Introducing SCAAR FX for UltraPulse
We’ve taken CO₂ lasers to the limit

Physician Presentation (May 2012)
Ann Berzak

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Agenda

- UltraPulse – History of Firsts
- The SCAR Market
- The UltraPulse SCAAR Story
- What is SCAAR FX?
- SCAAR FX Mode
- SCAAR FX Clinical Proof
- The SCAAR Story Continues
UltraPulse - A History of Firsts

Lumenis – Carrying the Gold Standard in CO₂ Lasers

1973
First CO₂ laser supplied to Albert Einstein Hospital

1986
Introduced 1020 CO₂ for surgical applications

1998
Introduced UltraPulse Encore; revolutionized aesthetic laser industry

2005
Launched ActiveFX, the world’s first Fractional CO₂

2007
Launched DeepFX, the world’s first micro-fractional CO₂

1980
Introduced SuperPulse CO₂, established as the standard in modern laser applications

1990
Introduced UltraPulse technology

2002
Received FDA approval for UltraPulse SurgiTouch; the world’s first application-guided pulsed CO₂ laser

2012
Launched SCAAR FX, the world’s first fractional CO₂ to impact up to 4.0mm for effective treatment of conspicuous, complex scars

UltraPulse
ActiveFX | DeepFX \ TotalFX | SCAAR FX
UltraPulse®: The Gold Standard CO₂

UltraScan™ CPG
Spot Size: 1.3 mm
Depth: 10-300 μm
Density: 55-100%

Used in Active FX™ and Total FX™

Microscanner
Spot Size: 0.12 mm
Depth: 100-3500 μm
Density: 1-25%

Used in Deep FX™, Total FX™ and SCAAR FX™
UltraPulse - Optimal Versatility

- Fine lines
- Blepharoplasty
- Syringoma
- Actinic keratosis
- Deep wrinkles
- Acne scars
- Surgical scars
- Dyschromia

Some of the 34 FDA cleared dermatology and plastic surgery indications
SCAR Market
Scar Market Size

- **Scar Revision***
  - 162,803 procedures (2008) vs 150,080 (2007), increase of 8%

- **Burn Care***
  - 19,501 procedures (2008) vs 18,141 (2007), increase of 7%
  - 240 Burns Centers (USA) with market potential of $33 M
  - International burn treatment facilities estimated at $60 M

*2009 ASPS USA Statistics
USA & International Burn Incidence Rates

In USA
- 70% of burn patients are men. Mean age - 32 years old.
- Children younger than 5 accounted for 17% of cases.
- Patients age 60+ represented 12% of cases.
- Etiologies were fire/flame and scalds. Scald injuries are most prevalent in children under 5, while fire/flame injuries dominate the remaining age categories.

Outside of USA
- 80% of burn patients are women and children.
- Etiologies were domestic violence and open fire cooking.
- Severe social stigma and poor acceptance.

Scar Market Potential - Caesarean Sections Scars

- **Caesarean section surgical scars**
  - 20% of all UK births are C-sections
  - 22% of all Canadian births are C-sections
  - 32% of all US births are C-sections
  - 35% of all Brazilian births are C-sections
  - A remarkable 46% of all births in China are C-sections

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1 CTV
2 National Center for Health Statistics
3 Medical News Today, Jan. 15, 2010
Types of Scars

**Hypertrophic scars:** Elevated scars that do not develop beyond the site of injury or incision.

**Keloid scars:** Overgrowth of scar tissue that grows beyond the site of the injury.

**Contracture scars:** Permanent skin tightening that may affect the underlying muscles and tendons and limit mobility, possible damage or degeneration of nerves.

**Atrophic scars:** Depressed scars caused by loss of tissue.

Photos courtesy J. Waibel, M.D.
Clinical Aspects of Various Scars

- Scars, such as surgical scars, have various side effects:
  - Complications
  - Pain
  - Poor range of motion
  - Wound closure

- Scar treatment options:
  - Grafting
  - Release
  - Laser scar revision

- Laser scar revision observations by treating physicians & patients:
  - Improved range of motion
  - Improved pliability
  - Improved texture
  - Improved appearance
  - Less pain
The UltraPulse SCAAR* Story

* Synergistic Coagulation and Ablation for Advanced Resurfacing
# UltraPulse - The SCAAR Story

<table>
<thead>
<tr>
<th>Chapter 1</th>
<th>First to Market Advantage</th>
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<tbody>
<tr>
<td>• At San Diego Scar Symposium, UltraPulse was reported BEST in class by ALL presenting physicians.</td>
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<table>
<thead>
<tr>
<th>Chapter 2</th>
<th>Patient Driven Treatment</th>
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<tbody>
<tr>
<td>• Patients seek scar treatment &amp; travel long distances to expert physicians.</td>
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</table>

<table>
<thead>
<tr>
<th>Chapter 3</th>
<th>Competitors Can’t Compete with UltraPulse</th>
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<tbody>
<tr>
<td>• Competitors jump on bandwagon to provide scar treatments.</td>
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<table>
<thead>
<tr>
<th>Chapter 4</th>
<th>Strong Clinical Results</th>
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<tbody>
<tr>
<td>• Research by Lumenis KOLs on UltraPulse for scar treatments.</td>
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<thead>
<tr>
<th>Chapter 5</th>
<th>The Best Gets Better</th>
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<tbody>
<tr>
<td>• SCAAR FX introduced to market</td>
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</table>
UltraPulse leads in the scar revision market - Laser thought leaders, globally recommend, UltraPulse

- **ASLMS 2012 Scar Revision Session** – Drs. Waibel and Hivnor led session on Scar Revision
- **ASLMS 2011 Advisory Board Meeting** – Drs. Dierickx, Geronamus, Ross, Zelickson, Chan, Mordon, Clementoni, Li
- **Scar Symposium 2011**, Naval Medical Center San Diego – Drs. Waibel, Ross, Hivnor, Uebelhoer, Shumaker

Physicians indicated that **every single patient**, following treatment with UltraPulse, saw improvement in their scars in one or more of the following parameters: pliability, flexibility, or cosmetic appearance.
Patients seek treatment, traveling long distances to find physicians who are proficient in UltraPulse treatments.
Patient Driven Treatment - Increased Mobility in Scar Tissue

Use of a Fractional Ablative 10.6-µm Carbon Dioxide Laser in the Treatment of a Morphea-Related Contracture

Figure 2. The goniometer demonstrates restricted plantar flexion of the left foot, with the indicator line at the 135° mark (45° of plantar flexion from neutral, or 90°).

Figure 3. One year after the initial fractional ablative carbon dioxide laser treatment with continued methotrexate and physical therapy, the goniometer shows normalized plantar flexion of the left foot, with the indicator line at the 155° mark (65° of plantar flexion from neutral, or 90°). No an-
Preliminary results of a study evaluating biopsy specimens obtained from mature burn scars pre- and post-fractional CO₂ laser resurfacing show histologic changes that are consistent with the clinical improvement achieved, but further data is needed to understand the mechanisms leading to normal skin regeneration, reported David M. Ozog, M.D., at the 2011 annual meeting of the American Society for Laser Medicine and Surgery. The study was conducted with Ron Moy, M.D., at the Moy-Fincher Medical Group in Beverly Hills, and enrolled 18 patients with mature burn scars defined as more than one year elapsed since the injury. Patients were recruited from the Grossman Burn Institute. All patients underwent three or four treatments using a fractional CO₂ laser (UltraPulse, Lumenis) over a period of six months. Outcomes were evaluated two to three months after the last treatment and included subjective ratings of clinical features by the investigator and patients; gross and computer-assisted histologic evaluation; and polymerase chain reaction to identify changes in gene expression of several cytokines.

Study results...
Clinical Results – One of the Bern Triplets – TotalFX

Courtesy Jill Waibel, M.D., Miami, Florida, USA
Mature 20 yr. old Burn Scar

Photos courtesy Jill Waibel, M.D., Miami, Florida, USA
Clinical Results – TotalFX

Photos courtesy Jill Waibel, M.D., Miami, Florida, USA
First to market advantage
- It took years for UltraPulse to have the **technology** (ActiveFX, DeepFX, TotalFX and SCAAR FX), the **science**, the **clinical proof** and the **effective results**.

Physicians requested, we delivered
- **Requested by physicians** – “*For UltraPulse improve DeepFX performance with energy >50mJ and ActiveFX performance***.”

**Target market**
- Dermatologists
- Plastic Surgeons
Introducing SCAAR FX

The next chapter in the UltraPulse story
What is SCAAR FX?

SCAAR = Synergistic Coagulation & Ablation for Advanced Resurfacing

- SCAAR FX is:
  - A NEW Aesthetic mode in UltraPulse.
  - A NEW treatment affecting lesions up to 4 mm deep.
  - A NEW paradigm in CO2 lasers.
Synergistic Coagulation & Ablation for Advanced Resurfacing is used to treat:

- Conspicuous, complex skin lesions requiring precise, deep fractional treatment.
- Using a unique ablation/coagulation ratio, UltraPulse with SCAAR FX was designed to substantially improve the structure of deep contracted skin lesions, such as surgical scars. This leads to increased range of motion in these areas and enhanced skin appearance.
Why can UltraPulse perform SCAAR?

SCAAR = Synergistic Coagulation & Ablation for Advanced Resurfacing

UltraPulse has the technology need to perform SCAAR:

- Highest Energy (150 mJ per pulse)
- Deepest Treatment (up to 4.0 mm)
- Best Performance (optimal ablation / coagulation ratio)
Only UltraPulse has the power, pulse characteristics, and delivery devices to provide effective treatments.

- **The precision** of UltraPulse has made it the Gold Standard for CO2 lasers.
- **The precision** of UltraPulse enables it to deliver up to 150 mJ / pulse / spot in the SCAAR FX mode.
- **The precision** results from the combination of short pulses and the highest energy per pulse per spot.
UltraPulse - Best is Now Better

UltraPulse treats conspicuous, complex and deep skin lesions, such as surgical and acne scars: **shallow lesions** (Active FX), **medium lesions** (DeepFX) & **deeper lesions** (SCAAR FX)

Treatments with SCAAR FX have shown remarkable results and minimal side effects. Using precision and high energy impact (up to 150 mJ per pulse per spot).

SCAAR FX allows direct impact up to **four millimeters deep** into the skin tissue, four times deeper than other CO$_2$ lasers.

The histological evidence also displayed an optimal ablation – coagulation ratio.
SCAAR FX - Main Features

- **Highest energy** – up to 150 mJ / pulse
- **Deepest effect** – up to 4 mm
- **Best performance** – optimal ablation / coagulation ratio
SCAAR FX Mode
SCAAR FX Treatment Screen

From 1 to 10%

From 60 to 150mJ
(in increments of 10mJ)
Deep FX™ microscanner

Articulated arm of the UltraPulse®

Purge air compressor connection

Blue thread adaptor

Disposable tip

Communication cable connection

SCAAR FX is performed using the DeepFX Scanner
# SCAAR FX Parameters

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Default</th>
<th>Range</th>
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<tbody>
<tr>
<td>Energy</td>
<td>60 mJ</td>
<td>60-150 mJ</td>
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<tr>
<td>Number of Pulses</td>
<td>1</td>
<td>1</td>
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<tr>
<td>Repeat Delay</td>
<td>Off</td>
<td>On / Off</td>
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<tr>
<td>Pattern Shape</td>
<td>2</td>
<td>2-5</td>
</tr>
<tr>
<td>Pattern Size</td>
<td>10</td>
<td>5-10</td>
</tr>
<tr>
<td>Pattern Density</td>
<td>1%</td>
<td>1-10%</td>
</tr>
<tr>
<td>Rate</td>
<td>250 Hz</td>
<td>150-250 Hz</td>
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</tbody>
</table>
### Treatment Parameters
**SCAAR FX™ Microscanner 0.120 mm spot size**

#### Shallow skin lesion (1-2mm)

<table>
<thead>
<tr>
<th>Energy (mJ)</th>
<th>Scan Size/Shape</th>
<th>Density</th>
<th>Hertz</th>
<th>Number of Pulses</th>
<th>Repeat delay</th>
<th>Number of Passes</th>
</tr>
</thead>
<tbody>
<tr>
<td>60-70</td>
<td>Lesion related</td>
<td>1 - 10%</td>
<td>150-250</td>
<td>One</td>
<td>0.3 - 1.5 sec.</td>
<td>One</td>
</tr>
</tbody>
</table>

#### Medium skin lesion (2-3mm)

<table>
<thead>
<tr>
<th>Energy (mJ)</th>
<th>Scan Size/Shape</th>
<th>Density</th>
<th>Hertz</th>
<th>Number of Pulses</th>
<th>Repeat delay</th>
<th>Number of Passes</th>
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<tbody>
<tr>
<td>70-120</td>
<td>Lesion related</td>
<td>1 - 5%</td>
<td>150-250</td>
<td>One</td>
<td>0.3 - 1.5 sec.</td>
<td>One</td>
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#### Deep skin lesion (>3mm)

<table>
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<tr>
<th>Energy (mJ)</th>
<th>Scan Size/Shape</th>
<th>Density</th>
<th>Hertz</th>
<th>Number of Pulses</th>
<th>Repeat delay</th>
<th>Number of Passes</th>
</tr>
</thead>
<tbody>
<tr>
<td>120-150</td>
<td>Lesion related</td>
<td>1 - 3%</td>
<td>150-250</td>
<td>One</td>
<td>0.3 - 1.5 sec.</td>
<td>One</td>
</tr>
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</table>

*These guidelines only apply to Lumenis UltraPulse® device and not to any other fractional devices*
## Optimal Versatility

<table>
<thead>
<tr>
<th></th>
<th>ActiveFX</th>
<th>DeepFX</th>
<th>TotalFX</th>
<th>SCAAR FX</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>ActiveFX</strong></td>
<td>Treat fine lines, texture and dyschromia</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>DeepFX</strong></td>
<td>Treat wrinkles and scars</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>TotalFX</strong></td>
<td>Combine superficial and deep fractional effects</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>SCAAR FX</strong></td>
<td>Treat deep, conspicuous and complex scars</td>
<td></td>
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</table>

<table>
<thead>
<tr>
<th>Attribute</th>
<th>ActiveFX</th>
<th>DeepFX</th>
<th>TotalFX</th>
<th>SCAAR FX</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adjustable Healing Zone Volume</td>
<td><img src="image" alt="ActiveFX" /></td>
<td><img src="image" alt="DeepFX" /></td>
<td><img src="image" alt="TotalFX" /></td>
<td><img src="image" alt="SCAAR FX" /></td>
</tr>
<tr>
<td>Spot Size</td>
<td>1.3 mm</td>
<td>0.12 mm</td>
<td>0.12 mm</td>
<td></td>
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<tr>
<td>Depth</td>
<td><img src="image" alt="ActiveFX" /></td>
<td><img src="image" alt="DeepFX" /></td>
<td><img src="image" alt="Active FX and Deep FX" /></td>
<td><img src="image" alt="Deep FX" /></td>
</tr>
<tr>
<td>Handpiece</td>
<td>Active FX</td>
<td>Deep FX</td>
<td>Active FX and Deep FX</td>
<td>Deep FX</td>
</tr>
</tbody>
</table>
SCAAR FX Clinical Proof
SCAAR FX Histology - up to 4 mm depth

- SCAAR FX has the optimal ablation / coagulation ratio.
  - Ablation
  - Coagulation

- SCAAR FX affects tissue up to 4 mm in depth.

Energy - 150mJ; density - 3%
Compare DeepFX to SCAAR FX
3 weeks after one treatment (SCAAR FX 150 mJ, density 1%, 2 passes on the pre-sternal area, right anterior axillary pillar, left breast). Patient is now able to elevate her arms much more effective above her head.

Photos courtesy of Matteo Tretti Clementoni, M.D., Milan, Italy
SCAAR FX Treatment

Before                                                           After one treatment

Improvement in range of motion of 17° degrees
Photos courtesy of Matteo Tretti Clementoni, M.D., Milan, Italy
According to Dr. Matteo Tretti Clementoni, plastic surgeon at the Department of Dermotological Surgery and Laser Institute Europeo, Milan, Italy:

“Hypertrophic scars consist of contracted tissue of varying thicknesses. With SCAAR FX, I am able to treat deep skin conditions, like hypertrophic scars, with the results of enhanced skin condition and improved quality of life for patients with these types of deep lesions. UltraPulse’s SCAAR FX has the unique combination of short pulse durations and high energy per pulse which enables deep, precise and effective treatment.”
UltraPulse - The SCAAR Story Continues
Treatment of Traumatic Scars in China

The 4th Charity Activity of Fractional Laser Treatment for Scars of Children Involved in Wenchuan Earthquake
Clinical Results – ActiveFX + PDL

Photos Courtesy of Jun Tan, M.D., People’s Hospital, Hunan Province China
Clinical Results

Photos Courtesy of Jun Tan, M.D., People’s Hospital, Hunan Province China

PDL 4 times + UltraPulse 3 times
15J 3ms 175mJ, 40Hz
Clinical Results

Photos Courtesy of Jun Tan, M.D., People’s Hospital, Hunan Province China

PDL 15J 10ms 2passes
200mJ 40Hz 3-5-3, passes

UltraPulse 175mJ 40Hz 1pass
Clinical Results

Photos Courtesy of Jun Tan, M.D., People’s Hospital, Hunan Province China

治疗前

六次治疗后

VPW 532 4 times + UltraPulse 3 times
Clinical Results

PDL 3 times 15J, 3ms + UltraPulse 3 times 200mJ, 40Hz

Photos Courtesy of Jun Tan, M.D., People’s Hospital, Hunan Province China
Clinical Results

PDL 4 times, 15J, 20ms +

ActiveFX 2 times 150mJ, 40Hz, 3-5-3

Photos Courtesy of Jun Tan, M.D., People’s Hospital, Hunan Province China
Clinical Results

治疗前 Photos Courtesy of Jun Tan, M.D., People’s Hospital, Hunan Province Chin

VPW 532 + UltraPulse 2 times
Clinical Results

PDL X2 15J, 10ms +
Active FX 150mJ, 40Hz, 3-5-3

Photos Courtesy of Jun Tan, M.D., People’s Hospital, Hunan Province China
Clinical Results

Photos Courtesy of Jun Tan, M.D., People’s Hospital, Hunan Province China

PDL 2 times + Active FX