





2wks after 4 Tx



Courtesy of Dr. Scott Scherer, MD, Stockholm, Sweden



Courtesy of Dr. Fernando Urdiales, Aesthetic Medicine, Instituto Médico Miramar, Málaga, Spain



Courtesy of Dr. Rafael Nunes , plastic surgeon, Slim Clinique, Rio De Janeiro, Brazil



Courtesy of Dr. Tania Aparecida Meneghel, Dermatologist, Clínica Renaissance, São Paulo, Brazil



Courtesy of Maria Angelo-Khattar, PhD, Aesthetica Clinic, Dubai



Courtesy of Dr. Fernando Urdiales, Aesthetic Medicine, Instituto Médico Miramar, Málaga, Spain



Best indication

- 1. Motivated patient with realistic expectation: most important!!!
- 2. In their 20- early 30s preserving nice projection but chubby face ; for slimming by generalized fat reduction
- 3. In their late 30s- 50s with plump face & local adiposities ; for subregional contouring by isolated lipolysis such as medial cheek, jowl, lower madibular border, submentum, etc



Clinical Evidence - Body

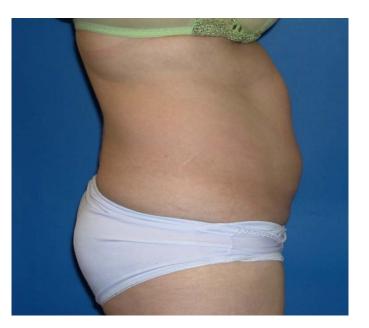


Ρ

Before

After 2 Treatments







K

Before

After 5 Treatments







K







After 5 Treatments

D



Before



After 2 Treatments

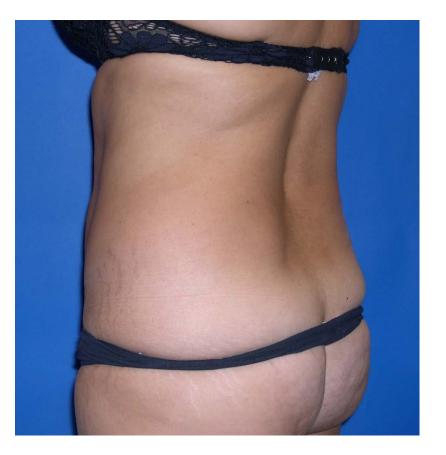






D





After 2 Treatments



D

(2 wks)



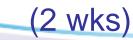




After 5 Treatments

before after 5 treatments [-7cm]





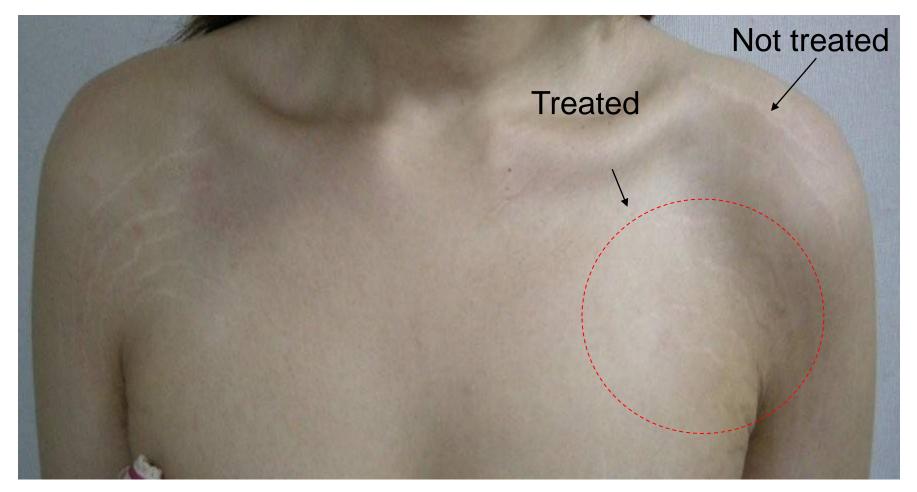
Stretch Mark by RF Pixel





4/1 L. shoulder: One month After 1st Tx; 25W x 2 pass

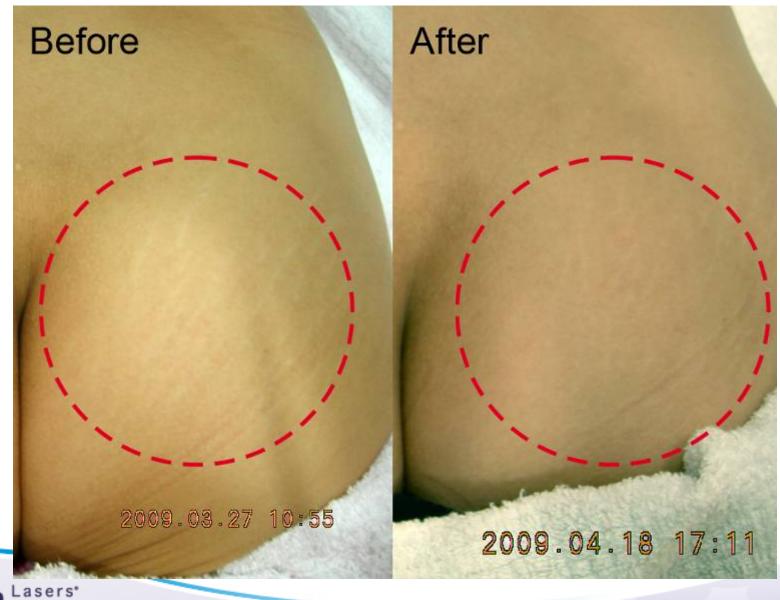
Stretch Mark by RF Pixel





4/1 Left side: 1 month after 1st RelaxF Pixel; 25W x 2 pass

RF Pixel 30 W 2 Pass



Courteousy by Dr. Ming-Shi Sheng

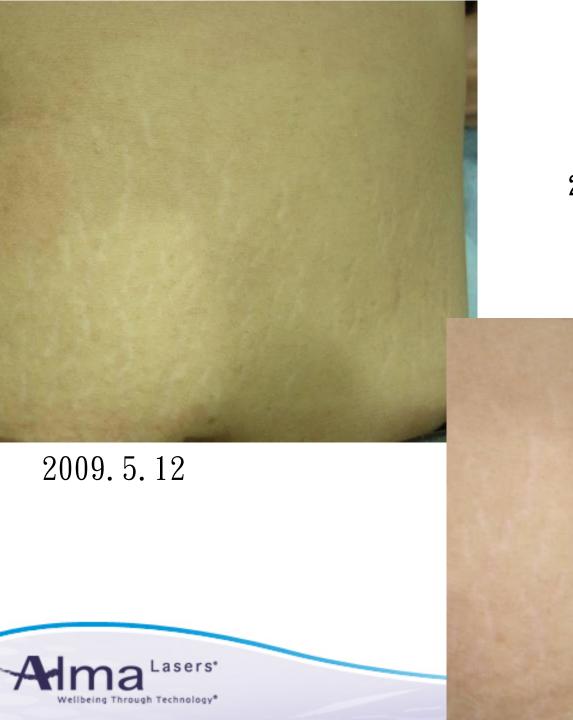
Ibeing Through Technology*

RF Pixel 30 W 2 Pass





Courteousy by Dr. Ming-Shi Sheng



2009.6.15 RF Pixel 23W 1 month after 1st Tx By Accent Pixel

Stretch Marks





2 weeks After 2 Treatments

50 Watts, 6 seconds 5 passes



Photos Courtesy: Dr. Dinko Kuliterna, Croatia

RF Pixel - Stretch Marks



Before

3 Months After 3 Tx



Roller tip, power 50 Watts, 4-6 passes

RF Pixel - Stretch Marks/Lax Skin



Before

1 Year After 2 Treatments



Roller tip, power 50-55 Watts, 4-6 passes

Before

1 Wk After 4 Tx





Photos Courtesy: Dr. Joseph Lepselter, Alma Lasers Ltd.

Before

1 Wk After 4 Tx





Photos Courtesy: Dr. Joseph Lepselter, Alma Lasers Ltd.

Before



Photos Courtesy: Dr. Joseph Lepselter, Alma Lasers Ltd.

1 Wk After 4 Tx





