Insert to

CRST EUROPE

Cataract & Refractive Surgery Today

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ZEISS Refractive Technologies

Opt for excellence when performing 2nd Generation Laser Vision Correction

Three Generations of Laser Vision Correction

A historical review, status quo, and future prospects.

BY IOANNIS G. PALLIKARIS, MD, PHD

Refractive surgery has come a long way in the past half-plus century. Since the moment that José I. Barraquer, MD, of Spain, proposed that adding or removing tissue could modify the refractive power of the eye,[1] he and other surgeons have taken strides toward modern lamellar refractive surgery.

Building upon his discovery that each layer of the cornea must be preserved in order for lamellar surgery to be successful, Dr. Barraquer developed keratomileusis in situ, a procedure that included creation of a corneal lamellar disc followed by removal of stroma.[2] Development of a manual microkeratome, applanator lenses, and suction rings of various heights helped improve postoperative outcomes with keratomileusis in situ; however, induced corneal irregular astigmatism and corneal scarring persisted as disadvantages of the technique.

Since this first lamellar refractive surgery technique was performed, many milestones have been achieved in this field, and surgeons worldwide have experience three generations in corneal refractive surgery in only 30 years.

THREE GENERATIONS OF LASER VISION CORRECTION

PRK: The 1st generation. It all started with PRK, the 1st generation of laser vision correction. Introduced in the late 1980s by Stephen L. Troekel, MD, of New York,[3] this corneal surface ablation procedure was designed to reshape the cornea with an excimer laser. Despite a lengthier recovery period and some patient discomfort, the procedure is still widely performed today.

LASIK: The 2nd generation. Only a handful of years later, the Pallikaris group combined the principles of keratomileusis in situ and corneal surface ablation to create a procedure we called *laser in situ keratomileusis*, later shortened to LASIK. Considered the 2nd generation of laser vison correction, LASIK requires a corneal flap and, like PRK, involves reshaping of the cornea with an excimer laser. In June 1989, we performed our first LASIK case on a blind human eye at the University of Crete, Greece,[4] and in a seeing eye in 1990.[5] The procedure proved to ensure better tissue alignment after photoablation than previous attempts at laser vision correction and only minimally affected the anatomical relations of the corneal layers.

Over the following years, refinements in excimer laser and wavefront technologies and the discovery of the high-precision femtosecond laser technology for flap creation helped to strengthen LASIK to the level at which it is today. Due to good visual outcomes and short postoperative recovery time, as demonstrated in numerous investigations, femtosecond LASIK (femto-LASIK) continues to be the dominant refractive surgery procedure performed today.

SMILE: The 3rd generation. Introduction of the concept of intrastromal lenticule creation has ushered us into the 3rd generation in laser vision correction. As one of the pioneers of LASIK, I believe that small incision lenticule extraction, or SMILE, a minimally invasive flapless procedure, is an exciting evolution in corneal refractive laser surgery. Only 4 years after its international launch in September 2011, SMILE has been established successfully in all major markets. The procedure is based on removal of a lenticule instead of tissue ablation, distinguishing it from PRK and LASIK. An excimer laser is not required.

CONCLUSION

Today, a quarter-century later, it is a pleasure not only take a look back at the history of LASIK and femto-LASIK but to take a look ahead to future prospects. Although LASIK remains the dominant laser vision correction procedure performed today, SMILE is growing its market share, mainly due to its advantages of being a minimally invasive, flapless procedure.

On the occasion of LASIK's 25th anniversary, this insert to *CRST Europe* is dedicated to femto-LASIK, the 2nd generation of laser vision correction. ■

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MEL 90: The Latest Excimer Laser Technology

The device's compactness, ergonomic design, and functionality make it a must-have for refractive surgeons.

BY FEDERICO ALONSO ALISTE, MD; AND JONATAN AMIÁN CORDERO, MD

Equipped with the best technologies, Technolaser Clinic Vision, in Sevilla, Spain, aims to provide patients with the highest standard of care in ophthalmic surgery. The volume of refractive surgery procedures we perform and the excellent outcomes we have achieved in the past 15 years make us a reference center in Spain and other countries. We have participated in the evaluation of surgical procedures and nomograms. Technolaser has also become a learning center for young ophthalmologists, and we are often visited by colleagues who wish to learn new procedures.

We have worked with ZEISS' laser systems, among others. In 1999, we began using the company's MEL 70 excimer laser and were satisfied with both the outcomes and handling of the laser. For these reasons, we upgraded to the refined MEL 80 in 2002 and to the MEL 90 in 2014.

We have also worked with the VisuMax femtosecond laser (ZEISS) and own the WASCA aberrometer, ATLAS Topographer, and the CRS-Master (all by ZEISS) for treatment planning.

ADVANTAGES OF THE MEL 90 PLATFORM

Ergonomics and functionality. The MEL 90 is a compact unit, which allows perfect integration with the VisuMax femtosecond laser and optimizes our space in the operating room (Figure 1). The ergonomics and functionality of the MEL 90 are the greatest aspects of its design. It is convenient, both for the surgeon and the surgical staff, thanks to its dual tactile visualization screen. Furthermore, patient data is shared automatically with the VisuMax, increasing our workflow and decreasing patients' wait times.

In terms of fixation, the target light has also been improved on the MEL 90, making it easier for the patient to fixate on the light during treatment. ZEISS optics provide a quality image of the surgery, and the HDMI video recording system allows us to obtain high-resolution images, improve the control of the procedure, and evaluate every aspect of the anterior and posterior segment.

FLEXIQUENCE. A new feature on the MEL 90 platform, FLEXIQUENCE, allows one to switch between 500- and 250-Hz frequencies, according to the surgeon's preferences and the refractive technique to be performed. In surface procedures (PRK, LASEK, EPI-LASIK) the preferable frequency is 250 Hz, whereas 500 Hz is typically used in LASIK and femtosecond LASIK (femto-LASIK) procedures. The 500-Hz frequency can produce an ablation speed of 1.3 seconds per 1.00 D intraoperatively when used with the Advanced Ablation Algorithm (Triple-A), which is further described below. From the patient's point of view, these short treatments are perceived as more comfortable and create less anxiety; from the surgeon's, short treatment times translate to a more relaxed atmosphere. The decrease in surgical time also means that the exposure time of the flap and the stromal bed decrease, as well as the time to visual recovery. Patients examined immediately after surgery present with visual acuities that, with other platforms, were typical on the day after surgery; this is especially true in patients who require moderate and high refractive corrections.

Triple-A profile. The MEL 90 features the Triple-A profile—a uniform, aspherical ablation profile designed for a wide range of spherocylindrical corrections. It simplifies the treatment-planning process, as we no longer have to choose between the Advanced Surface Ablation (ASA) and Tissue Saving Ablation (TSA) profiles, as in former times with the MEL 80. The appeal of the Triple-A profile is that it combines the advantages of the ASA and TSA profiles.

Iris recognition with the CRS-Master can be supported by marking the 0º to 180º axis at slit lamp and checking the image with the MEL 90. Immediately afterward, the Triple-A correction can be applied.

OUTCOMES

We have been pleasantly surprised with the outcomes obtained with VisuMax/MEL 90 platform in our clinic, as they are even better than the results we achieved with the MEL 80. Generally speaking, corneas are clear with virtually no edema, even moments after surgery. This translates to faster visual recovery and an earlier return to the patient's daily life.

The excellent results in high hyperopic and astigmatic eyes are of special interest for us, and these patients, too, achieve better visual acuities than those who were operated with the MEL 80 when this technology was available in our clinic. This has been especially noticeable when we have combined the refractive treatment with hyper-accelerated CXL, as patients can obtain higher visual quality and stability due to the potentially decreased risk of regression.

As mentioned previously, the combination of the Triple-A nomogram and the laser's 500-Hz frequency allows quicker and more comfortable procedures, both for the patient and the surgeon. Compared with what we have experienced before, the change is remarkably noticeable in higher myopic and hyperopic corrections.

Figure 1. Because the footprint of the MEL 90 is compact, it can be easily integrated with the VisuMax femtosecond laser without taking up much space in the operating room.

VARIOUS OPTIONS

In all preoperative consultations, we use the CRS-Master to determine the patient's previous aberrations and plan our surgical treatment. Our approach is that we use the Triple-A profile in the presence of normal spherical aberrations and the ASA profile, due to its aspherical characteristics, at a 250-Hz frequency in the presence of higher spherical aberrations. We no longer use the TSA nomogram in virgin corneas, as we perform almost all procedures with the Triple-A profile at a 500-Hz frequency. This has helped us achieve higher accuracy and speed compared with MEL 80 laser procedures.

With regard to retreatments performed at least 1 year after the femto-LASIK treatment, we perform a surface ablation procedure, with measurement of epithelial thickness and the option to use the Triple-A profile with a 250-Hz frequency. If the patient presents with higher-order aberrations, especially coma, we use the ASA profile and CRS-Master in aberrometric or topographic mode. We currently use the TSA nomogram less often in retreatments, and only after evaluating the previous aberrations, as the induction of excess aberrations could decrease the patient's visual quality.

The outcomes with PRESBYOND Laser Blended Vision in presbyopia are equal to or better than MEL 80 results. PRESBYOND Laser Blended Vision has become our technique of choice in patients over the age of 40 who do not yet suffer from cataract.

CONCLUSION

From our point of view, in the highly competitive field of refractive surgery, choosing equipment with the latest technology is always a good bet. In the specific case of ZEISS, there is an additional advantage: The image of the innovative company transcends the professional ophthalmological world, as our patients also value it.

Currently, our technique of choice for myopia is small incision lenticule extraction, or SMILE. Nevertheless, there are situations in which we consider the possibility that femto-LASIK may be a better option, such as nervous patients and those with high astigmatism or possible unstable refractive errors. Another consideration is that we need a good excimer laser when treating hyperopia and presbyopia; an excimer laser is also essential in order to convert any SMILE procedure in which a suction loss occurred during lenticule creation and in order to perform a touch-up postoperatively if needed. ■

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MEL 90: Advantages and Reasons for Use

The laser's speed, safety, and reliability make it the device to choose for almost any refractive surgery task.

BY IGOR SOLOMATIN, MD; AND JANA GERTNERE, MD

With the introduction of the surgical technique LASIK, the scope of laser vision correction was changed. Stunning efficiency, safety, and high predictability have made this procedure the most used in refractive surgery today, as its wide range of vision correction and fast recovery time are popular selling features to patients around the world. Despite the availability of a minimally invasive, flapless procedure, small incision lenticule extraction, or SMILE, the 3rd generation in laser vision correction, LASIK still has not lost its values and potential.

Our clinic is a long-term partner of Carl Zeiss Meditec. We have consistently used the MEL 60, MEL 70, and MEL 80 lasers throughout the years. Each generation is more sophisticated than the one before, making the handling of this laser platform easier and more intuitive for surgeons and staff. For us, it was natural to continue our cooperation with the company in updating new equipment, and when Carl Zeiss Meditec suggested that we participate in its postmarket clinical study of the MEL 90, we were pleased to accept.

All the tests carried out before the clinical trial has shown that the newly integrated 500-Hz frequency was safe. The laser's compactness, compatibility with the VisuMax femtosecond laser (ZEISS), and Advanced Ablation Algorithm (Triple-A) profile, coupled with the possibility of reducing the frequency to 250 Hz for surface ablation and customized treatments, gave us full confidence in the MEL 90.

APPARENT ADVANTAGES

We started using the MEL 90 in early 2013, and the feature we were most curious about was the FLEXIQUENCE function, which allows one to switch between a frequency of 250 and 500 Hz. Below I review the two most apparent advantages of this laser system, which are its high speed and the Triple-A profile.

High speed. The effect of the 500-Hz ablation rate was immediately apparent; an ablation rate two times faster than the MEL 80 and an intraoperative ablation rate of 1.00 D in up to 1.3 seconds reduced surgery time. Although we use the 500-Hz frequency for most of our cases, we continue to rely on 250 Hz for surface ablation procedures. The special CCA+ plume removal system, which was also integrated into the MEL 80, was updated to include automatic sensor-controlled adaptation to the speed of the laser

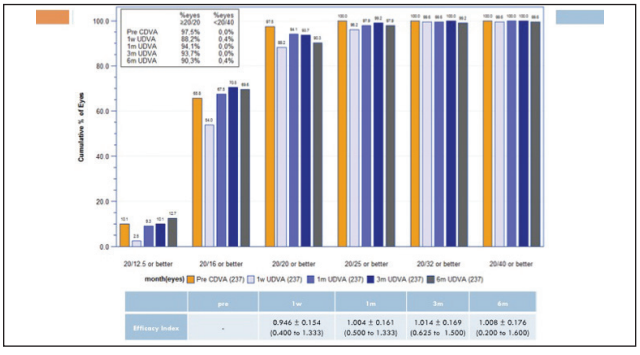

Figure 1. Postoperative distance UCVA versus preoperative distance BCVA.

(250 vs 500 Hz) and support optimal atmospheric conditions around the patient's eye. Another thing we noticed rather quickly is the presence of two screens, which now allows our assistants to prepare patient data for the next case while the current procedure is still ongoing.

Triple-A profile. The second main advantage of MEL 90 is the laser's Triple-A profile. With the MEL 80, the surgeon had to choose between two profiles (Advanced Surface Ablation [ASA] and Tissue Saving Ablation [TSA]) and, for the correction of high myopia or astigmatism and also for virgin eyes, the topography-guided algorithm was also applied in our clinical routine. Alternatively, the MEL 90 has one ablation profile for all treatment ranges only, the Triple-A, an aspherically optimized profile with high tissue-saving properties. It also compensates for induced spherical aberrations. Using the Triple-A profile, postoperative outcomes are as good as we expected them to be.

In the more than 2,000 eyes we've treated with the MEL 90 in the past 2 years, we have had great result in the treatment of low, moderate, and high myopia and in the treatment of myopic, hyperopic, and mixed astigmatism. We have been able to achieve stable emmetropic refractions in up to 3.00 D of hyperopia.

CLINICAL EVALUATION

Study design. The multicenter postmarket clinical trial was a prospective, nonrandomized investigation of 237 eyes of 121 patients with myopia (-0.50 to -10.00 D) or myopic astigmatism (-0.25 to -4.00 D). All patients had

a distance BCVA of 20/25 or better, and all procedures were performed bilaterally using the MEL 90 eximer laser with the Triple-A profile and the VisuMax for flap creation; follow-up was set for 3 and 6 months postoperative.

Results. The mean spherical equivalent was within ±0.50 D in 97% of eyes at 1 month and 97.5% at 6 months. With regard to distance BCVA, 98.3%, 97%, and 97.5% of eyes had achieved at least 20/20 at 1, 3, and 6 months, respectively. At these same time points, 94.1%, 93.7%, and 90.3% of eyes, respectively, had achieved a distance UCVA of at least 20/20 (Figure 1). There was no reported haze, complications, or adverse events.

In terms of safety, 86.9%, 85.7%, and 89% of eyes either gained lines of vision or the lines of vision remained the same at 1, 3, and 6 months, respectively. Only one eye (0.4%) lost 2 lines, and this was because of dry eye keratopathy. By dividing patients into three groups according to their grade of myopia (ie, low, moderate, and high), we found that the Triple-A profile provided excellent outcomes in high and moderate myopes, with stable outcomes at 6-month follow-up.

According to a patient questionnaire, no more than 4% of patients across all groups complained of night vision disturbances, and just two listed moderate problems with night driving. The average patient satisfaction response was 9.2 on a scale of 10, and all patients answered that they would recommend the procedure to others.

CONCLUSION

In our experience, the MEL 90 is the perfect tool for the correction of the widest range of ammetropia. The laser's optimal speed, safety, predictability, and reliability make it the ideal device for any refractive surgery procedure. In addition to the excellent LASIK results we have seen with the MEL 90, surface ablation procedures with this device are also safe, with results that are comparable with LASIK.

The MEL 90 perfectly compliments the VisuMax femtosecond laser and infinitely expands our capabilities as a refractive surgery center. Because certain groups of patients, including those with mixed astigmatism, hyperopia, irregular astigmatism, or very low myopia, cannot currently be treated with SMILE, we can use the MEL 90 to still achieve excellent refractive correction and visual results. Additionally, some patients prefer to undergo LASIK, and the possibility to use both lasers makes us confident that we maximize our treatment safety and get the best results for all patients. ■

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Clinical Data Supporting PRESBYOND Laser Blended Vision

The procedure can be an effective treatment for presbyopia in hyperopes, myopes, and even emmetropes.

BY DAVID DONATE, MD

For several years, surgeons have been able to create a binocular treatment approach for presbyopic patients using an excimer laser ablation technique called PRESBYOND Laser Blended Vision. Developed by Dan Z. Reinstein, MD, MA(Cantab), FRCSC, DABO, FRCOphth, FEBO, and Carl Zeiss Meditec, this treatment helps patients with presbyopia achieve good binocular vision at far, intermediate, and near and allows them to maintain good optical quality, contrast sensitivity, night vision, and functional stereoacuity.

We started using the PRESBYOND Laser Blended Vision software module for the treatment planning station CRS-Master (ZEISS) with the MEL 80 and now perform it with the MEL 90 (both by ZEISS), which we acquired in 2013. In PRESBYOND, LASIK is used to modulate spherical aberration on the cornea and increase the depth of focus of the entire visual system by approximately 1.50 D. When the increased depth of field is combined with a micro-monovision strategy, as in PRESBYOND Laser Blended Vision, patients are able to achieve good near vision with a lower degree of anisometropia than traditional monovision. Additionally, this strategy

creates a blend zone of vision between eyes at intermediate distances, and distance vision in the near (nondominant) eye is better than what can be achieved using other techniques. The procedure is performed with a nominal target refraction of -1.50 D in the nondominant eye (Figure 1).

WHY PRESBYOND?

I have been performing Laser Blended Vision for 6 years as a way to both attract more presbyopic patients to my practice and to increase our surgical volume. What convinced me to add this technique to my armamentarium was the published clinical results,[1] various papers presented at congresses, and personal contact with colleagues who perform PRESBYOND.

As a refractive surgeon, PRESBYOND Laser Blended Vision has been a good way to attract a new group of patients to my practice: presbyopes between the age of 40 and 60. After I introduced the technique to my practice, my surgical volume increased by approximately 30%. PRESBYOND is a good option for patients who are candidates for LASIK because it meets all of the goals of good binocular vision at all distances and minimizes many of the compromises seen with other presbyopia-correcting solutions. Furthermore, I like that the treatment is reversible by either spectacle wear or by performing a standard retreatment ablation.

MARKETING THE PROCEDURE

As many of our patients have been waiting for a presbyopia-correcting treatment like PRESBYOND Laser Blended Vision for a long time, marketing has essentially taken care of itself. In addition to showing promotional videos in our waiting room, my practice promotes the PRESBYOND procedure by sharing informational graphics and statistics to patients during their initial consultations. In the beginning, these statistics were those of my colleagues who were performing the procedure for longer than I; now that I have enough results of my own, these are what we share with patients. If patients are interested in learning more, we schedule a follow-up meeting with one of the surgeons.

After implementing the procedure into my practice, my impressions were quickly confirmed: PRESBYOND Laser Blended Vision has many advantages over a standard monovision strategy, including better intermediate vision, better distance vision in the near eye, better binocular contrast sensitivity, and better stereoacuity for my patients. Our patients' high satisfaction rates are testament to the results of the procedure and, because patients who have undergone PRESBYOND Laser Blended Vision are happy with their results, the only marketing we rely on is word of mouth.

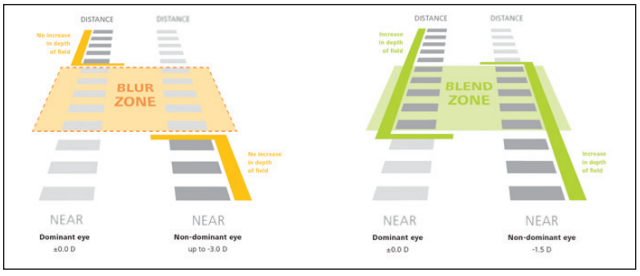

Figure 1. Treatment principles of conventional monovision (left) versus PRESBYOND Laser Blended Vision (right).

SELECTION CRITERIA

When considering PRESBYOND Laser Blended Vision treatment, I use the same exclusion criteria as I do for LASIK, and I also take into account the limits of the software: intolerance of micro-monovision, more than -8.00 D of myopia, more than 2.00 D of hyperopia, more than -4.50 D of astigmatism, age above 62 years, presence of cataract, and exaggerated visual expectations and requirements. Corneal thickness, remaining total corneal thickness, and remaining residual stromal corneal bed (250 µm) are additional exclusion criteria for micro-monovision. I prefer to perform ocular dominance testing with a cross-blur tolerance test.

Assuming no exclusion criteria, the PRESBYOND laser treatment is planned using the CRS-Master in preparation for the MEL 90 treatment. The device's software combines patient factors such as age, accommodative amplitude, preoperative wavefront, tolerance to anisometropia, and amount of refractive error and generates an ablation profile that is designed to leave the patient with the appropriate amount of spherical aberration to maximize his or her depth of field without compromising contrast sensitivity, stereoacuity, or night vision.

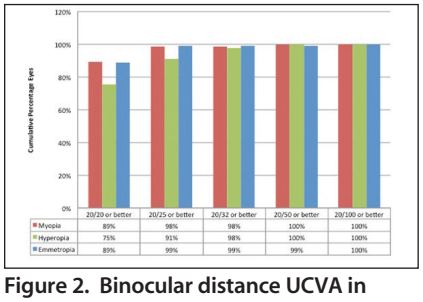

Figure 2. Binocular distance UCVA in myopic, hyperopic, and emmetropic eyes at 1 month.

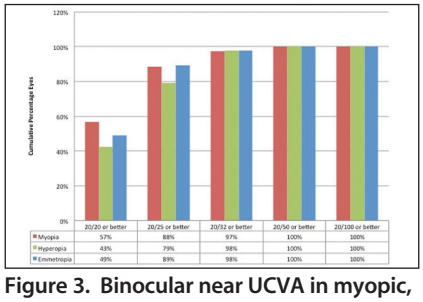

Figure 3. Binocular near UCVA in myopic, hyperopic, and emmetropic eyes at 1 month.

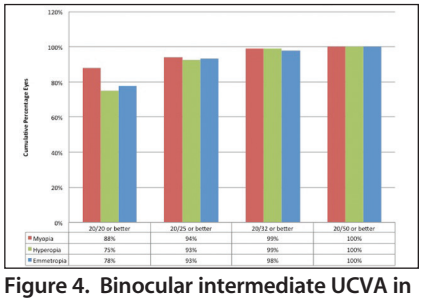

Figure 4. Binocular intermediate UCVA in myopic, hyperopic, and emmetropic eyes at 1 month.

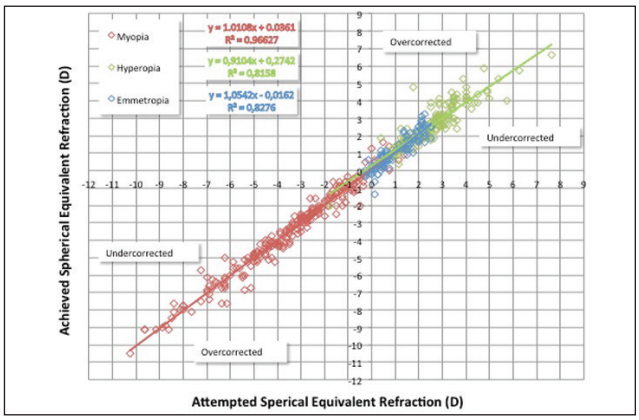

Figure 5. Scatter plot of attempted versus achieved spherical equivalent refraction for myopic (red; n=234), hyperopic (green; n=175), and emmetropic (blue, n=94) eyes.

PATIENT OUTCOMES

I recently performed an outcomes analysis on my PRESBYOND Laser Blended Vision results in myopic (n=133), hyperopic (n=106), and emmetropic (n=53) patients. The preoperative spherical equivalent refraction was -4.09 ±2.29 D, 1.78 ±1.00 D, and 0.33 ±0.34 D in these groups, respectively, and the preoperative cylinder was -0.75 ±0.70 D, -0.42 ±0.57 D, and -0.39 ±0.34 D, respectively.

Binocular distance, near, and intermediate UCVAs at 1-month postoperative are depicted in Figures 2 through 4. In short, binocular distance UCVA was 20/25 or better in 98% of myopic, 91% of hyperopic, and 99% of emmetropic eyes (Figure 2); binocular near UCVA was 20/25 or better in 88% of myopic, 79% of hyperopic, and 89% of emmetropic eyes (Figure 3); and intermediate UCVA was 20/25 or better in 94% of myopic, 93% of hyperopic, and 93% of emmetropic eyes (Figure 4). The attempted spherical equivalent refraction is depicted in Figure 5.

CONCLUSION

PRESBYOND Laser Blended Vision is an excellent addition to my refractive surgery center. It has helped me increase the number of procedures I perform and is now an integral part of my presbyopia-correction practice. With good results in myopic, hyperopic, and even emmetropic patients, PRESBYOND Laser Blended Vision minimizes compromises in contrast sensitivity, stereoacuity, night vision, and intermediate and distance vision that are typical of other procedures. ■

David Donate, MD, is in private practice at Ophthalmology Clinic Lyon, France. Dr. Donate states that he is a paid consultant to Carl Zeiss Meditec. He may be reached at contact@donate-ophthalmo.com.

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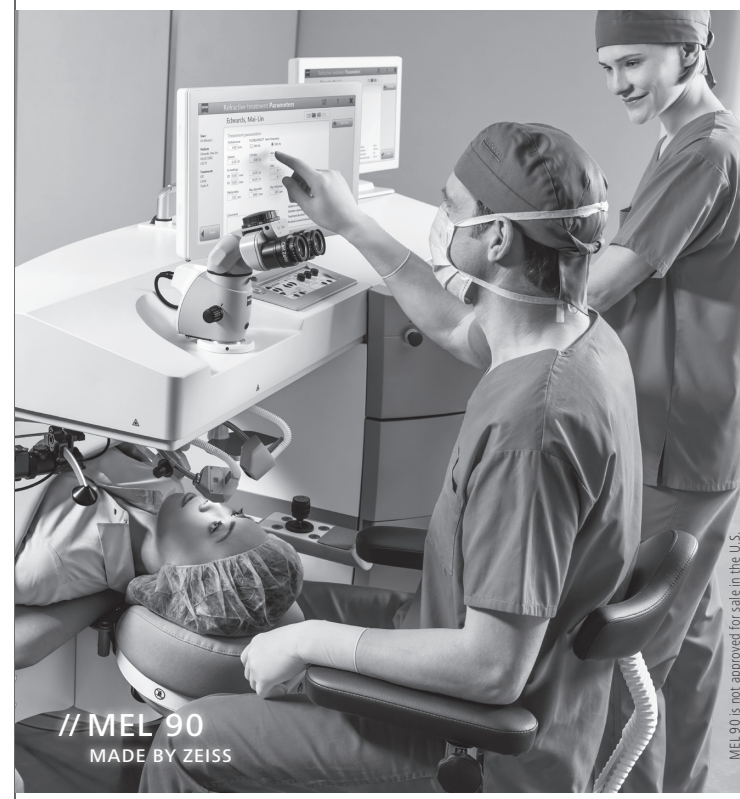

The excimer laser that intelligently combines experience and advancement – that is the MEL® 90 from ZEISS. Refractive surgeons will be fascinated by its practical flexibility. With the FLEXIQUENCE switch function, they can easily choose between 250 Hz or 500 Hz operation as their personal or individual practice situation requires. The innovative Triple-A profile and intra-operative ablation speed of 1.3 seconds per diopter enable fast, safe and tissue-saving treatments. These along with many other performance features make the MEL 90 a customized, success-oriented power package.

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