

Ray tracing for laser corneal refractive surgery

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It seems almost unbelievable that despite technological advances in medicine and ophthalmic surgery, we still use the Nobel Prize-winning Gullstrand Eye Model (Figure 1), developed in 1911, to calculate ablation profiles used during corneal laser surgery. Gullstrand's schematic eye is one of the most widely accepted models and almost every corneal laser refractive procedure to date has been performed using this model. It works well for the average eye and most eyes treated are average. Certain patients, however, have a higher chance of needing enhancement surgery, specifically those with non-average characteristics with regard to corneal curvature/axial length relationship and/or aberrations. This is as a direct result of using the Gullstrand model, which was found to fit the average eye very well but to do less well for the outlier eyes. Currently, laser epithelial keratomileusis (LASEK), laser-assisted in situ keratomileusis (LASIK) and photorefractive keratectomy (PRK) procedures are based on this model. Even the more advanced ablation profiles such as Wavefront-Optimized, Topography-Guided, Custom-Q and Wavefront-Guided, which is known to measure the entire optical characteristics of the eye, are all calculated using this 100-year-old model.

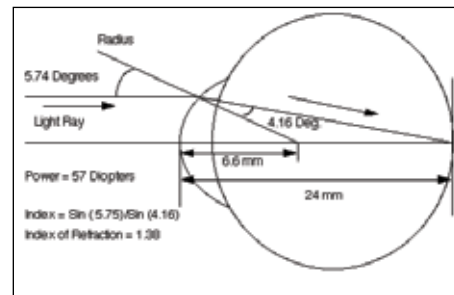


Figure 1
 Gullstrand's Schematic Eye

3. Posterior corneal surface data is collected by the Pentacam or Allegro Oculyzer.
 4. Biometric data such as corneal pachymetry, anterior chamber depth, lens thickness, and axial length are all collected by the Allegro BioGraph (WaveLight GmbH, Germany) (Figure 2).

The current ray tracing study protocols use the Scheimpflug principles of the Pentacam and/or Allegro Oculyzer to obtain both anterior and posterior corneal surface data. Potentially, future ray tracing profiles may also include

The Ray Tracing Profile

The highest possible accuracy in ablation profile planning can only be achieved by taking all of the optical structures in the patient's eye into consideration. With the advent of partial coherence reflectometry (similar to IOL Master technology for calculating IOL powers) the intraocular structures and dimensions can now be measured with extreme accuracy. Using these details, an exact computer model of each individual patient's eye can be generated. This method can greatly enhance the outcomes of laser refractive surgery, both in terms of predictability (accuracy) and safety (lines of best-corrected visual acuity (VA) either lost or gained).

The ray tracing ablation profile is calculated using the following data:
 1. Wavefront maps of the optics of the entire eye are collected with a Tscherning Wavefront Analyser.

2. Topographical corneal data is collected with the Pentacam (Oculus GmbH, Germany) or Allegro Oculyzer (WaveLight GmbH, Germany).



Figure 2
 Allegro BioGraph
 (WaveLight GmbH, Germany)



Figure 3

Allegro BioGraph Printout (WaveLight GmbH, Germany)

data from the topographer/Allegro Topolyzer (placido disc) for additional anterior surface data. (Note that the Allegro Oculyzer is the same as the Pentacam but it has been licensed to WaveLight to become a therapeutic device and hence the name change; it is still manufactured by Oculus).

Based on the Optical Low Coherence Reflectometry (OLCR) measuring principle, the Allegro BioGraph is a multifunctional biometry device used to determine the axial dimensions of the eye, as well as the complete anterior segment. This optical system will combine future technologies with established biometry applications. Its applications include central corneal thickness measurement, anatomic anterior chamber depth measurement, axial length measurement, central lens thickness measurement, retina thickness measurement, keratometry, 'white to white' measurement, and pupillometry (Figure 3). It also measures the patient's visual-optical line to the fovea, which leads to improved VA when compared to calculations based on the theoretically-derived optical axis from the Gullstrand schematic eye. Using the ray tracing profile (Figure 4) we now know the exact locations of the various ocular interfaces. We have much more useful data about the cornea, not just an average refractive power of 43D based on keratometry that the Gullstrand eye model assumes. We now know where the corneal

inner surface is and we know where the anterior and posterior lens surfaces are. We now know the exact position of the macula. This allows us to create an accurate pathway for light passing through the various structures in the eye and being in perfect focus at the macula.

This data is then used to create the "perfect" ablation profile for that specific eye. "Test surgery" is then performed on the computer-generated ocular model. Once the surgery has been completed,

the new optics are tested again by projecting an image into the virtual eye. Looking at the quality of the image on the retina now allows the ablation profile to be modified or refined in order to make the retinal image even more defined. This "loop" is reiterated six or seven times in order to finally achieve an ultimate ablation profile for this eye.

A further two parameters are included in the final ablation profile, namely anticipated biomechanical corneal effects of corneal laser refractive surgery and the predicted epithelial healing response. These last two items have a very small effect on the final outcomes with LASIK but nevertheless are incorporated as we endeavour to find the ultimate ablation profile for any given eye.

The Ray Tracing Study

The ray tracing ablation profile comes from the Institute for Refractive and Ophthalmic Surgery (IROC) Clinic in Zurich, Switzerland, where Professor Theo Seiler is the lead ophthalmologist and Professor Michael Mrochen is the optical engineer. Together with WaveLight GmbH in Germany, they have initiated a clinical trial into Ray Tracing LASIK. It is a multi-centre, prospective, European trial

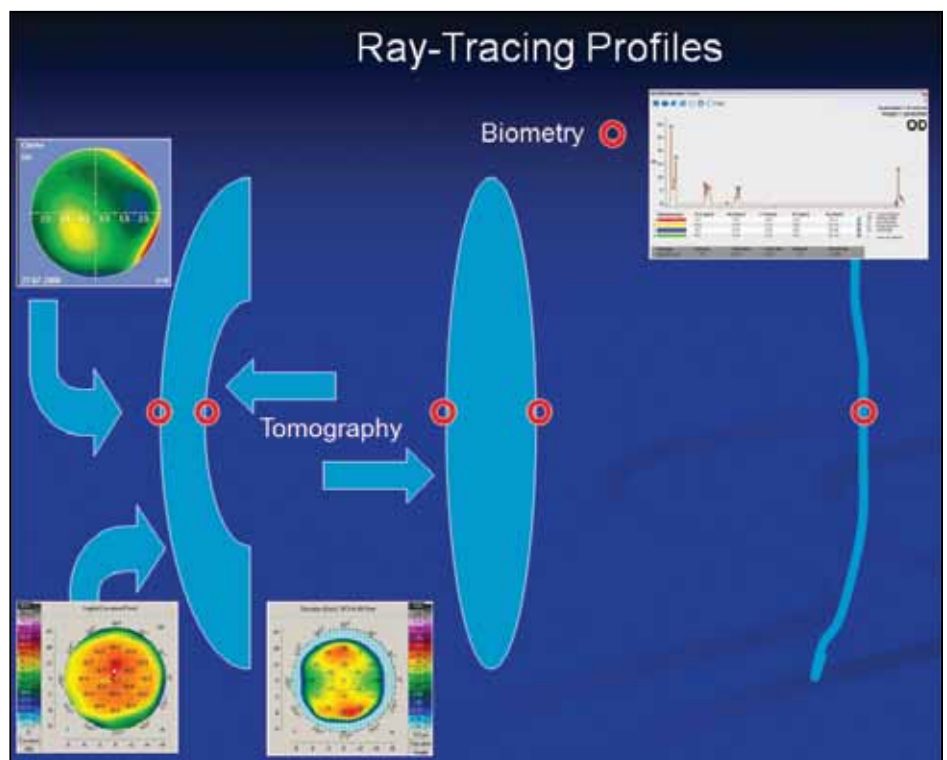


Figure 4

Ray tracing profile depicting topography, tomography and BioGraph measurements relative to the eye

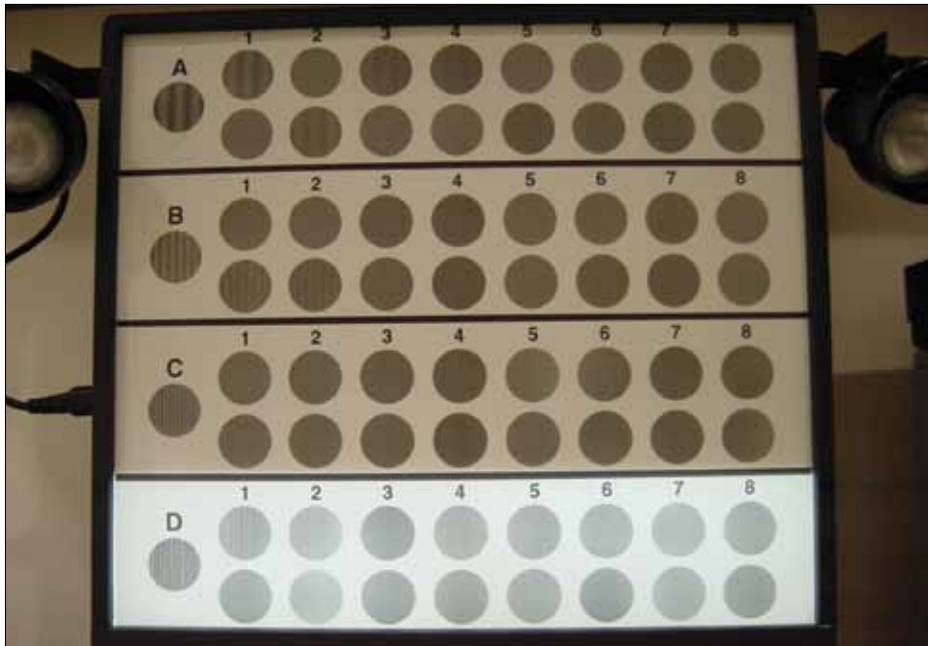


Figure 5
The contrast sensitivity test used in study

with three eye clinics taking part to validate the data. These clinics are at IROC, where Professor Seiler performs the surgery, the SehKraft Clinic in Cologne, Germany, where Dr. Matthias Maus performs the surgery, and the Wellington Eye Clinic (WEC) in Dublin, Ireland, where Dr. Arthur Cummings performs the surgery.

In order to do the study, the WEC received ethical approval from the Beacon Hospital Ethics Committee. The study is under the Irish Medicines Board (IMB) jurisdiction. The study includes 120 eyes, with the Wellington Eye Clinic performing 50% of the procedures and the other two clinics performing the remaining 50% between them. The study is currently halfway in the recruitment phase and the current article discusses the results of 23 eyes treated at the WEC, all of which had Day 1 follow up and 17 of which have had a 1-month follow-up.

Patient Selection

For patients to meet the criteria for the study, they are required to have a spectacle refraction of greater than -4.00 Dioptres Sphere Equivalent (DSE) and/or more than 2.00 DC of astigmatism.

Methods

Dr. Cummings sees each WEC patient at the first visit. He explains the study to them if their refractive error

meets the inclusion criteria. They undergo a multitude of tests including uncorrected VA (UCVA), best-corrected VA (BCVA), manifest and cycloplegic refraction, four wavefront maps, four Oculyzer maps, four topography maps and four Biograph measurements. A complete anterior segment examination as well as a dilated peripheral retinal examination is performed, as per all routine refractive surgery cases.

All of this information is recorded and transferred to IROC via file transfer protocols (ftp) online, where a computer-generated ray tracing profile is created for that patient. On the day of surgery, a contrast sensitivity test is performed (Figure 5) and a pregnancy test for the female patients. The patient fills out a questionnaire and they also sign an informed consent form, which has been explained to them by Dr. Cummings. The Ray Tracing Ablation Profile is loaded into the Wavelight Allegretto Laser and the surgery is performed. During the surgery, the time from when the flap is lifted to the end of the laser treatment is measured. This is to determine whether corneal dehydration plays any role in refractive outcomes. The treatment lasts a little longer than a WaveFront Optimized (WFO) Treatment for a similar prescription and a little less corneal tissue is ablated too.

On the first post-operative day

and the 1-month and 3-month post-operative exams, the UCVA, BCVA, manifest refraction and topography measurements are all performed. An additional contrast sensitivity test and a wavefront analysis are performed and the patient completes another questionnaire at the 3-month post-operative visit. The questionnaire includes details on how often the patient wears contact lenses or spectacles, how they rate their vision without spectacles or contact lenses, if they experience fluctuations in their vision during the day, if they experience light sensitivity, their rating of their vision for night driving, experience of glare with headlights, streetlights, halos, etc., and a rating of their self-esteem. The answers are indicated on visual analogue scales by placing a cross mark on a line; these are later analysed by placing a transparency carrying numbered divisions over the page and seeing what number from 1 to 10 the mark corresponds to.

Early Results

At the time of writing this article 23 eyes had been treated with ray tracing profiles, of which 17 had 1-month follow-up data. For the purposes of this article, the current results are compared to patients meeting the same inclusion criteria (>-4.00DSE or -2.00DC) that were treated with Wavefront-Optimized profiles, prior to the ray tracing trial commencing. There were 234 eyes in the Wavefront-Optimized group.

The results are portrayed graphically in Figures 6 to 9; the Wavefront-Optimized results are in red and the ray tracing results are in blue. At 1-month post-operatively, in the Wavefront-Optimized group, 58% of eyes have uncorrected VA of 6/5 while 100% of the ray tracing group have uncorrected VA of 6/5; 41% have uncorrected VA of better than 6/5. For BCVA, 82% of the Wavefront-Optimized group have a VA of 6/5 whilst 100% of the ray tracing group have a VA of 6/5. In the Wavefront-Optimized group, more than 9% of eyes have lost at least one line of BCVA while none of the ray tracing group have lost any lines of BCVA. In fact, more eyes have gained lines of VA in the ray tracing group. The FDA

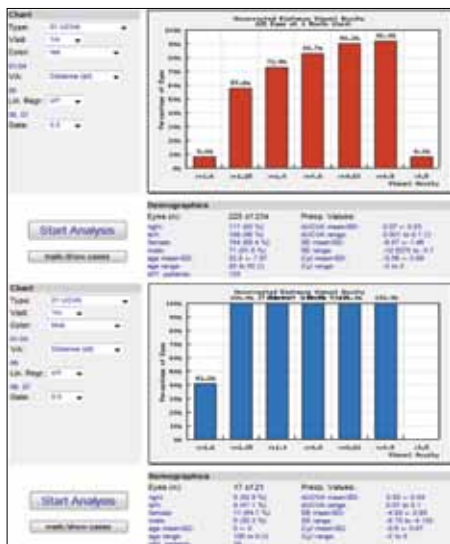


Figure 6

Uncorrected VA at the 1-month post-operative visit in the Wavefront Optimized group (58% see 6/5 or better) and the ray tracing group (100% see 6/5 and 41% see better than 6/5)

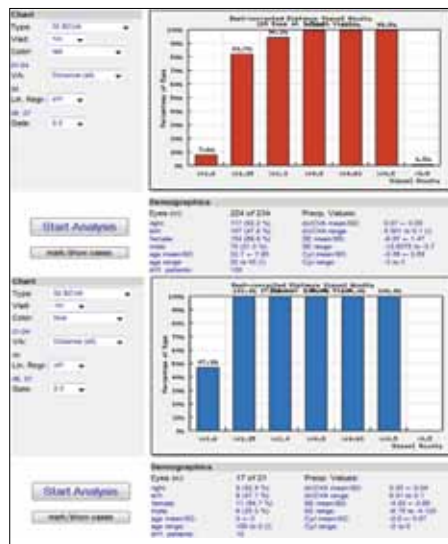


Figure 7

Best-corrected VA at the 1-month post-operative visit in the Wavefront Optimized group (82% have a VA of 6/5) and the ray tracing group (100% have a VA of 6/5)

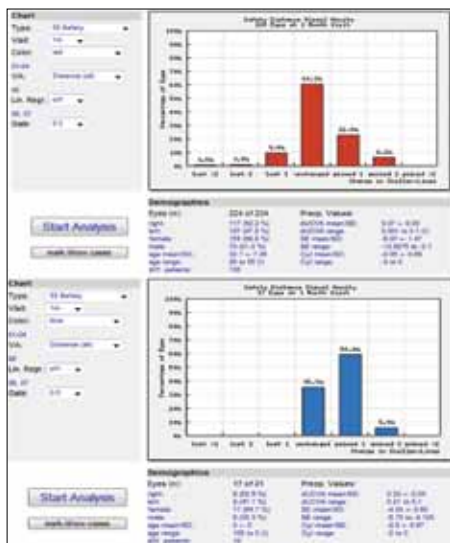


Figure 8

Safety data at 1-month post-operatively, as determined by BCVA. In the Wavefront Optimized group, more than 9% of eyes lost at least one line of VA, while none lost any lines of acuity in the ray tracing group. More eyes gained lines of acuity in the ray tracing group than in the Wavefront Optimized group.

allows the loss of more than two lines in no more than 5% of eyes to be declared a safe procedure.

As far as astigmatism outcomes are concerned, the ray tracing results demonstrate a much tighter outcome. In the Wavefront-Optimized group the residual astigmatism is 0.25 ± 0.27 DC whilst in the ray tracing group, the

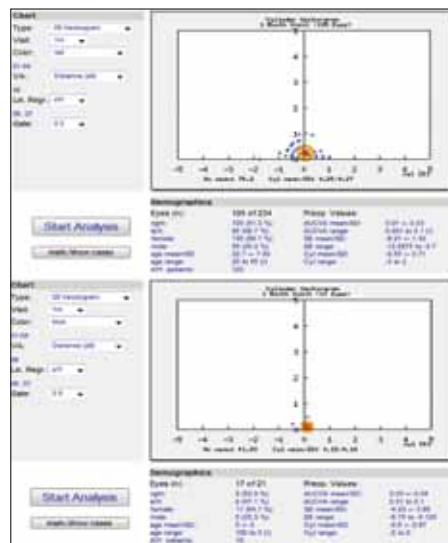


Figure 9

Residual astigmatism in the Wavefront Optimized group (0.25 ± 0.27 DC) and the ray tracing group (0.15 ± 0.18 DC)

residual astigmatism is 0.15 ± 0.18 DC. It needs to be stated that the ray tracing group had significantly more pre-operative astigmatism compared to the Wavefront-Optimized group, which makes the outcomes even more impressive.

Early indications from five eyes at 3-months post-operatively reveal improved contrast sensitivity performance. Questionnaire data has been completed by three patients and all claimed that they have never seen better before!

Summary

Further data will become available as the study continues and more analysis will reveal the true outcomes of the ray tracing profiles. Early evidence in this article suggests that ray tracing profiles promise to deliver the best results seen for corneal laser refractive surgery, with increased predictability and safety and the highest levels of patient satisfaction. It needs to be stressed that the 1-month interval is an early stage at which to be comparing data but early indications at the 3-month interval continues to support this trend.

The FDA allows the loss of more than 2 lines in less than 5% of eyes to be declared a safe procedure and based on this it is obvious that Wavefront-Optimized surgery remains a very safe procedure but ray tracing promises to be even safer.

The future will hopefully see the ray tracing calculations being performed locally in the clinic and this should be available on a much wider basis within the next year. With the increased data that helps to calculate the ablation profile, the opportunity also arises to find more effective presbyopia ablation profiles too. These clinical trials commenced early in 2010 and the results are eagerly anticipated.

About the Authors

Mr. Arthur Cummings is a consultant ophthalmologist practicing at the Wellington Eye Clinic in Dublin. He is a clinical investigator for WaveLight and Alcon, and conducts research in Corneal Cross-linking (CXL), combined topography-guided PRK and CXL for keratoconus (SimLC), LASIK, and is part of a collaborative group researching better ways to predict IOL power calculations and ELP (effective lens position). Clare Maguire is an optometrist practicing at the Wellington Eye Clinic in Dublin. She also works as a Professional Affairs consultant for Johnson and Johnson Vision Care.

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