Clinical investigation of laser correction using an all solid-state deep UV laser: 6 month follow-up

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¹) Sperimentatore Katana
Katana LaserSoft vs Excimer Laser

- **Wavelength**
  - Katana LaserSoft: 210 nm (1)
  - Excimer Laser: 193 nm

- **Laser fluence**
  - Katana LaserSoft: 140 mJ/cm²
  - Excimer Laser: 100-200 mJ/cm²

- **Beam diameter**
  - Katana LaserSoft: 0.2-0.3 mm flying spot
  - Excimer Laser: 0.8-2.0 mm flying spot

- **Beam homogenization method**
  - Katana LaserSoft: Not required
  - Excimer Laser: Use of UV-optic

- **Beam colimation**
  - Katana LaserSoft: Collimated (2)
  - Excimer Laser: Focussed

(1) – Much less adsorption in water
(2) - Alation is independent from cornea’s height position
Introduction

First wide experience with Katana LaserSoft: more than 500 eyes treated.

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

- 259 Eyes of
- 110 patients, mean age 37±15
- Follow-up: 6 months
- Treatments:
  - optical zone 6.5 to 7.5 mm and
  - 1 mm transition zone

<table>
<thead>
<tr>
<th>Group</th>
<th>N°</th>
</tr>
</thead>
<tbody>
<tr>
<td>Myopia and Myopic Astigmatism</td>
<td>198</td>
</tr>
<tr>
<td>Hyperopia and Hyperopic Astigmatism</td>
<td>42</td>
</tr>
<tr>
<td>Mixed Astigmatism</td>
<td>19</td>
</tr>
<tr>
<td>Total</td>
<td>259</td>
</tr>
</tbody>
</table>
## Refraction (D)

<table>
<thead>
<tr>
<th>Group</th>
<th>Sfere ±SD</th>
<th>Min/Max</th>
<th>Astigmat ±SD</th>
<th>Min/Max</th>
<th>Sf.Eq. ±SD</th>
<th>Min/Max</th>
</tr>
</thead>
<tbody>
<tr>
<td>Myopia and Myopic Astigmatism</td>
<td>-2,56 ±1,96</td>
<td>0,0</td>
<td>-0,87 ±0,99</td>
<td>0,0</td>
<td>-3,0 ±1,97</td>
<td>0,0</td>
</tr>
<tr>
<td>Hyperopia and Hyperopic Astigmatism</td>
<td>+1,31 ±1,21</td>
<td>+0,00</td>
<td>+1,11 ±1,0</td>
<td>0,0</td>
<td>+1,81 ±1,20</td>
<td>+0,0</td>
</tr>
<tr>
<td>Mixed Astigmatism</td>
<td>+0,10 ±0,80</td>
<td>-1,00</td>
<td>-1,50 ±3,24</td>
<td>-4,50</td>
<td>-0,65 ±0,86</td>
<td>-1,50</td>
</tr>
<tr>
<td>Total</td>
<td>-1,72 ±2,38</td>
<td>-9,50 ±5,50</td>
<td>-0,61 ±1,36</td>
<td>-5,75 ±4,0</td>
<td>-2,01 ±2,58</td>
<td>-10,50 ±6,13</td>
</tr>
</tbody>
</table>
Clinical Results: EFFICACY
Postop. UCVA % over time
Clinical Results: EFFICACY

Postop. UCVA % over time

- After 15 days 97.30% of the eyes showed a UCVA of 0.5 or better,
  95.61% after 1.5 months,
  97.55% after 3 months
  96.15% after 6 months.

- Faster visual recover in myopic treatments.
Clinical Results: SAFETY

<table>
<thead>
<tr>
<th>Katana Treatments</th>
<th>PRE-OP (n°259)</th>
<th>15 Days (n°228)</th>
<th>45 Days (n°163)</th>
<th>3 Months (n°78)</th>
<th>6 Months (n°78)</th>
</tr>
</thead>
<tbody>
<tr>
<td>BCVA ±SD</td>
<td>0,98 ±0,12</td>
<td>0,92 ±0,19</td>
<td>1,02 ±0,19</td>
<td>1,06 ±0,17</td>
<td>1,08 ±0,20</td>
</tr>
</tbody>
</table>

BCVA value reaches the preoperative value just after one month.
Clinical Results: SAFETY

BCVA \geq 1,0: before surgery 85,33\%, 54,44\% after 15 days, 73,25\% after 1,5 months, 83,44\% after 3 months and 87,18\% after 6 months.
Clinical Results: STABILITY

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<th>PREOP</th>
<th>15 Days (n°259)</th>
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<th>3 Months (n°163)</th>
<th>6 Months (n°78)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sf.Eq. ±SD</td>
<td>-2.01 ±1.58</td>
<td>-0.07 ±0.38</td>
<td>-0.08 ±0.46</td>
<td>-0.06 ±0.35</td>
<td>-0.03 ±0.16</td>
</tr>
</tbody>
</table>
### Clinical Results vs FDA Targets

#### 3 Months Clinical Results in Myopic Treatments

<table>
<thead>
<tr>
<th></th>
<th>FDA</th>
<th>KATANA Myopia</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Efficacy Variables</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>UCVA 1,0 or better</td>
<td>50%</td>
<td>83%</td>
</tr>
<tr>
<td>UCVA 0,5 or better</td>
<td>85%</td>
<td>97%</td>
</tr>
<tr>
<td>MRSE ± 0,5D</td>
<td>50%</td>
<td>93%</td>
</tr>
<tr>
<td>MRSE ± 1D</td>
<td>75%</td>
<td>98%</td>
</tr>
<tr>
<td><strong>Safety Variables</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>BCVA Loss &gt; 2 lines</td>
<td>&lt; 5%</td>
<td>2%</td>
</tr>
<tr>
<td>BCVA Worse than 0,5</td>
<td>&lt; 1%</td>
<td>No</td>
</tr>
</tbody>
</table>
Clinical Results: centering

- Difference between center of the treatment and pupil center.
- Difference altitudinal maps: myopic treatments (82).
  - Mean ± SD: 0.206 ± 0.12
  - Lower 95% conf. limit: 0.136
  - Upper 95% conf. limit: 0.275
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 (82).
- Coma 3 mm: $P = 0.7931$ not significant
- Coma 5 mm: $P = 0.4332$ not significant
Thank you for your attention

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