

One month LASIK outcomes with SCHWIND PresbyMAX® – the new presbyopia solution

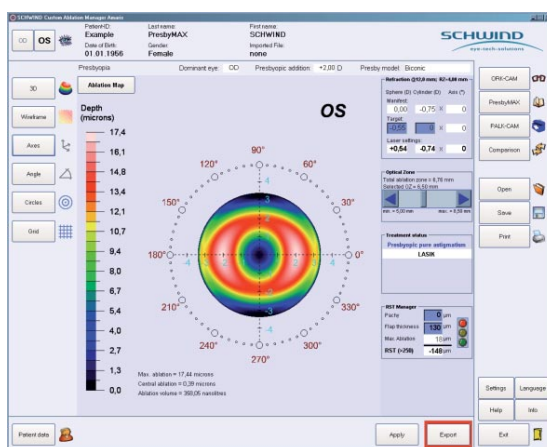
J.L. Alió, MD (Alicante, Spain), E. Martines, MD (Sao Paulo, Brazil),
T. Wahab, MD (Cairo, Egypt), D. Uthoff, MD (Kiel, Germany)

Introduction

Fast, powerful, precise, and safe – if it is presbyopia, the SCHWIND PresbyMAX® is a step ahead. It provides an enhanced prolate multifocal cornea, based upon bi-aspherical multifocal ablation profiles developed by SCHWIND eye-tech-solutions in cooperation with VISSUM^{1,2} and the OCIVIS¹ group from the University of Alicante. This solution ensures a multifocal corneal surface to reduce spectacle dependence for near vision by increasing the depth of focus based on modifications of the corneal ablation profile without compromising distance vision.

Methods

- All patients were corrected with PresbyMAX®
- Only LASIK procedures have been included
- All evaluated eyes were healthy
- The optical zone was set between 6.5 mm and 7.0 mm
- Treatments were performed on the basis of both eyes, same addition, same optical zone, same surgical day, same surgeon, and same microkeratome or femtosecond laser
- Preoperative manifest refraction
Defocus: -4.00 D to +4.00 D
Astigmatism: up to 2.50 D
Addition: up to 2.50 D
- 72 eyes in 3 groups: 36 hyperopic eyes (defocus >+0.50 D or defocus >0.00 D and astigmatism >0.50 D), 14 emmetropic eyes (defocus between -0.50 D and +0.50 D and astigmatism <0.50 D), 22 myopic eyes (defocus <-0.50 D or defocus <0.00 D and astigmatism >0.50 D)
- All data from the 72 eyes were analyzed for a postoperative period of 1 month



PresbyMAX® software module

One month LASIK outcomes with SCHWIND PresbyMAX® – the new presbyopia solution

Results

1 month postoperative outcomes are presented in table 1.

Binocular	DUCVA logMAR	NUCVA logRAD	Sph D	Cyl D	DBCVA logMAR	Change Add D	NBCVA logRAD
Goal	0.1	0.1	-0.50	-0.25	0.0	0.75	0.0
Hyperopia (36 eyes)	0.0	0.1	-0.26	-0.60	0.0	0.85	0.1
Emmetropia (14 eyes)	0.0	0.2	-0.11	-0.23	-0.1	0.38	0.0
Myopia (22 eyes)	0.1	0.2	-0.33	-0.22	-0.1	0.55	0.0
Total (72 eyes)	0.0	0.1	-0.25	-0.41	0.0	0.67	0.0

Table 1: Postoperative outcomes after PresbyMAX® stratified per refraction groups and overall outcomes.

Postoperatively, binocular DUCVA was on average 0.0 logMAR (or 20/20), binocular NUCVA was on average 0.1 logRAD (or J2), and the required addition was reduced by about 0.75 D.

Predictability outcome

Table 2 represents the predictability outcomes 1 month postoperatively compared with the

extended benchmarks proposed by the FDA. Postoperatively, binocular DUCVA was 0.3 logMAR or better (20/40 or better) in 97% of the patients, binocular NUCVA was 0.3 logRAD or better (J5 or better) in 95% of the patients, postoperative distance refraction was reduced below 1.00 D of SEq in 86% of the patients, and no patient lost more than 2 lines of DBCVA or NBCVA.

Binocular	DUCVA <0.3 logMAR	NUCVA <0.3 logRAD	PostSEq ±1 D	PostSEq ±0.5 D	DBCVA >0.3 logMAR	NBCVA >0.3 logRAD
FDA Benchmarks	85%	85%	75%	50%	1%	1%
Hyperopia (36 eyes)	94%	81%	75%	42%	0%	0%
Emmetropia (14 eyes)	100%	100%	100%	79%	0%	0%
Myopia (22 eyes)	100%	90%	95%	59%	0%	0%
Total (72 eyes)	97%	95%	86%	54%	0%	0%

Table 2: Predictability outcomes after PresbyMAX® referred to extended FDA benchmarks, stratified per refraction groups and overall outcomes.

One month LASIK outcomes with SCHWIND PresbyMAX® – the new presbyopia solution

Simultaneous distance and near vision

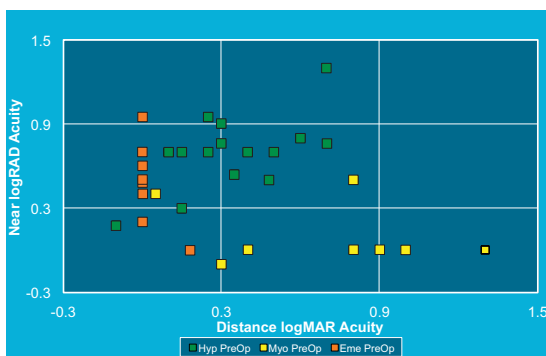


Figure 1: Distance and near uncorrected binocular visual acuity before surgery

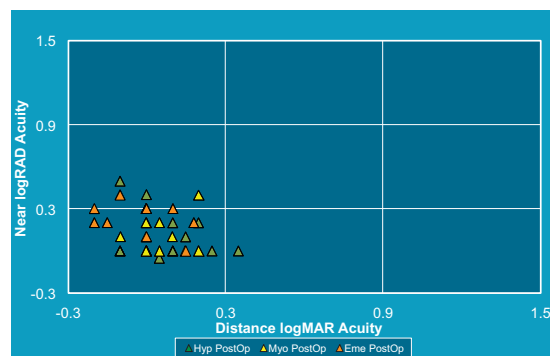


Figure 2: Distance and near uncorrected binocular visual acuity after surgery

The preoperative situation shows a large scatter (figure 1) for both distance and near uncorrected. The 1 month postoperative results are located almost only in the lower left corner (figure 2) which goes along with very good uncorrected visual acuities (spectacle-free) for both distance and near.

Figure 3 displays that 97% of all 36 patients obtained an uncorrected distance acuity of 0.2 logMAR or better (20/32 or better). 75% of all 36 patients showed an uncorrected reading acuity of 0.2 logRAD or better (J3 or better) which contributes to good newspaper reading qualities.

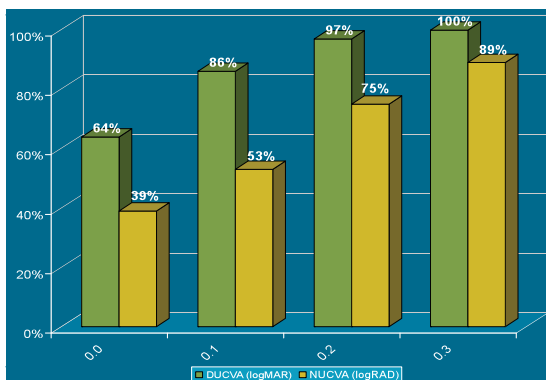


Figure 3: Distance and near uncorrected binocular visual acuity outcomes in percentage

In 72% of treated patients both distance and near uncorrected visual acuity was equal or better than 0.2 logMAR respectively logRAD.

Conclusion: A higher quality of life is attained due to spectacle-free condition in normal day life situations in almost every patient.

One month LASIK outcomes with SCHWIND PresbyMAX® – the new presbyopia solution

Refractive outcome

Figure 4 displays the refractive outcome in terms of defocus from the target.

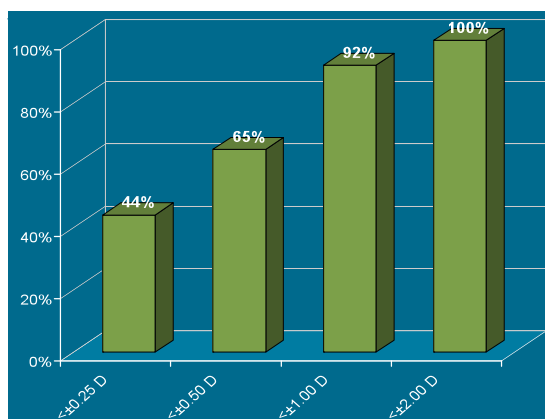


Figure 4: Refractive outcome in percentage

Impressive 79% of all 72 evaluated eyes are in the range of 0.75 of defocus and 100% of all evaluated eyes within $\pm 1.50\text{ D}$.

Aberrations

Multifocally, the centre is corrected for near and the periphery for far vision by means of an optimised bi-aspheric ablation profile, which includes a pre-calculated amount of different high-order aberrations.

It is intention of the PresbyMAX profiles to induce aberrations such as spherical aberration and coma to a certain extent as to bring the focus from light exiting a near point to the retina, without bringing the focus of rays of light coming from infinity in front of the retina.

The magnitude of such aberrations is not fix and depends on addition, selected OZ for the treatment, offset of the pupil centre respect to the corneal vertex, offset of the pupil centres between photopic and scotopic conditions, and analysis diameter for the wave aberration.

The amount of induced aberrations by PresbyMAX® was about -0.15 D of spherical aberration, and -0.15 D of coma aberration per each diopter of addition.

Key factors for success

- Clinical decision to enrol patients shall be made in an ethical way (e.g. professional drivers may suffer from the reduced distance vision)
- Postoperatively, the pupil size plays a critical role. For that reason it is important to have an adjustable illumination condition in the refracting unit in order to teach the patient how to get the best possible results under changing light conditions
- High photopic conditions postoperatively are optimal for reading
- Use of sunglasses in photopic conditions postoperatively helps for distance vision

Acronyms

DUCVA	Distance UnCorrected Visual Acuity
DBCVA	Distance Best Corrected Visual Acuity
NUCVA	Near UnCorrected Visual Acuity
NDCVA	Near Distance Corrected Visual Acuity
NBCVA	Near Best Corrected Visual Acuity
logMAR	logarithm of the Minimum Angle of Resolution
20/n	Distance visual acuity in 20 feet scale
logRAD	logarithm of the Reading Acuity Determination
Jn	Near visual acuity in Jaeger scale

References

- ¹ Ortiz D, Alió J, Illueca C, Mas D, Sala E, Pérez J, Espinosa P, Optical analysis of PresbyLASIK treatment by a light propagation algorithm. J Refract Surg. 2007; 23:39-44.
- ² D. P. Pinero and J. L. Alió, PresbyMax: Presbyopia Correction by Multifocal LASIK. Cataract & Refractive Surgery Today Europe, January 2009.