

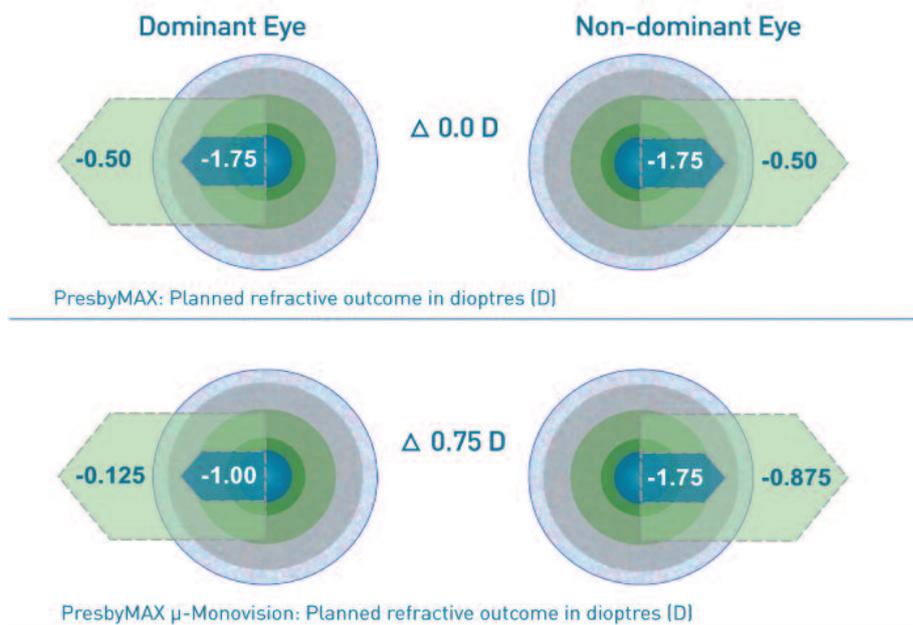
Special issue
PresbyMAX®

Faster recovery of visual acuity at all distances

PresbyMAX® μ -Monovision: The latest technique for treating presbyopia

SCHWIND now offers PresbyMAX μ -Monovision – as a new option and latest technique for treating presbyopia with SCHWIND AMARIS laser systems. It is based on the unique, well-established and successful PresbyMAX procedure using bi-aspheric multifocal ablation profiles. Rapid laser pulses are used to model the corneal surface extremely accurately in a very short time, creating several focal points for all distances in the eye – similar to the principle of refractive, multifocal contact and intraocular lenses. The difference between both procedures: while PresbyMAX plans ~ -0.50 D as refractive outcome for both eyes, PresbyMAX μ -Monovision assigns ~ -0.125 D for the dominant eye and ~ -0.875 D for the non-dominant eye. In this way, PresbyMAX μ -Monovision focuses the dominant eye slightly more on distance and directs the non-dominant eye slightly more towards near vision.

The central region of the corneal surface is steepened and multifocally shaped. This provides an enhanced depth of focus. Compared to PresbyMAX, the PresbyMAX μ -Monovision procedure enables better monocular distance



vision in the dominant eye and better monocular near vision in the non-dominant eye, combined with a faster visual adaption to multifocality.

The marginal anisometropia of 0.50 D to 0.75 D enables unrestricted stereo acuity. The main goal of the PresbyMAX μ -Monovision concept is to significantly shorten recovery of distance visual acuity and to ensure excellent intermediate and near vision quality at the same time. This was confirmed by first clinical outcomes of the Eye Clinic Bellevue, Kiel, Germany. In addition to presbyopia, PresbyMAX and PresbyMAX

μ -Monovision can correct simultaneously visual defects as myopia, hyperopia and astigmatism with great precision via the SCHWIND AMARIS laser systems. Every visual condition can be corrected with either aberration-free treatment or customised treatment based on corneal or ocular wavefront data. All treatment methods are possible – whether PRK, TransPRK, LASEK, LASIK or FemtoLASIK. PresbyMAX and PresbyMAX μ -monovision are the only presbyopia solutions available on the refractive surgery market which offer such a comprehensive range of treatments for the most diverse of indications.

First clinical results with PresbyMAX® μ -Monovision Fast recovery of visual acuity and high patient satisfaction



Detlef Uthoff, MD



Detlef Holland, MD

36 eyes of 18 patients were treated with the new PresbyMAX μ -Monovision concept at the Eye Clinic Bellevue, Kiel, Germany. All presbyopic patients underwent FemtoLASIK and were monitored up to three months postoperatively. The mean patient age was 53 years (ranging from 44 to 73 years). The preoperative sphere ranged from -3.75 to +4.00 D, and astigmatism was treated up to -4.00 D. All eyes underwent cornea treatment using the PresbyMAX software module delivering bi-aspherical multifocal ablation

profiles. The dominant eye was targeted with 0.75 D less postoperative myopia than the non-dominant eye. The monocular uncorrected distance visual acuity (UDVA) improved from preoperative 0.5 logMAR to postoperative 0.1 logMAR. The preoperative corrected near visual acuity (CNVA) was 0.0 logRAD and resulted in post-

operative uncorrected near visual acuity (UNVA) of 0.0 logRAD. The mean postoperative sphere was +0.13 D and the mean postoperative astigmatism was -0.35 D. Conclusion: The PresbyMAX μ -Monovision procedure provides fast visual recovery at all visual distances and is optimal tolerated in uncorrected conditions.

Take-Home Message

Eye Clinic Bellevue – PresbyMAX® μ -Monovision

- High patient satisfaction
- Fast recovery time of visual acuity comparable to conventional LASIK
- Low retreatment rate comparable to conventional LASIK
- High visual acuity comparable to latest generation multifocal intraocular lenses
- Significantly better intermediate visual acuity compared to multifocal intraocular lenses
- Also suitable for pseudophakic eyes

Eye surgeon treated with PresbyMAX® μ -Monovision



Michael Stade, MD, after the treatment

Michael Stade (54), MD, Medical Director at the Bad Laer Medical Centre, recently underwent successful laser eye surgery with the PresbyMAX μ -Monovision procedure from SCHWIND eye-tech-solutions.

In addition to his presbyopia (required near addition +1.75 D), the eye surgeon also had an existing hyper-

opia (+0.75 D) and an astigmatism (-0.25 D) corrected at the same time. The procedure was performed with the SCHWIND AMARIS 750S, which ablates the cornea at a pulse rate of 750 hertz.

Three weeks

Just three weeks after the treatment, the desired quality of vision had

recovered at all distances. Result: best corrected distance visual acuity of 20/12.5p, no loss of Snellen lines and excellent near visual acuity without any further correction. Dr. Stade no longer needs to wear glasses in usual day-to-day situations. He gave the following statement: "In my opinion, PresbyMAX μ -Monovision is currently the most sophisticated laser procedure available for the simultaneous treatment of presbyopia and other visual deficiencies".

Best possible solutions

When he noticed detrimental changes in his near vision, the eye surgeon decided to look for the best possible solution for treating his presbyopia. His reading glasses had already become his constant companion: both in the clinic when reading, setting and operating the diagnostic devices and the laser – sometimes under sterile conditions – and in his free time when shopping and paying, deciphering the menu in a restaurant or making calls on his mobile phone.

Multifocal contact lenses allowed Dr. Stade to see well both at distance and close up, but intolerance problems made their use impractical, particularly in work situations. The only alternative to laser treatment that did not involve glasses or con-



Michael Stade, MD, and his team

tact lenses was a lens implant, in other words, intraocular surgery.

In-depth investigation

Dr. Stade decided for PresbyMAX μ -Monovision after an in-depth investigation of the treatment options available for presbyopia. He concentrated in particular on the question of which procedures can achieve an optimal ratio between distance and near visual acuity. He also used special multifocal contact lenses to test his future quality of vision after PresbyMAX μ -Monovision treatment.

His conclusion: "As an eye surgeon, I was impressed both by the sound scientific basis of PresbyMAX, and especially by the excellent study results reported for the μ -Monovision treatment. My own treatment experience confirmed that the procedure is currently the best solution available for presbyopia treatment not involving glasses or contact lenses when the natural lens is still completely clear."

More than 4,500 eyes treated so far

Clinical outcomes with PresbyMAX®



Pierre Baudu, MD, Reunion

Groundbreaking for the development of PresbyMAX μ -Monovision were the very good clinical results already achieved with the PresbyMAX procedure. Two peer reviewed publications of these results have been already released.^{1,2}

To date, SCHWIND AMARIS users successfully treated more than 4,500 patient eyes with the PresbyMAX procedure. Clinical results from the Clinique Avicienne, Reunion, and VisionClinics, The Netherlands, convincingly demonstrate to what extent presbyopia patients have profited from a treatment with PresbyMAX.

¹ M. H. A. Luger, T. Ewering, S. Arba-Mosquera, 3-Month experience in presbyopic correction with bi-aspheric multifocal central presbyLASIK treatments for hyperopia and myopia with or without astigmatism, Journal of Optometry, available online 21 February 2012

² D. Uthoff, M. Pölzl, D. Hepper, D. Holland. A new method of cornea modulation with excimer laser for simultaneous correction of presbyopia and ametropia. Graefe's Archive for Clinical and Experimental Ophthalmology, available online 22 February 2012.

Outcomes at Clinique Avicienne

Pierre Baudu, MD, Clinique Avicienne, Le Port, Reunion, possesses the most experience among SCHWIND users with more than 600 patients successfully treated so far. Through his comprehensive experience, fundamental parameters were derived which formed the basis of the very good treatment results:

- ▶ The best outcomes were obtained applying additions between +1.50 D and +2.75 D. An addition of +1.75 D seemed to be the optimal setting.
- ▶ The optical zone should be planned not smaller than 6.3 mm and not larger than 7.2 mm. The best results were achieved with an optical zone of 6.5 mm.
- ▶ Patients from 40 to 55 years of age showed the highest visual satisfaction at all distances.
- ▶ Instead of the normal planned refractive results with PresbyMAX of -0.50 D, a target refraction of -0.13 D in the dominant eye and -0.50 D in the non-dominant eye achieved the best results and a high level of satisfaction at all distances.

It is noteworthy that a residual with-the-rule astigmatism of 0.13 D in both eyes lead to a higher UNVA without

noticeable compromises on UDVA. Furthermore, the best objective outcomes were obtained in the group of patients with low myopia (up to -2.50 D). In contrast, the group of patients with low hyperopia (up to +1.75 D) showed the highest level of satisfaction.

Six-month data for 436 eyes

218 patients (436 eyes) were reviewed after the six-month follow-up was completed. At six months, 72% of treated eyes achieved a CDVA 0.1 logMAR or better. 54% obtained a distance corrected near visual acuity (DCNVA) of 0.1 logRAD or better. 72% of patients achieved an UDVA 0.1 logMAR or better. 93% of patients obtained an UNVA 0.1 logRAD or better. 94% achieved the planned refractive result within ± 0.75 D. The mean postoperative SEQ was -0.17 ± 0.32 D.

88% of eyes achieved a CDVA 0.2 logMAR or better and a DCNVA 0.2 logRAD or better. The mean monocular CDVA degraded from 0.01 ± 0.03 logMAR to 0.09 ± 0.07 logMAR. The mean monocular UNVA improved from 0.53 ± 0.14 logRAD to 0.17 ± 0.08 logRAD.

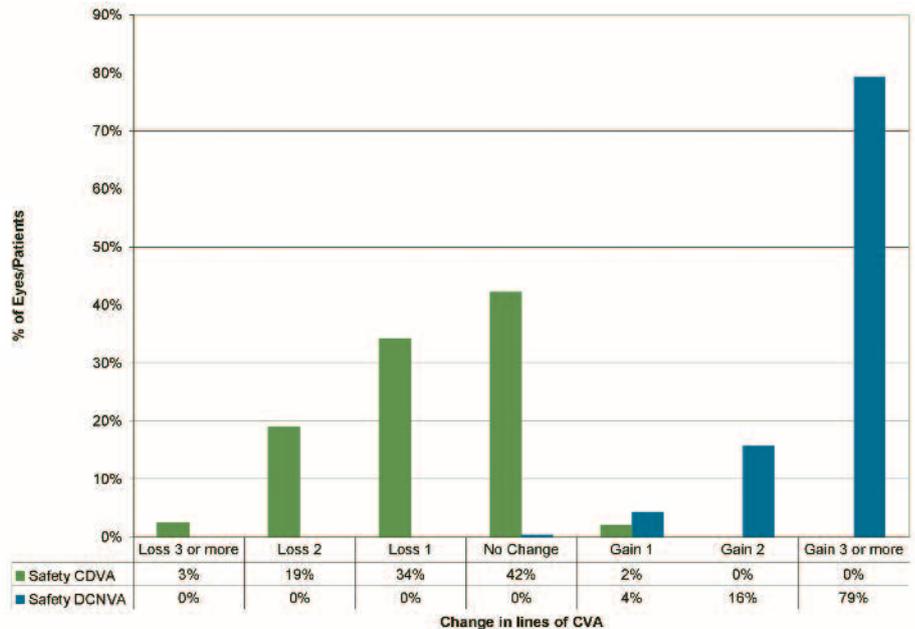
97% of patients achieved an UDVA 0.2 logMAR or better and an UNVA 0.2 logRAD or better. The mean binocular

CDVA degraded from 0.00 ± 0.01 logMAR to UDVA 0.10 ± 0.07 logMAR. The mean binocular CNVA degraded from 0.02 ± 0.01 logRAD to UNVA 0.07 ± 0.07 logRAD.

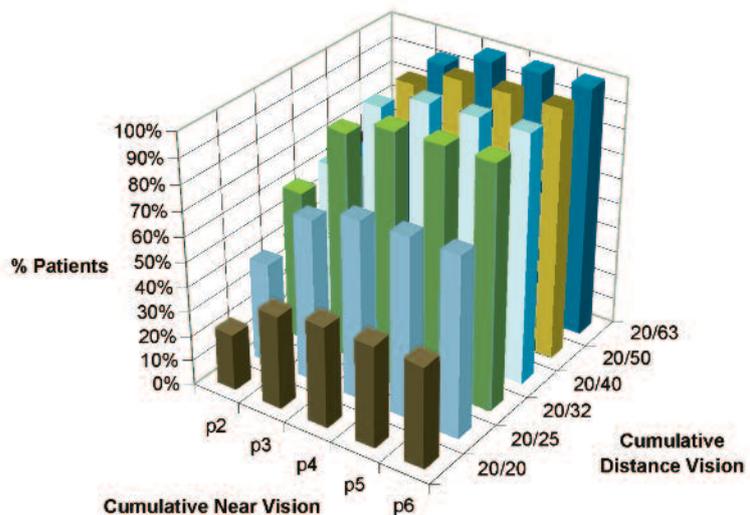
The distance vision was fairly good, with a mean UDVA of 0.14 logMAR monocularly and 0.07 logMAR binocularly for young presbyopes, but 0.20 logMAR monocularly and 0.12 logMAR binocularly for advanced presbyopes. Recommendation is to plan multifocal ablations with close to emmetropic residual refractions of both eyes in patients up to 53 years. In older patients, limiting multifocality to +2.25 D and providing μ -monovision is helpful.

Acronyms:

- logMAR:** logarithm of the Minimum Angle of Resolution
- logRAD:** logarithm of the Reading Acuity Determination
- UDVA:** Uncorrected Distance Visual Acuity
- UNVA:** Uncorrected Near Visual Acuity
- CDVA:** Corrected Distance Visual Acuity
- DCNVA:** Distance Corrected Near Visual Acuity
- CNVA:** Corrected Near Visual Acuity
- SEQ:** Spherical Equivalent



Safety of monocular CDVA and DCNVA six months after the treatment: 22% of eyes (10% of patients) lost 2 or more lines of monocular CDVA but 95% of eyes (96% of patients) gained 2 or more lines of monocular DCNVA.



	p2	p3	p4	p5	p6
20/20	23%	38%	41%	41%	41%
20/25	41%	65%	72%	72%	72%
20/32	61%	90%	97%	97%	97%
20/40	62%	92%	99%	99%	99%
20/50	63%	93%	100%	100%	100%
20/63	63%	93%	100%	100%	100%

Distribution of binocular UDVA and UNVA six months after the treatment. The near vision data p2 to p6 correspond with 0.0 logRAD to 0.4 logRAD. 72% of patients achieved 20/25 (0.1 logMAR) UDVA and p4 (newsprint) UNVA simultaneously.

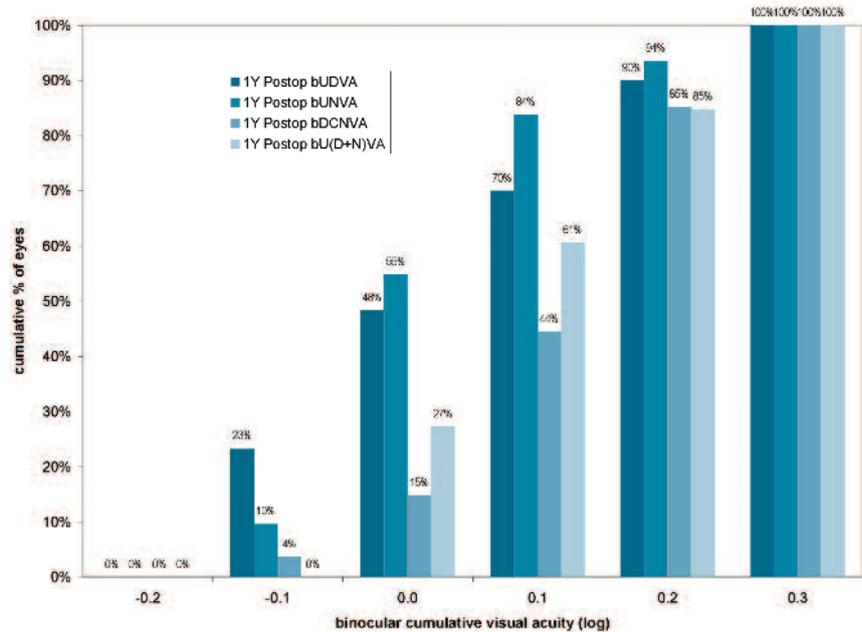


Michiel Luger, MD, The Netherlands

Outcomes at VisionClinics

Michiel Luger, MD, VisionClinics, Utrecht, The Netherlands, also significantly contributed to the further development of the PresbyMAX technique with more than 65 patients successfully treated so far. His parameters for optimal treatment results at all distances:

- The best outcomes were obtained applying additions not below +1.50 D and not beyond +2.50 D. An addition of +1.75 D in hyperopia, +2.00 D in emmetropia and +2.25 D in myopia showed the best results.
- The optical zone should be planned not smaller than 6.3 mm and not



Distribution of cumulative binocular visual acuity twelve months after the PresbyMAX treatment (UDVA, UNVA, DCNVA, U(D+N)VA): 90% of patients achieved 0.2 logMAR (20/32) UDVA, 94% 0.2 logRAD (newsprint) UNVA, and 85% 0.2 logMAR UDVA and logRAD UNVA simultaneously.

larger than 7.0 mm. The best results were achieved with an optical zone of 6.5 mm.

- The planned target refraction was established at -0.25 D.

The following parameters had an especially positive effect on far vision:

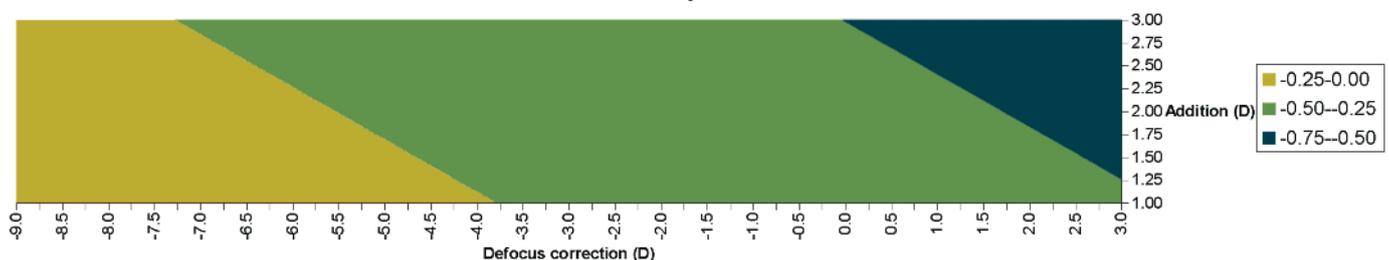
- The higher the hyperopic refraction, the better the result.
- The lower the preoperative astigmatism, the better the result.

➤ The larger the optical zone, the better the result.

➤ The larger the distance between the corneal vertex and the pupil, the more important is its consideration.

The three- and twelve-month data showed comparable results. At three months after the PresbyMAX treatment, 71% of patients (at twelve months: 70%) achieved an

Induction of SphAb



The efficacy of spherical aberrations increases with higher hyperopia and higher addition

UDVA 0.1 logMAR or better. 79% (at twelve months: 84%) obtained an UNVA 0.1 logRAD or better. 83% of eyes (at twelve months: 83%) achieved the planned refractive result within ± 0.75 D. The post-operative SEQ was -0.15 ± 0.50 D (at twelve months: -0.47 ± 0.44 D). 92% of patients (at twelve months: 85%) obtained a CDVA 0.2 logMAR or better and an UNVA 0.2 logRAD or better.

Conclusion: In both laser clinics, objectively excellent and exactly predictable clinical outcomes were achieved with the PresbyMAX procedure.

Additionally, the vast majority of patients subjectively showed high satisfaction with the results after treatment with PresbyMAX and an adaptation time of several weeks. This is not only due to the high quantitative visual acuity. Adequate patient selection and a comprehensive counselling at all aspects played a large role in the achievement of high patient satisfaction.

Patient Selection

However, not every patient is well suited for a treatment with PresbyMAX. The first consideration is to individually check the patient's tolerance for PresbyMAX at an in-depth preexamination. Two options are available: a trial with multifocal contact lenses or trial frames that

Pupil \varnothing	3.0 mm	3.8 mm	4.5 mm	5.5 mm
Far (6 m)				
Far Intermediate (1.5 m)				
Intermediate (70 cm)				
Near (40 cm)				

Simulation of visual ability after a PresbyMAX treatment for different visual distances and pupil sizes

create slightly defocused images to the retina should simulate post-operative visual impressions to verify patient's acceptance of the final outcome. The patient's profession, hobbies, and visual expectations must be identified before deciding whether the postoperative visual performance provided by the ablation profile will comply with the patient's needs and expectations regarding the result.

The aim of a treatment with PresbyMAX is spectacle-free vision in usual day-to-day situations. Well-lit conditions allow the best near performance, while dim conditions are optimal for distance vision. If these preconditions are not met, the sporadic use of spectacles may be necessary. The patient's adaptation to multifocal vision requires several weeks and is primarily related to the uncorrected visual acuity.

Request your PresbyMAX Guide now

The "PresbyMAX Guide" provides detailed references for optimal patient selection and satisfaction. It is based on the evaluation of clinical outcomes and patient interviews conducted in cooperating clinics. The PresbyMAX Guide can be requested from SCHWIND via email at presbymax@eye-tech.net.

PresbyLASIK and Monovision

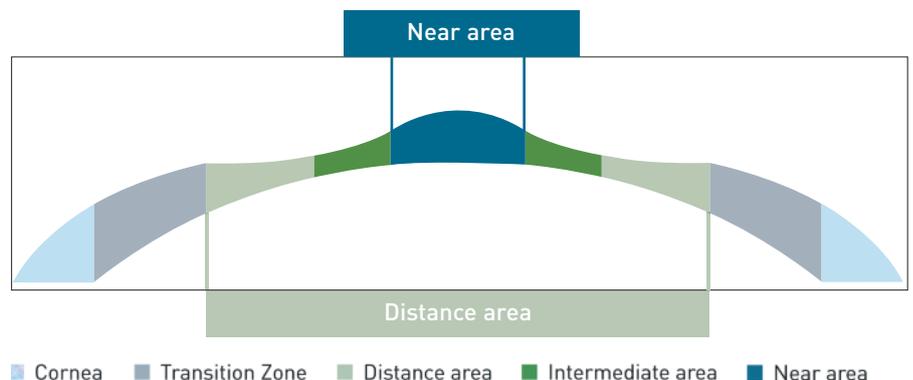
Fundamentals and principles of Presbyopia Treatment

The main goal of any surgical procedure that aims to correct presbyopia is to enhance the quality of vision in the entire distance range, particularly for intermediate and near vision.

Presbyopia-correction surgery can be broadly categorised as follows: techniques that mimic the crystalline lens and bifocal or multifocal techniques that enhance depth of focus. Amongst bifocal or multifocal approaches PresbyLASIK is a very popular procedure. PresbyLASIK uses the principle of LASIK to create a multifocal corneal surface, corrects visual defects for distance and provides spectacle-free near vision in presbyopic patients. PresbyLASIK constitutes the next generation in the laser treatment of presbyopia after Monovision LASIK.

Best possible depth of focus

Neither multifocality nor other procedures creating pseudoaccommodation can slow or stop the progress of presbyopia. However, the PresbyMAX technique from SCHWIND uses the positive effects of multifocality and change of pupil size depending on light conditions to ensure spectacle-independence and best possible depth of focus.



Bi-aspheric profiles – the PresbyMAX procedure

PresbyMAX was developed by SCHWIND in cooperation with the VISSUM Corporation under the direction of Prof. Jorge Alió, Spain, and the OCIVIS group from the University of Alicante. The product was launched in 2009. The ultimate goal of the PresbyMAX development was to provide a scientifically-based and efficient approach for the correction of presbyopia with excimer laser treatment.

The cornea is corrected in the centre for near vision surrounded by an area corrected for distance vision. This is carried out with a specially optimised bi-aspheric profile for presbyopia treatment that adds a customised amount of higher-order aberrations. As presbyopia progresses and in case

that reading glasses are required again, another PresbyMAX treatment could be performed.

Higher degree of maturity

Restoration of natural accommodation is a topic of intense research. A very high degree of maturity is already achieved through innovative treatments such as PresbyMAX μ -Monovision, which ensures an increased depth of focus through pseudoaccommodation.

In the future, optimised wavefront analysis through adaptive diagnostic systems will become even more effective in facilitating solutions for the specific visual requirements of each individual patient.

Imprint

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