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))
<table>
<thead>
<tr>
<th>Authors</th>
<th>Published</th>
<th>Title</th>
<th>Protocol</th>
<th>Main Results</th>
</tr>
</thead>
</table>
| 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. | • Skin volume enhancement along with improvement of skin texture and diminished appearance of wrinkles.  
• No significant adverse effects were detected.  
• VoluDerm is a safe and effective micro-needle technology for dermal volumizing and treatment of wrinkles with minimal pain and no downtime.                                                                                                                                                                                                 |

**Before**

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

**After 5 tx**

**Before**

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

**After 1 tx**
## 14. VoluDerm In Vivo Animal Histology

<table>
<thead>
<tr>
<th>Authors</th>
<th>Published</th>
<th>Title</th>
<th>Protocol</th>
<th>Main Results</th>
</tr>
</thead>
</table>
| Gershonowitz, G<br>Gat Israel<br>2014 | Journal of Cosmetics and Laser Therapy | VoluDerm Microneedle Technology for Skin Treatments – In Vivo Histological Evidence. | • 2 pigs  
• VO pulses at L,M,H levels  
• Biopsies after 14, 7, 4 days and immediately | • Immediate VO epidermal and dermal effects  
• Progress of healing process, as function of time following treatment (days 4 and 7)  
• Complete healing on Day 14 for all energy levels |

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

<table>
<thead>
<tr>
<th>Authors</th>
<th>Published</th>
<th>Title</th>
<th>Protocol</th>
<th>Main Results</th>
</tr>
</thead>
</table>
| Boisnic, Branchet Paris 2014 | European Journal of Dermatology | Ex vivo study of hybrid energy technology using a human skin model. | • Skin fragments from donors undergoing facial lifts  
• Skin maintained in survival medium  
• Skin artificially aged by UV irradiation  
• Single HE treatment of Low or High energy | • Significant collagen remodeling  
• Significant increase in GAGs *(hyaluronic acid (HA) is the most prominent GAG in the skin therefore results reflect HA content)*  
• Significant increase in epidermal renewal (mitotic index)  
• Effect intensity correlates to HE level |

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

<table>
<thead>
<tr>
<th>Authors</th>
<th>Published</th>
<th>Title</th>
<th>Protocol</th>
<th>Main Results</th>
</tr>
</thead>
</table>
| Potekaev, Zhukova,  | *Journal of Cosmetics, Dermatological Sciences* | Evaluation of Safety and efficacy of the Maximus™ System for facial   | 20 subjects, 8 weekly Txs Fu: 1w, 1m | **Visioscan & microcamera:**  
  • **Reduction in depth and length of wrinkles**  
  • **Increased smoothness and Reduction in roughness**  
  Significant improvement after 8 treatments, with additional improvement at 1 month follow-up.  
  **Ultrasound:**  
  Increased thickness and improved structural homogeneity of epidermal and dermal layers  
  No adverse events or negative sensations |
| Russia 2013         | *Dermatological Sciences and Applications*     | wrinkles.                                                             |                                 |                                                                                                                     |

### Images

- **Baseline**
- **1 week after T8**

*3D Imaging of "Crow’s feet" wrinkle area & sectional drawing of the skin test area*
## 11. TriFractional USA Clinical Study

<table>
<thead>
<tr>
<th>Authors</th>
<th>Published</th>
<th>Title</th>
<th>Protocol</th>
<th>Main Results</th>
</tr>
</thead>
</table>
| Gold, Adelglass  | Journal of Cosmetic and Laser Therapy | Evaluation of Safety and Efficacy of the TriFractional RF technology for treatment of facial wrinkles. | • 30 females and 2 males were recruited in 2 sites (30 completed)  
• 3 TF facial treatments once every 3 weeks. FU: 1 and 3 months after last treatment  
• Baseline and 3 m fu photos were graded using the Fitzpatrick Wrinkle Scale by 2 ‘blinded’ doctors  
• Any wrinkle score improvement (downgrade of at least 1 score) at 3m fu compared to baseline, was considered a success | • Both ‘blinded’ doctors revealed improvement in the majority of subjects (80% and 73.3%)  
• 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  
• 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.  
• No unexpected adverse effects were detected or reported |

A 64 year old female, skin type V, Before (left) and 3 month after 3 TF treatments (right)
### 10. TriFractional Dr. Experience + Histology

<table>
<thead>
<tr>
<th>Authors</th>
<th>Published</th>
<th>Title</th>
<th>Protocol</th>
<th>Main Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Levenberg, Gat, Boisnic, Branchet</td>
<td>Israel, France 2012</td>
<td>Treatment of Wrinkles and Acne Scars using the TriFractional, a Novel Fractional Radiofrequency Technology – Clinical and Histological Results</td>
<td>• <strong>Clinical:</strong> TriFractional and Complete TriLipo Med™ Procedure treatments  &lt;br&gt; • <strong>Histology:</strong> In-vivo human abdominal skin  &lt;br&gt; • Pulses performed one week and one day before abdominoplasty surgery  &lt;br&gt; • Skin samples were taken for histology  &lt;br&gt; • Ex vivo human and in vivo porcine histologies were also presented</td>
<td><strong>Clinical:</strong>  &lt;br&gt; • <strong>Added value of TriLipo MED:</strong> (TriFractional + TriLipo RF and DMA)  &lt;br&gt; • Additional facial contouring  &lt;br&gt; • Optimal for Acne scars  &lt;br&gt; • No significant undesired effects  &lt;br&gt; • Subjects reported tolerable pain and satisfaction with clinical results  &lt;br&gt; <strong>Histology:</strong>  &lt;br&gt; • <strong>Shows healing process</strong>  &lt;br&gt; • Ex-vivo results support in-vivo findings  &lt;br&gt; • Ex-vivo: <strong>15.5% increase of collagen content in treated vs. control</strong></td>
</tr>
</tbody>
</table>

- Epidermal necrosis  
- Collagen contraction  
- Neutrophilic infiltrate  

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

post treatment: 1 day  
1 week
## 9. Apollo FDA clinical Study

<table>
<thead>
<tr>
<th>Authors</th>
<th>Published</th>
<th>Title</th>
<th>Protocol</th>
<th>Main Results</th>
</tr>
</thead>
</table>
| Shapiro, Eros,        | Lasers in Surgery and      | Evaluation of Safety and Efficacy of the TriPollar Technology for     | • 37 subjects were recruited in 2 sites (37 completed treatments, 3 lost to fu)  
• 8 apollo facial treatments once a week. FU: 1 and 3 months after last treatment  
• Baseline and 3 m fu photos were graded using the Fitzpatrick Wrinkle Scale by 2 ‘blinded’ doctors  
• Any wrinkle score improvement (downgrade of at least 1 score) at 3m fu compared to baseline, was considered a success | • A downgrade of at least 1 score in Fitzpatrick scale was found in 94% (1st reviewer) and 97% (2nd reviewer) of study subjects.  
• Subjects satisfaction: high level of satisfaction.  
• Investigators scoring of subjects’ facial skin appearance demonstrated average reduction of 1.55 (Dr. Leviav) and 2.4 (Dr. Shapiro).  
• No unexpected adverse effects were detected or reported |
| Abrahami, Leviav      | Medicine                  | Treatment of Wrinkles                                                |                                                                                                                                                                                                          |                                                                                                                                                                                                                                                                                                                                                                                                    |
| USA, Israel           | 2012                      |                                                                      |                                                                                                                                                                                                          |                                                                                                                                                                                                                                                                                                                                                                                                    |

| ![A 51 year old female, Before (left) and 3 month after 8 treatments (right)](image-url) |
8. TriPollar Acne Study

<table>
<thead>
<tr>
<th>Authors</th>
<th>Published</th>
<th>Title</th>
<th>Protocol</th>
<th>Main Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yu, Huang</td>
<td>Journal of Cosmetic and Laser Therapy</td>
<td>Use of a TriPollar radio-frequency device for the treatment of acne vulgaris</td>
<td>• 20 patients</td>
<td>Average reduction - 42% in active acne lesions after 6 TriPollar sessions</td>
</tr>
<tr>
<td>Philippines</td>
<td></td>
<td></td>
<td>• 6 weekly Apollo treatments ; FU 4 weeks after last visit</td>
<td>• Reduction sustained at 4 weeks follow up visit.</td>
</tr>
<tr>
<td>2011</td>
<td></td>
<td></td>
<td>• 13 patients completed all visits, 4 completed 4 treatments, withdrawal was for personal reasons, not treatment related.</td>
<td>• Patient satisfaction rate: 2.5 indicating good to very good satisfaction with the clinical results.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Evaluation methods:</td>
<td>• No significant adverse events were recorded</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>o Photographs</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>o Count of active lesion</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>o Patients satisfaction rating on a 5 score scale</td>
<td></td>
</tr>
</tbody>
</table>
7. TriPollar Chapter in Cellulite Book

<table>
<thead>
<tr>
<th>Authors</th>
<th>Published</th>
<th>Title</th>
<th>Content</th>
</tr>
</thead>
<tbody>
<tr>
<td>Manuskiatti (Woraphong)</td>
<td>Cellulite Pathophysiology and Treatment. 2010 Second Edition, Editors: Mitchel P. Goldman and Doris Hexsel.</td>
<td>TriPollar® Radiofrequency</td>
<td>• The chapter reviews the advantages of TriPollar RF over mono and bipolar RF</td>
</tr>
<tr>
<td>Thailand</td>
<td></td>
<td></td>
<td>• Provides an overview of treatment technique</td>
</tr>
<tr>
<td>2010</td>
<td></td>
<td></td>
<td>• Reviews studies using the regen and apollo TriPollar RF systems</td>
</tr>
</tbody>
</table>
### 6. Apollo face and Body – Clinical Experience

<table>
<thead>
<tr>
<th>Authors</th>
<th>Published</th>
<th>Title</th>
<th>Protocol</th>
<th>Main Results</th>
</tr>
</thead>
</table>
| Levenberg Israel | European Journal of Dermatology | Clinical Experience with a TriPollar® Radiofrequency system for Facial and Body Aesthetic treatments | • 37 female patients  
• Average of 7 treatments (wrinkles, laxity, circumference reduction)  
• 5 patients had blood tests to assess liver function and lipid profile following treatment  
  • Evaluation:  
    o Facial results objectively analyzed with Primos 3D imaging system  
    o Circumferential measurements.  
    o Blood tests | • Average circumference reduction, in main body areas (abdomen, buttocks, thighs): 3.6cm  
• No statistically significant changes were found in any of the liver function and lipid profile indicators |

#### Before

![Before Image](before_image.png)

#### After 8 Tx

![After Image](after_image.png)
### 5. TriPollar Ex-vivo Human Histologies

<table>
<thead>
<tr>
<th>Authors</th>
<th>Published</th>
<th>Title</th>
<th>Protocol</th>
<th>Main Results</th>
</tr>
</thead>
</table>
| Boisnic, Branchet   | Journal of Cosmetics and Laser Therapy | Ex vivo human skin evaluation of localized fat reduction and anti aging effect by TriPollar® radiofrequency treatments. | • Human skin samples from 8 abdominoplasty and 4 face lifts  
  • Kept in survival medium, sterile conditions, 37°C  
**TriPollar lipolytic effect:** Glycerol released from hypodermis was measured (enzymatic methods)  
**TriPollar anti-aging effect:**  
• Aging of skin samples by UV radiation  
• evaluation of collagen quantity (computerized methods)  
• Collagen synthesis rate (biochemical methods) | • Increase of glycerol release in treated skin samples (120%)  
• Change in structure of fat cells: less homogenous, shrunk, partially ruptured membrane, thinning of fibrous tract  
• Histological quantification of dermal collagen (computerized image analysis): significant increase in superficial and mid dermis collagen  
• Fibroblasts activity for collagen synthesis (biochemical methods) increased significantly in treated skin vs. UV exposed |

![TriPollar Ex-vivo Human Histologies](untreated, UV, UV+Treated)
4. TriPollar Stretch Marks Treatment

<table>
<thead>
<tr>
<th>Authors</th>
<th>Published</th>
<th>Title</th>
<th>Protocol</th>
<th>Main Results</th>
</tr>
</thead>
</table>
| Manuskiatti et al. (Woraphong) | Journal of Dermatological Treatment | Treatment of striae distensae with a TriPollar radiofrequency device: A pilot study | • 17 females with stretch marks received 6 weekly treatments with the Apollo  
• Follow up: 1 and 6 weeks after the final treatment  
• Photos of stretch marks - improvement scored by 2 blinded evaluators  
• UVA-light video camera - for skin texture observation  
• Subjects satisfaction | • **Evaluators’ scores:**  
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 >75% improvement.  
• **Satisfaction:**  
65% (11/17) - very satisfied  
23 % (4/17) – satisfied  
12% (2/17) - slightly satisfied |

![Before](image1.png)    ![After](image2.png)  

![Before](image3.png)    ![After](image4.png)
### 3. TriPollar Circumference & Cellulite Treatment

<table>
<thead>
<tr>
<th>Authors</th>
<th>Published</th>
<th>Title</th>
<th>Protocol</th>
<th>Main Results</th>
</tr>
</thead>
</table>
| Manuskiatti (Woraphong) et al. | Journal European Academy of Dermatology and Venerology | Circumference reduction and cellulite treatment with a TriPollar radiofrequency device: A pilot study. | - 39 females with cellulite (at least grade II)  
- 81 treated anatomical sites: Thigh, Abdomen, Buttock, Arm  
- 8 weekly treatments  
- FU: 4 weeks after last Trt.  
- Evaluation  
  - Circumferential measurements  
  - Ultrasound measurement of subcutaneous fat thickness  
  - Rating of cellulite improvement by subjects | Average circumference reduction:  
- 3.5cm at the abdomen  
- 1.7cm at the thigh  
US measurements thigh region: Average reduction of 10.5% in the thickness of adipose tissue  
Cellulite Appearance: Average improvement of cellulite appearance, as rated by the patients was 2.32 (~60%) after the treatments |

**Before**

![Figure 3. 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.](image)

**After**

![Before](image) ![After](image)
2. TriPollar In vivo Histology

| Authors       | Published                  | Title                                                                 | Protocol                                                                 | Main Results                                                                                           |
|---------------|----------------------------|                                                                     |                                                                          |                                                                                                         |
| Kaplan, Gat   | Journal of Cosmetic and Laser Therapy | Clinical and Histopathological results following TriPollar® radiofrequency skin treatments | • Abdominal patient consented to a series of TriPollar treatments prior to her scheduled abdominoplasty   | • Dermal thickness increased by 49% on average                                                           |
| Israel        |                            |                                                                      | • Only one side of her abdomen was treated                               | • Focal thickening of collagen fibers                                                                  |
| 2009          |                            |                                                                      | • Histopathology analysis was performed                                 | • In some areas fat cells appear to be smaller with irregular shape                                     |

![Before](image1.png)  ![After 5 Trx](image2.png)  ![Immed After 6th Trx](image3.png)
### 1. TriPollar Ex-vivo Human Histologies

<table>
<thead>
<tr>
<th>Authors</th>
<th>Published</th>
<th>Title</th>
<th>Protocol</th>
<th>Main Results</th>
</tr>
</thead>
</table>
| Boisnic France | Nov. Dermatol (In French) | An Ex-Vivo study of the regen™ TriPollar RF device using an experimental human skin model. | 8 human skin fragments after Tummy tuck  
A TriPollar treatment in same conditions as in vivo  
Samples kept in sterile survival medium for up to 20 days at 37°C  
Skin aging by UV radiation was used to evaluate collagen repair | **Glycerol dosage** - increase in glycerol amount in treated versus untreated tissue was detected  
**Histology** - fat cells in treated tissue: Less homogenous shape, elongated, irregular, shrunk, partially ruptured membrane  
Histology prove an increase in collagen content, leading to dense, organized dermal layer.  
Collagen synthesis rate in treated skin increased by 28.9% |

#### Fat

![Fat untreated](image1)  
![Fat UV](image2)  
![Fat TriPollar](image3)

#### Collagen

![Collagen untreated](image4)  
![Collagen UV](image5)  
![Collagen TriPollar](image6)

![Graph](image7)