Clinical Investigation of Laser Vision Correction Using an All-Solid State Deep-UV Laser: 6 Months Follow-up

Dr. M. Rossi MD*, Dr. P. Garimoldi MD, Dr. P. Giorgi, Dr. M. Schmidt
Dipartement of Ophthalmology, Busto Arsizio Hospital, Varese – Italy

ASCRS – Washington DC, April 15-20, 2005

* The authors have financial interest in product presented
The reasons of a choice

Clinical Advantages

- Small spot size, **0.2 µm with perfect gaussian mode** creates very detailed contours:
  - very smooth surface with fast healing
  - best for a Custom Laser Vision Correction
- **210 nm Wavelength** passes through water and BSS: ablation is not effected by cornea hydration
- Fast and accurate eyetracker
- Aspheric ablation profile
The reasons of a choise

The clinical advantages of the LaserSoft system can be differentiated into:

- Fast and accurate eyetracker
- Aspheric ablation profile

The larger the treatment zone, the more the beam is made elliptical and the more reflection we get. This effect can be anticipated, and additional pulses are being set in the periphery. This creates effectively large optical zones and maintains the original asphericity of the cornea.
Introduction

- First wide experience with Katana LaserSoft: *six month follow-up.*
- The **purpose** of this study is to evaluate the **efficacy, safety** and **stability** of this laser system with standard treatments.
- Surgery: phorefractive cheratectomy (PRK)
### Patients and Methods

**TOTAL TREATMENT**
- 185 patients - 322 eyes
- Mean age: 37 +/- 13
- Mean refractive error sf.eq. -2.03D +/- 2.66

<table>
<thead>
<tr>
<th>Type of Refractive Error</th>
<th>Number of Eyes</th>
<th>Mean Refractive Error sf.eq.</th>
<th>Max sf.eq.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Myopia and myopic astigmatism</td>
<td>244</td>
<td>-3.08D +/- 2</td>
<td>-11D</td>
</tr>
<tr>
<td>Hyperopia and hyperopic astigmatism</td>
<td>58</td>
<td>+1.9D +/- 1.13</td>
<td>+6.13D</td>
</tr>
<tr>
<td>Mixed astigmatism</td>
<td>19</td>
<td>-0.31D +/- 0.66</td>
<td>+2 D; min sf.eq. -4.50D</td>
</tr>
</tbody>
</table>
Clinical Result: corneal temperature during treatment

- **SP01: 32.0**

Before treatment

Corneal temperature before treatment and during treatment - N° 10 eyes.

- **SP01: 32.4**

During treatment

0.5°C mean temp. increase (max 1°C) VS 5.3°C (max 7°C) in eyes treated with excimer laser
Clinical Results: EFFICACY
Postop. UCVA % over time

Constant improvement of visual acuity over time
Clinical Results: EFFICACY
Post-op. UCVA % over time

- 15 days 96.89% of the eyes showed a UCVA of 0.5 or better,
- 97.34% after 1.5 months,
- 98.41% after 3 months,
- 99.07% after 6 months.

- Faster visual recover in myopic treatments:
  - 97.95% after 15 days,
  - 98.68% after 3 months.
Clinical Results: SAFETY
Post-op. BCVA% over time

<table>
<thead>
<tr>
<th>Katana Treatments</th>
<th>PRE-OP (n°322)</th>
<th>15 Days (n°322)</th>
<th>45 Days (n°263)</th>
<th>3 Months (n°198)</th>
<th>6 Months (n°107)</th>
</tr>
</thead>
<tbody>
<tr>
<td>BCVA ±SD</td>
<td>0,97 ±0,13</td>
<td>0,90 ±0,20</td>
<td>1,0 ±0,16</td>
<td>1,07 ±0,16</td>
<td>1,11 ±0,17</td>
</tr>
</tbody>
</table>

BCVA value reaches the preoperative value just after one month
...more about SAFETY

Total treatments and myopic treatments
...more about SAFETY

Before surgery 83% of the eyes had a BCVA of 1.0 or better: after 15 days 52% of the eyes showed a BCVA of 1.0 or better; the percentage increased to 73% after 1.5 months, to 86% after 3 months and to 92% after 6 months.
Clinical Results: **STABILITY**

- **Total treatments**
- **Myopic treatments**
Clinical Results vs FDA Targets

3 months results

<table>
<thead>
<tr>
<th>CLINICAL RESULTS</th>
<th>FDA</th>
<th>KATANA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Efficacy Variables</td>
<td></td>
<td></td>
</tr>
<tr>
<td>UCVA 1,0 or better</td>
<td>50%</td>
<td>72%</td>
</tr>
<tr>
<td>UCVA 0,5 or better</td>
<td>85%</td>
<td>98%</td>
</tr>
<tr>
<td>MRSE ± 0,5D</td>
<td>50%</td>
<td>90%</td>
</tr>
<tr>
<td>MRSE ± 1D</td>
<td>75%</td>
<td>96%</td>
</tr>
<tr>
<td>Safety Variables</td>
<td></td>
<td></td>
</tr>
<tr>
<td>BCVA Loss &gt; 2 lines</td>
<td>&lt; 5%</td>
<td>3,7%</td>
</tr>
<tr>
<td>BCVA Worse than 0,5</td>
<td>&lt; 1%</td>
<td>0,5%</td>
</tr>
</tbody>
</table>
Clinical Results: centering

- Difference between center of the treatment and pupil center.
- Difference altitudinal maps: myopic treatments (30).
- Mean ± SD: 0.163 ± 0.057
  - lower 95% conf. limit: 0.127
  - upper 95% conf. limit: 0.2
Clinical Results: Ablation

- Regularity of the ablation.
- Difference between pre-op and post-op coma at 3 mm and 5 mm; topographic analysis; myopic treatments (30).
  - Coma 3 mm: $P = 0.7817$ not significant
  - Coma 5 mm: $P = 0.3894$ not significant
Thank you for your attention

Dr. M. Rossi
For information: mrossi@aobusto.it