Recentration of a small-aperture corneal inlay

Damien Gatinel, MD, Alaa El Danasoury, MD, Stephane Rajchles, MD, Alain Saad, MD

We report 2 patients implanted with a small-aperture corneal inlay to correct presbyopia. After the surgery, both patients complained of visual symptoms and poor visual acuity. The distances from the center of the inlay to the corneal vertex center were 593 μm nasally and 159 μm superiorly in Case 1 and 72 μm temporally and 17 μm superiorly in Case 2. The 2 inlays were recentered at 2 weeks and 3 weeks postoperatively, resulting in significant improvement in the visual acuity and quality of vision. Accurate centration of a small-aperture corneal inlay seems to be an important factor in obtaining a satisfactory result. Recentration is possible and improves visual acuity if proper centration was not obtained after the first surgery.

Financial Disclosure: Dr. Saad is a consultant to Acufocus, Inc. Dr. Gatinel is an investigator for a clinical trial conducted with the small-aperture inlay. He does not have any financial interest in relation to this inlay. Neither of the other authors has a financial or proprietary interest in any material or method mentioned.

J Cataract Refract Surg 2012; ■:■–■ © 2012 ASCRS and ESCRS

The Kamra small-aperture intracorneal inlay (Acufocus, Inc.) is designed to increase depth of field in the implanted eye, based on the principle of small-aperture optics. The inlay restores near and intermediate visual acuity without a significant impact on the distance vision.[1–3] The 5 μm thick microperforated inlay has a 1.6 mm central aperture and measures 3.8 mm in overall diameter. Implantation can be combined with excimer ablation to simultaneously address presbyopia and ametropia. The inlay is implanted monocularly in a lamellar pocket or under a 200 μm femtosecond laser–created flap in the nondominant eye.

As with photoablative surgery, correct centration of a corneal inlay is important to improve distance and near visual acuity and to avoid a reduction in quality of vision. The corneal intersection of the visual axis is probably the best point on which to center the inlay. The visual axis is the line joining the fixation point and the foveal image by the nodal points. The line of sight is the line joining the fixation point and the center of the entrance pupil. The position at which this line intercepts the cornea is called the *corneal sighting center*.[4] Le Grand and El Hage[5] referred to the intersection of the visual axis with the cornea as the ophthalmometric pole. However, the true position of the visual axis at the corneal plane is unknown and whether to center the correction on the entrance pupil center or on the coaxially sighted corneal reflex has not been determined.[6–9]

The coaxially sighted corneal reflex provides an easy reference to center procedures performed over the corneal surface. Angle kappa is the angle between the visual axis and the pupillary axis, which is perpendicular to the cornea through the center of the entrance pupil. Angle lambda is the angle between the line of sight and the pupillary axis; in practice, these angles can be confounded. Their estimation in angular degree is difficult without proper knowledge of the geometry and depth of the anterior chamber. Because of the angle kappa, the corneal reflex usually appears to be located on the nasal side of the pupil center. The position of the corneal reflex does not mark the intersection of the visual axis with the cornea (ophthalmometric pole); however, it may be the closest landmark[10] and can be used to center the placement of the inlay.We present 2 cases of decentered inlays requiring recentration because pf unsatisfactory visual outcome after the first surgery.

CASE REPORTS

Case 1

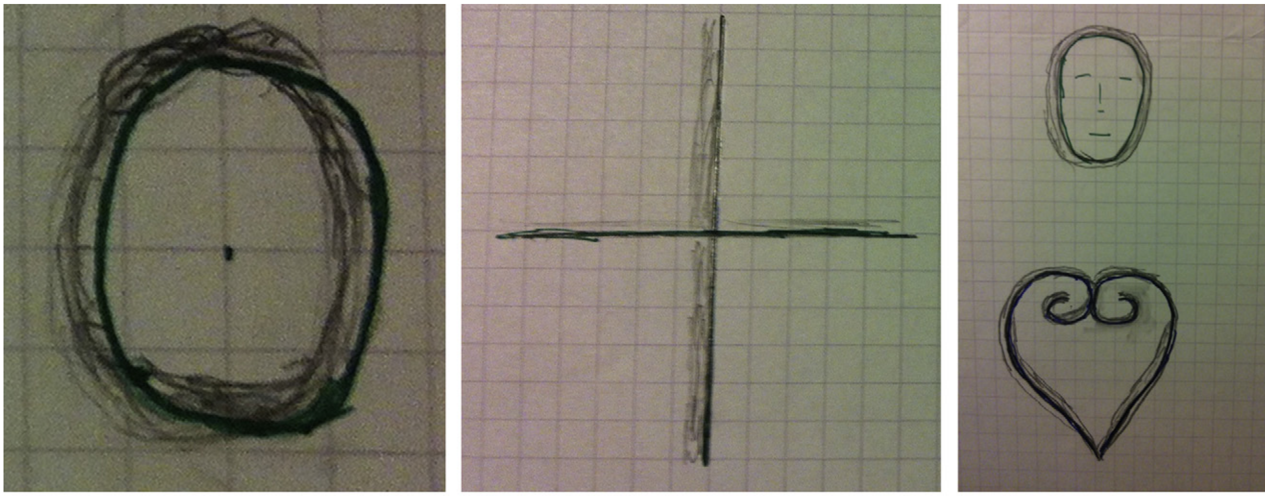
A 56-year-old man seeking a solution for presbyopia was referred to our practice. The refraction was +1.50 diopter

Submitted: January 23, 2012.
Final revision submitted: May 17, 2012.
Accepted: May 21, 2012.

From the Rothschild Foundation (Gatinel, Rajchles, Saad) and the Center for Expertise and Research in Optics for Clinicians (Gatinel, Saad), Paris, France; Magrabi Eye Hospital (El Danasoury), Jeddah, Saudi Arabia.

Corresponding author: Damien Gatinel, MD, Fondation Ophtalmologique Adolphe de Rothschild, 25, Rue Manin, 75019, Paris, France. E-mail: gatinel@gmail.com.

0886-3350/$ - see front matter
http://dx.doi.org/10.1016/j.jcrs.2012.09.009



A B C

Figure 1. Case 1; Simulation of shadow images of a circle (*A*), a cross (*B*), and a human face and heart shape (*C*).

sphere (DS) in the right eye and +1.00 DS in the left eye. The corrected distance visual acuity (CDVA) was 20/20 in both eyes. Corneal topography obtained with Orbscan II (Technolas Perfect Vision GmbH) revealed no inferior steepening or superior–inferior asymmetry and the anterior and posterior elevation maps were normal. Laser in situ keratomileusis (LASIK) was performed in the right eye, and a combination of LASIK treatment and inlay implantation was performed in the left eye. The Intralase 60 kHz femtosecond laser was used to make a 130 μm thick flap in the right eye and a 200 μm flap in the left eye. The Bausch & Lomb 217z excimer laser with eye tracking, including cyclorotational tracking, was used for LASIK ablation. The right eye was targeted for plano, and the inlay eye was targeted for −0.75 DS. The right eye surgery was uneventful. During the excimer ablation in the left eye, the patient had difficulty maintaining fixation on the coaxial microscope light source. As a result, inlay centration on the corneal vertex was difficult.

One week postoperatively, the uncorrected distance visual acuity (UDVA) was 20/20 in the right eye and 20/50 in the left eye. The CDVA in the left eye was 20/40 with a manifest refraction spherical equivalent of −0.50 D. Subjective refraction did not show any refractive astigmatism in the left eye. The uncorrected near visual acuity (UNVA) was Jaeger (J) 5 in the right eye and J4 in the left eye. The patient complained of double vision in the left eye. An illustration of his visual symptoms shows an image with lateral doubling or shadowing of the original image (Figure 1). It was not possible to register the position of the inlay by inspecting the corneal topography. The Acutarget Diagnostic Unit (Acufocus, Inc.) showed that the center of the inlay was 835 μm nasal and 53 μm superior to the pupil image center. The center of the inlay was also 593 μm nasal and 159 μm superior to the corneal vertex (Figure 2). Ocular wavefront measurements could not be obtained because the inlay obstructed the pupil.

Based on these findings, it was decided to recenter the inlay in the temporal direction, aiming for placement half way between the corneal vertex and the pupil center. The surgery was performed 2 weeks later. The flap was lifted and the inlay easily separated from the underlying stroma. While the patient was fixating on the coaxial light source, the inlay was repositioned temporally and slightly inferiorly (Figure 3). The width of the inlay ring body (3.8 mm or 3800 μm) was used as a gauge. The final placement was slightly superior to a distance equivalent to half the outer body ring.

One month after recentration, the UDVA was 20/30 in the left eye, the UNVA was J2, and all complaints of double vision were resolved. The diagnostic unit showed the new centration of the inlay (Figure 4).

Case 2

A 60-year-old man presenting for presbyopia correction was treated with LASIK in the right eye and LASIK treatment and inlay implantation in the left eye. The refraction was +1.75 −0.50 × 80 and +2.75 -1.25 × 105, respectively. The CDVA was 20/20 in both eyes. Corneal topography obtained with the OPD-Scan (Nidek Co., Ltd.) revealed a mean keratometric power of 43.02 D in the right eye and 42.94 D in the left eye (Figure 5). The corneal topography was normal.

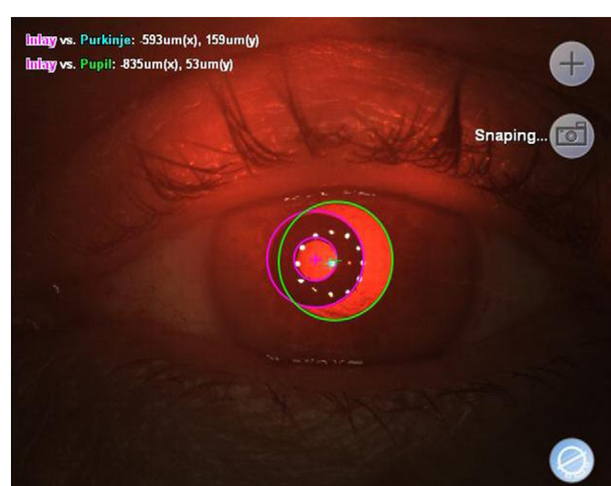


Figure 2. Case 1. Before recentration, the inlay is 593 μm nasal to the first Purkinje reflex and 835 μm nasal to the center of the pupil.

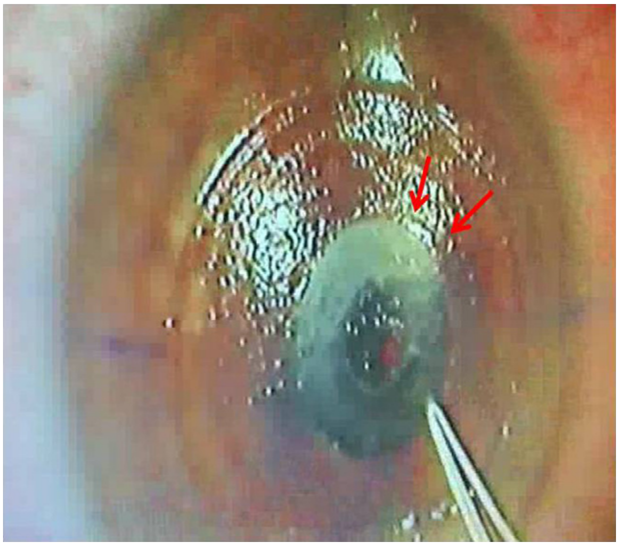


Figure 3. Case 1. Surgical view showing the stromal landmark of the previous inlay location.

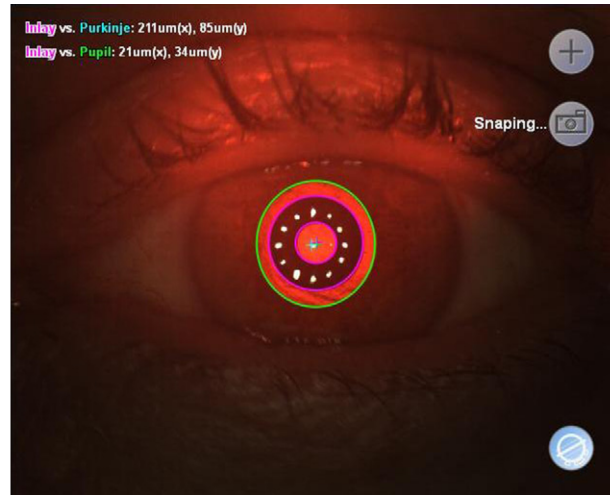


Figure 4. Case 1. After recentration, the inlay is almost directly over the pupil image center.

The Intralase 150 kHz femtosecond laser was used to make a 110 thickness flap in the right eye and a 200 μm flap in the left eye. The right eye was targeted for a postoperative refraction of plano and the left eye, for −0.75 DS. The Nidek Quest excimer laser was used for the excimer ablation. This laser was also equipped with eye tracking compensation similar to that used in Case 1. After the ablation was performed in the left eye, the inlay was centered on the corneal vertex. Both surgeries were uneventful.

Three weeks postoperatively, the UDVA was 20/20 in the right eye and 20/100 in the left eye. The CDVA was 20/50 with −0.50 DS in the left eye. The UNVA was J5 in both eyes. The patient complained of blurred and horizontal double vision in the left eye, and the diagnostic unit showed that the center of the inlay was 509 μm nasal and 27 μm inferior to the pupil image center. The center of the inlay was very close to the corneal vertex—72 μm nasal to the corneal vertex and 17 μm superior to the corneal vertex (Figure 6). It was decided to recenter the inlay between the center of the pupil and the corneal vertex, which required a temporal shift of the inlay by 250 μm.

One month after recentration, the UDVA was 20/25 in the left eye and the UNVA was J2. The final position of the inlay is shown in Figure 7.

DISCUSSION

The reports describe 2 patients who benefited from recentration of a small-aperture inlay due to unsatisfactory results after their primary surgery. One

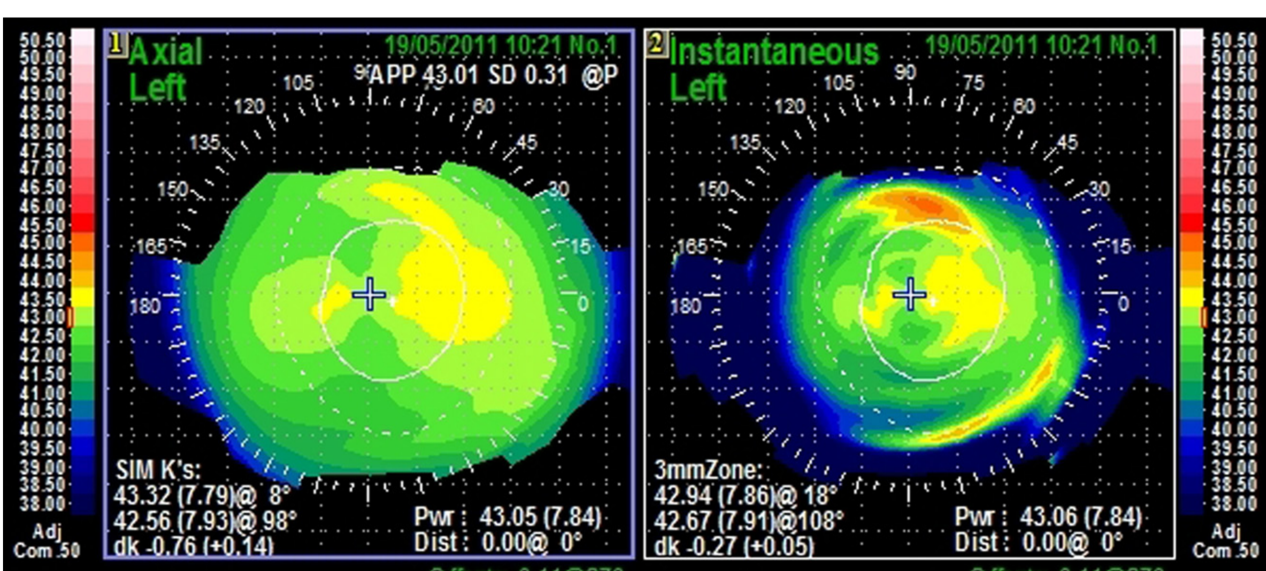


Figure 5. Case 2. Corneal topography shows a regular cornea without suspicion of keratoconus.

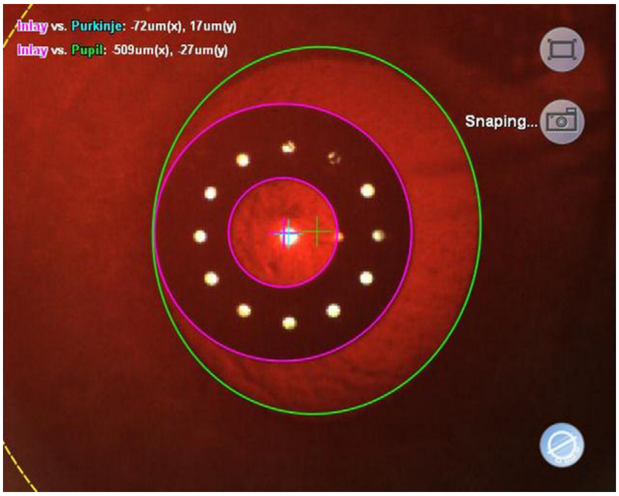


Figure 6. Case 2: Before recentration, the inlay is almost perfectly centered on the first Purkinje reflex.

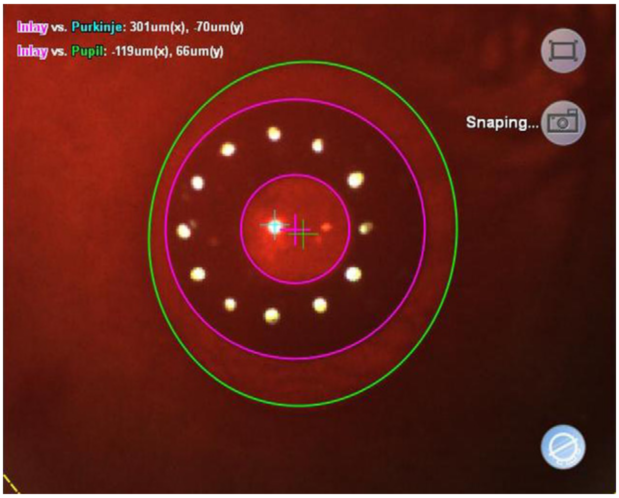


Figure 7. Case 2. After recentration, the inlay is positioned between the first Purkinje image and the center of the pupil.

advantage of the corneal inlay is the ability to recenter. However, as with LASIK, relifting a flap can increase the risk for infection or epithelial ingrowth,[11,12] so achieving proper inlay centration during the initial surgery is preferable.

In Case 1, decentered placement of the corneal inlay was partly caused by poor patient fixation during the surgery. The resulting inlay position was clearly distant from the intended position. During the recentration procedure, care was taken not to move the inlay while lifting the flap and to use the original inlay position as a landmark. The inlay was moved 600 μm temporally, which represented approximately one-sixth the total inlay diameter. The final position of the inlay was very close to the entrance pupil center. The post-recentration improvements in the visual acuity and symptoms were remarkable.

In Case 2, the small-aperture inlay was perfectly centered on the corneal vertex. However, the visual acuity was not satisfactory and the patient described typical symptoms of decentration such as monocular double vision. Recentration of the inlay between the corneal vertex and the entrance pupil center led to significant improvement in the quality of vision. In keratorefractive surgery, decentered ablations may be responsible for visually disabling side effects such as glare, ghosting, halos, loss of contrast, monocular diplopia, and irregular astigmatism.[13,14] Even if dramatic progress in the treatment of decentered corneal laser ablation has been made, the surgical correction remains a challenging problem.

It has been debated whether to use the entrance pupil center or the corneal vertex as the ideal reference for ablation centration.[15–17] The corneal light reflex has been described as the basis of centration techniques. The reflection of a light source by the anterior surface of the cornea creates virtual images behind the cornea, also known as the first Purkinje-Sanson image. The location of this image depends on the location of the light source and the patient's direction of gaze.

Pande and Hillman[10] have stated that the ideal physiologic centration point for keratorefractive surgical procedures is the corneal intercept of the visual axis, but it is difficult to identify this in clinical practice. Using a modified autokeratometer to photograph the corneas of 50 patients, Pande and Hillman concluded that the coaxially sighted corneal light reflex was the closest to the corneal intercept of the visual axis. They proposed use of the corneal light reflex for centration instead of the entrance pupil.

Determining the location of the corneal light reflex is instrument dependent, and simulations have shown that the location may change between preoperatively and postoperatively.[18] Uozato and Guyton[9] discounted this technique, emphasizing that the corneal light reflex may not be used because of errors arising from the angle lambda (ie, the angle between the line of sight and the pupillary axis of the eye). In eyes with a large angle lambda (which in practice can be considered equivalent to angle kappa), the location of the ophthalmometric pole may drift significantly from the corneal reflex.

In corneal excimer laser-based surgery, the prevailing method for centration is to use the center of the entrance pupil, which corresponds to the line of sight when the surgeon and patient are fixating coaxially. The inlay manufacturer recommends centering the inlay over the corneal vertex. However, in patients with a significant angle kappa, the inlay should be placed half-way between the corneal vertex and the center of the entrance pupil. To achieve optimal centration, the surgeon should try to identify the coaxial light reflex and its position versus the center of the entrance pupil. Additionally, use of the Acutarget Diagnostic Unit provides an objective measure of the distance and direction of first Purkinje versus the pupil center.

The diagnostic unit is designed to image corneal reflection of 12 light-emitting diodes (LEDs) arranged around a fixation target coaxial to the camera's charge-coupled device array. This arrangement ensures that patients are coaxial with the optical axis of the instrument when they are fixated on the target. During acquisition, 5 images are sequentially acquired and the centroid of the 5 images is stored to disk. During post hoc analysis, the coaxially sighted corneal reflex is determined as the center of the reflection of 12 LEDs. In addition, the pupil is fitted with a circle and the centroid of the pupil is determined. Based on the 2 measured reference points, distance between the coaxially sighted corneal reflex and the pupil is calculated. In the postoperative mode, the instrument is designed to use red light to retroilluminate the eye to visualize the inlay better against the red pupillary reflex; the coaxially sighted corneal reflex is also obtained, along with the inlay location and pupillary center.

The use of objective measurements based on the analysis of preoperative specular Placido disk-based topography, including pupil contour delineation, can assist with estimating the distance between the vertex and the pupil center.

Because of the reduction of the entrance pupil to 1.6 mm with the inlay, imprecise centration may not result in a significant increase in higher-order aberrations (HOAs), at least for entrance pupils smaller than the diameter of the inlay (3.8 mm). In cases involving a small pupil diameter, diffraction governs the optical quality of the eye. In mesopic conditions, the artificial 1.6 mm pupil created by the inlay may also reduce the optical disturbance caused by decentration. The Stiles-Crawford effect may also contribute to the reduced impact of peripheral light rays stimulating the fovea. Therefore, the primary cause of the visual symptoms reported by the 2 patients may not have been an increase in monochromatic wavefront HOAs (eg, defocus, coma, spherical aberration, astigmatism).

Similar to other refracting optical systems, the eye can experience chromatic aberration, longitudinal and transverse, both of which are caused by varying refractive indices for different wavelengths. Transverse chromatic aberration at the fovea varies among individuals but is usually less than 2 minutes of arc in most human eyes.[19–22] The optical transverse chromatic aberration can be measured as the chromatic difference of position between a red and a blue target viewed through a small centered pupil.[21] Hence, experiments have shown that controlled amounts of transverse chromatic aberration may be induced at the fovea by displacing an artificial pupil from the visual axis.[20,21] Transverse chromatic aberration affects contrast sensitivity, localization of visual direction, color vision, and stereopsis.[23] To quantify the magnitude of transverse chromatic aberration present at the fovea and the functional impact on vision, Rynders et al.[19] defined a secondary reference axis called the *foveal achromatic axis* because it defines the path of light rays passing through the eye to the fovea without experiencing the dispersive effects of chromatic aberration. This path, joining the nodal point to the fovea, was also considered a reasonable operational definition of the visual axis by Thibos et al.[21,22]

In the special case of a small-aperture inlay, any decentration from the achromatic axis may increase the level of transverse chromatic aberration. We may hypothesize that in the presented reports, the visual complaints of the patients were partly caused by increased transverse chromatic aberration at the fovea. The monocular diplopia and blur may have been caused by the relative defocus and laterally spread light rays of varying wavelengths emanating from the observed polychromatic sources. Better insight into the effect of the inlay on transverse chromatic aberrations may be required for ideal placement of the device. Further study may be necessary to investigate the relationship between the inlay centration relative to the natural pupil and subsequent effects on transverse chromatic aberration.

REFERENCES

1. Waring GO IV. Correction of presbyopia with a small aperture corneal inlay. J Refract Surg 2011; 27:842–845
2. Seyeddain O, Hohensinn M, Riha W, Nix G, Rückl T, Grabner G, Dexl AK. Small-aperture corneal inlay for the correction of presbyopia: 3-year follow-up. J Cataract Refract Surg 2012; 38:35–45
3. Dexl AK, Seyeddain O, Riha W, Hohensinn M, Hitzl W, Grabner G. Reading performance after implantation of a small-aperture corneal inlay for the surgical correction of presbyopia: two-year follow-up. J Cataract Refract Surg 2012; 37:525–531
4. Mandell RB. Locating the corneal sighting center from videokeratography. J Refract Surg 1995; 11:253–259
5. Le Grand Y, El Hage SG. Physiological Optics. New York, NY, Springer-Verlag, 1980; 72
6. Reinstein DZ, Archer TJ, Gobbe M. Is topography-guided ablation profile centered on the corneal vertex better than wavefront-guided ablation profile centered on the entrance pupil? J Refract Surg 2012; 28:139–143
7. Mandell RB. Optical zone centration in keratorefractive surgery [letter]. Ophthalmology 1994; 101:216–217; reply by M Pande, 217–219
8. Mandell RB, Chiang CS, Klein SA. Location of the major corneal reference points. Optom Vis Sci 1995; 72:776–784.

Available at: http://journals.lww.com/optvissci/Abstract/1995/11000/Location_of_the_Major_Corneal_Reference_Points.2.aspx. Accessed July 6, 2012

9. Uozato H, Guyton DL. Centering corneal surgical procedures. Am J Ophthalmol 1987; 103:264–275; correction, 852
10. Pande M, Hillman JS. Optical zone centration in keratorefractive surgery; entrance pupil center, visual axis, coaxially sighted corneal reflex, or geometric corneal center? Ophthalmology 1993; 100:1230–1237
11. Chan CCK, Boxer Wachler BS. Comparison of the effects of LASIK retreatment techniques on epithelial ingrowth rates. Ophthalmology 2007; 114:640–642
12. Caster AI, Friess DW, Schwendeman FJ. Incidence of epithelial ingrowth in primary and retreatment laser in situ keratomileusis. J Cataract Refract Surg 2010; 36:97–101
13. Doane JF, Cavanaugh TB, Durrie DS, Hassanein KM. Relation of visual symptoms to topographic ablation zone decentration after excimer laser photorefractive keratectomy. Ophthalmology 1995; 102:42–47
14. Gatinel D, Bains HS. Treatment of highly aberrated eyes using the NIDEK CXIII excimer laser. J Refract Surg 2010; 26:453–457
15. Applegate RA, Thibos LN, Bradley A, Marcos S, Roorda A, Salmon T, Atchison DA. Reference axis selection: subcommittee report of the OSA Working Group to establish standards for measurement and reporting of optical aberrations of the eye. J Refract Surg 2000; 16:S656–S658. Available at: http://www.vision.csic.es/Publications/Articles/Reference%20axis%20selection.-%20A%20subcommittee%20Report%20of%20the%20OSA%20standards.pdf. Accessed July 6, 2012
16. Applegate RA, Thibos LN, Twa MD, Sarver EJ. Importance of fixation, pupil center, and reference axis in ocular wavefront sensing, videokeratography, and retinal image quality. J Cataract Refract Surg 2009; 35:139–152
17. Salz JJ, Stevens CA, for the LADARVision LASIK Hyperopia Study Group. LASIK correction of spherical hyperopia, hyperopic astigmatism, and mixed astigmatism with the LADARVision excimer laser system. Ophthalmology 2002; 109:1647–1656; discussion by RR Krueger, 1657–1658
18. Bueeler M, Iseli HP, Jankov M, Mrochen M. Treatment-induced shifts of ocular reference axes used for measurement centration. J Cataract Refract Surg 2005; 31:1986–1994
19. Rynders M, Lidkea B, Chisholm W, Thibos LN. Statistical distribution of foveal transverse chromatic aberration, pupil centration, and angle ψ in a population of young adult eyes. J Opt Soc Am A Opt Image Sci Vis 1995; 12:2348–2357
20. Simonet P, Campbell MCW. The optical transverse chromatic aberration on the fovea of the human eye. Vision Res 1990; 30:187–206
21. Thibos LN, Bradley A, Still DL, Zwang X, Howarth PA. Theory and measurement of ocular chromatic aberration. Vision Res 1990; 30:33–49
22. Thibos LN, Bradley A, Zhang X. Effect of ocular chromatic aberration on monocular visual performance. Optom Vis Sci 1991; 68:599–607. Available at: http://journals.lww.com/optvissci/Abstract/1991/08000/Effect_of_Ocular_Chromatic_Aberration_on_Monocular.5.aspx. Accessed July 6, 2012
23. Bradley A, Glenn A. Fry Award Lecture 1991: perceptual manifestations of imperfect optics in the human eye: attempts to correct for ocular chromatic aberration. Optom Vis Sci 1992; 69:515–521. Available at: http://research.opt.indiana.edu/Library/Fry91/Fry1991.pdf. Accessed July 6, 2012

First author:
Damien Gatinel, MD

Fondation Ophtalmologique Adolphe de Rothschild, Paris, France