



EXPECT MORE

## Pollogen Publications

Peer Reviewed Papers  
White papers

Sep 2014



# Scientific Publications - Introduction



- **Articles published in peer-reviewed scientific journals**
  - Content reviewed by experts (novelty, accuracy, research level).  
Not always accepted
  - Various standards of journals (impact factor)
  - Submitted article should present new data
  - Based on results from:
    - **Clinical study** aimed to evaluate safety and efficacy of new technology/ indication.  
Study follows protocol and forms, ethical committee approval (Helsinki, IRB), monitored, results substantiate regulatory clearance (FDA)
    - **'Doctor experience' study** – Patients' data, results and photos are documented and analyzed and Dr. publishes his experience
    - **Histology study**: human / animals, in vivo / ex-vivo
- **White papers**- Marketing material, technological/clinical content.
  - Designed like scientific articles but not submitted to journals
  - Issued quickly, no need to wait for journal reviewing process
  - Promoting newly launched technology with initial results
  - Presents results that were not accepted or not sufficient for journal

# Pollogen Publications

## 18 Articles published in peer-reviewed scientific journals:

- **15 published articles - Professional devices**

- 2 VO: *Gershonowitz in vivo animal 2014, VoluDerm Dr. Shapiro experience 2015*
- 1 HE: *Dr. Boisnic, ex-vivo human 2014 (Gag's)*
- 2 TF: *Levenberg –Dr. experience + histologies 2012, Gold - TF FDA study 2013*
- 1 Maximus: *Russian – face 2013*
- 9 TriPollar: *regen /apollo, face/body/acne, clinical/histology*

- **3 published articles - Home use devices**

Stop clinical/ Stop ex vivo histology/ Pose clinical + ex vivo histology

**6 White papers – Professional technologies** (Although there are ~10, 6 are useful such as about *geneo, Surgen, Maximus, TriPollar case studies (Kim, Buhsem)*)

# 15. VoluDerm Dr. experience USA



Authors	Published	Title	Protocol	Main Results
Steven D. Shapiro  USA  2015	Jacobs Journal of Experimental Dermatology	Voluderm Micro-Needle Technology for Treating Skin Laxity and Wrinkles-Initial Clinical Experience	Typical treatment protocol included 5 treatments; 3 treatments performed once a week and an additional 2 treatments spaced 2-3 weeks apart.	<ul style="list-style-type: none"> <li>• Skin volume enhancement along with improvement of skin texture and diminished appearance of wrinkles.</li> <li>• No significant adverse effects were detected.</li> <li>• <b>VoluDerm is a safe and effective micro-needle technology for dermal volumizing and treatment of wrinkles with minimal pain and no downtime.</b></li> </ul>



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

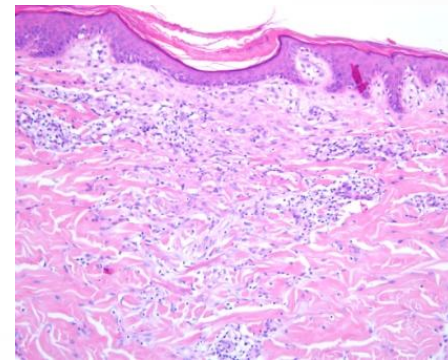
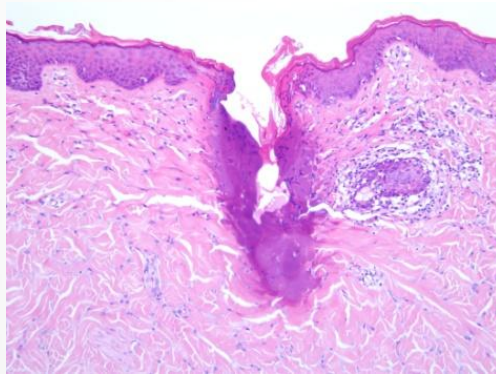


After 1 tx

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

# 14. VoluDerm In Vivo Animal Histology


Authors	Published	Title	Protocol	Main Results
Gershonowitz, Gat  Israel  2014	Journal of Cosmetics and Laser Therapy  	VoluDerm Microneedle Technology for Skin Treatments – In Vivo Histological Evidence.	<ul style="list-style-type: none"><li>• 2 pigs</li><li>• VO pulses at L,M,H levels</li><li>• Biopsies after 14, 7, 4 days and immediately</li></ul>	<ul style="list-style-type: none"><li>• Immediate VO epidermal and dermal effects</li><li>• Progress of healing process, as function of time following treatment (days 4 and 7)</li><li>• <b>Complete healing on Day 14 for all energy levels</b></li></ul>



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



# 13. Hybrid Energy Ex-vivo Human Histology

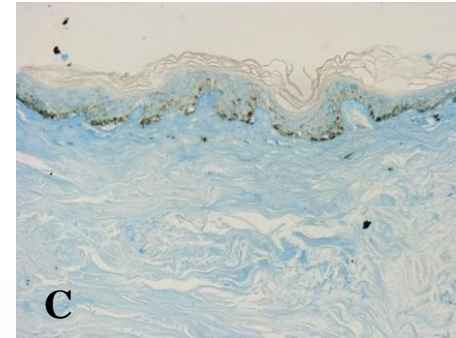
Authors	Published	Title	Protocol	Main Results
Boisnic, Branchet  <b>Paris</b>  <b>2014</b>	European Journal of Dermatology  	Ex vivo study of hybrid energy technology using a human skin model.	<ul style="list-style-type: none"> <li>• Skin fragments from donors undergoing facial lifts</li> <li>• Skin maintained in survival medium</li> <li>• Skin artificially aged by UV irradiation</li> <li>• Single HE treatment of Low or High energy</li> </ul>	<ul style="list-style-type: none"> <li>• <b>Significant collagen remodeling</b></li> <li>• <b>Significant increase in GAGs</b> (<i>hyaluronic acid (HA) is the most prominent GAG in the skin therefore results reflect HA content</i>)</li> <li>• Significant increase in epidermal renewal (mitotic index)</li> <li>• Effect intensity correlates to HE level</li> </ul>



**A:** UV aged control




**B:** UV aged +Low HE

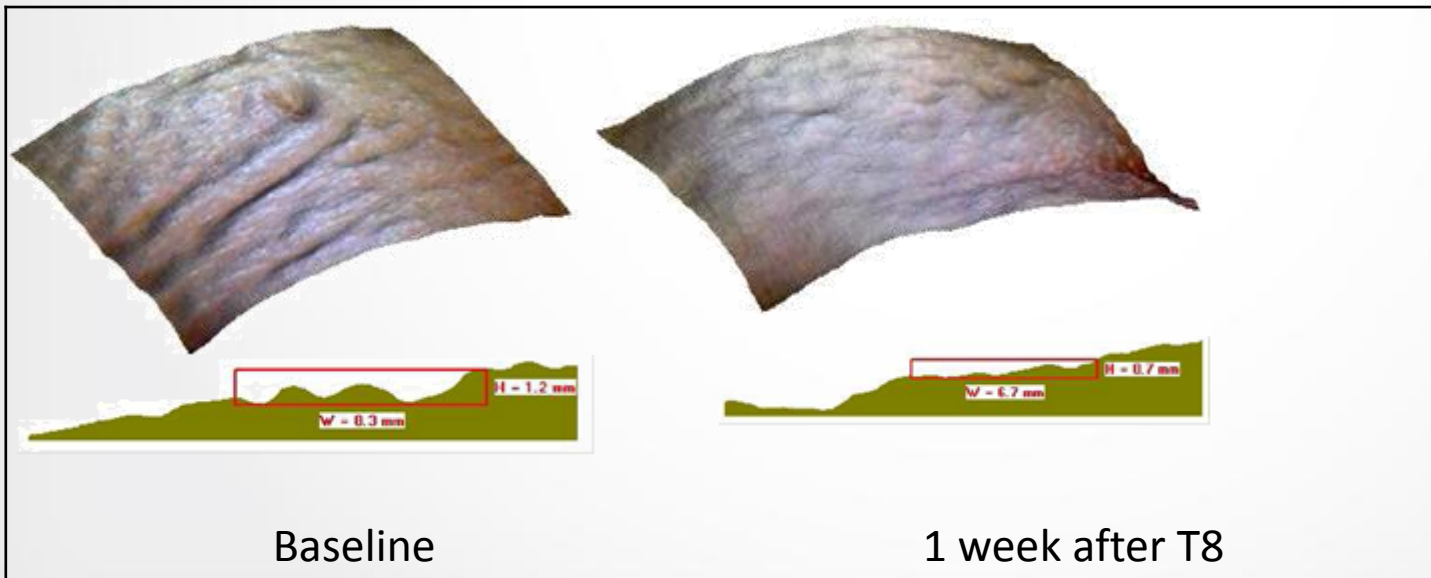


**C:** UV aged + High HE

GAGs augmentation in epidermis and dermis of treated fragments


# 12. Maximus Face

Authors	Published	Title	Protocol	Main Results
Potekaev, Zhukova  <b>Russia</b>  <b>2013</b>	Journal of Cosmetics, Dermatological Sciences and Applications  	Evaluation of Safety and efficacy of the Maximus™ System for facial wrinkles.	20 subjects, 8 weekly Txs Fu: 1w, 1m	<u>Visioscan &amp; microcamera:</u> <ul style="list-style-type: none"> <li>• <b>Reduction in depth and length of wrinkles</b></li> <li>• <b>Increased smoothness and Reduction in roughness</b></li> </ul> Significant improvement after 8 treatments, with additional improvement at 1 month follow-up. <u>Ultrasound:</u> Increased thickness and improved structural homogeneity of epidermal and dermal layers  <b>No adverse events or negative sensations</b>



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

# 11. TriFractional USA Clinical Study


Authors	Published	Title	Protocol	Main Results
Gold, Adelglass  USA  2013	Journal of Cosmetic and Laser Therapy  	Evaluation of Safety and Efficacy of the TriFractional RF technology for treatment of facial wrinkles.	<ul style="list-style-type: none"> <li>• 30 females and 2 males were recruited in 2 sites (30 completed)</li> <li>• 3 TF facial treatments once every 3 weeks. FU: 1 and 3 months after last treatment</li> <li>• Baseline and 3 m fu photos were graded using the Fitzpatrick Wrinkle Scale by 2 'blinded' doctors</li> <li>• Any wrinkle score improvement (downgrade of at least 1 score) at 3m fu compared to baseline, was considered a success</li> </ul>	<ul style="list-style-type: none"> <li>• <b>Both 'blinded' doctors revealed improvement in the majority of subjects (80% and 73.3%)</b></li> <li>• Investigators evaluation of subject's Fitzpatrick Wrinkle Scores revealed reduction from an average baseline score of 4.8 to 3.4 at 3 m fu</li> <li>• Majority of subjects (83.3%) noted that treatment results met their expectations or to some extent, and 70% indicated that they will recommend the TF treatment to their friends.</li> <li>• No unexpected adverse effects were detected or reported</li> </ul>



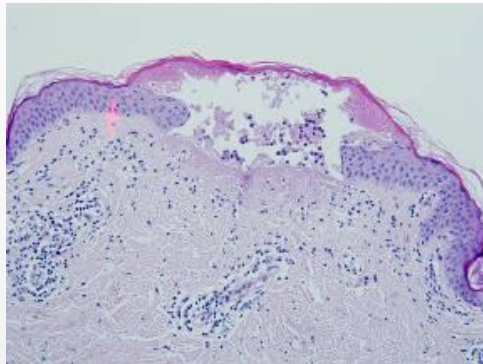
A 64 year old female, skin type V, Before (left) and 3 month after 3 TF treatments (right)



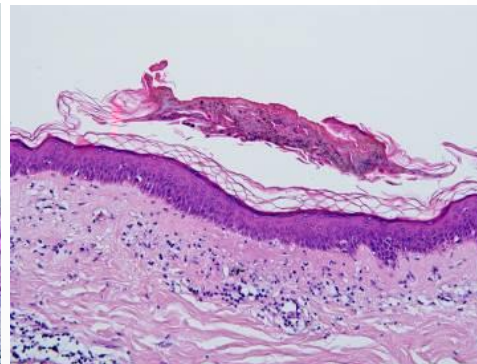
# 10. TriFractional Dr. Experience + Histology

Authors	Published	Title	Protocol	Main Results
Levenberg, Gat, Boinsic, Branchet  Israel, France  2012	Journal of Cosmetics, Dermatological Sciences and Applications  	Treatment of Wrinkles and Acne Scars using the TriFractional, a Novel Fractional Radiofrequency Technology – Clinical and Histological Results	<ul style="list-style-type: none"> <li>• <b>Clinical:</b> TriFractional and Complete TriLipo Med™ Procedure treatments</li> <li>• <b>Histology:</b> In- vivo human abdominal skin</li> <li>• Pulses performed one week and one day before abdominoplasty surgery</li> <li>• Skin samples were taken for histology</li> <li>• Ex vivo human and in vivo porcine histologies were also presented</li> </ul>	<p><b>Clinical:</b></p> <ul style="list-style-type: none"> <li>• <b>Added value of TriLipo MED:</b> (TriFractional + TriLipo RF and DMA)                             <ul style="list-style-type: none"> <li>• Additional facial contouring</li> <li>• Optimal for Acne scars</li> </ul> </li> <li>• No significant undesired effects</li> <li>• Subjects reported tolerable pain and satisfaction with clinical results</li> </ul> <p><b>Histology:</b></p> <ul style="list-style-type: none"> <li>• <b>Shows healing process</b></li> <li>• Ex-vivo results support in-vivo findings</li> <li>• <b>Ex-vivo: 15.5% increase of collagen content in treated vs. control</b></li> </ul>

- Epidermal necrosis
- Collagen contraction
- Neutrophilic infiltrate




post treatment: 1 day



1week

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


# 9. Apollo FDA clinical Study

Authors	Published	Title	Protocol	Main Results
Shapiro, Eros, Abrahami, Leviav  <b>USA, Israel</b>  <b>2012</b>	Lasers in Surgery and Medicine  	Evaluation of Safety and Efficacy of the TriPollar Technology for Treatment of Wrinkles	<ul style="list-style-type: none"> <li>• 37 subjects were recruited in 2 sites (37 completed treatments, 3 lost to fu)</li> <li>• 8 apollo facial treatments once a week. FU: 1 and 3 months after last treatment</li> <li>• Baseline and 3 m fu photos were graded using the Fitzpatrick Wrinkle Scale by 2 'blinded' doctors</li> <li>• Any wrinkle score improvement (downgrade of at least 1 score) at 3m fu compared to baseline, was considered a success</li> </ul>	<ul style="list-style-type: none"> <li>• <b>A downgrade of at least 1 score in Fitzpatrick scale was found in 94% (1st reviewer) and 97% (2nd reviewer) of study subjects.</b></li> <li>• Subjects satisfaction: high level of satisfaction.</li> <li>• Investigators scoring of subjects' facial skin appearance demonstrated average reduction of 1.55 (Dr. Leviav) and 2.4 (Dr. Shapiro).</li> <li>• No unexpected adverse effects were detected or reported</li> </ul>



A 51 year old female, Before (left) and 3 month after 8 treatments (right)

# 8. TriPollar Acne Study

Authors	Published	Title	Protocol	Main Results
Yu, Huang Philippines 2011	Journal of Cosmetic and Laser Therapy 	Use of a TriPollar radio- frequency device for the treatment of acne vulgaris	<ul style="list-style-type: none"> <li>• 20 patients</li> <li>• 6 weekly Apollo treatments ; FU 4 weeks after last visit</li> <li>• 13 patients completed all visits, 4 completed 4 treatments, withdrawal was for personal reasons, not treatment related.</li> <li>• Evaluation methods:                             <ul style="list-style-type: none"> <li>○ Photographs</li> <li>○ Count of active lesion</li> <li>○ Patients satisfaction rating on a 5 score scale</li> </ul> </li> </ul>	<ul style="list-style-type: none"> <li>• <b>Average reduction - 42% in active acne lesions after 6 TriPollar sessions</b></li> <li>• Reduction sustained at 4 weeks follow up visit.</li> <li>• Patient satisfaction rate: 2.5 indicating good to very good satisfaction with the clinical results.</li> <li>• No significant adverse events were recorded</li> </ul>

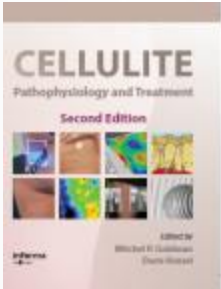
BASELINE 27Y/OFEMALE

AFTER 6 TREATMENTS


4 WEEKSFU



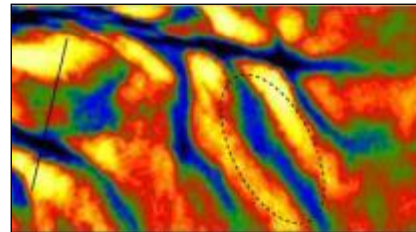
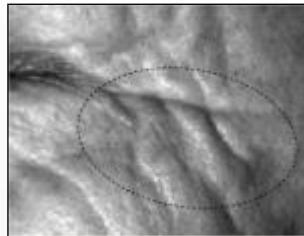
# 7. TriPollar Chapter in Cellulite Book

Authors	Published	Title	Content
<p>Manuskiatti (Woraphong)</p> <p>Thailand</p> <p>2010</p>	<p>Cellulite Pathophysiology and Treatment. 2010 Second Edition, Editors: Mitchel P. Goldman and Doris Hexsel.</p> 	<p>TriPollar® Radiofrequency</p>	<ul style="list-style-type: none"> <li>• The chapter reviews the <b>advantages of TriPollar RF over mono and bipolar RF</b></li> <li>• Provides an overview of treatment technique</li> <li>• Reviews studies using the regen and apollo TriPollar RF systems</li> </ul>

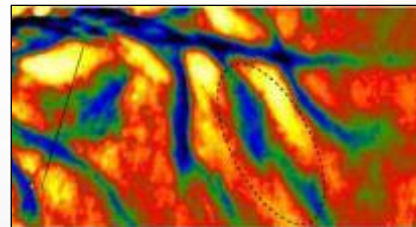
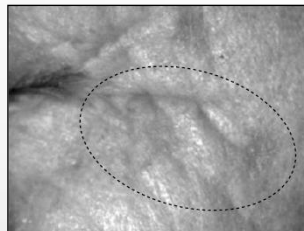
# 6. Apollo face and Body – Clinical Experience

Authors	Published	Title	Protocol	Main Results
Levenberg  Israel  2010	European Journal of Dermatology  	Clinical Experience with a TriPollar® Radiofrequency system for Facial and Body Aesthetic treatments	<ul style="list-style-type: none"> <li>• 37 female patients</li> <li>• Average of 7 treatments (wrinkles, laxity, circumference reduction)</li> <li>• 5 patients had blood tests to assess liver function and lipid profile following treatment</li> <li>• Evaluation:                             <ul style="list-style-type: none"> <li>○ Facial results objectively analyzed with Primos 3D imaging system</li> <li>○ Circumferential measurements.</li> <li>○ Blood tests</li> </ul> </li> </ul>	<ul style="list-style-type: none"> <li>• <b>Average circumference reduction, in main body areas (abdomen, buttocks, thighs): 3.6cm</b></li> <li>• <b>No statistically significant changes were found in any of the liver function and lipid profile indicators</b></li> </ul>

Before




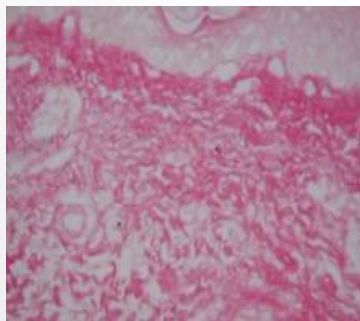
After 8 Tx



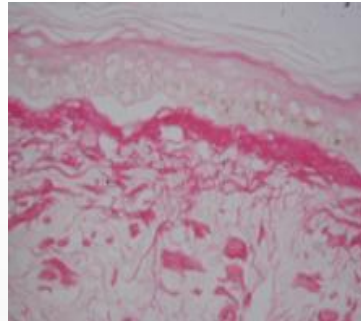


# 5. TriPollar Ex-vivo Human Histologies

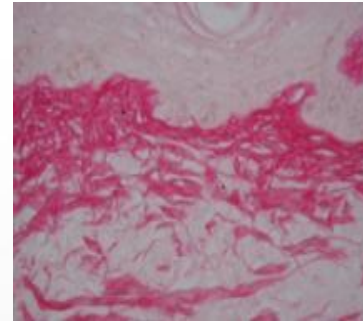
Authors	Published	Title	Protocol	Main Results
Boisnic, Branchet  Paris  2010	Journal of Cosmetics and Laser Therapy  	Ex vivo human skin evaluation of localized fat reduction and anti aging effect by TriPollar® radiofrequency treatments.	<ul style="list-style-type: none"> <li>Human skin samples from 8 abdominoplasty and 4 face lifts</li> <li>Kept in survival medium, sterile conditions, 37°C</li> </ul> <p><b>TriPollar lipolytic effect :</b> Glycerol released from hypodermis was measured (enzymatic methods)</p> <p><b>TriPollar anti-aging effect :</b></p> <ul style="list-style-type: none"> <li>Aging of skin samples by UV radiation</li> <li>evaluation of collagen quantity (computerized methods)</li> <li>Collagen synthesis rate (biochemical methods)</li> </ul>	<ul style="list-style-type: none"> <li><b>Increase of glycerol release in treated skin samples (120%)</b></li> <li>Change in structure of fat cells: less homogenous, shrunk, partially ruptured membrane, thinning of fibrous tract</li> <li>Histological quantification of dermal collagen (computerized image analysis): significant increase in superficial and mid dermis collagen</li> <li>Fibroblasts activity for collagen synthesis (biochemical methods) increased significantly in treated skin vs. UV exposed</li> </ul>



Untreated




UV



UV+Treated

# 4. TriPollar Stretch Marks Treatment



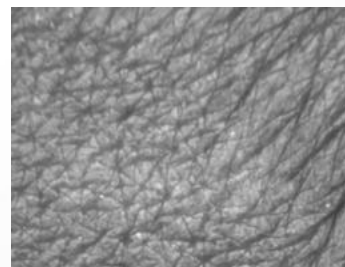
Authors	Published	Title	Protocol	Main Results
Manuskiatti (Woraphong) et al.  <b>Thailand</b>  <b>2009</b>	Journal of Dermatological Treatment  	Treatment of striae distensae with a TriPollar radiofrequency device: A pilot study	<ul style="list-style-type: none"> <li>• 17 females with stretch marks received 6 weekly treatments with the Apollo</li> <li>• Follow up: 1 and 6 weeks after the final treatment</li> <li>• Photos of stretch marks - improvement scored by 2 blinded evaluators</li> <li>• UVA-light video camera - for skin texture observation</li> <li>• Subjects satisfaction</li> </ul>	<ul style="list-style-type: none"> <li>• <b>Evaluators' scores:</b> 6 weeks FU - a higher percentage of subjects were rated to have improvement compared to 1 week FU. 26.5% showing 51%-75% and 5.9% showed &gt;75% improvement.</li> <li>• <b>Satisfaction:</b> 65% (11/17) - very satisfied 23 % (4/17) – satisfied 12% (2/17) - slightly satisfied</li> </ul>



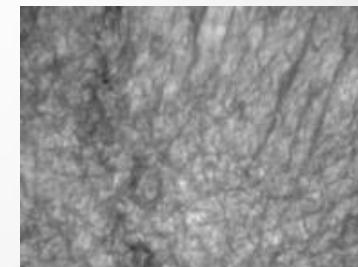
Before



After




Before

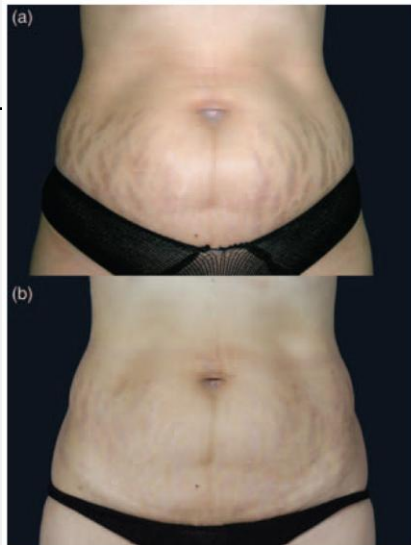


After

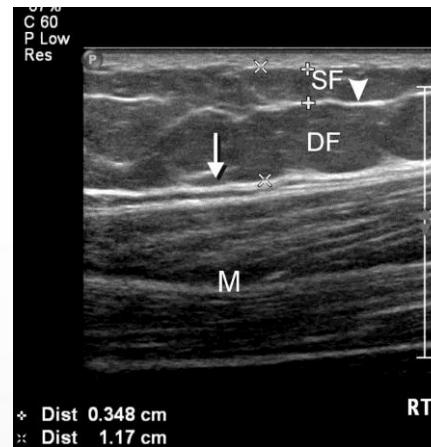
# 3. TriPollar Circumference & Cellulite Treatment



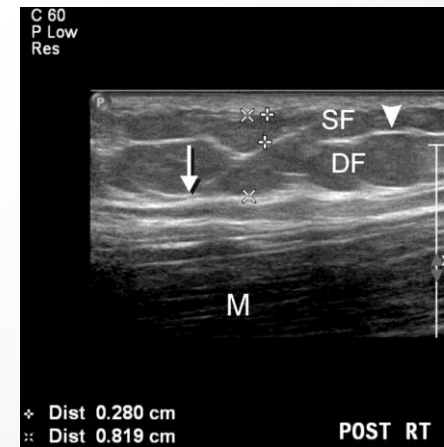
Authors	Published	Title	Protocol	Main Results <small>EXPECT MORE</small>
Manuskiatti (Woraphong) et al.  Thailand  2009	Journal European Academy of Dermatology and Venerology  	Circumference reduction and cellulite treatment with a TriPollar radiofrequency device: A pilot study.	<ul style="list-style-type: none"> <li>39 females with cellulite (at least grade II)</li> <li>81 treated anatomical sites : Thigh, Abdomen, Buttock, Arm</li> <li>8 weekly treatments</li> <li>FU: 4 weeks after last Trt.</li> <li><b>Evaluation</b> <ul style="list-style-type: none"> <li>Circumferential measurements</li> <li>Ultrasound measurement of subcutaneous fat thickness</li> <li>Rating of cellulite improvement by subjects</li> </ul> </li> </ul>	<p><b>Average circumference reduction:</b></p> <ul style="list-style-type: none"> <li>3.5cm at the abdomen</li> <li>1.7cm at the thigh</li> </ul> <p><b>US measurements thigh region:</b> Average reduction of 10.5% in the thickness of adipose tissue</p> <p><b>Cellulite Appearance:</b> Average improvement of cellulite appearance, as rated by the patients was 2.32 (~60%) after the treatments</p>



**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.






Before



After

## 2. TriPollar In vivo Histology

Authors	Published	Title	Protocol	Main Results
<p>Kaplan Gat</p> <p>Israel</p> <p>2009</p>	<p>Journal of Cosmetic and Laser Therapy</p> 	<p>Clinical and Histopathological results following TriPollar® radiofrequency skin treatments</p>	<ul style="list-style-type: none"> <li>• Abdominal patient consented to a series of TriPollar treatments prior to her scheduled abdominoplasty</li> <li>• <b>Only one side of her abdomen was treated</b></li> <li>• Histopathology analysis was performed</li> </ul>	<ul style="list-style-type: none"> <li>• <b>Dermal thickness increased by 49% on average</b></li> <li>• <b>Focal thickening of collagen fibers</b></li> </ul>   <ul style="list-style-type: none"> <li>• In some areas fat cells appear to be smaller with irregular shape</li> </ul>



Before



After 5 Trx



Immed After 6<sup>th</sup> Trx

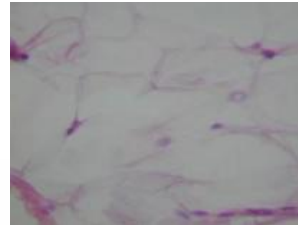
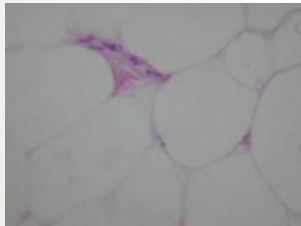


# 1. TriPollar Ex-vivo Human Histologies

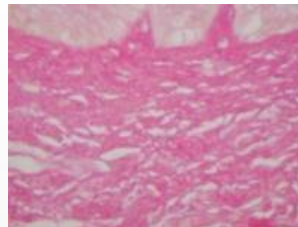
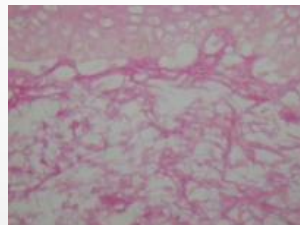
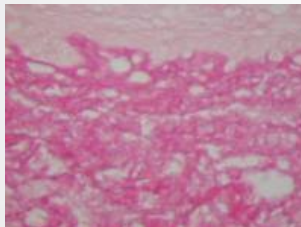


Authors	Published	Title	Protocol	Main Results
Boisnic <b>France</b>  2008	Nouv. Dermatol (In French)  	An Ex-Vivo study of the regen™ TriPollar RF device using an experimental human skin model.	<ul style="list-style-type: none"> <li>8 human skin fragments after Tummy tuck</li> <li>A TriPollar treatment in same conditions as in vivo</li> <li>Samples kept in sterile survival medium for up to 20 days at 37°C</li> <li>Skin aging by UV radiation was used to evaluate collagen repair</li> </ul>	<ul style="list-style-type: none"> <li><b>Glycerol dosage</b> - increase in glycerol amount in treated versus untreated tissue was detected</li> <li><b>Histology - fat cells</b> in treated tissue: Less homogenous shape, elongated, irregular, shrunk, partially ruptured membrane</li> <li>Histology prove <b>an increase in collagen content</b>, leading to dense, organized dermal layer.</li> <li><b>Collagen synthesis rate</b> in treated skin increased by <b>28.9%</b></li> </ul>

Fat



Collagen



Untreated

UV

TriPollar

