CustomVis™ Presentations at ASCRS 2004

CustomVis™ will be displaying their Pulzar™ Z1 Solid State Refractive Laser System at the upcoming American Society of Cataract and Refractive Surgery (ASCRS) Meeting in San Diego. The booth number at ASCRS is 2053. The following papers will be presented which address solid state technology and related subjects.

Paper Presentations:
- Early Clinical Trials with the Solid State 213nm Laser on Standard and Non-Standard Cases. Peter Stewart, MD., Donald R. Sanders MD., PhD., Paul van Saarloos, PhD., Mukesh Jain, PhD., William J. Ardrey, PhD.

Poster Presentations:
- Laser Wavelengths in Ophthalmology: A Critical Review. Ian Anderson, MD., Mukesh Jain, PhD., Pauline Vitale, BSc., Paul P. van Saarloos, PhD., William A. Ardrey, PhD.
- Quality of Life and Disruptive Technologies: A Validation of the NEI QOL #2 Instrument for Custom Surgery. Y. Ralph. Chu, MD., Jessica L. Springbett, BSc., & William J. Ardrey, PhD.

Customised Corneal Surgery

Recent advancements in refractive technology have allowed custom corneal surgery to evolve with the aid of wavefront diagnostic tools. However, limitations for treatment of severe visual anomalies remains a problem. An efficient and precise customised approach requires several essential technical features in refractive laser systems.

A small laser spot size coupled with a fast pulse rate, fast scanning ability and homogenous beam are some of the essential requirements to perform precise ablations with reduced treatment time, thus minimising thermal heating and drying of the corneal surface. Implementation of both wavefront as well as topography data is necessary for the patient’s custom ablation plan. Wavefront accurately represents the patient’s visual world, thus correctly diagnosing their major refractive disorders, while the topography data unveils the small aberrations on the corneal surface.

Presence at International Meetings

CustomVis™ demonstrated its Pulzar™ Z1 Solid State Refractive Laser System at the 2003 American Academy of Ophthalmology (AAO) Annual Meeting in Anaheim, California and at the 2004 Winter ESCRS, Barcelona. At both meetings the Pulzar™ Z1 attracted numerous enquiries from many curious surgeons. The simple solid state 213 nm delivery system, using an Nd:YAG source, intrigued many visitors to the booth.
Pulzar™ Z1 Solid State Refractive Laser

The Pulzar™ Z1 solid state refractive laser has been developed by Paul van Saarloos, PhD, who has also designed corneal topography systems, excimer laser systems and interferometers. “The advances over the past dozen years in keratorefractive surgery have been simply breathtaking. The coupling of imaging and laser technologies has provided for the introduction of stunning technology and with each step forward the bar of expectations has been raised. No longer are we content with correcting lower order aberrations, for the technology now exists for correction of more complex irregularities with the goal of super acuity. The correction of higher order aberrations can only be achieved by improved techniques for measurement and methods for reshaping the cornea. To correct the corneal surface to the sub-micron levels required by customised surgery demands a laser system with a small spot size, a very fast pulse repetition rate, a correspondingly fast eye tracker incorporating gaze tracking, and the use of wavelength for efficient ablation of the cornea. The Pulzar™ combines these attributes with a range of features designed to make customised surgery safe, predictable and rewarding for all involved.”

Dr. van Saarloos expects the clinical results for customised surgery to continue to improve, not just for the simple cases, but for the challenging cases, many of which have not been treatable in the past.

The CustomVis™ Pulzar™ Z1 Solid State Laser provides a breakthrough in custom laser vision technology.

The all solid state design eliminates the need for toxic gases and requires less maintenance. The reliable energy stability of the 213nm laser produces uniform Gaussian beam characteristics, and smooth, clean corneal ablations. Also, fluctuations in hydration or humidity are unlikely to have a significant effect upon the 213nm laser performance.

The Pulzar™ Z1 0.6mm flying spot allows high resolution sculpturing of the cornea, guided by the ZCAD™ customised ablation profiles. The optimal ablation plan, designed using topography and wavefront data, are matched 1:1 to the operative corneal position to ensure accurate treatment. Quick customised ablations are achieved with the fast pulse rate of 300 - 400 Hz.

The Pulzar™ Z1 eye tracking technologies include ZTRAK™, a limbal tracking system eliminating the need for pupil dilation, and the Intra-operative GAZETRAK™ system that monitors patients' gaze direction; temporarily disabling the laser output if there is significant eye drift from the fixation target. Superior laser beam scanning is achieved by new solid state “crystal scan” technology; significantly faster than the existing Galvanometer based systems.

Note: The Pulzar™ System is TGA and CE Mark approved but not for sale in the U.S.A.

Customised Corneal Surgery (Continued from page 1)

A solid state laser system is an important transition from a typical excimer 193nm laser system which allows better optimisation of customised refractive surgery. The essential features of the solid state CustomVis™ Pulzar™ Z1 laser meet the necessary technical requirements and can overcome current treatment limitations faced with other laser systems. As a result, treatment of patients with severe visual anomalies is now possible with this new technology.

Further, solid state systems operating at 213nm wavelength enhance predictability as the laser light can pass through water with very little energy loss, in comparison to 193 nm which has a high water absorption rate. As a result a solid state laser’s performance may be less susceptible to variations in humidity or corneal hydration, which enables a more environmentally friendly laser room with less emphasis on climate controlled conditions.

Customised Treatment of Irregular Astigmatism

The first treatments using the CustomVis™ Solid State Pulzar™ laser were performed by Dr. Ian Anderson in Perth, Australia and were limited to eyes with severe anomalies. Dramatic initial results were achieved with five patients who had highly irregular corneas and severe irregular astigmatism following either penetrating keratoplasty or photorefractive keratectomy. Treatments were performed with either no loss or gain of BSCVA. Uncorrected vision improved by between 1 and 5 lines and keratometric cylinder decreased by as much as 10D.

The Pulzar™ was also used to successfully treat a simple myope; uncorrected vision improved from 20/200 to 20/13 and the BSCVA of 20/13 remained unchanged.

The corneal topography maps show the dramatic improvement in surface regularity across the optical zone for one of these patients treated with the Pulzar™. This patient suffered from high myopia with very high corneal astigmatism. Previous surgery involved 2 pairs of 90° limbal relaxing incisions and photorefractive keratectomy. After treatment with the Pulzar™, the patient enjoyed a 2-line improvement in BSCVA, a 5-line improvement in uncorrected vision (20/80 to 20/20), and a 2.4 D decrease in keratometric cylinder (6.7 D to 4.3 D).

The dramatic results with these challenging cases showcase the Pulzar™’s leading edge technology and CustomVis™’s commitment to providing surgeons with the latest refractive laser technology to meet the demands for customized surgery.

About CustomVis™

CustomVis™ is an innovative ophthalmic company established in March 2001 by respected physicist and Chief Executive Officer, Paul van Saarloos, PhD. The company was formed to address the current technological limitations found in customised refractive surgery. CustomVis™ has developed and produced a solid state refractive laser system, the Pulzar™ Z1, for customised refractive surgery, which represents the next generation in the refractive surgery market. The Pulzar™ Z1 will be used to treat the most difficult refractive disorders as well as optimise the treatment of standard refractive disorders. The system incorporates new scanning, eye tracking and laser technologies to make LASIK, LASEK and PRK treatments safer and more predictable.

CustomVis™ designs, develops and produces its lasers at its office in Perth, Western Australia with its head office located in Dundee, Scotland. CustomVis presently employs in excess of 50 staff, engineers, scientists, technicians and clinicians. In July 2003, the company floated on the London Stock Exchange’s AIM board, with the symbol CUS, raising over £11.5 million.

CustomVis™ has achieved significant regulatory approvals (CE Mark and Australian TGA) enabling the distribution of its Pulzar™ Z1 system to most countries outside of the USA. The company has geared up its production and has shipped the first system to Germany in early January 2004.

CustomVis™ has an experienced management team and board of directors who have achieved international recognition with extensive experience in research and development of innovative technology, commercialisation and international business in the ophthalmic industry.