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Articles

Long Term Efficacy, Safety, Predictability and Stability of Surface Ablation with All Solid-State Laser for Laser Vision Correction. LaserSoft Katana Technologies.

M. Rossi MD, M. Schmidt MD, P. Garimoldi MD

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Long Term Efficacy, Safety, Predictability and Stability of Surface Ablation with All Solid-State Laser for Laser Vision Correction.
LaserSoft Katana Technologies.

M. Rossi MD, M. Schmidt MD, P. Garimoldi MD

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Introduction

LaserSoft is an all-solid state UV laser for refractive laser vision correction (LVC). The UV laser radiation for ablation is generated by nonlinear frequency conversion of infrared laser light in nonlinear crystals. The highly stable cw-diode pumping of a laser crystal leads to very stable shot to shot and long term stability of the UV output of the system. The resonator structure ensure an emission of the laser radiation with a TEM_{oo} transversal mode. This true Gaussian beam gives a very good light spot distribution on the cornea, without putting special beam forming elements in the beam path. The ablation pattern utilized in **LaserSoft** ensures a very homogenous cornea surface due to the right overlap of true Gaussian spots.

The device is using a tiny flying spot with a diameter of 0.2 mm and it operates at repetition rate of 1 kHz. The eye-tracker has a latency of 1 ms and controls the centration of the ablation at very high repetition rates.

The ablation profiles are designed in such a way that they preserve the strongly aspherical curved cornea. Therefore the induced spherical aberration after surgery is minimized. The treatment calculation is done by taking in to account also different reflection losses and fluence values for different angles of incidence of the ablating laser radiation during surgery.

There is no gas exchange and gas discharge involved like in Excimer lasers which lead to instabilities in the output radiation due to the physical nature of the discharge process. The solid-state approach reduces the requirements for maintenance and also its costs.

The cw-nature of the pumping process and the appropriate implementation of state of the art solid-state laser components as well as the laser spot intensity distribution makes this source a safe, reliable and stable alternative to Excimer lasers for LVC and customized LVC.

Due to the high repetition rate the energy per pulse is lower than in Excimer treatments. This leads to an ablation with strongly reduced stress waves. There is no audible sound due to ablation or laser firing. As a result of this the patients remain very calm during surgery.

Methods

959 eyes undergone PRK procedure with **LaserSoft.** The mean age of patients was 38+/-13 years.

Refractive errors distribution:

- Myopia and myopic astigmatism: 759 eyes (mean SE -3,68D+/-2,50)
- Hyperopia and hyperopic astigmatism: 154 eyes (mean SE +1,97D+/-1,07)
- Mixed astigmatism: 46 eyes (mean SE -0,25D+/-0,65)

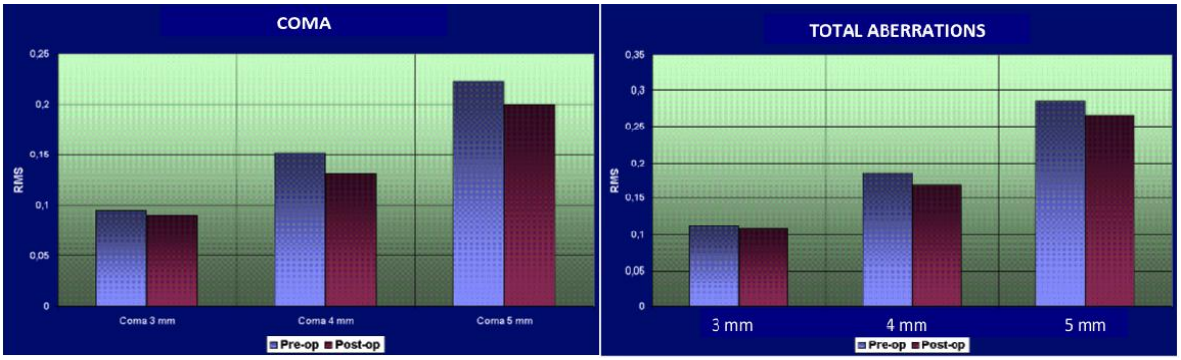
Wavefront and topographic evaluation of the corneal profile after PRK with the solid-state laser LASERSOFT in the correction of refractive errors was done by using corneal topographer Keratron and corneal topographer Tomey. The following data was considered:

- The centering of the treatment with respect to the pupil center (differential elevation map analysis) is studied.
- Evaluation of the regularity of the treated area and the corneal curvature (preoperative and postoperative hemimeridians at 3 and 5 mm), total aberrations and coma aberrations using Zernike analysis at 3 mm, 4 mm and 5 mm were considered.
- In the analysis of the corneal curvature the Refractive Power Symmetry Index (RPSI) was introduced (average of the difference of the curvature of the two opposite hemimeridians at 3 and 5 mms

The refractive results were gathered after one, 3, 6 and 12 months and were analyzed using graphs recommended by G. O. Waring III et al. [1].

Results

Corneal profile



Data: Dr. M. Rossi MD, Dr. M. Schmidt MD, Dr. P. Garimoldi MD, Dr. P. Giorgi MD, Poster: "Aspetti topografici dei trattamenti con laser allo stato solido Katana LASERSOFT".

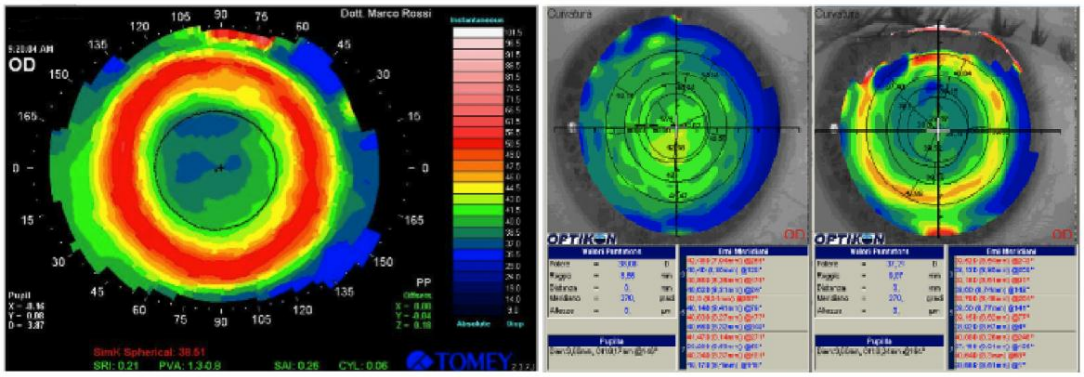
Treatment centration: difference between treatment center and pupil center	
Mean±SD 0,206±0,12 mm	Confidence interval 95% <0,136 mm 95%> 0,275 mm

Aberrometric evaluation: difference between preop and postop aberrations		
Coma at 3 mm	P=0,7931	NS
Coma at 4 mm	P=0,3993	NS
Coma at 5 mm	P=0,4332	NS
Total aberrations at 3 mm	P=0,9828	NS
Total aberrations at 4 mm	P=0,4853	NS
Total aberrations at 5 mm	P=03821	NS

Topographic evaluation: difference between preop and postop RPSI		
RPSI at 3 mm	P=0,8539	NS
RPSI at 5 mm	P=0,2454	NS

NS: Not Significant

The fast eye-tracking ensures a reliable centration of ablation for x-y directions as well as the rotation of the eye at high repetition rates.



Data: Dr. M. Rossi MD, Dr. M. Schmidt MD, Dr. P. Garimoldi MD, Dr. P. Giorgi MD, Poster: "Aspetti topografici dei trattamenti con laser allo stato solido Katana LASERSOFT".

The retrofitting of the flap to the ablated surface of the eye is very smooth.
The topographic and aberrometric study show a good centration of the ablation and a very regular corneal profile after the treatment is achieved with the solid-state laser LASERSOFT.

Refractive and Visual Results

1. Safety

After 12 months 4% of eyes lost 1 line of the BCVA, 57% were remained unchanged, 35% gained 1 line and 4% gained 2 lines of the BCVA.

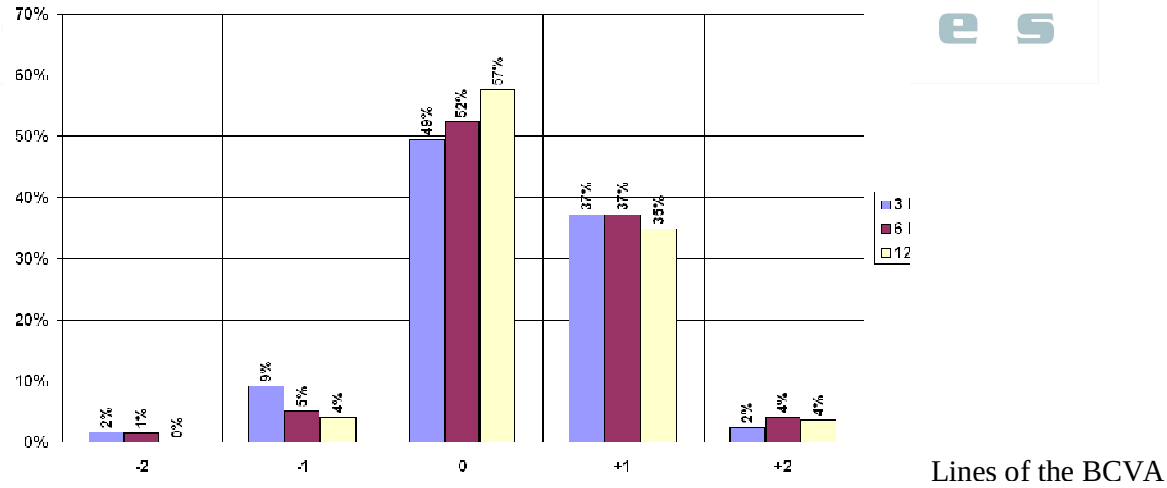


Fig1 The bar graph depicts the change in best spectacle-corrected visual acuity (BSCVA) at 3, 6 and 12 months in terms of the number of Snellen lines changed. Data: Dr. M. Rossi, Talk in SOI Milan, 26 November-2 December 2006.

2. Efficacy

12 months UCVA ≥ 0 in 82% and ≥ 0,3 in 98% of eyes

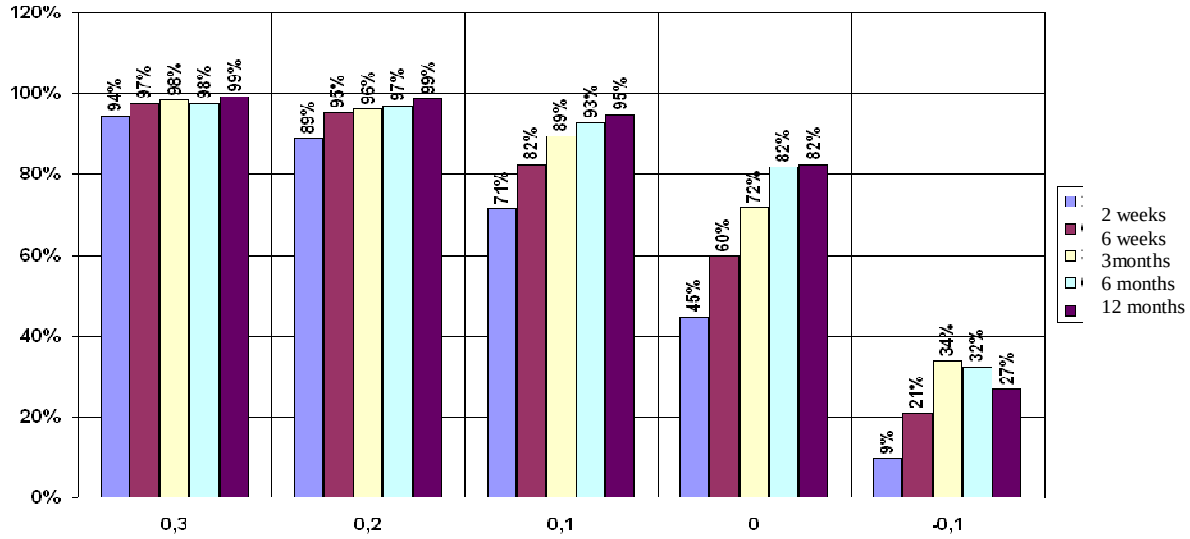


Fig. 2 Uncorrected visual acuity (UCVA) expressed in LogMar over time. Data: Dr. M. Rossi, Talk in SOI Milan, 26 November-2 December 2006.

All 12 months post-operative results are found within ± 2.0 D range. 98 % of all eyes are found within ± 1.0 D, 96 % of all eyes are found within ±0.5 D.

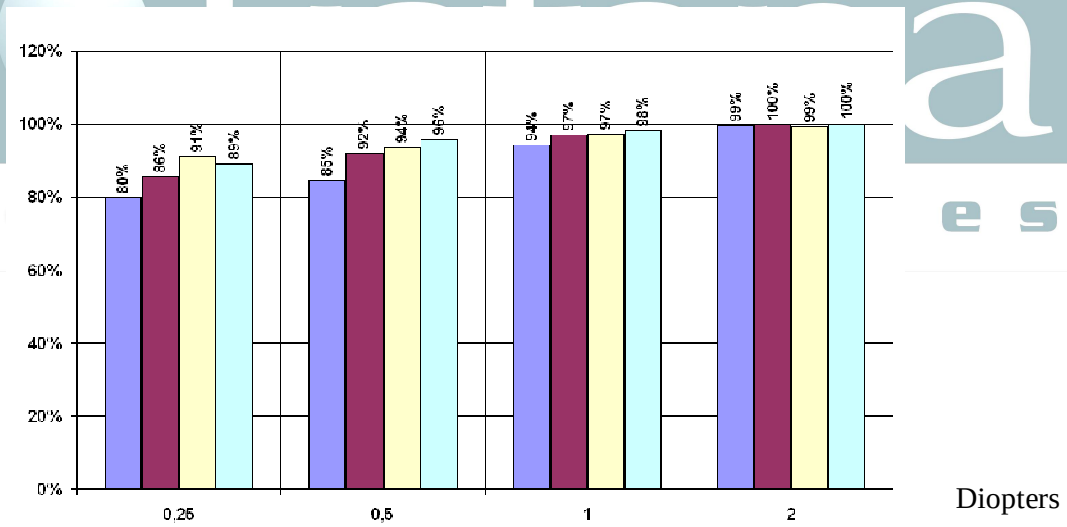


Fig. 3: Residual refraction outcome during the follow up period. Purple bars: 6 weeks, red bars: 3 months, yellow bars: 6 months, turquois bars: 12 months. Data: Dr. M. Rossi, Talk in SOI Milan, 26 November-2 December 2006.

3. Stability

Good stability of SE was observed during the 12 months period.

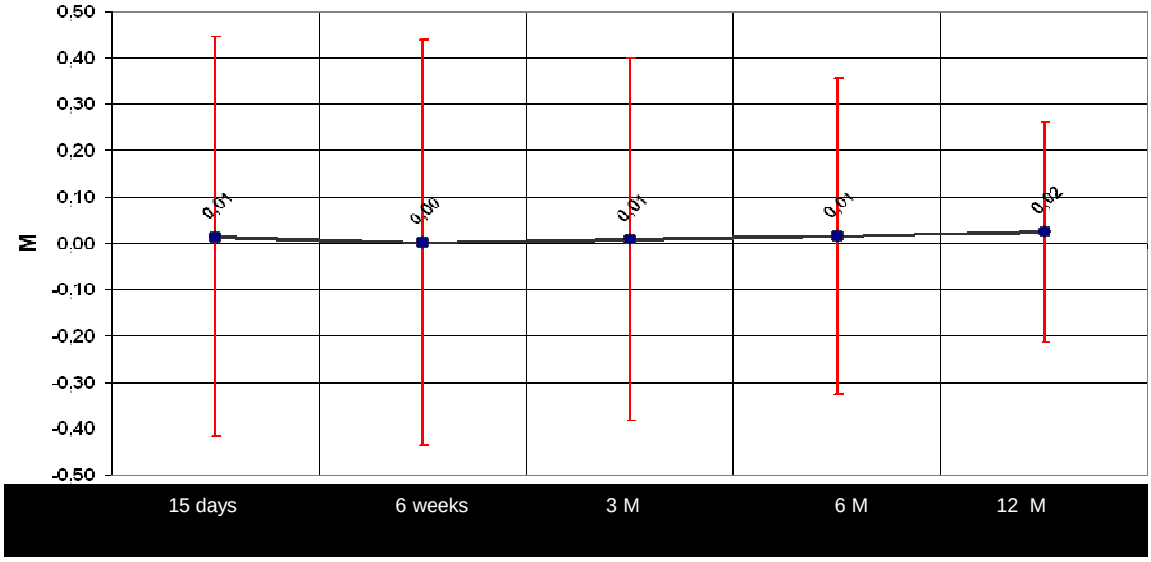


Fig. 4 shows the stability of refraction during the 12 months follow up period. Data: Dr. M. Rossi, Talk in SOI Milan, 26 November-2 December 2006.

4. Corneal transparency.

The small true Gaussian spot produces a very smooth and clear cornea. In fact very good corneal transparency was observed during the whole follow up. Cornea healed quickly in all eyes and no clinically relevant haze was registered.

Corneal transparency after the treatment. Data: A. M. Roszkowska, M. Piovella MD and G. Ferreri .

[1] George O. Waring III et al., "*Standardized Graphs and Terms for Refractive Surgery Results*", Journal of Refractive Surgery Vol. 27, No. 1, 2011

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KATANA Clinical Results vs. FDA Targets (6Months)	FDA	KATANA
Efficacy		
• **UCVA 1.0 or better**	50%	82%
• **UCVA 0.5 or better**	85%	97%
• **MRSE ± 0.5D**	50%	94%
• **MRSE ± 1.0 D**	75%	98%
Safety		
• **BCVA line lost > 2**	< 5%	2%
• **BCVA less than 0.5**	< 1%	0%

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