Clinical Investigation of Laser Vision Correction Using an All-Solid State Deep-UV Laser: two year experience

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* The authors have financial interest in product presented
Introduction

- First wide experience with Katana LaserSoft: one year follow-up.
- Two years experience
- 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**
- 554 eyes
- mean age 38 +/- 13
- mean refractive error sf.eq. -2.32D +/- 2.96

**myopia and myopic astigmatism**
- 425 eyes
- mean refractive error sf.eq. -3.43D +/- 2.37
- max sf.eq. -12.50D

**hyperopia and hyperopic astigmatism**
- 91 eyes
- mean refractive error sf.eq. +1.86D +/- 1.09
- max sf.eq. +6.13D

**mixed astigmatism**
- 38 eyes
- mean refractive error sf.eq. -0.31D +/- 0.66
- max sf.eq. +2 D; min sf.eq. -4.50D
Clinical Result: corneal temperature during treatment

Before treatment

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

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: SAFETY

Before surgery 84% of the eyes had a BCVA of 1.0 or better: after 3 months 83% of the eyes showed a BCVA of 1.0 or better; the percentage increased to 91% after 6 months, to 91% after 1 year. BCVA value reaches the preoperative value just after 3 months.
Clinical Results: STABILITY

Total treatments

Myopia sf.eq. > 8D: over-correction

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# Clinical Results vs FDA Targets

## 6 months results

<table>
<thead>
<tr>
<th>Efficacy Variables</th>
<th>FDA</th>
<th>KATANA</th>
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<tbody>
<tr>
<td><strong>UCVA 1.0 or better</strong></td>
<td>50%</td>
<td>84%</td>
</tr>
<tr>
<td><strong>UCVA 0.5 or better</strong></td>
<td>85%</td>
<td>98%</td>
</tr>
<tr>
<td><strong>MRSE ± 0.5D</strong></td>
<td>50%</td>
<td>97%</td>
</tr>
<tr>
<td><strong>MRSE ± 1D</strong></td>
<td>75%</td>
<td>98.5%</td>
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<table>
<thead>
<tr>
<th>Safety Variables</th>
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<tbody>
<tr>
<td><strong>BCVA Loss &gt; 2 lines</strong></td>
<td>&lt; 5%</td>
<td>2%</td>
</tr>
<tr>
<td><strong>BCVA Worse than 0.5</strong></td>
<td>&lt; 1%</td>
<td>0%</td>
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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
Conclusion

◊ Advantages:
  ■ Effective and safe laser for refractive surgery
  ■ Reduced corneal inflammation: less pain, faster corneal healing, faster visual recovery

◊ Disadvantages:
  ■ Overcorrection in high myopia due to longer treatments: the problem should be solved with 2 KHz frequency
Thank you for your attention

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