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Artemis 2 Gives the Most Accurate Measurements Within the Cornea and Anterior Segment

By Ana Hidalgo-Simón

NICE – New technical advances suggest ultrasound diagnostic tools may become the slit-lamp of the 21st century, Dan Z Reinstein MD, MA(Cantab) FRCSC told a Clinical Research Symposium during the XX ESCRS Congress.

Dr Reinstein highlighted the potential of the new VHF Digital Ultrasound Arcscan Artemis 2 across a range of anterior segment applications.

Figure 1. Artemis 2: Table-top compact design incorporating reverse immersion technology.

With the ability to reveal sub-surface micro-anatomy within the anterior segment and discern epithelial from stromal components within the cornea, the instrument promises to be the 'crystal ball' anterior segment surgeons have been waiting for, he said.

"No neurosurgeon would operate on a patient without a decent MRI. In the same way, our most direct path towards proper surgical management is going to come from the best – most accurate – diagnostic information before surgery," Dr Reinstein said.

He described the accuracy and precision of the measurements as "unprecedented". M-scan studies within the cornea allowed investigators to determine that the interface localisation precision of the system has less than 1.0 micron of standard deviation (±0.87–µm). This was shown experimentally to translate to the ability to make measurements within the cornea with a precision of approximately 1.0 micron.

Scanning is performed in multiple meridians therefore providing data in three dimensions. Based on these data, Dr Reinstein and co-workers who created the instrument developed 3D mapping techniques for individual corneal layers before and after LASIK with 1 micron precision. It is also possible to determine the angle-to-angle or sulcus-to-sulcus dimensions of an eye, with approximately 100-micron precision and map these in 3D for localization of the largest axis.

"We also spent considerable time developing other features that are critical for using this technology as a surgical planning device. For example, there is simultaneous optical infrared video-image of the eye with each ultrasound scan. (Figure 2). This is a crucial element of the system because knowledge of the position from which a scan was taken is critical if scan measurements are to be used for surgical planning, both for the cornea and phakic IOL placement in the anterior segment. We developed this, because of early experience with a hand held high-frequency ultrasound device without co-axial video monitoring, where the lack of scan positional accuracy was high enough to affect surgical accuracy and safety," he commented.

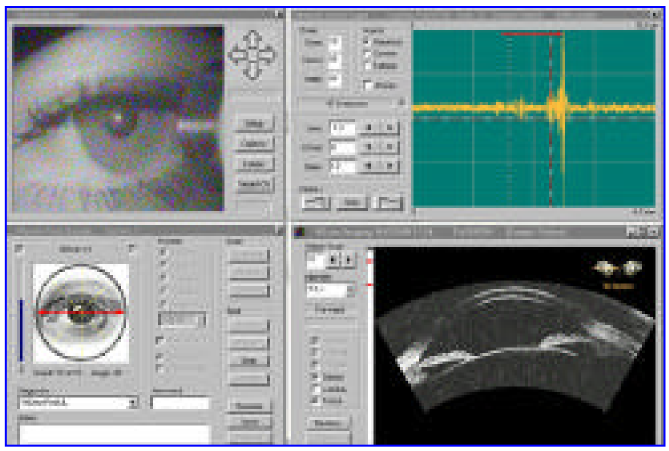

Figure 2. Artemis 2 scan control console: The anterior segment B-scan image is taken with the patient fixating on a coaxial light source that enables centering on the corneal reflex. In this case, for a sulcus to sulcus

In relation to LASIK surgery, the system has the advantage of being able to detect the epithelial thickness separately from the stromal component of the flap and from the residual stroma in 3D. All these measurements – with approximately 1.0 micron precision and in three dimensions – allow the creation of maps of the thickness of each layer. (Figure 3).

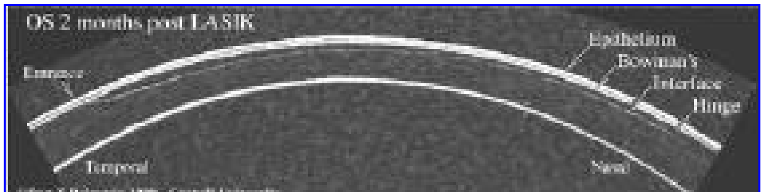

Figure 3. B-scan through cornea 2 months post-LASIK demonstrating the ability to clearly delineate the flap interface from one end to the other in one scan sweep. Measurements within the cornea are provided with 1–µm precision.

"This permits currently the most accurate planning of surgical interventions and follow-up of the evolution of each corneal component postoperatively. We can also determine very precisely the efficacy of microkeratomes in 3D – not just at one point," Dr

Reinstein explained. See Figure 4.

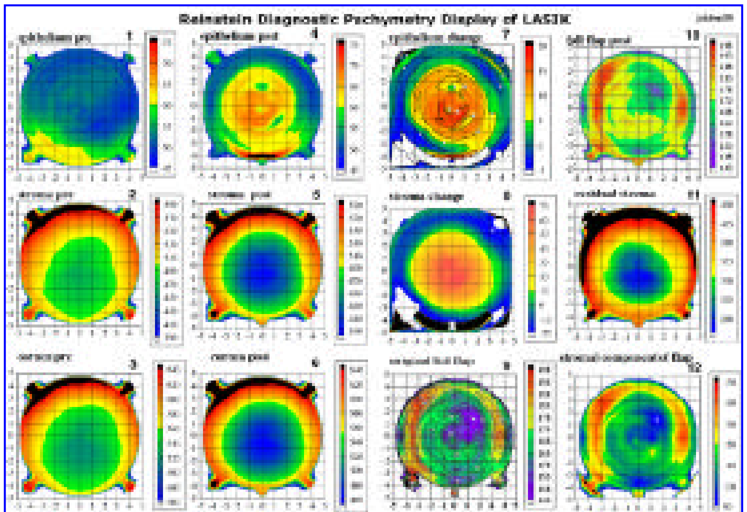

Figure 4. Reinstein Diagnostic Pachymetry Display of LASIK showing epithelial, flap, residual stromal thickness before (1st column) and after surgery (2nd column). Difference maps of epithelial and stromal thickness profile change are calculated (3rd column). The residual stromal thickness in 3D is shown in map 11

In a study comparing central pachymetry by Orbscan with the Artemis 2, Dr. Reinstein and colleagues found an estimated improvement of 25 microns (of standard deviation) in the accuracy of pachymetry by Orbscan compared to the Artemis 2 technology with its state-of-the-art three-dimensional pachymetry. This same study showed that 36% of eyes were significantly overestimated by Orbscan, while 17% of patients were underestimated by Orbscan. Patients overestimated could, in principle, be incorrectly deemed to be candidates for LASIK, while some would be rejected on the basis of an incorrect low thickness measurement. “This is good for business on two fronts; good candidates are not turned away, while patients with corneas too thin are detected accurately” added Dr. Reinstein.

Regarding the assessment of complications in LASIK, Dr. Reinstein has studied microfolds in Bowman’s membrane and was able to differentiate two sub-types: Bowman’s cracks, possibly caused by traumatic elevation or repositioning of the flap and what he called ‘True Microfolds’, actually grooves in Bowman’s caused by inadequate flap distension or repositioning. (Figure 5). He pointed out that although both lead to loss of best corrected vision, the re-lifting of patients with Bowman’s cracks will not improve vision and could potentially worsen it. Therefore distinguishing microfolds form cracks becomes very

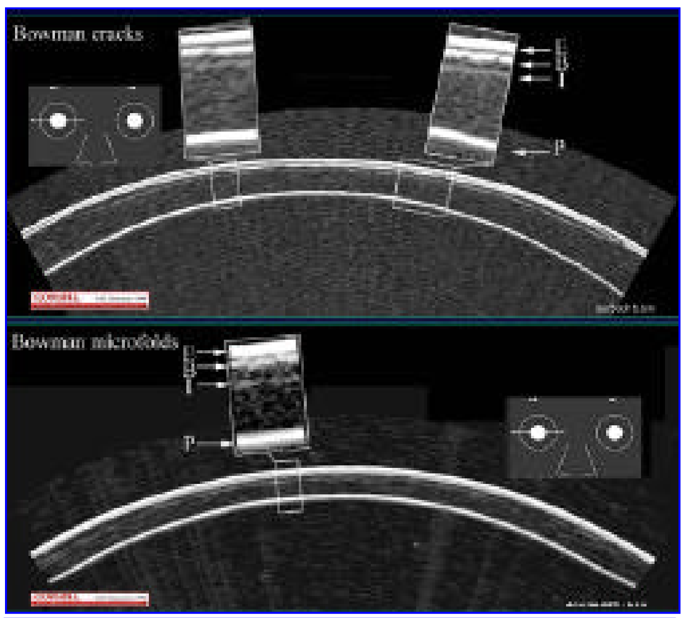

Figure 5. Reinstein Classification of Microfolds: Bowman’s Cracks (above) or True Microfolds (bottom)

important.

Such studies also led to modifying his flap handling to a minimal-touch technique he called the ‘door-opening’ and ‘door-closing’ manoeuvres. “Many surgical technique modifications and improvements have been made thanks to our new ability to ‘see’ what is going on at the microscopic level in these tissues,” he added.

He also discussed his group’s findings regarding the wound healing process within the cornea after LASIK and PRK, separating epithelial factors from biomechanical factors.

They found that the epithelial response was unexpectedly complex. When they plotted the amount of myopia treated against the epithelial power shift produced by the surgery, and found that the epithelial response was non-linear and biphasic.

“At lower levels of myopia the epithelial power shift causes more and more myopisation with the level of myopia treated. But that is true only up to a certain point. Treating higher levels of myopia, a paradoxical epithelial hyperopic shift appears to take place,” he reported.

The researchers concluded that the actual corneal power change in LASIK is degraded by an average biomechanical shift of 15%. That combines with the observed epithelial effect which accounts for about an extra 5% of variation in the final postoperative refractive error.

“This comes to a possible total of 20%. The refractive errors we are observing after LASIK can be explained by epithelial and biomechanical factors. And understanding of these processes, combined with adequate modelling and predictive calculations, will enable us to further improve the accuracy of customised ablation procedures,” he predicted. “We want to take these elements out of the nomogram side and put them into the parameter side of the ablation profile.”

There has been a tremendous amount of interest in the use of custom ablation to repair corneas. However, the epithelium tends to compensate for stromal surface irregularities (it is almost always thicker in the ‘crevices’ than over the ‘bumps’) and therefore the epithelium masks the true topographic and/or wavefront error being caused by an asymmetric stromal surface.

According to Dr Reinstein, systems based on topographic guidance have failed to adequately provide the surgeon with the accurate tools needed to help these patients.

This new Artemis 2 technology also promises to help understand the physiological dynamics of the anterior segment which will have implications for the insertion of IOLs.

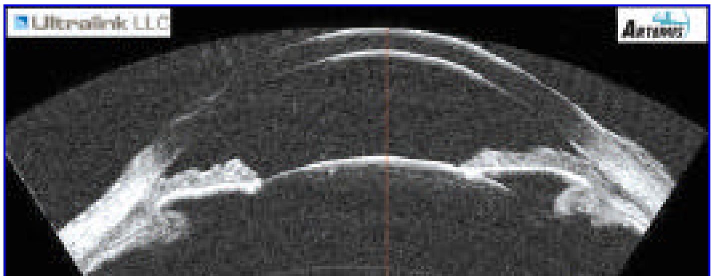

Figure 6. Full anterior segment scan in one sweep: corneal epithelium angles, sulci, ciliary bodies and anterior retina are all imaged instantaneously and within one high-precision scan plane using patented Cornell University arc-scan

The instrument allows the measuring of internal dimension changes from light to dark and during accommodation as the pupil and ciliary body shift position. This could be particularly important in the long term safety of angle-supported or posterior chamber IOLs.

"In a study in which we looked at the correlation between white-to-white measurements with sulcus-to-sulcus distances, we found no significant correlation for myopic and hyperopic eyes. Figure 6.

"For angle-to-angle association with white-to-white measurements, we founded no correlation for myopes but a weak albeit significant correlation in hyperopic patients. Unfortunately, hyperopic patients are the least likely candidates for an angle-supported IOL," Dr Reinstein said.

In presbyopic insert surgery, Dr Reinstein pointed out that the ability to accurately measure scleral thickness is going to be a very important issue because the depth of implantation and position of the implant relative to the lens equator are key success factors. The scleral thickness and localisation of the zonular plane can be accurately measured using a special software routine developed specifically for this application.

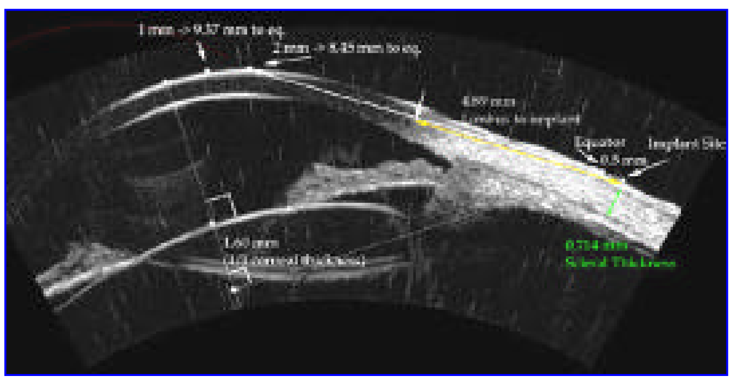

Figure 7. Artemis 2: Software application for determining the exact placement location for scleral expansion band inserts. These must be placed 500–μm behind the point on the sclera intersecting with the line bisecting equator of the lens. Only Artemis can provide this determination thanks to the combined optical and ultrasound B-scan image capture technology

"Using the optical-image to ultrasound-scan correlations, we have developed a special software that enables us to calculate the exact plane in which the presbyopia inserts should be located to achieve maximum effect," he explained. See Figure 7.

"Finally, in cataract surgery, many of the formulas for anterior chamber depth and lens thickness are based on the fact that the lens thickness and the zonular plane are in some way related. By drawing a line across the zonular plane and measuring anterior chamber depth to that plane, one can predict to a much better level of accuracy where an IOL in the bag will end up.

"If we were able to determine the exact location of the zonular plane and therefore the actual chamber depth predicted after phaco and insertion of an IOL in the bag, it should be possible to move to IOL cataract implants in quarter dioptre sizes, adapted specifically to a particular eye." Dr. Reinstein is working together with Dr. Jack T. Holladay on developing a new formula that will incorporate this improved measure of anterior chamber depth.

"We are dealing here with a technology that is enabling ophthalmologists to see beyond the surfaces they have been examining in the last few decades with microscopes. We are now entering into an era of sub-surface anatomy and micro-structure to better plan surgery and treatment modalities," Dr Reinstein said.

The VHF Digital Ultrasound Arcscan technology, now embodied in the Artemis 2 was developed at Cornell University by Dr. Reinstein with co-workers Dr. Ronald H Silverman and Dr. D. Jackson Coleman. It is the world's first very high frequency (VHF) digital ultrasound arc-scanner.

Dr Reinstein, Dr. Silverman and Dr. Coleman retain have a financial interest in Ultralink LLC, the company producing and marketing the Artemis 2. Artemis 2 has received US FDA approval and is commercially available.

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