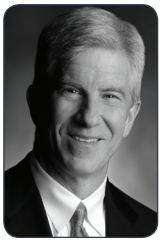
MORE THAN NEW

Upgrades to a laser refractive surgery system yield superior results.

BY COLMAN R. KRAFF, MD



The Star excimer laser (Visx, which was acquired by Abbott) was first approved for the treatment of myopic astigmatism in March 1996. The FDA-approved indication for treatment was PRK for low to moderate myopia that addressed only the spherical equivalent, with up to 1.00 D of astigmatism. Over the past 2 decades, the indications for corneal refractive surgery with this platform have expanded. Technological advances have improved safety, efficacy, and long-term outcomes, all of which has increased the range of refractive errors that can be treated with the device.

Among the milestones since the laser's original US release is FDA approval for LASIK in 1999. This was followed by the indication for wavefront-guided treatments in June 2004 using the WaveScan Wavefront System (Abbott, now Johnson & Johnson [J&J] Vision). Fast forward to May 2015, when the iDesign Advanced WaveScan Studio System (J&J Vision; Figure) was approved for the treatment of myopic astigmatism (up to -11.00 D of myopia and up to -5.00 D of astigmatism). In January 2017, the FDA approved the platform for the treatment of mixed astigmatism (1.00-5.00 D), and a hyperopic astigmatism indication has been submitted to the agency. The iDesign is available for commercial use with J&J Vision's Star S4 IR Excimer Laser System in the United States. Internationally, the iDesign has been available for commercial use for several years.

THE UPGRADES

The iDesign offers numerous advantages over the CustomVue wavefront-guided system (J&J Vision). The new Hartman-Shack sensor has five times greater resolution than the old one. In addition, the iDesign uses 1,257 microlenses versus 240 with the CustomVue. The iris registration (IR) system has been upgraded to use much higher-contrast imaging, which increases the IR capture rate to over 95%, even in blue eyes, which were often more difficult to capture using the CustomVue.

With its upgraded sensors, the iDesign uses a Fourier reconstruction algorithm that performs 1,257 micro-refractions over a 7-mm diameter, yielding a threefold greater dynamic range in refractions compared to the older WaveScan Wavefront System. The goal is to deliver a much more precise refraction, more precise detection of higher-order aberrations, and easier, more consistently reproducible measurements in order to achieve more accurate refractive results when the data are integrated with variable spot scanning software and the Star S4 IR Excimer Laser System.

In addition to greater precision in data capture, the iDesign integrates non-Placido corneal topography technology, keratometry, and controlled scotopic and photopic pupillometry.

RESULTS

Unless it can provide superior results and/or safety, new technology is nothing more than new. In the FDA clinical trial, the iDesign performed better than prior systems. Six months postoperatively in the multicenter prospective study, 98.2% (328/334) of myopic eyes had 20/40 UCVA or better, 82.6% (276/334) had 20/20 UCVA or better, and 61.7% (206/334) had 20/16 UCVA or better. These results were over the widest range of treatment to date and were superior to results with the CustomVue at each level of UCVA. Similar superiority occurred in the mixed astigmatism group with an expanded range of treatment (data on file with J&J Vision).

Figure. The iDesign Advanced WaveScan Studio System.

AT A GLANCE

- The iDesign Advanced WaveScan Studio System offers numerous advantages over the CustomVue system.
- The new platform is currently approved in the United States for the treatment of myopic astigmatism and mixed astigmatism, and a hyperopic astigmatism indication has been submitted to the FDA.

CONCLUSION

Like the CustomVue, the iDesign Advanced WaveScan Studio System is fully compatible with the Star S4 IR Excimer Laser System and the iFS Laser (J&J Vision) for flap creation. The combined suite gives surgeons a complete refractive workstation. All the key refractive workup diagnostics can be achieved with one machine. The variable spot scanning software module takes the targeted shape and creates a series of commands for the Star S4 IR Excimer Laser System to produce it on the corneal bed. The achieved results (data on file with J&J Vision) have been outstanding in line with results from systems that have been available internationally for the past few years. It is to be hoped that a final indication for hyperopia will be approved in the near future. ■

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- financial disclosure: consultant to Abbott and a principal clinical investigator for the iDesign FDA clinical trials for myopia, mixed astigmatism, and hyperopia