

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

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Azienda Ospedaliera –

Ospedale di Circolo di Busto Arsizio (VA)

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1) Sperimentatore Katana



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Ospedale di Circolo di Busto Arsizio
Busto Arsizio Saronno Tradate

Katana LaserSoft vs Excimer laser

	◆ Katana LaserSoft	◆ Excimer Laser
◆ Wavelength	◆ 210 nm ⁽¹⁾	◆ 193 nm
◆ Laser fluence	◆ 140 mJ/cm ²	◆ 100-200 mJ/cm ²
◆ Beam diameter	◆ 0.2-0.3 mm flying spot	◆ 0.8-2.0 mm flying spot
◆ Beam homogenization method	◆ Not required	◆ Use of UV-optic
◆ Beam collimation	◆ Collimated ⁽²⁾	◆ Focussed

(1) – Much less adsorption in water

(2) - Ablation 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

Group	N°
Myopia and Myopic Astigmatism	198
Hyperopia and Hyperopic Astigmatism	42
Mixed Astigmatism	19
Total	259



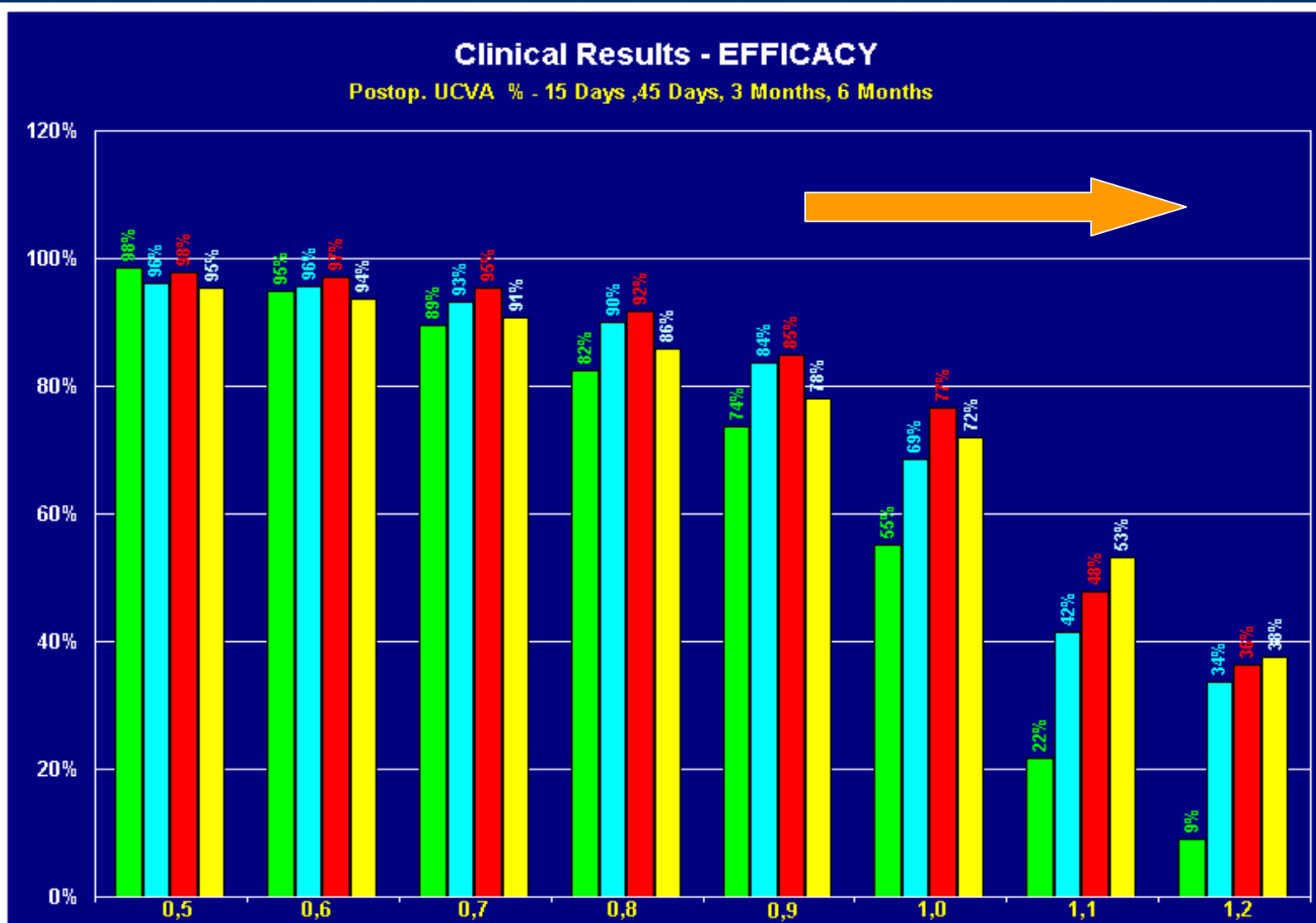
Refraction (D)

Group	Sfere ±SD	Min/ Max	Astig m ±SD	Min/ Max	Sf.Eq. ±SD	Min/ Max
Myopia and Myopic Astigmatism	-2,56 ±1,96	0,0 -9,50	-0,87 ±0,99	0,0 -5,75	-3,0 ±1,97	0,0 -10,50
Hyperopia and Hyperopic Astigmatism	+1,31 ±1,21	+0,00 +5,50	+1,11 ±1,0	0,0 +4,0	+1,81 ±1,20	+0,0 +6,13
Mixed Astigmatism	+0,10 ±0,80	-1,0 +0,75	-1,50 ±3,24	-4,50 +2,0	-0,65 ±0,86	-1,50 0,0
Total	-1,72 ±2,38	-9,50 ±5,50	-0,61 ±1,36	-5,75 ±4,0	-2,01 ±2,58	-10,50 ±6,13



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.



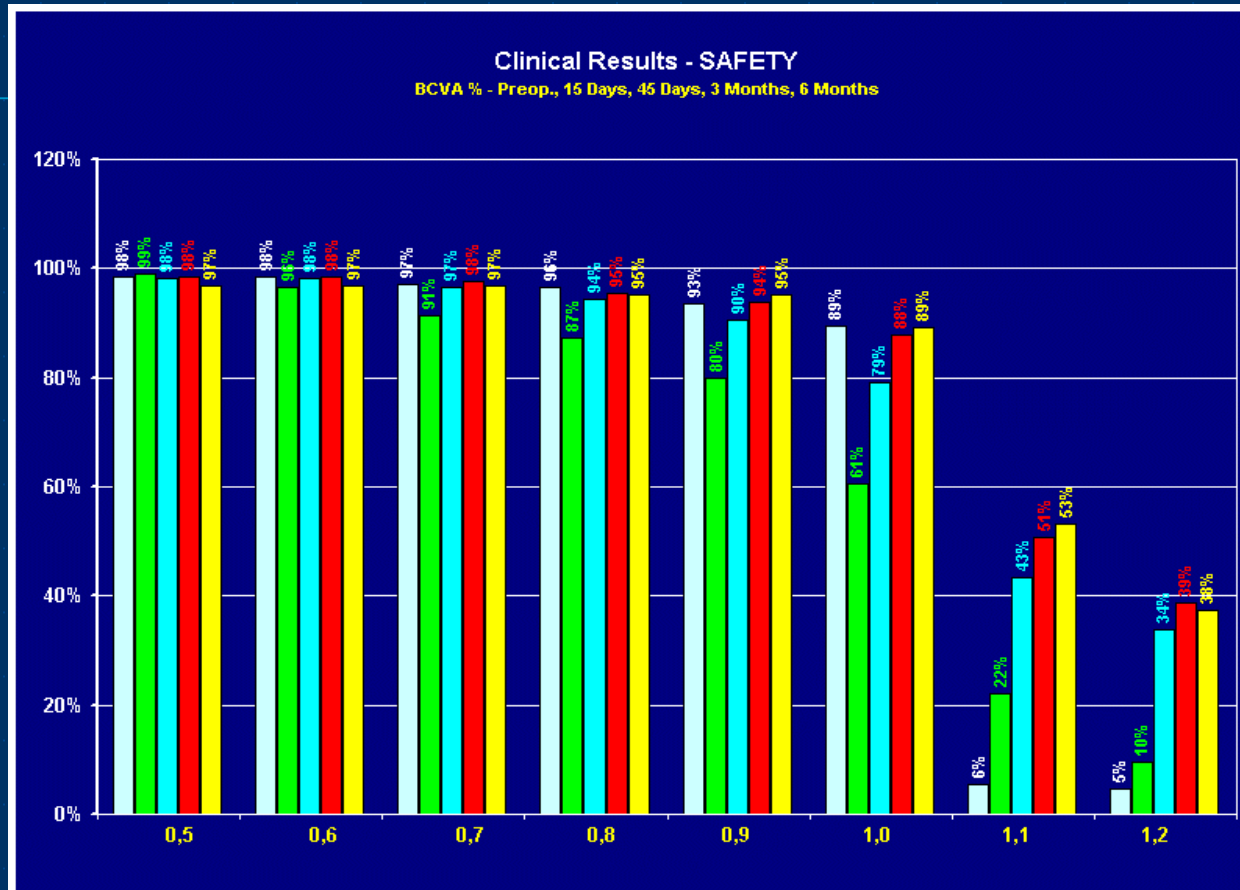
Clinical Results: SAFETY

Katana Treatments	PRE-OP	15 Days (n°259)	45 Days (n°228)	3 Months (n°163)	6 Months (n°78)
BCVA ±SD	0,98 ±0,12	0,92 ±0,19	1,02 ±0,19	1,06 ±0,17	1,08 ±0,20

BCVA value reaches the preoperative value just after one month



Clinical Results: SAFETY

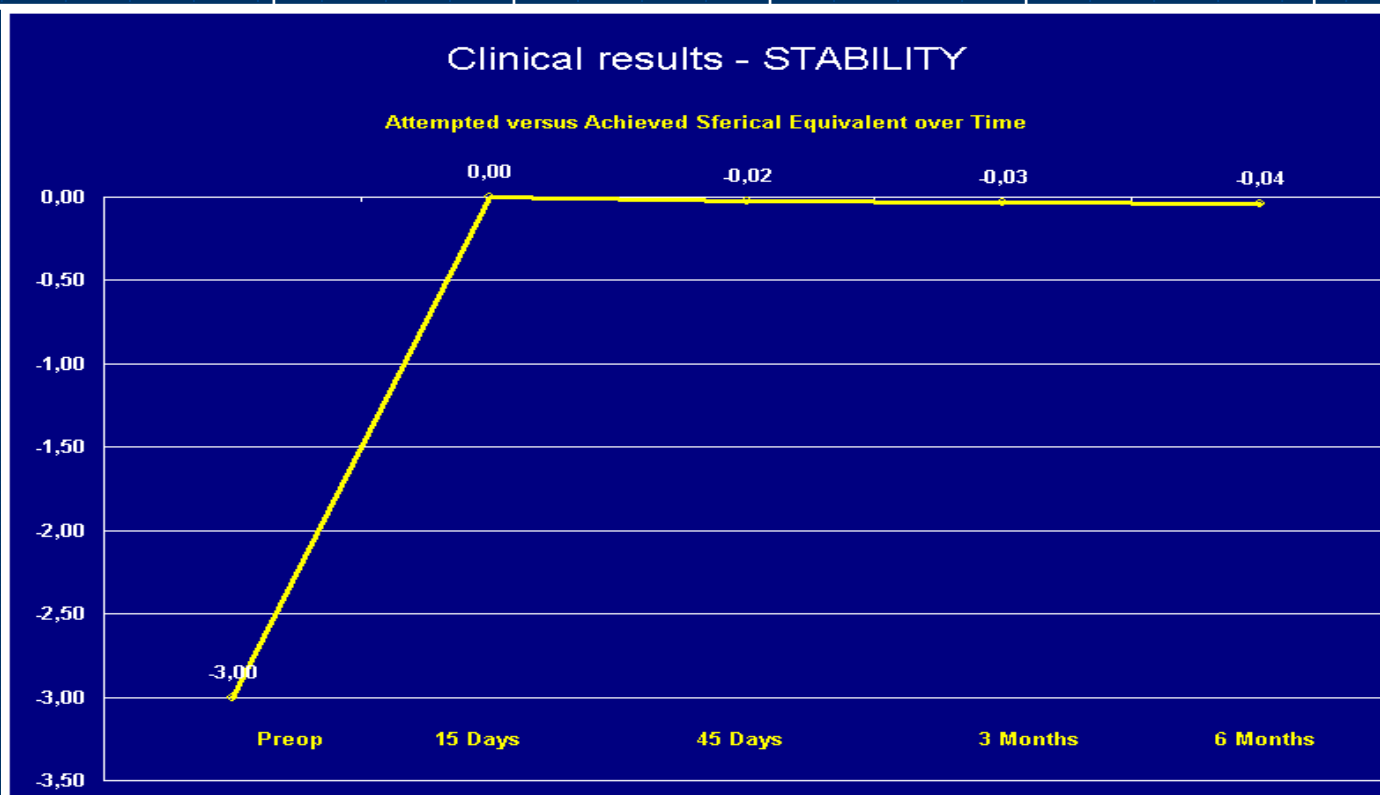


- ◇ BCVA $\geq 1,0$: before surgery 85,33%, 54,44% after 15 days, 73,25% after 1,5 months, 83,44% after 3 months and 87,18% after 6 months.



Clinical Results: STABILITY

Katana Treatments	PREOP	15 Days (n°259)	45 Days (n°228)	3 Months (n°163)	6 Months (n°78)
Sf.Eq. ±SD	-2,01 ±1,58	-0,07 ±0,38	-0,08 ±0,46	-0,06 ±0,35	-0,03 ±0,16



Clinical Results vs FDA Targets

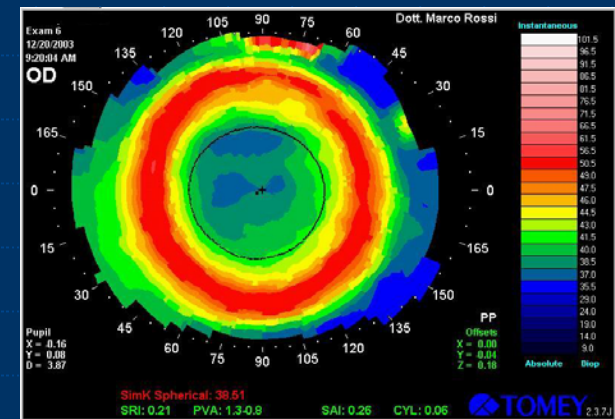
3 Months Clinical Results in Myopic Treatments

CLINICAL RESULTS	FDA	KATANA
<i>Efficacy Variables</i>		<i>Myopia</i>
◆ UCVA 1,0 or better	50%	83%
◆ UCVA 0,5 or better	85%	97%
◆ MRSE $\pm 0,5D$	50%	93%
◆ MRSE $\pm 1D$	75%	98%
<i>Safety Variables</i>		
◆ BCVA Loss > 2 lines	< 5%	2%
◆ BCVA Worse than 0,5	< 1%	No



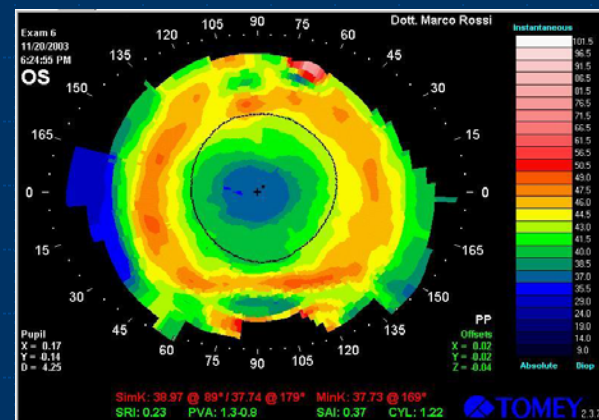
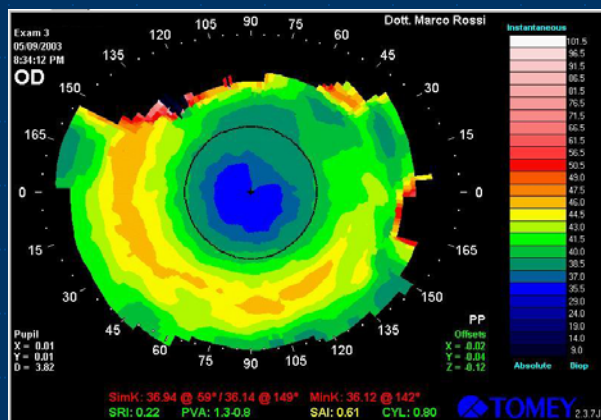
Clinical Results: centering

- ◆ Difference between center of the treatment and pupil center.
- ◆ Difference altitudinal maps: myopic treatments (82).
- ◆ Mean \pm SD: $0,206 \pm 0,12$
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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