"Wavefront”-Guided Laser Vision Correction Surgery

ADDENDUM OR INSERTION

INDICATIONS AND ALTERNATIVES

“Standard” or “conventional” laser vision correction surgery refers to correction of spherical (near- or farsightedness) and cylindrical (astigmatic) refractive errors of the eye. Such treatment is rendered based upon measurements of the refraction, using lenses combined within an instrument called a phoropter.

“Wavefront”-guided treatment is based upon an imaging system called wavefront (aberrometer) measurement of the whole eye. In August of 2002, Alcon/Autonomous received FDA approval for use of its laser system (the LADARVision laser) in performing “Custom Cornea” treatments, guided by aberrometer (LADARWave) measurements; in June, 2004, the approval criteria were expanded. In May of 2003, Visx received similar approval for its “CustomVue” treatments using their WaveScan aberrometer and S4 laser, with approval for hyperopia with astigmatism in December, 2004.

Wavefront measurement is relatively new to the eye care profession, having evolved around imaging and manufacturing applications in the fields of astronomy, aerospace engineering, and photography. Wavefront measurement is able to detect subtle imperfections in an optical system that contribute to imperfect focus of an image. “Sphere” and “cylinder” are referred to as “low-order aberrations,” while other optical factors comprise the “higher-order aberrations.” Higher-order aberrations include spherical aberration, coma, trefoil, and others. Most people are not at all familiar with these terms. Unfortunately, it is not easy to graphically or pictorially represent the influence that higher-order aberrations have on human vision.

It is recognized that a minority of patients treated with conventional laser treatment describe some visual difficulties after their treatment, including glare, haloes around lights, diminished comfort at night, and ghosting of images (among other things). Data presented to the FDA suggests that a significant amount of these adverse visual consequences may be reduced by wavefront-guided treatment. The data also suggest that with wavefront-guided treatment a higher percentage of patients achieve better visual acuity, and a lower percentage have complaints, even in reduced illumination. The research was performed in very tightly-controlled circumstances on a relatively small number of patients (several hundred) by a small group of surgeons (less than 10). These results have not yet been reproduced or confirmed in large-scale studies on thousands of patients treated by larger numbers of surgeons in diverse settings more typical of the public domain.

CANDIDATES FOR WAVEFRONT-GUIDED VISION CORRECTION

At present, the range of prescriptions treatable by wavefront-guided systems is narrower than the range of treatments approved for conventional treatment. Alcon’s LADARVision system is approved only for nearsightedness up to -8.00 diopters sphere, with -0.50D to -4.00D of astigmatism. The Visx Star S4 &
WaveScan WaveFront System is approved for up to -6.00 D of myopia, with or without astigmatism up to -3.0 diopters, and for hyperopia with or without astigmatism up to +3.00D MRSE, with cylinder up to +2.00D.

POSSIBLE ADVANTAGES AND BENEFITS OF WAVEFRONT-GUIDED VISION CORRECTION

The advantages of wavefront-guided treatment may include:
- A higher percentage of patients are reported to achieve better visual acuity (“20/20” and “20/15”) after wavefront ablation treatment than with conventional therapy. There is no guarantee that you will achieve these results.
- A lower percentage of patients report glare, halo, or discomfort with night vision after treatment.
- The process eliminates some of the subjective component of the refraction measurement process (the “Which is better, one or two?” part).

POSSIBLE DISADVANTAGES AND BENEFITS OF WAVEFRONT-GUIDED VISION CORRECTION

There are some potential disadvantages to wavefront-guided treatment. These include, but are not limited to:
- Wavefront-guided treatment removes more tissue (typically 18 - 30% more) than conventional treatment.
- Currently, it is only possible to treat for “full distance correction” as a target, so it is not appropriate for those desiring monovision.
- Wavefront treatment is currently more expensive than conventional treatment, and the supposed benefit is intangible, as it cannot always be measured.
- Wavefront measurements of the eye, like refraction measurements, can fluctuate somewhat from hour to hour, day to day, or week to week.

WAVEFRONT OR CONVENTIONAL TREATMENT

As with any elective surgery decision, you are well-advised to make your decision based upon multiple factors. Speak to your surgeon; do your research; consult the websites of the laser manufacturers and the FDA; and satisfy your own curiosity before making a determination.

PATIENT’S STATEMENT OF ACCEPTANCE AND UNDERSTANDING

I have read and understand the above information about wavefront-guided vision correction surgery and wish to have this type of vision correction surgery on my ______ Right eye ______ Left eye

______________________________________________________________
Patient Signature (or Person Authorized to Sign for Patient) Date