Maui + Derm 2017
March 19 - 24, 2017

Lasers, Lights, Radiofrequency and More

Fat and Acne

Presented by Michael H. Gold, MD

Gold Skin Care Center, Tennessee Clinical Research Center Nashville, TN USA

Academic Appointments

- Assistant Clinical Professor
  - Department of Medicine, Division of Dermatology, Nashville, TN USA
    - Vanderbilt University School of Medicine: 2006 - 2014
    - Vanderbilt University School of Nursing: 2006 - Present
- Adjunct Assistant Professor
  - Meharry Medical College: 2013 - Present
    - School of Medicine, Nashville, TN USA
- Visiting Professor of Dermatology
  - Huashan Hospital, Fudan University (Shanghai Medical University), Shanghai, China: 2006 - Present
  - The First Hospital of China Medical University, Shenyang, China: 2008 - Present
  - Guangdong Provincial People's Hospital, Guangzhou, China: 2013 – Present
  - The People's Hospital of Hunan Province: 2016 - 2019
- Visiting Professor of Plastic Surgery
  - First People's Hospital of Foshan University, Guangdong, China: 2012 - Present
  - The First Affiliated Hospital of Zhejiang University, Hangzhou, Zhejiang: 2013 - Present

Conflict of Interest

- Consultant to many pharmaceutical, cosmeceutical, laser and energy-based device companies
- Consultant, performs research and speaks on behalf of numerous pharmaceutical and medical device companies
- For the benefit of this presentation: consultant, investigator, speaker for Lumenis, Syneron-Candela, Aerolase, Advantix, Invasix, Allergan (Kybella), Neothetics, Zeltiq, Zimmer, and Syneron-Candela

Acne Vulgaris & EBDs

Presented by Michael H. Gold, MD

Gold Skin Care Center, Tennessee Clinical Research Center Nashville, TN USA

Acne Vulgaris

- Laser/Light technology for the treatment of acne vulgaris
  - Work typically for acne via 3 main premises:
    - Destruction of the *P. acnes* bacteria
    - Destruction of the entire sebaceous gland and sebaceous output
    - ? Destroy *P. acnes* and partial destruction of sebaceous glands -- ALA-PDT

ALA-PDT for Acne
Expert Review of Dermatology 2006

Novel treatment options for severe inflammatory acne vulgaris

Michael H Gold

Acne vulgaris is one of the most common dermatological disorders encountered in everyday practice. Treatment options for this often psychologically scarring disease are numerous and, for many individuals, provide relief from the disorder. However, factors such as antibiotic resistance and, slow onset of action from many topical therapies has led researchers to seek out alternative therapies, especially for those suffering from moderate to severe inflammatory acne vulgaris.

Expert Rev. Dermatol. 1(1), 13–23 (2006)

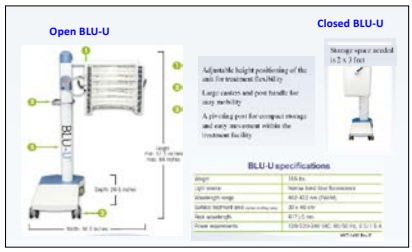
Acne Vulgaris

- Laser/Light technology
  - Lasers/light sources to reduce the *P. acnes* population
    - Blue Light Sources - Blu-U (Dusa)
    - Intense Pulsed Light Devices– Quantum/Vasculight/Lumenis One/M22 (Lumenis),, Ellipse (DDD), elos Plus(Syneron), BBL/Joule (Sciton),, Harmony XL (Alma), Lumecca (Invasix)
    - Vascular Lasers –Cynergy (Cynosure), V-Beam Perfecta (Candela), N-Lyte (ICN), AdvaTX (Advantix)
    - Short-Pulsed 650 usec 1064 nm – Aerolase Neo

Acne Vulgaris

- Blu-U device FDA cleared for inflammatory acne
  - Used originally for ALA-PDT therapy
  - Works for mild to moderate inflammatory acne vulgaris as well
  - 2004 AAD Poster Presentation; J Drugs Dermatol 2004– Gold, Goldman, Rao
    - Blu-U more effective in inflammatory acne lesions than 1% clindamycin solution
    - Safety and efficacy proved

BLU-U Blue Light Photodynamic Therapy Illuminator Model 4170



IPL Technology

Presented by Michael H. Gold, MD
Gold Skin Care Center, Tennessee Clinical Research Center Nashville, TN USA

Acne Vulgaris

- Laser/Light technology
  - Intense Pulsed Light (IPL) technology for acne-many systems exist
    - Quantum, VascuLight, Lumenis One, M22 by Lumenis
    - Other systems – Harmony by Alma, BBL by Sciton, Isolaz by Solta, Elos Plus by Syneron, Lumecca (Invasix)
    - ClearTouch, SkinStation by Radiancy
      - Ross V (2002 ASLMS) – 50% inflammatory acne lesion improvement
      - Elman M, Lebzelter J. Light therapy in the treatment of acne vulgaris. Dermatol Surg 2004; 30: 130-146.
        - 85% > 50% improvement; 15-20% non-responders

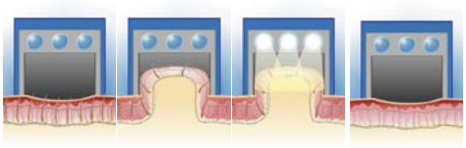
Solta Isolaz

Presented by Michael H. Gold, MD
Gold Skin Care Center, Tennessee Clinical Research Center Nashville, TN USA

Solta - ISOLAZ
In Side Out Light Amplified Tx Zone

- Multi-Application Platform
  - Acne therapy - **iAC** Therapy
  - Skin rejuvenation - **iSR** Therapy
  - Hair removal - **iHR** Therapy
- Only system to clear the pores from the dermis outward
- Only system FDA cleared to treat comedonal & pustular acne
- Proprietary iTM Technology
  - Accumulates 3x Energy in Deep Targets While Keeping the Epidermis Cool
  - Uses IMP Multi-Pulse technology for enhanced deep pore cleansing

Photopneumatic Technology: The Mechanism



- Hand piece is placed on treatment area
- Targets elevated closer to skin`s surface
- Blood concentration reduced
- Melanin concentration reduced
- Light applied to treatment area
- Targets are safely and painlessly destroyed

Gold MH, Biron J. J Drugs Dermatol 2008; 7(2):139-145

EFFICACY OF A NOVEL COMBINATION OF PNEUMATIC ENERGY AND BROADBAND LIGHT FOR THE TREATMENT OF ACNE

Michael H. Gold MD; Julie Biron BS

Abstract

AdvaTX

Presented by Michael H. Gold, MD

Gold Skin Care Center, Tennessee Clinical Research Center Nashville, TN USA

ADVATx Dermatological Laser

High powered, 589nm, yellow laser 1319nm,infra-red laser

Easy use and no downtime

No consumables

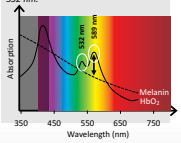
Long-term reduction of vascular conditions

Potent and efficient elimination of acne

Effective treatment for psoriasis, scars, warts & wrinkles

Yellow laser – the optimal wavelength

The yellow laser is the optimal choice of therapy because it deposits more energy into the target region per treatment than any other laser wavelength. At the same time, the energy loss in the melanin in the epidermis is lower at 589 nm than at 532 nm.



Aerolase Neo

Presented by Michael H. Gold, MD

Gold Skin Care Center, Tennessee Clinical Research Center Nashville, TN USA

LightPod Neo®

The Single Most Versatile Laser in the World. Period.

- 650-microsecond technology for up to 255 J/cm2 in a single pulse duration
- More than 50 FDA cleared medical aesthetic indications
- Ability to perform anesthetic, gel & skin contact free treatment on all skin types
- Eliminates pain, burns or adverse effects of the previous generation of lasers
- No costly service contracts

aerolase

Acne Vulgaris

- Laser/Light technology
  - Lasers to reduce the sebaceous glands themselves
    - 810 nm diode laser with indocyanine green *(Cynosure)*
    - *1450 nm SmoothBeam laser (Candela-Syneron)*
    - 1320 nm CoolTouch III laser (*CoolTouch Corp-Syneron*)
    - 1319 nm Sciton Profile laser (*Sciton Corp*)

Acne Laser – 1450 nm

Acne Treatment With a 1,450 nm Wavelength Laser and Cryogen Spray Cooling

Dilip Y. Paithankar, PhD,[1]* E. Victor Ross, MD,[2] Bilal A. Saleh, MD,[1] Mark A. Blair, MD,[2] and Bradley S. Graham, MD[2]
[1]Candela Corporation, 530 Boston Post Road, Wayland, Massachusetts
[2]Naval Medical Center, San Diego, 34620 Bob Wilson Drive, San Diego, California

Smoothbeam-Candela

Significant reduction in acne counts – 5.43 to 0.43 – destruction of sebaceous glands

Laser Therapy of Acne Vulgaris in Asians
Photoderm, Photoimmun Photomed 2009;25:3-7

Summary

ORIGINAL ARTICLE

Clinical effect of low-energy double-pass 1450 nm laser treatment for acne in Asians

Reiko Noborio, Emi Nishida & Akinichi Morita
Geriatric and Environmental Dermatology, Nagoya City University of Medical Sciences, Nagoya, Japan

Fractora by Invasix for Acne

Presented by Michael H. Gold, MD
Gold Skin Care Center, Tennessee Clinical Research Center Nashville, TN USA

FRACTORA™

Fat Reduction

Presented by Michael H. Gold, MD

Gold Skin Care Center, Tennessee Clinical Research Center Nashville, TN USA

Kybella by Allergan

Presented by Michael H. Gold, MD

Gold Skin Care Center, Tennessee Clinical Research Center Nashville, TN USA

Introducing KYBELLA™ (deoxycholic acid) Injection

- KYBELLA™ 10 mg/mL is supplied in 2 mL, single patient use vials (4 pack)
- Store at room temperature 20°C to 25°C (68°F to 77°F)
- Excursions are permitted between 59° F to 86° F
- Each vial is for a single patient use
- Do not dilute or admix KYBELLA™
- Discard unused portion

Please see complete KYBELLA™ (deoxycholic acid) injection Important Safety Information on slides 58 - 60.

KYBELLA™ has a unique hologram on the vial label – If you do not see a hologram, do not use the product and call 1-844-KYTHERA (1-844-598-4372)

KYBELLA™ (deoxycholic acid) Injection

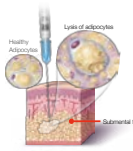
KYBELLA™ is the first and only FDA approved injectable drug that contours and improves the appearance of submental fullness

When injected into subcutaneous fat, KYBELLA™ causes the destruction of fat cells. Once destroyed, those cells cannot store or accumulate fat

Treatment with KYBELLA™ is customized by the physician to the patient's aesthetic goals for an improved chin profile

Once the aesthetic response is achieved with KYBELLA™, retreatment is not expected

The most common adverse reactions are edema/swelling, hematoma/bruising, pain, numbness, erythema, and induration



KYBELLA™ (deoxycholic acid) injection is indicated for improvement in the appearance of moderate to severe convexity or fullness associated with submental fat in adults.

The safe and effective use of KYBELLA™ for the treatment of subcutaneous fat outside the submental region has not been established and is not recommended.

Please see complete KYBELLA™ (deoxycholic acid) injection Important Safety Information on slides 58 - 60.

Lipo 202 by Neothetics

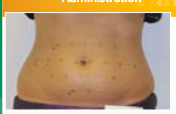
Presented by Michael H. Gold, MD

Gold Skin Care Center, Tennessee Clinical Research Center Nashville, TN USA

LIPO-202: Potential Best-in-Class Non-Surgical Procedure

- **Salmeterol Xinafoate**
- Long-acting beta-2 adrenergic receptor agonist
- **Target Patients Are Not Obese**
- Maintain stable weight and lifestyle
- BMI < 30 kg/m²
- **Once-Weekly Injections for 8 Weeks**
- Measurable results as soon as Week 4
- **30-gauge, ½ - Inch Needle**
- No numbing agent required
- No recovery or down time
- **Favorable Safety and Tolerability Profile**
- Similar to placebo

LIPO-202 Administration

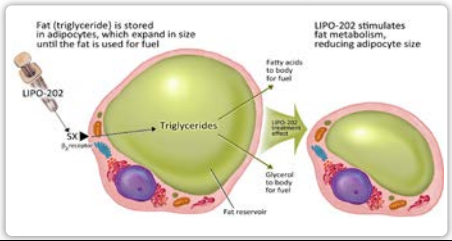


- 20 injections spaced 4 cm apart
- Drug diffuses ~2 cm in radius

Well Understood, Targeted Mechanism of Action

- Triggers body's metabolism of stored triglycerides via natural process of lipolysis
- Resulting in reduction in size / volume of fat cells in treatment area

LIPO-202 shrinks fat cells without killing them



Key Highlights

LIPO-202 Phase 3 - Ready	• Salmeterol Xinafoate (SX) for Injection for non-ablative, localized fat reduction and body contouring in central abdominal bulging due to subcutaneous fat in non-obese subjects
Known Mechanism	• Mimics endogenous process • Stimulation of lipolysis via β_2-adrenergic receptor • No fat cell death or apoptosis
Compelling Data	• ~800 patients in 6 clinical studies • Statistically significant and clinically meaningful reductions • Safety equivalent to placebo
505(b)(2) Regulatory Pathway	• Referenceable safety profile of SX as SEREVENT DISKUS® ADVAIR® HFA and ADVAIR DISKUS®
Phase 3 in 2015	• Pivotal Phase 3 studies to be completed in 2015 • 2 concurrent studies in the U.S. – 800 patients each (400 LIPO-202, 400 Placebo)

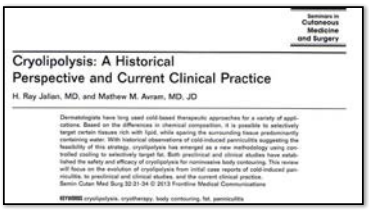
The Emerging market for Lipodissolving

- So this field is changing and changing quickly
- Use only FDA approved products

CoolSculpting System and Applicators

The *next evolution* of the world's #1 non-invasive fat reduction treatment

Cryolipolysis
Semin Cutan Med Surg 32; 31-34: 2013



Seminars in Cutaneous Medicine and Surgery

Cryolipolysis: A Historical Perspective and Current Clinical Practice

H. Ray Jalian, MD, and Mathew M. Avram, MD, JD

Zeltiq CryoLipolysis

Lasers Surg Med 2009; 41: 703 – 708.

Cryolipolysis™ for Subcutaneous Fat Layer Reduction

Zeltiq CryoLipolysis

Lasers Surg Med 2009; 41: 785 – 795.

Non-Invasive Cryolipolysis™ for Subcutaneous Fat Reduction Does Not Affect Serum Lipid Levels or Liver Function Tests

Long-term efficacy follow-up on two cryolipolysis case studies

Journal of Cosmetic Dermatology, 15, 561-564

CoolMini

Submental and Other Small Area Indications

Presented by Michael H. Gold, MD

Gold Skin Care Center, Tennessee Clinical Research Center Nashville, TN USA

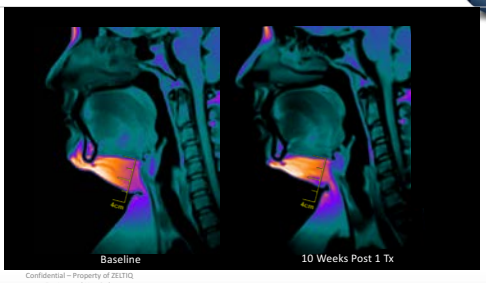
CoolMini Applicator

- Designed for submental fat
- Ideal for smaller bulges
- Treat new areas of undesirable fat

Clinical Studies

- Submental Area
  - IDE Pilot – 15 subjects (2013)
  - Mexico Feasibility Study – 32 Subjects (Q3 2014)
  - US Pivotal Study – 60 Subjects (Q1/Q2 2015)
    - Brian Zelickson – Minneapolis
    - Suzanne Kilmer – Sacramento
    - Jay Burns - Dallas
  - European Pilot Evaluation – 150+ Subjects (current
- Distal Thigh (Above Knee)
  - Multi-Centered Study – 40 Subjects (current)
    - Brian Biesman – Nashville
    - Jeffrey Dover/Michael Kaminer – Boston
    - Roy Geronemus – New York
    - Leyda Bowes - Miami

Mexico Feasibility Subject 005 MRI Results



Methods

- Multi-center study: Drs. Burns, Kilmer, and Zelickson
- Study population: n=60 male and female subjects
- Device: CoolMini small volume vacuum applicator (prototype)
- 60 minute cycle at -10°C
- 1 treatment cycle per visit
- Up to 2 treatment visits, 6 weeks apart
- Final follow-up 12 weeks after final treatment

Applicator Shapes

Surface	Parallel Plate	Cup
		
• Special purpose • Non-pinchable fat • Slow heat extraction	• General purpose • Medium heat extraction	• General purpose • Fast heat extraction • Enhanced comfort • The basis for the new CoolAdvantage Applicators

What's Next?

- Let's make a big CoolMini for the flanks and abdomen!
- **Prototype** machined metal insert modified a standard parallel plate CoolCore into a **cooled, contoured cup applicator**

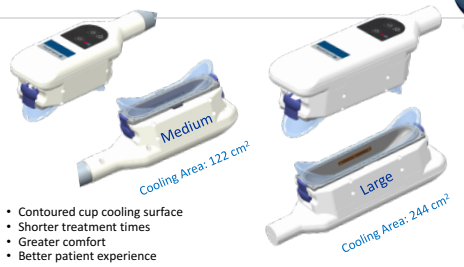
Cool Advantage Family

3–in–1 Design
- Three different contours

Single Applicator Replaces Three Applicators
- CoolCore
- CoolCurve+
- CoolFit

Introducing the CoolAdvantage Family of Applicators

Introducing the CoolAdvantage Applicator Series



- Contoured cup cooling surface
- Shorter treatment times
- Greater comfort
- Better patient experience

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It Starts with…Years of Research

Improved Comfort

Greater Comfort
- New cup design
- Lower suction pressure for gentler tissue draw

It Starts with…Years of Research

Faster Treatment Time

Colder Temperatures → Shorter Time

Almost half the time!
(35 minute treatment time)

It Starts with…Years of Research

Better Patient Experience

Even distribution of cold
Greater versatility
More tissue is in contact with the cold surface

Study Objective

- Contoured cup, medium-sized applicator was developed to cool tissue more efficiently
  - increase tissue contact
  - reduce vacuum pressure
  - reduce treatment time
- Evaluate prototype CoolAdvantage vs. standard CoolCore applicator for safety, efficacy, and patient preference

Methods

- Study population: n=19 male and female subjects
- Randomized left / right flank treatments to compare applicators
- CoolCore applicator vs. CoolAdvantage (prototype)
  - CoolCore 60 minutes at -10°C
  - CoolAdvantage 35 minutes at -11°C
- 1 treatment cycle
- Final follow-up 12 weeks post-treatment

Equivalent Efficacy, Reduced Pain, Greater Patient Preference

- Equivalent Efficacy: Bilateral flank treatments showed similar efficacy by
  - Ultrasound fat layer reduction measurements
  - Independent photo review by 3 blinded physician evaluators
- 45% reduced procedure discomfort compared to standard CoolCore
- 85% preferred CoolAdvantage in patient surveys

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Z Wave by Zimmer

Beyond Submental Fat

Presented by Michael H. Gold, MD
Gold Skin Care Center, Tennessee Clinical Research Center Nashville, TN USA

Radial Pulsed Therapy

Zimmer Z-Wave Shock Wave Technology

The Handpiece & Software





Major Use in US: Acceleration of Recuperation, Diminished Pain, Quicker Recovery and Improvement of Fat Reduction

- Cool Sculpt
- Vanquish
- Liposonix
- Thermi
- Liposuction

UltraShape
and the new UltraShape Power

Presented by Michael H. Gold, MD
Gold Skin Care Center, Tennessee Clinical Research Center Nashville, TN USA

UltraShape Power

New configuration with small transducer

Small U-Sculpt Transducer (12gr)

Why USculpt Only?

- Best clinical outcome ever archived with UltraShape technology so far (even when comparing to multi-focus)
- Better user experience:
  - Lighter
  - Easier to move and maneuver on curvy areas
- Minimal impact on treatment time

Small U-Sculpt Transducer (12gr)

User Interface & Usability

User Interface & Usability

User Interface & Usability

Proven Outcomes Through Clinical Publications

- 20 + Clinical Published Studies and Abstracts Presented
- Over 900 Study Subjects
- 220,000 + Patient Treatments performed world wide
  - Study Findings Conclude
    - High Safety Profile
    - Results visible as early as 2 weeks post treatment
    - MRI images show reduction in fat layer

UltraShape Clinical Studies
Abdomen, Flanks and Thighs

Investigator	Year	Patient Population	Average Circumference Reduction	Results
Teitelbaum S. et al [1] US, UK, Japan	2004-05	164	2.0 cm (Single Treatment)	82% ≥ 0.5 cm circumference reduction
Leal H. [2,3] Monterrey, Mexico	2009	24	3.0-3.4 cm (1 combo therapy Tx)	96% > 1.5 cm circumference reduction 100% patient satisfaction
Moreno-Moraga J [1] Madrid, Spain	2006	30	3.95 cm	100% measurable and visual improvement
Ascher B. [1] Paris, France	2007-08	25	3.58 cm	83% ≥ 1.0 cm circumference reduction
Leal-Silva H. [2,3] Monterrey, Mexico	2007-08	36	5.0 cm	100% measureable reduction 94% patient satisfaction
Ad El D. [2,3] Beilinson Med, Israel	2008	26	3.96 cm	90% ≥ 2.0 cm circumference reduction
Mulholland S. [2] Toronto, Canada	2008	21	3.48 cm	86% patient satisfaction
Inglefield C. [2] London, UK	2005-06	148	6.3 cm	93% patient satisfaction
de Almeida G. [2] Sao Paulo, Brazil	2007-08	20	5.4 cm	100% measurable reduction 86% patient satisfaction
Benchetrit A. [2] Montreal, Canada	2007-09	109	4.5 cm	96% measurable reduction 86% patient satisfaction

[1]Published in peer-reviewed journal [2]Presented in scientific conference [3]Data on file

UltraShape Clinical Studies
Summary

- Over 600 patients studied in clinical studies
- 3 treatment regimen
- Average circumference reduction ranges from 3.5 to 6.3 cm
- Average response rate ranged from 83% to 100%
- Average patient satisfaction rate 86% to 94%

Note: with UltraShape fat cell destruction is immediate and permanent

UltraShape Flank Study
USA – Dr. Gold
July 2016

Clinical Study to Evaluate the Performance of the UltraShape Device for Fat Reduction Treatment in the Flank Area vs. Control

Methods

- Multi-center study at 3 sites in the USA
- 3 non-thermal, focused ultrasound treatments with small transducer (Usculpt) at 2-week intervals to one randomized flank (contralateral flank served as untreated control)
- Measurements:
  - Fat thickness by ultrasound measurements
  - Fat thickness by skin caliper
  - Weight change
- Follow-up at 4 -, 8 -, and 16 weeks after the last treatment

Clinical Study to Evaluate the Performance of the UltraShape Device for Fat Reduction Treatment in the Flank Area vs. Control

Results at Single Site (Dr. Gold)

- 22 subjects (21 females) enrolled and received at least 1 treatment
- Skin Type II-V
- Age range: 21-60 years (Mean ± SD; 41.7±10.8)
- BMI range: 22-29 (Mean ± SD; 24.7±1.9)
- Weight range: 55-84 kg (Mean ± SD; 66.2±7.7)

Treatments

- 63 treatment sessions (20 subjects had 3 txs, 1 subjects had 2 txs, 1 subject had 1 tx)
- Mean treatment duration of 11±6 min
- Mean focal treatment zones (FTZ): 2.0±0.6
- Mean discomfort with treatment: 0.2±0.6 (Scale of 0=no pain to 10)
- Mild erythema post-treatments (17% of treatments)
- Mild edema post-treatments (1.6% of treatments)
- No adverse events

Clinical Study to Evaluate the Performance of the UltraShape Device for Fat Reduction Treatment in the Flank Area vs. Control

Results at Single Site (Dr. Gold)

- Weight increase of 1.3% at the 8-week follow-up and 1.9% at the 16-week visit
- Significant fat reduction in ultrasound measurements of treated flanks
- Difference of 23.4% fat reduction between the treated and control flanks at 16 weeks
- Difference of 2.1mm fat reduction between the treated and control flanks at 16 weeks

Clinical study

NEW UltraShape POWER

- Clinical Study Design
- Clinical Outcome
- Before & Afters

A Single-Center, Controlled Study to Assess the Effectiveness and Safety of the UltraShape Power System for Abdominal Non-Invasive Circumference Reduction

Study Site

In-house clinic – Dr. Ruthie Amir

Study Design

- 43 subjects enrolled (41 female, 2 male; Fitzpatrick Skin Types I-V; mean age 48±8 years, range 30-65 years) with mean baseline weight = 73±14 kg and body mass index (BMI) 27.36±4.21, range 20.64-38.06
- 3 biweekly treatments to the abdomen with a single pass, using the 12 gram transducer (660W/cm^2)
- 6 biweekly assessments at 2-12 weeks after the 3rd treatment

Measurements

- Fat thickness by ultrasound imaging
- Abdominal circumference measurements
- Caliper fat thickness
- Weight
- Patient comfort & satisfaction

A Single-Center, Controlled Study to Assess the Effectiveness and Safety of the UltraShape Power System for Abdominal Non-Invasive Circumference Reduction

Results at follow-up

- All subjects (n=43) completed all 3 treatments
- Significant fat layer reduction (mean 32.3%) on ultrasound imaging (at 12wk FU)
- Significant circumference reduction (midline mean 2.62 cm at 12wk FU)
- 80% of clinical study patients reported an improvement already 2 weeks after the treatment phase
- Mean reported pain level of 0.68 on a scale of 0-10
- No adverse events

Clinical Trial Results Showed:

32% average **fat layer reduction** after 3 sessions

2.62 cm average abdominal circumference reduction after 3 sessions

3.26 cm average abdominal circumference reduction in patients with BMI>28

Treatments were accompanied with none to minimal discomfort (mean 0.68 on 0-10 scale)

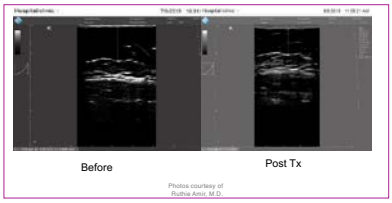
No safety issues

Patient Satisfaction

- 100% of clinical study patients reported they felt comfortable during treatment
- No downtime or visible signs of treatment, unlike other fat destruction methods.
- The most painless treatment – Average reported pain level of 0.68 on a scale of 0-10.
- 80% of clinical study patients reported an improvement already 2 weeks after the treatment phase
- Customizable for each patient- The only fat destruction procedure that can be adjusted to individual body areas and shape, including BMI>28.
- Patient proven – More than 350,000 treatments worldwide

Fat Layer Measurement Example

Δ US reduction: -26%

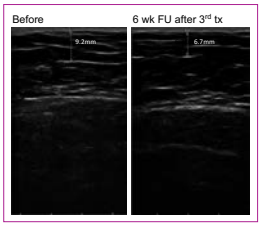


Before Post Tx

Photos courtesy of Ruthie Amir, M.D.

Fat Layer Measurement Example

Δ US reduction: -27.2%



Body FX & Mini FX by Invasix

Presented by Michael H. Gold, MD
Gold Skin Care Center, Tennessee Clinical Research Center Nashville, TN USA

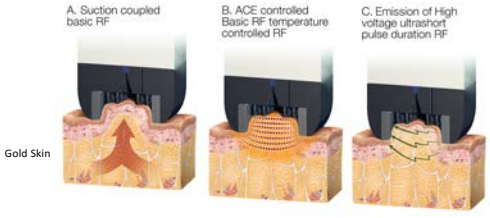
BodyFX™ MiniFX™ by INMODE

BodyFx

- ONLY non-invasive body contouring device proven in peer reviewed and published human studies to both permanently kill adipose tissue AND tighten skin.
  - LSM February 2014
  - Lask, Nelson, Divaris et el
  - 30% adipose cells APAF-1 at 2.5cm depth
  - 13.7% new collagen

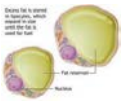
BODYFX & MINIFX

BodyFX mechanism of action



The BodyFx Mechanism

- How does it effect the Adipocyte?
  - **RF #1 = Basic RF**
    - Heats adipose tissue
    - Increase metabolic rate
    - LOWERS IRE threshold
    - Make electroporation easier
    - LIKE ELOS concept
  - **RF #2 = HVP**
    - Electroporation
    - IRE
    - Apoptosis



Clinical & Experimental Dermatology Research

Peer Reviewed Journal

A Clinical and Biological Evaluation of a Novel, Non-invasive Radiofrequency Device for the Long-Term Reduction of Adipose Tissue

Objective: A novel, non-invasive technology, utilizing suction-coupled radiofrequency (RF) heating and ultra-short pulse duration, high-voltage electrical pulses was studied for its efficacy and safety on adipose tissue reduction.

Method: 21 subjects underwent treatment of their abdominal fat once weekly for 6 weeks. Biopsies from the RF-treated and untreated sides were harvested during abdominoplasty and cultured; measurements of adipocyte size and shape, rate of apoptosis, collagen production, and dermal thickness were determined.

Results: Significant clinical improvements ($P < 0.05$) were observed for the reduction of abdominal circumference (113.4–110.7 cm). Within the adipose tissue of the treated areas, increased levels of adipocyte apoptosis were observed immediately following the treatment series, with approximately 20% of all adipocyte cells staining positive for APAF-1, a validated marker of apoptosis. At day 14 of culture, fat cell apoptosis had further increased (30% of adipocytes staining positive for APAF-1) within the RF-treated adipose tissue. Additionally, a significant increase in collagen synthesis (neocollagenesis) representing an average increase of 13.7% was observed after treatment by the RF device, with a mean collagen level of 57.6 mg/mg in the treated zone versus 49.7 mg/mg in the non-treated zone, as determined by the Spectro colorimetric method.

Authors: Sylvie Boisnic- MD, Marc Divaris- MD, Andrew A. Nelson- MD, Nima M. Gharavi- MD, PhD and Gary P. Lask-MD

View full article here: http://inmodemd.com/wp-content/uploads/2014/02/PeerRev_JCED_TiteFX.pdf

BodyTite™ by InMode

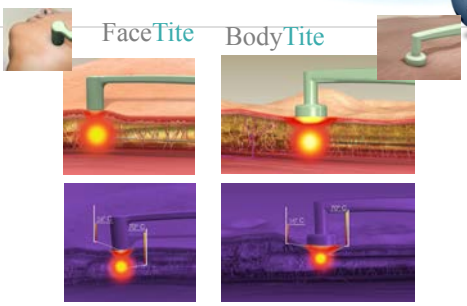
FaceTite / BodyTite

- Deliver surgical results to patients without the scalpel or scars.
- Mini-facelift, neck-lift, brachioplasty like results using RFAL accessed through 16 gauge needle entry port.
- Significantly tighten abdominal area, flanks, bra-line, inner thigh and other areas with unheralded outcomes.
- Improve surgical outcomes with RFAL for a more complete and natural look in excisional procedures

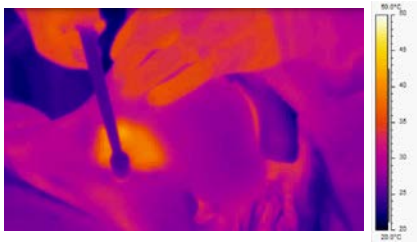
InMode RFAL Intended Use

- InMode RFAL stands for **RF A**ssisted **L**ipolysis by **coagulation of soft tissue.** FDA approval was based on fat coagulation data submitted by the company. Device can be marketed for any procedure where treatment outcome is a result of soft tissue coagulation.
- By-product of subcutaneous fat coagulation is heating of fibrous septa and papillary dermis surrounding fat clusters up to 70°C providing significant collagen contraction.

RFAL Technology: Directional Thermal Profile



Uniform Skin Temperature



Tissue Electrical Properties

Tissue	Conductivity , S/m @ 1MHz	Conductivity , S/m @ 460KHz
Skin	0.221	0.175
Fat	0.025	0.025
Muscle	0.503	0.443
Blood	0.822	0.745

Clinical results

CLINICAL RESULTS

Clinical results in peer reviewed publications legitimize the role of **RFAL** in the skin tightening and fat reduction market:

- Chia, C. T., Theodorou, S. J., Hogan, A. E., & Pitman, G. H. (2015). Radiofrequency-Assisted Liposuction Compared with Aggressive Superficial, Subdermal Liposuction of the Arms. *Plastic and Reconstructive Surgery - Global Open*.
- Paul, M., Blugerman, G., Kreindel, M., & Mulholland, R. S. (2014). Three-Dimensional Radiofrequency Tissue Tightening: A Proposed Mechanism and Applications for Body Contouring. *Aesthetic Plastic Surgery*.
- Duncan, D. I. (2013). Noninvasive Tissue Tightening: Creating Skin Surface Area Reduction During Abdominal Liposuction by Adding Radiofrequency Heating. *Aesthetic Surgery Journal*.

  The mean skin surface area reduction was 25.8% in regions treated with radiofrequency plus RAL at 6 weeks, and increased to 36.4% at 1 year.
- Divaris, M., Boisnic, S., Branchet, M., & Paul, M. D. (2011). A Clinical and Histological Study of Radiofrequency-Assisted Liposuction (RFAL) Mediated Skin Tightening and Cellulite Improvement - RFAL for Skin Tightening. *Journal of Cosmetics, Dermatological Sciences and Applications*.
- Blugerman, G., D., M., Schwartzov, D., Stephen, R., Sandhoffer, M., Ludwig, P., Kreindel, M. (2011). Radio Frequency-Assisted Liposuction (RFAL): Advanced Techniques in Liposuction and Fat Transfer.

Plastic & Reconstructive Surgery

Peer Reviewed Journal

Authors: Christopher T. Chia, MD Ryan M. Weinstein, MD Spero J. Theodorou, MD

Evidence-Based Medicine: Liposuction Article Type: Maintenance of Certification (MOC) – CME

RFAL is legitimized as a standard liposuction option, with a good safety record and up to 47 percent contraction.

With increased focus on one's aesthetic appearance, liposuction has become the most popular cosmetic procedure in the world since its introduction in the 1980s. For the present article, a systematic review of the relevant literature regarding patient workup, tumescent fluid techniques, medication overview, and operative technique was conducted with a practical approach that the reader will possibly and clinically applicable. Recent trends regarding energy-assisted liposuction and body contouring local anesthesia use are addressed. Deep venous thromboembolism prophylaxis is mentioned, as are other common and less common possible complications. The article provides a literature-supported overview on liposuction techniques with an emphasis on preoperative assessment, medicines used, operative technique, and outcomes.

View full article here: http://www.invasix.com/upload/ARTICLES/PeerReviewed_APS_3DTightening.pdf

Aesthetic Surgery Journal

Peer Reviewed Journal

Authors: Dr. Diane Duncan

Improving Outcomes in Upper Arm Liposuction: Adding Radiofrequency-Assisted Liposuction to Induce Skin Contraction

Objectives: The author investigates the degree of skin contraction resulting from treatment with radiofrequency-assisted liposuction (RFAL) and attempts to determine whether, after long-term follow-up, the classification of upper arm deformities and their corresponding treatment protocols can be refined to offer patients with prominent skin laxity an alternative to traditional brachioplasty.

Results: One year after treatment with RFAL, the mean surface area reduction in the volar upper arm region was 33.5% bilaterally. The mean degree of pendulous vertical "hang" shortening was 50% bilaterally. Statistical analysis showed a P value of >.001 for both measurements.

Conclusion: Treatment with RFAL achieved statistically significant skin contraction in the upper arm region. Patients in categories 2b and 4 were successfully treated with RFAL instead of traditional brachioplasty (which is recommended by the current classification system). Category 3 patients, however, did require a short-scar brachioplasty procedure to obtain satisfactory results.

View full article here: http://mmodernd.com/wp-content/uploads/2016/08/pwerrev_aej_rfalarms_dd1.pdf

Aesthetic Plastic Surgery

Peer Reviewed Journal

Authors: M. Paul, G. Blugerman, M. Kreindel, S. Mulholland

Three Dimensional Radiofrequency Tissue Tightening: A Proposed Mechanism and Applications for Body Contouring

Excerpt: "Linear contraction observed at 3 months follow-up were much more significant than reported with any other technology and varied from 12.7% up to 47% depending on patient and treatment variables."

Abstract: The use of radiofrequency energy to produce collagen matrix contraction is presented. Controlling the depth of energy delivery, the power applied, the target skin temperature, and the duration of application of energy at various soft tissue levels produces soft tissue contraction, which is measurable. This technology allows precise soft tissue modelling at multiple levels to enhance the result achieved. **Conclusion:** The mechanism of subcutaneous collagen contraction during RF-assisted liposuction is similar to that witnessed in other types of collagen, in that the contraction process has thermal contraction thresholds in the range of 60–70°C. This RFAL thermal process and contraction can be effectively applied during a liposuction treatment in selected cases, improving patient satisfaction and extending liposuction procedures to higher-weight patients and patients with compromised skin conditions.

View full article here: http://www.invasix.com/upload/ARTICLES/PeerReviewed_APS_3DTightening.pdf

Plastic & Reconstructive Surgery

Peer Reviewed Journal


ORIGINAL ARTICLE

Radiofrequency-assisted Liposuction for Neck and Lower Face Adipodermal Remodeling and Contouring

Authors: Evangelos Keramidas, MD, Stavroula Rodopoulou, MD

Radiofrequency-assisted Liposuction for Neck and Lower Face Adipodermal Remodeling and Contouring

Background: The purpose of this study is to report our experience using radio-frequency-assisted liposuction (RFAL) for neck and face contouring.
Methods: From November 2009 to November 2013, 55 patients who underwent RFAL treatment were enrolled in the study. Postoperative patient satisfaction surveys were conducted, and 2 independent plastic surgeons evaluated contour and skin quality with randomized preoperative and postoperative photographs at 6 months post operatively. Our longest follow-up was 4 years.
Results: All patients were followed up for a minimum of 6 months. Eighty-five percent of patients were satisfied with their contouring result and degree of skin tightening (48/55 patients). Two independent plastic surgeons considered the improvement in contouring and degree of skin tightening good to excellent in 52 of 55 cases.
Conclusion: In appropriately selected patients, RFAL neck and face contouring represent a safe procedure to achieve significant improvement of the skin laxity and fat deposits of the cervicomental zone and jowls.

View full article here:
http://www.invasix.com/upload/Downloads/file_47.pdf

Lasers, Lights, Radiofrequency and More

- We have novel EBDs that work well for the treatment of acne vulgaris and we need to consider using them for our patients
- We have great technology for fat reduction == with increasing safety and efficacy for our patients
- This is an exciting time for EBDs in our world