Rejuvenation with light-based home devices: a new option?

IMCAS
Paris, 31st January – 3rd February 2013

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Statement of Disclosure

Godfrey Town
Godfrey Town receives travel expenses and salary from CyDen Ltd., UK; Salary and equity position with GCG Healthcare Ltd., UK; Consulting fees from Unilever, USA. He is a committee member of TC76 WG4 and TC61 WG30.

Kim Thorne
Kim Thorne receives salary from CyDen Ltd., SA1 8PJ, UK.

Eleanor Dyke
Eleanor Dyke has no disclosures.

This work is presented thanks to the support of CyDen Ltd., Swansea, UK
Objectives:

The aims of this study were to:

- assess the relative comfort in-use of a home-use IPL device compared to a competitor home-use laser device
- examine the erythema side effect profile of IPL and laser home-use rejuvenation devices
- comment on efficacy grading.

Materials and Methods:

- 45 eligible female subjects completed one IPL treatment on one side of their face and one laser treatment on the other side of their face
- Treatment areas included peri-orbital area and full cheek.
- Devices used according to manufacturer’s instructions.
- Discomfort in-use was assessed at specific intervals by the subjects recording a discomfort / pain score on a Visual Analogue Scale (VAS).
- Sensations experienced, any redness observed and the smoothness of the area were recorded on a self-assessment questionnaire at 120 minutes post-treatment.
- Hemi-facial images were taken at specific intervals and a trained assessor blind-graded the test sites for erythema.
**Home-Use Rejuvenation Lasers**

*Philips ReAura:* 1.2 W, 1435 nm, spot size $1.963 \times 10^{-7}$ cm$^2$

*Palomar PaloVia:* max energy 15 mJ, wavelength 1410 nm, pulse duration 10 ms, beam divergence 0.15, 9x6 grid = 54 pulses, repetition rate 15.4 Hz

*Tria Beauty, Tria Laser*

*Intenzity Innovation Inc Laser:* Power 900 mW, wavelength 1425 nm, spot size 100 μm, power density at skin surface 10 kW/cm$^2$, fluence 50 J/am$^2$ at 5 mJ/pulse; 70 J/am$^2$ at 7 mJ/pulse; coverage per scan 5%. [Investigational device]
Home-Use Rejuvenation IPL

iPulse prototype IPL: 7 J/cm², pulse duration 19 ms (double pulse), wavelengths 525-1100 nm, spot size 3 cm²

Materials & Methods

Two home use devices for skin rejuvenation were compared in this study for erythema response and comfort in-use - a novel IPL device and a representative home-use fractionated laser device. The home-use devices had the following specifications:

<table>
<thead>
<tr>
<th>Device</th>
<th>Novel IPL</th>
<th>Home-Use Laser</th>
</tr>
</thead>
<tbody>
<tr>
<td>Technology</td>
<td>Intense Pulsed Light</td>
<td>NIR Laser</td>
</tr>
<tr>
<td>Mechanism</td>
<td>Non ablative</td>
<td>Fractionated</td>
</tr>
<tr>
<td>Wavelength</td>
<td>525-1100 nm</td>
<td>1435 nm</td>
</tr>
<tr>
<td>Pulse duration</td>
<td>19 ms (double pulse)</td>
<td>&lt; 9 ms</td>
</tr>
<tr>
<td>Fluence</td>
<td>7 J/cm²</td>
<td>680 J/cm²</td>
</tr>
<tr>
<td>Treatment Area</td>
<td>3 cm²</td>
<td>1.963×10⁻⁷ cm²</td>
</tr>
</tbody>
</table>
Results: Pain Scores

Scatterplot of subject-reported VAS scores for the IPL (x-axis) and laser (y-axis) for each subject (n = 45). VAS scale: 0 = no pain whatsoever; 100 = worst pain imaginable.

41 out of 45 subjects recorded higher VAS scores for the laser device than the IPL device post-treatment.

Erythema Grading Examples

Results: Erythema Scores


Results: Erythema Scores

Mean subject-reported redness assessment at each time point for the IPL and laser devices. Analogue Scale: 0 = None, 1 = Slight, 2 = Definite.
Erythema (home-use laser vs IPL)

IPL 15 minutes post

Laser 15 minutes post

IPL 120 minutes post

Laser 120 minutes post
Erythema (home-use laser vs IPL)

IPL 360 minutes post

Laser 360 minutes post

Personal experience of testing another fractional home-use laser on my inner arm (edema, confluent erythema)

24 hrs post
Home Use Skin Rejuvenation (PaloVia)

Before and after 4 weeks of daily treatments

Clinical photography courtesy of Dr. C. Zachary, USA

Home Use Skin Rejuvenation (ReAura)

Before Treatment  After 16 Treatments

Clinical photography courtesy of Dr. C. Zachary, USA
Home Use Skin Rejuvenation (ReAura)

Before Tx

Home Use Skin Rejuvenation (at-home IPL)

Patient Name: LJS 010 Age: 49
Visia Texture: 0.043932 – 60
Visia Wrinkles: 0.080199 – 54
Visia Spots: 0.030153 – 64
Visia UV Spots: 0.135968 – 47
Visia Brown Spots: 0.106549 – 40
Visia Texture Count: 1280
Visia Wrinkle Count: 38
Visia Spot Count: 104
Visia UV Spot Count: 464
Visia Brown Spot Count: 376
Home Use Skin Rejuvenation (at-home IPL)

Patient Name: LJS 010 Age: 49
Visia Texture: 0.027594 – 79
Visia Wrinkles: 0.060138 – 64
Visia Spots: 0.018637 – 85
Visia UV Spots: 0.125493 – 54
Visia Brown Spots: 0.084459 – 56
Visia Texture Count: 802
Visia Wrinkle Count: 26
Visia Spot Count: 77
Visia UV Spot Count: 451
Visia Brown Spot Count: 339

After 3 Tx per week x 3 weeks + 9 weekly Tx

Home Use Skin Rejuvenation (at-home IPL)

Before and after 3 Tx per week + 9 weekly Tx
**Home Use Skin Rejuvenation (at-home IPL)**

**Before Tx**

- Patient Name: V-S 064 Age: 63
- Visia Texture: 0.077892 – 38
- Visia Wrinkles: 0.081754 – 67
- Visia Spots: 0.057357 – 27
- Visia UV Spots: 0.186278 – 36
- Visia Brown Spots: 0.142321 – 26
- Visia Texture Count: 1632
- **Visia Wrinkle Count: 34**
- Visia Spot Count: 125
- Visia UV Spot Count: 293
- **Visia Brown Spot Count: 261**

**After 3 Tx per week x 3 weeks + 9 weekly Tx**

- Patient Name: V-S 064 Age: 63
- Visia Texture: 0.061167 – 52
- Visia Wrinkles: 0.112113 – 54
- Visia Spots: 0.047505 – 42
- Visia UV Spots: 0.162226 – 51
- Visia Brown Spots: 0.121538 – 39
- Visia Texture Count: 1290
- **Visia Wrinkle Count: 27**
- Visia Spot Count: 101
- Visia UV Spot Count: 293
- **Visia Brown Spot Count: 240**
Home Use Skin Rejuvenation (at-home IPL)

Before and after 3 Tx per week + 9 weekly Tx

Clinical Results:

• The results of this study indicate that the IPL device caused significantly less pain / discomfort and erythema (p < 0.001 for both measures) than the laser device at each time point measured and for all time points combined.

• This finding was also supported by the completed subject questionnaires, where specific references were made by subjects to the degree of pain felt using the laser device but not the IPL device.
Conclusions:

• The IPL treatment was a well-tolerated, non-invasive, non-ablative method for rejuvenating photoaged skin with minimal side effects, no downtime, no long-term sequelae, and a high measure of patient satisfaction when compared with the laser device tested in this study.
• The fractionated laser caused a higher incidence of immediate erythema within this study, following a histamine reaction within the dermis.
• Further comparative clinical studies are required to establish the extent of user acceptance of treatment-related side effects and tolerable discomfort associated with self-treatment.
• Further studies are required to compare efficacy in reducing pigmentation, fine lines and wrinkles.

Standards & Regulatory Controls

• New IEC standards have been drafted: 60825-1 Ed/3 CDV and 60335-2-xx CD and are at voting / review stage by national committees.
• Because skin changes are intended, GPSD guidelines may be insufficient for these consumer appliances (i.e. risk assessment by the manufacturer is required).
• The MDD is being re-cast and will probably capture these products as OTC medical devices.
• A few national GPSD committee representatives are pressing for an outright ban on home-use lasers and IPLs to restrict them to use by doctors only.
• Given that other ‘directed energy’ products incl. electrolysis kits, high frequency skin cleansing, ultrasound, galvanic and radio frequency skin stimulation appliances all intentionally cause at least minor effects to the skin, perhaps a new MDD class of cosmetic medical devices needs to be considered?
Thank you for your attention!

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