Supplement to

Cataract & Refractive Surgery TODAY

February 2010

Forthcoming Applications for the Excimer Laser

Topography-guided and presbyopic laser vision correction.

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Jointly sponsored by the Dulaney Foundation and *Cataract & Refractive Surgery Today*.

Release date: February 2010. Expiration date: February 2011.

This continuing medical education activity is supported by an unrestricted educational grant from Alcon Laboratories, Inc.

STATEMENT OF NEED

The rapid growth in strategies for surgical vision correction imparts a significant burden on clinicians to identify and learn about new procedures they must consider offering to their patients. Importantly, increasing patient expectations and demand for optimal vision due to population demographic changes in the next decade place mounting pressure on surgeons to deliver superior clinical outcomes to more patients.[1]

Busy clinicians may not be fully aware of comparative data and expert opinion regarding available techniques for correcting vision among presbyopic patients as well as evolving technology regarding topography-guided strategies. Reliance upon outdated or uncertain procedures may not provide patients with the best possible option for superior visual function. Continued attention and research in the area of laser vision correction for presbyopia is especially important for practicing ophthalmologists to understand in the context of quality of vision following premium refractive surgery.[2,3]

This educational activity is designed to address considerations of presbyopic laser vision correction and topography-guided techniques in refractive surgery. Healthcare authorities are increasingly calling for ophthalmologists and other physicians to follow evidence-based recommendations to maximize efficiency, increase effectiveness of care, and ensure optimal patient outcomes.[4] This becomes especially critical in light of increasing societal needs for presbyopic refractive surgery.[5,6]

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6. Baby boomers will increase demand for eye care. OSN SuperSite. November 11, 2008. Available at: http://www.osnsupersite.com/view.aspx?rid=32642.

TARGET AUDIENCE

This certified CME activity is designed for general ophthalmologists and anterior segment surgeons specializing in cornea, refractive, and cataract surgery.

LEARNING OBJECTIVES

Upon successfully completing this learning program, participants should be able to:

- understand the status of presbyopic laser vision correction in the United States, current Food and Drug Administration (FDA) clinical trials, and future applications of the technology
- recognize the status of topography-guided laser vision correction in the United States
- know the current experience with topography-guided laser vision correction outside the United States
- analyze how to switch from an all-IOL practice to incorporating presbyopic laser vision correction as an offering
- effectively use laser vision correction in patients following premium IOL implantation

METHOD OF INSTRUCTION

Participants should read the continuing medical education (CME) activity in its entirety. After reviewing the material, please complete the self-assessment test, which consists of a series of multiple-choice questions. To answer these questions online and receive real-time results, please visit http://www.dulaneyfoundation.org and click "Online Courses."

Upon completing the activity and achieving a passing score of over 70% on the self-assessment test, you may print out a CME credit letter awarding 1 *AMA PRA* Category 1 Credit.™ The estimated time to complete this activity is 1 hour.

ACCREDITATION AND DESIGNATION

This activity has been planned and implemented in accordance with the Essential Areas and policies of the Accreditation Council for Continuing Medical Education (ACCME) through the joint sponsorship of the Dulaney Foundation and *Cataract & Refractive Surgery Today*. The Dulaney Foundation is accredited by the ACCME to provide continuing education for physicians. The Dulaney Foundation designates this educational activity for a maximum of 1 *AMA PRA Category 1 Credit*.™ Physicians should claim credit only commensurate with the extent of their participation in the activity.

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In accordance with the disclosure policies of the Dulaney Foundation and to conform with ACCME and US FDA guidelines, anyone in a position to affect the content of a CME activity is required to disclose to the activity participants: (1) the existence of any financial interest or other relationships with the manufacturers of any commercial prod-

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CONTENT VALIDATION

In compliance with ACCME standards for commercial support and the Dulaney Foundation's policy and procedure for resolving conflicts of interest, this CME activity was peer reviewed for clinical content validity to ensure the activity's materials are fair, balanced, and free of bias. The activity materials represent a standard of practice within the medical profession. Any studies cited in the materials upon which recommendations are based are scientifically objective and conform to research principles generally accepted by the scientific community.

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All those involved in the planning, editing, and peer review of this educational activity have indicated that they have no financial relationships to disclose.

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Topography-Guided Laser Vision Correction

A preview of an ongoing US clinical trial for topography-guided customized ablations.

BY R. DOYLE STULTING, MD, PHD

Topography-guided customized ablation treatments (T-CAT) are a new treatment modality currently available internationally and under investigation in the United States.[1] A phase 3 FDA clinical trial has recently commenced to evaluate the new technology on the Allegretto Wave Eye-Q excimer laser (Alcon Laboratories, Inc.; Fort Worth, TX). What follows is general information about the procedure and preliminary details about the study.

WHAT IT IS

Conventional and wavefront-optimized excimer laser treatments place a spherocylindrical correction on the cornea. Wavefront-guided treatments measure aberrations in the optical system of the eye and change the corneal curvature to correct them. T-CAT differs from traditional procedures available in the US because they use information about corneal topography along with refractive data to design a treatment plan.

The topography-guided procedure may offer several advantages over wavefront-guided and wavefront-optimized ablations. First, because higher-order aberrations in the young eye typically arise from the cornea, it makes sense to measure and correct the cornea rather than measuring the optical system of the entire eye and then correcting aberrations on cornea. Second, T-CAT may be more accurate and reproducible than wavefront-guided measurements, especially in eyes that are highly aberrated and in most need of correction.[2] Third, T-CAT may provide a more accurate correction of peripheral corneal curvature compared to wavefront-guided treatments, which are limited in coverage by the diameter of the pupil (topography-guided corrections are independent of pupil size). For these reasons, topography-guided treatments may provide a better quality of vision in both bright and dim lighting conditions than wavefront-guided treatments. T-CAT may also offer better outcomes than wavefront-guided treatments for individuals with highly aberrated corneas.[3]

HOW IT MAY BE USED

Topography-guided ablations may be used as a primary treatment for patients who want to eliminate their need for glasses or contact lenses. This treatment may also be used as a secondary procedure to correct eyes that are symptomatic after previous LASIK or PRK—especially those that have decentered ablations and small optical zones (*see Dr. Lin's article on page 11*). Topography-guided ablations may also be effective for the treatment of patients who have undergone previous radial keratotomy or corneal transplants.

> "T-CAT may be more accurate and reproducible than wavefront-guided measurements."

CLINICAL TRIAL

So far, about 20 patients with myopia or hyperopia have been treated as part of the ongoing FDA T-CAT clinical trial, and the early postoperative observations have been extremely encouraging. The sponsor also submitted a plan to treat patients who had visual symptoms after previous refractive surgery, but the FDA has so far not approved a protocol to do so. It is our hope that the FDA will take this opportunity to offer treatment to this small but important segment of the population that might benefit from T-CAT.

SUMMARY

The FDA clinical trial will evaluate whether topography-guided laser vision correction provides a strategy to improve objective and subjective visual performance in patients who otherwise would receive conventional, wavefront-optimized or wavefront-guided treatments. The approval range is expected to be similar to that in existence for excimer lasers that are currently marketed in the US. Many hope that future clinical trials will include patients who are symptomatic after previous corneal refractive surgery. ■

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Six-Year Experience With Topography-Guided Ablations

Clinical use in a Canadian practice.

BY DAVID T. C. LIN, MD, FRCSC

The advantage of topography-guided laser vision correction is that it can direct the excimer laser to ablate individual topographic points on the cornea in order to smooth it to a congruent shape. Thus, the procedure is ideal for corneal irregularities that standard wavefront-guided and wavefront-optimized ablations cannot treat.

Surgeons may use topography-guided laser vision correction as either a primary or secondary procedure. Primary treatments usually involve corneas with irregular astigmatism or forme fruste keratoconus. Secondary treatments are used to smooth induced astigmatism or to steepen the central cornea to increase the strength of a patient's reading vision after IOL implantation.

My staff and I now have 6 years of experience with topography-guided ablations using the Allegretto Wave Eye-Q excimer laser (Alcon Laboratories, Inc., Fort Worth, TX). What follows is a summary of our experience thus far.

APPLICATIONS

Irregular Astigmatism

Most standard ablation profiles that lack customized topography-guided software cannot treat irregular corneal astigmatism, such as that induced by previous laser surgery, buttonholes, and decentered ablations. The ability of topography-guided ablations to smooth irregular corneas into a normal shape serves an undertreated patient population (Figure 1).

Keratoconus

Topography-guided laser vision correction can treat certain types of keratoconus, including forme fruste, and thereby provides an option for patients who are contact-lens intolerant. Again, topography-guided treatments succeed in these eyes because they can ablate the superior and inferior cornea differently. They will not, however, significantly improve the UCVA of these eyes. Therefore, my staff and I are experimenting with performing customized topography-guided PRK treatments followed by corneal cross-linking with ultraviolet light and riboflavin to lock the ablation into position. So far, our results have been remarkable; the keratoconic patients we have treated now see 20/40 to 20/60 UCVA, which is life-changing for some of them (Figure 2).

> "It is much easier to get a topographic image than a wavefront map of an irregular cornea."

Presbyopic Correction

Topography-guided laser vision correction may be used to steepen the center of the cornea to improve midrange and reading vision. Surgeons must be careful not to overdo the treatment, however. The excimer laser I use features a software program called Custom Q that measures asphericity. The more negative the asphericity is, the more prolate the cornea is and the better the individual can read up close. Thus, surgeons can adjust the Q value to improve reading ability without losing too much distance vision.

WAVEFRONT-OPTIMIZED VERSUS WAVEFRONT-GUIDED VERSUS TOPOGRAPHY-GUIDED

A topography-guided laser treatment, in essence, smoothes the cornea to a normal shape. It does not treat refractive error; a refractive treatment must be performed on top of the topographic ablation. Therefore, surgeons using this procedure will need a separate algorithm to take into account the eye's refraction, both preoperatively and after the topographic smoothing. I enjoy the process of altering my treatment algorithms to make the topography-guided procedure predictable.

Wavefront-optimized ablations are based on the cornea's refraction. This profile determines the amount of tissue to be removed to achieve a particular correction. It assumes that the cornea has a normal prolate shape, and it will ablate tissue until the cornea matches that shape.

Wavefront-guided ablations also take the cornea's refraction into account. The main drawback to wavefront-guided ablations is that the aberrometer cannot measure highly irregular corneas. Unless there is a reproducible wavefront-guided reading, the system cannot treat the error. Topography-guided ablations excel in this regard; it is much easier to get a topographic image than a wavefront map of an irregular cornea.

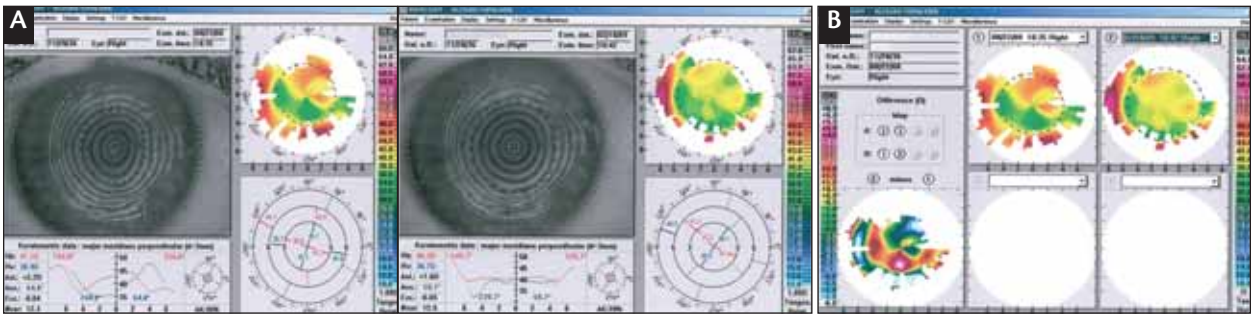


Figure 1. Severe postoperative irregular astigmatism was corrected with topography-guided PRK (A). Subtraction topography shows the flattening of the steep points and steepening of the flat points (B).

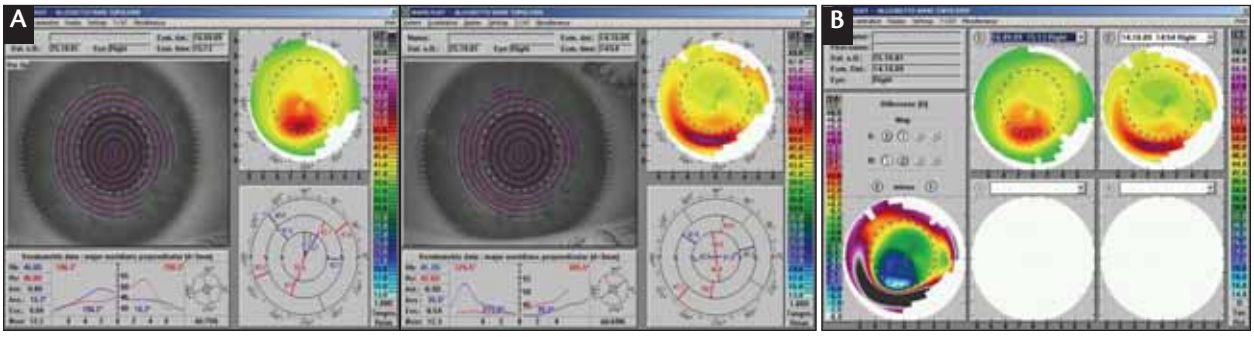


Figure 2. A severe case of contact-lens-intolerant keratoconus treated with topography-guided PRK followed by cross-linking (A). Subtraction topography shows the flattening of the steep points and steepening of the flat points (B).

CLINICAL USE

Thus far, my staff and I have treated 3,000 to 4,000 eyes for different indications with topography-guided laser vision correction. We have shifted our practice to using topography-guided PRK exclusively to treat post-LASIK eyes that have superior and inferior asymmetry and also for all irregular corneas (approximately 10% of our patients). We have been very happy with the results thus far, especially with our latest sixth-generation algorithm. The average preoperative BCVA of patients who present to us is 20/60 or 20/70, and the topography-guided treatment improves their visual acuity to 20/30 or 20/25, on average. Even some of our worst keratoconic eyes have achieved 20/60 UCVA, which is incredible compared with their preoperative acuity.

We recently studied 22 eyes of 15 patients with contact-lens–intolerant keratoconus who underwent topography-guided PRK with an Allegretto Wave excimer laser with simultaneous cross-linking (CXL). All of the 16 eyes that completed 6 months of follow-up had improved UCVA. Eight subjects experienced two or more lines of improvement in BSCVA, six patients saw no change, and two patients lost lines of BSCVA. The subjects' mean astigmatism decreased from 4.20 D to 1.50 D, and their mean K readings reduced from 47.2 to 44.3 D. One patient developed herpetic keratitis but recovered his preoperative BSCVA and gained improved UCVA.

Because topography-guided treatments, by definition, are used on eyes that either have undergone previous surgery or are irregular, their enhancement rate is higher than for traditional ablations. Our re-treatment rate is less than 10%, which I think is outstanding considering the difficulty of treating these eyes with an unrefined nomogram.

PEARLS

I suggest that first-time users reserve topography-guided ablations for enlarging optical zones (to decrease nighttime glare and halos) or re-treating previous LASIK or PRK patients who are slightly undercorrected. These types of procedures require simple adjustments to the algorithm and will positively affect these patients. I feel that all superior and inferior asymmetries should be treated with topography-guided PRK as a primary procedure. This type of correction also requires a fairly simple nomogram adjustment.

However, I tend not to use topography-guided ablations as a primary treatment for absolutely irregular corneas. In my experience, the results are not very different from those with standard wavefront-optimized ablations. Keratoconic treatments require the greatest changes to the excimer laser's algorithm, but they account for such a small percentage of a practice's volume that surgeons can begin using the other types of treatments quite safely and effectively.

CONCLUSIONS

Topography-guided laser vision correction is exciting, but it is not a cure-all for difficult corneas. Surgeons have to remember that smoothing the corneal surface can induce some refractive error. For example, flattening a steep central island will leave the eye slightly hyperopic, and algorithms for these two-step procedures will need to compensate for this reshaping. Certainly, additional training would be needed if this procedure gains FDA approval. ■

Presbyopic Laser Vision Correction: US Experience

An overview from American surgeons who are beginning to use this procedure.

BY MICHAEL GORDON, MD, AND CHARLES R. MOORE, MD

Presbyopia is a problem every middle-aged person faces. Baby boomers, who are beginning to notice or are already experiencing symptoms of presbyopia, are the fastest-growing demographic in ophthalmic surgery. We have not been able to completely resolve these symptoms in patients who did not need cataract surgery or could not wear monovision contact lenses. These patients are used to seeing well. Either they are former LASIK recipients who threw away their glasses 15 years ago but are starting to need them again, or they are using glasses for the first time to see their cell phones and computers, and they don't like it. Thus, the potential market for procedures that provide relief from the inconvenience and stigma of glasses is tremendous, as was the market for myopic LASIK. Many presbyopes could benefit from a procedure that can fine-tune both their distance and reading vision. Presbyopic laser vision correction may be able to meet this demand.

HOW IT WORKS

Roberto Pinelli, MD, of Italy developed presbyopic laser vision correction during the past 7 years using the Technolas laser (Bausch & Lomb, Rochester, NY).[1] In the United States, the procedure is only available off-label on the Allegretto Wave Eye-Q laser (Alcon Laboratories, Inc., Fort Worth, TX), although several companies, including Abbott Medical Optics, Inc., and Nidek Co. Ltd, are exploring it. The technique evolved from the observation by many refractive surgeons that overcorrecting a myope (for example, correcting a -4.00 D myope to +1.50 D, and then postoperatively enhancing the eye to make it plano) improved the reading vision in that eye beyond what was expected for the patient's age. Based on our current understanding of optics and higher-order-aberrations, Dr. Pinelli realized that this effect was the result of giving the cornea a prolate shape. Negative spherical aberration increases the depth of field, which improves reading vision. Presbyopic laser vision correction does not give exactly the same reading ability as young eyes that can accommodate, however. The effect is more static; these patients cannot continually accommodate while bringing reading material in from arm's length, and they may not be able to read the smallest print. Functionally, however, the procedure effectively allows patients to read normal-sized print and view their computers and cell phones.

Presbyopic laser vision correction differs from wavefront-optimized and wavefront-guided ablations by inducing rather than eliminating aberrations. It is currently an off-label procedure that can be performed with scanning-spot excimer lasers. The authors have only applied presbyopic corrections with the Allegretto Wave Eye-Q laser, which produces a true optical zone size and subtle blend zones. This laser gives the cornea a seamless curve instead of a stepped transition seen with other lasers. We believe this smooth transition is what makes presbyopic laser vision correction with the Allegretto Eye-Q laser successful.

Presbyopic laser correction uses two FDA-approved treatments—a myopic and a hyperopic treatment—binocularly. First, we deliver a smaller myopic treatment (5.5-mm optical zone), which we overcorrect by 1.00 to 2.25 D. Then, we perform a larger hyperopic treatment

TABLE 1. PRESBYLASER PROCEDURE PLAN

Preoperative MR	**Plano**	**+1.50 D**	**-2.25 D**	**-3.50+1.25 x 090**
Initial Target	-1.25 D	-1.25 D	+1.25 D	+1.25 D
Treatment 1 (overminus)	+1.50 D 6.0-mm OZ	+3.00 D 6.0-mm OZ	-3.50 D 5.5-mm OZ	-4.75 D 5.5-mm OZ
Treatment 2 (reversal)	-1.25 D 5.5-mm OZ	-1.25 D 5.5-mm OZ	+1.50 D 6.0-mm OZ	+1.50+1.25 x 090 6.0-mm OZ

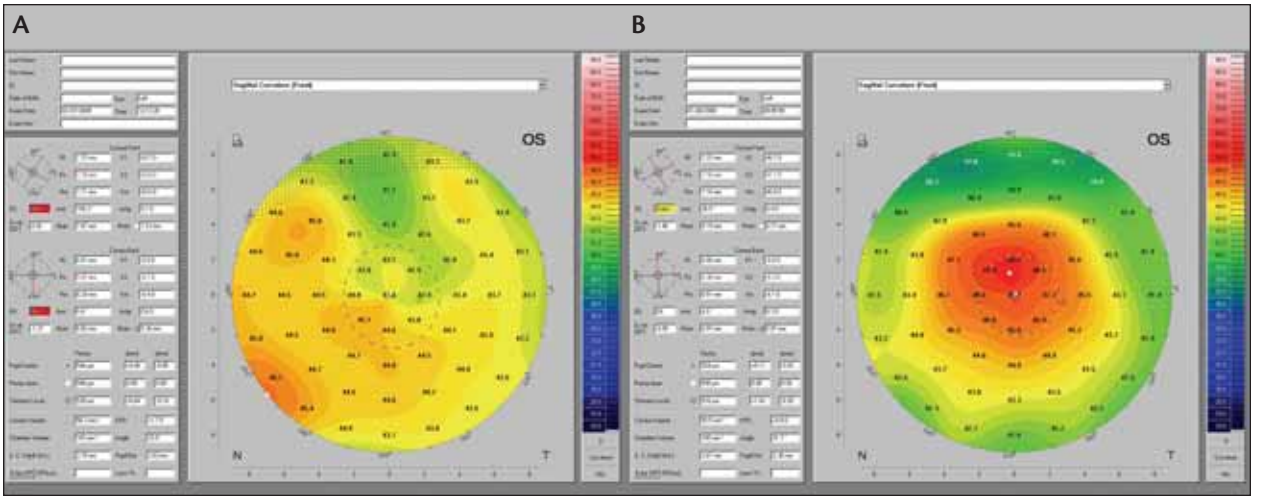


Figure 1. An example of improved Q-Value from pre- (+0.20; A) to postoperatively (-0.66; B) after presbyopic laser vision correction with the Allegretto Wave Eye-Q excimer laser.

(6.0-mm optical zone) to reverse the overcorrection. In hyperopes, we perform the overcorrected hyperopic treatment first, and then we fix the overcorrection with a smaller myopic treatment.

The patients we target for presbyopic laser correction treatment range from -4.00 D myopes to emmetropic presbyopes to +3.00 D hyperopes (Table 1). We also use the procedure to treat 3.00 D or less of cylinder across the board with good results. Patients with asymmetric cylinder on topography are poor candidates for this treatment.

The data indicate that presbyopic laser vision correction is a stable result. Dr. Pinelli's patients in Italy are the furthest out from treatment (7 years), and their results are stable.[2]

HOW IT COMPARES TO OTHER TREATMENTS

Presbyopic laser vision correction compares favorably to monovision. Presbyopic LASIK patients generally have better distance vision than monovision patients, because both eyes are corrected for distance, and they do not experience subtle changes in depth perception. We also feel that this procedure is comparable to the presbyopia-correcting IOL technologies currently available. Ninety-five percent of our presbyopic laser vision correction recipients see 20/30 UCVA at distance and J3 at near.

Presbyopic laser vision correction may also be used as a secondary procedure to enhance the reading vision of IOL recipients. The authors have had success with the procedure in eyes with monofocal lenses. We both explain the option to patients preoperatively as a two-step procedure. Currently, the treatment range for presbyopic laser vision correction is -4.00 to +2.00 D.

Patients should be counseled that the procedure will not enable them to read J1+ print. Contraindications for presbyopic laser vision correction are the same as those for any LASIK procedure: severely dry eyes, abnormal corneal topography, and unrealistic patient expectations.

RESULTS

Dr. Gordon's

A number of refractive surgery centers around the United States have started offering presbyopic laser vision correction with promising results. My staff and I have treated more than 400 patients with presbyopic laser vision correction on the Allegretto Eye-Q laser over the past year and a half. To date, my patients' range of distance UCVA measured binocularly is 20/15 to 20/30. No patient sees worse than 20/30, no one has experienced a loss of BSCVA, and 97% see 20/25 or better at distance. Ninety-five percent of these patients read J3 or better, and 70% read J2 or better.

Dr. Moore's

My first presbyopic laser vision correction patients are nearing their 1-year outcomes. Across the board, these individuals have experienced an improvement in near vision and no lost lines of BSCVA (Figure 1). I have treated 165 eyes to date, of which 96% have achieved 20/25 UCVA at distance. Eighty-five percent of these patients read J3 or better, which is comparable to a multifocal lens implant. The procedure has proven to be safe and efficacious with a high level of patient satisfaction.

My enhancement rate with presbyopic laser vision correction has been higher than I would like (3.8%), because I began using the procedure without a nomogram. This rate has been falling as I continue to refine my personal nomogram. Enhancement rates with presbyopic laser vision correction average approximately 5%—slightly higher than with regular LASIK procedures, due to the newness of the procedure and the fact that it requires two ablations. Fortunately, the procedure is easy to enhance. If a patient's distance vision is not what he or she desires, we can enhance it while preserving his or her near vision, and vice versa.

(Continued on page 14)

Corneal Presbyopic Correction

Where it's been, where it's going.

BY KARL G. STONECIPHER, MD, AND ARTHUR CUMMINGS, MD, FRCSED

As we all know, the correction of presbyopia is currently ophthalmology's Holy Grail. Every person loses the ability to accommodate as he or she ages, and much time and expense has been invested into finding a treatment that will enhance near vision and correct refractive errors without introducing aberrations to the existing optical system. This article is a brief review of the recent history and current status of most corneal presbyopic corrections.

WHAT HAS NOT WORKED

It is important to understand which corneal presbyopic treatments have not worked and why in order to judge the potential of newer technologies. Surgeons have tried many combinations of keratorefractive reshaping techniques in an attempt to give patients near and distance-viewing zones on the cornea.

Near Vision in the Center, Distance Vision in the Periphery

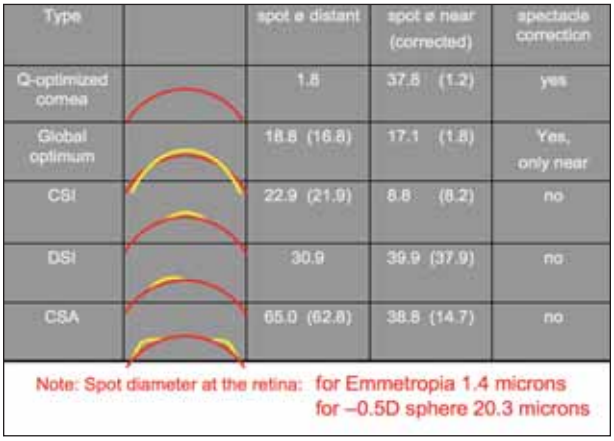
The first such technique was a steep central island, which gave the central cornea a higher refractive power than the peripheral cornea.[1] This made the eye more prolate. Abbott Medical Optics Inc. is still seeking FDA approval for this procedure on its Visx laser platform. Steep central islands provided strong near vision and reasonable distance vision. However, spectacles cannot improve the vision further if the patient is dissatisfied with his visual acuity or quality.

Distance Vision in the Center, Near Vision in the Periphery

The second technique was an inferior decentered hyperopic ablation, otherwise known as a *decentered steep central island*, which gave distance vision in the center and near vision in the periphery.[2-5] In these eyes, both distance and near vision were negatively affected and could not be improved further by spectacles.

Annular Ablations

Annular ablations deliver an intermediate plus near midperipheral ablation pattern to the cornea. This laser technique is still being studied, as it results in poor distance and near vision that cannot be corrected by glasses (Figure 1).



(Courtesy of Theo Seiler, MD, PhD.)

Figure 1. The Custom-Q LASIK treatment profile compared with other ablation profiles.

CONSIDERATIONS

As these past treatments illustrate, there are several potential problems with using an excimer laser to create multifocality on the cornea. The primary issues are these procedures' longevity (do these treatments regress?) and side effects (will they induce more aberrations and visual symptoms such as glare and halos?). Are the benefits of these treatments worth the potential risks? If we consider how much time and energy has gone into improving visual quality and reducing aberrations over the past 10 years, it seems counterproductive to be willfully introducing them now with multifocal ablations. The first three multifocal laser ablations have had issues with regression and postoperative symptoms, regardless of the platform used. They are also quite sensitive to decentration. Another consideration with these procedures is enhancements—reshaping the center of the visual axis does not leave much room for re-treatments if the patient is unhappy with his postoperative vision (and any residual refractive error will compromise the distance acuity). Finally, steepening the cornea can cause or worsen dry eye syndrome, which is prevalent in the presbyopic patient population anyway.

PROMISING TECHNOLOGIES

The Aspheric Hyperprolate Profile

A technique available on the Allegretto Wave Eye-Q laser (Alcon Laboratories, Inc., Fort Worth, TX) outside the US is the aspheric Q-adjusted global optimized ablation. This treatment does not produce a true multifocal

cornea but rather an aspheric hyperprolate corneal profile.[6] The ablation creates one foci of vision, which may be enhanced with monovision adjustments to correct one eye more for distance and the other eye more for residual nearsightedness. Because it does not split light, it is not associated with glare and halos like multifocal IOLs. It makes the cornea prolate and creates a large optical zone, which potentially improves depth of focus. There are two potential drawbacks of the Q-adjusted global optimized ablation: (1) it is pupil-dependent, and pupils get smaller with age; and (2) adjusting Q-values reduces the predictability of the refractive outcome. This particular problem of refractive stability, however, may be overcome with the advent of ray tracing. A multicenter clinical trial currently ongoing in Europe (investigators Theo Seiler, MD, PhD; Michael Mrochen, MD; Matthias Maus, MD; and Arthur Cummings, MD) on ray-tracing ablation profiles has produced extremely accurate results. Now that more data are available for planning the ablation profile, the global optimum profile should enjoy increased predictability both in terms of refractive outcomes as well as the amount of asphericity achieved. FDA clinical trials to study ray tracing will commence in 2010.

Two-Step Ablations

Surgeons in both the United States and overseas are testing a two-step presbyopic laser ablation profile on the Allegretto Wave Eye-Q laser to try to create negative asphericity on the cornea to improve near acuity. This treatment involves using two treatment cards, one for a myopic ablation and one for a hyperopic ablation, in either a presby-LASIK or presby-PRK procedure. The effect is highly pupil-dependent. The procedure is currently in premarket studies. Questions remain about visual quality in these patients postoperatively and what amount of aberration is left on the surface of the cornea.

Flapless Intrastromal Ablation

The IntraCOR procedure is an intrastromal application of the FEMTEC femtosecond laser (20/10 Perfect

RECENT LITERATURE

Although the authors in this monograph are describing their personal experience, recently published studies involving topography-guided and presbyopia-correcting excimer ablations have included domestic and international investigators using varying techniques to improve patient outcomes. Following is a summary of additional ongoing studies (the list may not be comprehensive).

TOPOGRAPHY-GUIDED EXCIMER LASER ABLATIONS

WaveLight Allegretto Wave excimer laser (Alcon Laboratories, Inc.)

- Cummings AB, Mascharka N. Outcomes after topography-based LASIK and LASEK with the WaveLight Oculyzer and Topolyzer platforms. *J Refract Surg.* 2009;2:1-8.
- Lin DT, Holland SR, Rocha KM, Krueger RR. Method for optimizing topography-guided ablation of highly abberated eyes with the Allegretto Wave excimer laser. *J Refract Surg.* 2008;24(4):S439-445.

EC-5000 CXII excimer laser with CATz algorithm (Nidek Co. Ltd.)

- Dougherty PJ, Waring G 3rd, Chayet A, et al. Topographically guided laser in situ keratomileusis for myopia using a customized aspherical treatment zone. *J Cataract Refract Surg.* 2008;34(11):1862-1871.
- Waring G, Dougherty PJ, Chayet A, et al. Topographically guided LASIK for myopia using the Nidek CXII customized aspheric treatment zone (CATz). *Trans Am Ophthalmol Soc.* 2007;105:240-246; discussion 247-248.

Zyoptix on the Technolas 217z (Bausch & Lomb)

- Kanjani N, Jacob S, Agarwal A, et al. Wavefront- and topography-guided ablation in myopic eyes using Zyoptix. *J Cataract Refract Surg.* 2004;30(2):398-402.
- Alió JL, Belda JI, Osman AA, Shalaby AM. Topography-guided laser in situ keratomileusis (TOPOLINK) to correct irregular astigmatism after previous refractive surgery. *J Refract Surg.* 2003;19(5):516-527.

PRESBYOPIA-CORRECTING ABLATIONS

(Multiple Platforms)

- Alió JL, Amparo F, Ortiz D, Moreno L. Corneal multifocality with excimer laser for presbyopia correction. *Curr Opin Ophthalmol.* 2009;20(4):264-271.

VISX S4 excimer laser (Abbott Medical Optics, Inc.)

- Epstein RL, Gurgos MA. Presbyopia treatment by monocular peripheral presbyLASIK. *J Refract Surg.* 2009;25(6):516-523.

EC-5000 CXIII excimer laser (Nidek Co. Ltd.)

- Uy E, Go R. Pseudoaccommodative cornea treatment using the NIDEK EC-5000 CXIII excimer laser in myopic and hyperopic presbyopes. *J Refract Surg.* 2009;25 (1 Suppl):S148-155.

MEL 80 excimer laser (Carl Zeiss Meditec, Inc.)

- Reinstein DZ, Couch DG, Archer TJ. LASIK for hyperopic astigmatism and presbyopia using micro-monovision with the Carl Zeiss Meditec MEL 80 platform. *J Refract Surg.* 2009;25(1):37-58.

"The research to date supports the conclusion that an aspheric hyperprolate cornea is proving to be a better option for presbyopes."

Vision AG) intended to correct low refractive errors (myopic, hyperopic, and astigmatic). It uses a specific algorithm to create five concentric stromal rings at a predetermined distance from each other and from the corneal epithelium and endothelium. The design of the cuts and their depth in the stroma depend on the eye's refraction and pachymetry. Three-month results from a small, ongoing study in Germany show a mean gain of 4.42 lines of UCVA at near but no statistically significant difference in distance vision.[7]

Intracorneal Inlays

The KAMRA (formerly the AcuFocus) intracorneal inlay (Bausch & Lomb) is a 5-µm-thick biocompatible polymer device that is implanted either under a corneal flap or in a pocket in the cornea of the nondominant eye. This device now has data out to 1 year in a large series of patients. If the treatment does not work, however, the surgeon must contend with the potential for a distorted visual axis related to the device's removal.[8] Similar devices have also been developed by other companies.[9]

Presbyopia-Correcting IOLs

Despite the prevalence of research into corneal presbyopic treatments, the best treatments may be lenticular, because accommodation is largely a mechanism of the crystalline lens. Although problems with halos and glare persist,[10] presbyopia-correcting multifocal IOLs continue to gain momentum, and new accommodating lenses continue to be added to the marketplace. Additionally, the Light Adjustable Lens (Calhoun Vision, Inc., Pasadena, CA), which is a three-piece photosensitive silicone IOL that changes shape in response to ultraviolet light, is available commercially in Europe, and it began FDA phase 2 clinical trials in January 2009.

Monovision: Tried and True

Finally, monovision still remains the most successful presbyopic treatment to date that does not change the patient's visual perspective. Many surgeons still believe that monovision contact lens wearers who present for cataract surgery are best left with monovision. We believe this adage holds true for refractive surgery as well. With a wavefront-optimized ablation profile, leaving one eye corrected for distance and one eye corrected for near pleases many patients. Most of my patients with monovision are entirely free from glasses; only a small percentage (7%) use glasses to drive at night (personal experience with 6,000+ monovision cases; Arthur Cummings, MD). The most common complaint from this procedure is nighttime glare in the reading eye. If a patient is unable to adapt to monovision, it can be fully corrected either with spectacles or corneal refractive surgery.

CONCLUSIONS

Despite the anatomical challenges, most ophthalmologists are hopeful that a long-term corneal treatment for presbyopia will come to fruition. For now, we feel that multifocal corneal ablations are not the best option for presbyopes. The research to date supports the conclusion that an aspheric hyperprolate cornea is proving to be a better option for presbyopes. The two-step laser vision correction treatment may prove to become the frontrunner corneal presbyopia-correcting modality, because it most closely mimics the natural optics of the eye. Only time will tell, however. Of course, amidst the excitement of these new technologies, surgeons must remember that monovision is still a viable option for patients; it gives them reliable vision at a predetermined distance, and it has a lengthy track record. Also, monovision does not compromise the optics of the eye, and the effect can be further enhanced with either glasses or additional corneal refractive surgery.

Although corneal solutions to presbyopia are improving and do provide satisfactory results, accommodation occurs primarily in the crystalline lens. Therefore, the best solution for presbyopia will likely be an intraocular procedure, such as a truly accommodating IOL, that simulates our natural crystalline lens. ■

1. Hafezi F, Jankov M, et al. Customized ablation algorithm for the treatment of steep central islands after refractive laser surgery. *J Cataract Refract Surg*. 2006 May;32(5):717-21.
2. Bauerberg JM. Centered vs. inferior off-center ablation to correct hyperopia and presbyopia. *J Refract Surg*. 1999 Jan-Feb;15(1):66-69.
3. El Danasoury AM, Gamaly TO, Hantera M. Multizone LASIK with peripheral near zone for correction of presbyopia in myopic and hyperopic eyes: 1-year results. *J Refract Surg*. 2009 Mar;25(3):296-305.
4. Telandro A. The pseudoaccommodative cornea multifocal ablation with a center-distance pattern: a review. *J Refract Surg*. 2009 Jan;25(1 Suppl):S156-9. Review.
5. Pinelli R, Ortiz D, Simonetto A, et al. Correction of presbyopia in hyperopia with a center-distance, paracentral-near technique using the Technolas 217z platform. *J Refract Surg*. 2008 May;24(5):494-500.
6. Mrochen M. Hyperprolate corneas for pseudo-presbyopia corrections. *Cataract & Refractive Surgery Today Europe*. 2009;4(1):28-29.
7. Holzer MP. Clinical outcomes of IntraCOR: Flapless intrastromal ablation with the FEMTEC femtosecond laser. Paper presented at: The 13th ESCRS Winter Meeting; February 6, 2009; Rome, Italy.
8. Seiler T. Presbyopia correction at the cornea: optical challenges. Paper presented at: the XXVI Congress of the ESCRS; September 13-17, 2008; Berlin, Germany.
9. Yilmaz OF, Bayraktar S, Agca A, et al. Intracorneal inlay for the surgical correction of presbyopia. *J Cataract Refract Surg*. 2008;34(11):1921-1927.
10. Woodward MA, Randleman JB, Stulting RD. Dissatisfaction after multifocal intraocular lens implantation. *J Cataract Refract Surg*. 2009 Jun;35(6):992-997.

Laser Enhancements After Premium Cataract Surgery

My experience compared with limbal relaxing incisions.

BY CARLOS MANRIQUE, MD, FACS

This article discusses the off-label use of excimer lasers for performing corneal refractive and astigmatic correction secondary to IOL implantation surgery.

We ophthalmologists have various options available when it comes to premium IOLs; these include the AcrySof Restor IOL +3.0 D and +4.0 D (Alcon Laboratories, Inc, Fort Worth, TX), the Rezoom and Tecnis IOLs (Abbott Medical Optics, Inc, Abbott Park, IL), and the Crystalens HD (Bausch & Lomb, Inc, Aliso Viejo, CA). At my practice's multiple locations, my staff and I implant a high volume of premium refractive IOLs. We have implanted more than 2,000 of the AcrySof ReSTOR IOL +4.0 D (Alcon Laboratories, Inc.) and over 400 of the +3.0 D version since it received FDA approval.

I currently use the Allegretto Wave Eye-Q excimer laser (Alcon Laboratories, Inc.) to correct residual refractive error in these patients. The Eye-Q's wavefront-optimized profile is so adept at correcting the error postoperatively that it gives me the confidence to place this IOL in eyes that have more astigmatism than what was reported in the FDA studies. Other excimer laser technologies can be used to correct residual refractive error, such as the Star S4 IR (Abbott Medical Optics, Inc) or the Zyoptix Laser (Technolas Perfect Vision, St. Louis, MO).

LASER VERSUS INCISIONS

I prefer to use an excimer laser rather than limbal relaxing incisions to enhance premium IOL recipients' outcomes, because this group expects more postoperatively than traditional cataract surgery patients. I feel that astigmatic correction is more precise with an excimer laser than limbal relaxing incisions, because I found the latter to be fairly unpredictable for patients who have more than 1.00 D of astigmatism. The advanced IOL calculations for premium cataract surgery leave most patients' postoperative spherical equivalent close to plano. Consequently, the amount of postoperative correction these patients need is generally very small (less than 3.00 D). I find the Allegretto Eye-Q's precision to be incredible, and it treats these small amounts of correction very adeptly.[1] In fact, my enhancement rate after primary laser vision correction with this laser is near zero for these small corrections.

SURGICAL COURSE

I perform topographic mapping in all my premium IOL patients in case they need LASIK afterward. This step

Figure 1. An eye that underwent PRK with the Allegretto Wave Eye-Q laser after cataract surgery with implantation of an AcrySof ReSTOR IOL.

Figure 2. An eye that underwent LASIK with the Allegretto Wave Eye-Q laser after cataract surgery with implantation of an AcrySof Restor IOL.

allows me to explain the procedure and prepare the patients before the initial cataract surgery in case they need laser vision correction. I also require an evaluation of the endothelial cell count. I have found that my IOL calculations are more accurate using the IOLMaster (Carl Zeiss Meditec, Inc., Dublin, CA). External disease is treated before the cataract surgery. As it has been observed that minor postoperative fluctuations in vision are frequently related to dry eyes, I pretreat aggressively to achieve a healthy ocular surface.[2] During the cataract surgery, I assess the integrity of the capsular bag and zonules carefully.

The laser vision correction procedure itself is exactly the same for primary and secondary treatments. I use a femtosecond laser to cut all LASIK flaps, because it places much less pressure on the postsurgical eye than mechanical microkeratomes. If I have any doubt about the strength of the cornea, however, I will proceed with PRK instead of LASIK for the enhancement.

I perform PRK enhancements 8 weeks after the original lenticular surgery (Figure 1), and I wait 3 months for LASIK enhancements (Figure 2). I generally prefer PRK to LASIK for these secondary procedures, because the former will not compromise the integrity of the capsular bag or zonules. If I know preoperatively that the patient will need a re-treatment, however, I will cut a LASIK flap before performing the cataract surgery and then lift the flap and perform the enhancement 8 weeks later.

For example, I recently performed cataract surgery in a patient whose preoperative refraction was plano +6.75 X 108 = 20/60 on the right eye and +1.25 +5.00 X 084 = 20/50 on the left eye (the highest postoperative correction I have performed with the Allegretto Eye-Q laser; beyond the FDA-approved treatment range for the Allegretto laser). I cut a LASIK flap prior to performing the cataract surgery and implanted each eye with an AcrySof Restor IOL +3.0 D (1 week apart). Eight weeks later, her refraction in her right eye was -2.75 + 4.50 X

WHEN A CATARACT SURGEON BUYS A LASER

Do you need an excimer laser to work with premium refractive IOLs?

BY ROBERT J. CIONNI, MD

When implanting premium refractive IOLs, there is occasionally the need to fine-tune results with a refractive enhancement. PRK or LASIK is sometimes the best modality for these corrections, especially if the eye has residual astigmatism. In the past, I had relied on partnering with a laser refractive surgeon to perform these enhancements, but I found this arrangement to be flawed for a few reasons: (1) the laser refractive specialist does not know the patient as well as you do; (2) this practitioner is being asked to manage your problem and does not feel a sense of ownership of the problem; and (3) the patient may feel abandoned by you or lose confidence in your ability to manage his or her problem yourself. For these reasons, I felt it was important to stay engaged with my patients' care, including any needed enhancements. I was already taking part in my patients' refractive consultations and surgeries, so it was relatively simple to take the next step to performing the re-treatment myself. I decided to purchase the wavefront-optimized excimer laser platform.

WHY WAVEFRONT-OPTIMIZED VERSUS WAVEFRONT-GUIDED

As a cataract surgeon, I have learned the importance of using aspheric IOLs, the optics of which are based on averages of corneal spherical aberrations. This optical concept is quite similar to that of the wavefront-optimized ablation profile. Hearing many surgeons report excellent outcomes and extremely low enhancement rates with the wavefront-optimized laser profile confirmed my initial impression that it would be relatively easy to learn and use to deliver superior results.

INCORPORATING THE LASER INTO A LENTICULAR PRACTICE

I began using wavefront-optimized laser vision correction strictly for postsurgical refractive IOL patients, but I have gradually adopted primary refractive laser procedures. I found the transition fairly easy, having developed the necessary mindset from my experience with elective IOLs.

I still prefer limbal relaxing incisions for primary cataract and refractive lens exchange procedures. If the original corneal astigmatism is less than 1.50 D, usually no enhancement is needed. If the refractive error is mostly spherical, I still prefer to use a piggyback IOL or refractive lens exchange. The laser is my first choice for spherical and cylindrical correction. In all incidences of postsurgical refractive error, the surgeon must first confirm (with trial contact lenses) that the enhancement will satisfy the patient before proceeding.

LEARNING CURVE

Surgeons who have never trained in laser refractive surgery will experience a learning curve, as they will when adopting any technology. The biggest challenge is understanding the indications, limitations, and possible complications associated with performing LASIK or PRK after lenticular surgery.

105 = 20/25 and in her left eye was -1.75 + 3.50 X 091. I lifted the flaps and ablated the astigmatism. Now, her uncorrected distance visual acuity is 20/25 with both eyes and 20/20 at near. Obviously, this patient has been very satisfied with her outcome.

PATIENT POPULATIONS

In my experience, I have found minor but distinct differences between the patient populations of primary and secondary laser vision correction procedures. Cataract patients who will receive secondary laser treatments present with higher prescriptions and the complications of presbyopia. They are generally pleased with their vision after the cataract surgery and even happier after the enhancement. Primary laser vision correction patients, by comparison, are younger, have healthier eyes with simpler prescriptions, but are more demanding.

SUMMARY

Having an excimer laser is not a prerequisite to adopting premium IOLs, but surgeons who do not own a laser will need to partner with another practitioner who can treat the patients who have residual refractive error. Such an arrangement will enable cataract surgeons to offer premium IOLs to a wider range of patients. ■

1. Kuo IC, Reviglio VE. Wavefront-guided refractive surgery after multifocal lens implantation. *Curr Opin Ophthalmol*. 2009;20(4):255-259.

2. Woodward MA, Randleman JB, Stulting RD. Dissatisfaction after multifocal intraocular lens implantation. *J Cataract Refract Surg*. 2009;35(6):992-997.

(Continued from page 8)

Clearly, surgeons need more experience with presbyopic laser vision correction to fine-tune it. The procedure requires using different optical zones than those used in single LASIK treatments and therefore different nomograms. Also, there is a delay between the two treatments. The surgeon performs either the hyperopic or the myopic treatment first, and then must recalibrate the laser, which takes 35 to 40 seconds. The surgeon must account for dehydration in the cornea during this time.

Like with any ocular surgery, surgeons and their staff must help presbyopic laser vision correction patients set realistic expectations for their outcomes. Patients must understand that the procedure has a slower healing profile than standard myopic or hyperopic LASIK; patients' vision can continue to improve up to 6 months postoperatively. Second, because people who undergo presbyopic laser vision correction are over 50, they naturally have more problems with their ocular surface than their younger LASIK counterparts. Physicians therefore must be especially vigilant about managing dry eye and other ocular surface disease both pre- and postoperatively. We use artificial tears and nutritional supplements preoperatively. After surgery, we monitor patients' surface irregularity index and use a significant amount of artificial tears, cyclosporine, steroids, etc. We also place 90-day collagen plugs in all our presbyopic laser vision correction patients before the procedure.

Finally, we feel it is important to use a femtosecond laser to make the flap in presbyopic laser vision correction. We believe the improved accuracy and safety profile of femtosecond flaps add to the efficacy of these procedures. ■

1. Pinelli R, Ortiz D, Simonetto A, et al. Correction of presbyopia in hyperopia with a center-distance, paracentral-near technique using the Technolas 217z platform. *J Refract Surg*. 2008;24(5):494-500.
2. Pinelli R. More on peripheral PresbyLASIK as a center-distance technique. *J Refract Surg*. 2008;24(7):665.

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CME QUESTIONS

1. Which of the following is NOT a pitfall of using a laser to create multifocality on the cornea?

a. Regression

b. Induction of visual symptoms

c. Leaving enough tissue for enhancements if necessary

d. A prolate shape

2. An aspheric hyperprolate corneal profile creates what type of effect on the cornea?

a. Multifocal

b. Single focal point

c. Neither of the above

3. If found efficacious, a two-step excimer ablation profile would be used to:

a. Increase near acuity

b. Increase distance acuity

c. Create a multifocal profile

d. None of the above

4. If found efficacious, a flapless intrastromal ablation would be used to treat:

a. High refractive errors

b. Low refractive errors

c. Presbyopia

d. None of the above

5. Which of the following is NOT a recommended application of a topography-guided ablation?

a. Treating superior and inferior corneal asymmetries

b. Enlarging optical zones

c. As a primary treatment for absolutely irregular corneas

6. What do topography-guided laser corrections NOT treat?

a. Refractive error

b. Presbyopia

c. Certain types of keratoconus

d. All of the above

7. Enhancement rates following topography-guided ablations are expected to be:

a. Lower than traditional ablations

b. Higher than traditional ablations

c. The same as traditional ablations

8. Which of the following techniques benefits from the ability to correct dissatisfied patients with spectacles?

a. Near vision center, distance periphery ablation

b. Distance vision center, near periphery ablation

c. Monovision

d. Annular ablation

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