

Improvements in pain management aid surface ablation outcomes

Newer technologies and certain nonsteroidal anti-inflammatory drugs have allowed surgeons to offer superior results.

by **Ming Wang, MD, PhD, and Tracy S. Swartz, OD, MS, FFAO**

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The field of vision correction has undergone significant enhancements since the 1990s introduction of photorefractive keratectomy. Changes include new imaging technologies such as wavefront and corneal imaging, new applications of such technologies and an increased understanding of the biomechanical effects of keratorefractive surgery.

Use of advanced wavefront technology in ablative procedures has resulted in a resurgence of surface ablation, including PRK, epi-LASIK and LASEK. LASIK with conventional microkeratomes covers the detailed ablation patterns with a relatively thick flap, essentially eliminating the benefit of wavefront ablation. Although this is lessened using

subbasal nerve density after LASIK compared to PRK has also been reported. Three years after LASIK, a 3.4% reduction was found compared with a nearly unchanged subbasal nerve density after PRK. The reduction of corneal nerve regeneration and the actual number of fibers noted in post-LASIK patients were not found in patients post-LASEK.

Thus, many surgeons are increasing the amount of surface ablations to alleviate dry eye complaints postoperatively. In addition to the dry

a thin sub-Bowman's flap created with the femtosecond laser, surface ablation appears to lead to the best outcomes compared with LASIK.

Topography has also become more robust to assess more aberrant eyes. Originally used to demonstrate corneal curvature, new technologies address curvature and shape, as well as optical pachymetry. Highly detailed pachymetry maps (Figure) may indicate early keratoconus in patients seeking LASIK, and such irregularities may result in increased surface ablations to avoid ectasia after elective surgery.

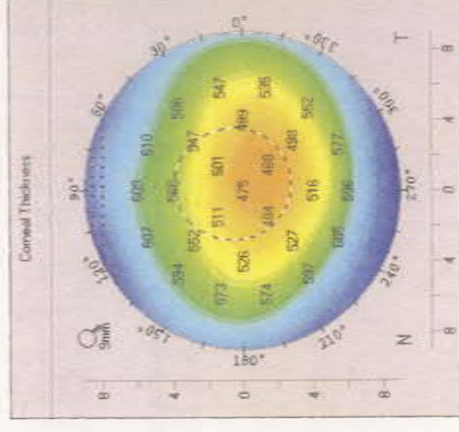
Increased understanding of biomechanics

These advancements in technology have increased our understanding of the posterior surface and corneal biomechanics after keratorefractive surgery. PRK was initially used with excimer lasers, and the associated pain and risk of corneal hazing are well-known. The haze results from damage to the epithelium and stroma simultaneously during the procedure, resulting in cross talk between the stromal keratocytes and epithelial cells.

Historically, LASIK was preferred because of the quick visual recovery, significantly less pain and patient convenience. Increased understanding of the biomechanics of flap creation and ectasia after LASIK, in addition to the dry eye and complications from manual microkeratomes, led to increased use of femtosecond lasers for flap creation and a resurgence of surface ablation.

Complications from LASIK, although rare, include dry eye, corneal weakness, ectasia and questionable corneal flap adhesion. Dry eye continues to be the most common complication from LASIK. Up to 37% of patients without pre-existing dry eye will be symptomatic 6 months after LASIK. Flap creation causes damage to corneal nerves, which may not regenerate to their preoperative level. Total disappearance of the subepithelial nerve layer at 1 month after LASIK has been reported.

Prolonged recovery of corneal



A pachymetry map revealing early keratoconus. Image: Wang M, Swartz TS

100 µm may produce less biomechanical changes and dry eye. The reliability of flap thickness makes them safer for those with thin cor-

44 Dry eye continues to be the most common complication from LASIK. 77

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eye complications, LASIK has been found to be less stable long term because of the severance of collagen fibers. This is illustrated by the displacement of flaps years after surgery. The National Institute for Health and Clinical Excellence reported the main problem with LASIK was long-term risk of corneal ectasia.

To avoid these complications, many surgeons have turned to laser-created flaps. Femtosecond laser planar flaps are clearly advantageous over meniscus flaps created by conventional microkeratomes. The creation of thin flaps less than

neas and prevention of ectasia. Wavefront ablations after laser-created flaps were found to lead to faster recovery, better uncorrected vision and better corneal sensitivity compared with treatments using conventional microkeratomes.

Unfortunately, the femtosecond lasers are expensive, enticing other surgeons to turn to advanced surface ablation techniques: PRK, LASEK and epi-LASIK. The application of wavefront to refractive surgery in conjunction with improved pain management alternatives has also

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TASS prevention

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intraocular inflammation, occurring with implantation of a particular IOL after cataract extraction.

Antibiotic prophylaxis as a possible culprit

Another possible culprit in the development of TASS is the use of intracameral antibiotic prophylaxis, Dr. Kertes said. He noted that toxicity can result because of improper administration of antibiotics due to an error in drug concentration or the use of preservatives or solutions with which the antibiotics are mixed.

Ophthalmic surgeons must be informed when the hospital pharmacy or the medication supplier has made any changes to the medications or solutions, Dr. Kertes said.

"The doctors, the residents, the fellows, the nurses, staff who clean instruments, the hospital pharmacist and the pharmaceutical representatives all need to be aware of the complications that can occur with TASS and that changes to any processes are not trivial," he said.

As with endophthalmitis, the most effective means of minimizing the burden of TASS is through its prevention, Dr. Kertes said.

For more information:

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Improvements

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increased surgeons willingness to return to surface ablations.

Epi-LASIK, which uses an epithelium keratome to remove the epithelium along Bowman's membrane, has the advantages of LASIK and PRK without the disadvantages of either. Without a stromal flap, fewer higher-order aberrations are induced. Patients who underwent LAASEK or other surface ablations report fewer

astigmatism asymmetry, and corneal scarring secondary to contact lens wear.

Using an effective nonsteroidal anti-inflammatory drug such as bromfenac to control pain enables us to do what we feel is in our patients' best interest without disrupting their daily lives and decreasing the "wow factor" of elective surgical vision correction.

For more information:

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4 Newer technologies and better medical management of postop discomfort have allowed us to offer superior results with patient safety in mind.

— Ming Wang, MD, PhD, and Tracy S. Swartz, OD, MS, FAAO

night vision problems, including smaller starbursts, and have better contrast sensitivity than those after LASIK. Mild corneal opacities are easily treated using surface ablations as well.

We were impressed with the effect on pain postop started soaking the bandage contacts in bromfenac before placing the lens on the eye after the surface ablation, which has dramatically decreased patients' discomfort during the first 24 hours. Many of our patients report not needing oral pain medications. We have found the postop day 1 visual acuities after PRK to be significantly better such that we now warn our patients that their vision may actually dip slightly due to healing on day 2 or 3. This has greatly reduced the amount of calls after-hours as well.

Newer technologies and better medical management of postop discomfort have allowed us to offer superior results with patient safety in mind. Surface ablation is often the preferred method of elective visual correction in cases of mild dry eye, corneal irregularities or mild

ing schedule, our patients are more compliant and therefore more comfortable over the early postop course.

Patients more compliant, comfortable

At our center, we have increased the number of surface ablations we perform because of our experience with Xibrom (bromfenac ophthalmic solution 0.09%, Ista Pharmaceuticals), which we use both intraoperatively and postoperatively to control pain.

Conductive keratoplasty procedures, which cause considerable discomfort, initially led us to investigate topical pain management. Use of Acular LS (ketorolac tromethamine ophthalmic solution 0.4%, Allergan) and Nevanac (nepafenac ophthalmic suspension 0.1%, Allcon) did not significantly reduce patients' discomfort, and we noted slower healing of the epithelial defects in patients using nepafenac.

Contributions

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WAVEFRONT-GUIDED LASIK INDICATIONS AND INTERESTED USERS:

The VISX STAR 54 R™ Excimer Laser System and Wavefront System are approved to perform wavefront-guided laser assisted in-situ keratomileusis (LASIK) treatments for the reduction or elimination of low to moderate myopic astigmatism to -6.00 D MRSE, with cylinder between 0.00 and -3.00 D in patients 21 years of age or older, and in patients with documented evidence of a change in refractive error to be treated that is greater than 0.50 D in both cylinder and sphere components for at least one year prior to the date of pre-operative examination.

Wavefront-guided LASIK for correction of low to moderate myopic astigmatism is an elective procedure with the alternative including, but not limited to, eyeglasses, contact lenses, photorefractive keratotomy (PRK), conventional LASIK, and other refractive surgeries. Approval of the use of wavefront-guided LASIK for correction of low to moderate myopic astigmatism is based on a clinical trial of 351 eyes with 172 patients. The study included 100 eyes with 50 patients with documented evidence of a change in refractive error to be treated that is greater than 0.50 D in both cylinder and sphere components for at least one year prior to the date of pre-operative examination. The study showed that of 102 eyes with 51 patients with documented evidence of a change in refractive error to be treated that is greater than 0.50 D in both cylinder and sphere components for at least one year prior to the date of pre-operative examination, 97 eyes (95.1%) were corrected to 20/40 or better, and 66.2% were corrected to 20/20 or better in 74 eyes with 37 patients with documented evidence of a change in refractive error to be treated that is greater than 0.50 D in both cylinder and sphere components for at least one year prior to the date of pre-operative examination. The study showed that of 102 eyes with 51 patients with documented evidence of a change in refractive error to be treated that is greater than 0.50 D in both cylinder and sphere components for at least one year prior to the date of pre-operative examination, 97 eyes (95.1%) were corrected to 20/40 or better, and 66.2% were corrected to 20/20 or better in 74 eyes with 37 patients with documented evidence of a change in refractive error to be treated that is greater than 0.50 D in both cylinder and sphere components for at least one year prior to the date of pre-operative examination.

The VISX STAR 54 R™ Excimer Laser System and Wavefront System are approved to perform wavefront-guided laser assisted in-situ keratomileusis (LASIK) treatments for the reduction or elimination of low to moderate hyperopic astigmatism to +6.00 D MRSE, with cylinder between 0.00 and +3.00 D in patients 21 years of age or older, and in patients with documented evidence of a change in refractive error to be treated that is greater than 0.50 D in both cylinder and sphere components for at least one year prior to the date of pre-operative examination.

Wavefront-guided LASIK for the correction of hyperopic astigmatism is an elective procedure with the alternative including, but not limited to, eyeglasses, contact lenses, photorefractive keratotomy (PRK), conventional LASIK, and other refractive surgeries. Approval of the use of wavefront-guided LASIK for correction of low to moderate hyperopic astigmatism is based on a clinical trial of 144 eyes in 74 primary and 70 secondary eyes with 36 patients. The study included 134 eyes with 67 patients with documented evidence of a change in refractive error to be treated that is greater than 0.50 D in both cylinder and sphere components for at least one year prior to the date of pre-operative examination. The study showed that of 134 eyes with 67 patients with documented evidence of a change in refractive error to be treated that is greater than 0.50 D in both cylinder and sphere components for at least one year prior to the date of pre-operative examination, 118 eyes (88.1%) were corrected to 20/40 or better, and 62.7% were corrected to 20/20 or better in 74 eyes with 37 patients with documented evidence of a change in refractive error to be treated that is greater than 0.50 D in both cylinder and sphere components for at least one year prior to the date of pre-operative examination. The study showed that of 134 eyes with 67 patients with documented evidence of a change in refractive error to be treated that is greater than 0.50 D in both cylinder and sphere components for at least one year prior to the date of pre-operative examination, 118 eyes (88.1%) were corrected to 20/40 or better, and 62.7% were corrected to 20/20 or better in 74 eyes with 37 patients with documented evidence of a change in refractive error to be treated that is greater than 0.50 D in both cylinder and sphere components for at least one year prior to the date of pre-operative examination.

The VISX STAR 54 R™ Excimer Laser System with VIS and Wavefront System are approved to perform wavefront-guided laser assisted in-situ keratomileusis (LASIK) treatments for the reduction or elimination of naturally occurring mixed astigmatism when the magnitude of the cylinder or astigmatism is greater than the magnitude of sphere and the cylinder and sphere components are of the same sign (both plus or both minus) and the magnitude of the cylinder and sphere components is greater than 0.50 D in both cylinder and sphere components for at least one year prior to the date of pre-operative examination.

Wavefront-guided LASIK for the correction of mixed astigmatism is an elective procedure with the alternative including, but not limited to, eyeglasses, contact lenses, photorefractive keratotomy (PRK), conventional LASIK, and other refractive surgeries. Approval of the use of wavefront-guided LASIK for correction of low to moderate mixed astigmatism is based on a clinical trial of 144 eyes in 74 primary and 70 secondary eyes with 36 patients. The study included 134 eyes with 67 patients with documented evidence of a change in refractive error to be treated that is greater than 0.50 D in both cylinder and sphere components for at least one year prior to the date of pre-operative examination. The study showed that of 134 eyes with 67 patients with documented evidence of a change in refractive error to be treated that is greater than 0.50 D in both cylinder and sphere components for at least one year prior to the date of pre-operative examination, 118 eyes (88.1%) were corrected to 20/40 or better, and 62.7% were corrected to 20/20 or better in 74 eyes with 37 patients with documented evidence of a change in refractive error to be treated that is greater than 0.50 D in both cylinder and sphere components for at least one year prior to the date of pre-operative examination. The study showed that of 134 eyes with 67 patients with documented evidence of a change in refractive error to be treated that is greater than 0.50 D in both cylinder and sphere components for at least one year prior to the date of pre-operative examination, 118 eyes (88.1%) were corrected to 20/40 or better, and 62.7% were corrected to 20/20 or better in 74 eyes with 37 patients with documented evidence of a change in refractive error to be treated that is greater than 0.50 D in both cylinder and sphere components for at least one year prior to the date of pre-operative examination.

CONTRAINDICATIONS:

Wavefront-guided LASIK is contraindicated in patients with collagen disease, autoimmune or immunodeficiency disease, acute or latent/occasional corneal keratitis, keratoconus, keratic lamellar dystrophy, "bull's eye" keratopathy, or autoimmune hypotension (collagenolytic) or a program of therapy.

WARNINGS:

Wavefront-guided LASIK is not recommended in patients who have diabetes, a history of herpes simplex or herpes zoster keratitis, significant dry eye that is unresponsive to treatment, or severe dry eye. For the treatment of low to moderate myopic astigmatism, lower uncorrected visual acuity (50 to 60) is required.

PRECAUTIONS:

The use of wavefront-guided LASIK for the correction of low to moderate myopic astigmatism is an elective procedure with the alternative including, but not limited to, eyeglasses, contact lenses, photorefractive keratotomy (PRK), conventional LASIK, and other refractive surgeries. Approval of the use of wavefront-guided LASIK for correction of low to moderate myopic astigmatism is based on a clinical trial of 144 eyes in 74 primary and 70 secondary eyes with 36 patients. The study included 134 eyes with 67 patients with documented evidence of a change in refractive error to be treated that is greater than 0.50 D in both cylinder and sphere components for at least one year prior to the date of pre-operative examination. The study showed that of 134 eyes with 67 patients with documented evidence of a change in refractive error to be treated that is greater than 0.50 D in both cylinder and sphere components for at least one year prior to the date of pre-operative examination, 118 eyes (88.1%) were corrected to 20/40 or better, and 62.7% were corrected to 20/20 or better in 74 eyes with 37 patients with documented evidence of a change in refractive error to be treated that is greater than 0.50 D in both cylinder and sphere components for at least one year prior to the date of pre-operative examination. The study showed that of 134 eyes with 67 patients with documented evidence of a change in refractive error to be treated that is greater than 0.50 D in both cylinder and sphere components for at least one year prior to the date of pre-operative examination, 118 eyes (88.1%) were corrected to 20/40 or better, and 62.7% were corrected to 20/20 or better in 74 eyes with 37 patients with documented evidence of a change in refractive error to be treated that is greater than 0.50 D in both cylinder and sphere components for at least one year prior to the date of pre-operative examination.

The use of wavefront-guided LASIK for the correction of low to moderate hyperopic astigmatism is an elective procedure with the alternative including, but not limited to, eyeglasses, contact lenses, photorefractive keratotomy (PRK), conventional LASIK, and other refractive surgeries. Approval of the use of wavefront-guided LASIK for correction of low to moderate hyperopic astigmatism is based on a clinical trial of 144 eyes in 74 primary and 70 secondary eyes with 36 patients. The study included 134 eyes with 67 patients with documented evidence of a change in refractive error to be treated that is greater than 0.50 D in both cylinder and sphere components for at least one year prior to the date of pre-operative examination. The study showed that of 134 eyes with 67 patients with documented evidence of a change in refractive error to be treated that is greater than 0.50 D in both cylinder and sphere components for at least one year prior to the date of pre-operative examination, 118 eyes (88.1%) were corrected to 20/40 or better, and 62.7% were corrected to 20/20 or better in 74 eyes with 37 patients with documented evidence of a change in refractive error to be treated that is greater than 0.50 D in both cylinder and sphere components for at least one year prior to the date of pre-operative examination. The study showed that of 134 eyes with 67 patients with documented evidence of a change in refractive error to be treated that is greater than 0.50 D in both cylinder and sphere components for at least one year prior to the date of pre-operative examination, 118 eyes (88.1%) were corrected to 20/40 or better, and 62.7% were corrected to 20/20 or better in 74 eyes with 37 patients with documented evidence of a change in refractive error to be treated that is greater than 0.50 D in both cylinder and sphere components for at least one year prior to the date of pre-operative examination.

The use of wavefront-guided LASIK for the correction of mixed astigmatism is an elective procedure with the alternative including, but not limited to, eyeglasses, contact lenses, photorefractive keratotomy (PRK), conventional LASIK, and other refractive surgeries. Approval of the use of wavefront-guided LASIK for correction of low to moderate mixed astigmatism is based on a clinical trial of 144 eyes in 74 primary and 70 secondary eyes with 36 patients. The study included 134 eyes with 67 patients with documented evidence of a change in refractive error to be treated that is greater than 0.50 D in both cylinder and sphere components for at least one year prior to the date of pre-operative examination. The study showed that of 134 eyes with 67 patients with documented evidence of a change in refractive error to be treated that is greater than 0.50 D in both cylinder and sphere components for at least one year prior to the date of pre-operative examination, 118 eyes (88.1%) were corrected to 20/40 or better, and 62.7% were corrected to 20/20 or better in 74 eyes with 37 patients with documented evidence of a change in refractive error to be treated that is greater than 0.50 D in both cylinder and sphere components for at least one year prior to the date of pre-operative examination. The study showed that of 134 eyes with 67 patients with documented evidence of a change in refractive error to be treated that is greater than 0.50 D in both cylinder and sphere components for at least one year prior to the date of pre-operative examination, 118 eyes (88.1%) were corrected to 20/40 or better, and 62.7% were corrected to 20/20 or better in 74 eyes with 37 patients with documented evidence of a change in refractive error to be treated that is greater than 0.50 D in both cylinder and sphere components for at least one year prior to the date of pre-operative examination.

ADVERSE EVENTS AND COMPLICATIONS:

The clinical trial for low to moderate myopic astigmatism showed that the following adverse events or complications occurred in at least 1% of the 351 eyes with 172 patients: 1.2% of eyes with 0.6% of patients had double vision (1.2%) under the flap (1.4%), double or ghost images (1.4%), and scratch on the surface of the eye (1.4%). The following subjective symptoms frequency rated "often" or "always" were increased in the effectiveness cohort at 6 months post-treatment (on 258 eyes compared with pre-treatment) on 252 eyes (97.3% vs. 5%), fluctuation of vision (0% vs. 2%), glare (4% vs. 2%), and haze (7% vs. 5%).

The clinical trial for low to moderate hyperopic astigmatism showed that the following adverse events or complications occurred in at least 1% of the 144 eyes at one or more postoperative examinations up to 6 months post-treatment: epithelium in the surface of the eye (1.4%), double or ghost images (1.3%), and scratch on the surface of the eye (2.1%). The following subjective symptoms frequency rated "often" or "always" were increased in the effectiveness cohort at 6 months post-treatment (on 131 eyes compared with pre-treatment) on 136 eyes: dryness (17% vs. 6%), blurry vision (10% vs. 7%), fluctuation of vision (14% vs. 6%), haze (10% vs. 5%), double or ghost images (7% vs. 3%).

The clinical trial for mixed astigmatism showed that the following adverse events or complications occurred in at least 1% of the 144 eyes with 74 patients: 1.2% of eyes with 0.6% of patients had double vision (1.2%) under the flap (1.4%), double or ghost images (1.4%), and scratch on the surface of the eye (1.4%). The following subjective symptoms frequency rated "often" or "always" were increased in the effectiveness cohort at 6 months post-treatment (on 131 eyes compared with pre-treatment) on 136 eyes: dryness (17% vs. 6%), blurry vision (10% vs. 7%), fluctuation of vision (14% vs. 6%), haze (10% vs. 5%), double or ghost images (7% vs. 3%).

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