SEE US AT ...

APAO
Singapore
10 - 14 Jun, 2006
Booth No's.
905, 1002, 1004

ESCRS
London, England
9 - 13 Sep, 2006
Booth No. F4

AAO & APAO
Las Vegas, USA
11 - 14 Nov, 2006

CV-MKT-ENL-02-01
REVISION: A
EFFECTIVE 04/04/05

Service Intervals

One of the commercial benefits of Solid State technology is that intervals between scheduled service visits are longer than what is considered typical for excimer lasers. CustomVis's scheduled service visits are at three month intervals, after initial installation, configuration and one month post installation inspection.

Servicing is carried out by one of CustomVis's fully qualified and trained engineers who, as part of their training have to dismantle and reassemble the test laser at the head office in Perth multiple times so they have familiarity with the whole unit. Amongst the service team they have fluency in six languages enabling effective communication with our clients and removing ambiguity from the technical translations allowing a higher standard of user knowledge and operator ability.

Also of interest is regression analysis of the life of the laser source. This analysis on the drop off in performance with time shows the Solid State laser source will last significantly longer than the expected five years (assuming regular proper service is maintained). The Solid State diode pumped laser source is proving to be extremely reliable with little or no degradation in performance over years of use.

Customer Training

The extensive training facility at CustomVis will be busy over the coming weeks with engineers visiting from our customers in Korea, Columbia and Puerto Rico, to receive either level one or level two training on the Pulzar™ Z1. The structured training programme developed for all customer engineers consists of three levels of training. Level zero can be completed in a single training session over two days and can be carried out at the installation site. Levels one and two are more intensive courses and requires access to a test machine to enable the visiting engineers to trial what they have learnt. Upon completion and passing the test requirements of each level, the engineer has satisfied the CustomVis Head of Service that they are accomplished in the requirements and are certificated to perform maintenance to their training level.

Whilst the visiting engineers will be subject to a heavy training schedule, they will still have time for the arranged sightseeing of Perth's attractions and sampling a little bit of the Australian lifestyle.

New Faces at CustomVis

CustomVis is pleased to welcome Dr Tarak Pujara as Clinical Manager and Mr Keith Jewitt as Business Manager.

Tarak has obtained his Masters of Surgery (Ophthalmology), D.O. (Diploma in Ophthalmology) and M.B.B.S. (Bachelor of Medicine and Bachelor of Surgery). He will provide clinical expertise across the organisation, for example; product development and servicing protocols. Tarak brings a wealth of experience to the company and will provide a valued role in the collection, analysis and storage of all clinical data.

Keith comes from the UK where he has worked for multinational organisations in fields of software distribution, retail and human resource supply. The past years have seen Keith successfully establish his own company in the manufacturing arena. With experience across strategic direction, planning, commercialisation and business controls Keith is a welcome addition to the management team where his experience will assist CustomVis in achieving its corporate objectives.

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LATEST@CUSTOMVIS™

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IN THIS ISSUE

Welcome

It has been a busy year at CustomVis since the last edition of LATEST@CUSTOMVIS was distributed. The Pulzar™ Z1, the companys flagship product, is currently situated in eleven sites worldwide.

With enhancements to its software, the benefits of Solid State technology are becoming more appreciated by the market. After having treated over 2,500 eyes, the clinical data is showing that the Pulzar™ Z1 is delivering the results expected by all and continues to generate a level of high interest from surgeons internationally.

CustomVis is extremely proud to announce that during Asia Pacific Academy of Ophthalmology (APAO) Conference to be held in Singapore from 10th – 14th June 2006 the highly respected surgeon Professor Pallikaris is delivering a lecture entitled "CustomVis Solid State Refractive Surgery Today". A further three papers will also be presented on the Solid State Refractive Technology.

Accurate Eye Tracking

A fundamental requirement for customised refractive surgery is a fast and accurate eye tracking technique for precise laser positioning. The CustomVis solution to this challenge is the combination of two tracking systems, ZTRAK and GAZETRAK™.

It has widely been accepted that latency is an extremely important parameter for comparing eye trackers. However, accuracy should be considered to be just as important. Taylor et al* showed that the error from poor lateral accuracy of an advanced pupil based eye tracker was as high as 0.1mm while looking through a lasik bed without firing the laser.

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Commercial Benefits of Solid State Now Established

The commercial benefits of using a Solid State laser are becoming clearer to those in the know. CustomVis has continually stated that Solid State is the future of refractive surgery. We are now receiving feedback from clinics confirming that the low cost, high volume capability of the Pulzar™ Z1 is contributing to a commercially successful clinic. When clinics were asked about the benefits of the Pulzar™ Z1 laser they quoted:

- ✓ Overall treatment times are faster, managing more patients per hour.
- ✓ Faster laser turn on times.
- ✓ Running cost are lower - i.e. no associated costs and no difficulties associated with obtaining, handling and freighting gas.
- ✓ Simplicity of operation – windows based software, touch screen operation, less requirement for highly educated users to set the device prior to surgery.
- ✓ Stability of device with minimum downtime since delivery in late 2005.

Accurate Eye Tracking

(Continued from page 1)

This is the same error induced by slow eye tracking with latencies of 0.1s (10Hz) as measured by Bueeler and Mrochen**. Pupil based eye trackers need to "see" through the treatment surface. The bed of the LASIK flap, desiccation of the tissue by the laser ablation, plume and laser flashes all make it difficult to accurately detect the pupil edges.

The solution is limbus based eye tracking. CustomVis has developed unique and very powerful (patent pending) algorithms to track the limbus. Preliminary measurements indicate that the accuracy of this new technology is better than 20 microns, which is substantially more accurate than pupil based eye trackers, and the accuracy does not drop off as the laser treats over the pupil.

For custom surgery the effect of errors created by pupil tracking is doubled. Not only does the laser not fire exactly where it believes the pulse should go, but also the surgical plan is registered to the pupil, so where the laser believes the pulse should go is also in error. CustomVis has developed it's ZCAD custom surgery planning software to locate and register the treatment to the limbus using the same eye tracking algorithms. Ensuring highly accurate 1:1 registration of the surgical plan with corneal position.

**Bueeler and Mrochen. Journal of Refractive Surgery 2005; 21: pp 28-36

*Taylor et al. Journal of Refractive Surgery 2000; 16: pp S643-S646

APAO Singapore 10th - 14th June 2006 Presentations

- ***CustomVis Solid State Refractive Surgery Today.***
  To Be Presented By Prof I. G. Pallikaris
- ***Effectiveness of Solid State Laser (213 nm) in Correcting Myopia and Myopic Astigmatism.***
  To Be Presented By Dr Marc Tay
- ***Effectiveness of Limbal Eye Tracking Over Pupil Eye Tracking in Refractive Surgery.***
  To Be Presented By Dr Paul van Saarloos
- ***Lasik Correction of Spherical Hyperopia and Mixed Astigmatism with the CustomVis Solid State Laser (213nm).***
  To Be Presented By Dr Tarak Pujara

About CustomVis

It is well known that CustomVis is a research and development company currently specialising in the commercialisation of the Solid State refractive laser, the Pulzar™ Z1. But what elements go into making CustomVis the world leader in the design, manufacture and commercialisation of Solid State refractive surgery equipment?

CustomVis believes that by having total control of all elements it will ensure the delivery and continuing performance of a quality product and service offering. The company feels that the best way to maintain quality and control is to manufacture as much of the Pulzar™ Z1 in-house at its facility in Perth, Western Australia.

To meet the stringent demands required by the company for its customers, CustomVis designs and provides specifications for all software utilised on the Pulzar™ Z1 to its in-house software department who code, test, validate and then release the latest versions of software for extensive in-house trials prior to it being authorised for release to the marketplace.

The CAD department utilises mechanical 3D software to produce parametric models and assemblies of Electro–Mechanical devices along with producing detailed designs of components and assemblies for manufacturing, assembly and documentation purposes.

These drawings are utilised by CustomVis's own production facility, which manufacturers the laser frame, tower, laser table, crystal housing plus many other elements.

Construction, delivery, installation and commissioning is carried out by CustomVis service engineers, whose extensive initial and on going training is carried out in-house to provide continuity to high standards of knowledge and service levels to be achieved and maintained. CustomVis is accredited under ISO 13485 and is audited by TGA on a regular basis.

Expertise in all areas of the development and manufacturing process, a highly skilled and ethical workforce across the business coupled with a strong and knowledgeable management team have enabled CustomVis to produce the world's most advanced refractive device, and shows that Solid State is, and will be the standard for the future.

Latest Clinical Results

The Pulzar™ Z1 has been used to treat a wide range of myopia, myopic astigmatism, hyperopia and hyperopic astigmatism. More than 2,500 eyes with highly satisfactory results were treated at some international sites including Singapore, Colombia, Norway, Korea, Holland, Portugal, Greece and Australia. The Pulzar™ Z1 was used effectively and regularly to treat standard and custom surgery.

To date we have data with three months follow up of 295 eyes from all our sites having SE ≤ -6 D (mild to moderate myopia). Out of 295 eyes, 221 eyes (75%) were within half a diopter of intended refractive correction and 280 eyes (95%) were within one diopter of intended refraction (Figure 1). A total of 37% of eyes gained one line in their Best Spectacle Corrected Visual Acuity. 67 % of eyes had 20/20 or better Uncorrected Visual Acuity (UCVA) and 93% had 20/25 or better UCVA.

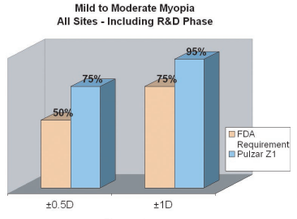

Figure 1

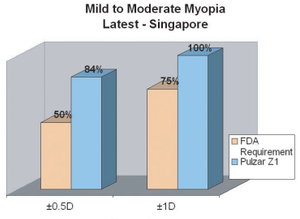

Figure 2

During January and Febuary 2006 a total of 44 eyes having SE ≤ -6 D, (mild to moderate myopia) were operated upon and followed for at least one month at our Singapore clinical site. Figure 3 illustrates attempted v's achieved. Thirty eight eyes (84 %) were within half a diopter of intended refractive correction and all forty four eyes (100%) were within a 1 diopter of intended refractive correction (Figure 2). 89% (39 eyes) demonstrated 20/20 or better Uncorrected Visual Acuity (UCVA) and 98% (43 eyes) demonstrated 20/25 or better UCVA.

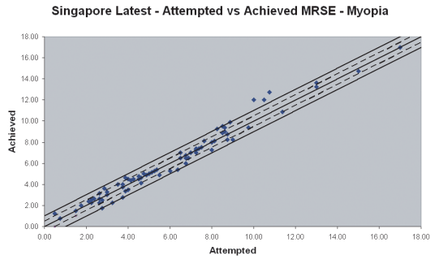

Figure 3

For high myopia and myopic astigmatism, a total 34 eyes were treated at The Lasik Surgery Clinic, Singapore during January and Febuary 2006. Treatment ranges were from -6 to –17 D of spherical equivalent. All cases were followed for one month. Figure 3 illustrates attempted v's achieved. Out of thirty four eyes 61% (23 eyes) were within +/- 0.5 D of intended refractive correction and 91% (32 eyes) were within +/- 1 D of intended refractive correction (Figure 4). 88% (30 eyes) had a 20/25 or better UCVA and 96% (33 eyes) had a 20/30 or better UCVA.

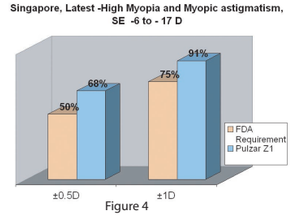

Figure 4

To date 229 hyperopic eyes with minimum one week follow up were treated with Pulzar™ Z1. Pre operative SE was up to + 8 D and astigmatism was up to -4 D. 89% (204 eyes) had 20/25 or better UCVA. A total 11% (21 eyes) had improvement in one line in their Best Spectacle Corrected Visual Acuity (BSCVA).

The Lasik Surgery Clinic Managing Director, Mr Felix Huang commented that he is very pleased and excited about the results coming out of his clinic with CustomVis Pulzar™ Z1. In his own words *"I am convinced that the Pulzar™ Z1 has the potential to be a world-class product. The impressive attribute that me and my team have observed is that the Pulzar™ Z1 is a real work horse. The second most impressive attribute is the quality of your service team but the most impressive is the low operating cost!"* Felix Huang and his surgical team are also very pleased with the system's ease of use and consistency of its results, which have contributed to his strong confidence in the Pulzar™ Z1.

Prof. Pallikaris has recently treated patients with the Pulzar™ Z1 and commented *"Refractive surgery with CustomVis Pulzar™ Z1 Laser System seems to be a safe procedure to treat patients with myopia with or without myopic astigmatism".*

PRESBYOPIA COMING SOON

Software Complete and Awaiting
Clinical Trials and Regulatory Approval