



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

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# ?The reasons of a choice

## Clinical Advantages

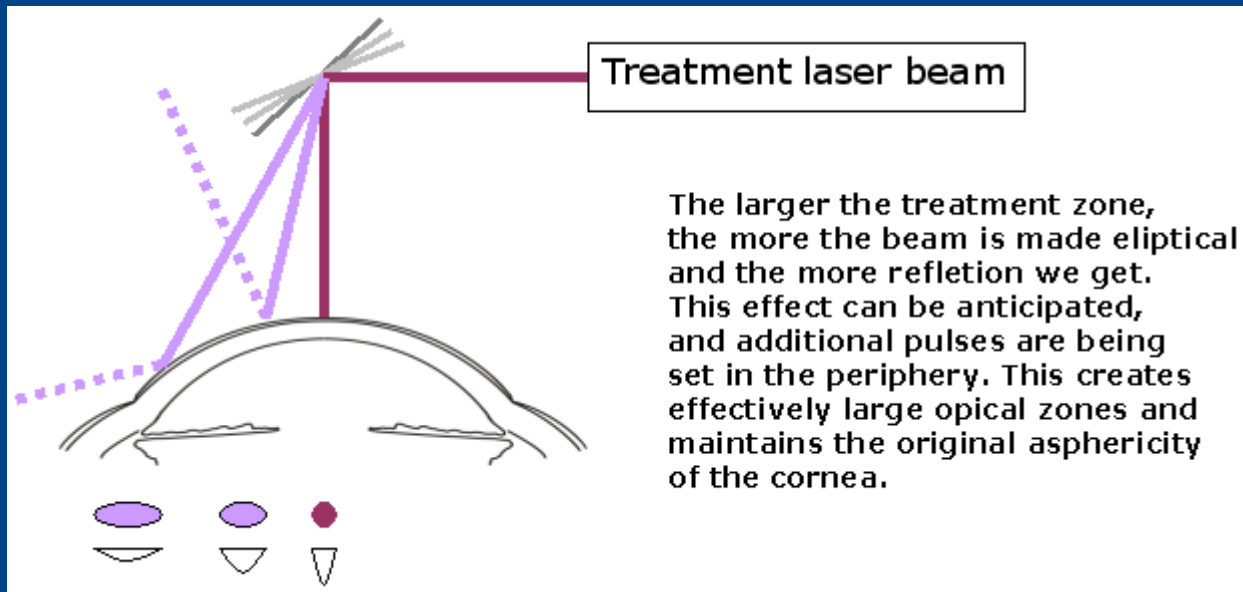
- ➡ Small spot size, 0,2  $\mu\text{m}$  with perfect gaussian mode creates very detailed contours:
  - very smooth surface with fast healing
  - best for a Custom Laser Vision Correction
- ➡ **210 nm Wavelength** passes through water and BSS: ablation is not effected by cornea hydratation
- ➡ **Fast and accurate eyetracker**
- ➡ **Aspheric ablation profile**



# The reasons of a choice

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

- ✓ Fast and accurate eyetracker
- ✓ Aspheric ablation profile



# 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

myopia and myopic astigmatism

244 eyes

mean refractive error sf.eq. -3,08D +/- 2

max sf.eq. -11D

hyperopia and hyperopic astigmatism

58 eyes

mean refractive error sf.eq. +1,9D +/- 1,13

max sf.eq. +6,13D

mixed astigmatism

19 eyes

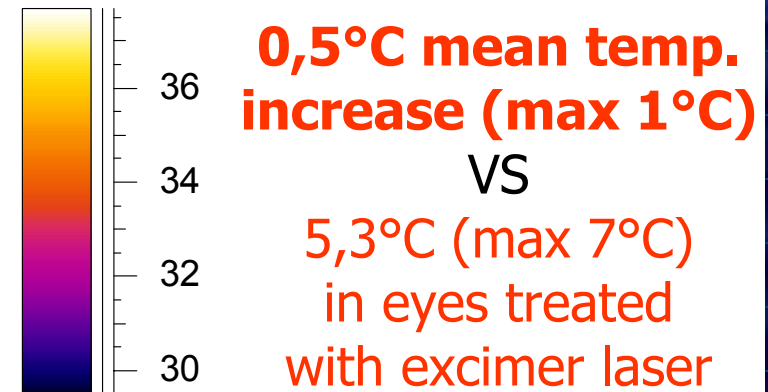
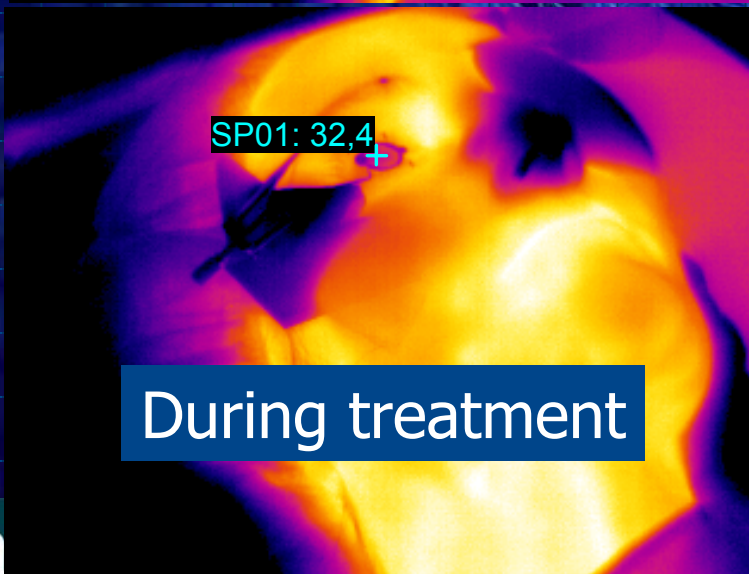
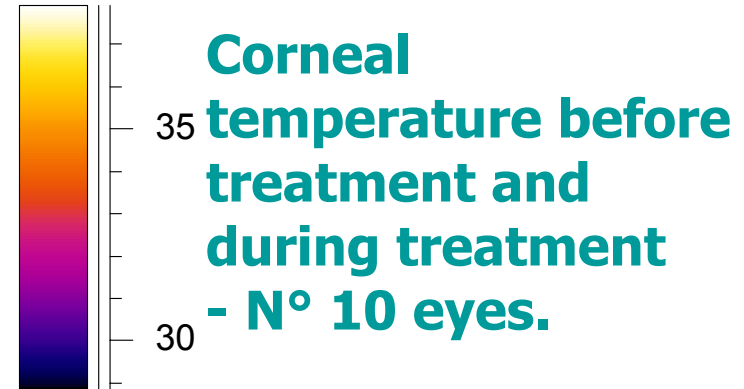
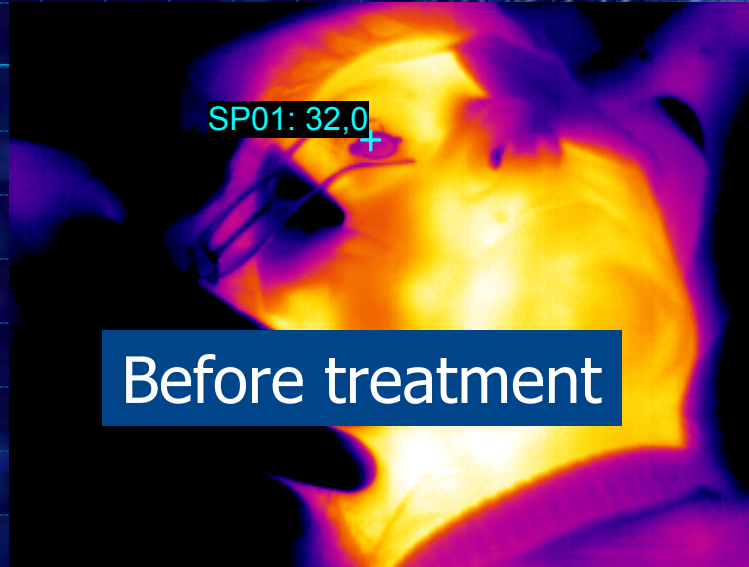
mean refractive error sf.eq. -0,31D +/- 0,66

max sf.eq. +2 D; min sf.eq. -4,50D





# Clinical Result: corneal temperature during treatment

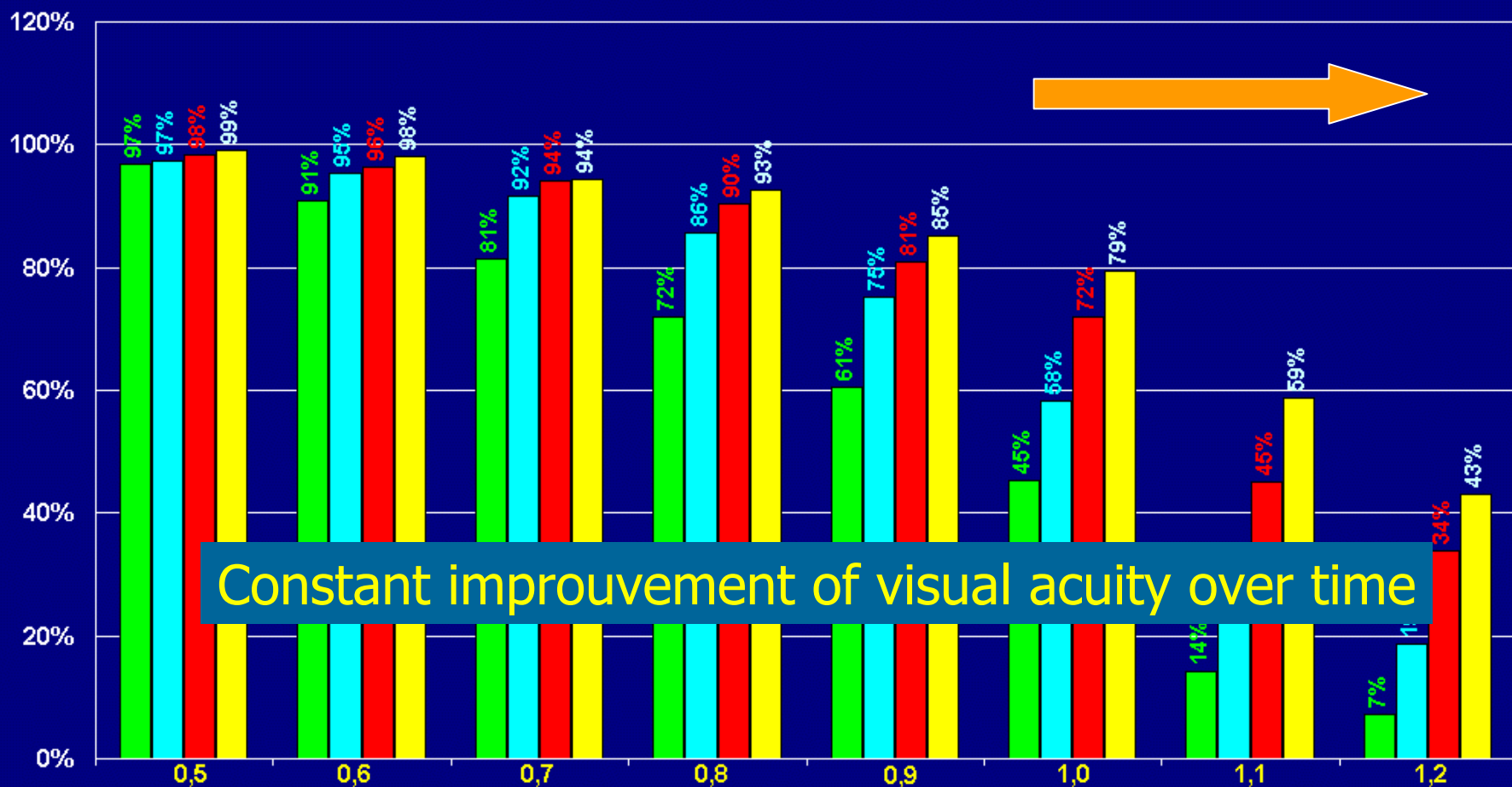


# Clinical Results: EFFICACY

Postop. UCVA % over time

## Clinical Results - EFFICACY

Postop. UCVA % - 15 Days, 45 Days, 3 Months, 6 Months



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

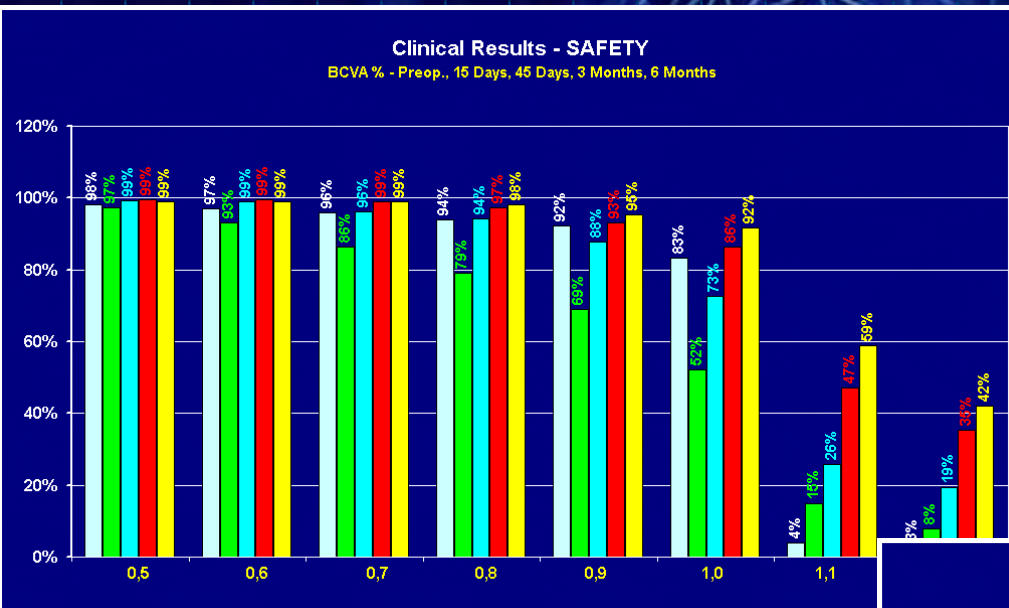
Post-op. BCVA% over time

Katana Treatments	PRE- OP (n°322)	15 Days (n°322)	45 Days (n°263)	3 Months (n°198)	6 Months (n°107)
BCVA ±SD	0,97 ±0,13	0,90 ±0,20	1,0 ±0,16	1,07 ±0,16	1,11 ±0,17

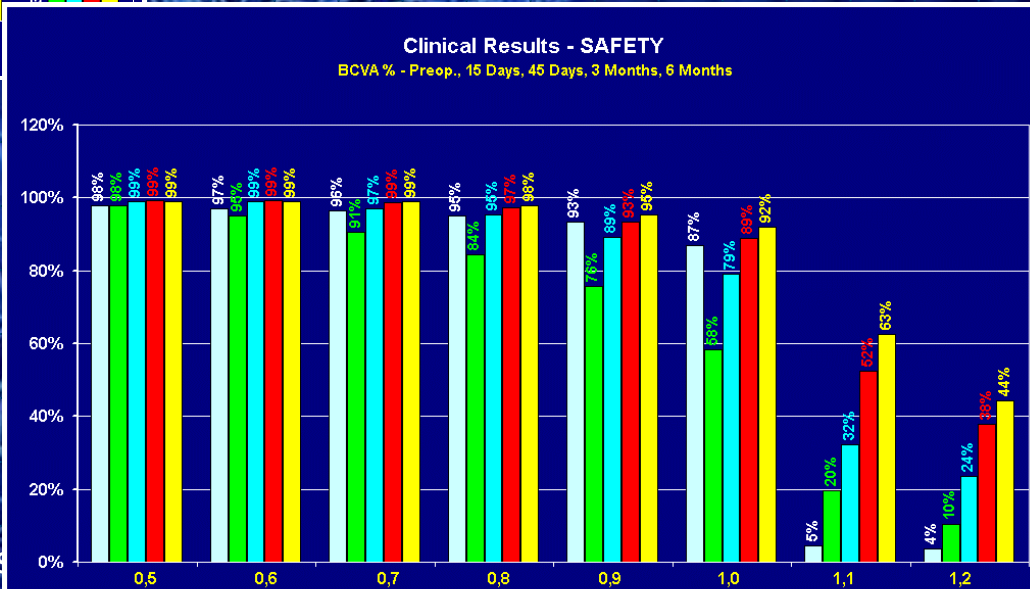
BCVA value reaches the preoperative value just after one month



# ?...more about SAFETY

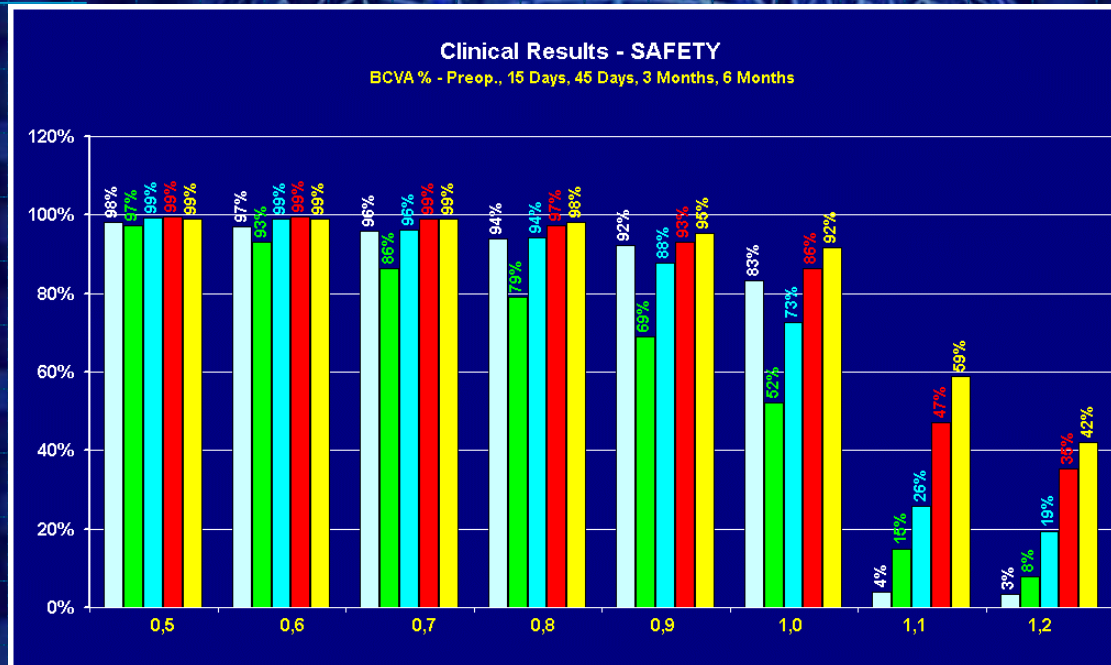


Total treatments and  
myopic treatments



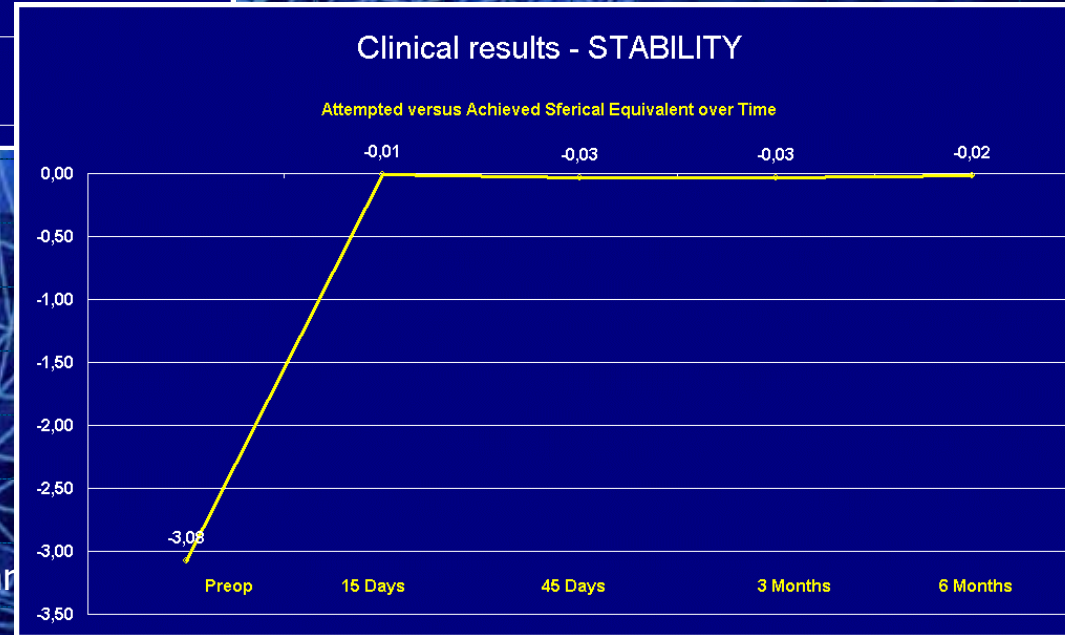
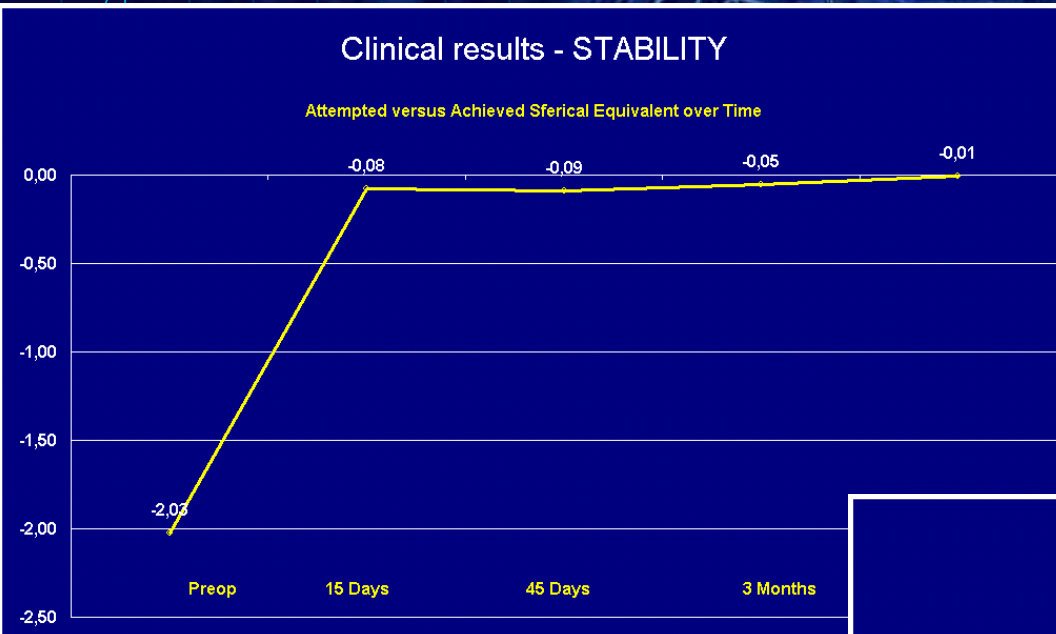


# ...more about SAFETY



- ➡ 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

<b>CLINICAL RESULTS</b>	<b>FDA</b>	<b>KATANA</b>
<b>Efficacy Variables</b>		
• <b>UCVA 1,0 or better</b>	50%	72%
• <b>UCVA 0,5 or better</b>	85%	98%
• <b>MRSE <math>\pm</math> 0,5D</b>	50%	90%
• <b>MRSE <math>\pm</math> 1D</b>	75%	96%
<b>Safety Variables</b>		
• <b>BCVA Loss &gt; 2 lines</b>	< 5%	3,7%
• <b>BCVA Worse than 0,5</b>	< 1%	0,5%

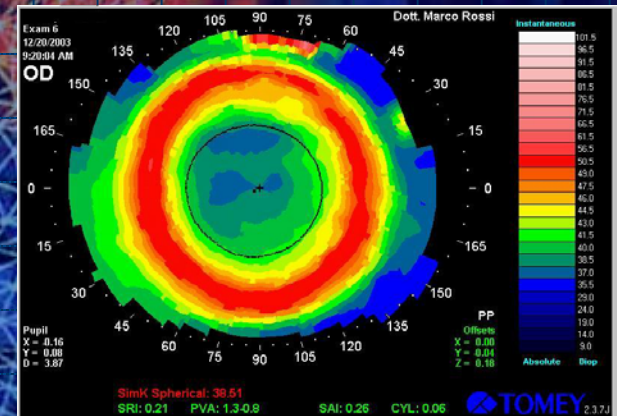


# Clinical Results: centering

- ✿ Difference between center of the treatment and pupil center.
- ✿ Difference altitudinal maps: myopic treatments (30).
- ✿ Mean  $\pm$  SD:  $0.163 \pm 0.057$

lower 95% conf. limit:  $0.127$

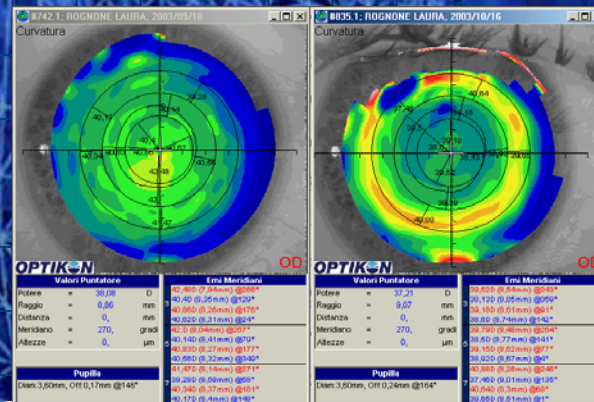
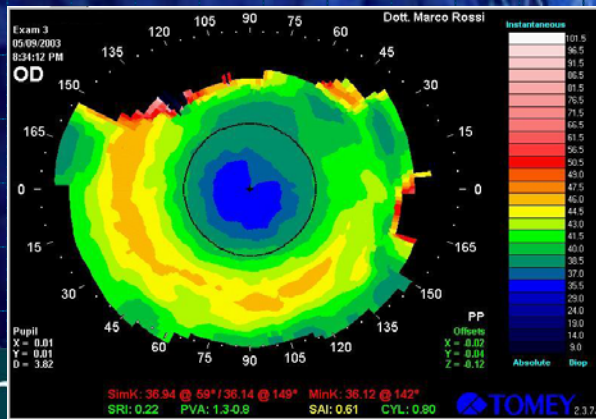
upper 95% conf. limit:  $0.2$





# 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





A wireframe model of a human head in profile, facing right, rendered in a light blue color. It is set against a dark blue background with a fine grid pattern. The head is composed of a mesh of lines, with some areas on the face highlighted in a reddish-orange color. The text is overlaid on the left side of the head.

# Thank you for your attention

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