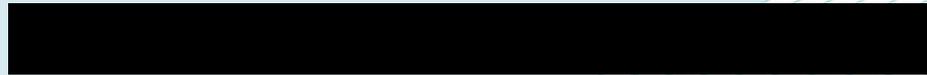


SCHWIND PresbyMAX[®] - Multicenter Study Expected vs. Clinical Outcome

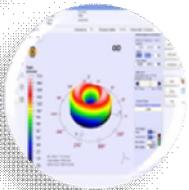


An Ablation Planner for Presbyopic Refractive Surgery

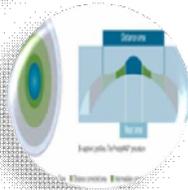
Directory



PresbyMAX® - Unique treatment range



PresbyMAX® – Acronyms and near visual acuity scales



PresbyMAX® – Expected outcome



PresbyMAX® – Clinical outcome



PresbyMAX® – Literature

PresbyMAX[®] - Unique Treatment Range

Before PresbyMAX[®]	With PresbyMAX[®]
<p>Limited treatment range</p> <ul style="list-style-type: none">● e.g. only hyperopic patients● e.g. only patients with minor astigmatism● e.g. no presbyopia treatment of emmetropic or myopic patients● e.g. only in combination with standard treatments● e.g. only in combination with wavefront guided treatments	<p>The only presbyopia software that is offering a broad treatment spectrum for different indications:</p> <ul style="list-style-type: none">● Treatment of emmetropic, myopic, hyperopic, and astigmatic eyes● Correction of these visual defects can be performed as “Aberration-Free” or “Customized” treatments● Any treatment method possible: PRK, TransPRK, LASEK, LASIK and FemtoLASIK

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
- SphAb: Spherical Aberration

Near Visual Acuity Scales

Near Visual Acuity Scales			Distance Visual Acuity Scales		
logRAD (40 cm)	Revised Jaeger (35 cm)	Nieden (40 cm)	logMAR	Feet 20/	decimal
-0.2	-	-	-0.2	10	1.60
-0.1	-	N1	-0.1	12.5	1.25
0.0	J1: = 1.00	N2	0.0	20	1.00
0.1	J2: = 0.80	N3	0.1	25	0.80
0.2	J4: = 0.63	N4	0.2	32	0.63
0.3	J5: = 0.50	N5	0.3	40	0.50
0.4	J6: = 0.40	N6	0.4	50	0.40
0.5	J8: = 0.32	N7	0.5	63	0.32
0.6	J9: = 0.25	N8	0.6	80	0.25
0.7	J10: = 0.20	N9	0.7	100	0.20
0.8	J12: = 0.16	N10	0.8	125	0.16
0.9	J13: = 0.13	N11	0.9	160	0.13
1.0	J14: = 0.10	N12	1.0	200	0.10

PresbyMAX[®] - Mean Expected Outcomes

	Monocular	Binocular
DUCVA:	+ 0.2 logMAR (20/32 or 0.63)	+ 0.1 logMAR (20/25 or 0.80)
NUCVA:	+ 0.2 logRAD (20/32 or J4)	+ 0.1 logRAD (20/25 or J2)
DBCVA:	+ 0.1 logMAR (20/25 or 0.80)	0.0 logMAR (20/20 or 1.00)
NDCVA:	+ 0.3 logRAD (20/40 or J5)	+ 0.2 logRAD (20/32 or J4)
NBCVA:	+ 0.1 logRAD (20/25 or J2)	0.0 logRAD (20/20 or J1)
Defocus:	~ - 0.50 D	depends on amount of addition; compare with target refraction that is automatically calculated within the software
Astigmatism:	~ 0.25 D	depends on treatment centring [corneal vertex vs. pupil centre]
Addition:	~ + 1.00 D	depends on amount of addition; roughly half of the preoperative addition
Change in SphAb:	~ - 0.2 D	per each dioptre of addition
Change in Coma:	~ - 0.1 D	per each dioptre of addition; depends on treatment centring [corneal vertex vs. pupil centre].

The aim of about -0.50 D defocus bilaterally keeps normal stereopsis

PresbyMAX® - Mean Expected Outcomes

Diminished image quality postoperatively as compromise between distance and near vision.

The multifocal corneal surface (i.e. spherical aberrations) creates an effect of halos that appears to be significant in low mesopic to scotopic pupil conditions but disturbing glare is not expected. The patient will adapt to the halos and will usually not recognize these after a while anymore (neural adaptation).

The postoperative progress behaves in all refraction types similar but the acceptance patient by patient may differ.

Basically, from the 1st day the patient gets excellent near vision.

Between 1st day and 1 month distance vision is not very good (20/40 to 20/32).

Between 1st day and 3 month near vision slightly declines (J1+ to J2) and then stabilizes.

Between 1 month and 6 months distance vision improves (20/32 to 20/25) and then stabilizes.



PresbyMAX® - The Need in Additives

Patients may need additives (sunglasses, reading glasses, ...) in certain environmental conditions:

- » Outdoors in sunny days sunglasses are needed for distance but indoors glasses for distance are not required.
- » Indoors for near stronger lightings are requested.
- » For working shorter distance than 40 cm or for longer time extensively reading extra addition (reading glasses) is needed.
- » For long distances driving spectacles for distance (-0,50 D to -1,00 D) are probably more convenient.

PresbyMAX[®] - Multicenter Study Experience

- Presby Aberration-Free
- LASIK or FemtoLASIK
- Sphere within - 4.00 D to +4.00 D
- Astigmatism up to 2.50 D
- Addition up to 2.50 D
- Preoperative corneal curvature between 40 D and 48 D
- Pachymetry thicker than 500 μm
- Preoperative distance best corrected visual acuity (DBCVA) 20/25 (equals 0.1 logMAR) or better.
- Near vision of J3 (equals 0.2 logRAD) or better with addition of +1.50 D.
- Corneal topography with no signs of keratoconus or irregular astigmatism.
- Pupilometry: mesopic high within 2.50 to 3.00 mm.

PresbyMAX® - The Multicenter Study Team



**Prof. Alio,
Spain**



**Prof. Uthoff,
Germany**



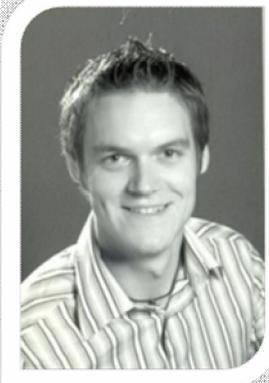
**Dr. Tarek,
Egypt**



**Dr. Martines,
Brasil**



Jens Flügge



Tobias Ewering



**Samuel Arba
Mosquera**

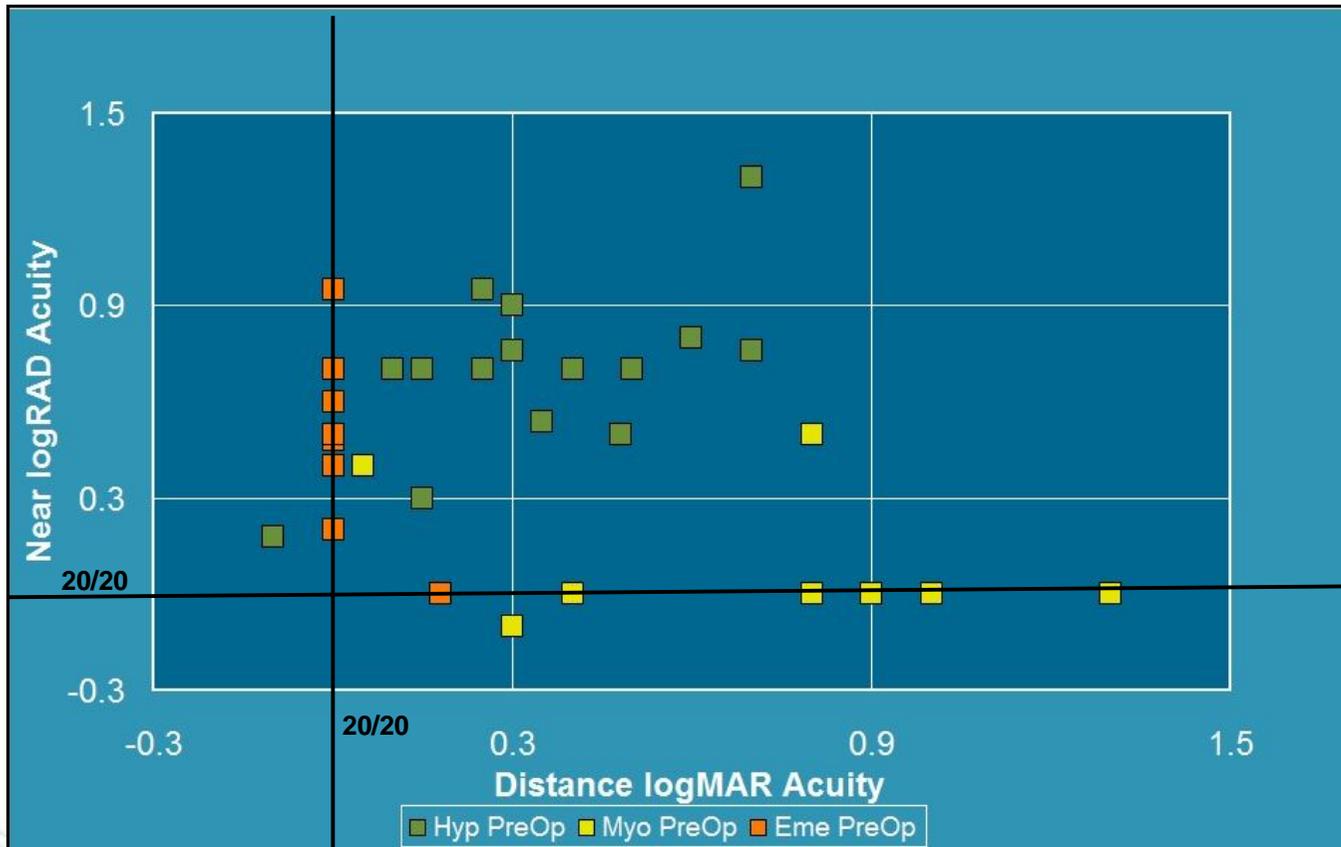
PresbyMAX® - Patient Population and Average Values (72 eyes)



PresbyMAX® LASIK study	Total (36 patients)		Hyperopes (18 patients)		Myopes (11 patients)		Emmetropes (7 patients)	
	PreOP	PostOP 1 month	PreOP	PostOP 1 month	PreOP	PostOP 1 month	PreOP	PostOP 1 month
Age (years)								
Mean	50		51		48		50	
StD	5		6		3		3	
Median	49		51		49		50	
Min.	39		39		43		43	
Max.	63		63		51		55	
SEq (D)								
Mean	0,38	-0,43	1,90	-0,51	-2,04	-0,44	0,27	-0,22
StD	1,90	0,58	0,85	0,72	0,94	0,39	0,39	0,38
Median	0,63	-0,50	1,75	-0,50	-2,25	-0,50	0,50	-0,19
Min.	-3,25	-1,63	0,63	-1,63	-3,25	-1,25	-0,50	-0,88
Max.	3,88	1,00	3,88	1,00	-0,25	0,38	0,63	0,38
Cyl (D)								
Mean	-0,45	-0,37	-0,40	-0,51	-0,67	-0,22	-0,21	-0,23
StD	0,44	0,32	0,35	0,30	0,57	0,30	0,19	0,27
Median	-0,38	-0,25	-0,38	-0,50	-0,50	0,00	-0,25	-0,25
Min.	-2,25	-1,00	-1,50	-1,00	-2,25	-1,00	-0,50	-0,75
Max.	0,00	0,00	0,00	0,00	0,00	0,00	0,00	0,00
Add (D)								
Mean	1,77	1,19	1,78	1,10	1,78	1,16	1,84	1,46
StD	0,40	0,57	0,48	0,42	0,32	0,68	0,30	0,68
Median	1,75	1,00	1,75	1,00	1,75	1,38	1,75	1,75
Min.	0,75	0,00	1,50	0,50	1,25	0,00	1,25	0,00
Max.	2,50	2,00	2,50	2,00	1,75	2,00	1,75	2,00

PresbyMAX® - Patient Data

DUCVA and NUCVA preoperative (log)

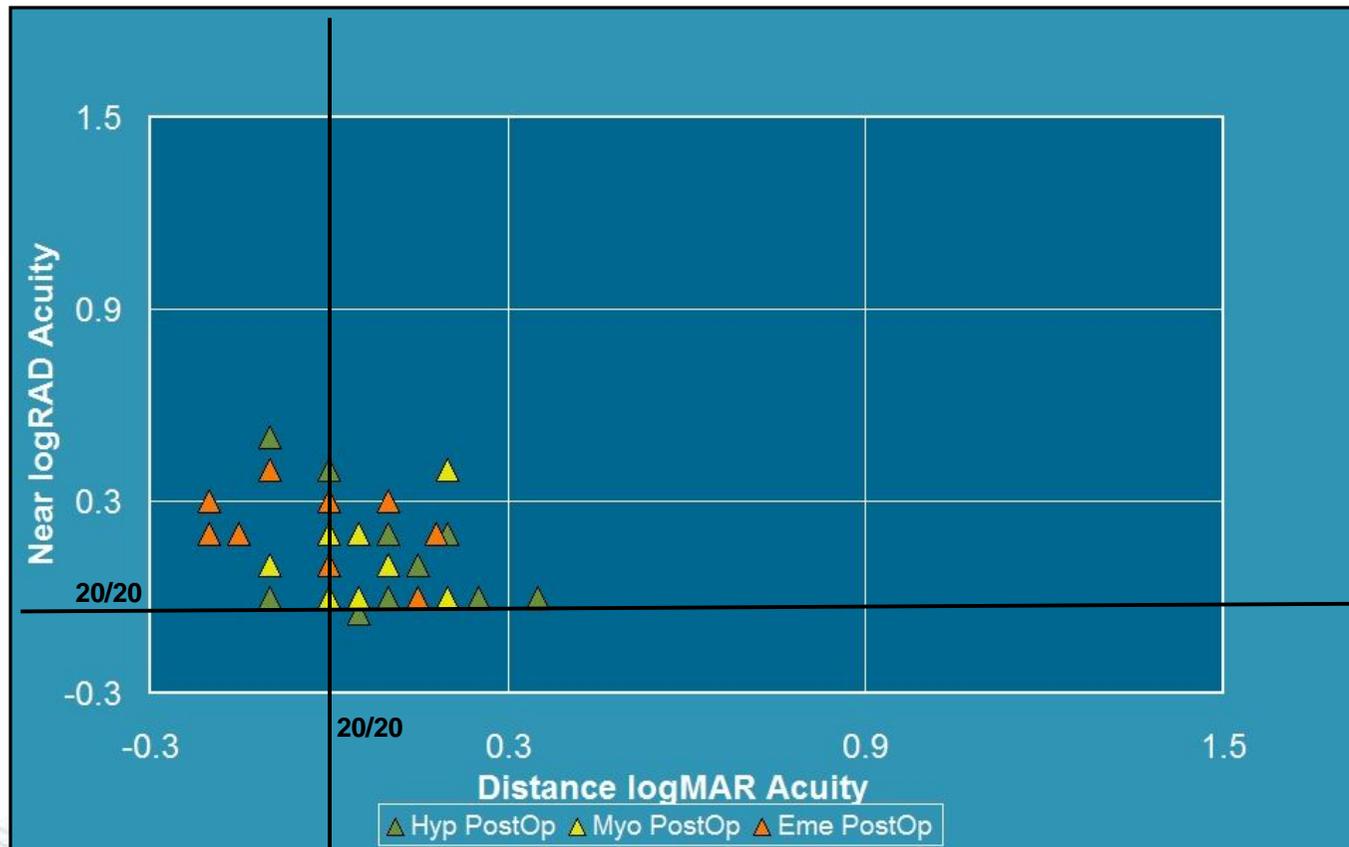


The preoperative situation shows a large scatter for both distance and near **uncorrected** binocular visual acuity

logMAR 0.0 => feet 20/20 => decimal 1.00
logMAR 0.2 => feet 20/32 => decimal 0.63

logMAR 0.1 => feet 20/25 => decimal 0.80
logMAR 0.3 => feet 20/40 => decimal 0.50

PresbyMAX® - Promising LASIK Outcome DUCVA vs. NUCVA postoperative 1 month (log)

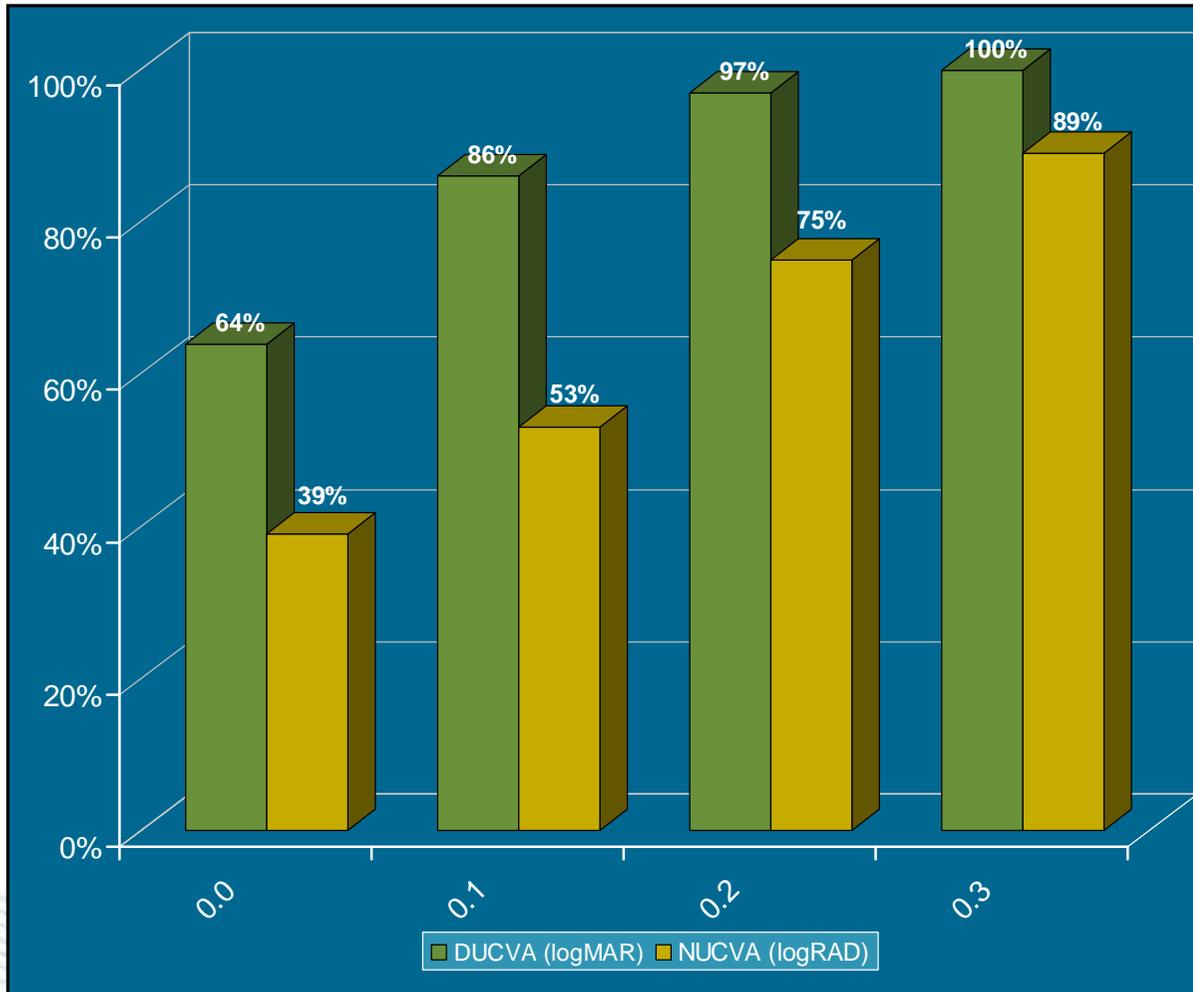


Nearly all eyes attained postoperative distance and near **uncorrected** visual acuity of 0.3 logMAR or better (20/40 or better) and 0.3 logRAD or better (J5 or better).

logMAR 0.0 => feet 20/20 => decimal 1.00
logMAR 0.2 => feet 20/32 => decimal 0.63

logMAR 0.1 => feet 20/25 => decimal 0.80
logMAR 0.3 => feet 20/40 => decimal 0.50

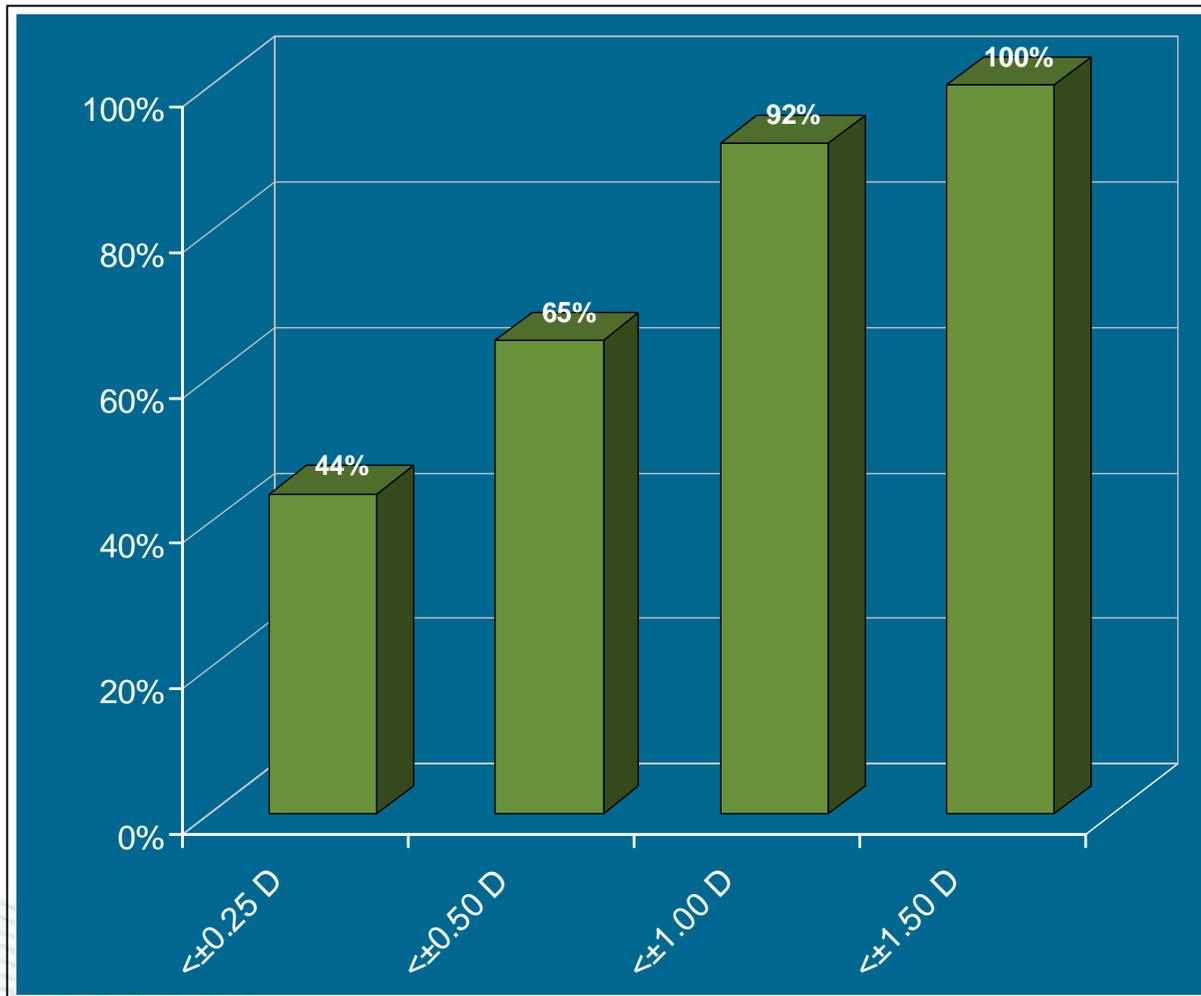
PresbyMAX[®] - Promising LASIK Outcome DUCVA and NUCVA postoperative 1 month (%)



97% of the treated eyes obtained an uncorrected far vision of 0.2 logMAR or better (20/32 or better). 75% achieved an uncorrected near vision of 0.2 logRAD (J4 or better).

PresbyMAX[®] - Promising LASIK Outcome

Refractive outcome postoperative 1 month (%)



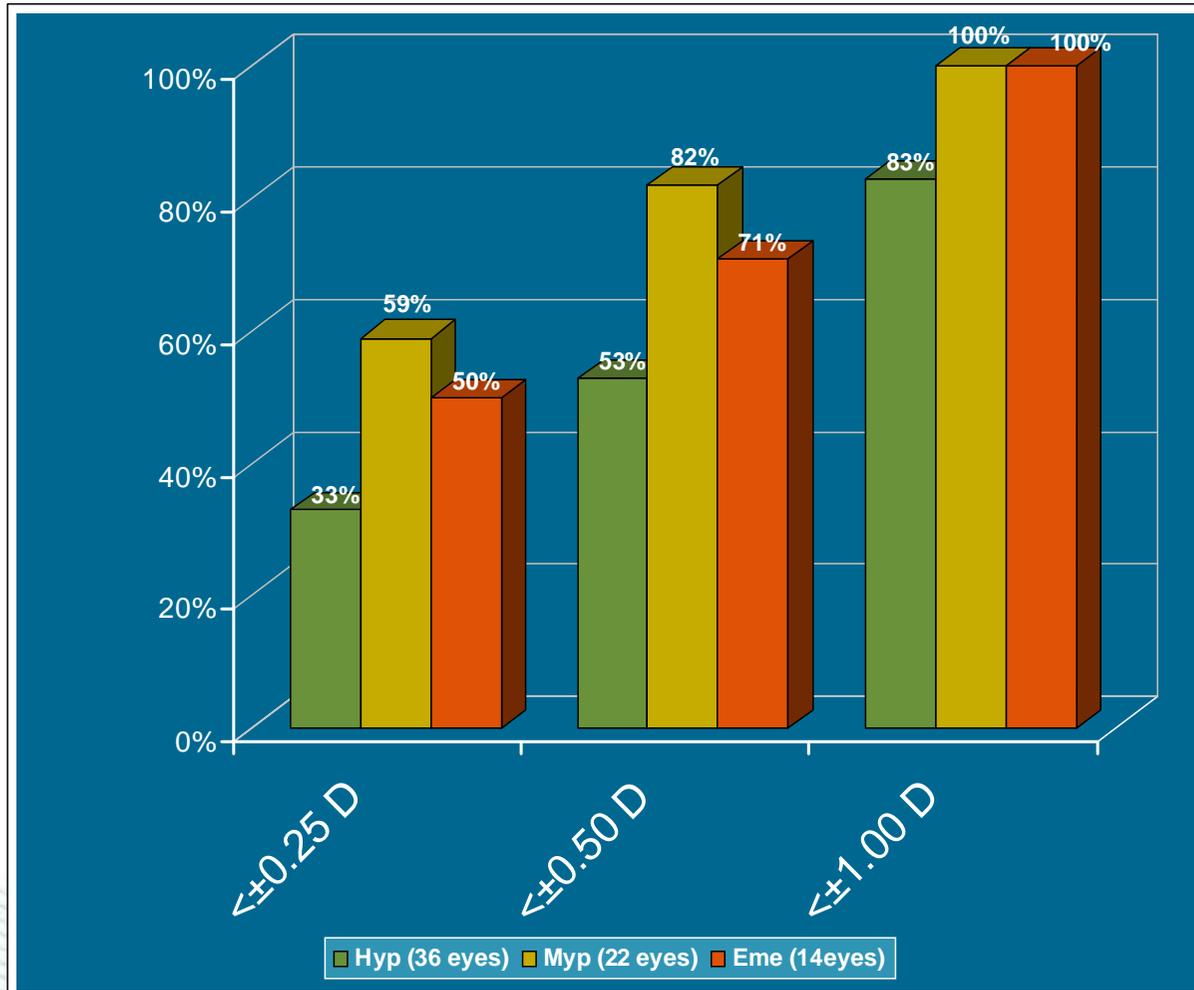
Refractive outcome in terms of defocus from the expected target



Impressive 79% of all 72 evaluated eyes are in the range of 0.75 of defocus and 100% of all evaluated eyes within ± 1.50 D

PresbyMAX® - Promising LASIK Outcome

Refractive outcome postoperative 1 month (%)



Refractive outcome in terms of defocus from the expected target



Almost all evaluated eyes are in the range of 0.75 defocus:

64% of hyperopes, 95% of myopes, and 100% of emmetropes.

PresbyMAX® - Multicentre Study Experience

In 72% of treated patients (36 in total) both distance and near uncorrected visual acuity was equal or better than 0.2 logMAR respectively logRAD.

It can be concluded that a higher quality of life is attained due to spectacle-free condition in normal day life situations in almost every patient.

Reference: "One month LASIK outcomes with SCHWIND PresbyMAX® - the new presbyopia solution" [SCHWIND, 2009]



PresbyMAX® - Comparison with the FDA Benchmarks



Binocular	DUCVA <0.3 logMAR	NUCVA <0.3 logRAD	PostSEq ±1 D	PostSEq ±0.5 D	DBCVA >0.3 logMAR	NBCVA >0.3 logRAD
<i>FDA Benchmarks</i>	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%

FDA Requirement: preoperative DBCVA has to be 0.0 logMAR (20/20; 1.0) or better to be evaluated.



Altogether, the FDA benchmarks were achieved or significantly exceeded



PresbyMAX® - Literature

- 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.
- J. L. Alió, E. Martines, T. Wahab, D. Uthoff, One month LASIK outcomes with SCHWIND PresbyMAX® - the new presbyopia solution. SCHWIND, September 2009

Thank you very much for your kind attention!
Vielen Dank für Ihre Aufmerksamkeit!
¡Muchas gracias por su amable atención!

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