

LASEK

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Introduction

In LASEK, excimer laser stromal ablation is performed under a hinged flap of corneal epithelium. No microkeratome is used, and no stromal lamellar cut is made. In this chapter, we first summarize the history of LASEK and the rationale for LASEK. We then discuss preoperative evaluation and preparation, the standard surgical technique, postoperative management, pain management, potential complications, postoperative haze, and clinical results. In the Appendices you will find a sample LASEK consent form, information on LASEK instrumentation and a recipe for the preparation of autologous serum eye drops.

History

LASEK was first described in print by Dr. Massimo Camellin of Rovigo, Italy (Michela Cimberle, "LASEK may offer the advantages of both LASIK and PRK," Ocular Surgery News, March 1999, page 28). Dr. Camellin's LASEK acronym (for "laser epithelial keratomileusis") has become widely adopted. However, many surgeons, including the authors, now use "laser assisted sub-epithelial keratectomy" to more accurately describe the LASEK procedure.

In March 1999, Dr. Sunil Shah of Birmingham, England presented his technique and 6-month data for PRK with an epithelial flap at a meeting of the British Society of Refractive Surgery. His technique was essentially the same as that described by Dr. Camellin. In this study, subsequently published in the British Journal of Ophthalmology,¹ 36 patients had traditional PRK on one eye and PRK with epithelial flap on the other eye, with one-year follow-up. Less corneal haze was seen in the

Laser-assisted subepithelial keratectomy for low to high myopia and astigmatism

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Purpose: To evaluate the safety and efficacy of laser-assisted subepithelial keratectomy (LASEK) for the treatment of low to high myopia and astigmatism.

Setting: Solo private practice, Mountain View, California, USA.

Methods: Laser-assisted subepithelial keratectomy was performed in 146 eyes of 83 consecutive patients with myopia or myopic astigmatism using a VISX Star S2 excimer laser (72 eyes) or a Nidek EC-5000 excimer laser (74 eyes). The mean preoperative myopic spherical equivalent was -5.32 diopters (D) (range -1.25 to -14.38 D). Data were collected prospectively with a follow-up of 1 to 12 months. Outcome measurements included uncorrected visual acuity (UCVA), manifest refraction, best spectacle-corrected visual acuity (BSCVA), corneal haze, and complications.

Results: After 6 and 12 months, no eye lost 2 or more lines of BSCVA. After 6 months, the UCVA was 20/20 in 57% of eyes and 20/40 or better in 96%. After 12 months, it was 20/20 in 56% of eyes and 20/40 or better in 96%. No eye developed corneal haze that affected visual acuity. There were no serious or vision-threatening complications.

Conclusions: Laser-assisted subepithelial keratectomy was safe and effective in treating a wide range of myopia and astigmatism. The potential advantages of LASEK over laser in situ keratomileusis (LASIK) include the elimination of stromal flap complications and greater choice in patient selection. The disadvantages include varying degrees of pain for 2 days and blurry vision for several days postoperatively.

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Refractive surgery entered a new era with the introduction of the excimer laser.¹ While photorefractive keratectomy (PRK), the first excimer procedure, gave generally excellent results, postoperative pain and corneal haze limited its usefulness and acceptance.^{2–5} The subsequent development and widespread acceptance of laser in situ keratomileusis (LASIK) by patients and surgeons are well known.^{6–8} The main advantages of LASIK are postoperative comfort, rapid recovery of vision, and absence of corneal haze. However, numerous complications have been reported, most associated with the stromal flap.^{9–11}

In 1999, Massimo Camellin, MD, described LASEK (M. Cimperle, "LASEK May Offer the Advantages of Both LASIK and PRK," *Ocular Surgery News*, March 1999, page 28). While his acronym originally

stood for laser epithelial keratomileusis, Dr. Camellin and I now use laser-assisted subepithelial keratectomy to more accurately describe the procedure (personal communication, September 19, 2000). In LASEK, excimer laser stromal ablation is performed under a hinged flap of corneal epithelium. No microkeratome is used, and no stromal lamellar cut is made.

The purpose of this study was to examine the safety and efficacy of LASEK in a myopic/astigmatic population and discuss the potential role of the procedure in refractive surgery.

Patients and Methods

In this prospective study, 146 myopic eyes of 83 consecutive patients were treated by me with LASEK from January

2000 to July 2001 and followed for 1 to 12 months. The remaining 20 eyes of the 83 patients were excluded for the following reasons: 10 eyes were purposely undercorrected and 6 were left untreated for monovision; 1 had had LASIK; 1 had had PRK; 1 is scheduled for LASEK; and 1 remains untreated because the patient prefers the vision in the untreated contact-lens-corrected eye.

The preoperative myopic spherical equivalent (SE) ranged from -1.25 to -14.38 diopters (D): 16%, -1.25 to -3.00 D; 50%, -3.01 to -6.00 D; 25%, -6.01 to -9.00 D; and 9%, -9.01 to -14.38 D. The preoperative astigmatism ranged from 0 to $+4.5$ D. The mean patient age was 42 years (range 18 to 69 years); 41% of patients were men and 59%, women. Patients were initially selected because they were not good candidates for LASIK (thin corneas, steep corneas, epithelial basement membrane dystrophy, deep-set eyes, glaucoma filtering blebs, high myopia, or patient concern about the microkeratome). Eventually, as my preference for LASEK developed, all cases were treated by this method. Patients with connective tissue disease, severe dry eye, forme fruste keratoconus, a history of herpes eye infection, and uncontrolled diabetes or glaucoma were excluded.

The preoperative evaluation included general and eye medical histories, uncorrected visual acuity (UCVA), manifest and cycloplegic refractions, best spectacle-corrected visual acuity (BSCVA), slitlamp examination, keratometry, corneal topography, central corneal pachymetry, intraocular pressure, Schirmer test with anesthetic, dim-light pupillometry (Colvard pupillometer, Oasis), and dilated fundus examination. Daily-wear soft contact lenses were removed 1 week before examination, toric soft contact lenses 3 weeks before examination, and gas-permeable hard contact lenses 3 to 4 weeks before examination with follow-up serial refractions every 2 weeks until stable.

Each patient was informed about laser refractive surgery in general and LASEK in particular, comparing it to LASIK. Patients were required to read and sign a LASEK consent form and a separate consent for off-label use of the excimer laser. Investigational review board/ethics committee approval was not required for this study.

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Dr. Shahinian holds patents on dilute topical anesthetic agents for analgesia.

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Patients were instructed to discontinue eye makeup 3 days before surgery, use lid scrubs twice daily for 3 days before surgery, and discontinue perfume the day of surgery. Of the 73 patients who had bilateral LASEK, 11 had both eyes done on the same day and 62 had separate-day surgery. The interval between surgeries in these 62 patients was 1 week (62%), ≤ 2 weeks (80%), ≤ 1 month (95%), and ≤ 2 months (100%).

Preoperative medications consisted of diazepam (Valium®) 10 mg sublingually in most cases and ciprofloxacin 0.3% (Ciloxan®) and proparacaine 0.5% (Alcaine®) drops every 5 minutes $\times 4$. All procedures were performed by me. On the operating table, the eyelids were prepared with povidone-iodine 10% (Betadine®); a Tegaderm 1624W drape (3M Healthcare) was used to isolate the lashes. A lid speculum was inserted.

Under the laser operating microscope, a guarded 8.0 mm, 270-degree blunt trephine (Janach) was centered on the pupil, pressed downward, and rotated approximately 5 to 10 degrees to cut through the corneal epithelium, leaving a hinge at 12 o'clock. Next, an 8.5 mm retaining well (Janach) was centered on the trephine mark. This well was filled with a 20% alcohol solution prepared in the following manner: 1.0 cc of dehydrated 98% ethyl alcohol USP from a glass ampule for injection was mixed with 4.0 cc of preservative-free sterile water for injection and passed through a 0.2 μm filter into a 10 cc sterile multidose vial. The alcohol solution was prepared every 1 to 2 weeks and refrigerated until used.

After 35 seconds, the alcohol solution was removed from the well with a Merocel® sponge (Xomed Surgical Products). The eye surface was rinsed with several drops of balanced salt solution (BSS®). The peripheral cornea was dried with a Merocel sponge to reveal the trephine mark. A microhoe (Janach) was used to create the edges of the epithelial flap, moving along the trephine mark with a slight digging action, similar to the way one might use a garden hoe. If the flap edges did not elevate easily with this instrument, the alcohol well and solution were applied for an additional 10 seconds, the alcohol was removed, and the surface rinsed again. Next, the epithelial flap was elevated and gathered at its 12 o'clock hinge with an epithelial detaching spatula (Janach). To avoid creating tears in the epithelial flap, the basal lamina was carefully separated from Bowman's layer instead of the epithelium being separated from its basal lamina. The detaching spatula was used to remove epithelial debris or excess moisture from Bowman's layer.

Myopia or myopic astigmatism was treated with the Nidek EC-5000 excimer laser (74 eyes) or the VISX Star S2 excimer laser (72 eyes). Treatment parameters were as follows: VISX—6.0 mm treatment diameter (70 eyes) and 6.5 mm treatment diameter (2 eyes), 6 to 10 Hz. The manifest sphere (plus-cylinder format) was reduced by 10% (< -8.0 D), 15% (-8 to -10.0 D), or 20% (> -10.0 D), and the cylinder power was unchanged in plus-cylinder format. Nidek—6.0 to

Table 1. Uncorrected visual acuity over time.

Time Postop	UCVA (%)			
	≤20/20	≤20/40	≤20/80	≤20/200
1 day	0	10 (14/145)	68 (99/145)	97 (141/145)
1 week	12 (12/101)	78 (79/101)	—	—
1 month	36 (53/146)	95 (139/146)	—	—
3 months	50 (58/117)	95 (111/117)	—	—
6 months	57 (55/96)	96 (92/96)	—	—
12 months	56 (31/55)	96 (53/55)	—	—

6.5 mm optical zone, 6.8 to 8.0 mm transition zone. The manifest sphere (minus-cylinder format) was reduced 10% (< -8.0 D), 15% (-8.0 to -10.0 D), or 20% (> -10.0 D) and further reduced by 25% of the cylinder power. The cylinder power was increased by 25% of its value in minus-cylinder format.

Immediately after laser treatment, chilled BSS was dripped onto the cornea, approximately 10 drops for every diopter of correction. The epithelial flap was then returned to its approximate original position with a smooth epithelial replacement spatula (Janach). Unlike in LASIK, it was not necessary to align the epithelial flap precisely and the flap edges typically extended beyond their original position. A Soflens® 66 F/M, -0.5 D soft contact lens (Bausch & Lomb) was applied to the eye. Diclofenac (Voltaren®) drops and Ciloxan drops were instilled. The Tegaderm drape and eyelid speculum were removed, and the Betadine was rinsed off the eyelids. Epithelial flap and contact lens position were examined under the laser microscope.

Patients were examined by me, assisted by an in-office optometrist, at 1 and 4 days, 1 week, 1, 3, and 6 months, and 1 year, with additional visits as needed. The postoperative medications were fluorometholone 0.1% (FML®) and Ciloxan 4 times daily, ketorolac (Acular®) or Voltaren drops 4 times daily for 2 days, and artificial tears 4 times daily. Patients were also given tetracaine 0.05% drops (one-tenth the anesthetic concentration) and 2 hydrocodone and acetaminophen tablets (Vicodin®) to use as needed for pain. The contact lens was usually removed on the fourth postoperative day, although occasionally it was necessary to leave it in for an extra 1 to 2 days to allow complete epithelial healing.

If the refraction at 1 week was \pm plano, FML drops were continued 4 times daily for 1 month, twice daily for 1 month, and once a day for 1 month. For preoperative myopia > -8.0 D, FML once a day was extended for 1 to 3 months. If the refraction at 1 week was \geq +1.0 D, FML drops were discontinued and the refraction rechecked in 1 week. If the refraction remained \geq +1.0 D at 2 weeks, an 8.4/14.0 bandage soft contact lens (Ciba Vision) was applied and the eye checked in 1 to 2 weeks.

Retreatment was performed if the patient desired better vision after 4 months and the surgeon believed that retreatment was likely to improve the patient's function with acceptable risk. The surgical technique for retreatment was identical to the initial procedure except for the amount of laser treatment.

Information at postoperative visits was collected on data forms and included patient symptoms and comments, medications, UCVA, manifest refraction, BSCVA, and slitlamp examination with assessment of tear film and corneal haze. Haze was defined as barely discernible at the slitlamp (+0.5), easily seen but not affecting vision (+1.0), dense patches affecting vision (+2.0), dense haze partially obscuring iris detail (+3.0), and dense haze completely obscuring iris detail (+4.0).

Patient data were analyzed using the SCORE database program (Ajay Sanan, MD), with each eye considered separately. A chi-square test was used to compare the amount of haze in eyes with preoperative sphere less than or greater than 6.0 D of myopia.

Results

One day postoperatively, slitlamp examination showed a slightly gray epithelial flap under the bandage soft contact lens. If the contact lens was cleaned or exchanged on day 1, examination with fluorescein dye revealed a central area of fluorescein staining overlying a glassy smooth base with no laser stromal etching marks visible. This appearance suggests that an intact epithelial basement membrane overlies the ablated stromal surface. The central epithelium was healed in 88% of eyes by day 4 and in 100% by day 6.

The percentage of eyes with UCVA of 20/40 or better improved from 10% at 1 day to 78% at 1 week (Table 1). At 3, 6, and 12 months, the UCVA was 20/40 or better in 95% to 96% of eyes. At 3 months, the

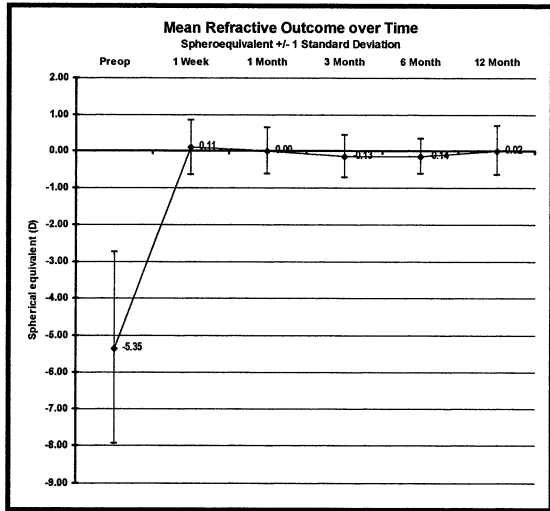


Figure 1. (Shahinian) Mean refractive outcome (SE) over time.

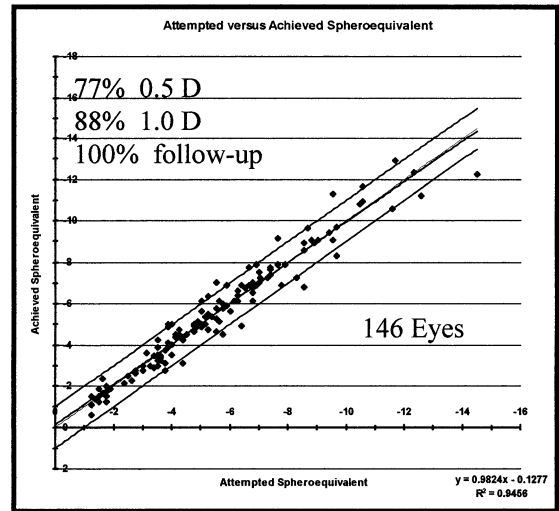


Figure 2. (Shahinian) Attempted versus achieved SE (D) 1 month postoperatively. The 4 lines represent ideal outcome, best fit, +1.0 D, and -1.0 D.

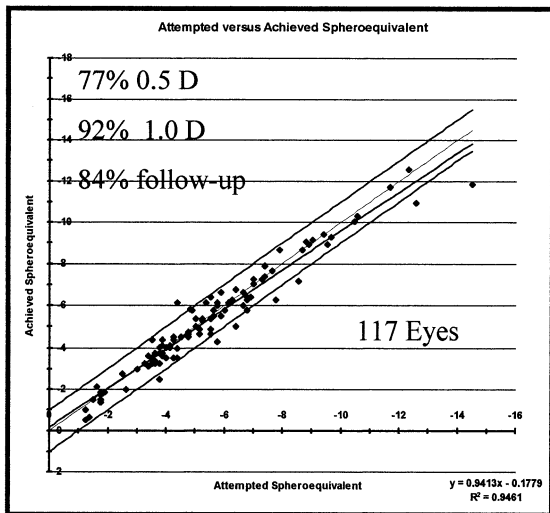


Figure 3. (Shahinian) Attempted versus achieved SE (D) 3 months postoperatively. The 4 lines represent ideal outcome, best fit, +1.0 D, and -1.0 D.

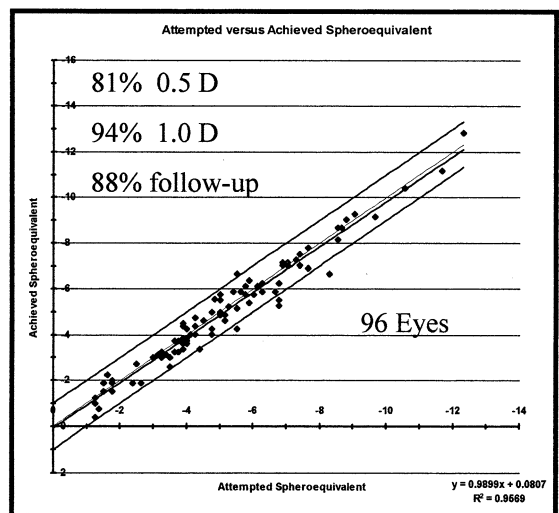


Figure 4. (Shahinian) Attempted versus achieved SE (D) 6 months postoperatively. The 4 lines represent ideal outcome, best fit, +1.0 D, and -1.0 D.

UCVA was 20/20 or better in 50% of eyes. This improved to approximately 57% at 6 and 12 months.

The mean refraction was stable and close to zero from 1 to 12 months (Figure 1), indicating no significant regression in the treated population.

Figures 2 to 5 show the attempted versus achieved SE at 1, 3, 6, and 12 months. Some overcorrections seen at 1 month were gone at 3 months. As seen in Figure 5, 3 eyes of 2 patients experienced late overcorrection.

No eye lost more than 1 line of BSCVA at 6 and 12 months (Table 2). At 3 months, 1 eye lost 3 lines of BSCVA (from 20/20 to 20/50). Corneal topography revealed a central island, which was traced to poor laser maintenance. The BSCVA in this eye spontaneously improved to 20/25 by 6 months.

The mean postoperative astigmatism was approximately one third of the preoperative value and remained stable from 1 to 12 months postoperatively (Figure 6). Figures 7 to 9 are double-angle plots showing the power

Table 2. Change in BSCVA over time.

Months Postop	Lines of Vision Gained or Lost (%)					
	-3	-2	-1	0	+1	+2
3	1 (1/117)	0	29 (34/117)	52 (61/117)	16 (19/117)	2 (2/117)
6	0	0	22 (21/96)	60 (58/96)	18 (17/96)	0
12	0	0	16 (9/55)	66 (36/55)	18 (10/55)	0

BSCVA = best spectacle-corrected visual acuity.

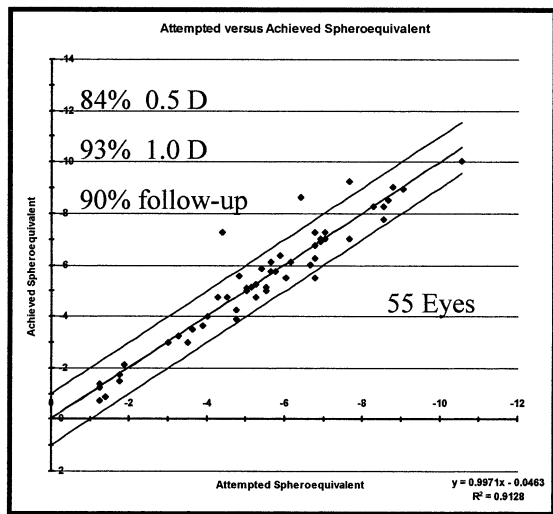


Figure 5. (Shahinian) Attempted versus achieved SE (D) 12 months postoperatively. The 4 lines represent ideal outcome, best fit, +1.0 D, and -1.0 D.

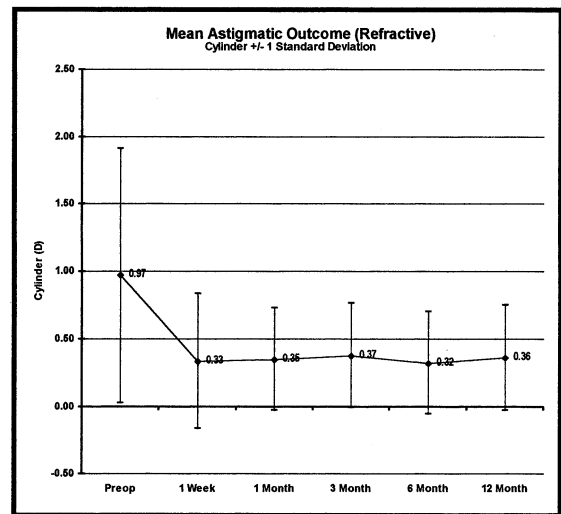


Figure 6. (Shahinian) Mean refractive astigmatism over time.

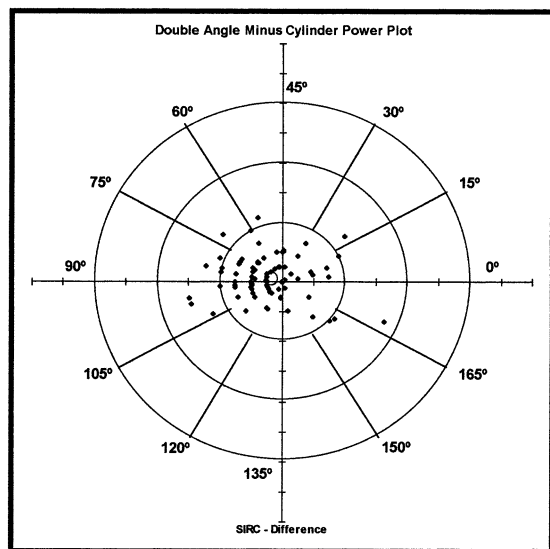


Figure 7. (Shahinian) Double-angle plot showing the SIA minus the TIA at 3 months. Each circle equals 1.0 D of astigmatism. The centroid is denoted by a small circle.

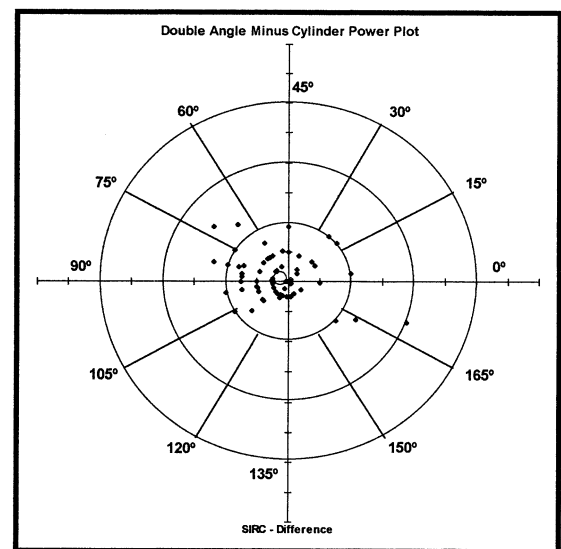


Figure 8. (Shahinian) Double-angle plot showing the SIA minus the TIA at 6 months. Each circle equals 1.0 D of astigmatism. The centroid is denoted by a small circle.

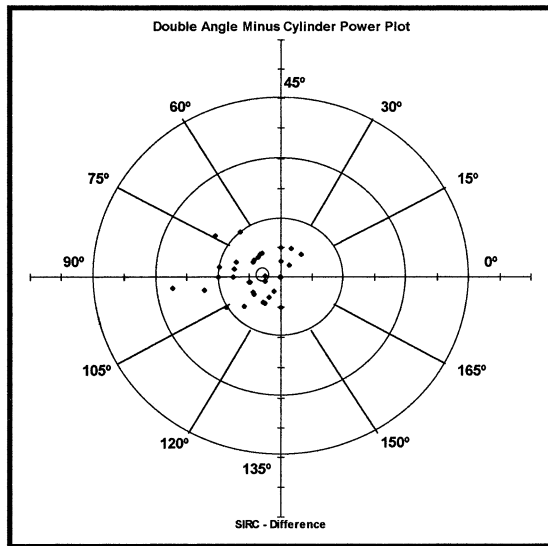


Figure 9. (Shahinian) Double-angle plot showing the SIA minus the TIA at 12 months. Each circle equals 1.0 D of astigmatism. The centroid is denoted by a small circle.

and axis of the surgically induced astigmatism (SIA) minus the target-induced astigmatism (TIA) at 3, 6, and 12 months.

Haze did not affect the visual acuity in any eye at any time. At 1 and 3 months, +0.5 haze was significantly more common ($P < .01$) in eyes with higher preoperative myopia (Table 3). No eye showed more than +1.0 haze.

Of the 55 eyes followed for 1 year, 3 were retreated once at 7, 10, and 10 months for an enhancement rate of 5.5%. The initial refraction in these 3 eyes before any

Table 3. Incidence and grade of corneal haze over time. Eyes with <6 D of myopia preoperatively are compared with eyes with >6 D preoperatively.

Months Postop	Preop Sphere (D)	Haze Grade, n (%)		
		0	+0.5	+1.0
1	<6	72 (84)	10 (12)	3 (4)
	>6	36 (60)	22 (37)	2 (3)
3	<6	56 (79)	14 (20)	1 (1)
	>6	23 (50)	21 (46)	2 (4)
6	<6	49 (89)	6 (11)	0
	>6	31 (77)	9 (23)	0
12	<6	22 (96)	1 (4)	0
	>6	23 (72)	7 (22)	2 (6)

0 = no discernible haze; +0.5 = haze barely discernible at slitlamp; +1.0 = haze easily seen but not affecting vision.

laser treatment was $-9.00 + 1.50 \times 83$, $-8.00 + 2.50 \times 80$, and $-2.00 + 1.50 \times 110$, respectively.

Minor corneal tear film changes, similar to those in epithelial basement membrane dystrophy, were seen postoperatively near the superior limbus in 48 of 146 eyes (33%). These changes were subtle, often transient, and did not affect vision. Five female patients with such changes noted minor symptoms at 3 to 12 months described as occasional pain if they opened their eyes too quickly in the morning, eye sticking in the morning, occasional scratchy sensation, slight pulling sensation, and slight foreign-body sensation, respectively. Sodium chloride 5% drops and ointment (Muro[®] 128) relieved these symptoms.

Twenty of the 146 eyes (14%) had small flap tears at the time of surgery. The tears did not appear to affect the surgical outcome.

Discussion

Based on these results, LASEK appears to be safe and effective for treating a wide range of myopia and myopic astigmatism. This procedure also appears to have some advantages over LASIK. First, LASEK is a safer procedure because all stromal flap complications are eliminated. Laser in situ keratomileusis complications related to the stromal flap include buttonhole,^{12,13} thick flap making full laser treatment impossible,¹⁴ decentered flap, incomplete flap,¹⁵ free cap, corneal perforation,¹⁶ optic atrophy,¹⁷ glaucomatous field loss,^{18,19} poor flap adherence,²⁰ poor epithelial adherence,^{21,22} striae,²³ epithelial ingrowth,^{24,25} flap melt,²⁶ diffuse lamellar keratitis (DLK),²⁷ secondary DLK,^{28,29} deep infections,^{30,31} interface blood or debris, late traumatic flap dislocation,³² and corneal ectasia.³³⁻³⁷ By eliminating these problems, LASEK significantly improves the risk/benefit ratio of refractive surgery.

Second, LASEK can be performed in cases in which LASIK may be contraindicated. These include patients with thin, steep, and flat corneas; epithelial basement membrane dystrophy; large pupils (requiring wider and therefore deeper ablations); high myopia; deep-set eyes or tight orbits; glaucoma; filtering blebs; scleral buckle; previous vitrectomy; optic nerve drusen; and activities increasing the likelihood of eye trauma postoperatively.

Preliminary evidence suggests that surface ablation procedures such as LASEK or PRK may give more ac-

curate results than LASIK when doing customized wavefront ablations.³⁸

Laser-assisted subepithelial keratectomy also has some disadvantages compared to LASIK. First, LASEK patients have varying degrees of discomfort in the first 2 days after surgery. A shortcoming of the current study is that postoperative pain was not quantified. This issue was addressed by Lee et al.³⁹ in a study in which PRK was performed in 1 eye and LASEK in the fellow eye of 27 patients with moderate myopia. The LASEK eyes had lower postoperative pain scores than the PRK eyes ($P = .047$). Most patients (63%) preferred the LASEK procedure.

Second, vision is somewhat blurry for the first 4 to 7 days after LASEK. Third, mild recurrent erosion symptoms are seen in a small percentage of LASEK patients. Finally, most LASEK patients require a longer course of postoperative steroid eyedrops than LASIK patients.

Several LASEK topics need further investigation. In the current study, no significant corneal haze was seen in LASEK eyes, even when treating up to -14.0 D of myopia. Lee et al.³⁹ found less corneal haze in LASEK eyes than PRK eyes ($P = .02$), although the follow-up was only 3 months. Shah et al.⁴⁰ found significantly less haze in LASEK eyes than in PRK eyes in 36 patients who were followed for 1 year after PRK in 1 eye and LASEK in the fellow eye. Despite these encouraging results, late-onset haze has been reported with PRK⁴¹ and could emerge as a problem with LASEK. Further studies with longer follow-up comparing haze with LASEK and PRK, ideally in the same patient, are needed.

The effect of the LASEK epithelial flap on stromal healing or remodeling after excimer laser ablation also needs more study. For years it has been known that stromal keratocytes disappear after corneal abrasion.⁴² Wilson et al.³⁸ recently suggested that these stromal changes are caused by cytokines released by the injured epithelium. An alternative mechanism was proposed by Zhao and coauthors,⁴³ who demonstrated that merely exposing the bare stroma to normal tears caused a loss of stromal keratocytes. Either hypothesis suggests a protective role for a layer of epithelium/basal lamina overlying the ablated stroma postoperatively as a tissue bandage. Confocal microscopy has been used to study and compare the healing responses of PRK⁴⁴ and LASIK⁴⁵ and might be a method to study the tissue-bandage effect of the epithelial flap in LASEK.

Finally, LASEK is an evolving procedure. If the partial devitalization of the epithelial flap caused by the alcohol solution could be avoided, there might be less postoperative pain and more rapid recovery of vision. Therefore, techniques for elevating the epithelial flap without using alcohol should be explored.

In conclusion, LASEK was effective in treating a broad range of myopia and myopic astigmatism. The procedure is safer than LASIK, can be used in some cases in which LASIK is contraindicated, and may be more adaptable to customized wavefront ablation. However, LASEK patients have more postoperative discomfort and slower recovery of vision and require more postoperative topical steroids than LASIK patients. A small percentage of LASEK patients have mild, recurrent erosion symptoms postoperatively.

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epithelial flap eyes.

Since the pioneering work of Camellin and Shah, many refractive surgeons have adopted LASEK. However, few surgeons perform this procedure exclusively, and LASEK still accounts for a relatively small percentage of all laser vision correction surgery. Two main factors account for this lack of wider acceptance. First, LASEK cannot match LASIK for postoperative comfort and rapid vision recovery. Second, some surgeons are not convinced that clinical results are any better with LASEK than with PRK.

Rationale for LASEK

Any examination of the rationale for LASEK must compare this procedure with LASIK and PRK.

As noted by the authors,^{2,3} LASEK is a safer procedure than LASIK because all stromal flap complications are eliminated. LASIK complications related to the stromal flap include buttonhole,^{4,5} thick flap making full laser treatment impossible,⁶ decentered flap, incomplete flap,⁷ free cap, corneal perforation,⁸ optic atrophy,⁹ glaucomatous field loss,^{10,11} poor flap adherence,¹² poor epithelial adherence,^{13,14} striae,¹⁵ epithelial ingrowth,^{16,17} flap melt,¹⁸ diffuse lamellar keratitis (DLK),¹⁹ secondary DLK,^{20,21} interface infections,^{22,23} interface blood or debris, and late traumatic flap dislocation.²⁴⁻³⁰ By eliminating these problems and greatly reducing the incidence of corneal ectasia,³¹⁻³⁵ LASEK significantly improves the risk/benefit ratio of refractive surgery.

Furthermore, LASEK can be performed in some cases where LASIK may be contraindicated, as in patients with thin, steep, or flat corneas, anterior basement membrane dystrophy, large pupils, high myopia, deep-set eyes or tight orbits, glaucoma, filtering bleb, scleral buckle, previous vitrectomy, and optic nerve drusen. LASEK may also be a safer procedure than LASIK when activities (for example, public

safety, contact sports, machining) increase the likelihood of eye trauma postoperatively.

Thus, while both LASIK and LASEK give excellent vision results in most patients, LASEK is emerging as a safer procedure with broader indications than LASIK. While LASIK remains the more popular procedure, the authors suspect that many patients do not adequately understand the risks of LASIK. Today there is an irrational exuberance for LASIK. It is worth remembering that stromal flap complications occur in approximately 4% of eyes.³⁶ Whenever safety issues are downplayed or ignored, there is a risk that when a change in attitude finally occurs, it may be sudden and wrenching, with significant financial and professional liability implications.

Comparing LASEK and PRK, considerable laboratory and clinical evidence suggests that less postoperative haze is seen with LASEK than with PRK. It has been known for almost 40 years that stromal keratocytes disappear after corneal abrasion.³⁷ Wilson and coworkers³⁸ suggested that these stromal changes are caused by cytokines released by the injured epithelium. An alternative mechanism was proposed by Zhao, Nagasaki, and Maurice.³⁹ They demonstrated that merely exposing the bare stroma to normal tears caused a loss of stromal keratocytes. Either hypothesis suggests a protective role for a layer of epithelium/basal lamina overlying the ablated stroma postoperatively as a tissue bandage.

The need to apply less laser treatment for LASEK than for PRK to achieve the same correction indicates a decreased stromal healing response in LASEK compared with PRK.

Choi et al⁴⁰ found that the application of amniotic membrane after PRK reduces keratocyte proliferation and corneal haze in a rabbit model, possibly by reducing the

infiltration of inflammatory cells and loss of keratocytes in the ablation area during the early postoperative period.

Confocal microscopy has been used to study and compare the healing responses of PRK⁴¹ and LASIK,⁴² and might be a method to study the tissue-bandage effect of the epithelial flap in LASEK.

As for clinical studies, Lee et al⁴³ found less corneal haze in LASEK eyes than PRK eyes ($p=.02$), although the follow-up was only three months.

Shah et al¹ found significantly less haze in LASEK eyes compared with PRK eyes in 36 patients who were followed for a year after PRK on one eye and LASEK on the fellow eye.

In a prospective study, Autrata and Rehurek⁴⁴ compared PRK in one eye with LASEK in the fellow eye of 92 myopic patients. They found significantly less haze in the LASEK eyes at 1, 3, 6, 12, and 24 months postoperative. In a subsequent study,⁴⁵ the same authors compared PRK and LASEK in a hyperopic population. Again they found significantly less postoperative corneal haze in the LASEK eyes over 2 years.

Astle, Huang, and coauthors⁴⁶ found less postoperative haze in a pediatric LASEK population than they had previously experienced with PRK.

While visually significant postoperative haze has been reported with both PRK and LASEK, the authors have the clinical impression^{2,3} that less haze is seen with LASEK, and the routine use of MMC can be avoided.

Preoperative Evaluation and Preparation

The patient's motives for LASEK should be carefully noted. It is important that patients have realistic expectations and a mature understanding of the potential risks and benefits of this elective procedure. Laser vision correction should be presented as a method to reduce rather than to eliminate the patient's dependence on glasses and contact lenses.

Preoperative evaluation should include general medical and eye history, contact lens history, corrected and uncorrected visual acuity, keratometry, corneal topography, photopic and scotopic pupil measurements, manifest and cycloplegic refractions, external eye and slit lamp examination, intraocular pressures, Schirmer tear test, corneal pachymetry, and dilated fundus examination.

LASEK should not be performed on persons:

- with herpes eye infection;
- with severely dry eyes;
- with excessive corneal scarring, keloid formation;
- with ectatic corneal dystrophies;
- with autoimmune disease, rheumatoid arthritis, systemic lupus erythematosus;
- with uncontrolled diabetes;
- taking Accutane or amiodarone (Cordarone);
- who are pregnant or are nursing, or who expect to become pregnant within six months following the LASEK procedure;
- who are not available for postoperative care or who have unrealistic expectations or a poor understanding of the procedure and its risks.

There may be additional contraindications.

Soft contact lenses should be discontinued one week before the examination. Toric soft lenses and hard contact lenses should be discontinued three weeks before the examination. For the latter group, serial refractions should be performed every two weeks until stable.

Although the patient should be given a detailed written consent (see Appendix A), that information accompanies but does not replace the surgeon's discussions with the patient before and after LASEK. Also, American surgeons should explain to their patients that LASEK is an off-label use of the excimer laser.

Makeup and perfume should be avoided on the day of surgery. Contact lenses should be removed three days prior to treatment. Patients with rosacea facial changes should be started on doxycycline 100mg BID one week preoperatively, continuing until there is good remodeling of the epithelial surface postoperatively. Surgeons can follow their usual regimen for preoperative sedation.

Standard Surgical Technique

Preparation of the 20% Alcohol Solution

1. Glass ampoule of dehydrated 98% ethyl alcohol injection, USP 1.0 cc
Available from: Priority Healthcare 800 348 5578
2. Sterile water for injection, preservative-free (or BSS) 4.0 cc
3. Mix the alcohol and water in a syringe. Pass the resulting 19.6% alcohol solution through a 0.2 micron filter into a 10 cc sterile multidose vial. Store refrigerated.
4. Draw up 0.4cc of the dilute alcohol solution in a tuberculin syringe, remove needle, push 0.1cc through cannula to clear any autoclave moisture and avoid further dilution.

LASEK Nomograms:

(Camellin/Shahinian) Visx (plus cylinder format) and Nidek (minus cylinder format):

≤8 D	10-15% off sphere (spectacle plane)
8-10D	15% off sphere
≥10D	20% off sphere
Cylinder:	Visx: treat full cylinder Nidek: increase by 25% and further decrease absolute value of sphere by 40% of cylinder
Hyperopia:	Visx: Decrease sphere by 20-30%

(Claringbold) Visx (plus cylinder format):

Step 1: Determine refraction at corneal plane (i.e. similar to fitting contacts):

- For refractions less than -4.75 D use manifest refraction
- For refractions greater than -4.75 D: With the patient still in the phoropter, the vertex distance to the corneal surface is measured using the phoropter side mirrors. Using a distometer wheel (House of Vision Inc., Chicago, Illinois) the patient's refraction at the corneal plane is determined.

Step 2: For patients <40 years of age, an additional 0.25 D is subtracted from the value determined in Step 1. For patients >40 an additional 0.5 D is subtracted from the value determined in Step 1. This value is used for the spherical correction.

Step 3: Cylindrical correction is treated for 100% of the value. (*All treatments performed in PLUS cylinder)

**Leave VISX default vertex at 12.5 mm **

These nomograms are general guidelines, and must be customized based on the individual surgeon's equipment, location, environment (especially operating suite temperature and humidity), and experience.

LASEK Instruments

See Appendix B

LASEK Procedure Steps, including specific pearls based on our experience:

1. Proparacaine 0.5% q5min x 5. The multiple doses are important to loosen the epithelium. Topical antibiotic. Oral sedation prn.
2. Betadine prep, 3M Tegaderm drape (1624W), lid speculum.
3. Drip ice-cold BSS onto the cornea, 50 drops.

4. Trephine the epithelium, centered on the pupil. Use 8.0 or 9.0mm, 270-degree dull trephine. Moderate downward pressure is applied to score the corneal epithelium. The trephine can also be slightly rotated. Because the blade extends only 270 degrees, a hinge is created at 12:00.
5. Center the alcohol cone (9.0 or 10.0mm) on the trephine mark, pressing down gently with uniform pressure to create a good seal.
6. Fill cone with 20% alcohol solution (approx. 0.1cc) for 30-40 seconds. Timing may be altered, depending on the patient (slightly longer for younger patients and contact lens wearers) and experience with the fellow eye. During the period of alcohol application, continuously observe the light reflex on the alcohol surface. Any movement of the light reflex indicates that a leak is occurring.
7. Remove alcohol from cone with Merocel sponge, allowing the alcohol solution to come up to the sponge rather than touching the delicate epithelium. Rinse cornea and conjunctiva with BSS.
8. Dry the peripheral cornea with a Merocel sponge to reveal the trephine mark.
9. Starting at 6:00, create the edges of the epithelial flap with the microhoe, pressing down; Bowman's membrane will not be damaged. Use short chopping strokes inferiorly, like a garden hoe. Use a sliding action temporally and laterally, like a capsulorhexis. Reapply well and alcohol for 10 seconds if flap edge is adherent.
10. Elevate the epithelial flap with the epithelial detaching spatula ("hockey stick" spatula) or bow dissector. It is important to press DOWN as you advance the spatula or dissector, to avoid separating the epithelium from its basement membrane. The flap will lift more easily if there is a narrower front to work with, that is, if the flap is brought in from the sides as you advance it from 6:00 toward 12:00. When using the bow dissector, STOP if the epithelium begins to move, as this indicates the epithelium is separating from its basement membrane. Do not continue with the bow dissector unless the basement membrane detaches easily from the underlying Bowman's. Care should be taken not to advance the dissection beyond the hinge. The epithelial flap is gathered on its hinge at 12:00 o'clock, exposing a glassy-smooth Bowman's membrane.
11. Sweep Bowman's with the same spatula to remove any epithelial debris or excess moisture.
12. Apply laser according to your nomogram. (NB: the bed (i.e. Bowman's) is smoother than the usual bed seen after a LASIK microkeratome incision. Care should be taken to assure the focal plane is indeed at the stromal surface.)
13. Immediately drip chilled BSS onto the cornea, about 10 drops for every diopter of treatment. Do not dry the cornea.
14. Replace the epithelial flap with the smooth epithelial replacement spatula. Unlike traditional LASIK, flap alignment is not critical. The flap usually overlaps the edges of its bed, but that is OK.
15. Apply a bandage soft contact lens (the authors' preference is the B&L Soflens 66, F/M).

16. Instill antibiotic and NSAID drops. Apply eye shield.

Postoperative Management

Patients use antibiotic eye drops QID until the epithelium is healed. Fluoromethalone is also started QID immediately postoperatively, continued for one month, and then selectively tapered. In one practice (TC), the fluoromethalone is tapered beginning at post-operative day 14 in mild to moderate myopes (< -5.00 D). A shield should be worn at night until the epithelium is healed and the bandage soft lens is removed, typically on postoperative day 4.

Eye cosmetics, strenuous exercise, gardening, and dusty environments should be avoided for one week after the procedure, swimming for two weeks.

The eye is examined the first day after LASEK. The central epithelial defect usually closes by day 4, although occasionally epithelial healing is delayed. Best visual acuity follows remodeling of the healed epithelial surface. Vision is often worse on days 2-3 than on day 1, but returns to approximately 20/20 to 20/30 by 7-10 days. Vision usually stabilizes within one month.

Initial overcorrections are common with LASEK. Refract all patients at one month. For low to moderate myopia, stop the steroid drops if there is overcorrection >0.5 D. For high myopia, stop the steroids if there is overcorrection > 1.00 D and recheck in 1-2 weeks. If overcorrection persists, consider inserting an 8.4/14.0 soft contact lens to induce regression. If refraction is near plano, restart the steroids, tapering one drop per day per month over 3 months. This regimen should be taken as a general guideline to postoperative steroid use, to be adjusted according to the individual surgeon's experience.

Pain Management

It is important that patients understand that some pain occurs in the first 24-72 hours after LASEK. Specific preoperative, intraoperative, and postoperative steps can be taken to minimize or eliminate the pain associated with LASEK.

Preoperative counseling of patients is a very important, if not *the most* important, step. One must be proactive in discussing the likelihood of postoperative pain with the patient. LASIK and LASEK patients will compare notes, and LASEK patients must have a clear understanding of what to expect postoperatively. Here is an example of what one might say to the patient preoperatively:

“You will likely have some discomfort for a day or two after your laser procedure. That’s one of the downsides of LASEK. Let me tell you about some specific steps we are going to take to manage any discomfort you might have, because there are some distinct advantages to LASEK and that’s why we are choosing this procedure.”

Preoperative medications include diazepam 5-10mg sublingually 30-60 minutes before the procedure. While a single dose of topical anesthetic (proparacaine or tetracaine 0.5%) is usually adequate for anesthesia, multiple doses help loosen the corneal epithelium, making it easier to elevate during surgery. This is in distinct contrast to LASIK, where minimal preoperative medication is used to protect the epithelium. Therefore, for LASEK we typically apply a drop of topical anesthetic every 5 minutes times 5, with an additional drop when starting the procedure.

Proper contact lens selection can minimize postoperative discomfort. Tight-fitting lenses should be avoided. Dr. Durrie⁴⁷ has demonstrated better results with low-water, non-ionic soft lenses. Our lens of choice is the Bausch and Lomb Soflens 66, F/M (flat medium base curve). This lens does not come in plano power, so we usually select a -

.50D lens. It is thin, fits flattened corneas well, and is easy to handle during insertion; in addition, it is flexible (so it doesn't pop out during healing). Alternative lenses include the Ciba Night and Day silicone hydrogel lens and the Biomedics 55 ocufilcon D lens (BC 8.9).

After surgery, let patients know the surgeon is on their team 100%. We give each patient our pager, cell, and home phone numbers and encourage them to reach us directly at any time with questions or concerns. We do not want a patient in pain to have to go through an answering service or the on-call doctor. Just as they are warned to expect some pain after LASEK, patients also know the surgeon is available if they need help.

Second, patients should limit their activities in the first 3-4 postoperative days. Excessive activity seems to be associated with more eye pain. Specifically, patients should avoid gardening, going out for dinner and evening entertainment, travel, and exposure to wind and dust (for example, cleaning out the attic). This admonition should be repeated on the second and third postoperative days, even if a patient is feeling better, as increased activity in the first 3-4 days seems to correlate with relapses of pain.

Third, check the bandage contact lens. A tight lens can cause pain. There should be 1-3mm of vertical lens movement with blinking. If no other reason can be identified when examining a patient with increased post-operative pain, simply exchanging the contact lens in the office can sometimes alleviate the discomfort. The contact lens should be left in place until the central epithelial defect is healed, usually 3-4 days. If only blotchy or punctate fluorescein staining remains, the eye is usually more comfortable with the contact lens removed. If the contact lens falls out at home, instruct patients not to try to reinsert the old contact lens but to return to the office for a new lens.

Fourth, there are specific therapeutic measures patients should use to reduce postoperative pain. Ice packs applied to the temples are sometimes helpful. Ibuprofen 400-600mg should be taken TID. Additionally, the patient is given 3 Vicodin tablets, to be used 1 PO Q4-6 hours for severe pain and/or to help with sleep the first night or two.

While topical nonsteroidal anti-inflammatory drops (NSAIDs) have been advocated to mitigate postoperative pain, some surgeons avoid these medications because of reported corneal complications.

We have found dilute topical anesthetics to be a useful adjunct in controlling postoperative pain in LASEK patients. Studies have shown that topical anesthetics at one-tenth their normal concentration have an analgesic effect without inducing anesthesia or toxicity.⁴⁸ These drops can be used as often as every 30 minutes for several days without apparent toxicity. Tetracaine preparations have proven to be more stable than proparacaine in dilute concentrations. A stabilized preparation of dilute (0.05%) tetracaine is available from Leiter's Pharmacy in San Jose, CA.

In summary, despite the advantages of LASEK, patients should be counseled to expect pain postoperatively. Intraoperatively, chilled BSS should be applied before and after laser ablation, and a proper bandage soft contact lens selected. Bonding with the patient, limiting activity, temple ice packs, contact lens management, oral pain medication, and dilute topical anesthetics are all important in ameliorating the postoperative pain and improving patient acceptance of this procedure.

Potential Complications

Intraoperatively, it is important to avoid alcohol leaks onto the conjunctiva, as that will cause postoperative pain. The risk of leaks is increased in patients with higher amounts

of astigmatism and care should be taken to apply even, downward pressure on the holding well. After the dilute alcohol solution has been instilled into the well, the surface meniscus should be carefully observed through the operating microscope for any movement or change in light reflex. If a substantial alcohol leak occurs, immediately remove the remaining alcohol from the well with a cellulose sponge, remove the well, and then thoroughly rinse the eye surface with chilled balanced salt solution (BSS). Reapply the well and alcohol solution if additional alcohol exposure is necessary to loosen the epithelium.

Small to moderate size tears in the epithelial flap do not impact the clinical result and can be ignored. If the epithelial flap is inadvertently detached from its hinge, care should be taken to reposit the flap in its original location, basement membrane down, following laser ablation. If the flap is badly damaged or lost, the operation is merely converted to PRK.

Potential postoperative complications include problems related to topical steroid use (glaucoma, cataract, ptosis), infection, mild recurrent erosion symptoms, delayed epithelial healing, and stromal haze.

Increased intraocular pressure can occur with fluoromethalone, and periodic pressure checks are mandatory as long as steroids are continued. A single case of fluoromethalone-induced cataract has been reported,⁴⁹ and that was after prolonged heavy dosage. This risk is greater in young patients. Infections have been reported after LASEK, but the incidence is unknown. The authors have not noted any infections during the immediate post-operative period in their respective practices. A low incidence of mild recurrent erosion symptoms without frank epithelial defect was reported in one series.³

Treatment options for delayed epithelial healing include bandage contact lens, patching,

artificial tears, punctal plugs, oral doxycycline 100mg BID, elimination of toxic eye drops (antibiotics, preservatives), and autologous serum eye drops.^{50,51}

Post-Operative Haze

Any discussion of surface ablation techniques such as LASEK needs to include the current concepts regarding post-surgical haze. One of the main concerns regarding PRK is that some patients develop visually significant corneal haze. Of particular concern is the sometimes severe haze that can develop 4-12 months after the procedure, which has been termed late-onset corneal haze (LOCH). New insight into the mechanism of haze formation has led to new prophylactic regimens and decreased risk of vision loss following laser vision correction.

After any surface ablation procedure, the *wound healing response* prior to epithelial healing is thought to play a significant role in the formation of haze.⁵² Stromal healing immediately after keratorefractive surgery occurs in three main phases.^{38,52} Various biochemical factors are released during these phases and can play a role in the development of LOCH. In the initial phase, keratocyte apoptosis is thought to initiate the healing response.⁵³ This response appears to be regulated by transforming growth factor- β 1 (TGF- β 1).⁵⁴ The second phase of healing is characterized by proliferation of the keratocytes adjacent to the wound area. These keratocytes transform into fibroblasts and migrate into the area of cell apoptosis.⁵⁵ During the third phase of stromal wound healing, fibroblasts may become myofibroblasts. The extent to which this occurs is thought to be related to the type of corneal wound as well as the amount of stromal tissue removed.^{56,57} These cells deposit extra-cellular matrix (ECM) material below the surface of the epithelium. The reflective properties of the ECM deposits are thought to be responsible for the development of LOCH.

Studies comparing LASEK to PRK indicate that the presence of the *epithelial flap* in LASEK may help protect the stroma during this early period of wound healing. Less TGF- β 1 is released in the early post-operative period following LASEK than following PRK⁵⁸. LASEK, which leaves the epithelial basement membrane relatively intact within the flap, creates less of a wound response and therefore may decrease the transformation of fibroblast into myofibroblasts. The authors speculate that the epithelial flap acts as a “tissue bandage” in the early post-operative period and plays a key role in the absence of LOCH in their personal LASEK results^{2,3}.

The association between *UV exposure* and the development of LOCH has recently gained increased acceptance. Alexander Stojanovic, MD of Tromso, Norway was first to report this connection.⁵⁹ Tromso is located above the Arctic Circle and therefore has periods when it is dark for 24 hours per day during the winter and light for 24 hours per day during the summer. Dr. Stojanovic reviewed 314 cases of PRK and found a 3.7% LOCH rate. When these cases were analyzed, they were found to all occur during the summer months and were correlated with increased levels of environmental UV radiation.

In an effort to prevent post-operative haze caused by UV exposure, Dr. Stojanovic studied the use of *Vitamin C prophylaxis*. The rationale for using Vitamin C was based on animal studies showing that diurnal animals had higher levels of ascorbic acid in their corneas compared to nocturnal animals. In particular, reindeer (an animal whose habitat is primarily above the Arctic Circle) had some of the highest levels found in nature. This observation has been interpreted as an environmental adaptation which protects the eye from UV radiation. Vitamin C has been ascribed a protective role as a UV filter as well as a scavenger of free radicals (i.e. anti-oxidant).

In a prospective study,⁶⁰ Dr. Stojanovic prescribed Vitamin C to all of his patients undergoing PRK or LASEK. Each patient received Vitamin C 500 mg BID orally for one-

week pre-operatively and two-weeks post-operatively. After one year, no patients (>250 PRK/ >100 LASEK) developed LOCH.

Bilgihan and coworkers⁶¹ have demonstrated a significant decrease in the normal levels of ascorbic acid in human tears during the first 5 post-operative days following all laser refractive procedures. These findings led us to utilize Vitamin C prophylaxis for high myopes (LS) or all patients (TC) undergoing LASEK. No studies have quantified the dose or time period to obtain maximum benefit from taking Vitamin C. Currently, our LASEK patients are asked to begin taking 1000 mg Vitamin C orally QD as soon as the decision to proceed with surgery is made. They are then asked to continue this regimen for at least 3 months after the procedure.

Mitomycin C (MMC) has been shown to be very efficacious when used to treat patients who have developed visually significant LOCH.⁶² Recently, MMC has also been proposed to prophylactically prevent the formation of post-operative haze.^{63,64} MMC's anti-neoplastic properties inhibit fibroblast function and proliferation. Early studies show that this use of MMC is safe and effective. However, anecdotal cases of complications due to incorrect dilution of the MMC, as well as over- and under-corrections from intended refraction have been reported. To date, no studies have demonstrated the long-term safety of MMC used in this setting. Currently, given the extremely low incidence of haze reported when LASEK is performed correctly (i.e. good epithelial flap creation and replacement) and when such prophylactic measures as oral Vitamin C and topical steroids are used appropriately, the authors do not advocate the prophylactic use of MMC in LASEK for the prevention of LOCH.

Clinical Results

Claringbold, in a retrospective, single-surgeon interventional case series,² reported outcomes of 222 consecutive eyes with myopia ranging from -1.25 to -11.25 diopters (D) and astigmatism up to +2.25 D treated with LASEK. Results were analyzed at 4 days, 2 weeks, 3 months, 6 months, and 12 months after surgery. Postoperatively, uncorrected visual acuity (UCVA) was 20/40 or better in 84% of eyes at Day 4 and in 98% of eyes at 2 weeks. In 84 eyes followed for 12 months, UCVA was 20/15 in 16 eyes (19.0%), 20/20 in 53 eyes (63.1%), and 20/25 in 15 eyes (17.9%). There was no loss of best spectacle-corrected visual acuity (BSCVA), and no eyes required retreatment.

In a prospective study,³ Shahinian reported LASEK results in 146 eyes with myopia (range -1.25 to -14.38 diopters) or myopic astigmatism. No mitomycin C was used. After 6 and 12 months, no eye lost 2 or more lines of BSCVA. After 6 months, UCVA was 20/20 in 57% and 20/40 or better in 96% of eyes. After 12 months, UCVA was 20/20 in 56% and 20/40 or better in 96% of eyes. No eye developed corneal haze affecting visual acuity. There were no serious or vision-threatening complications.

Taneri et al⁶⁵ reviewed literature reporting 21 LASEK series, 1,421 eyes in total. LASEK provided long-term stable results without serious complications such as infection or late haze formation. Postoperative discomfort and prolonged visual recovery until the epithelium closes remain the biggest disadvantages of LASEK compared to LASIK.

Summary

LASEK (laser assisted sub-epithelial keratectomy), first described in 1999, has proven to be a useful form of surface ablation. Visual results are comparable to those of LASIK. Most importantly, all stromal flap complications are eliminated. However, LASEK still represents a relatively small percentage of laser vision correction procedures, principally because it cannot match LASIK for postoperative comfort and rapid vision recovery.

Although corneal haze affecting vision has been reported after LASEK, the authors have seen no visually significant haze, treating up to -14D of myopia. Published comparative studies indicate that LASEK produces less postoperative haze than PRK.

While patient preparation, instrumentation, surgical technique, and postoperative management vary somewhat from surgeon to surgeon, the authors have detailed a specific approach designed to shorten the learning curve and aid the transition from PRK and LASIK to LASEK.

Appendix A Sample LASEK Consent Form

1. This consent form is provided as a sample only, on the assumption that each surgeon will develop a personal written consent.
2. This written consent does not replace the physician's responsibility surrounding the informed consent process, which includes discussions with the patient.
3. In both discussion and written consent, the surgeon may need to address patient-specific risks and benefits not covered in this sample consent.

4. There may be specific state requirements for informed consent which are not covered in this sample consent.
5. The surgeon's professional liability insurance carrier should be consulted for further input regarding what to include in the written consent form.

INFORMED CONSENT FOR LASER ASSISTED SUB-EPITHELIAL KERATECTOMY (LASEK)

Introduction

Laser Assisted Sub-Epithelial Keratectomy (LASEK) is a relatively new laser procedure to correct myopia, hyperopia, and astigmatism. The excimer laser has not been approved by the Food and Drug Administration (FDA) for use in LASEK. The FDA considers LASEK an "off-label" use of the excimer laser, an approved medical device. The FDA clearly states that it will not regulate the practice of medicine or the performance of the procedure by a physician. "Off-Label" usage of FDA-approved devices and drugs is commonly practiced by physicians without interference from the FDA and allows physicians to practice medicine in a manner they feel is most beneficial to their patients.

This consent form describes the diagnosis, procedure, alternative treatments, fees, possible risks and benefits of LASEK. Because LASEK is a relatively new surgery, there may be long-term effects not yet known or anticipated at this time. The material provided will help you make an informed decision on whether to choose LASEK. This information accompanies but does not replace our discussions before and after LASEK. You are encouraged to ask questions about the diagnosis, procedure, alternative treatments, fees, risks, benefits, descriptions, medical terms, and language in this consent form.

The Normal Eye, Myopia, Hyperopia, and Astigmatism

The cornea is the clear, dome-shaped window which forms the front wall of the eye. It acts as a lens to focus incoming light rays onto the retina, the light-sensitive tissue in the back of the eye.

In the normal eye, light rays are brought to a single sharp focus directly on the retina, resulting in clear

vision without glasses or contact lenses. Any deviation from this normal focusing is called a “refractive error.” Myopia, hyperopia, and astigmatism are different types of refractive errors.

In myopia or nearsightedness, the eye is longer than normal. The light rays come together at a point in front of the retina, and thus are out of focus on the retina. Distant objects appear blurry, whereas near objects may be seen clearly. Myopia affects approximately one-fourth of adults in the United States.

In hyperopia or farsightedness, the eye is shorter than normal. The light rays come together at a point behind the retina, and thus are out of focus on the retina. Both distant and near objects appear blurry.

In astigmatism, the curvature of the cornea (and therefore its focusing power) is not the same in the horizontal and vertical directions. Therefore, light rays entering the eye do not focus at a single point, causing distorted vision. Many people with myopia or hyperopia also have some degree of astigmatism.

Correction of Refractive Errors - Alternative Treatments

Eyeglasses remain the most common method of correcting vision. In myopia, a concave or “minus” lens causes the incoming light rays to diverge before they reach the cornea. The cornea, in turn, focuses these divergent light rays directly onto the retina, and vision becomes clear once again. In hyperopia, a convex or “plus” lens causes the incoming light rays to converge, bringing their focus onto the retina. Glasses are safe, relatively inexpensive, and usually well tolerated. To correct large refractive errors, glasses must be thick and may reduce or increase the size of the visual image by up to 25%.

Contact lenses correct myopia and hyperopia much like glasses. If fitted and used properly, they are effective and relatively safe for correcting myopia, hyperopia, and astigmatism. However, complications such as allergic reactions, infections, and mechanical injury to the cornea can sometimes occur with the use of hard or soft contact lenses.

Radial keratotomy (RK) is an incisional procedure to correct myopia and astigmatism. Deep (90% of corneal thickness) radial cuts, like the spokes of a wheel, are made in the cornea with a hand-held surgical knife. These incisions cause the peripheral cornea to bulge and the central cornea to flatten, thus correcting up to 6 diopters of myopia. Unstable results and other problems have caused this procedure to be largely abandoned.

Photorefractive keratectomy (PRK) uses an excimer (“x’-i-mur”) laser to reshape the front surface of the cornea. This argon fluoride laser was developed by IBM in the early 1980s to etch silicon chips. It was subsequently discovered that the laser can be used to cleanly and precisely reshape the cornea. The laser’s ultraviolet light pulses evaporate tissue without burning or cutting. The distribution of laser energy on the cornea is computer-controlled. With multiple laser pulses, the cornea is reshaped, making it optically correct for the eye. For every diopter of correction, approximately 10 microns of corneal tissue are removed. For example, correcting 5 diopters of myopia requires the removal of roughly 50 microns of tissue, about 10% of the corneal thickness (less than the thickness of a human hair!).

Laser-Assisted In Situ Keratomileusis (LASIK) is a modification of excimer laser PRK that is particularly effective for correcting moderate to high myopia, astigmatism, and hyperopia. In this procedure, a miniature precision-cutting device called a microkeratome is used much like a carpenter’s plane to create a hinged flap on the front surface of the cornea. This flap is folded back, and the underlying corneal tissue is reshaped with the same excimer laser used for PRK. The corneal flap is then replaced in its original position.

The main difference between LASIK and PRK is that the former does not disrupt the front surface of the cornea. LASIK may have several advantages. First, haze and regression (loss of effect) appear to be less of a problem with LASIK than with PRK in patients with high myopia and hyperopia. Second, steroid drops are only needed for one week instead of 4 months or longer after surgery. Third, vision recovers more quickly after LASIK than after PRK, and patients usually have less pain after LASIK. However, the use of a microkeratome in LASIK carries risks that do not occur with PRK. Complications with the creation and healing of the corneal flap can affect visual outcome.

LASEK - A Hybrid Procedure

In LASEK (Laser Assisted Sub-Epithelial Keratectomy), the excimer laser treatment is applied to the cornea under a flap of the superficial epithelium, or surface cells, of the cornea. The epithelial flap can be lifted without using a microkeratome. Thus, unlike LASIK, no deep cut is made in the cornea. LASEK is a hybrid procedure which creates less haze and regression than PRK and avoids the deep corneal flap complications of LASIK.

Epi-LASIK is the newest addition to the family of refractive procedures. This procedure is identical to

LASEK, except that the epithelial flap is created with a special microkeratome, making the application of a dilute alcohol solution (see “Procedure” page 4) unnecessary.

Preoperative Consultation and Patient Selection

The preoperative consultation with Dr. ----- and his staff provides an explanation of LASEK, its benefits, risks, and alternatives. Specialized testing determines your suitability for treatment. To allow accurate measurements, soft contact lenses must not be worn for at least one week prior to this appointment (3 weeks for toric soft contact lenses and gas permeable lenses).

LASEK is appropriate for individuals with myopia, hyperopia, and astigmatism who wish to be less dependent on glasses or contact lenses, and are willing to assume the risks associated with the procedure. Minimum age is 21 years. There should be no significant change in glasses or contact lens prescription for the previous 12 months.

Contraindications: The treatment should not be performed on persons:

- with herpes eye infection;
- with severely dry eyes;
- with excessive corneal scarring, keloid formation;
- with keratoconus;
- with autoimmune disease, rheumatoid arthritis, systemic lupus erythematosus;
- with uncontrolled diabetes;
- taking Accutane or amiodarone (Cordarone);
- who are pregnant or are nursing, or who expect to become pregnant within six months following the LASEK procedure;
- who are not available for postoperative care;
- who have unrealistic expectations or a poor understanding of the procedure and its risks.

Fees

The fee for LASEK is per eye. This fee includes preoperative assessment, the LASEK procedure, laser center charges, a royalty payment to the laser company, initial postoperative medications, and one

year of postoperative care. Additional eye medications and postoperative glasses or contact lenses are not included and are the patient's responsibility. Patients should be prepared to pay for LASEK, as it is not usually covered by health insurance or Medicare.

If a retreatment is performed by Dr. ----- within 18 months of the original surgery, the fee is ----- (depending on the laser used), payable to the laser center.

Preparation for Treatment

If you qualify and opt for LASEK, we will schedule the procedure. We recommend that patients take a few days off from work or school. We also recommend that you do not drive for a few days after the procedure. **Three days prior to surgery**, contact lenses must be removed and makeup and perfume discontinued.

The Procedure

LASEK is an outpatient procedure. Eye drops given a few minutes before treatment provide suitable anesthesia. No injections are necessary.

The patient is positioned under the operating microscope. The eyelids are held gently open with a speculum. The patient is asked to look at a fixation light in the microscope. The eye not being treated is covered during the procedure.

With the eye well anesthetized by drops, a trephine (circular marker) outlines the area of epithelium to be lifted. A dilute alcohol solution is then applied to the marked area for about 30 seconds. This allows the epithelium, or superficial cells of the cornea, to be lifted. The epithelial flap is then folded to one side, and laser energy is delivered through the microscope to reshape the front surface of the remaining cornea. The patient may hear a ticking sound as each laser pulse removes a small amount of tissue. A computer controls the distribution and number of laser pulses, based on the amount of myopia (or hyperopia) and astigmatism to be corrected. The actual laser treatment lasts about 30 to 90 seconds, during which time the patient must look at the fixation light. At the end of the laser treatment, the epithelial flap is returned to its original position. A thin soft contact lens is placed on the eye.

After the Procedure

There is usually mild to moderate irritation or foreign body sensation for 1-2 days after surgery. Serious pain is less likely after LASEK than after PRK. Pain medicine is provided as needed. Steroid and antibiotic drops are used for the first week, and steroid drops are used for several months in some cases. **To avoid dislodging the epithelial flap, it is extremely important not to poke or rub your eye in the first week after LASEK.** Cosmetics and strenuous exercise, gardening, and dusty environments should be avoided for one week after the procedure, swimming for two weeks.

The eye is examined the first day after LASEK, and on the fourth day the contact lens is usually removed. The eye is then checked typically at 1 month, 3 months, 6 months, and 1 year. Additional visits may be necessary. Vision is initially blurry after surgery, but typically shows marked improvement in the first week. Stable vision is usually achieved within 1-3 months.

Possible Benefits

The purpose of LASEK is to reduce your level of nearsightedness, farsightedness, and/or astigmatism in order to provide better vision than you now have without eyeglasses or contact lenses. Often, the procedure allows people to function most or all of the time without eyeglasses or contact lenses. However, excellent uncorrected vision cannot be guaranteed, especially when high degrees of myopia, hyperopia, or astigmatism are being treated, and some correction with glasses may still be necessary. The visual improvement may also have psychological benefits if you feel that you look better, or can function better, without glasses or with thinner glasses.

Potential Risks and Other Considerations

No surgical procedure is completely free of risk. It is not possible to list every complication that can occur, and there may be adverse reactions which are unknown at this time. Since glasses or contact lenses in general safely correct myopia, hyperopia, and/or astigmatism, you need to consider thoroughly if the risks of having the LASEK procedure outweigh the possible benefits.

1. Undercorrection or Overcorrection

It is not possible to completely predict how your eye will respond to this procedure. As a result, you may not achieve acceptable vision without glasses. In some cases, contact lenses may not be tolerated. In many cases, but not all, a second procedure can be done. It is also possible that your myopia may be overcorrected, resulting in farsightedness. If you are farsighted after LASEK, you may need eyeglasses for close as well as far viewing.

2. Presbyopia and Reading Glasses

Even if LASEK is successful in correcting your vision, you may require reading glasses sooner than you would otherwise. As a person grows older, the lens of the eye is less able to focus, and near vision becomes more difficult. This normal aging process is called presbyopia, a condition that can be alleviated with reading glasses or bifocal lenses. An advantage of being myopic, or nearsighted, is that it generally takes longer to be affected by presbyopia. The myopic person can usually remove his distance glasses to read. Therefore, if you do not have LASEK and remain myopic, you may not need additional reading glasses or bifocals until age 50 or older. If you have LASEK, you may need reading glasses in your early forties, as do most individuals who are not myopic. For farsighted patients, even if the laser corrects your distance vision, you will still need reading glasses typically in your early forties, as do most people with good distance vision.

3. Decrease of Best Corrected Vision

After LASEK, some patients find that their vision with the best eyeglass or contact lens correction is not as good as it was before the procedure with eye glasses or contact lenses.

4. Regression

In some patients the effect of LASEK treatment is partially lost over a few weeks to several months. In some, but not all cases, significant regression can be retreated.

5. Excessive Corneal Haze

Mild corneal haze occurs as part of the normal healing process after LASEK. In most cases, it has little or no effect on the final vision and can only be seen by the ophthalmologist with a microscope. Rarely, excessive haze could permanently decrease your vision. In some cases, a retreatment may be successful in removing the corneal haze.

6. Halo / Glare / Sensitivity to Light

Halo is an optical effect that is noticed primarily in dim light. As the pupil enlarges, a

second faded image is produced by the untreated peripheral cornea. Some patients who have undergone LASEK notice this effect especially while driving at night, and this can interfere with night driving. Some patients notice glare and increased or decreased sensitivity to light, usually improving with time. These symptoms may not completely go away.

7. Decentration

Significant decentration of the zone of treatment (the laser beam not centered on the pupil) can occur when the patient does not fixate correctly during surgery. Halo and blurry vision can result.

8. Irregular Laser Ablation

The excimer laser may not create a smooth tissue removal, leaving the vision distorted. In some cases, the distortion clears with time, and in others, retreatment may be possible.

9. Flap Damage or Loss

During the creation of the hinged flap of epithelium on the central cornea, the entire flap could come off. If this occurs, the flap can usually be repositioned at the end of the procedure. However, there might be more postoperative haze, similar to PRK.

10. Dry Eye

Dry eye is common following laser vision correction. It may be necessary to use artificial tears or to have punctal plugs inserted, a simple 5-minute office procedure.

11. Inconvenience Between Procedures

In the time between LASEK on the first and second eye, the two eyes may not work well together because of their temporary difference in refraction (glasses strength). If a contact lens is not tolerated on the unoperated eye, work and driving may be awkward or impossible until the second eye has had LASEK.

12. Steroid Side Effects

Steroid eye drops are often needed for a few weeks to several months after LASEK to reduce corneal haze and prevent regression. Potential side effects of these steroid eye drops include clouding of the lens inside the eye (cataract), drooping of the eyelid (ptosis), and increased eye pressure, resulting in optic nerve damage (glaucoma) in rare cases. The occasional pressure rise can usually be treated with additional eye drops. The pressure returns to normal when the steroid eye drops are

discontinued. Cataract is extremely rare with this steroid dosage. Ptosis has occasionally persisted for several months after steroid treatment.

13. Rare Complications and Unknown Risks

Other reported complications include: endothelial cell loss (loss of cell density in the inner layer of the cornea), possibly leading to corneal swelling and poor vision; ptosis (droopy eyelid); contact lens intolerance; unstable corneal shape; fluctuating vision; allergic reaction to drops or oral medications. If the cornea is severely damaged, a corneal transplant using a donor cornea might be necessary. As with any eye procedure, there is a remote possibility of severe infection, drug reaction, or other rare complication which could cause chronic pain, an unsightly eye, or partial or complete loss of vision. Because LASEK is a relatively new procedure, there may be other risks to vision and health that are still unknown and unanticipated.

Summary

I have read this Informed Consent for Laser Assisted Sub-Epithelial Keratectomy (LASEK) and I fully understand it, including the possible risks, complications, and benefits that can result from the treatment.

Specifically, I understand the following (a summary of this Informed Consent):

1. That Laser Assisted Sub-Epithelial Keratectomy (LASEK) is an “off-label” surgical procedure that reshapes the cornea with an excimer laser under an epithelial flap to reduce or eliminate myopia, hyperopia, and astigmatism.

2. That the results of the procedure cannot always be predicted, nor the safety guaranteed. I may still need corrective eyeglasses or contact lenses to achieve satisfactory vision after LASEK. Contact lens fit may not be possible in some cases.

3. That alternative treatments such as PRK and LASIK have been explained to me.

4. That complications from the procedure, such as under- or over-correction, decrease of best-corrected vision, dry eye, corneal haze or swelling, regression, haloes, glare, change in sensitivity to light,

fluctuating vision, and ptosis (droopy eyelid), can occur. Retreatment may be possible to attempt to achieve satisfactory uncorrected vision. As with any eye procedure, there are remote risks such as severe infection and partial or complete loss of vision. Because LASEK is a relatively new procedure, there may be other unknown and unanticipated risks.

5. That if LASEK is reducing my myopia, I may need reading glasses sooner than I would if I were to remain nearsighted. If LASEK corrects my hyperopia for distance vision, I will still need reading glasses, usually by my early forties.

6. That LASEK is an elective procedure. I do not have to have this operation.

7. That it is important to protect the operated eye from rubbing and poking.

8. That I am expected to return for scheduled follow-up visits 1 day, 4 days, 1 month, 3 months, 6 months, and 12 months after the procedure. Additional visits may be necessary. Beyond this one-year follow-up, routine eye check-ups are important to help assure good vision.

9. That if there is a time interval between LASEK on my first and second eye, inconvenience and visual discomfort may result from having a temporary difference in refraction in my two eyes as a result of having had LASEK on one eye.

10. That I will be charged a fee for LASEK which includes postoperative care for one year. There will be additional charges for medications, contact lenses, and glasses after the procedure, and for postoperative visits after one year. Health insurance and Medicare do not usually cover LASEK.

The procedure of Laser Assisted Sub-Epithelial Keratectomy (LASEK), along with the alternative treatments, advantages and disadvantages, risks and possible complications of this procedure, have been explained to me by the doctor. Although it is impossible for the doctor to inform me of every possible complication that may occur, the doctor has answered all my questions to my satisfaction.

I understand that information gathered about my procedure and postoperative course may be used to further study the safety and efficacy of the procedure. I give permission for my case to be presented at scientific meetings or published in scientific journals, as long as I am not identified by name.

I give permission to be photographed by still camera, movie camera, or videotape, and for these photographs to be shown at scientific meetings or published in scientific journals, as long as I am not identified by name.

I wish to have Laser Assisted Sub-Epithelial Keratectomy (LASEK) performed on my _____ eye (s).

Patient's Signature _____

Patient's Name (printed) _____

Date _____ Time _____ Place _____

Witness's Signature _____ Date _____

Witness's Name (printed) _____

Appendix B LASEK Instruments

1. E. Janach srl, via Borgovico 35, Como 22100, Italia
Tel 011 39 031 574 088 Fax 011 39 031 572 055 www.janach.it
Email: international@janach.it

We also highly recommend their CDROM by Dr. Camellin, an excellent introduction to LASEK.

Instruments can be ordered directly from Janach or from
MAXWELL MEDICAL exclusive U.S. reseller

Mr. Mack Maxwell
316 Daylily Drive, Lexington SC 29072
Tel 803 356 3188 Fax 803 356 0400
e-mail mmax@usit.net

2. Katena Products, Inc., 4 Stewart Court, Denville, NJ 07834
Tel 800 225 1195 Fax 973 989 8175 www.katena.com

Katena LASEK Instruments (Selected)

K2-7810 LASEK Epithelial Trephine, 8mm
K2-7812 LASEK Epithelial Trephine, 9mm

K3-1830 Shahinian LASEK Alcohol Well, 9mm
K3-1832 Shahinian LASEK Alcohol Well, 10mm

K3-1840 Sloane LASEK Micro Hoe
K3-1845 Sloane LASEK Epi Peeler
K3-1855 Sloane LASEK Flap Repositor

K7-3805 LASEK Alcohol Cannula, Olive Tip

K9-2026 Sterilizing Case for LASEK Instrument Set
Shahinian LASEK Alcohol Well



Features dual fixation rings for a tight seal and is cone-shaped to provide maximum visibility for the surgeon while centering the instrument over the precut flap. The handle is mounted at a 55° angle for applying direct pressure on the ring to ensure a secure seal.

Janach LASEK Instruments (Selected)

Camellin Epithelial Trehphine 8mm (J2900) and 9mm (J2901)



Shahinian Alcohol Well 9mm (J2907) and 10mm (J2908)



Camellin Epithelial Microhoe J2915A



Camellin Epithelial Detaching Spatula J2910A



Camellin Bow Dissector J2930A



Camellin Flap Replacement Spatula J2920A



LASEK Sterilization Tray J4715

Appendix C Preparation of 20% Autologous Serum Eye Drops

Draw 10cc of patient's blood using plastic BD Vacutainer tube with clot activator. (The clot activator consists of silica beads sprayed over the inside of the tube. The interior of the tube is sterile.)

Gently invert the tube 5 times to expose the blood to the clot activator. Do not shake like a cocktail, to avoid hemolyzing the red cells.

Allow Vacutainer tube to sit upright for 30-60 minutes, until clot forms. As clot retracts, it pulls the silica into the clot. Serum is free of silica.

Spin the red top tube down to obtain the serum.

Using sterile technique, pop the nipple off a new 15cc bottle of BSS (Alcon) and draw off 3cc of solution.

Remove the stopper from the red top tube and draw off 3cc of serum. Inject this serum into the BSS bottle. Reinsert the nipple of the BSS bottle.

This procedure creates a 20% solution of autologous serum in BSS, that can be used as an eye drop.

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