Competitive Analysis

Spectra

Melasma
One of the most troublesome and its Treatments

July 2011

Lutronic
Lutronic: Poised for Dynamic Growth
**Versatility** - *SPECTRA* does many things to cover wide range of indications from **epidermal pigmented lesions** of freckles, seborrheic keratosis, café au lait to **dermal pigmented lesions** of melasma, PIH, tattoos, nevus of ota, abnom, large pore, and inflammatory acne, etc.

**Melasma** - With the true 5~7ns of Very Short Pulse Duration and High Peak Power, compared to a competitor with 5~20ns which produces only the first pulse of 5 ns and then the peak power drops off immediately that *SPECTRA* is the clearly best choice for improving melasma.

**New Theory of SSP** - The new Sub-Cellular Selective Photothermolysis theory gives serial removal of melanin in epidermal melanocytes and dermal melanophages without destroying or activation of the melanocyte.

**Active Acne** – *SPECTRA*’s only Quasi-Long Pulse of 300 microseconds of SPECTRA MODE provides additional photothermal stimulation of the epidermis and dermis by gently heating and mildly exfoliating the outermost layer of the skin to greatly improve active acnes.

**Safest & Reliable Laser** - More than 13 years of experience in Q-Switched Nd:YAG laser with over 3000 installations of *SPECTRA* worldwide, Lutronic provides high quality, reliable and safest lasers.

"Proprietary & Confidential" - Lutronic
With SPECTRA, wide-range of indications can be treated

- **Epidermal Pigmented Lesions**: Freckles, seborrheic keratosis, café au lait,
- **Dermal Pigmented Lesions**: melasma, PIH, tattoos, nevus of ota, abnom, large pore, and inflammatory acne.

**532 nm Wavelength**
- Freckles
- Seborrheic Keratosis
- Café Au Lait

**1064 nm Wavelength**
- Melasma
- PIH
- Hori’s Nevi
- Large Pores
- Active Acne
- Tattoo
- Nevus of Ota
SPECTRA’s only 5 to 7 nsec pulse width, has high enough peak power to breakdown its chromophore (melanin).

Less lateral thermal damage which minimizes inflammation, thus preventing side effect such as PIH or melasma recurrence.

Other products could not reach the same peak power due to its longer pulse width.
• Peak power dramatically drops off after the first pulse on lower energy's. User can hear it drop from 5ns to 20 ns after the first shot. This is not effective for treating melasma.

• Peak power is very stable throughout the treatment which maintains 5ns to 7ns for effective melasma treatment.
Competitor A 1064nm Arm mode Beam
Spot Size: 8 mm  Fluence: 1.6 J/cm²

SPECTRA 1064nm Arm mode Beam
Spot Size: 8 mm  Fluence: 1.2 J/cm²

- **SPECTRA**: Even distribution of energy shows that there’s no excessive or irregular distribution of energy. Thus, doctors can expect the optimal clinical outcome without side-effects

- **Competitor A**: Due to the irregular and excessive beam profile, there’s possibility of side effects as shown above

00 Dermatology clinic, Korea
SPECTRA is very stable at 532nm wavelength. The energy variable found in the other competitors are usually 30% deviation.

SPECTRA’s PTP shows less than 10% deviation.

As the 532 energy (PTP) is lower, the energy is more stable. Competitors have high PTP that energy is unstable.

The stable energy distribution of SPECTRA results expected clinical outcome.
Competitor B shows that excessive and irregular beam profile. Below is not Top Hat mode.

SPECTRA’s 532 Arm mode beam shows that energy is evenly distributed. Also shows the true top hat beam profile.
SPECTRA’s TOP HAT vs. GAUSSIAN BEAM PROFILE

TOP HAT Beam Profile

- Uniform Energy Distribution
- No hot spots—even distribution of energy (green)
- Energy is absorbed uniformly to the melanin.

GAUSSIAN Beam Profile

- Irregular Energy Distribution
- High energy in the center and uneven energy distribution on the edge
- Irregular absorption to the melanin. Burn in the center

NO hot spots!
SPECTRA’s TOP HAT BEAM PROFILE skin reaction

**Skin Reaction at Skin Type IV, 2.6mm Spot Size**

*Immediate after*

- 2.1 J/cm²
- 1.9 J/cm²
- 1.6 J/cm²
- 1.3 J/cm²
- 1.0 J/cm²

*1min. after*

Whitening after treatment

After 1 minute, energy is evenly diffused that mild and even erythema is seen
GAUSSIAN BEAM PROFILE skin reaction

- Immediate
- Whitening after treatment

- 30 secs
- Erythema due to strong energy on the treated area

- 2 mins

- 5 mins
- Bleeding after 5 minutes due to irregular energy distribution

- GAUSSIAN Beam Profile
<table>
<thead>
<tr>
<th>Brand Name</th>
<th>Spectra</th>
<th>Medlite C Series (C6)</th>
<th>RevLite</th>
</tr>
</thead>
<tbody>
<tr>
<td>Company</td>
<td>Lutronic Corporation</td>
<td>HOYA Conbio</td>
<td>HOYA Conbio</td>
</tr>
<tr>
<td>Laser Type</td>
<td>Dual Pulsed Nd:YAG Laser (1064nm / 532nm)</td>
<td>Dual Pulsed Nd:YAG Laser (1064nm / 532nm)</td>
<td>Dual Pulsed Nd:YAG Laser (1064nm / 532nm)</td>
</tr>
<tr>
<td>Power</td>
<td>1200mj</td>
<td>1000mj</td>
<td>1300mj not 1600mj as they claim. In all settings it is at best 1300mj. In ptp mode they double pulse 800mj and call it 1600mj with no clinics it is just double pulsing. Spectra Mode has more power as it is a continuously pulsing.</td>
</tr>
<tr>
<td>Beam Type</td>
<td>Top-Hat Beam Profile</td>
<td>Flat top</td>
<td>Flat top</td>
</tr>
<tr>
<td>Quasi-long Pulsed Mode (300us)</td>
<td>Spectra Mode</td>
<td>None</td>
<td>None</td>
</tr>
<tr>
<td>Thermal Effect, Soft Peel, Acne Tx</td>
<td>None</td>
<td>Yes it is only a double pulse of 800mj each separated by 400 microseconds. No proven clinical benefit. Shown not effective on tattoo removal. No clinicals</td>
<td></td>
</tr>
<tr>
<td>PTP = Photoacoustic Technology Pulse</td>
<td>No, The Spectra Mode is more effective with clinical's to prove it.</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>Pulse Duration</td>
<td>5-7ns Very Short Pulse Duration, 5-20ns The first pulse is 5 ns and then the peak power drops off immediately after the first shot. Explain this to the doctors that only the first pulse is good.</td>
<td>5-20ns The first pulse is 5 ns and then the peak power drops off immediately after the first shot. Explain this to the doctors that only the first pulse is good.</td>
<td>5-20ns The first pulse is 5 ns and then the peak power drops off immediately after the first shot. Explain this to the doctors that only the first pulse is good.</td>
</tr>
<tr>
<td>Peak Power of 1064nm</td>
<td>Sharp High Peak Power Beam, No Thermal Damage</td>
<td>High Peak Power first shot only</td>
<td>High Peak Power first shot only</td>
</tr>
<tr>
<td>Beam Quality of 532nm</td>
<td>1.2J/cm²</td>
<td>1.0J/cm²</td>
<td>1.0J/cm²</td>
</tr>
<tr>
<td>Handpiece</td>
<td>Very Stable and Uniformed beam quality</td>
<td>Stable</td>
<td>Stable</td>
</tr>
<tr>
<td>Initialization</td>
<td>7mm Zoom-Collimated Handpiece &amp; 1-7mm Zoom handpiece</td>
<td>All spot sizes are collimated</td>
<td>All spot sizes are collimated</td>
</tr>
<tr>
<td>Guide Beam</td>
<td>Within 30 seconds</td>
<td>Within 5 minutes</td>
<td>Within 5 minutes</td>
</tr>
<tr>
<td>Presets</td>
<td>Laser Toning Button</td>
<td>No</td>
<td>Multiple but lots of bugs</td>
</tr>
</tbody>
</table>
By comparing each energy, **Competitor B** shows higher PTP which means Competitor B’s energy is NOT as stable as **SPECTRA**.
Competitor B does not have advance pumping feature. Therefore due to unstable 532nm initial shot, PTP(%) is also very unstable. However, after the first few shots PTP(%) gets stabilized.
1064 Arm Mode Comparison: Competitor B

1064nm Arm mode Beam Profile
- 800mJ Output Energy, 10Hz Pumping

The intensity in the center of the beam is not regular but distributed and concentrated in the middle.

The intensity in the center of the beam is regular and shows even distribution of the energy.
The intensity in the center of the beam shows close to regular energy distribution but it is not a Top Hat mode. It is rather showing Gaussian mode. The intensity in the center of the beam shows even energy distribution and shows true Top Hat mode.
Gold Standard Technique
Laser toning for melasma

Before laser treatment
After laser treatment
Subcellular Selective Photothermolysis

**SSP:** Subcellular Selective Photothermolysis in melanosomes without destroying or activating the melanocytes (epidermal melanosome and dermal melanophages)
Changes of pigmentations in the black stripe of zebra-fish 5 days after LT
Figure. Ultrastructural changes of melanosomes in melasma patient.

A,B,C: before treatment, fully-developed stage IV melanosomes; D,E,F: after treatment, internal electron lucency and disruption of internal contents after treatment. (A-F; x100,000)
Why we need Laser Toning and What is it?

• In Asians referred to as ‘laser toning (LT)’ therapy in melasma was introduced to **overcome the PIH** by excessive thermal damage which usually occurs after conventional **high fluence** Q-switched laser therapy.

• **Laser Toning**: Use 1064nm Q-switched Nd:Yag laser, with **short pulse** (5nsec), **low fluence** (1.4~2.0J), **large spot** (7mm) with top-hat collimated beam mode, even though SP reaction is minimal.

Mechanism of melanin destruction

1064nm Q-switched pulse

“Minimal Thermal Damage” +

“Subcellular Selective Photothermolysis”
Laser toning tx. Steps – 3 OR 1

1. Continue or Select Q-switched Mode
   (5 – 10nsec Short Pulse)
2. 2 – 5 passes (End point is mild erythema)

Fluence 1.0J/cm² ~

Treat Melasma area only !!
Immediate post tx. skin reaction

Before

Immediately After
New Modality in Laser Therapy: “Laser Toning” (LT) Technique

1. **Serial removal** of overproduced melanin **without destroy or activation of epidermal melanocytes**

2. Serial removal of persistent melanin in dermal melanophages without destroy or activation of melanocytes

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**Subcellular Selective Photothermolysis (SSP) without cell death**
New Melasma Treatment by Collimated Low Fluence Q-switched Nd:YAG Laser (Laser Toning)
Study 1.

Moderate Improvements
Low Fluence Q-Switched Nd:YAG laser for Melasma with Pre- or Post-Treatment Triple Combination Cream

Split-Face Comparison Crossover Prospective Study
The lesion of melasma was mostly cleared after 8 weeks laser Tx. However, the improved lesion was aggravated after 8 weeks TC treatment. (A) Before Tx, (B) after 8 weeks laser Tx, (C) after 8 weeks TC Tx.
2nd Study: Clinical Efficacy & Safety of LT

Low Fluence Q-Switched Nd:YAG laser for Melasma with Pre- or Post-Treatment Triple Combination Cream

MASI Score Comparison

L* value Comparison

(Before Tx, After 8weeks, After 16weeks
=> The lower sticks, The better results)

(Before Tx, After 8weeks, After 16weeks
=> L* value means the lightness of melasma.
=> The higher sticks, The better results)
Melasma

Before

After - 8 treatments, Post 2 months

Treatment 1: Soft Peel 1.5 J/cm², 1 pass; Laser Toning 1.5 J/cm², 1 pass
Treatment 2: Laser Toning 1.6 J/cm², 2-4 passes
Treatment 3: Soft Peel 1.6 J/cm², 1 pass; Laser Toning 1.6 J/cm², 1 pass
Treatment 4: Laser Toning 1.6 J/cm², 3-4 passes

Treatment 5: Soft Peel 1.7 J/cm², 1 pass; Laser Toning 1.7 J/cm², 1 pass
Treatment 6: Laser Toning 1.7 J/cm², 3-4 passes
Treatment 7: Soft Peel 1.7 J/cm², 1 pass; Laser Toning 1.7 J/cm², 1 pass
Treatment 8: Laser Toning 1.8 J/cm², 2-5 passes

Photos courtesy of Dr. Kevin Duplechain
Melasma

Before

After - 10 treatments, Post 2 months

Photos courtesy of Dr. Kevin Duplechain

Treatment 1: Soft Peel 1.6 J/cm², 1 pass; Laser Toning 1.6 J/cm², 1 pass
Treatment 2: Laser Toning 1.5 J/cm², 3 passes
Treatment 3: Soft Peel 1.6 J/cm², 1 pass; Laser Toning 1.5J/cm², 1 pass
Treatment 4: Laser Toning 1.5 J/cm², 3 passes
Treatment 5: Soft Peel 1.6 J/cm², 1 pass; Laser Toning 1.6 J/cm², 1 pass

Treatment 6: Laser Toning 1.7 J/cm², 3-4 passes
Treatment 7: Soft Peel 1.7 J/cm², 1 pass; Laser Toning 1.7 J/cm², 1 pass
Treatment 8: Laser Toning 1.7 J/cm², 2-5 passes
Treatment 9: Soft Peel 1.8 J/cm², 1 pass
Treatment 10: Laser Toning 1.8 J/cm², 3-5 passes
Melasma

Before

After - 10 treatments, Post 2 months

Photos courtesy of Dr. Kevin Duplechain

Treatment 1: Soft Peel 1.6 J/cm², 1 pass; Laser Toning 1.6 J/cm², 1 pass
Treatment 2: Laser Toning 1.5 J/cm², 3 passes
Treatment 3: Soft Peel 1.6 J/cm², 1 pass; Laser Toning 1.5 J/cm², 1 pass
Treatment 4: Laser Toning 1.5 J/cm², 3 passes
Treatment 5: Soft Peel 1.6 J/cm², 1 pass; Laser Toning 1.6 J/cm², 1 pass
Treatment 6: Laser Toning 1.7 J/cm², 3-4 passes
Treatment 7: Soft Peel 1.7 J/cm², 1 pass; Laser Toning 1.7 J/cm², 1 pass
Treatment 8: Laser Toning 1.7 J/cm², 2-5 passes
Treatment 9: Soft Peel 1.8 J/cm², 1 pass
Treatment 10: Laser Toning 1.8 J/cm², 3-5 passes
Melasma

Photos courtesy of Dr. Kevin Duplechain
Efficacy and safety of 1,064-nm Q-switched Nd:YAG laser with low fluence for keloids and hypertrophic scars

Sung Bin Cho, MD et al

Department of Dermatology and Cutaneous Biology Research Institute, Yonsei University College of Medicine, Seoul, Korea
Minimized Selective Photothermolysis: new modality for melasma treatment

Il Hwan Kim, MD, Korea
SUBCELLULAR SELECTIVE PHOTOTHERMOLYSIS: AN ELECTRON MICROSCOPIC EVIDENCE IN MELASMA PATIENTS TREATED WITH COLLIMATED LOW FLUENCE Q-SWITCHED Nd:YAG

Jae Bin Shin, Se Yeong Jeong, Ki Woong Ro, Soo Hong Seo, Sang Wook Son, Il-Hwan Kim, Seoul, Korea

Figure 4. Light microscopic findings with comparison of before (A) and after treatment (B). Post-treated specimens showed less melanocytes (arrows) of basal layer than pre-treatment (A,B; Methylene blue, x200).

Figure 5. Electron microscopic alterations and the matched clinical photographs. Various degrees of melanocyte and melanosome distribution in pretreated specimens (A,C,E) and relatively decreased melanocytes and melanosomes in post-treated specimens (B,D,F; x2,000).

* Excerpted from ePosters at 2009 Annual Conference held by American Society for Laser Medicine and Surgery *
NEW TREATMENT FOR MELASMA WITH THE COLLIMATED LOW FLUENCE Q-SWITCHED Nd:YAG LASER

Se Yeong Jeong, Jae Bin Shin, Un Chul Yeo, Won Serk Kim, Il-Hwan Kim, Jae Hwan Kim, Korea University, Ansan, Korea

The adverse reactions included pain, erythema and edema. Erythema and edema resolved spontaneously causing no particular problems after 1–4 days. The hypopigmented macules were appeared in 3 patients in the first study (Fig. 1). However, there was no severe side reaction, such as hypopigmented macules in the second study.

Figure 1. M/55, (A) Before treatment (B) Two local hypopigmented lesions after the eight treatments in the first study.

Figure 2. Patient (F/41) in the first study had malar type melasma that was totally cleared after eight treatments in the first study (A) before treatment (B) Two months after the eight treatments. Patient (F/40) in the second study had malar type melasma that was totally cleared after eight treatments in the first study (C) before treatment (D) Two months after the eight treatments.
3D structural modification of melanocyte after Q-switched Nd:YAG laser toning treatment in melasma patients using serial section electron microscopy and electron tomodaphy.

Abstract

Methods

Results

Conclusion

Reference
Technical highlights of SPECTRA
AUTO-CALIBRATION AND self-RESTORATION

Note: Above design is subject to minor change for further improvement.

After auto-calibration, Spectra™ can restore its energy within normal range by itself. Therefore there is no need for regular check-up by an engineer.

Also clinical outcome is always guaranteed.
Customized Memory storage

Users can customize different indication names.

Users can customize different parameters at their preference.

Note: Above design is subject to minor change for further improvement.
All types of handpieces (even 585 and 650 Dye handpieces) are auto-detected now.
3-8 ZOOM COLLIMATED HANDPIECE, and other optional handpieces

- 3-8mm Zoom Collimated Handpiece (Standard)
- 1-7mm Zoom Handpiece (Optional)
- 7mm fixed Collimated Handpiece (Optional)
- Dye Handpiece (585nm) (Optional)
- Dye Handpiece (650nm) (Optional)
Collimated Handpiece:

**SoftPeel, SpectraPeel, Laser Toning**

There is no spot size change regardless of the distance from the tip of handpiece and skin surface, thus more convenient to do SoftPeel, SpectraPeel, Laser Toning.
Laser beam delivered by Zoom Hanpiece gets focused as it gets away from the tip of handpiece, resulting in higher fluence on smaller spot size, so tip of handpiece should always be in contact to skin surface.
Zoom Collimated Handpiece

Zoom Collimated HandPiece:

SoftPeel, SpectraPeel, Laser Toning, Pigmentary Lesions

• Spot size can be adjusted like zoom handpiece (e.g. 3-8 mm at 1064nm)

• Laser beam is still collimated (not focused). So operator can work even without having tip of handpiece in contact to skin surface.
Zoom-Collimated Handpiece

Spot size can be adjusted

Laser Beam is still collimated

Epidermis
Dermis

Sub-Qutaneous