



Laser-assisted *In Situ* Keratomileusis with the SCHWIND AMARIS – Clinical Results at Three Months

a report by

MC Arbelaez, F Carones, Y Aslanides, Tobias Neuhaus, C Barraquer, P Rozsival and A Feuermannova

SCHWIND eye-tech-solutions

DOI: 10.17925/EOR.2007.00.00.48

Fast, powerful, precise and safe, the SCHWIND AMARIS represents an important advance in laser-assisted *in situ* keratomileusis (LASIK). It combines a high ablation speed with a turbo eye tracker for monitoring pupil and limbus tracking, rotational balance and advanced cyclotorsion control. These factors ensure the perfect balance between extremely high speed and accuracy. With its repetition rate of 500Hz, minimum spot size of 0.54mm (full width at half maximum, FWHM) and its super-Gaussian beam profile, the SCHWIND AMARIS ensures very high ablation accuracy; this results in exceptionally smooth treatment surfaces and an extremely accurate reproduction of ablation volumes, allowing successful treatment.

Methods

In our trial, all LASIK procedures were performed using the SCHWIND AMARIS, and all patients were corrected using the SCHWIND-CAM 'aberration-free' treatment. All evaluated eyes were healthy and untreated. All flaps were created using the Carriazo-Pendular microkeratome (superior hinge), and the optical zone was set to 6.0, 6.5 or 7mm. Pre-operatively, spherical equivalent refraction (SEQ) was -0.50 to -8.25D, the sphere was 0.00 to -8.25D and the cylinder was up to -5D. All data from the 364 eyes were analysed for a post-operative period of three months.

Results

Scattergram

A scattergram is the best way to show the predictability of the refractive outcome. *Figure 1* shows attempted refraction versus achieved refractive change for each eye three months post-operatively. The narrow scatter between laser settings and achieved SEQ at three months is obvious. The mean post-operative SEQ was $-0.17 \pm 0.24D$.

Refractive Outcome

Figures 2a and *2b* show the refractive outcome in terms of SEQ and defocus equivalent. An impressive 75% of the 364 evaluated eyes were in the range of $\pm 0.25D$ of SEQ, and 89% were within $\pm 0.5D$ in terms of defocus equivalent.

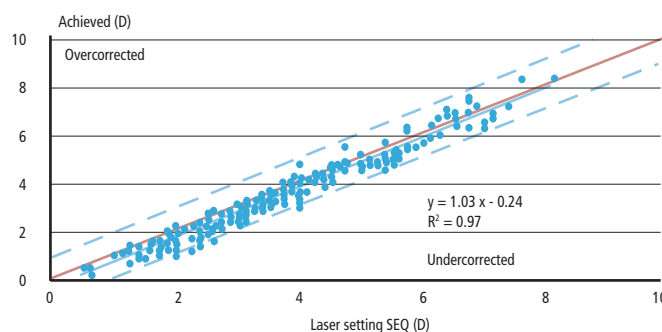
Change in Best Spectacle-corrected Visual Acuity – Safety

Safety is described by the change in best spectacle-corrected visual acuity (BSCVA), which is measured by the number of Snellen lines that change post-operatively. At three months, 44% of the evaluated eyes gained one or more Snellen lines, and no patient lost more than one Snellen line (see *Figure 3*).

Pre-operative Best Spectacle-corrected Visual Acuity versus Post-operative Uncorrected Visual Acuity

Figure 4 displays the pre-operative BSCVA compared with post-operative uncorrected visual acuity (UCVA) at three months. Fifty-five

Figure 1: Laser Settings – Spherical Equivalent Refraction versus Achieved Change in 364 Eyes



D = diopter; SEQ = spherical equivalent refraction.

Figure 2a: Refractive Outcome Percentage within Attempted Spherical Equivalent Refraction in 364 Eyes

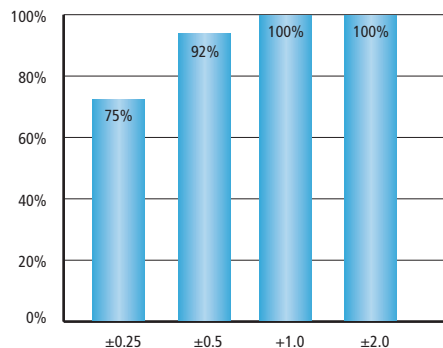
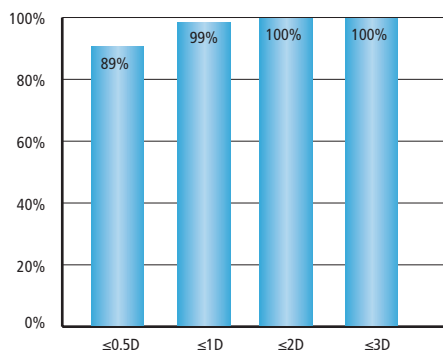


Figure 2b: Percentage Defocus Equivalent in 364 Eyes



Defocus equivalent is described as: sphere (diopter, D) + 1/2 * cylinder (D).

per cent of all treated eyes had a UCVA of 20/16 or better. In summary, a significant change towards improved visual acuity even for these early results is obvious.



Faster, stronger, more precise.

SCHWIND AMARIS – the TotalTech Laser



SCHWIND
eye-tech-solutions

SCHWIND AMARIS

- True 500 Hz Repetition Rate
- Automatic Fluence Level Adjustment
- Intelligent Thermal Effect Control
- 1050 Hz Turbo Eyetracker with Limbus Tracking and Rotation Balance
- Advanced Static and Dynamic Cyclotorsion Control
- Integrated Online Pachymetry
- Swiveling laser arm and patient bed

A dimension further. The new generation Excimer Laser from SCHWIND. The best player in all disciplines can redefine quality. The innovative Excimer Laser SCHWIND AMARIS is a step ahead in any situation. The perfect relationship between ablation speed and precision allows you to achieve maximum safety with a minimum of treatment time. We combine this high performance with a customized treatment planning and unique ergonomic advantages. And the benefit to you: optimized processes and the best possible prerequisites for excellent results. The TotalTech Laser – Performance you can rely on.

Figure 3: Change in Best Spectacle-corrected Visual Acuity (Safety) in 364 Eyes

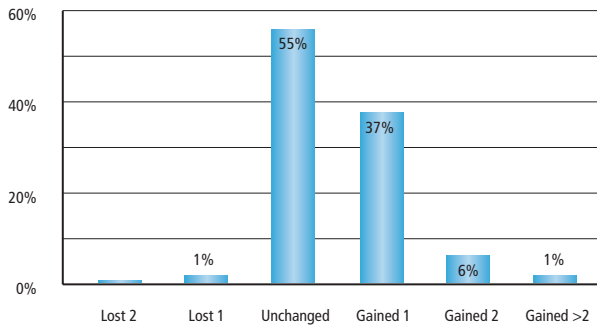
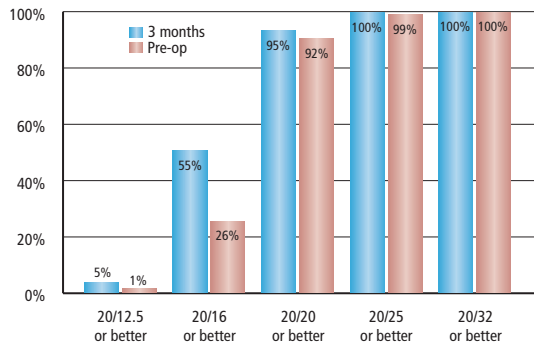


Figure 4: Pre-operative Best Spectacle-corrected Visual Acuity versus Post-operative Uncorrected Visual Acuity in 364 Eyes



Astigmatism

Figures 5a and 5b show the double-angle scatter plot of the cylindrical value, with a good post-operative scatter after three months. Mean post-operative cylinder was $0.06 \pm 0.23D$.

Achieved Correction Over Time – Stability

The stability of the results for the one-week, one-month and three-month follow-up examinations (see Figure 6) shows the high success rate.

Discussion and Comments by Dr Francesco Carones

The new AMARIS platform from SCHWIND incorporates some significant technological improvements, such as the 500Hz repetition rate, the dual-energy fluency output, the 5D 1,050Hz eye-tracking device and the super-Gaussian 0.54mm beam profile, making this device the state of the art in excimer laser technology. Our multicentre study presents the preliminary results of LASIK for correcting myopia and myopic astigmatism using standardised, aberration-free ablation profiles, with a three-month follow-up period. This time-frame is obviously too short to allow us to draw conclusions on medium- and long-term stability and results. However, the following comments can be made.

The technological improvements had a positive impact on the results achieved three months after LASIK. The accuracy proved to be very high given the range of attempted correction. The scattergram in Figure 1 shows very small deviations from target (no eyes outside the $\pm 1.00D$ range), while Figure 2 presents very precise outcomes, proving the accuracy of the original algorithm as no nomogram adjustments were made in this study. It is also interesting to note the very low variability of results among the investigation sites, meaning that the environment – i.e. humidity, temperature and altitude – plays only a secondary role. Figures 5a and 5b show by vector analysis that not only was the cylinder component dramatically reduced, but also that there was no induction of

Figure 5a: Pre-operative Double-angle Scatter Plot of the Cylindrical Component

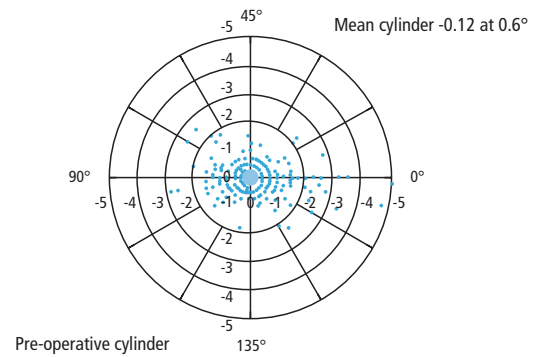


Figure 5b: Post-operative Double-angle Scatter Plot of the Cylindrical Component

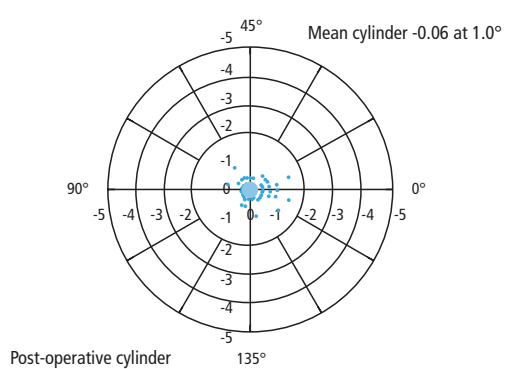
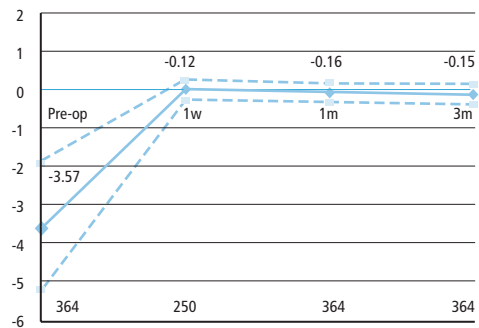


Figure 6: Stability Timeline of Spherical Equivalent Refraction



w = week; m = month.

astigmatism at all. The visual acuity results reflect the high accuracy. The treatments were not customised and targeted at reducing high-order aberrations, but rather were optimised with the aim of not inducing spherical aberrations. Nevertheless, there was an overall UCVA gain compared with pre-operative BSCVA and an overall BSCVA gain compared with pre-operative values. These improvements may be related to the high quality of the ablation pattern, which produces very smooth ablated surfaces and allows optimal visual performance to be achieved. Long-term follow-up on these patients will provide more indications about the stability of the results. In the meantime, our meta-analysis indicates that the SCHWIND AMARIS platform is more accurate, precise, reliable and safe in the correction of myopia and myopic astigmatism. In addition, all of the investigators indicated that the laser station is very comfortable for both the surgeon and the patient, with improved ergonomics and efficiency. In particular, ablation times are significantly reduced, allowing a much faster flow of patients in the surgical room. ■