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Fitting together the Custom Surgery Puzzle

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Abstract:

Custom surgery holds the promise of better outcomes for all patients, especially "non-standard" eyes with irregular astigmatism, previous unsuccessful surgeries, and otherwise untreatable corneas. Unfortunately, current technology has failed to meet the expectations of doctors and patients on many aspects of the custom approach. In this paper, the challenges and solutions to custom surgery are reviewed, and illustrated using initial clinical trials of custom surgery. In these preliminary trials, a laser is built specifically to the needs of custom surgery, thus validating a unique approach of combining solid-state lasers with solid state scanning and eye tracking. This "CustomVis" laser and its solid-state approach deliver a new answer to the custom puzzle. Results indicate that patient outcomes will be most favorable using lasers with small spot sizes, high-resolution ablation, fast eye tracking and detection response, and consistent beam characteristics. Proper registration of wave front and topography data is shown to significantly improve results through minimizing problems of centration, cyclorotation, and intra-operative eye and gaze tracking.

Introduction:

One of the things we hope someday we'll be able to do with this type of customized ablation is to rescue very irregular corneas.

Dick Lindstrom
Eye World *(August 2001)*

Custom surgery can be seen like a jigsaw puzzle of different pieces, which must be carefully fitted together to deliver superior patient outcomes. Promises, ranging from "supervision" to wave-front driven automatic surgical planning has failed to be kept by current procedures and technology. However, patients with serious refractive disorders continue to seek a solution to their vision problems. Surgeons see these "hard eyes" as an attractive market segment, as well as a challenging medical and patient management problem. Doctors in private practice, and larger laser surgery center, also find that the most difficult eyes to treat also come back for the most amounts of visits by their doctor, making the right solution to the puzzle of custom surgery an economic necessity for the industry.

In this study, we first review the literature on custom surgery, both the promises and problems with the procedure. This indicates that the puzzle has three major components, namely the Measurement Piece, the Integration Piece, and of course the Laser

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Technology piece, which must be fitted together to get good results for patients and their doctors. In the conceptual development section, we then define the parameters required to achieve good results, and conclude by applying these parameters to two patients enrolled in clinical trials for custom surgery in Perth, Western Australia. Results, and indications for future directions in custom surgery treatments, are then provided along with a discussion of patient outcomes and visual quality of life improvements.

Literature Review:

Custom surgery is a surgical planning approach, which seeks to "customize" refractive surgery to correct standard and non-standard vision disorders, based on the unique needs of each individual eye being treated. These needs typically center on ability for functional customization (age, needs, refraction, occupation, circumstances, etc.), anatomical customization (corneal thickness, pupil size, etc.) and optical aberration customization (topographical or wave front errors within the eye). Promised benefits of custom surgery range from "super-vision," to superior vision under various light conditions, as well as ensuring that refractive errors are properly corrected. Indeed, not all outcomes of standard LASIK and PRK treatments deliver positive results; some surgery has historically caused over-correction, or induced other aberrations in the eyes being treated. Custom surgery can potentially correct this problem and re-focus the location of the image formed by the eye back onto the retina. Custom surgery is also an option for patients requiring re-treatment (from previous refractive surgery or other procedures such as corneal keratoplasty), and for certain patients who suffered corneal injury or from significantly irregular corneal shapes.

Custom surgery also offers economic benefits to medical practices. Between 5-20% of patients of many practices have vision disorders, which can be termed "non-standard." Ability to treating these patients rings the cash registers of doctors and surgery centers, while offering positive outcomes to the patients. A solution to "problem patients" also has economic benefits. Doctors also find that these patients, as well as other patients who have complaints about earlier surgeries with poor results, are sources of problems, complaints, and necessitate re-treatments. It is these problem patients, who require an inordinate amount of time due to recurring complaints, who cannot be treated with older laser and eye tracking technology. Doctors lacking the technology to provide a custom solution sacrifice lost revenue, from non-standard disorders. Also, lost time and money is sunk into the problem patients who typically complain the most often, who re-visit the practice repeatedly, and who may spread negative word of mouth about refractive surgery and its practitioners.

Technological Hurdles to Custom Ablation:

Custom surgery as a concept also has its detractors. Due to market pressures, many laser manufactures, as well as makers of devices to diagnose the visual pathways of they eye (e.g., wave front devices to map aberrations of the eye, and topography (corneal shape) measurement devices) have overpromised and – in many cases—under delivered. One typical example is wave front measurement based on the Hartmann-Shack technology and measurement algorithms, tools originally designed to register flaws in precision optics, not diagnose the human eye. Hartmann Shack has significant technical limitations when registering irregular corneas, and this approach creates an incorrect map of the very corneas most needing custom treatment (the Hartmann Shack method results in a map which lacks a one-to-one correspondence to actual corneal position, making this tool problematic for the high accuracy demanded for custom surgery, where as newer devices (based on technology by Tracey, and others) provide higher degrees of accuracy for irregular corneas). By over-promising the benefits of tools unsuited for custom surgery, many surgeons are beginning to question whether many of these products—which work quite well for standard refractive procedures—truly deliver the necessary precision for custom surgery.

Conceptual Development:

To make custom surgery work, a number of critical components are necessary, focused around the need for appropriate laser technology, proper measurement, and integration among the measurement, eye tracking and laser technologies. When the pieces fit together, custom surgery can deliver on all promises, to both standard and non-standard eyes. Inappropriate matching of different pieces creates less favorable results for patients. The technical definitions of the pieces of the custom puzzle are defined below.

Laser:

Many of the most reliable commercial lasers for standard refractive surgery were not, unfortunately, originally designed for custom ablation. Unfortunately, slow pulse rates (<200 Hz), large spot sizes (> 0.8 mm) and slit beams complicate the provision of custom treatment. For superior custom performance, fast pulse rates are more desirable than slower lasers, and pulse rates of between 200-400Hz are needed for superior outcomes to prevent the long treatment times, which create thermal damage to the eye. Very fast scanning can help reduced treatment times. Also, suitable laser fluency and regular energy distribution is needed as well as a predictable energy output across a wide range of pulse repetition rates. Only reliable beam characteristics permit establishment of small spot sizes, which are critical for high-resolution laser treatments. An appropriate laser is required to deliver the benefits of predictable results, improved visual acuity (UCVA/BSCVA), stability, safety and patient satisfaction (e.g., NEI RQL-42 Refractive Error Quality of Life Survey Instrument). Many recent studies have suggested that solid-state lasers may deliver more reliable energy distributions, and are capable of producing wavelengths more suitable to custom surgery (211-13nm). Comparative studies between solid state (211-213) and excimer (193) ablations have demonstrated that tissue effects were similar, however the solid-state wavelengths have advantages for custom refractive surgery. For example, thermal-imaging tests during ablation indicated smaller temperature rises, and lower absorption rates in physiological saline. Indeed, the increased penetration depth through saline and BSS for solid-state wavelengths may prove extremely beneficial for custom surgery. Also, for custom surgery requiring extremely small spot sizes and very fast pulse repetition rates, gas-based excimer lasers are less efficient in terms of energy conversion and beam energy distributions.

Measurement:

Proper registration rarely occurs in custom surgical planning. Placido-based topography maps are generated centered on the corneal vertex, yet surgical lasers are generally centered on the pupil (and the center of the pupil itself actually shifts as much as 1 mm during dilation and contraction). If the eye rotates in its socket when the patient lies down (almost a certainty) the surgical map and the eye are no longer rotated to the same axis. Thus, spending money on expensive devices ensures neither centration, nor matching of the topography with actual eye position.

Wave front, while having the potential to clarify the surgical plan by correctly mapping aberrations, also falls short in custom surgery, especially if calculated on Hartmann-Shack (this method does not have one-to-one correspondence with corneal position, especially in irregular eyes). Wave front, when combined with corneal topography measurements, provide better accuracy. Ensuring, however, that both wave front and topography are centered on the same point remains important to deliver accuracy. Neither the rotated eye, the initial topography, nor the wave front are likely to line up exactly with the eye, and the seemingly easiest method—that of centering on the pupil-- actually compounds these errors as the center of the pupil moves as well. Centering on the limbus, or combining improved centration with gaze tracking, are the only possible solutions for accurate custom surgery.

It is important to remember that most eye trackers generally lock on to the pupil, rather than the clear corneal tissue that they intend to track. Therefore, there remains a built in assumption that the patient is always looking at the fixation light. If the patient actually looks to the side, the eye tracker can accurately follow the pupil, but the laser *will not* hit the correct part of the cornea. These errors can be significant for custom surgery, and can only by fixed by some sort of gaze tracking.

Solutions to measurement problems reside in properly registering the maps and measurements with each other, and with the actual position of the eye. Advances in wave front technology, limbal tracking and integration of diagnostic data to provide true and consistent reference points for custom surgery. Merely spending dollars on expensive gear does not guarantee centration, nor of correspondence among various measurement devices and laser scanning tools with the true position of the eye during surgery.

New technology, especially around the need for faster, “solid state eye tracking,” assist in improving the measurement problems. Where many standard systems fail the integration test is around the issue of total response time of the scanning and eye tracking functions. A fast eye tracker tied to a slow laser will create a slow total response. Many of these problems are inherent in the "flying spot" scanning technology, which employs a mechanical galvanometer to move a mirror to try to catch up with any eye movements. Unfortunately, the laser pulse rate is faster than the combined detect time and mechanical mirror movement, no matter how robust the software and tracking algorithms may be. A better approach may be found in tying the faster lasers to the newer technologies such as solid-state scanning, which speeds up total response time (>5000 Hz/1 ms) by eliminating the slow, mechanical galvanometer. The need for proper integration, to speed up total response time, is often overlooked by many doctors when selecting lasers appropriate for custom surgery.

Integration:

Integration of fast eye tracking with a fast laser helps put the custom puzzle together most efficiently. Integration helps "model" the eye through Computer-Aided-Design (CAD) software, and provide customized surgical plans for the ophthalmologists. This integration thus creates a more "scientific" approach to custom surgery. Integration ensures the incorporation of high frequency detection with fastest total response time (5000 Hz/1ms). Also, intra-operative feedback is possible, and the laser can be programmed to "gaze track" the patient, and suspend treatment if either proper centration or the patient's proper gaze (at fixation light) is lost. Integration can also "show" the surgeon where the eye is positioned, and even project a visible laser cross on the treatment zone.

Research Methodology:

Study Design:

A non-randomized, unmasked, single-center, multi-investigational trial was designed, wherein a pre-treatment baseline is created with a combination of topography, and eye tracking measurements along with patient data. The CustomVis™ platform calculates the surgical plan for the doctor, customizing to each patient eye being treated. CAD software integrated into a solid-state laser calculates the most appropriate surgical plan customized to the unique needs of each eye. After treatment, completed on an out patient basis, the effect of the corneal reshaping is compared against pre-treatment baseline measurements.

Apparatus:

The CLVR CustomVis™ Customized Laser Corneal Shaping System, based on the CustomVis™ Solid-State Refractive Laser and operating at wavelengths between 211-213nm. This laser systems and operates the CustomVis™ Super speed Solid State CAD Eye Tracking advanced eye scanning device. Preliminary registration data was obtained with Orbscan© and diagnostic instrument, and this data was entered into the CustomVis™ software package to generate a custom surgical plan.

Procedure:

Initial patients were identified due to their non-standard vision disorders, and enrolled in the study as follows.

1) **August, 2002**: Early Clinical Trials in Australia at the Ophthalmic Day Surgery in Western Australia. This day

surgery center conducts clinical trials for major ophthalmic companies, worldwide. Patients were identified based on rigorous selection procedures for their suitability to participate in one of the appropriate studies, and assigned a sequential, unique and secure identifying number. These studies are:

- Treatment and Re-treatment Protocol For Eyes with Irregular Astigmatism Investigational Plan using the CustomVis© Customized Laser Corneal Shaping System

- Treatment Protocol for Myopia with or Without Astigmatism (-0.75D to -10D Sphere, up to -5D of Cylinder) using the CustomVis©

2) **January, 2003**: US Food and Drug Administration Trials in the USA organized at five investigational sites by The Center for Clinical Research in Chicago, Illinois. This Center, and its investigators, has gained approval for such major players as Summit, Autonomous, Sunrise, and other major ophthalmic companies worldwide.

- Treatment and Re-treatment Protocol For Eyes with Irregular Astigmatism Investigational Plan using the CustomVis© Customized Laser Corneal Shaping System

- Treatment Protocol for Myopia with or Without Astigmatism (-0.75D to -10D Sphere, up to -5D of Cylinder) using the CustomVis© Customized Laser Corneal Shaping System.

Discussion:

Patients are evaluated regularly, up to three months post-stability. Contrast testing and endothelial cell count sub-studies are also included in the investigational plan. Results will validate the applicability of the CustomVis™ Customized Laser Corneal Shaping System for refractive surgery.

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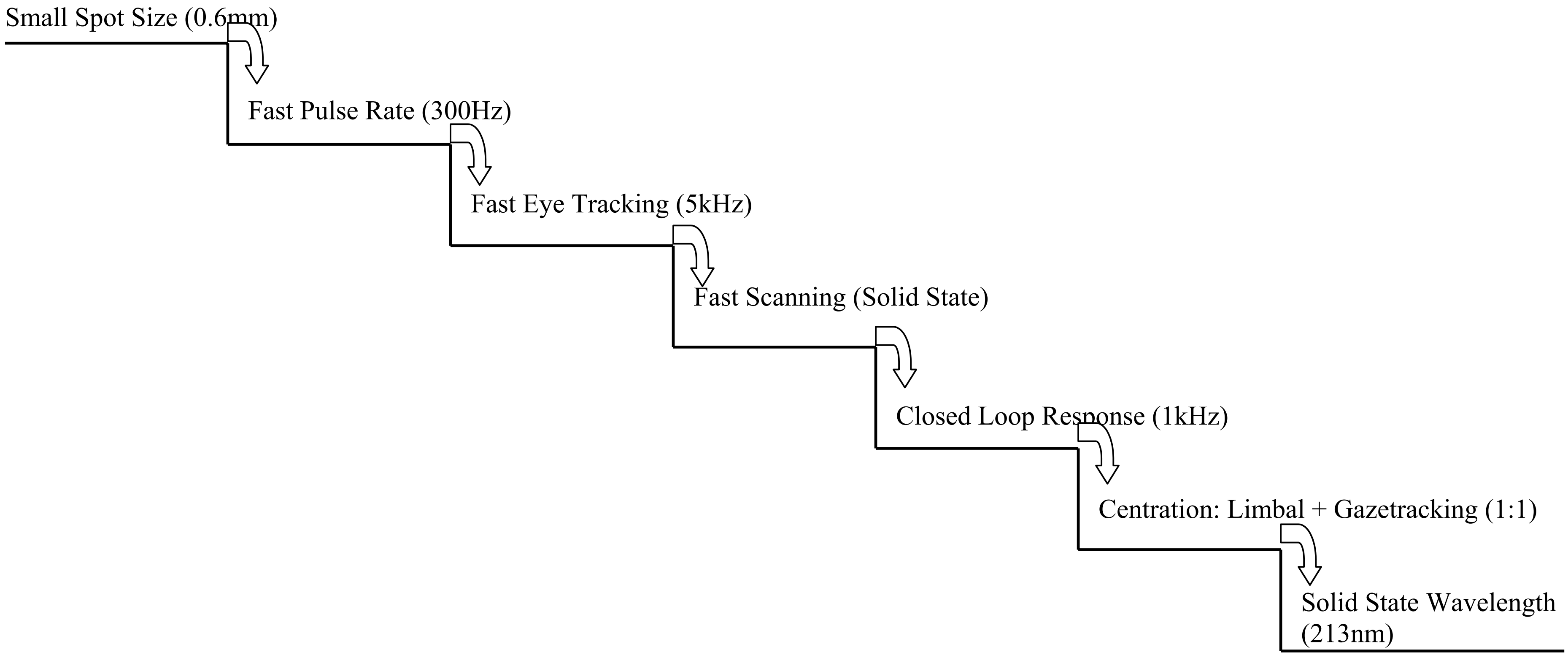
FITTING TOGETHER THE CUSTOM SURGERY PUZZLE[1]



[1] See Eye World (2001)