

Clinical investigation of laser correction using an all-solid-state deep-UV laser

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Introduction

- ✿ First wide experience with Katana LaserSoft: 161 eyes treated so far.
- ✿ The purpose of this study is to evaluate the efficacy of this laser system with standard treatments.
- ✿ Surgery: photorefractive Keratectomy (PRK)



Katana LaserSoft vs Excimer laser

◊ Katana LaserSoft	■ Excimer Laser
■ Wavelength	■ 193 nm
■ Laser fluence	■ 100-200 mJ/cm ²
■ Beam diameter	■ 0.8-2.0 mm flying spot
■ Beam homogenization method	■ Not required
■ Beam collimation	◊ Collimated ⁽²⁾ ■ Focussed

(1) – Much less adsorption in water

(2) - Alation is independent from cornea's height position



Patients and Methods

- *82 Eyes of
- *45 patients, mean age 29±06
- *Follow-up: 6 months
- *Treatments:
optical zone 6.5 mm and
1 mm transition zone

Group	N°
Myopia and Myopic Astigmatism	61
Hyperopia and Hyperopic Astigmatism	16
Mixed Astigmatism	5
Total	82

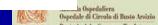
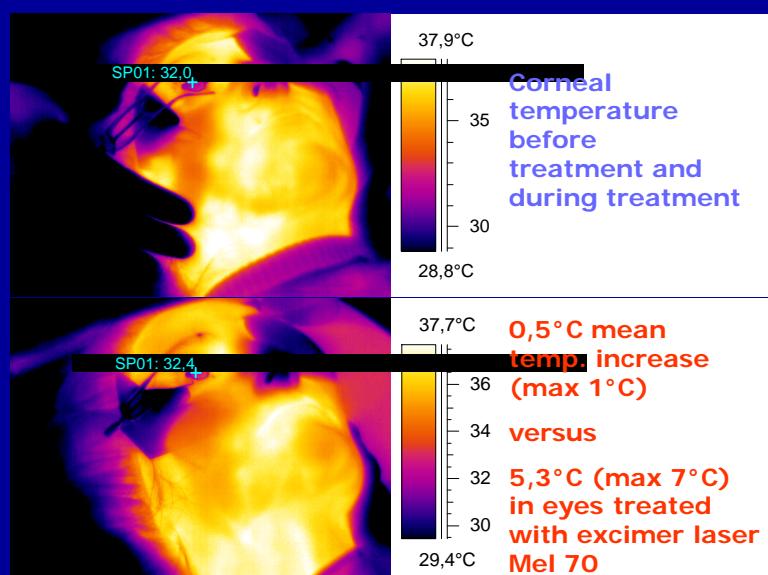


Refraction (D)

Group	Sfere ±SD	Min/ Max	Astig m ±SD	Min/ Max	Sf.Eq. ±SD	Min/ Max
Myopia and Myopic Astigmatism	-2,46 ±1,45	-0,25 -7,50	-0,92 ±1,02	0,0 -3,75	-2,92 ±1,44	-0,63 -9,0
Hyperopia and Hyperopic Astigmatism	+1,59 ±1,55	+0,00 +5,50	+1,20 ±0,82	0,0 +3,0	+2,20 ±1,55	+0,50 +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	-1,48 ±2,17	-7,50 ±5,50	-0,56 ±1,48	-4,50 ±3,00	-1,76 ±2,48	-9,00 ±6,13



Clinical Result: corneal temperature during treatment



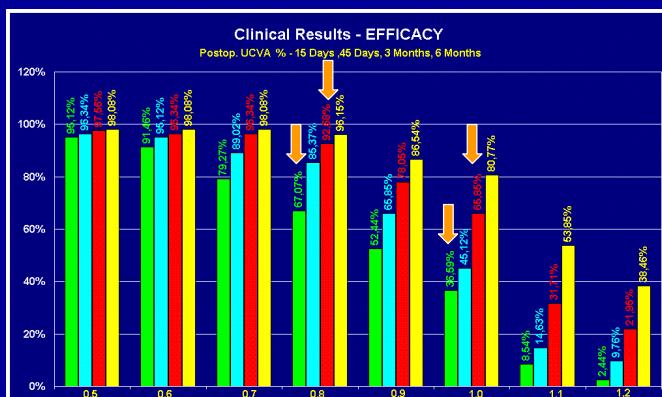
Clinical Results: EFFICACY, SAFETY, STABILITY

Katana Treatments	PREOP	15 Days (n° 82)	45 Days (n° 82)	3 Months (n° 82)	6 Months (n° 52)
UCVA ±SD	0,23 ±0,16	0,83 ±0,20	0,90 ±0,21	0,98 ±0,18	1,07 ±0,20
BCVA ±SD	0,97 ±0,12	0,91 ±0,17	0,97 ±0,16	1,03 ±0,14	1,09 ±0,17
Sf.Eq. ±SD	-1,76 ±2,48	-0,22 ±0,60	-0,22 ±0,63	-0,14 ±0,47	-0,06 ±0,21



Clinical Results: EFFICACY Postop. UCVA % over time

- Constant improvement over time, with about thirty points in the postoperative UCVA of 0.8 and 1.0 from 15 days to 3 months



Clinical Results: EFFICACY

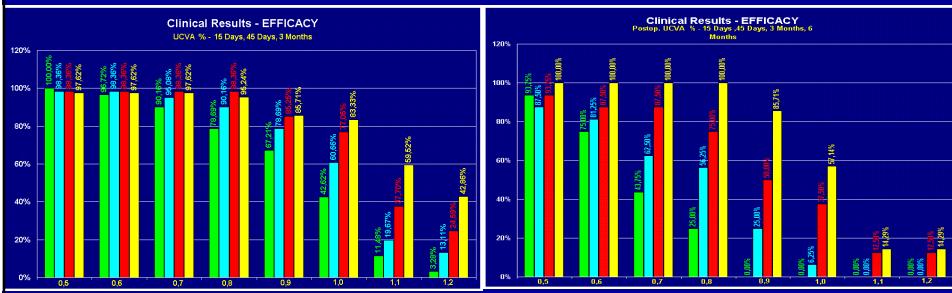
Postop. UCVA % over time

- After 15 days 95.12% of the eyes showed a UCVA of 0.5 or better; the percentage increased to 96.34% after 1.5 months, to 97.56% after 3 months and to 98.08% after 6 months.
- The visual performance is slightly different if we consider only myopic treatments: we have a faster visual recover.



Clinical Results: EFFICACY

Postop. UCVA % over time



- Myopic treatments: fast visual recover
- Hyperopic treatments: good visual improvement



Clinical Results: EFFICACY

Myopia and Myopic Astigmatism	PREOP	15 Days (n° 61)	45 Days (n° 61)	3 Months (n° 61)	6 Months (n° 42)
UCVA ±SD	0,18 ±0,12	0,89 ±0,18	0,96 ±0,19	1,02 ±0,16	1,08 ±0,21
Hyperopia and Hyperopic Astigmatism	PREOP	15 Days (n° 16)	45 Days (n° 16)	3 Months (n° 16)	6 Months (n° 7)
UCVA ±SD	0,37 ±0,19	0,63 ±0,14	0,71 ±0,21	0,86 ±0,22	0,97 ±0,13



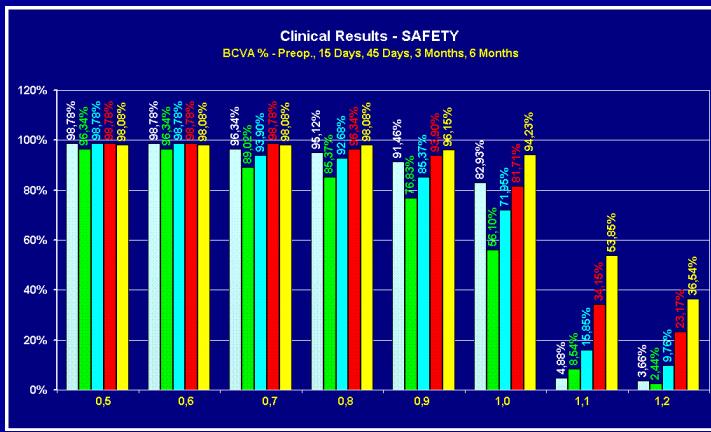
Clinical Results: SAFETY

Katana Treatments	PREOP	15 Days (n° 82)	45 Days (n° 82)	3 Months (n° 82)	6 Months (n° 52)
BCVA ±SD	0,97 ±0,12	0,91 ±0,17	0,97 ±0,16	1,03 ±0,14	1,09 ±0,17

BCVA value reaches the preoperative value just after one month



Clinical Results: SAFETY



- Before surgery 82.93% of the eyes had a BCVA of 1.0 or better: after 15 days 56.10% of the eyes showed a BCVA of 1.0 or better; the percentage increased to 71.95% after 1.5 months, to 81.71% after 3 months and to 94.23 after 6 months.



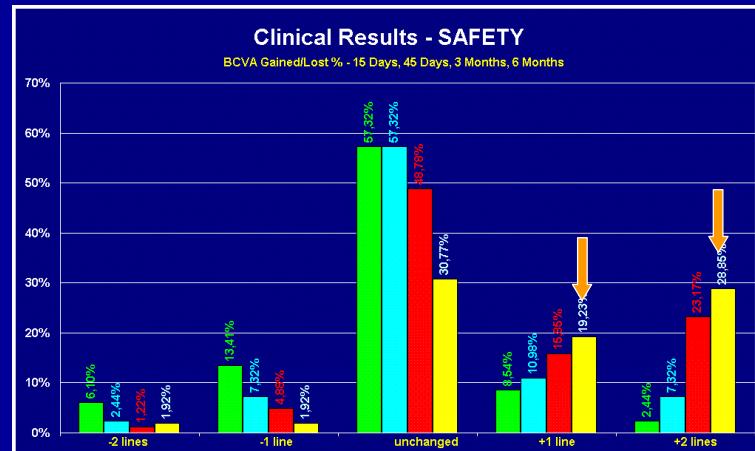
Clinical Results: SAFETY

Myopia and Myopic Astigmatism	PREOP	15 Days (n° 61)	45 Days (n° 61)	3 Months (n° 61)	6 Months (n° 42)
BCVA ±SD	0,97 ±0,14	0,93 ±0,16	1,0 ±0,17	1,05 ±0,14	1,11 ±0,11

Hyperopia and Hyperopic Astigmatism	PREOP	15 Days (n° 16)	45 Days (n° 16)	3 Months (n° 16)	6 Months (n° 7)
BCVA ±SD	0,98 ±0,05	0,87 ±0,05	0,90 ±0,14	0,97 ±0,13	0,99 ±0,12



Clinical Results: SAFETY



- After two weeks the 6.10% and 13.41% of the eyes lost two and one line of BCVA, respectively; these percentages decreased to 1.22% and 4.88% after 3 months.



Clinical Results: SAFETY

- 15.85% of the eyes gained one line of BCVA after 3 months and 19.23% after 6 months.
- 28.85% of the eyes gained two or more line of BCVA.
- In the myopic group, where none eye has a loss of two or more lines of BCVA after 3 months and only 4.92% show a loss of one line.



Clinical Results: STABILITY

Katana Treatments	PREOP	15 Days (n°82)	45 Days (n°82)	3 Months (n°82)	6 Months (n°52)
Sf.Eq. ±SD	-1,76 ±2,48	-0,22 ±0,60	-0,22 ±0,63	-0,14 ±0,47	-0,06 ±0,21



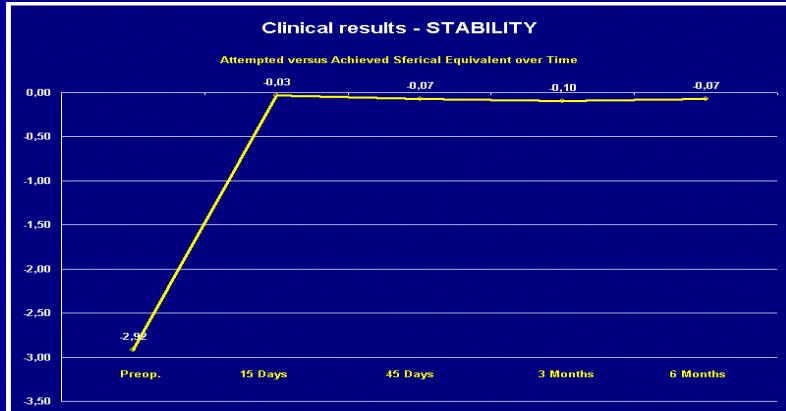
Clinical Results: STABILITY

Myopia and Myopic Astigmatism	PREOP	15 Days (n°61)	45 Days (n°61)	3 Months (n°61)	6 Months (n°42)
Sf.Eq. ±SD	-2,92 ±1,44	-0,03 ±0,30	-0,07 ±0,43	-0,10 ±0,31	-0,07 ±0,24



Clinical Results: STABILITY

■ Myopia treatments



Clinical Results: STABILITY

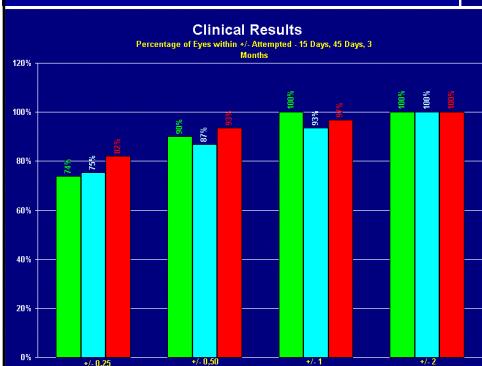
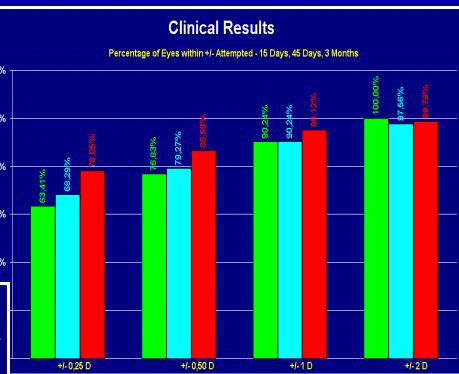
Hyperopia and Hyperopic Astigmatism	PREOP	15 Days (n° 16)	45 Days (n° 16)	3 Months (n° 16)	6 Months (n° 7)
Sf.Eq. ±SD	2,20 ±1,55	-0,96 ±0,89	-0,82 ±0,99	-0,47 ±0,71	-0,03 ±0,09



Clinical Results

Refractive results

All treatments



Myopic treatments



Clinical Results:

EFFICACY, SAFETY, STABILITY

Mixed Astigmatism	PREOP	15 Days (n° 5)	45 Days (n° 5)	3 Months (n° 3)
UCVA ±SD	0,23 ±0,19	0,69 ±0,31	0,95 ±0,06	0,95 ±0,06
BCVA ±SD	0,90 ±0,11	0,69 ±0,31	0,95 ±0,06	0,95 ±0,06
Sf.Eq. ±SD	-0,94 ±0,66	0	0	0

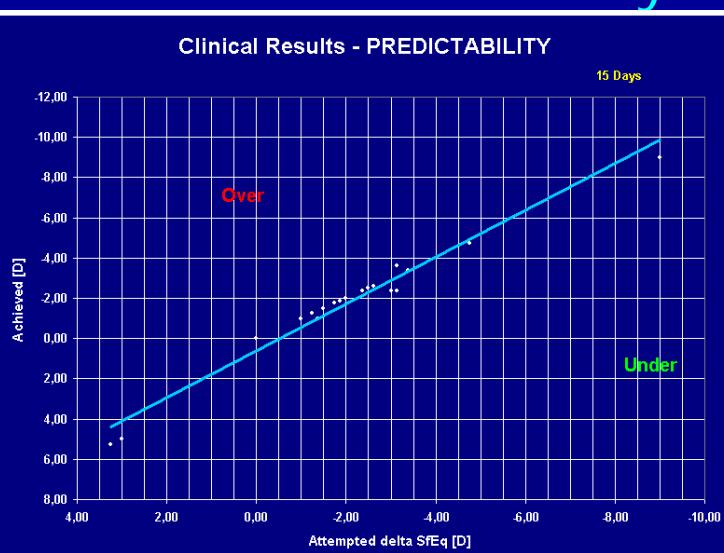


Clinical Results: EFFICACY, SAFETY, STABILITY

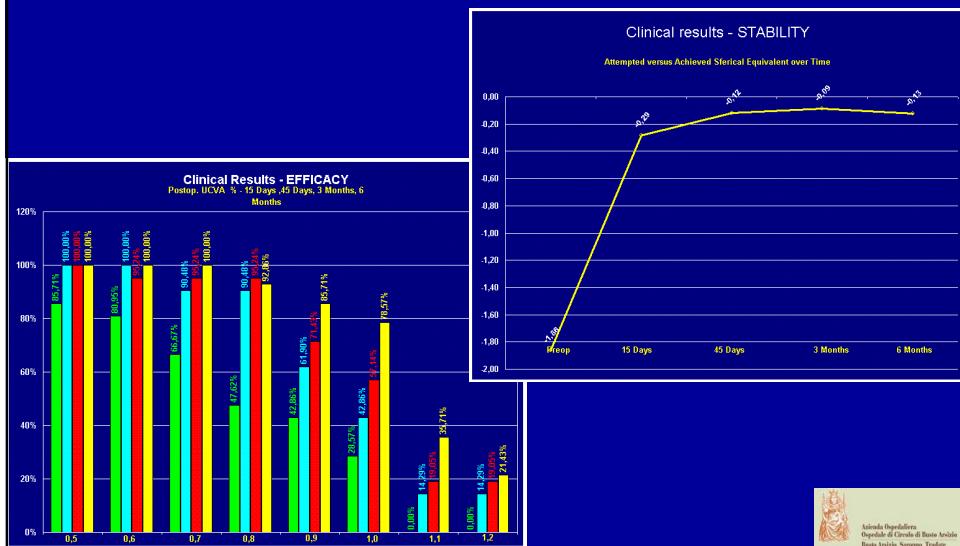
Astigmatism ≥ 2D	PREOP	15 Days (n° 21)	45 Days (n° 21)	3 Months (n° 21)	6 Months (n° 14)
UCVA ±SD	0,20 ±0,15	0,75 ±0,22	0,93 ±0,20	0,95 ±0,17	1,04 ±0,18
BCVA ±SD	0,94 ±0,12	0,83 ±0,19	0,98 ±0,18	1,01 ±0,10	1,07 ±0,13
Sf.Eq. ±SD	-1,86 ±2,53	-0,29 ±0,64	-0,12 ±0,44	-0,09 ±0,56	-0,13 ±0,36



Clinical Results: Astigm. >2D PREDICTABILITY 15 Days



Clinical Results: Astigm. >2D EFFICACY, STABILITY



Clinical Results vs FDA Targets

3 Months Clinical Results in Myopic and

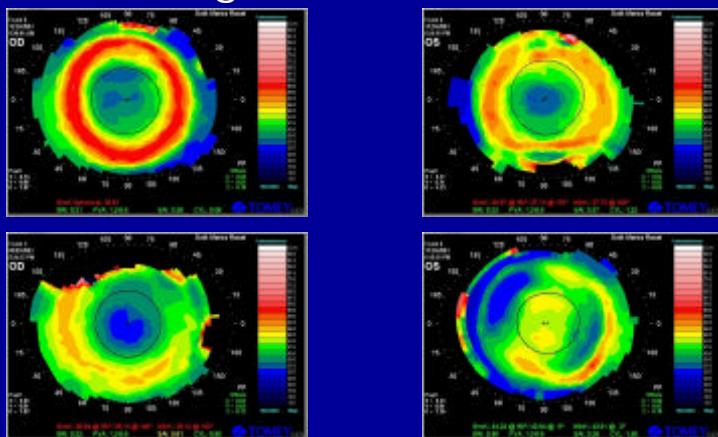
Myopic - Astigmatic Treatments

CLINICAL RESULTS	FDA	KATANA Myopia
Efficacy Variables		
• UCVA 1,0 or better	50%	77%
• UCVA 0,5 or better	85%	98%
• MRSE $\pm 0,5$ D	50%	93%
• MRSE ± 1 D	75%	97%
Safety Variables		
• BCVA Loss > 2 lines	< 5%	No
• BCVA Worse than 0,5	< 1%	No



Clinical Results:

topographic aspects: 3 myopic –
1 mixed astigmatism treatments



Thank you for your
attention

Dr. M. Rossi MD

