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Offering a treatment for patients with presbyopia

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Mechanism and outcomes of PRESBYOND

Glenn Carp, MD

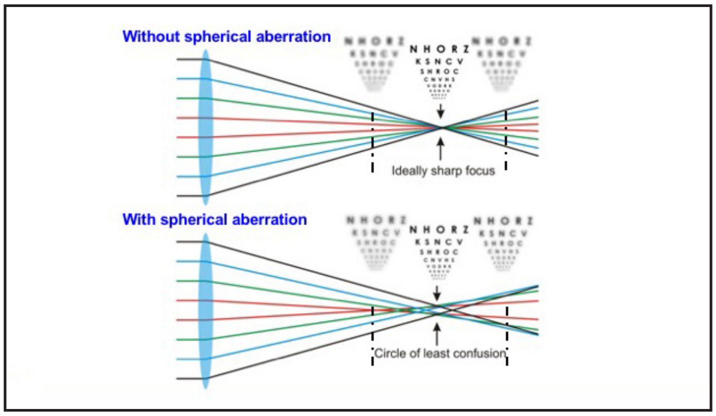

Figure 1. Influence of spherical aberration on depth of field

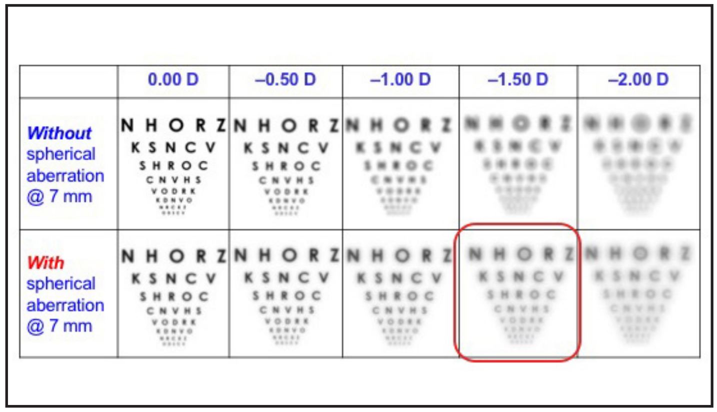

Figure 2. Spherical aberration and – 1.5 D of defocus

Monovision has—arguably until multifocality came into the picture—been the best option for presbyopia, said **Glenn Carp, MD**, London, U.K. However, there are a number of challenges to the procedure—problems with tolerance, loss of intermediate and distance vision, summation, and stereoacuity.

"Modest monovision," which limits the reading add to –1.50 D, is the best improvement on the procedure, addressing most of these problems. Unfortunately, the procedure does not provide enough acuity for reading very small print. Literature suggests this is because a defocus value of –1.3 D delivers the best balance of summation and near acuity—beyond this limit, you stop getting summation between the two eyes and start getting subtraction; at –3.5 D or greater defocus, you get suppression of the reading eye. This means that patients do better with stereoacuity and anisometropia with lower reading adds.

So while it addresses most of the challenges to monovision, the biggest challenge to modest monovision is the compromise in terms of near visual acuity.

This is where PRESBYOND steps in to improve on all of these factors.

Spherical aberration and depth of field

PRESBYOND increases depth of field by controlling spherical aberration along the optical pathway. Spherical aberration is a naturally occurring aberration that increases during accommodation and with age, and therefore something that the human brain is already programmed to process and filter out.

Without spherical aberration, light entering the optical pathway comes into focus at a single point, with everything in front of and behind that point out of focus; with spherical aberration, the point of focus expands to a circle of least confusion, resulting in improvement in the quality of the image of objects in front of and behind the original point of focus—that is, an increased depth of field (Figure 1).

Spherical aberration improves the image quality of a defocus of –1.5 D by increasing edge detection (Figure 2); pupillary constriction—which still occurs in presbyopic patients when looking at near objects—also increases the depth of field, and combining the two results in a clearer image that is further cleaned up by neural processing (Figure 3).

Moreover, increased spherical aberration increases depth of field whether it is positive or negative, so long as it is below the "toxic" limit of 1.5 D. More than that, you start to lose quality of vision, and contrast and night vision drop off.

To be clear, PRESBYOND is *not* a multifocal ablation—it simply controls spherical aberration so there is neither too little, when it would be of no benefit, nor too much, when it would become toxic.

Applying spherical aberration

How can this knowledge be applied scientifically to achieve optimum results? Most people start with a little bit of positive spherical aberration naturally. Myopic ablations induce positive spherical aberration, adding to the existing level. Eyes with low to moderate myopia will likely stay below the 1.5 D threshold after treatment, but surgeons should be wary of treating high levels of myopia.

On the other hand, hyperopic ablations induce negative spherical aberration. Reaching the threshold even with high hyperopia is therefore unlikely. However, in low hyperopia, the hyperopic ablation might simply eliminate existing

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In April 2017, Carl Zeiss Meditec AG (Jena, Germany) conducted a user meeting in Singapore. More than just a showcase for their latest technologies, the company's user meeting has grown into a venue for peer-to-peer sharing of information among the world's top ophthalmic surgeons.

The third symposium of the meeting focused on the uses of the femtosecond and excimer lasers in the management of a persistent challenge to ophthalmologists, one that has only grown as life expectancies increase and the world's population ages: presbyopia.

To establish some baseline information on the prevailing approach to presbyopia among attendees, moderator Sri Ganesh, MD, conducted an audience response survey at the beginning of the session. Based on the survey, the majority of attendees' practices (41%) were less than 5% treatments of presbyopic patients, with 31% of the practices not offering laser vision correction (LVC) for presbyopia. Most attendees (48%) said the largest barrier to increasing treatments of presbyopic patients in their practices was that patient expectations are too difficult to manage, and a similar number (49%) said they did not have enough data to compare monovision LVC with PRESBYOND in terms of visual acuity and patient satisfaction.

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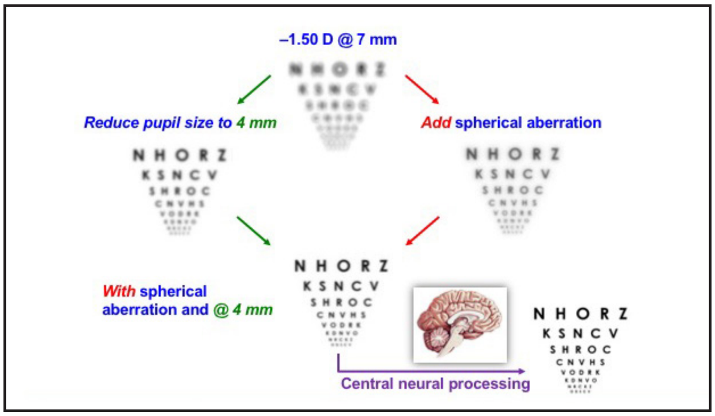

Figure 3. Spherical aberration, pupillary constriction, central neural processing

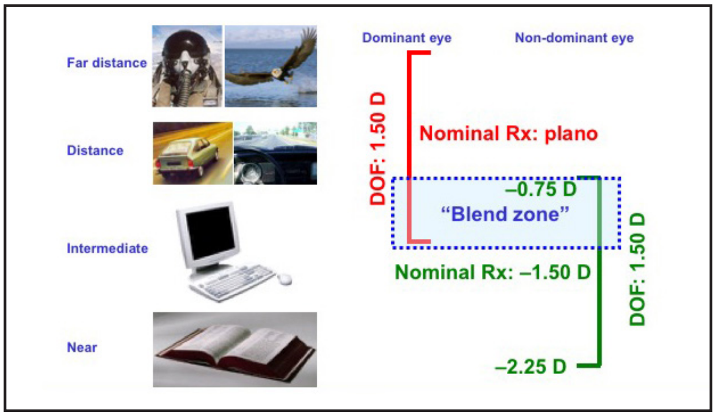

Figure 4. Laser blended vision – micro-monovision

Source (all): Glenn Carp, MD

aberration, though the near eye being treated with a target of –1.5 D will increase the treatment and therefore also the degree of spherical aberration induction.

In emmetropia, the surgeon cannot rely on the induction of spherical aberration by the ablation, particularly in the distance eye. A spherical aberration component can be included in the treatment to increase the existing spherical aberration. Again, the near eye being treated to –1.5 D will induce negative spherical aberration.

Note that increasing the spherical aberration in emmetropic eyes is difficult to achieve without compromising refractive accuracy, but emmetropic patients are the least tolerant of a bad refractive result, so the best option is to increase the depth of field as much as you can to make sure the micro-monovision component is as accurate as possible.

In order to give the patient good reading vision, the non-dominant eye is shifted toward myopia at –1.5 D, resulting in one eye being clearly focused for distance vision but only slightly blurred at near, the other clearly focused for near vision but only slightly blurred at distance. The increased depth of field in each eye creates a region where the range of clear vision overlaps—the *blend zone.* The result is that good binocular near and distance vision can be achieved with a lower degree of anisometropia than traditional monovision, called micro-monovision. Much less suppression is required, and there is no dissociation between the eyes (Figure 4).

Outcomes

Dr. Carp and his colleagues have published outcomes in myopic, hyperopic, and emmetropic populations.[1,2,3] They have published outcomes for myopic patients up to –8.5 D, hyperopic patients up to +5.75 D, and emmetropic patients, demonstrating that the solution works with simultaneous correction of almost any refractive error.

The outcomes speak for themselves: 95% of myopic patients, 77% of hyperopic patients, and 95% of emmetropic patients were at 20/20 and J2 after treatment; in terms of safety, no eyes lost two lines or more of corrected distance visual acuity—equivalent to standard LASIK; meanwhile, 99% of myopic patients and 96% of hyperopes could read computer font size 12, indicating good intermediate vision.

There was also no loss of contrast sensitivity, confirming that the quality of vision was not affected by the increased aberrations, and 97% of patients tolerated the anisometropia. There was a loss in uncorrected stereoacuity, but functional stereoacuity was maintained in all patients at 400 arc sec or better—patients can still see 3D movies after PRESBYOND.

Finally, PRESBYOND is performed as bilateral simultaneous 10-minute procedure with fast recovery.

References

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My personal success with PRESBYOND

Sri Ganesh, MD

Sri Ganesh, MD, Bangalore, India, began having difficulty reading in dim light by the age of 45 years; his intermediate vision was affected by the age of 47, and he became completely dependent on glasses.

After trying contact lenses, a number of factors led him to choose to undergo refractive surgery. He had become handicapped for near and intermediate vision without glasses; while it was more for functional than cosmetic reasons, refractive patients kept asking about his glasses; it was difficult to do refractive surgery during which he needed to see both the monitor and look through the operative microscope; dependence on glasses hampered his sporting activities; and he could not wear his collection of cool shades.

As a refractive surgeon, he found himself worrying about whether it would reduce his quality of vision, affect his stereopsis, and ultimately interfere with his surgical work. What if the result is not optimal, can the procedure be enhanced? With these concerns, what procedure should he have done?

Decisions

He was faced with three options: corneal inlays, LASIK, and refractive lens exchange with multifocal IOLs. At the time, he felt unconvinced by contemporary data on the use of corneal inlays, worrying in particular about some reports of hyperopic shift. He also felt he was too young for intraocular surgery, treatment indicated for cataract.

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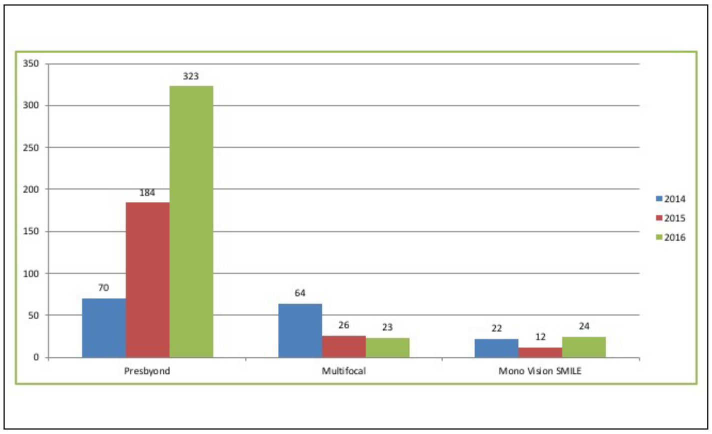

Figure 1. Comparative practice patterns

Source: Sri Ganesh, MD

In the end, he decided to opt for PRESBYOND, the procedure with the proven high patient satisfaction, providing good functional vision with the safety and track record of femtosecond LASIK. Follow-up data, the satisfaction of members of his staff who had undergone the procedure, enhanceability and reversibility, and the absence of permanent visual defects such as glare and halo all encouraged him to opt for PRESBYOND.

In addition, PRESBYOND closely simulates the natural condition existing in patients to retain good contrast sensitivity and stereopsis, and surgeons can adapt to the micro-monovision during surgery by adjusting the microscope ocular to the non-dominant eye—a particular concern for Dr. Ganesh who holds a high volume practice and performs anywhere from 30 to 40 surgeries a day. Finally, because the correction is on the corneal plain, he thinks blended vision can be maintained even after cataract surgery later in life and will not interfere with the surgery itself.

The case himself

Preoperatively, Dr. Ganesh's eyes both had +1.0 D of sphere and +0.5 D of cylinder, though the right eye was at 170 degrees and the left at 180 degrees.

Postoperatively, Dr. Ganesh's right eye had +0.25 D sphere and could see 6/3 N10 while his left eye had –1.75 D sphere and could see 6/4.5 N5, with binocular uncorrected visual acuity of 6/3 N5+.

In terms of intermediate vision, using his left eye his visual acuity was N5 at 60 cm and N8 at 80 cm, binocularly N5 at 60 cm and N6 at 80 cm, with stereopsis of 60 arc sec, corrected to 20 arc sec, and range of vision of N8 at the near point of 20 cm and N8 at the far point of 80 cm.

He experienced mild dry eye, especially after going through long surgical lists; halos at night in the left eye, correctable by wearing glasses, but which "magically disappeared" after 3 months; and the need for glasses for high speed highway driving. Dr. Ganesh was very satisfied overall with his vision and would strongly recommend the procedure to his colleagues.

Additional benefits

As an indirect benefit, the number of PRESBYOND surgeries in Dr. Ganesh's practice went up after he underwent the procedure because it became very easy to convince patients of the benefits, particularly of the possibility of independence from glasses.

In Dr. Ganesh's practice, PRESBYOND has grown over the years from 2014 to 2016 while other options for presbyopia have somewhat stagnated (Figure 1).

"Wow" factor

In the end, while Dr. Ganesh has been happy with patients themselves being happy with the procedure, and the real "proof of the pudding" being in the eating, he offers himself as his own best example of the benefits of the procedure—just 14 hours after receiving PRESBYOND, he went on to perform live surgery on complicated cases, free of glasses.

Clinical study of presbyopia treatment with the Zeiss excimer laser

Quan Liu, MD, PhD

Eyes	UDVA (Decimal acuity)		UNVA (Decimal acuity)	
	Preop	Post 12 m	Preop	Post 12 m
Dominant eye	0.08±0.06	1.24±0.20	0.35±0.30	0.56±0.27
Non-dominant eye	0.08±0.07	0.59±0.30	0.32±0.28	0.79±0.18
Binocular vision	0.15±0.16	1.33±0.20	0.37±0.22	0.81±0.18

Figure 1. Visual acuity results

By 2020, **Quan Liu, MD**, **PhD**, Guangzhou, China, estimates that 2.1 billion people globally will be presbyopic. The demand for spectacle independence in this group is growing.

The correction of presbyopia, he said, is the final frontier for refractive surgery.

There are different approaches to presbyopia correction, with options for corneal, lens, and scleral corrections currently available. PRESBYOND is one option that corrects presbyopia on the corneal plane.

PRESBYOND process

Before proceeding with PRESBYOND, the patient's tolerance for micro-monovision must be assessed using lenses, beginning with full correction to the dominant eye and a +1.5 D add to the non-dominant eye. If the patient is unable to tolerate this difference, the add can be decreased by +0.25 D until the patient's tolerance is established. Dr. Liu defined low tolerance as an add of –0.75 D.

Should the patient be tolerant of micro-monovision, the process of PRESBYOND can begin with

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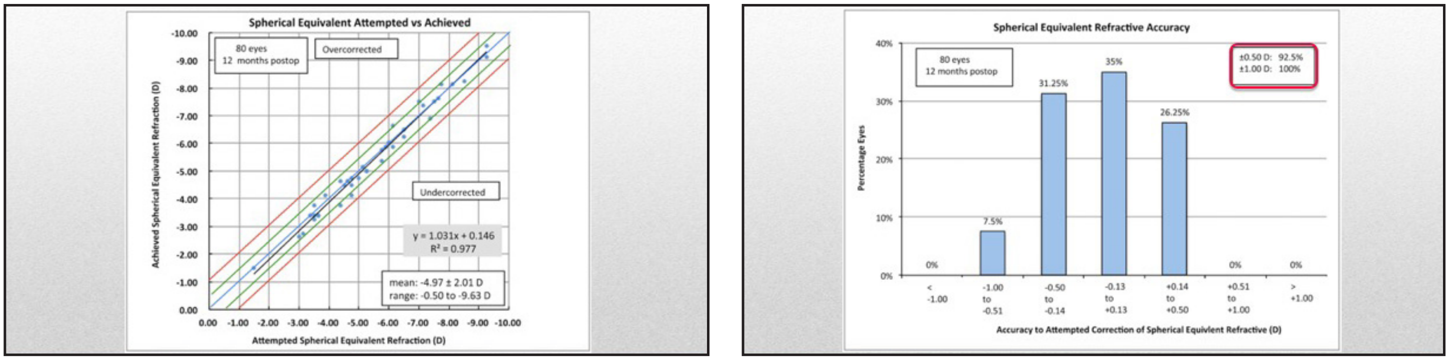

Figure 2. Accuracy in terms of spherical equivalent

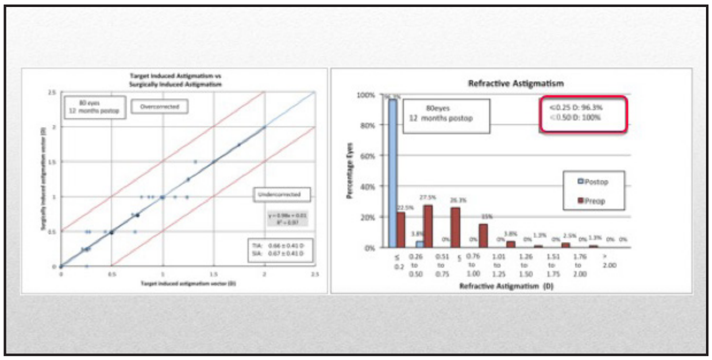

Figure 3. Accuracy in terms of astigmatism

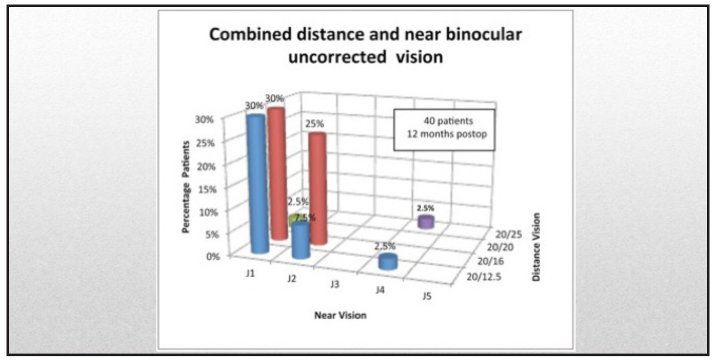

Figure 4. Uncorrected binocular visual acuity

Source (all): Quan Liu, MD, PhD

wavefront assessment using an aberrometer. The CRS-Master software platform (Carl Zeiss Meditec) is then used to calculate the laser profiles; the VisuMax femtosecond laser and MEL90 or MEL80 excimer laser (Carl Zeiss Meditec) are used for the procedure.

The study

Dr. Liu and his colleagues conducted a study of 80 eyes of patients with a mean age of 44.3 years (range 38–63 years), followed up to 2 years.

The patients' dominant eyes, targeted for emmetropia, had a preop mean spherical equivalent refraction of –5.57 ± 1.97 D (range –1.50 to +9.25 D). At 12 months postop, mean spherical equivalent refraction was –0.09 ± 0.26 (range –0.63 to +0.50).

The patients' non-dominant eyes, targeted for a mean of –1.41 ± 0.28 D (range –0.75 to –1.75 D), had preop mean spherical equivalent of –5.79 ± 2.38 (range –1.25 to –11.1). At 12 months postop, mean spherical equivalent refraction was –1.40 ± 0.30 (range –0.50 to –2.00).

The postop difference between dominant and non-dominant eyes was an average of 1.31 ± 0.30 D (range 0.75 to 2.00 D).

In terms of visual acuity, the patients achieved binocularly a mean uncorrected distance visual acuity (UDVA) at 12 months of 1.33 ± 0.20 and a mean uncorrected near visual acuity (UNVA) of 0.81 ± 0.18 (Figure 1).

Assessing accuracy, in terms of spherical equivalent, 92.5% of patients were within 0.50 D, 100% within 1.00 D of target (Figure 2); in terms of astigmatism, 96.3% of eyes had less than 0.25 D, 100% less than 0.50 D of astigmatism after surgery (Figure 3).

Assessing efficacy, in terms of uncorrected distance visual acuity (UDVA), 98% of distance eyes achieved a UDVA of 20/20 or better, 88% of near eyes achieved 20/20 or better, and 98% of patients achieved 20/20 or better binocularly; in terms of uncorrected near visual acuity (UNVA), 93% of near eyes achieved UNVA of J2 or better, 80% of distance eyes achieved J5 or better, and 95% of patients achieved J2 or better binocularly. Uncorrected binocular visual acuity was at least 0.0 logMAR (20/20) at distance and J2 at near in 95% of patients (Figure 4).

Assessing safety, only six eyes lost one line of corrected distance visual acuity (CDVA) and no eyes lost two or more lines. Refractive results were stable, with no eyes having spherical equivalent refraction change more than 0.75 D between 1 day and 12 months after surgery.

Postop contrast sensitivity in photopic and mesopic conditions was not significantly different from preop values at any frequency.

Significantly, since PRESBYOND works by dialing the amount of spherical aberration to enhance depth of field, spherical aberrations increased from 0.18 ± 0.10 μm preop to 0.43 ± 0.12 μm postop.

As expected, distance stereoacuity decreased after surgery, but somewhat surprisingly, near stereoacuity improved, though this change was not statistically significant.

Overall, Dr. Liu said that most patients were satisfied with the outcomes of the procedure, and at 2 years of follow-up the results are almost the same as at 1 year.

Summing up

Based on these results, Dr. Liu found that PRESBYOND achieves good visual acuity in the full range of vision with a small amount of anisometropia compared with traditional monovision. Significantly, increased spherical aberration has not influenced contrast sensitivity in the study patients, and the resulting "fusion field" from the combination of micro-monovision and spherical aberration provides good intermediate vision that is more comfortable for patients, in turn resulting in high satisfaction.

In addition, from Dr. Liu's experience, managing expectations is essential, and surgeons must communicate with patients, informing them in particular of the period of adaptation, which could last 1 to 3 months. Dr. Liu also adjusted the nomogram for their patients.

Based on the results of Dr. Liu's study, PRESBYOND is a feasible approach to correcting presbyopia in the Chinese elderly group, with the benefit of a short period of adaptation and high satisfaction.