

Cataract & Refractive Surgery

EUROPE

TODAY

SHAPING THE FUTURE

With SCHWIND AMARIS 1050RS
and PresbyMAX Hybrid



FEATURED AUTHORS:

Minoru Tomita, MD, PhD • María Clara Arbelaez, MD • Michiel H.A. Luger, MD
Pierre Baudu, MD • Samuel Arba-Mosquera, PhD, MSc

AMARIS 1050RS Versus Competing Technologies

Results indicate that safety, efficiency, predictability, and postoperative visual quality are extremely high with the AMARIS excimer laser.

BY MINORU TOMITA, MD, PhD

Shinagawa LASIK Center has the highest volume of refractive surgeries in the world, with more than 1.1 million procedures completed to date. Our Tokyo location is the largest of five Shinagawa LASIK Centers in Japan, and we have multiple satellite locations in China, the Philippines, and Singapore. Our centers have also performed the highest volume of SCHWIND AMARIS (SCHWIND eye-tech-solutions) treatments in the world, completing 378,958 procedures to date with the SCHWIND AMARIS first-generation, SCHWIND AMARIS 500E, SCHWIND AMARIS 750S, and SCHWIND AMARIS 1050RS models.

COMPARATIVE STUDY

We received two demo AMARIS systems in July 2009; now we currently own four AMARIS, six AMARIS 750S, and three AMARIS 1050RS in Japan, one AMARIS 750S in Singapore, and one AMARIS 500E in China. We also use the WaveLight Allegretto Eye-Q 400 and the WaveLight EX500 (both by Alcon), the VISX Star S4 IR (Abbot Medical Optics Inc.), and the LSX200 (LaserSight Technologies) excimer lasers. Recently we compared the different technologies available in the refractive surgery market, and below is a summary of our results (Table 1).

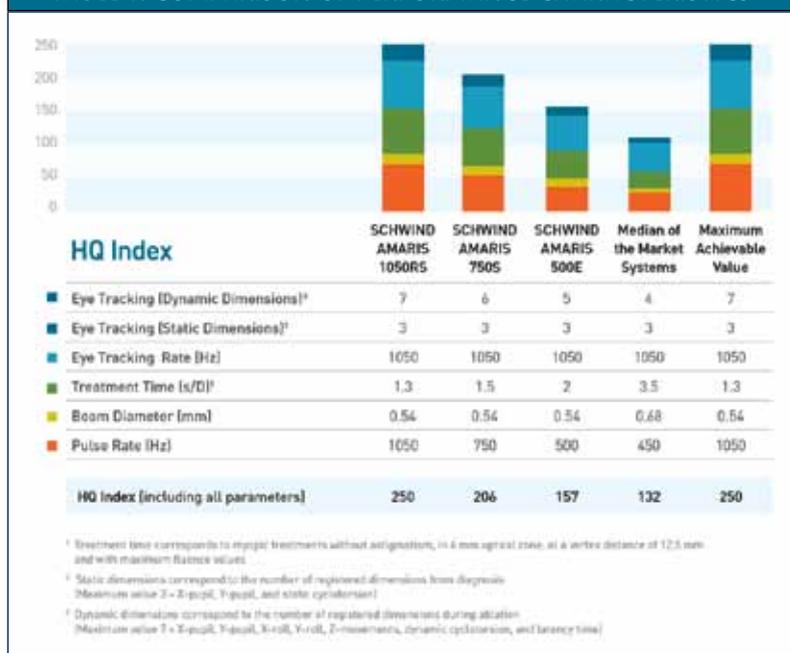
Speed. Launched at the 2013 European Society of Cataract and Refractive Surgeons (ESCRS) annual meeting in Amsterdam, the SCHWIND AMARIS 1050RS boasts an ablation time of 1.3 seconds per diopter in myopic cases.* This is the fastest excimer laser system on the market today, followed by the WaveLight EX500 (1.4 seconds per diopter), the SCHWIND AMARIS 750S (1.5 seconds per diopter),

the SCHWIND AMARIS 500E and WaveLight Allegretto Eye-Q 400 (both 2 seconds per diopter), and the VISX Star S4 IR.

Resolution. The SCHWIND AMARIS first-generation, AMARIS 500E, AMARIS 750S, and AMARIS 1050RS have a beam diameter of 0.54 mm (full width at half maximum) and a dual-fluence (high and low) concept. The WaveLight EX500 and WaveLight Allegretto Eye-Q 400 lasers have a beam diameter of 0.68 mm, and the VISX Star S4 IR uses variable spot scanning and a variable repetition rate to adapt the beam size and scanning frequency. Both WaveLight lasers and the VISX system use only one level for fluence.

Eye tracking. The SCHWIND AMARIS first-generation, AMARIS 750S, and AMARIS 1050RS use a 1,050-Hz, six-dimensional eye tracker to control lateral eye movements, pupil centroid shift, eye rolling movements, cyclotorsion, and z-movements. The AMARIS 1050RS

TABLE 1. COMPARISON OF PERFORMANCE CHARACTERISTICS



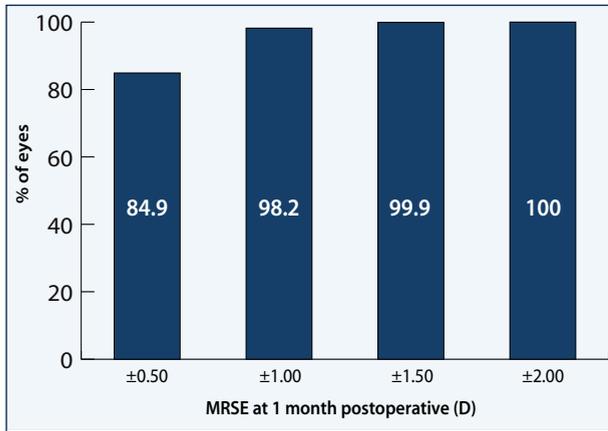


Figure 1. Manifest refraction spherical equivalent.

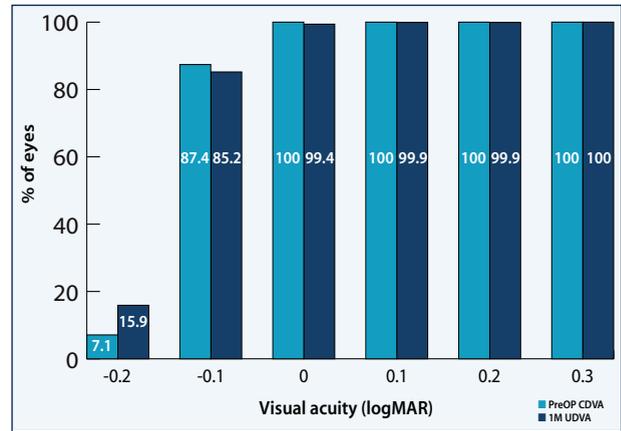


Figure 2. Visual acuity (logMAR).

includes an additional dimension—latency-free laser beam delivery—making it a seven-dimensional eye tracker.

Although WaveLight EX500 also uses a 1,050 Hz eye tracker, it controls only three dimensions including lateral movements, pupil centroid shift, and cyclotorsion. The WaveLight Allegretto Eye-Q 400 uses a 400-Hz eye tracker with up to three dimensions including lateral movements and neurotrack, and the VISX Star S4 IR uses a 60-Hz eye tracker with up to four dimensions including lateral eye movements, pupil centroid shift, cyclotorsion, and passive tracking of z-movements.

CALIBRATION AND ACCURACY

Calibration. In order to achieve accurate refractive outcomes and reduce the likelihood of retreatment, precisely calibrating the laser system is mandatory. AMARIS laser systems are calibrated with objective criteria including measuring the PMMA profiles with a laser-scanning refractometer. SCHWIND service technicians also perform regularly scheduled comprehensive tests to ensure our lasers are calibrated properly.

Accuracy. Many factors influence laser ablation and postoperative outcomes, including laser energy delivery, decentration, registration, eye tracking, flap creation, ablation patterns, wound healing, and corneal biomechanics. We recently reviewed our early results in 717 eyes of 364 patients (average age, 32.4 ± 8.0 years; range, 18–58 years) who underwent treatment with the nonwavefront-guided aspheric algorithm of the SCHWIND AMARIS 1050RS. Mean manifest refraction spherical equivalent (MRSE) was -4.35 ± 1.95 D (range, -0.75 to -11.25 D) with up to 6.00 D of astigmatism (mean, 0.77 ± 0.66 D).

All eyes were targeted for emmetropia and received treatment with 6.0- to 6.5-mm diameter optical zones, depending on the preoperative scotopic pupil diameter and the amount of astigmatism. The SCHWIND CAM

was used to calculate the size of the optimal transition zone, depending on the preoperative refraction and optical zone.

At 1-month postoperative, the MRSE was $+0.27 \pm 0.34$ D (Figure 1), and 85% of eyes were within ± 0.50 D; the manifest cylinder was 0.08 ± 0.21 D. Distance UCVA was logMAR 0.0 (20/20) or better in 99.4% of eyes (Figure 2). Only one eye lost more than 1 Snellen line of BCVA, and 23% gained two or more lines.

CONCLUSION

Parallel to the clinical developments in refractive surgery, laser systems are more capable, reliable, and safer than previous models. High-quality indices, an increased repetition rate, and a low thermal load make the AMARIS 1050RS the new flagship excimer laser. What is especially important for a high-volume center such as ours is that there is little to no need for nomogram adjustments between the AMARIS systems. We have not noticed any nomogram changes after integrating the six-dimensional eye-tracking module or upgrading our systems to 750 Hz. The same applies to the latest 1050RS development.

Today's laser systems successfully deliver highly precise corneal ablation patterns; however, variability of the cornea due to hydration changes and the cornea's healing response can affect surgical results.

With its extremely short ablation time, the AMARIS 1050RS has minimized these effects. According to our 1-month results, the SCHWIND AMARIS 1050RS excimer laser has very high safety, efficiency, predictability, and postoperative visual quality for the treatment of myopia with astigmatism. ■

Minoru Tomita, MD, PhD, is the Executive Director of Shinagawa LASIK Center. Dr. Tomita states that he has no financial interest in the products or companies mentioned. He may be reached at e-mail: tomita@shinagawa-lasik.com.



Technological Highlights and First Clinical Results

The SCHWIND AMARIS 1050RS nonwavefront-guided aspheric algorithm corrected sphere and cylinder and preserved corneal HOAs.

BY MARÍA CLARA ARBELAEZ, MD

The goal of excimer laser surgery is to correct refractive error by reshaping the anterior corneal surface. Successful surgery depends on correct design of the ablation profile, on the precise delivery of laser energy to the corneal position, and on an understanding of the corneal tissue's response to treatment. Ablation with a flying laser beam enhances energy delivery at each corneal position. In fact, today's complex wavefront-driven ablations not only achieve a truly customized procedure but also reduce the incidence of postoperative higher-order aberrations (HOAs).

Current excimer laser technology uses sophisticated algorithms and optimized tools to plan surgery and improve surgical outcomes including visual acuity and night vision. Additionally, because today's patients are better informed about the potential benefits of laser refractive surgery, their expectations and quality requirements are higher.

Over the past year, we have assessed the efficacy, predictability, and safety of LASIK for the correction of low to moderate myopia and astigmatism using the AMARIS 1050RS excimer laser (SCHWIND eye-tech-solutions). This laser has a repetition rate of 1,050 Hz and an ablation time of 1.3 seconds per diopter.* Its optical system is essentially identical to the AMARIS 750S, and other characteristics including online pachymetry (200-Hz), Intelligent Thermal Effect Control (ITEC), Automatic Fluence Level Adjustment, and particle aspiration are identical to the 750S. In contrast, the AMARIS 1050RS

provides seven-dimensional active eye tracking for the first time. This pioneering seventh dimension concerns the time factor and ensures latency-free tracking.

To date, 114 eyes with a manifest refraction spherical equivalent (MRSE) from -0.75 to -7.88 D (mean, -3.13 ±1.47 D) and up to 3.50 D of astigmatism (mean, 0.84 ±0.80 D) have been treated at our center. All eyes underwent treatment targeting emmetropia with the AMARIS 1050RS's nonwavefront-guided aspheric algorithm. Refractive outcomes and corneal HOAs were analyzed pre- and postoperatively.

Three month results are depicted in Figures 1 through 5. At 3 months, the average MRSE was -0.12 ±0.18 D. All but one eye was within ±0.50 D of intended correction, and all but two had astigmatism of 0.50 D or less. UCVA was 20/20 or better in 96% of eyes, and no eye lost 2 or more lines of BCVA. Additionally, the total corneal HOAs root-mean-square decreased by 0.157 μm, the change in spherical aberration was not statistically significant, and vertical and horizontal coma decreased by 0.049 μm and 0.045 μm, respectively. These results confirm that an aberration-free concept can correct sphere and cylinder and preserve corneal HOAs.

LOCAL FREQUENCY

The repetition rate with which a laser pulse with a given radiant exposure can be continuously delivered onto one location of corneal tissue without denaturing is

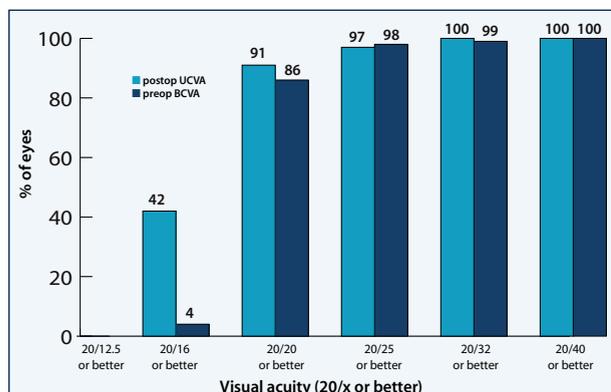


Figure 1. Preoperative BCVA versus postoperative UCVA.

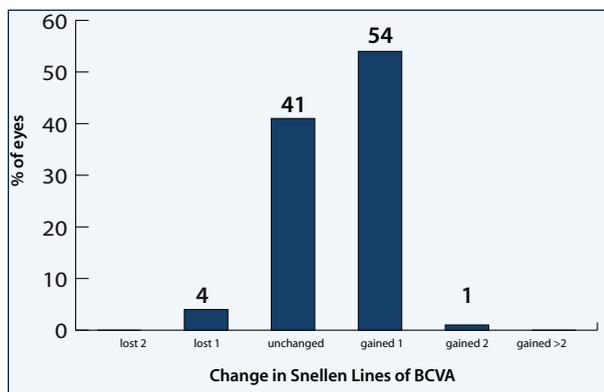


Figure 2. Change in distance BCVA.

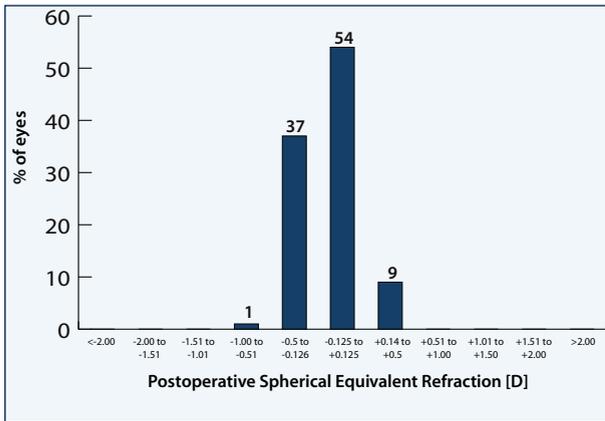


Figure 3. Spherical equivalent refractive accuracy.

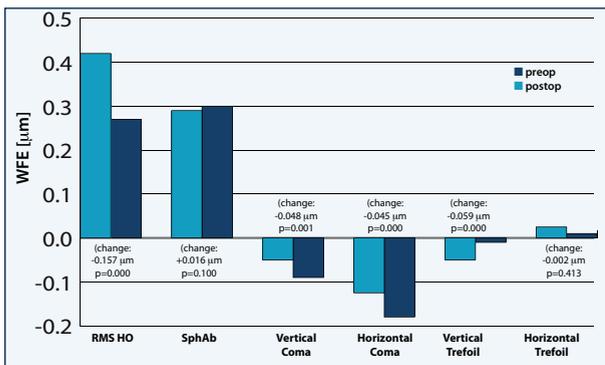


Figure 5. Corneal aberrations at 6-mm analysis diameter.

the proteins is defined as the maximum local frequency. Firing at higher local frequencies results in suboptimal ablation and produces excessive thermal load on the cornea. The advantage of the AMARIS laser systems is that it automatically controls local frequency, thus achieving optimum refractive outcomes and visual quality as well as smooth surfaces and gentle ablations.

By limiting local frequency, arranging the laser shot energy in spatial and temporal distribution, and controlling pulse re-creation time versus interspot distance, the AMARIS laser systems reduce the thermal impact of the ablation and the heat propagation during the ablation. Its ITEC algorithm calculates the allowed local frequency based on the fluence results and is irrespective of the repetition rate of the system.

For instance, an ablation of -10.00 D across a 6.0-mm optical zone and a 7.7-mm total ablation zone would take 21 seconds with the AMARIS 500E, 16 seconds with the AMARIS 750S, and 14 seconds with the AMARIS 1050RS. However, the local frequency is kept at maximums of 38 and 84 Hz for high and low fluence, respectively, for each system. Additionally, the thermal load of all treatments never exceeds 7 Kelvin (K); this is independent of the actual repetition rate of the laser. For a -10.00 D spherical myopia treatment and for a -4.00 D cylindrical astigmatism treatment, the estimated thermal load is 4 K; for a mixed astigmatism treatment of 3.00 D of sphere with -6.00 D of

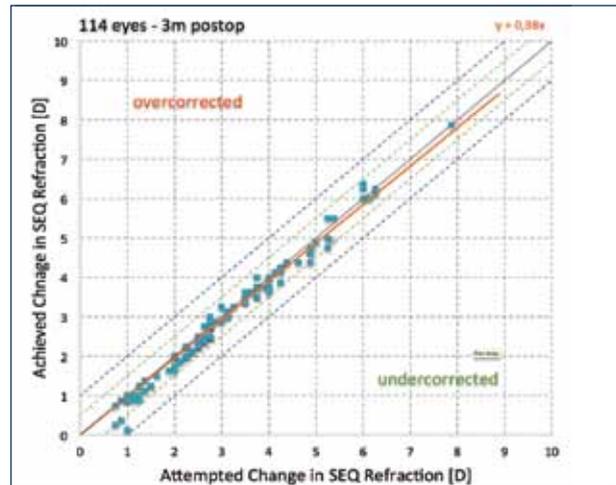


Figure 4. Attempted versus achieved spherical equivalent.

astigmatism, a phototherapeutic keratectomy treatment with a 75-μm depth, or a 7.00 D cylindrical astigmatism treatment, the estimated thermal load is 3 K. Also, for a 5.00 D spherical hyperopia treatment, the estimated thermal load is 2 K. The improper use of ablation algorithms that over- or underestimate the thermal load may result in suboptimal refractive corrections.

ABERRATION-FREE PROFILE

In my opinion, the major reason for the success of AMARIS technology is the aberration-free profile. In combination with smart blending zones and sophisticated eye tracking, this profile preserves HOAs and improves clinical outcomes by decreasing the need for nomograms and diminishing the incidence of surgically induced aberrations.

When a patient selects a nonwavefront-guided aspherical treatment, the surgeon should aim to unalter all existing HOAs, as the BCVA is not affected by the pre-existing aberrations. Hence, all factors that may induce HOAs, such as biomechanics, must be accounted for prior to the treatment to ensure that the preoperative HOAs are unchanged. With wavefront-guided ablations, the objective is not only to reduce the induction but also to reduce the eye's aberrations. In the case of aspheric aberration-free treatments, the slope of the cornea is remodeled to compensate for the attempted sphere and cylinder components, but no new aberrations are induced. ■

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One-Year Experience With PresbyMAX Hybrid

This treatment is especially promising for patients presenting with symptoms of presbyopia and ametropia.

BY MICHIEL H.A. LUGER, MD

We have been performing PresbyMAX at VisionClinics for the past 4 years, beginning with the basic approach, PresbyMAX Symmetric, and evolving to the latest approach, PresbyMAX Hybrid (Figure 1). Even though we took a yearlong break to explore the use of IOLs and corneal inlays for presbyopia correction, we eventually decided to return to performing presbyopia treatments with the latest excimer laser technology, which we believe is PresbyMAX Hybrid. This treatment combines different multifocalities in both eyes with μ -monovision. It provides better distance visual acuity compared with PresbyMAX Symmetric but still achieves all of its known advantages.

PRESBYMAX SYMMETRIC

Results with PresbyMAX Symmetric were predictable and fairly good. However, some patients had difficulty adapting to or were dissatisfied with a minor loss of distance visual acuity. In a clinical study carried out from 2009 to 2010, we performed 66 bilateral PresbyMAX Symmetric treatments ranging from -7.00 to +3.25 D. We treated eyes with up to 3.00 D of astigmatism and performed additions up to +2.75 D. No eye had undergone previous corneal refractive surgery, the preoperative corneal curvature ranged from 40.00 to 48.00 D, and the preoperative corneal thickness was greater than 500 μ m in all eyes. Preoperative distance BCVA was 20/25 or better, and near vision was 0.2 logRAD (J4) or better with up to +2.50 D of addition.

At 1 year postoperative, 70% of patients achieved a distance UCVA of 20/25 or better, 84% obtained

near UCVA of 0.1 logRAD (J2) or better, and 83% were within ± 0.75 D of target defocus. Postoperative mean spherical equivalent refraction was -0.47 ± 0.44 D, and stability was achieved by the 6-week follow-up. Although 85% of patients achieved distance and near UCVAs of 20/32 or better and 0.2 logRAD (J4) or better, respectively, only 61% achieved distance and near UCVAs of 20/25 or better and 0.1 logRAD (J2) or better, respectively.

Mean patient satisfaction, on a scale from 0 (worst) to 10 (best), was 7.2 (range, 1–10), and the mean percentage of spectacle-free time was 84% (range, 0%–100%). Vision quality values are listed in Table 1. These were satisfactory results; however, they were for near-to-intermediate postoperative dominance and may not have accurately portrayed the Dutch population. Therefore, we learned our lesson that maintaining good distance vision is essential to achieving maximal patient satisfaction. Patients desire correction of their near vision, but they do not want to sacrifice distance vision.

PRESBYMAX HYBRID

After our experience with PresbyMAX Symmetric, we experimented with Intracor in three patients and with a unilateral combination procedure of Kamra corneal inlay (AcuFocus, Inc.) implantation and LASIK performed in the nondominant eye. We also experimented with various presbyopia-correcting IOLs around the same time. Even though we have had success with modern multifocal IOLs and the Kamra inlay, of which the latter we found can be easily removed when nec-

TABLE 1. VISUAL QUALITY VALUES[†]

	Distance Vision Quality ^{††}	Intermediate Vision Quality ^{††}	Near Vision Quality ^{††}	Severity of Halos [*]	Severity of Glare [*]
Daylight	6.4	7.7	7.8	1.3	1.7
Nighttime	6.2	7.2	6.8	1.8	1.7

[†]Mean subjectively reported values in 33 patients, ^{††}Scale: 1 = worst, 10 = best *Scale: 10 = worst, 1 = best



Figure 1. PresbyMAX Symmetric, PresbyMAX μ -Monovision, and PresbyMAX Hybrid: These three treatments provide a broad range of vision at all distances for the dominant as well as the nondominant eye.

essary, we decided to collaborate with SCHWIND to develop the PresbyMAX Hybrid concept. This is a μ -monovision technique that can be used in a broader spectrum of patients and enables faster visual recovery at all distances compared with previous PresbyMAX approaches. This treatment focuses the dominant eye slightly more toward distance vision and the nondominant eye slightly more toward near vision. Additionally, different depths of focus are induced in the dominant and nondominant eyes.

Not only have our results been excellent, but SCHWIND PresbyMAX is the only excimer-laser-based technique to provide a full and easy reversibility option if necessary. Additionally, we have achieved higher rates of patient satisfaction—even in demanding patients—with PresbyMAX Hybrid than with other PresbyMAX approaches.

PROSPECTIVE ESTIMATIONS, PROMISING RESULTS

According to SCHWIND's internal simulations and prospective estimations, 74% of distance eyes should achieve 20/20 or better distance visual acuity after PresbyMAX Hybrid, and 26% should achieve J3 or better near visual acuity, without the side effects of halos or diminished distance vision in bright light. Additional estimations include that 71% and 85% of near eyes should achieve 20/32 or better distance visual acuity and J3 or better near visual acuity, respectively. Binocularly, 98% patients are expected to achieve 20/25 or better distance visual acuity, and 86% are expected to achieve J3 or better near visual acuity.

To achieve these promising results, we used a multifocal add of +1.13 D and a target refraction of 0.00 D in the distance-dominant eye and a target refraction of -0.88 D, with a multifocal add of +2.13 D in the near

eye. We followed a strict enrollment process (Durrie protocol) and performed quality of vision assessments using validated questionnaires for distance (quality of vision questionnaire; QoV) and near (near activity questionnaire; NAVQ) that included measuring distance, intermediate, and near visual acuities, contrast sensitivity with and without disability glare, corneal and ocular aberrations, and defocus curves. We performed all treatments as femtosecond LASIK with the SCHWIND AMARIS 750S.

To date, 6-month, 3-month, and 6-week follow-up is available for 12, 19, and 27 patients, respectively. Mean follow-up is 4-months. Patient age ranged from 46 to 55 years old, defocus ranged from -6.75 to +2.00 D, and up to 1.75 D of astigmatism was treated.

Preoperatively, distance and near BCVAs were 20/20 or better and 0.2 logRAD (J4) or better, respectively. At the latest follow-up (4 ± 1 months), 74% of patients had achieved a distance UCVA of 20/25 or better, and 86% obtained a near UCVA of 0.1 logRAD (J2) or better.

Additionally, the mean spherical equivalent refraction was -0.31 ± 0.40 D in distance eyes and -1.42 ± 0.85 D in near eyes, with 93% of patients achieving distance and near UCVAs of 20/32 or better and 0.2 logRAD (J4) or better, respectively, and 79% achieving distance and near UCVAs of 20/25 or better and 0.18 logRAD (J3) or better, respectively.

CONCLUSION

PresbyMAX Hybrid is a promising approach to maximize functional vision at all distances, especially distance vision. Already at 6 weeks, our results are significantly better than our 1-year results with PresbyMAX Symmetric. However, careful patient selection still plays an integral role in achieving high patient satisfaction.

Based on the results we have achieved so far, we now frequently use PresbyMAX Hybrid in patients presenting with symptoms of presbyopia and ametropia. ■

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The Safety Factor of PresbyMAX

Six-month follow up in 1,000 eyes confirmed consistent results and a high success rate.

BY PIERRE BAUDU, MD

La Réunion is a French island located in the Indian Ocean with a population of approximately 850,000. The majority of La Réunion residents have hyperopia and small pupils, and over the past 17 years I have performed more than 10,000 procedures using SCHWIND eye-tech-solution's line of excimer lasers. I started using simple monovision to treat presbyopia in 2005, but I was also interested in laser surgery for treatment of presbyopic symptoms, as the demand for presbyopia correction was—and continually is—increasing from day to day.

I began using PresbyMAX for presbyopia correction in 2010 and have treated more than 1,000 eyes, representing about 30% of the treatments I perform with the excimer laser. By adding PresbyMAX to the list of laser treatments I offer, I have been able to significantly increase the number of annual procedures I perform. In the majority of cases, this treatment achieves encouragingly satisfactory results.

RESULTS

We have long-term experience performing bilateral PresbyMAX in combination with LASIK. All 1,000 eyes to date have achieved a monocular distance BCVA of 20/32 or better. Of the last 500 patients I have treated, 86% achieved a distance UCVA of 20/25 or better, 92% obtained a near UCVA of 0.1 logRAD or better, and 99% were within 1.00 D of defocus. Additionally, mean postoperative spherical equivalent was -0.16 ± 0.34 D, with 83% of patients achieving a distance UCVA of 20/25 or better and a near UCVA of 0.2 logRAD or better. Mean binocular distance and near BCVAs both decreased postoperatively, from 20/20 to a distance UCVA of 20/25, and from 0.02 ± 0.01 logRAD to a near UCVA of 0.08 ± 0.07 logRAD, respectively. All patients achieved a distance UCVA of at least 20/40 and a near UCVA of Parinaud (P)5.

Approximately 95% of patients said that they were satisfied after surgery. Only 7% reported occasionally wearing glasses for reading, and 4% reported wearing them for driving. Even though, optically, the results were satisfactory, approximately 14% of patients did not feel that their objective outcome was fully achieved.

In presbyopic patients with refractive errors but without symptomatic cataracts, PresbyMAX decreases the symptoms of presbyopia and corrects distance refraction, offering spectacle-free vision for daily activities in a single treatment.

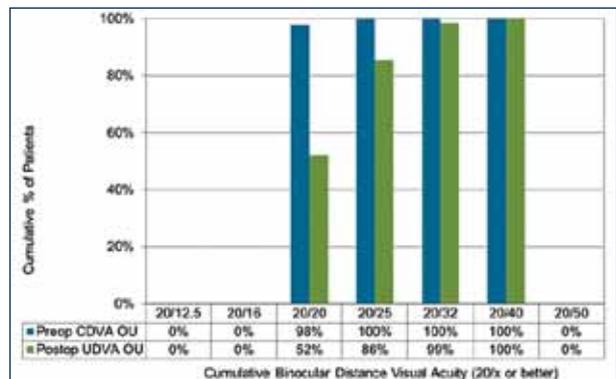


Figure 1. Cumulative binocular distance visual acuity: Comparison of preoperative distance BCVA and 6-month postoperative distance UCVA.

COMPARISON

Comparison of our first 500 versus our last 500 cases depict the effect of software improvements and of our ability to overcome the initial learning curve:

- Postoperative monocular distance UCVA in our last 500 cases was 0.5 lines better than in our first 500, but all had the same variance (1.0 line);
- In our first 500 cases, 39% of eyes achieved 20/25 or better monocular distance UCVA, compared with 47% in our last 500;
- Postoperative binocular distance UCVA in our last 500 treatments was 0.5 lines better than in our first 500, but all had the same variance (0.5 lines);
- In our first 500 cases, 42% of patients achieved 20/20 or better binocular distance UCVA, compared with 51% in our last 500;
- Postoperative monocular near UCVA was 0.25 lines worse in the last 500 cases than it was in the first 500, but both groups had the same variance (1.0 line);
- In our first 500 cases, 40% of eyes achieved a monocular near UCVA of P2 or better, compared with 33% of eyes in the last 500;
- Postoperative binocular near UCVA in the last 500 cases was 0.25 lines worse, with 0.5 lines worse variance than the first 500, and 64% of the first 500 patients achieved a near UCVA of P2, compared with 61% patients in the last 500;
- In the last 500 cases, there was 0.5 lines better safety for distance and 0.5 lines better variance than in the

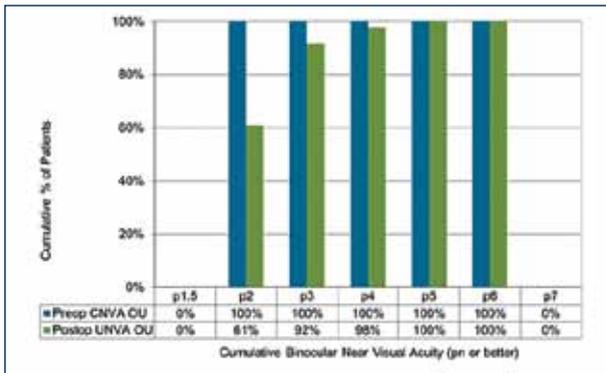


Figure 2. Cumulative binocular near visual acuity: Comparison of preoperative near BCVA and 6-month postoperative near UCVA.

first 500 cases, and 9% of patients in the first 500 cases lost 2 lines loss in distance BCVA, compared with 1% in the last 500.

We have concluded that our learning curve and use of PresbyMAX μ -monovision have helped to improve distance performance. With that said, I emphasize to patients three things: (1) a touch-up procedure for better near visual acuity may be needed in a few years, (2) PresbyMAX does not provide patients with the ability to read very small letters (eg, drug records) or to do near tasks under low light conditions, and (3) well-lit conditions allow the best near performance.

RETREATMENTS AND REVERSALS

Of the PresbyMAX treatments performed at Avicenne Clinic, 86% did not require a retreatment and 99% did not require a reversal. Of the last 500 patients we treated, only 74 required retreatments. Below is an overview of their associated 6-month follow-ups:

- In 32 patients (32 eyes), retreatment in the form of an aspheric myopic ablation was performed in the distance-dominant eye to improve distance vision. After PresbyMAX but before retreatment, the mean distance UCVA was 20/32 and the mean near UCVA was P3. After retreatment, the mean distance UCVA was 20/25 and the mean near UCVA was unchanged;
- In seven patients (seven eyes), retreatment in the form of an aspheric hyperopic ablation in the nondominant eye was performed to improve near vision. After PresbyMAX but before retreatment, the mean distance UCVA in this group was 20/22 and the mean near UCVA was P4. After retreatment, the mean distance UCVA was 20/25 and the mean near UCVA was P3;
- In 15 patients (30 eyes), retreatment in the form of an aspheric myopic ablation in the distance-dominant eye and an aspheric hyperopic ablation in the near nondominant eye was performed to improve distance and near vision. After PresbyMAX but before retreatment, these patients had a mean distance UCVA of

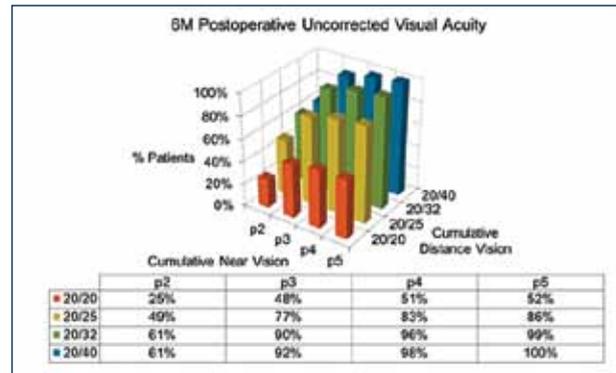


Figure 3. Six-month postoperative cumulative binocular distance and near UCVA.

20/25 and a mean near UCVA of P4. After retreatment, the mean distance UCVA was 20/23 and the mean near UCVA was P3;

- In 15 patients (21 eyes), retreatment in the form of a second PresbyMAX treatment was performed to improve both distance and near vision. After PresbyMAX but before retreatment, the mean distance UCVA in this group was 20/25 and the mean near UCVA was P4. After retreatment, the mean distance UCVA was 20/23 and the mean near UCVA was P3; and

- In five patients (9 eyes), PresbyMAX reversal was performed to improve distance vision. During this procedure, the previously induced multifocality was removed and simple monovision was added. After PresbyMAX but before PresbyMAX reversal, the mean distance UCVA in this group was 20/46 and the mean near UCVA was P2. After PresbyMAX reversal, the mean distance UCVA was 20/22 and the mean near UCVA was P5.

CONCLUSION

PresbyMAX is a promising corneal laser refractive surgery technique for presbyopia correction. In our clinical study, the flexibility of this treatment and the accuracy of the AMARIS' ablations have led to consistent results. In our experience, we have achieved an 86% success rate. Moreover, only 1% of our patients required a PresbyMAX reversal procedure. For the few patients who demanded retreatment or reversal, PresbyMAX or the ORK-CAM module (SCHWIND eye-tech-solutions) and the SCHWIND AMARIS excimer laser provided the best clinical solution. We feel that PresbyMAX reversal is a great back-up solution to remove corneal multifocality. In the rare case that retreatment or reversal is required, the patient can achieve a successful treatment with satisfactory outcome. ■

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PresbyMAX Versus Competing Technologies

This treatment decreases the risk for severe complications and can correct HOAs.

BY SAMUEL ARBA-MOSQUERA, PhD, MSc

I began my career in refractive surgery in 2000 and joined SCHWIND eye-tech-solutions just 4 years later. One recurring question has been how to correct presbyopic symptoms with laser ablation. My quest over the past 14 years has been to come up with an answer, which today I believe is PresbyMAX.

COMBINED CORRECTION

Recently, there has been increased interest in surgical options for presbyopia correction. But finding a treatment that simultaneously corrects presbyopia and refractive error is challenging. Presbyopia correction with excimer laser systems is as old as laser refractive surgery itself, and with so many different laser correction techniques, it can be inferred that the ideal solution has not yet been found.

With SCHWIND PresbyMAX, both eyes actively participate in the visual process to create binocular vision impressions. As a result, patients can achieve controlled multifocal vision, with good visual acuity at all distances. PresbyMAX's treatment profile achieves (1) multifocality, where the center of the cornea is corrected for near and the periphery for far vision, (2) optimized biasphericity, (3) addition of a precalculated amount of higher-order aberrations (HOAs), and (4) addition of defined residual myopia to enhance reading capabilities.

THREE PROFILES

The three currently available PresbyMAX profiles are PresbyMAX Symmetric, PresbyMAX μ -monovision, and PresbyMAX Hybrid (Figure 1). Each strategy is discussed in detail below; in short, PresbyMAX Symmetric provides the best stereopsis, PresbyMAX Hybrid offers the fastest distance vision recovery, and PresbyMAX μ -Monovision meets the balance between these approaches.

PresbyMAX Symmetric. As the most basic of the three, PresbyMAX Symmetric treats both eyes equally, with a target of -0.4 D of myopia with 1.5 D of corneal multifocality (depth of focus), which leads to central myopia of -1.9 D in both eyes and covers 2.5 m to 52 cm.

PresbyMAX μ -monovision. This treatment applies a different ablation to each eye, focusing the dominant eye slightly toward distance vision (targeted to 0.0 D of myopia with 1.5 D of extended depth of focus) and the nondominant slightly toward near vision (targeted to -0.8 D of myo-

pia with 1.5 D of extended depth of focus). This leads to a central myopia of -1.5 D, covering more than 6.0 m to 65 cm, and -2.3 D, covering 1.3 m to 44 cm, in the dominant and nondominant eyes, respectively. With PresbyMAX μ -monovision, both eyes cover half of the depth of focus (0.7 D, from 1.3 m to 65 cm) simultaneously.

PresbyMAX Hybrid. Reduced multifocality in the dominant eye and full multifocality in the nondominant eye is combined with μ -monovision. The distance eye is targeted at -0.1 D of myopia with 0.8 D of multifocality, leading to a central myopia of -0.9 D and covering from more than 6 m to 1.1 m. The near eye is targeted for -0.8 D of myopia with 1.5 D of multifocality, leading to a central myopia of -2.3 D and covering 1.3 m to 44 cm. The near addition of the dominant eye is half of the nondominant eye, with a depth of focus of 1.5 D.

RESULTS WITH PRESBYMAX

More than 8,000 PresbyMAX treatments have been performed to date, and published literature reports on approximately 800 of these with follow-up ranging from 6 months to 1 year.¹⁻³ Mean distance and near UCVA's ranged from 20/18 to 20/27 (average, 20/24) and J1 to J3 (average, J1), respectively, with 77% of patients achieving 20/25 or better distance UCVA and 90% achieving J2 or better near UCVA. Mean distance-corrected near VA ranged from J2 to J5 (average, J3), with 38% of patients improving by 2 or more lines. However, 3% to 13% of patients (average, 5%) experienced a 2 or more loss of lines of distance BCVA. Additionally, 0% to 8% of patients (average, 3%) experienced a 2 or more loss of lines of near BCVA.

Regarding refractive outcomes, 70% to 95% of eyes (average, 85%) were within ± 0.50 D of target refraction for sphere, and 90% to 99% (average, 98%) were within ± 0.50 D for astigmatism. Retreatment rates ranged from 0% to 14% (average, 10%), and PresbyMAX was reversed in 0% to 1% of patients (average, 1%).¹⁻³

COMPETING TREATMENTS

Competing treatments of PresbyMAX include monovision, Q-value adjustments of the nondominant eye, ablations that induce corneal multifocality, Laser Blended Vision (Carl Zeiss Meditec), peripheral presby-LASIK, Intracor (Bausch +

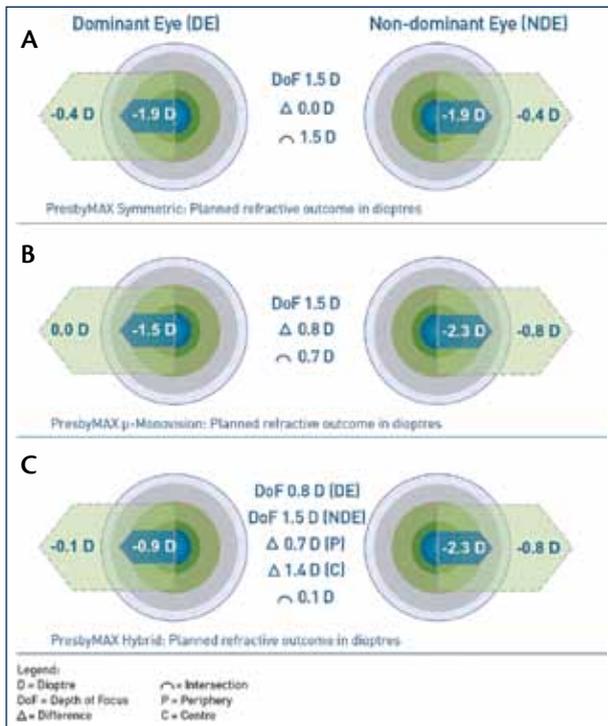


Figure 1. Planned refractive outcomes for PresbyMAX Symmetric (A), μ -monovision (B), and Hybrid treatments (C).

Lomb Technolas), and intrastromal corneal inlays.

Monovision. More than 300 treatments with follow-up times of 6 months to 5 years are reported in the literature.^{4,5} The mean distance UCVA was 20/20, with 87% of patients achieving 20/25 or better, and the mean near UCVA was J1, with 90% seeing J2 or better. However, more patients required retreatment (17%) or reversal (5%) after monovision compared with PresbyMAX.

Laser Blended Vision. With 1-year follow-up available for more than 600 Laser Blended Vision treatments,⁶ the mean distance and near UCVAs were 20/17 and J3, respectively, with 99% achieving 20/25 or better distance UCVA and 91% achieving J3 or better near UCVA. Additionally, no patient experienced a loss of 2 or more lines of distance BCVA, and 87% were within ± 0.50 D of target for sphere and cylinder; however, these outcomes include 19% retreatment rate.

Induced corneal multifocality. Reports on other forms of ablations that induce corneal multifocality are available for more than 150 treatments, and follow-up times range from 6 months to 2 years.^{7,8} The mean distance UCVA was 20/20, with 87% achieving 20/25 or better; the mean near UCVA was J4, with 81% achieving J3 or better; and the mean distance-corrected near VA was J5, with 49% improving by 2 or more lines. Additionally, 12% of patients experienced a loss of lines of distance BCVA of 2 or more, and the same percentage lost 2 or more lines of near BCVA. The percentage of eyes within ± 0.50 D of target refraction for sphere was lower than with PresbyMAX, at 76%, and there was a 21% retreatment rate.

Intrastromal corneal inlays. Of the 100 Kamra corneal inlay (AcuFocus, Inc.) treatments reported in the literature, with follow-up times between 6 months and 2 years,^{9,10} the mean distance and near UCVAs were 20/17 and J3, respectively, with 93% achieving 20/25 or better distance and 73% achieving J2 or better distance and near UCVAs, respectively. For both distance and near BCVAs, 5% of patients had a loss of lines of 2 or more. There was a 1% recentration rate and a 6% removal rate.

THE BEST RESULTS

In the published literature, not only does PresbyMAX have the highest number of treatments but it also has the best results for near UCVA and BCVA, distance-corrected near VA, and the lowest rate of treatment reversals. PresbyMAX can be used to induce any kind of corneal multifocality and can be performed monocularly or binocularly, with both eyes being equally or differently treated. The ablation can be centered or decentered and can be geared toward near or distance vision. After multifocal ablation, refractive outcomes are more variable than those achieved with monofocal corrections. This multifocality results in reduced distance BCVA in a significant portion of eyes, with a mean loss of 0.50 lines. Retreatments rates remain moderate, at approximately 10%.

In comparison to refractive lens exchange with multifocal IOLs, corneal multifocal surgery for presbyopia correction has the advantage of being a less-invasive technique, thus decreasing the risk of severe complications and enabling additional correction of HOAs. This is one of the reasons why corneal multifocal techniques such as PresbyMAX are preferably used for presbyopic patients between the ages of 45 and 60 years, as their crystalline lens is clear and lens exchange due to cataract is not appropriate. Additionally, some accommodative response remains in this population. ■

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- Active 6D, 1050 Hz Turbo Eye Tracking
- Swivelling Laser Arm and Patient Bed

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(*Editor's Note: Myopia treatment, without astigmatism, 12.5-mm vertex distance and a 6-mm optical zone)