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Papers**



# Peer Reviewed Papers



## **Voluderm Micro-Needle Technology for Treating Skin Laxity and Wrinkles-Initial Clinical Experience**

Publication: Jacobs Journal of Experimental Dermatology  
Early online January 2015,

(<http://jacobspublishers.com/index.php/journal-of-experimental-dermatology-article-in-press>) Published March 2015

Authors: Dr. Steven D. Shapiro



## **VoluDerm Microneedle Technology for Skin Treatments – In Vivo Histological Evidence**

Publication: Journal of Cosmetics and Laser Therapy  
August 2014

Authors: Amikam Gershonowitz, Andrea Gat,

# Peer Reviewed Papers



## **Ex vivo study of hybrid energy technology using a human skin model**

Publication: European Journal of Dermatology 2014,  
Published January, 2014 ( pg.46-52)

Authors: Sylvie Boisnic, Marie Christine Branchet



## **Evaluation of Safety and Efficacy of the Maximus™ System for Facial Wrinkles**

Publication: Journal of Cosmetics, Dermatological Sciences  
and Applications, 2013, 3, Published Online June 2013  
(<http://www.SciRP.org/journal/jcdsa>)

Authors: Nikolai Potekaev, Olga Zhukova

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## **Treatment of Wrinkles and Acne Scars Using the TriFractional, A Novel Fractional Radiofrequency Technology—Clinical and Histological Results**

Publication: Journal of Cosmetics, Dermatological Sciences and Applications, 2012, 2, Published Online September 2012  
(<http://www.SciRP.org/journal/jcdsa>)

Authors: Alex Levenberg, Andrea Gat, Sylvie Boisnic, Marie Christine Branchet



## **Evaluation of safety and efficacy of the TriPollar technology for treatment of wrinkles**

Publication: [Lasers In Surgery and Medicine](#)

Authors: Steven D. Shapiro & Amos Leviav

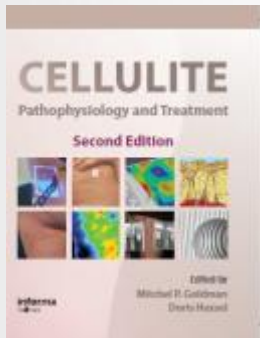
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## **Use of a TriPollar radio-frequency device for the treatment of acne vulgaris**

Publication: [Journal of Cosmetic and Laser Therapy, 2011](#)

Authors: Jonathan Neven T. Yu & Pamela Huang



## **TriPollar Radiofrequency- Chapter 22**

Book: [Cellulite Pathophysiology and Treatment. Second Edition, Chapter 22, pages 158-167, 2012.](#)

Editors: Mitchel P. Goldman and Doris Hexsel.

Authors: W Manuskiatti

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## **Clinical experience with a TriPollar radiofrequency system for facial and body aesthetic treatments**

Publication: [European Journal of Dermatology, 2010](#)

Author: Alex Levenberg



## **Ex-Vivo Human Skin Evaluation of Localized Fat Reduction and Anti-Aging Effect by TriPollar Radio Frequency Treatments**

Publication: [Journal of Cosmetic and Laser Therapy, 2009](#)

Authors: Sylvie Boisnic; Marie Christine Branchet

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## **Treatment of Striae Distensae with a TriPollar Radiofrequency device: a pilot study**

Publication: [Journal of Dermatological Treatment, 2009](#)

Authors: Woraphong Manuskiatti *et al*



## **Clinical and Histopathological results following TriPollar® Radiofrequency skin treatments**

Publication: [Journal of Cosmetic and Laser Therapy, June 2009 Volume 11, Issue, pages 78 – 84](#)

Authors: Haim Kaplan; Andrea Gat



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## **Circumference reduction and cellulite treatments with TriPollar radiofrequency device: A pilot study**

Publication: [Journal of the European Academy of Dermatology and Venereology, July 2009. Volume 23, Issue 7, pages: 820-827](#)

Authors: W Manuskiatti *et al.*



## **An Ex-vivo study of the regen™ TriPollar device using an experimental human skin model**

Publication: Les Nouvelles Dermatologiques. 2008 ; 28 :331-332

Author: S. Boisnic





# VoluDerma Micro-Needle Technology for Treating Skin Laxity and Wrinkles-Initial Clinical Experience

Authors: Dr. Steven D. Shapiro



## **Study Objective:**

Evaluation of the safety and efficacy of the novel VoluDerma (VO) technology for collagen remodeling, skin volume enhancing and wrinkle reduction.

## **Methods:**

Subjects underwent VoluDerma treatments for various aesthetic indications. Some of the subjects underwent a pre heating treatment with TriPollar radiofrequency prior to the VO as skin preparation for the VO phase of the treatment

## Evaluation Methods:

Typical treatment protocol – 5 treatments: 3 treatments performed once a week, and additional 2 treatments spaced 2-3 weeks apart.

Subjects were photographed at baseline, after the first treatment and before each following treatment.



## Results



Treatment photos demonstrated skin volume enhancement along with improvement of skin texture and diminished appearance of wrinkles. No significant adverse event were detected.



Before



After 5 tx

VO technology (with TriPollar preheating).  
Improvement of skin texture, significant volumizing in cheek area along with reduction of the naso-labial folds.



Before



After 1 tx

VO technology (with TriPollar preheating).  
Improvement of neck skin laxity and wrinkles



Before



After 5 tx

VO technology (with TriPollar preheating).  
Improvement of skin texture and facial contouring



Before



After 5 tx

VO technology (with TriPollar preheating).  
Improvement of fine lines and volumizing effect



## Conclusion



Voluderm is safe and effective micro needle technology, for dermal volumizing and treatment of wrinkles with minimal pain and no downtime.

### QUOTE FROM PAPER:

*“The results of the VO treatments demonstrated significant dermal volume enhancement, reduction of wrinkles, including naso - labial folds, per oral and orbital lines. Improvement of neck skin laxity and skin texture, were manifested by radiant skin, smaller pores and general volume increase.”*



# VoluDerm Micro needle Technology for Skin Treatments – In Vivo Histological Evidence

Authors: Amikam Gershonowitz, Andrea Gat

## **Study Objective:**

Assessment of the safety and efficacy of the VoluDerm through histological evaluation of morphological changes in the target tissue.

## **Methods:**

Treatments were conducted on two domestic pigs using VoluDerm disposable tips. Histological samples of 14, 7, 4 days and immediately after treatment with various energy settings were analyzed.

## Evaluation Methods:

Skin samples for histological and morphological analysis were collected.

Following excision, skin samples were fixed in formalin and embedded in paraffin.

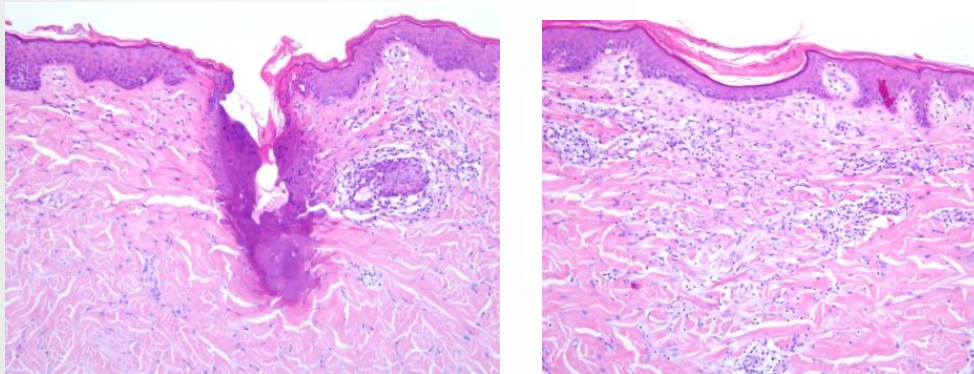
Serial sections were prepared and stained using hematoxylin & eosin (H&E) for derma pathological examination and analysis.



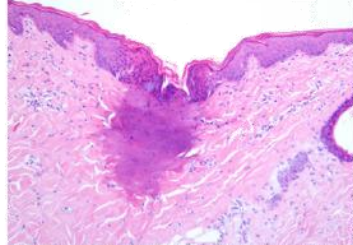
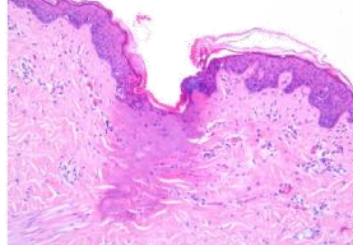
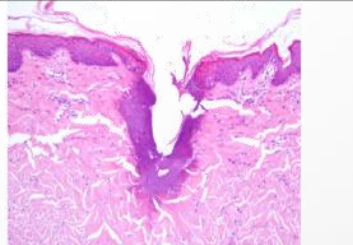


## Results

Immediate VoluDerm epidermal and dermal effects, and progress of healing process, as function of time following treatment (days 4 and 7), were demonstrated. Histology analysis of samples of 14 days demonstrated complete healing for all energy levels.



Skin histology samples at D0 (left) and D14 (right), after treatment with High setting, demonstrating complete healing on day 14.

Power Level	Dimensions of effect
 Low	Width 0.3mm Depth 0.4mm
 Medium	Width 0.3mm Depth 0.45mm
 High	Width 0.3mm Depth 0.5mm



## Conclusion



This In-Vivo histology confirmed the safe and effective performance of the VoluDerm treatment. A fractional pattern of effected areas, surrounded by healthy tissue, was demonstrated. Healing process proved natural dermal renewal and epidermal complete regeneration. Histology supports clinical advantages of the VoluDerm natural looking skin enhancement.

### QUOTE FROM PAPER:

*“The major impact of VoluDerm is on the dermal layer, thus treatment is associated with less to no downtime, less patient discomfort, and less predisposition to side effects compared with no needle fractional technologies, or other micro needles technologies, in which penetration mechanism is mechanical. With VoluDerm, the visible impact on the epidermal layer is relatively minor and less prominent compared with this technologies, although the desired micro resurfacing effect is achieved.”*





# Ex vivo study of hybrid energy technology using a human skin model

Sylvie Boisnic, Marie Christine Branchet

## Study Objective:

Evaluate the morphological and histological of the HE technology and epidermal and dermal skin layers using an ex vivo human skin model.

## Methods:

Human skin samples were collected and treated ex-vivo with the HE applicator. The effect was evaluated by skin histology and quantative analysis by assays of collagen fibers, elastin and glycosaminoglycan (GAGs) dosage, reflecting the hyaluronic acid content, in addition to epidermal mitotic index evaluation.

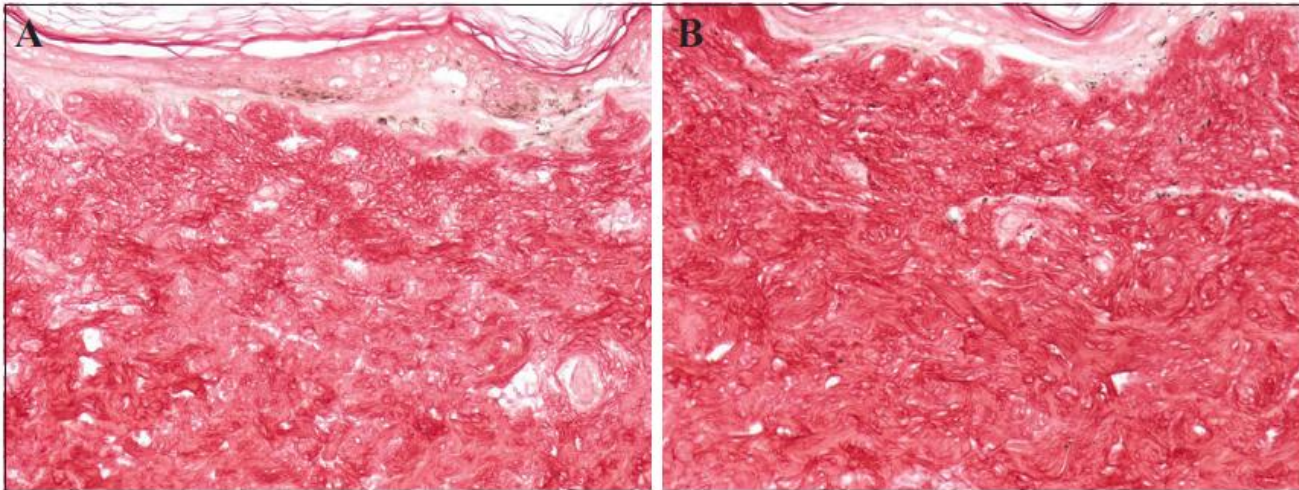
## Evaluation Methods:

- Histological evaluation using H & E staining
- Epidermal mitotic index evaluation using antibody Ki67
- Collagen fibers morphometric evaluation
- Glycosaminoglycan (GAGs) analysis using Hale staining
- Elastic fiber morphometrical analysis
- Statistical analysis

## Results

Histology demonstrated immediate and long term HE effect on both epidermal and dermal skin layers with a direct correlation between the treatment parameters and effects.

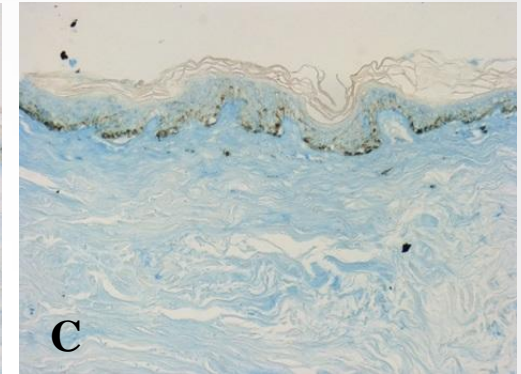
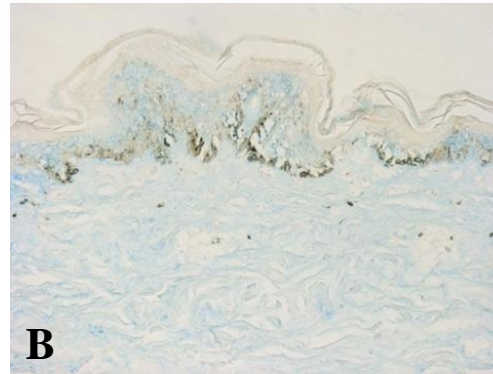
**Results demonstrated a significant increase of the epidermal mitotic index, significant dermal collagen remodelling and significant increase in both epidermal and dermal GAGs.**



**A:** D10 UV aged control

**B:** UV aged + High HE

An increase of collagen fibers in B in the dermis is demonstrated under the HE treated zone.

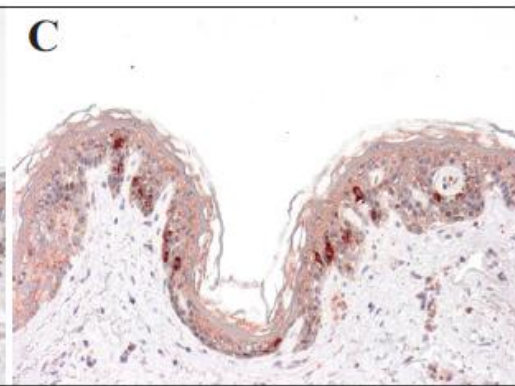
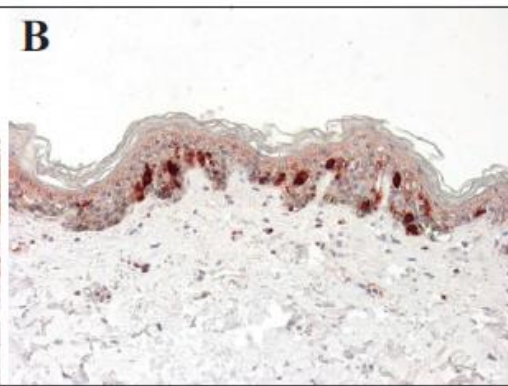
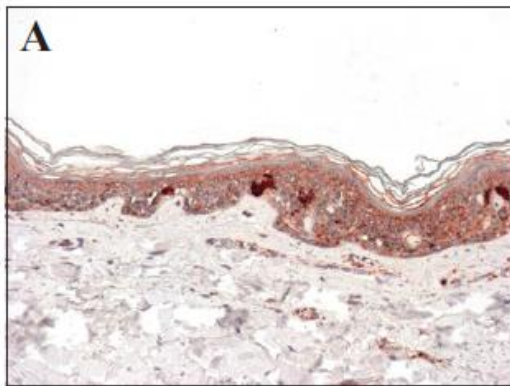


**A: UV aged control**

**B: UV aged +Low HE**

**C: UV aged + High HE**

### GAGs augmentation in epidermis and dermis of treated fragments



**A: UV aged control**

**B: UV aged +Low HE**

**C: UV aged + High HE**

Significant augmentation of positive epithelial cells in skin fragments B and C compared to A



## Conclusion

HE technology significantly affected collagen remodeling and an increase in mid to deep dermis GAGs in addition to epidermal mitotic index resulting in long term structural and biochemical dermal and epidermal improvement.

### QUOTE FROM PAPER:

*“The histological findings of this study demonstrated an effective wound healing process...all fragments exposed to HE demonstrated a significant increase in collagen compared to UV aged un exposed fragments demonstrating Neocollagenesis following exposure to HE. An increase in GAGs (reflecting hyaluronic acid) was noticed in the dermis and epidermis of the treated fragments.”*





# Evaluation of Safety and Efficacy of the Maximus™ System for Facial Wrinkles

Nikolai Potekaev & Olga Zhukova

## Study Objective:

Evaluate the safety and effectiveness of the Maximus system powered by the TriLipo technology, for skin rejuvenation and treatment of facial wrinkles

## Methods:

Subjects: 20 Female subjects ages 35-65.

Visits: 8 Weekly Maximus face treatments, Follow-Up : 1 week & 1 month after T8

## Evaluation Methods:

- Comparing pre- and post-treatment photographs
- 3D Visioscan + Soft Plus microcamera - skin characteristics
- DUB ultrasonic scanning - skin microtopography
- Laser Doppler Flowmetry (LDF) - assessing microcirculation conditions of skin
- Subject subjective evaluation of skin improvement.

## Results

### Safety

- No unexpected adverse side effects were detected or reported.
- No negative sensations were experienced during the Treatment.

### Efficacy

- Photos of B & A reveal: Improvement of wrinkles appearance, skin tightening and definition of jaw line.
- Researchers recorded:
  - Positive trend for skin quality
  - Obvious facial oval shape correction
  - Reduction in depth of wrinkles and folds and flattening of small lines.

**37-year old female:**

*A - Before treatment initiation*

*B - 1 week after T8*

**A**



**B**



## Results (Cont.)

### Skin characteristics through Visioscan & Soft Plus microcamera:

- Significant **improvement** for all measured skin characteristics after 8 treatments, with an **additional improvement** at 1 month follow-up.

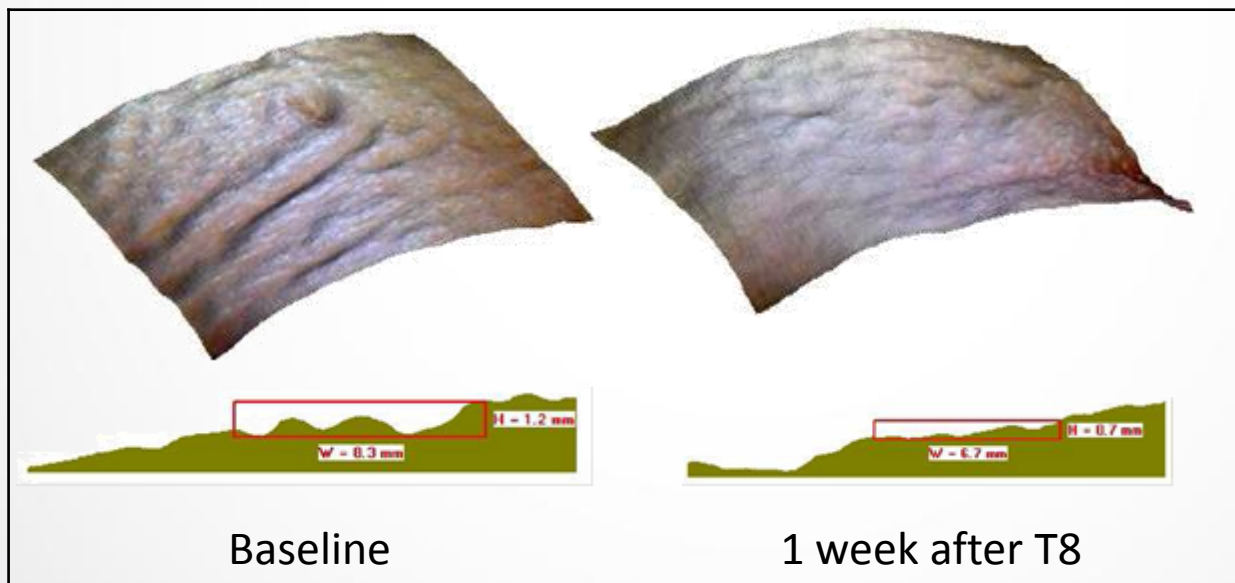
		Average Value (Units), M±m, p<0.05											
		SEsc– scaliness			SEr– roughness			SEsm- smoothness			SEw- wrinkles		
		Baseline	After T8	1 Month After T8	Baseline	After T8	1 Month After T8	Baseline	After T8	1 Month After T8	Baseline	After T8	1 Month After T8
Microrelief	0.63±1.2	0.56±0.30	0.35±0.23	4.2± 1.5	3.8± 0.7	2.5±0.8	23.9±3.0	27.9±6.2	43.8±5.7	72.1±4.0	67.2±5.8	50.5±4.2	
%		-12	-40		-10	-40		+17	+83		-7	-30	



## Results (Cont.)

### Skin characteristics through Visioscan & Soft Plus microcamera(Cont.)

- Smoothing of irregularities
- Reduction in depth and length of wrinkles
- Decreased diameter of pores

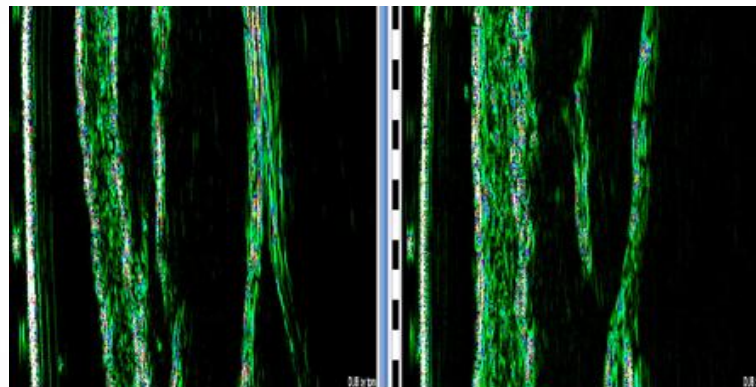


*3D Imaging of "Crow's feet" wrinkle area & sectional drawing of the skin test area*

## Results (Cont.)

### Ultrasonic Dermascanning:

- Skin characteristics show a **positive trend of improvement**
- Epidermal-dermal layer **increased in thickness** and **improved in structural homogeneity**
- **More even distribution** of the echo-signal **inside the dermis**.



Baseline

1 week after T8

	Av. Epidermal-Dermal Thickness, mm			Intensity (Density) of Dermal Structures, %		
	Baseline	1 week after T8	1 Month After T8	Baseline	1 week after T8	1 Month After T8
US Reading	1.30±0.16	1.6±0.22	1.75±0.12	3.8±0.51	4.0±1.2	5.5±1.15



## Conclusion



The Maximus system powered by the TriLipo technology demonstrated:

- Significant improvement in skin tonus
- Skin lift effect
- Reduction of sharpness of mimic and static wrinkles
- Increased thickness of dermal layer
- Effective facial contouring

### QUOTE FROM PAPER:

*“Results of the quantitative measures used in this study demonstrate the safety and clinical benefit of the Maximus device powered by the TriLipo technology due to combined effects of TriLipo RF and TriLipo DMA, for skin rejuvenation and the treatment of facial wrinkles”*

# Treatment of Wrinkles and Acne Scars Using the TriFractional, A Novel Fractional Radiofrequency Technology—Clinical and Histological Results

Alex Levenberg, Andrea Gat, Sylvie Boisnic, Marie Christine Branchet

## Objective and Methods

Evaluation of safety and effectiveness of the TriFractional technology for the treatment of wrinkles and acne scars.

## Clinical treatments of subjects:

- TriFractional treatments
- Complete TriLipo Med™ Procedure (TriFractional treatments combined with TriLipo® RF + DMA face treatments)

## Histology evaluation:

- Porcine skin
- In vivo and ex vivo human skin

# Clinical results

## TriFractional results:

- Reduction of fine wrinkles
- Improved appearance of acne scars
- Improvement of skin texture
- Skin brightening
- Skin tightening
- Improvement of skin irregularities

## TriLipo Med procedure results:

- Demonstrated the added value of a combination: TriFractional + TriLipo RF & DMA
- Demonstrated an additional facial contouring effect
- No significant undesired effects
- Subjects reported a tolerable pain level
- All subjects expressed satisfaction with the clinical results.

## TriLipo MED Procedure Acne scars and Skin Texture Improvement



Before



After TriLipo MED Procedure

## TriLipo MED Procedure Wrinkles Improvement and Skin Tightening



Before



After TriLipo MED Procedure



## TriLipo MED Procedure Skin Tightening and Improved Lips Appearance



Before



After

# TriFractional Histology Methods

## Porcine skin:

- Abdomen skin samples were exposed to TriFractional pulses
- Low and high energy
- Sections were stained with H&E

## In- vivo human abdominal skin:

- Patient prior to mini abdominoplasty
- Pulses of the high power (160msec) were performed
- One week and one day before the surgery
- Skin samples were taken during surgery for histology
- Sections were stained with H&E

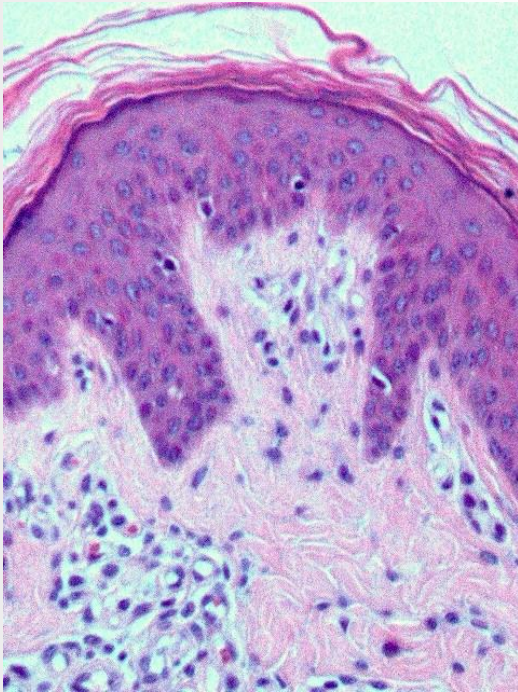
# TriFractional Histology Methods (Cont.)

- **Ex-vivo human skin study:**

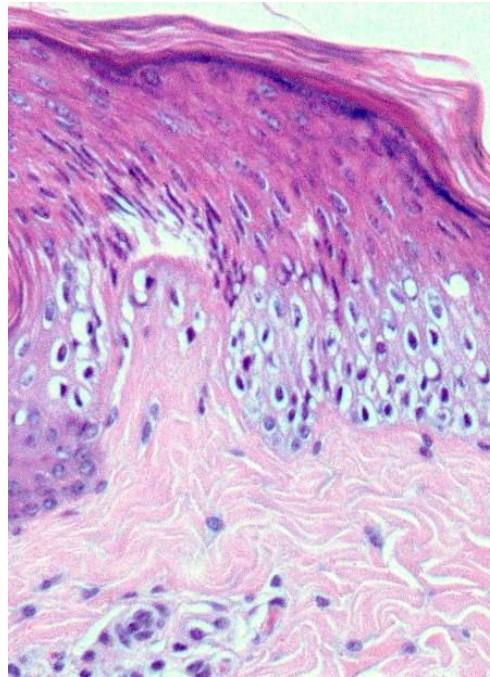
- Conducted by Dr. Boisnic, Gredeco Research Association, Paris
- Ex-vivo model - maintaining skin fragments in survival medium
- Skin harvested from donors undergoing plastic surgery
- Skin was artificially aged by UV irradiation
- TriFractional pulses (150msec) were performed
- Histological analysis:
  - H&E staining (Hematoxylin and eosin)
  - Immuno-histochemical analysis of epidermal mitotic index (measure of cells proliferation via stained antibodies)
  - Morphometrical analysis of collagen fibers (computerized image analysis of stained sections)

# Porcine Skin Histology Results

TriFractional **low** energy , (H&E stain, x200)



Normal skin, “skip area”  
between 2 electrodes

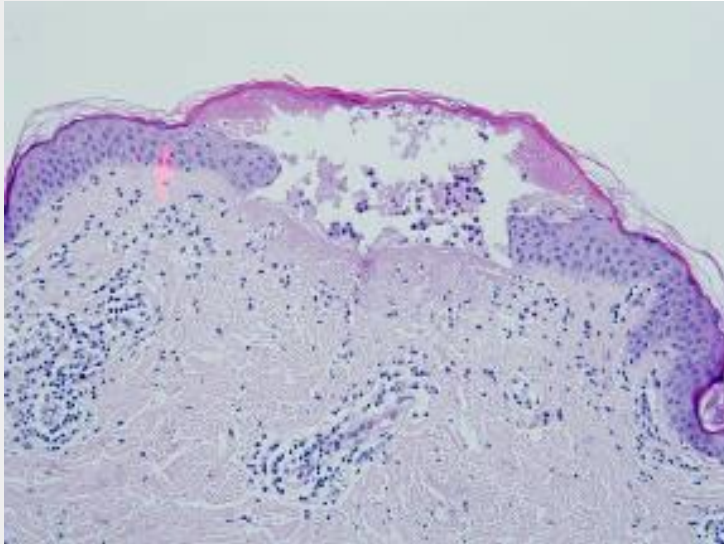


- Epidermal thermal effect under electrode
- Elongation of epidermal nuclei mainly in basal layer
- No thermal effect observed in dermis



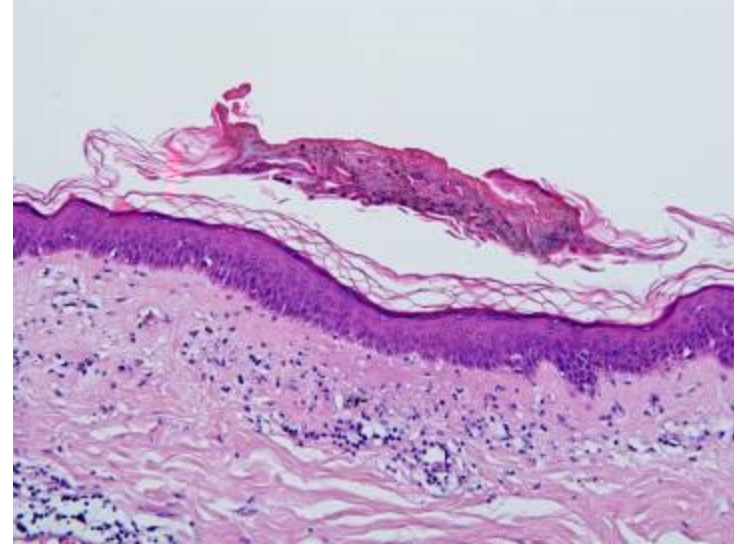
# In vivo Human Abdominal Skin Histology Results

TriFractional **High** default energy – 160ms (H&E stain x 100, 200)



## 1 day post treatment

- Epidermal necrosis covered by crust
- Collagen effect in papillary and upper reticular dermis
- Neutrophilic infiltrate

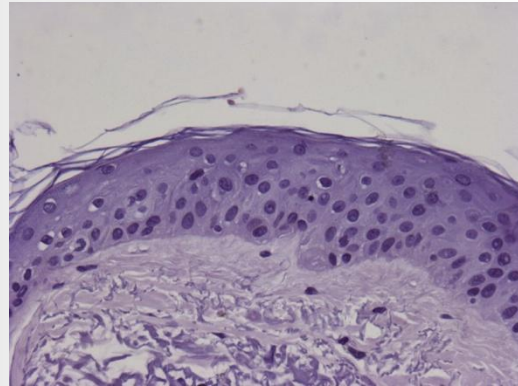


## 1 week post treatment

- Epidermis is regenerated and covered with scale crust,
- Dermal effect
- Lymphocytic infiltrate

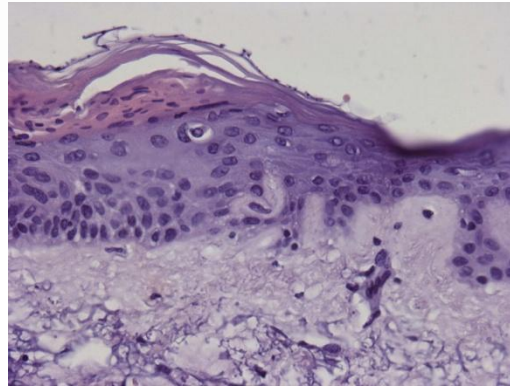
# Ex Vivo Human Skin Histology Results

## Control - Untreated



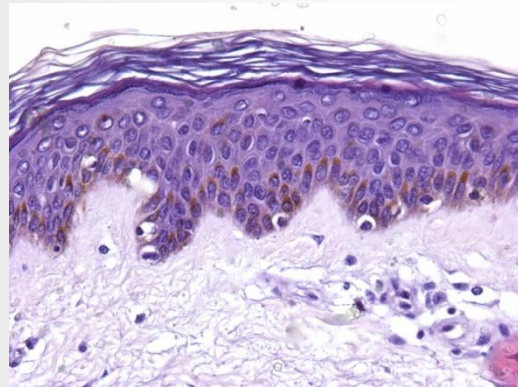
D3

## Treated

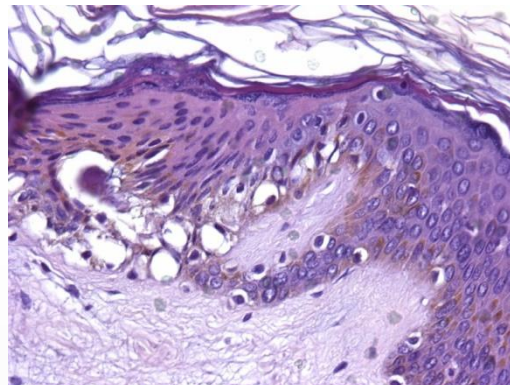


### At D3 after treatment:

- Epidermal scarring
- Formation of new epidermis while old is diminishing
- Condensation of upper dermal collagen fibers



D10



### At D10 after treatment:

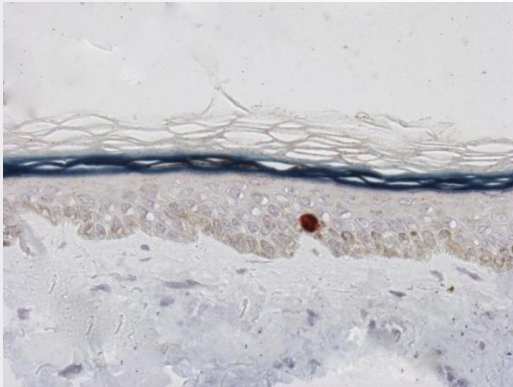
- Reparation with the elimination of the crust
- Moderate alteration of the epidermis and dermis

(H&E stain x 400, 1 cm = 19  $\mu$ m)

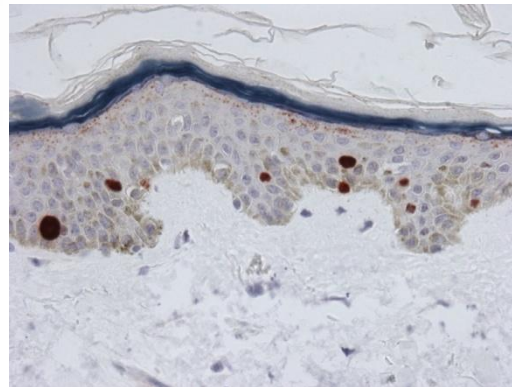
# Ex Vivo Human Skin Histology Results (Cont.)

## Immunohistochemical analysis of mitotic cells in the epidermis

**Control - Untreated**



**Treated**



**D2**

Increase of mitotic cells

- % of mitotic cells increased from an average of  $3.07 \pm 1.57\%$  in control (UV aged) skin to  $8.9 \pm 3.03\%$  in TriFractional treated (UV aged) skin ( $p=0.0017$ ).
- Statistically significant increase of  $\sim X 3$  in the amount of positive mitotic epithelial cells.

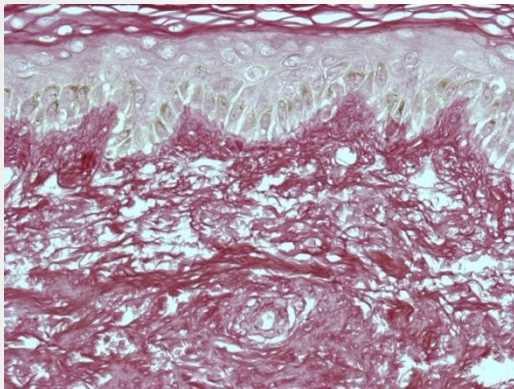
(Ki67, x 400, 1 cm = 19  $\mu$ m)



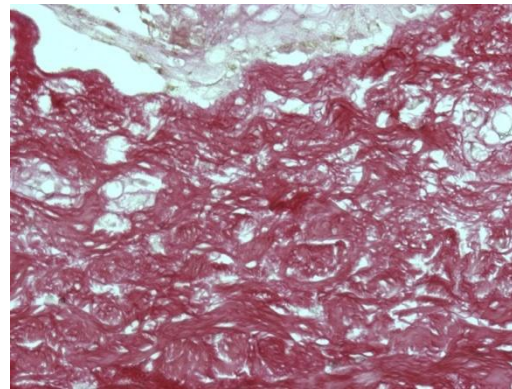
# Ex Vivo Human Skin Histology Results (Cont.)

## Morphometrical analysis of dermal collagen

Control - Untreated



Treated



D10

*Increase of dermal collagen fibers*

- Significant augmentation of dermal collagen by computerized image analysis resulted in **15.5%** increase of collagen content in treated compared to control

(Sirius red stain, x 400, 1 cm = 19  $\mu$ m)

## TriFractional Article Summary

- Safety and efficacy of the TriFractional technology was proved by clinical and histological evidence
- Histology confirmed the TriFractional impact on epidermal renewal and dermal regeneration
- Histologies demonstrated the biological mechanism of the effect
- Ex-vivo results support the in-vivo findings
- TriLipo MED Procedure provides a complete approach to enhance results
- Fractional mode of the treatment enables a faster, more effective healing process, eliminating downtime and resulting in a safe, tolerable, effective skin rejuvenation.



# EVALUATION OF SAFETY AND EFFICACY OF THE TRIPOLLAR TECHNOLOGY FOR TREATMENT OF WRINKLES

Steven D. Shapiro MD & Amos Leviav MD



## Study Objective:

- To evaluate the **safety** of the apollo™ system for treatment of wrinkles and rhytides.
- To evaluate the **efficacy** of the apollo™ system for treatment of wrinkles and rhytides.

## Methods:

Subjects: 37 Female subjects were recruited - 37 completed all treatments, 3 lost to follow-up due to travel or change of residence.

Visits: 8 Weekly treatments, Follow-Up at 1 month and 3 months after treatment 8.

## Two sites:

- Steven Shapiro MD (Dermatologist) – Gardens Dermatology and Cosmetic Surgery Center, Florida US
- Amos Leviav MD (Plastic Surgeon) - Kaplan Hospital, Israel



# Evaluation Methods & Results



## Evaluation Methods:

- Pre and post treatment photos (of 34 subjects who completed all visits including FU) were scored by two uninvolved physicians
- A subject was scored a success if he showed **at least one score improvement according to the Fitzpatrick Wrinkle Classification System**, by comparing photos of the last follow up visit to baseline photos.

## Results

### Safety

- No unexpected adverse side effects were detected or reported.
- All subjects reported no pain or mild pain during the treatments .

### Efficacy

- A downgrade of at least 1 score in Fitzpatrick scale was found in 94% (1<sup>st</sup> reviewer) and 97% (2<sup>nd</sup> reviewer) of study subjects.
- Subjects satisfaction questionnaires revealed high level of satisfaction.
- PI's scoring of subjects' facial skin appearance at baseline and 3 at month FU demonstrated average reduction of 1.55 (Dr. Leviav) and 2.4 (Dr. Shapiro) .

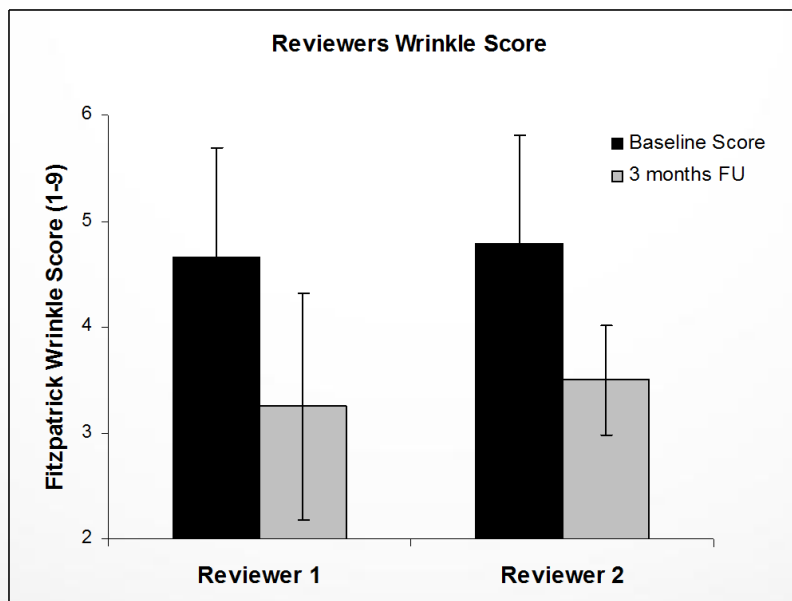
## Conclusions

*The results of this study clearly indicate that the TriPollar system offers a non-invasive, effective, safe and virtually painless wrinkle and rhytides reduction treatment.*



# Reviewers Scores Summary

Average Wrinkle Score						
Score time	1 <sup>st</sup> Reviewer			2 <sup>nd</sup> Reviewer		
	Average Score	Grade reduction (comparing to baseline)	Statistical (TTest ) Results of the Comparison	Average Score	Grade reduction (comparing to baseline)	Statistical (TTest ) Results of the Comparison
Baseline	4.65 ( $\pm 1.04$ )	-	-	4.79 ( $\pm 1.15$ )	-	-
3 months follow-up	3.24 ( $\pm 1.07$ )	1.41 ( $\pm 0.74$ )	$p < 0.001$	3.50 ( $\pm 1.02$ )	1.29 ( $\pm 0.52$ )	$p < 0.001$



## Sample photos: A 51 years old female

Before - Baseline



After - 3M following 8 Tx





## Sample photos: A 42 years old female

Before- Baseline



After - 3M following 8 Tx



## Sample photos: A 59 years old female

Before- Baseline



After - 3M following 8 Tx



## Sample results: A 61 years old female

Before- Baseline

After - 3M following 8 Tx







# USE OF TRIPOLLAR RADIOFREQUENCY DEVICE FOR THE TREATMENT OF ACNE VULGARIS

Dr. Jonathan Yu



## Study Objective:

To evaluate the **safety and efficacy** of TriPollar RF technology for non-invasive treatment of acne vulgaris lesions.

## Methods:

- **20 patients** (5 males and 15 females) with active acne lesions were enrolled
- Patients included:
  - were not satisfied with their current treatments
  - off topical or oral medications for at least 2 months.
- **6 weekly** Apollo treatments ; FU 4 weeks after last visit
- 13 patients completed all visits, 4 completed 4 treatments, withdrawal was for personal reasons, not treatment related
- Evaluation methods:
  - Photographs
  - Count of active lesion
  - Patients satisfaction rating on a 5 score scale



## Results:

- Average reduction - **42% in active acne lesions after 6 TriPollar sessions**
- Reduction sustained at 4 weeks follow up visit.
- Average improvement rated by patients at the 4 week follow up visit was 2.5 indicating good to very good satisfaction with the clinical results.
- No significant adverse events were recorded

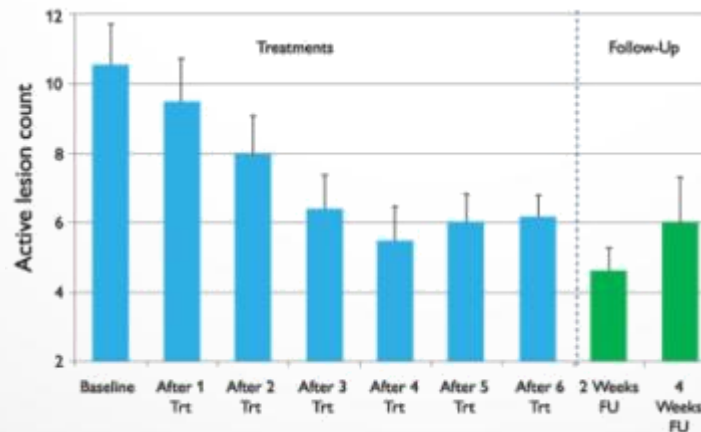


Figure 1. Average reduction in active acne lesions following TriPollar treatments.

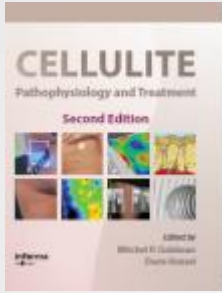
**QUOTE:**

“This modality (TriPollar RF) is particularly useful for patients who are not willing or capable of adhering to a daily regimen and for those who have failed medical management. There are also patients who prefer to avoid long-term drug treatment owing to concerns or experience with the significant side effects associated with isotretinoin and other medications.”

Jonathan Neven T. Yu







# TriPollar CHAPTER IN CELLULITE BOOK

Dr. W Manuskiatti



Title: TriPollar Radiofrequency

Book: Cellulite Pathophysiology and Treatment. 2010 Second Edition, Chapter 22, pages 158-167.

Editors: Mitchel P. Goldman and Doris Hexsel.

Authors: W Manuskiatti

## **Content:**

- The chapter reviews the **advantages of TriPollar RF over mono and bipolar RF**
- Provides an overview of treatment technique
- Reviews studies using the regen and apollo TriPollar RF systems

### CONCLUSION QUOTE:

“The TriPollar RF device is a multi-polar RF system which can safely and effectively be used for **skin tightening and circumference reduction**, particularly on the body and facial areas, as well as for the **treatment of cellulite, reduction of localized fat and improvement of striae appearance.**”

“Qualitative as well as quantitative assessments have been documented and the outcome from previous research studies has shown that **the improvements (in cellulite) are maintained as a long-term effect.**”



# CLINICAL EXPERIENCE WITH A TriPollar® RADIOFREQUENCY SYSTEM FOR FACIAL AND BODY AESTHETIC TREATMENTS

Dr. Alex Levenberg

## Study Objective:

To evaluate the **safety and efficacy of the Apollo™** for non-invasive treatment of localized excess fat and facial tightening

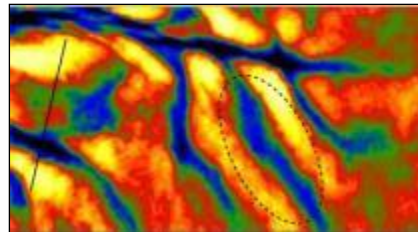
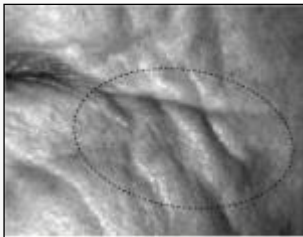
## Materials and Methods:

- **37 female** patients
- Average of **7 treatments** for wrinkles, laxity and circumference reduction on different facial and body areas.
- **5 patients had blood tests** to assess any changes in liver function and lipid profile following treatment
- Evaluation methods:
  - Facial results objectively analyzed with Primos 3D imaging system
  - Photographs – evaluate facial and body results
  - Circumferential measurements.
  - Blood tests-Liver function and Lipid Profile

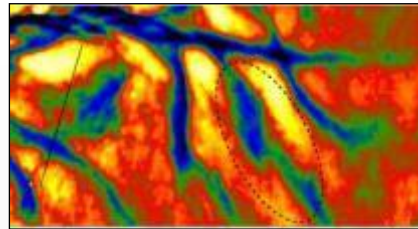
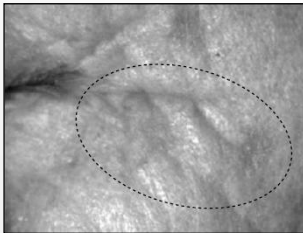
## Results:

- Average circumference reduction, in main body areas (abdomen, buttocks, thighs):  $3.6 \pm 2.4$  cm ( $P < 0.0001$ )
  - **Abdomen:**  $4.5 \pm 2.7$  cm, **max 10.5 cm**
  - **Buttocks:**  $3.1 \pm 1.7$  cm, **max 5 cm**
  - **Thighs:**  $2.4 \pm 2.0$  cm, **max 6.4 cm**
- **Improvement** of perioral and **periorbital wrinkles** was achieved

Before



After 8 Tx



**Following Apollo TriPollar treatments, no undesired effects on liver function and lipid profile were noted.**



# EX-VIVO HUMAN SKIN EVALUATION OF LOCALIZED FAT REDUCTION & ANTI – AGING EFFECT BY TriPollar RF TREATMENTS



Dr. Sylvie Boisnic; Dr. Marie Christine Branchet

## Study Objective:

To determine the biological mechanism of the TriPollar RF device for localized fat and cellulite reduction as well as the collagen remodeling effect.

## Study Procedure:

Human skin samples obtained from **8 abdominoplasty and 4 face lifts** placed on porous membrane in culture wells with survival medium, kept in sterile conditions, 37°C

### • TriPollar lipolytic effect analysis:

- A **single treatment** with the Apollo™ device was performed on 8 abdominoplasty skin samples
- Untreated samples were used as control
- Glycerol released from hypodermis was measured by enzymatic methods
- Histology of fat cells and fibrous tract

### • TriPollar anti-aging effect analysis:

- Premature aging of 4 abdominoplasty and 4 facial skin samples was induced by UV radiation
- A single treatment with the Apollo™ device was performed
- Collagen synthesis rate was evaluated by biochemical methods
- Histological quantification of dermal collagen by computerized image analysis





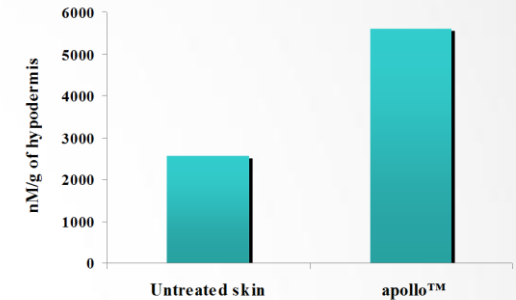
# LIPOLYTIC EFFECT OF TriPollar TREATMENT

## Glycerol dosage –

A statistically significant **increase of glycerol release** in treated skin samples was detected (120% increase Glycerol level)

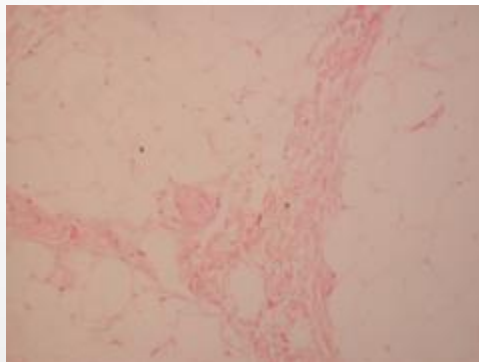
## Histology –

**Structure of fat cells was altered** in shape: less homogenous, shrunk, partially ruptured membrane and thinning of fibrous tract.

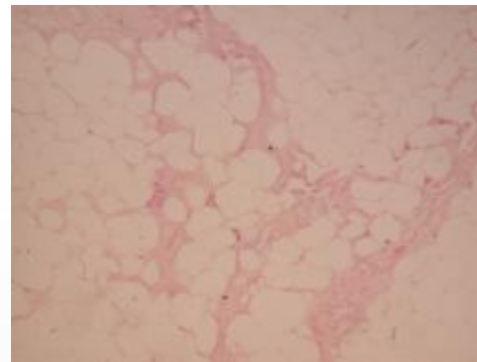


Glycerol dosage / g tissue

Untreated



TriPollar treated



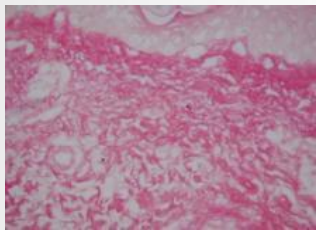
Results indicate increased fat metabolism leading to fat reduction



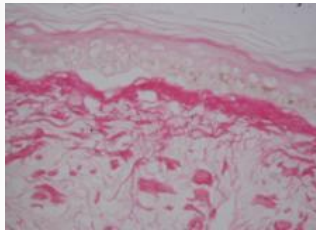
# ANTI – AGING EFFECT OF TRIPOLLAR TREATMENT



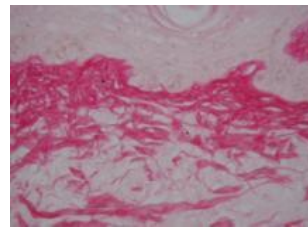
Histology of skin fragments from facial lifts show the repair of collagen bundles in the dermis with appearance of a dense zone under the basal lamina



Untreated



UV



UV+Treated

- Histological **quantification of dermal collagen** by computerized image analysis showed a **significant increase in superficial and mid dermis**
- Fibroblasts activity for **collagen synthesis** rate as measured by biochemical methods in treated skin vs. UV exposed skin was **increased significantly in abdominal and face samples**

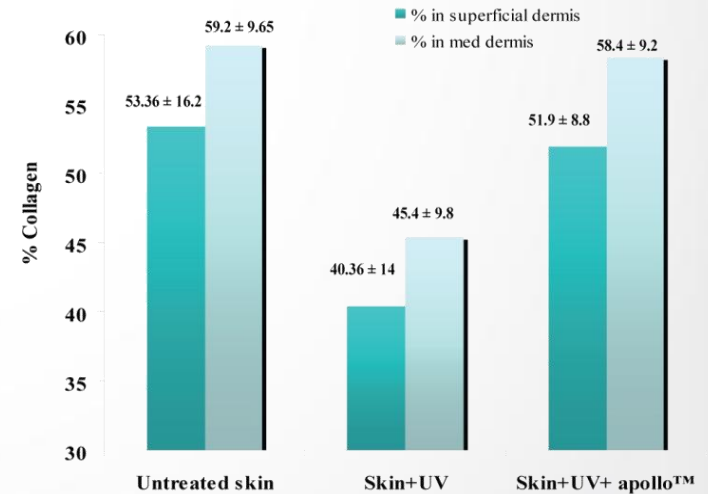


Figure 8. Histological and morphometrical analysis of collagen bundles from facial lift surgery (sirius red staining).



# TREATMENT OF STRIAR DISTENSEA WITH TriPollar RADIOFREQUENCY DEVICE : A PILOT STUDY

Dr. W Manuskiatti



## Study objective:

- To determine the efficacy and safety of TriPollar RF for the treatment of striae distensae in **skin phototypes IV-V**.

## Materials and Methods:

- **17 females** with striae received **6 weekly treatments** with the Apollo
- **Follow up: 1 and 6 weeks** after the final treatment

## Evaluation:

- Photos of stretch marks - improvement scored by 2 blinded evaluators, using a quartile grading scale
- UVA-light video camera - for skin texture observation
- Subjects satisfaction
- Side effects recorded at every session

## Striae alba

Before



One week FU



6 weeks FU



## Striae rubra

Before



One week FU



6 weeks FU



## Results

### Scores by Evaluators:

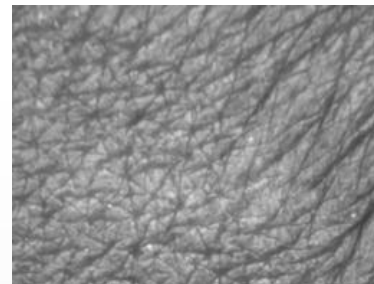
- 1 week FU: 41.2% and 11.8% of the subjects were assessed to have 25%-50% and 51%-75% improvement of striae appearance, respectively.
- 6 weeks FU - a higher percentage of subjects were rated to have improvement: 26.5% and 5.9% showing 51%-75% and >75% improvement, respectively.
- None of the subjects was rated as having no improvement.

### UVA camera:

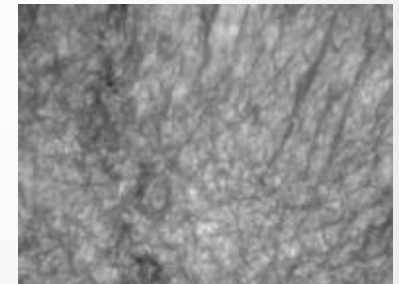
- Trend of striae surface smoothness improvement was observed 6-week FU

### Satisfaction:

- **65% (11/17) - very satisfied**
- 23 % (4/17) – satisfied
- 12% (2/17) - slightly satisfied
- No adverse effects were observed



Before



After



### QUOTE FROM PAPER:

“A sensation similar to a **warm massage without pain** was set as an ideal feeling during the treatment.”

“The feeling during treatment was described, by the subjects, as comfortable (29.4%), very comfortable (64.7%) and extremely comfortable (5.9%).

Worpahong Manuskiatti, M.D.





# CLINICAL AND HISTOPATHOLOGICAL RESULTS FOLLOWING TriPollar RADIOFREQUENCY SKIN TREATMENTS

Dr. Haim Kaplan & Dr. Andrea Gat



## Study Objective:

To evaluate the **safety and efficacy of the TriPollar** RF technology in reducing fat and collagen regeneration.

## Protocol:

- **13 patients** underwent weekly treatments on different body sites (**Average 7 Tx**)
- One abdominal patient consented to a series of TriPollar treatments prior to her scheduled abdominoplasty
- Only one side of her abdomen was treated
- A controlled histopathology analysis was performed on skin samples taken during the abdominoplasty procedure



## Clinical Results:

Tummy skin tightening and fat reduction in treated side

Before



Standing

Non treated  
side



After  
5 Tx

Treated  
side

Before  
6 Tx



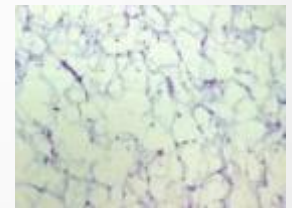
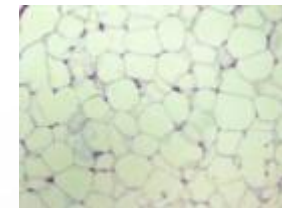
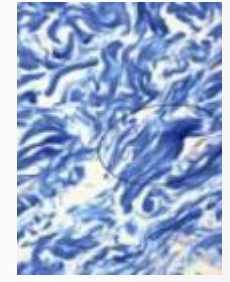
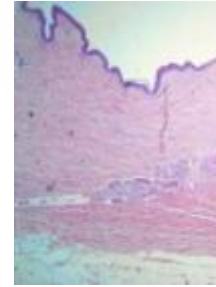
Lying



Immediately  
after  
6 Tx

## Histopathological Results:

- **Dermal thickness increased by 49% on average**
- **Focal thickening of collagen fibers**
- **In some areas of treated skin, the lobular fat cells appear to be smaller with irregular shape**



Untreated

Treated

### QUOTE FROM PAPER:

“The TriPollar system does not require skin cooling, **obtains measureable results and has high patient satisfaction** without the need for any auxiliary treatment modalities. The treatment is **extremely safe and easy to apply**. The availability of **applicators with various sizes optimizes the treatment of different anatomical sites** such as the face, neck, arms, abdomen and thighs.”

Haim Kaplan, M.D.







# CIRCUMFERENCE REDUCTION AND CELLULITE TREATMENTS WITH TriPollar RADIOFREQUENCY DEVICE : A PILOT STUDY

Dr. W Manuskiatti *et al*



## Study Objective:

To evaluate the **effect of TriPollar RF** on body contouring and cellulite reduction

## Methods

- **39 females** with cellulite (at least grade II)
- **Treatment areas:** Thigh, Abdomen, Buttock, Arm, a total of **81 anatomical sites**
- **8 weekly treatments**
- **Treatment Endpoint:** Maintaining skin at 40°- 42°C for at least 2 minutes
- **Follow-up: 4 weeks** after last treatments

## Evaluation

- Circumferential measurements
- B&A photographs
- Ultrasound measurement of subcutaneous fat thickness

## Results:

### Circumference Reduction:

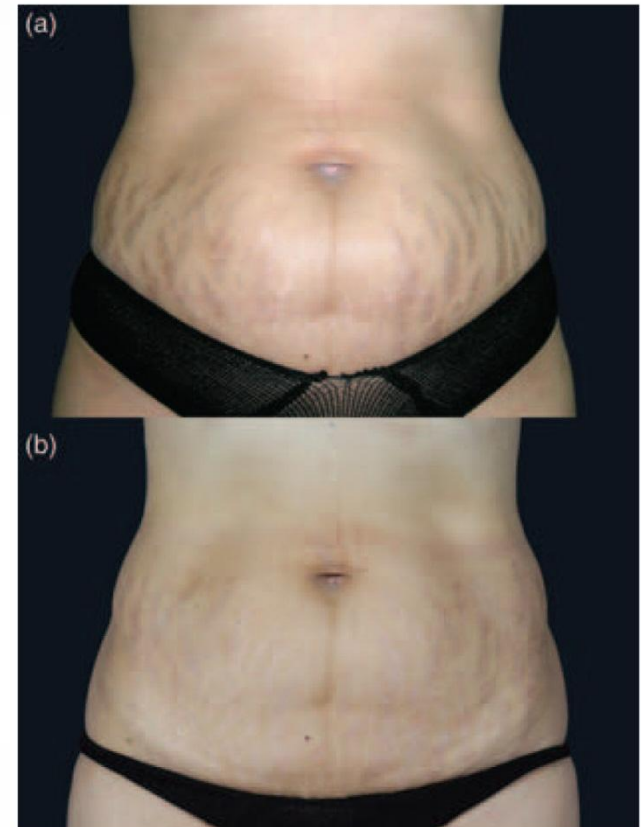
- Significant circumference reduction of **3.5cm (max 14.4cm) at the abdomen ( $p = 0.002$ ), and 1.7cm (max 9.1cm) at the thigh ( $p = 0.005$ ) regions. At four weeks after the final treatment, the average circumferential reductions were sustained**

### Ultrasound measurements:

- Thigh region: **Average reduction of 10.5% in the thickness of adipose tissue with a maximum reduction of 39%.**
- Results were statistically significant when compared to the baseline ( $p = 0.012$ )

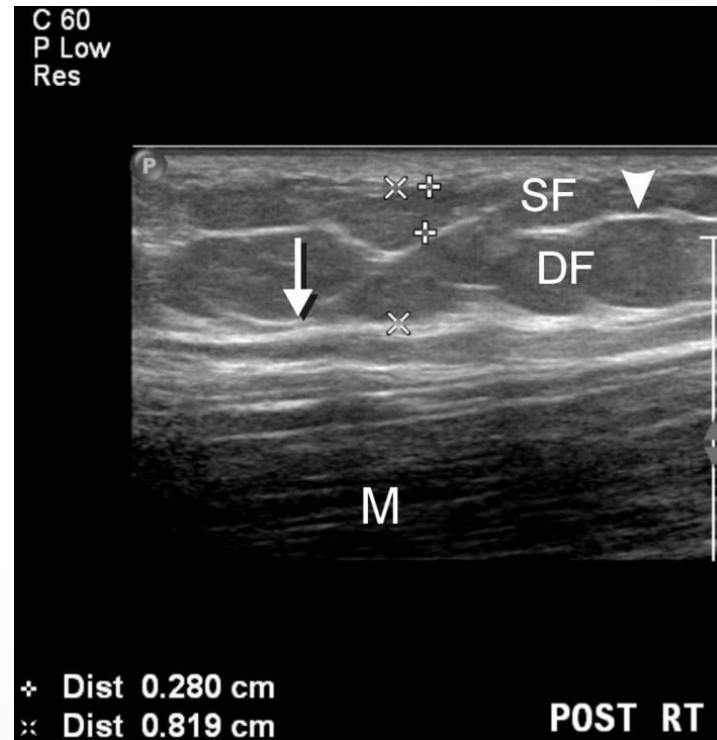
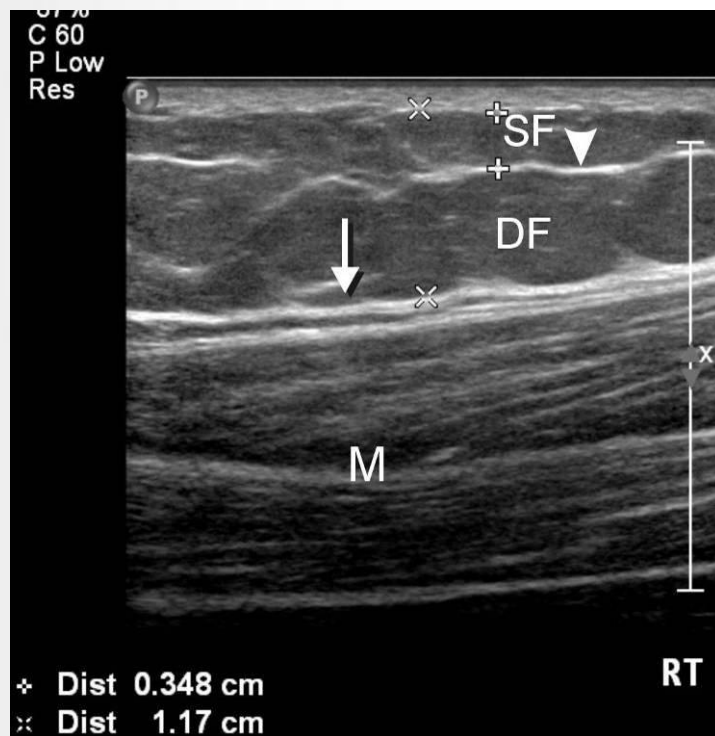
### Cellulite Appearance:

- **Average clinical improvement of cellulite appearance, as rated by the patients was 2.32 (~60%) after the series of treatments**



**Figure 2** Abdomen region, before treatment (a), Clinical appearance at 4 weeks after eight treatments (b). Note the appearance of stretch marks, before and after the series of treatment.

Ultrasound measurements of the distance between the epidermis and the superficial fascia showed a significant average distance **reduction of 10.5% in the thickness of adipose tissue** with a maximum reduction of 39% at the thigh region



SF, superficial fat layer; DF, deep fat layer; M, muscle; ▼, superficial fascia; ↓ deep fascia

### QUOTE FROM PAPER:

“TriPollar technology delivers simultaneously homogenous and deep volumetric heating using a three-electrode configuration. This special electrode configuration produces high density and focused RF energy of approximately 18 Watts/cm<sup>2</sup> deep into all skin layers compared with a bi-polar system which produces 1.2 Watts/cm<sup>2</sup> of bi-polar RF energy.”

“The efficacy of the TriPollar RF device for circumferential reduction was comparable to that reported in a previous study using unipolar RF and was better than those demonstrated by treating with a combined bipolar RF light source technology.”

W. Manuskiatti W. Manuskiatti





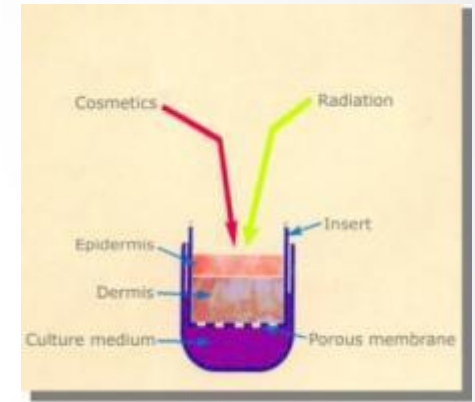
# AN EX – VIVO STUDY OF THE REGEN TriPollar DEVICE USING AN EXPERIMENTAL HUMAN SKIN MODEL

Dr. Sylvie Boisnic; Dr. Marie Christine Branchet



## Study Procedure:

- 8 Normal human skin fragments after Tummy tuck
- Skin fragments were placed on porous membrane in culture wells with culture survival medium.
- Samples were kept for up to 20 days in sterile conditions at 37°C
- A TriPollar treatment was performed on skin fragments under the same conditions as *in vivo* (skin temperature control, 10 minutes, 25 Watts)

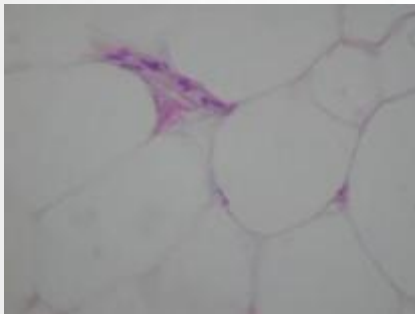




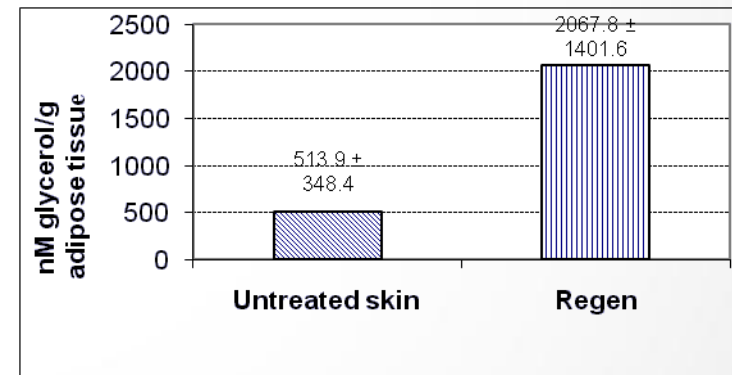
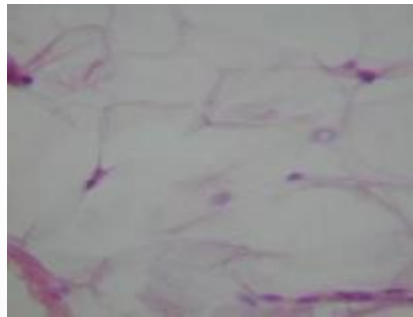
# LIPOLYTIC EFFECT OF TriPollar TREATMENT

- **Glycerol dosage** - a statistically significant **increase in glycerol** amount in treated versus untreated tissue was detected
- **Histology** - modifications of the adipocytes in certain areas of the hypodermis were detected in treated tissue: Less homogenous shape of fat cells, elongated, irregular, shrunk, partially ruptured membrane

Untreated



After TriPollar treatment



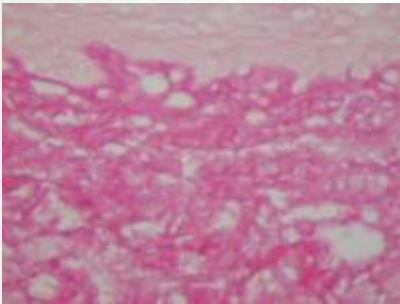
Glycerol dosage / g tissue

**Results indicate increased fat metabolism leading to fat reduction**

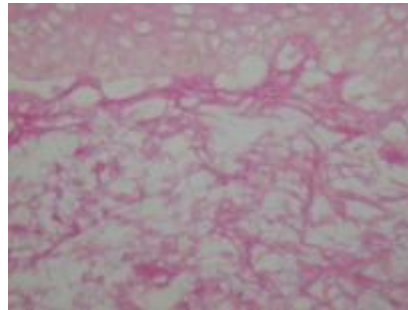
# ANTI – AGING EFFECT & SKIN VIABILITY

A skin aging model by UV radiation was used to evaluate collagen repair. Histology results below prove an **increase in collagen content**, leading to a dense, organized dermal layer.

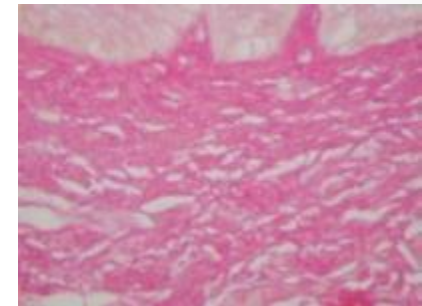
Untreated



UV



UV +TriPollar



**Collagen synthesis rate** in treated skin was increased by 28.9% as measured by biochemical methods (synthesis rate of 49.5  $\mu\text{g}/\text{mg}$  of skin vs. 38.4 for control skin).

**Skin Tolerance:** Analysis of skin cells viability and evaluation of mitochondrial activity showed excellent epidermal skin tolerance in treated skin (96.2%) as compared to non-treated skin (100%).

**Results indicate collagen regeneration, leading to firming/ tightening effect**

# Physician Testimonials

*“ This study presents objective facial improvement results following treatments with the TriPollar radiofrequency device and confirms previous reports on the safety and efficacy of this technology for the treatment of excess fat and body contouring. **The study demonstrates that there are no undesired changes in lipid profile and liver function following the procedure.***

*The treatment is painless and pleasant even when performed on sensitive areas with sagging and loose skin, such as the inner thighs, arms and neck. The TriPollar treatment is excellent for patients following pregnancy, liposuction or dramatic weight loss who have excessive loose skin. The treatment is also suitable for patients post face lift surgery, to improve the healing process. Following each treatment session, most patients benefitted from immediate as well as long term results.”*

**Alex Levenberg, M.D., Physicians Center, Plastic Surgery Dept., Tel Aviv, Israel**

# Physician Testimonials

*“Circumference and cellulite can be significantly and safely reduced with the use of the TriPollar RF technology.”*

Worophong Manuskiatti, M.D., Department of Dermatology & Department of Radiology, Faculty of Medicine,  
Siriraj Hospital, Mahidol University, Bangkok, Thailand

*“The TriPollar device is a high-power, multipolar, RF system that can safely and effectively be used for body contouring, particularly on the abdomen, thighs and arms, as well as for the treatment of cellulite, skin laxity and facial wrinkles. Application of this treatment modality is simple, non-invasive and extremely safe on all skin type. **Clinical and histological results have been documented and appear to be maintained for at least several months following a typical treatment course of 8 weekly sessions.**”*

Haim Kaplan, M.D. & Andrea Gat, M.D., Plastic Surgery Clinic, Tel Aviv, Israel & Dermatopathology Unit,  
Sourasky Medical Center, Tel Aviv Israel