Laser Treatment for Common Podiatric Conditions

Presented by Lisa Markle
Agenda

• Podiatry Market & Lasers
• Evolution of Laser Technology
• GenesisPlus
  • Onychomycosis*
  • Warts & Scars
• Laser Technology Comparison

* FDA and Health Canada clearance for the temporary increase of clear nail in patients with Onychomycosis
Podiatry Market & Lasers
Lasers in Podiatry

- Lasers are not new to Podiatry
  - CO2
  - Diode
  - Nd:Yag
- Recent FDA clearance 1064nm Nd:YAG laser for “temporary increase of clear nail in patients with onychomycosis”
Did you know? Lasers are hot...

- One-third of podiatrists use or are actively considering incorporating Laser Tx into practice.
- Nearly 3/4 of podiatrists consider Laser Tx to be a good alternative for patients with onychomycosis.
- Over 60% of podiatrists believe Laser Tx clears nails and relieves symptoms.
- On average, GenesisPlus users do more procedures than other laser owners.
- More GenesisPlus customers give Cutera higher company satisfaction rankings than other laser owners.
Laser Tx Onychomycosis

Laser Use (n=500)

- Yes: 14%
- No: 57%
- Not yet, but considering: 25%
- Would never consider laser: 2%
- Do not treat onychomycosis: 2%
Regional Distribution of those Considering Laser

Those considering are widespread

Considering Laser (n=90; 26 States)
Drivers for those considering laser

Those considering laser are motivated by:

- 71% - Opportunity to broaden practice
- 43% - Patient demand
- 41% - Potential new revenue stream (cash pay)

Biggest Motivator (n=99)

- Broadens my practice: 70%
- Patients are asking for laser Tx: 40%
- Self-pay (new revenue stream): 30%
- No-one is offering laser in my area: 20%
- Available clinical data on laser Tx for onych.: 10%
- Everyone is offering laser Tx in my area: 0%
Clinicians considering laser want options to treat more than onychomycosis

- **Multi-use Podiatry Laser @ $65k scored highest (3.56 on 5 pt scale)**

![Mean Score chart]

Respondents ranked 5 laser concepts
- $120K Laser Platform, multiple indications
- $65K Laser, treats more than onychomycosis
- $45K Laser, onych only
- $25K Laser, onych only + consumables per use
- $500/day Rental Laser, onych only
Lasers Currently Used (November 2011)

Users (n=67)

- Q-Switch: 13%
- Other: 21%
- CoolTouch: 18%
- Pinpointe: 21%
- Cutera: 9%
- Laser: 6%
- Nomir: 3%
- Other: 3%
- Other: 3%
- Other: 3%
- Other: 3%
- Other: 3%
- Other: 3%
- Other: 9%

Sources: Market Research Podiatry Survey, November 2011
# Pricing for Laser Tx

~60% charge per Treatment or Per Program

<table>
<thead>
<tr>
<th>Pricing Approach</th>
<th>% of Users</th>
<th>Common Price Range</th>
</tr>
</thead>
<tbody>
<tr>
<td>Per Toe</td>
<td>29%</td>
<td>$100-$400</td>
</tr>
<tr>
<td>Per Foot</td>
<td>10%</td>
<td>$400-$600</td>
</tr>
<tr>
<td>Per Treatment Session</td>
<td>29%</td>
<td>$600 - $1000</td>
</tr>
<tr>
<td>Per Program</td>
<td>28%</td>
<td>$700 - $1250</td>
</tr>
<tr>
<td>Other</td>
<td>3%</td>
<td>$900 - $1000</td>
</tr>
</tbody>
</table>

Sources: Market Research Podiatry Survey, November 2011

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Rev A 10/12
GenesisPlus Users

- Do more procedures
  - Higher revenue, easier payback
- Are highly satisfied with Cutera and Tx for onychomycosis
- Use and bill for other procedures, i.e., warts
- Are interested in other aesthetic procedures
  - Veins, hair removal, pain, etc.
- Enjoy incremental revenue with ancillary products and services (SteriShoe, Formula3, medi-pedi)

Compared with other laser owners
GenPlus Users Foresee Practice Shift to Onychomycosis and Cosmetic Procedures

- Laser users turn from Diabetic foot and Surgery.
- Key GenPlus Users predict that aesthetic procedures, like Laser Tx of Onychomycosis will become increasingly important to their practices.

### Key Areas of Podiatry Practice

<table>
<thead>
<tr>
<th>Area</th>
<th>Number of Responses</th>
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<tbody>
<tr>
<td>Onychomycosis</td>
<td>8</td>
</tr>
<tr>
<td>Cosmetic</td>
<td>6</td>
</tr>
<tr>
<td>Diabetic foot care</td>
<td>4</td>
</tr>
<tr>
<td>Plantar fascitis</td>
<td>3</td>
</tr>
<tr>
<td>Orthotics</td>
<td>2</td>
</tr>
<tr>
<td>Surgery</td>
<td>1</td>
</tr>
<tr>
<td>Wound Care</td>
<td>1</td>
</tr>
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</table>

Sources: GenPlus Focus Group, December 2011, n=9
GenPlus Highly Utilized for Wart Tx

Use of GenesisPlus For Additional Indications

<table>
<thead>
<tr>
<th>Percent Using GenPlus to Treat</th>
<th>Warts</th>
<th>Scars</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>100%</td>
<td></td>
</tr>
<tr>
<td>No</td>
<td></td>
<td>N/A</td>
</tr>
</tbody>
</table>

Sources: Market Research July/Aug 2011; GenPlus Focus Group, December 2011, n=17 GenPlus Users

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GenesisPlus owners give Cutera highest company satisfaction rating

- Vast majority are Very Satisfied!

**Satisfaction with Laser Company**

- **Cutera (n=12)**
  - Very satisfied
  - Satisfied
  - Neutral
  - Dissatisfied
  - Quite Dissatisfied

- **Pinpointe (n=11)**
- **CoolTouch (n=11)**
- **Q-Switch (n=8)**

Sources: Market Research Podiatry Survey, November 2011
GenesisPlus
Evolution of Laser Technology
GenesisPlus Evolution

- Initial project research in 2007/8
- Project launched in 2008/9
  - Investigation sites
  - R&D & product development
  - Clinical research & protocol development
- GenesisPlus proto-types 2010
  - Treatment protocol development
  - Clinical study
- FDA Clearance April 2011
- Health Canada clearance August 2011
GenesisPlus Evolution
Ergonomic Hand Piece

LED temperature indicators on both sides for operator visibility

Ergonomic design with thumb indent

LED temperature indicators

Light, thin short umbilical
Integrated temperature sensors monitor temperature 4cm from the skin.

6 LED indicators correspond with temperatures as shown:

- Green: 26°-30° C
- Green: 31°-34° C
- Green: 35°-38° C
- Yellow: 39°-42° C
- Yellow: 43°-46° C
- Red: 47°-50° C

Treat between 35 & 42°C or to point of discomfort and erythema, then move to adjacent regions.
GenesisPlus Evolution
Precision In Your Hands

- Two aiming beams ensure correct working distance
- Temperature sensors for real time temperature feedback
- Designed for safe & effective treatment outcomes

Invisible Temperature sensor

Visible working distance beam

Visible aiming beam
(coaxial with invisible treatment beam)
1.5mm removable adapter for onychomycosis treatment mode*

Stand off for correct working distance

*US only
GenesisPlus
How does it work?
Physician Experience

- Large 5mm spot size allows for faster treatment times
- No consumables
- High patient demand for treatment
- Quick, safe and effective treatment
  - Aiming beam ensures correct treatment distance
  - Temperature sensors provide feedback for safety
- High patient satisfaction
Safe & Effective Treatment Option

- No downtime
- No blood tests, hepatotoxicity or renal failure
  - Unlike oral medication (high risks)
- High patient satisfaction
  - Unlike topicals (low patient satisfaction)
Patient Experience

- Pain is minimal – “walk in” and “walk out” procedure
- No anesthetic or numbing required - very well tolerated
- No downtime after treatments
- Fast treatments; roughly 20 minutes
- Patient has input on temperature regulation
- Greater options for care
GenesisPlus Treatment Steps

• Start on the hallux
• Treat nail bed, matrix and lateral folds, extending approximately 2mm past the nail
• Treat to point of slight discomfort, then move to the adjacent toe
• Use multiple passes until the recommended number of pulses have been delivered
GenesisPlus Treatment Steps

- ~ 100 pulses per toe using multiple passes
- ~ 400-600 pulses per toe using multiple passes

• Number of passes may change from patient to patient depending on patient tolerance
Post Treatment Guidelines

To help prevent re-infection:
• Apply anti-fungal cream 2X per day for approximately 2 weeks to 3 months depending severity of the infection
• Apply anti-fungal powder to all shoes at least 1x per week for at least 1 month
• Nail polish may be applied 24 hours after treatment
• The average time interval between treatments is 4-6 weeks
• Due to slow nail growth, results may not be noticeable for 3+ months
• Consider shoe sterilizers
Infected Area = 23.6%  
Infected Area = 9.4%
Example – Subject (left)

Baseline

Infected Area = 42.0%

9 Mos Post Final Tx

Infected Area = 5.0%

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Rev A 10/12
Before and After

Before

3 months post treatment

Photos Courtesy of David Weiss, DPM
Before and After

Before

3 months post treatment

Photos Courtesy of David Weiss, DPM
Before and After

Before

3 months post treatment

Photos Courtesy of David Weiss, DPM
Before and After

Before: April 8, 2011 #1864

3 months post treatment: July 15, 2011 #1864

Photos Courtesy of Michael Uro, DPM
Before and After

Before

April 1, 2011
#1851

2 months post treatment

June 17, 2011
#1851

Photos Courtesy of Michael Uro, DPM
GenesisPlus
Verrucae and Scars
Verrucae

- GenesisPlus effectively treats verrucae
- Warts are very vascular, so laser parameters are set to target the blood vessels that feed the wart
- Debride hyperkeratotic tissue prior to laser treatment by planing the wart as thinly as possible but try to avoid bleeding
- May use local anesthesia if necessary for patient tolerance
Verrucae

Laser Settings

- 140-200 Joules/cm²
- 6-20 milliseconds pulse width
- 5 mm spot size

- Do not treat tissue beyond wart border, to avoid damage to healthy tissue
- Give one single pulse, assess result; give additional pulse(s) only if needed
- May cause hematoma
- Will require 1 or 2 treatments
- Wart should change color and fall off within a few weeks
Before and After

(A) Deep palmoplantar wart three days after treatment.  
(B) After one week.  (C) After two weeks

Before and After

Verruca vulgaris on the toe

Complete clearance after one treatment


Treatment with Cutera 1064nm Nd:YAG
Before and After

Before
200 J/cm², 5mm spot, 20 ms

1 Month After 1 Treatment

Photos Courtesy of David Weiss, DPM
Treatment with Cutera 1064nm Nd:YAG
Before and After

200 J/cm², 5mm spot, 20 ms

Treatment with Cutera 1064nm Nd:YAG

Photos Courtesy of David Weiss, DPM
Scar Tissue

- Laser Genesis Plus treats hypertrophic scars
- Comfortable treatments
- Number of treatments varies with size of scar, its location, and with each patient
- Use a sweeping, “paintbrush-like” motion
Before and After

Before

Post treatment

Photos Courtesy of Jodi Schoenhaus, DPM
Before and After

Before

Post 6 GenesisPlus treatments

Photos Courtesy of David Weiss, DPM

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Thyroid Scar
Skin type II, Caucasian, Female

Pre Tx (1 year post operation)  
6 months post 3 Tx

Treatment with Cutera 1064nm Nd:YAG
Basal Cell Carcinoma Mohs Surgery Scar
Skin type II, Caucasian, Male

6 weeks post Mohs surgery

5 months post 2 Tx

Treatment with Cutera 1064nm Nd:YAG

Photos courtesy of Aliy-Khan Somani, MD, PhD.
Before and After

Basal Cell Carcinoma Mohs Surgery Scar
Skin type II, Caucasian, Female

3 months post Mohs surgery
3 weeks post 2 Tx

Photos courtesy of Ally-Khan Somani, MD., PhD.

Treatment with Cutera 1064nm Nd:YAG

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Hypertrophic Scar on Chin
Skin type IV, Japanese, Male

Before and After

Before
2 weeks after 1 Tx
3 weeks after 5 Tx
4 weeks after 7 Tx

Photos courtesy of Teiichi Masuda, MD. Akasaka Clinic, Fukuoka, Japan

Treatment with Cutera 1064nm Nd:YAG
Laser Technology Comparison
Laser Podiatry Market

Users (n=67)

- Q-Switch: 13%
- LASER: 6%
- Pinpointe: 21%
- CoolTouch: 18%
- Cutera: 21%
- Other: 9%
- NOMIR: 3%
- aerolase: 3%
- SCITON: 3%
- Fotona: 3%

Sources: Market Research Podiatry Survey, November 2011

AP0417 GenesisPlus Presentation for CFPM
Rev A 10/12
# Laser Technology Comparison

<table>
<thead>
<tr>
<th>Name</th>
<th>Wavelength</th>
<th>Spot Size</th>
<th>FDA*</th>
<th>Health* Canada</th>
<th>Clinical Study</th>
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<tbody>
<tr>
<td>Cutera</td>
<td>1064nm</td>
<td>1 &amp; 5mm</td>
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<td>Yes</td>
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<tr>
<td>PinPointe</td>
<td>1064nm</td>
<td>1mm</td>
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<td>Yes</td>
<td>Yes</td>
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<tr>
<td>CoolTouch</td>
<td>1064nm</td>
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<td>Yes</td>
<td>No</td>
<td>No</td>
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<tr>
<td>Q-Clear</td>
<td>532/1064nm</td>
<td>2.5-mm</td>
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<td>No</td>
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<td>Sciton</td>
<td>1064nm</td>
<td>1mm</td>
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<td>No</td>
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<tr>
<td>Alma</td>
<td>1064nm</td>
<td>1mm</td>
<td>Yes</td>
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</tr>
</tbody>
</table>

*FDA and Health Canada clearance for the temporary increase of clear nail in patients with Onychomycosis. Clearance approvals were correct at time of printing.

* FDA
Advantages of GenesisPlus

- Size matters: 5mm spot size for faster treatment times
- Deeper penetration of tissue
- Auto calibration with every pulse
- No need to test before every case to ensure optimal power
- No degradation of cable or loss of efficacy over time
- Surface temperatures are monitored and displayed on hand piece and screen
- Effectively treats warts and scar tissue