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Over the past three years, TLC Laser Eye Centers Inc. has made considerable investments in time and money to pioneer and develop new technologies that may improve the quality of vision for patients who have developed surgical and healing irregularities from RK, PRK and LASIK.

In this newsletter I will do my best to educate and update you on these new technologies. We recognize that it is impossible to perform surgery of any kind without encountering some degree of risk, and that 95-99% of our patients do extremely well and are pleased. However, we recognize that even 1% means thousands of people have encountered vision problems. Some of the vision problems we have observed have been truly devastating to patients personally, professionally and emotionally. With more and more people each day electing to have LASIK, TLC has significantly increased its commitment in manpower and financial resources to find solutions.

The majority of you did not have your refractive procedure at



*Jeffery J. Machat, M.D. FRCSC DABO
TLC National Medical Director*

TLC Laser Eye Centers Inc. and so while TLC patients will not incur any further procedure fees, many of you will have to understand that these technological advancements will come at a price of several hundred to several thousand dollars. We are genuinely interested in helping, if possible, those of the 1% that other laser companies have all but forgotten.

This newsletter will update you on what we have tried to accomplish, where we are now, and where we expect to be in the next 6 months. We plan to keep you updated both through this

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newsletter and our new web site: www.customlasikinfo.com. This new website is scheduled to launch in 2001 and is yet another commitment by TLC Laser Eye Centers Inc. to our patients and those of you who have now turned to us for help.

A VARIETY OF PATIENT VISUAL COMPLAINTS

As TLC National Medical Director, I spend two full days a month caring for patients who have developed difficulties with their refractive surgery. Each patient is different in the symptoms they experience and the way in which their visual problems affect their lives. The most common symptom in general is dryness of the eyes, the most common visual symptom is night glare or halos, and the most severe symptom is visual blurring or distortion reducing best corrected vision.



These symptoms stem from problems with either the surgery or with the healing. Many times it is a combination. Since every person's corneal tissue

responds differently to treatment, a significant problem in one patient may not be a problem at all in another patient who heals well. Similarly, some patients have a tremendous surgical result only to encounter significant healing irregularities. Healing problems are by far the most common and most difficult to manage.

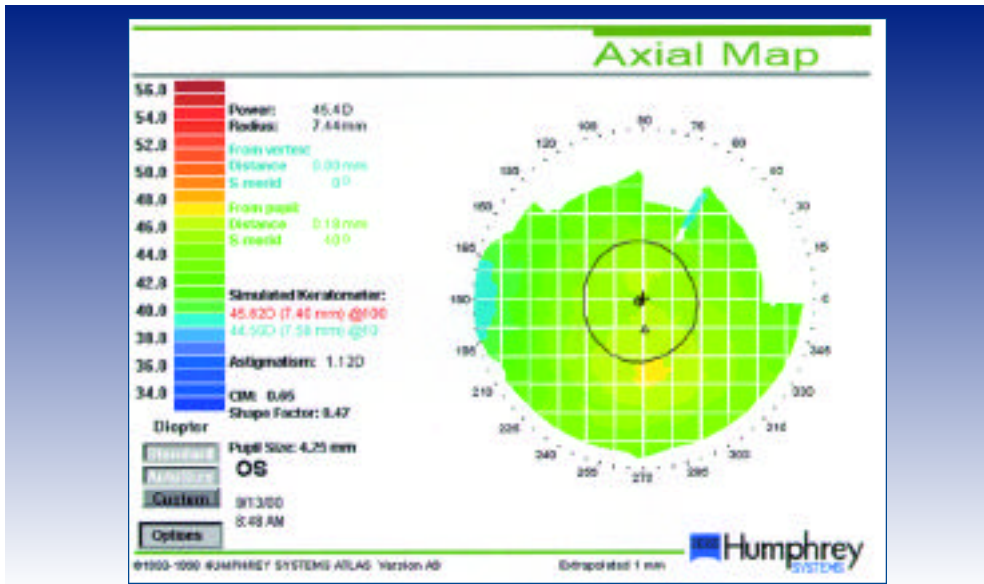
About 80% of the patients who are referred to me with visual problems have been significantly improved with additional surgery, or retreatment for under-or-over-healing responses, and with smoothing certain surgical complications. We now direct our attention to the 20% who have irregular healing with significant visual distortion.

UNDERSTANDING IRREGULAR ASTIGMATISM

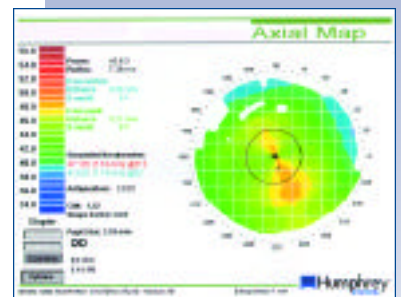
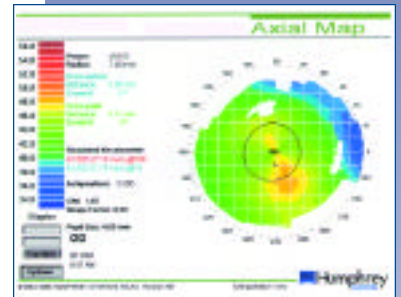
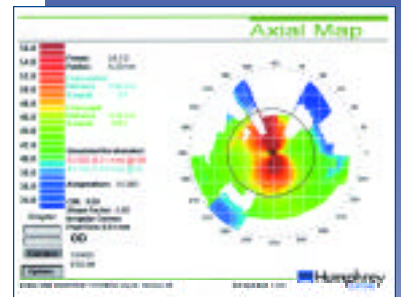
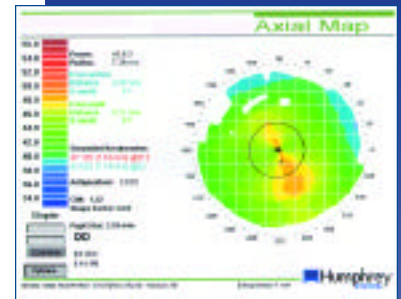
The first step in understanding the technology that can correct corneal irregularities is to understand the basic problem of what is known as irregular astigmatism. A variety of conditions all produce their negative visual effects through irregular astigmatism.

Poor healing or surgical complications that produce irregular astigmatism induce corneal unevenness characterized by peaks and valleys that need to be smoothed out. An analogy that I use to describe the effects of irregular astigmatism is that it is like aluminum foil wrapping that when flat and unused, bounces light smoothly, but when wrinkled, scatters light rays in multiple directions.

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Topography-Linked Maps



In an ideal visual system all the light rays traveling through the cornea and pupil must be focused precisely on the central retina known as the fovea—which is where the most precise visual receptors are located. When light rays are scattered, visual quality is degraded and visual sharpness is reduced. When light rays scatter in a particular direction, this may produce a second ghost image in that direction. Similarly, a variety of visual distortions can be produced through scattered light rays.

The goal of any treatment therefore is to refocus the light rays toward the fovea. If the light rays are evenly focused in front of the retina or behind the retina, the overall curve can simply be adjusted. However, if the light rays are unevenly focused, each point must be calculated and programmed separately. This is the basic challenge we are facing and is the reason a customized ablation pattern is needed to correct the problem.

TOPOGRAPHY-LINKED THERAPEUTIC PROCEDURES

Topography-linked therapeutic procedures utilize a map of the front curve of the cornea to create a template of corneal unevenness. For over two years, we struggled to treat corneal irregularities by smoothing the peaks and attempting to miss the valleys. We encountered mixed success with procedures using topography-linked technology.

Five sites worldwide performed a study to evaluate procedures using TopoLink® with the Technolas 217 excimer laser system. Two of these sites were TLC centers. The results: only about one third of the patients treated clearly improved; another one third demonstrated little or no improvement; and the final third actually seemed to experience a deterioration of their visual symptoms. The study appears to indicate that

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simply smoothing the corneal surface does not guarantee that the scattered light rays will be properly refocused at the fovea. Even in cases where the map appearance improved, the symptoms that some patients experienced did not. For that reason, we abandoned TopoLink®. Within six months, Technolas did as well.

ScanLink® by LaserSight uses their proprietary CIPTA software and has more success and achieved better clinical results. This system uses a more sophisticated corneal analysis device to assess the corneal irregularities and continues to be refined and demonstrate progress.

LaserSight has presented the best clinical data to date worldwide in the correction of corneal irregularities. Their Italian study shows 70-80% of patients demonstrating visual improvement. TLC has a significant financial investment in LaserSight and will have access to the revised program in the Spring of 2001. However, this approach may not be suitable for certain problems or be the preferred technique.



LaserSight LSX

ORBSCAN II MULTI-DIMENSIONAL CORNEAL ANALYSIS DEVICE

The OrbScan II is a diagnostic device that provides a three dimensional rather than a two dimensional analysis of the cornea. This offers additional information to better assess the structural parameter of the cornea following refractive surgery. It also provides clinical assessment of the thickness of the cornea across the entire surface, as well as an assessment of the corneal shape, both the front and back surfaces. The OrbScan II is part of a new group of diagnostic instruments that allow us to detect irregularities with greater detail and therefore plan retreatment procedures more accurately.



The Orbscan II provides a three dimensional view of the cornea.



COLVARD PUPILLOMETER

The Colvard pupillometer is an infrared pupil measuring device that allows TLC centers to measure the maximum pupil size in dim light under the lowest light conditions possible. This helps us better plan surgical procedures, select the most ideal laser platform and optical zone size, and better assess the night glare risk for patients post-operatively.

Post-operatively, the Colvard infrared pupillometer helps evaluate patients with night glare. Night vision disturbances are multifactorial — a pupil size that is greater than the treatment zone is only one risk factor. Other risk factors include a highly nearsighted prescription, a flat corneal curvature pre-operatively, and poor cortical adaptation to filter out the night glare. Software that expands the treatment zone, or simply reduces the peripheral light ray scattering that occurs at night when the pupil is dilated, is being developed. This should allow us to retreat patients with good day vision but poor night vision within 6-9 months.



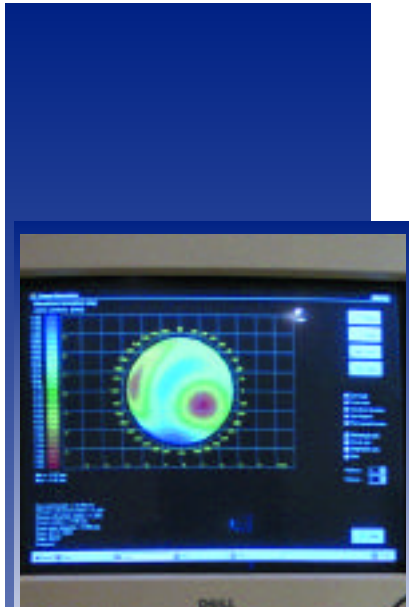
The Colvard Pupillometer measures the pupil size using infrared light.

TRACEY VISUAL FUNCTION ANALYZER

The technology that I am most excited about for the correction of irregular astigmatism is the Tracey Visual Function Analyzer. It may very well represent the key to improving visual function, rather than simply visual acuity. Many patients have commented to me that despite being 20/20 or 20/25 on an eye chart, they feel quite debilitated visually because of their reduced qualitative vision.

The Tracey Visual Function Analyzer uses a sophisticated ray tracing system to perform a visual analysis of the eye. Specifically, each point on the cornea can be tested separately to determine where any single light ray hitting that point will be focused on the retina. Therefore, all points that are focused properly on the fovea can be left untreated, and all points improperly

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The Tracey Visual Function Analyzer measures how each point on the cornea refracts light rays.

The degree to which each light ray is scattered and misdirected can be determined as well. The unit can actually predict the visual symptoms of a patient based upon the ray tracing analysis. We are already in the initial stages of developing a software link to create a treatment map that when linked with a laser system will determine the number of laser pulses required at each point on the cornea.

The Tracey Visual Function Analyzer assesses the entire visual system, not simply the cornea, in order to best determine how any aberrations or irregularities affect visual function.

Rather than simply smooth bumps, as we attempted with TopoLink®, this approach actually determines the treatment pattern based upon the entire visual system. Therefore bumps that are correct are untreated and seemingly smooth areas of the cornea that require treatment can be distinguished and corrected. The Tracey diagnostic instrument is a type of wavefront analyzer that has unique capabilities specifically suited for irregular corneas. We will keep you apprised of the development of this technology.

WAVEFRONT-GUIDED THERAPEUTIC LASER PROCEDURES

Wavefront technology was developed at the University of Heidelberg by astrophysicist Josef Bille, Ph.D., and truly represents the next major medical breakthrough in laser vision correction.

For over a decade scientists have been developing wavefront technology for astronomical applications. It can remove the distortion effects of an imperfect atmosphere to dramatically improve an astronomer's view of the universe through a telescopic lens. Based on the principles of adaptive optics, wavefront technology removes any visual distortion or irregularity from an optical path in order to bring an object into perfect focus. Wavefront technology has now been applied to vision correction, by attempting to eliminate not only the eye's prescription or refractive properties as we currently program, but also any naturally occurring and induced irregularities within the eye's visual system to potentially improve the visual quality and function.

The typical concept of excellent vision is 20/20, which simply means that the eye was capable of discerning the 20/20 letters on a standard Snellen visual acuity chart at 20 feet. The visual system of the eye is actually capable of far better vision and there are a number of people who are naturally able to discern the 20/15 or even the 20/10 line on an eye chart. The 20/10 letters represent letters twice as small as those on the 20/20 line. It is the spacing between retinal photoreceptors that actually limits the human visual system. Theoretically, vision of 20/8 is quite possible; this is two and a half times better than our typical concept of excellent vision today.

The reason this discussion is relevant in this newsletter is not that manufacturers are working on wavefront-guided programs to produce super vision.

Instead, it is because this technology can improve your visual potential by removing both naturally occurring aberrations, and those induced from prior refractive surgery, from the entire visual system.

Wavefront technology is already capable of improving best corrected vision and reducing system visual aberrations. Since March 2000, we have already performed customized ablation in normal, non-treated eyes with truly impressive clinical results. We improved best corrected vision from 20/20 pre-operatively to 20/15 post-operatively in 56% of cases. Similarly, we believe that with this technology we will be able to restore 20/25 or 20/30 vision back to 20/20 — with substantially improved visual quality.

Wavefront analysis determines the way in which the eye sees by sending a series of pinpoint light rays through the cornea either individually, as in the case of ray-tracing, or grouped, as with other wavefront systems and then analyzing the reflected pattern produced. In an irregular or distorted cornea, I believe it is vital to test each point separately, as grouped points may theoretically criss-cross in a highly distorted cornea and create a false wavefront map. In a normal cornea the system utilized for wavefront analysis is far less important because the aberrations detected are more regular and highly reproducible. This is not the case with post-refractive surgery eyes. Post-surgery, the scattering of light rays and distortion is much more

variable and therefore requires a different approach, one which TLC is pioneering and hopes to develop in the next six months or so.

FLYING SPOT TECHNOLOGY LASER SYSTEMS

Virtually every laser manufacturer worldwide is moving toward scanning laser technology utilizing flying spot technology. In contrast to a wide field or a broad beam laser delivery system, which treats the entire cornea at once, the flying spot approach utilizes a fine laser pulse less than 2 mm in diameter which scans rapidly across the corneal surface.

Although there are advantages to both systems, a fine beam ideally less than 1 mm in diameter is truly required for fine customized ablation. In addition, sophisticated eye-tracking methods are needed to ensure proper pulse placement of these small laser pulses. The third element in developing customized ablation is creating the software link to the wavefront analyzer. It is this last element that is currently being advanced and tested in clinical trials.

LIMITATIONS OF WAVEFRONT THERAPEUTIC PROCEDURES

While there is much to be excited about, it has taken many years of hard work and the development of new technologies to achieve this breakthrough in correcting visual irregularities. There are, however, a few distinct limitations that all patients need to understand and accept.

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New Web Site
Coming In
Early 2001

www.customlasikinfol.com

First, as wavefront technology is in the early stages of development, there will be many refinements and improvements over the next several years. New technology usually includes some setbacks and delays as we encounter unexpected problems. Second, it will take several months to adjust the algorithm to truly determine how many pulses are required to correct any mapped corneal irregularity or visual system aberration. Therefore enhancements will be commonly needed, with small improvements expected, rather than complete restoration of the visual quality. Finally, all clinical results and attempts will be subject to the individual healing pattern of the patient. Certain patients who are poor healers may improve only to regress in an irregular pattern a second time. For these individuals, programs will be developed to take healing patterns into account but this research and development will take much longer.

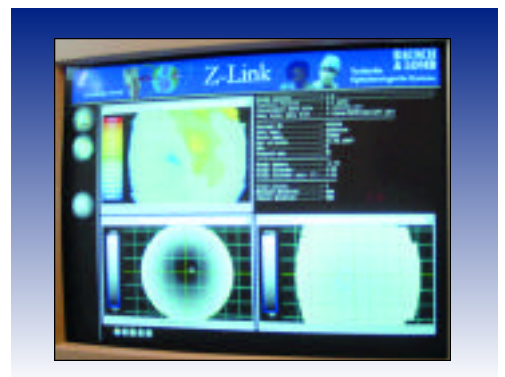
For these reasons, we need to select our initial cases for this technology more carefully. We need to begin with patients who have the most severe vision complications and then move to patients with less significant visual problems. There are also a number of patients who have minimal visual symptoms who we will evaluate for treatment when the safety profile for the new techniques is truly ready. That may take another year.

Importantly, all patients will need to understand and accept that there are risks associated with every surgical

procedure, including wavefront-guided therapeutic techniques designed to improve visual function.

Our goal will be to enhance all eyes with LASIK, even when the original procedure was not LASIK. Whenever possible, when using these new techniques, we will lift the original corneal flap, even when it has been several years since the original LASIK procedure, in order to reduce the risk profile.

In summary, we completely understand that visual problems affect each patient from the moment they wake up until the moment they sleep. We are working diligently on solutions. TLC has taken a clear leadership position in devoting manpower and money to pioneering solutions, however technology advancements do take time. We are also acutely aware that many of you are extremely apprehensive about considering more refractive surgery, and that is why we are taking a very cautious approach and trying to ensure you are educated and informed as much as possible through these preliminary stages.



Zywave wavefront aberrometer