

Poster – March 26, 2011 8AM

Cataract Surgery Using Biaspheric IOLs in Patients With Corneal Irregularities

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Six cases will be presented featuring patients with corneal irregularities. We will show that when implanting biaspheric IOLs, a significant reduction in optical aberrations at the retina reduced the need for intra and post-operative astigmatic correction by approximately half.

Case reports of six patients having pre-existing corneal irregularities were prepared. They included patients with keratoconus, hexagonal keratotomy, corneal transplant, LASIK, ABMD and previous penetrating injury. Pre and postoperative refraction and topography were analyzed. All patients received biaspheric IOLs and some received corneal or limbal relaxing incisions at the time of the surgical procedure.

Pre and post-operative refractions and topographies will be presented showing that these patients appeared to need approximately half the correction of astigmatic correction post-operatively than patients with conventional spherical intraocular lenses.

The optical benefits associated with these Biaspheric lenses appears to be due to a reduction in optical aberrations at the retina, which improves pseudophakic vision by controlling spherical aberrations. Thus, the need for astigmatic correction is substantially reduced, making this lens ideal for patients with corneal irregularities.

March 26, 2011 1:42-1:47 PM

Preoperative Prediction and Postoperative Determination of Effective Lens Position for Uniplanar Bifocal IOL Using UBM

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0. Harbin Clinic Eye Center, Rome, GA, United States.

To Determine the effective lens position (ELP) and stability of a recently FDA approved bifocal IOL. In addition, the predictability of the ELP will be assessed by comparing the actual post-operative ELP to multiple pre-operative measurements by regression analysis.

This prospective, IRB approved, multicenter study will enroll up to 150 cataractous eyes across three investigative sites. Preoperatively, UBM analysis to measure Lens Capsule Volume, Lens Equatorial Diameter, Lens Thickness, Anterior Chamber Depth, Sulcus-to-Sulcus and Angle-to-Angle metrics will be performed in addition to IOL master and immersion biometry. After standard small incision cataract surgery eyes will be scanned (UBM) at various intervals to determine actual IOL ELP and regression analysis will be performed to determine if the ELP can be predicted by one, or a combination of several preoperative measurements.

ELP over time will be reported and compared to the current lens label. Results of the regression analysis comparing the actual post-operative ELP to multiple pre-operative measurements will be reported.

Conclusions Pending

March 28, 2011 8:07-8:12 AM

Visual Function With High-Definition Accommodating IOL

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To examine the performance of patients implanted bilaterally with a Tetraflex IOL in one eye and the Tetraflex HD in the other.

Twenty patients were implanted with the Tetraflex IOL in one eye and the Tetraflex HD IOL in the other. Uncorrected and Best distance corrected visual acuity at distance (BCVA), intermediate (BDCIVA) and near (BDCNVA) (logMAR chart), contrast sensitivity (Pelli-Robson chart) and defocus curves from +1.5D to -5.0D in 0.5D randomised steps were measured in both photopic (85cd/m²) and mesopic (3cd/m²) conditions.

The Tetraflex HD IOLs showed improved best corrected distance visual acuity in comparison to the Tetraflex IOL $-0.04 \pm 0.08 \log\text{MAR}$ to $-0.04 \pm 0.07 \log\text{MAR}$. BCNVA was marginally better for the tetraflex HD $0.44 \pm 0.14 \log\text{MAR}$ to $0.51 \pm 0.11 \log\text{MAR}$. The Tetraflex HD IOL showed a consistently better defocus curve profile in comparison to the Tetraflex IOL over a range of 0.00D to -1.50D.

The Tetraflex HD demonstrates improved distance, intermediate and near visual acuity at the 3 month stage in comparison to the standard Tetraflex IOL.

March 28, 2011 3:02-3:07 PM

Clinical Evaluation of Aberration-Free Aspheric IOL

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To compare visual performance of a zero-aberration (SoftechHD) aspheric intraocular lens (IOL) with the spherical equivalent (Softec1).

Residual refraction, best-corrected distance and near visual acuity, reading speed, contrast sensitivity and aberrometry were recorded 1 month post-operatively in 37 patients with the SoftechHD in one eye and the Softec1 in the other.

Range of focus was significantly better in the SoftechHD IOL eye than the Softec1 IOL eye and the print size at which optimum reading speed could be achieved was significantly smaller.

Depth of field was significantly improved with the aspheric IOL compared with the spherical IOL, without any compromise in distance visual performance.

March 28, 2011 3:12-3:17 PM

Early Experience With Bi-Aspheric Monofocal IOL

R. R. Schulze

0. Schulze Eye Center, Savannah, GA, United States.

To investigate the refractive accuracy and outcomes with a new, bi-aspheric, monofocal intraocular lens manufactured in quarter diopter steps, the Softec HD manufactured by Lenstec.

A prospective evaluation was undertaken to investigate the refractive outcomes of patients undergoing clear corneal phacoemulsification utilizing the Softec HD lens. The IOL Master, software v 5.4, was used along with the Hoffer Q formula in all cases. Manifest refractions, uncorrected, and best corrected visual acuity were recorded at one month and three months after surgery. Eyes with pre-existing pathology and eyes that could not be measured with the IOL Master were excluded from the analysis.

To be presented.

To be presented.

March 28, 2011 4:03-4:08 PM

Spontaneous Near Vision With Distance-Targeted Balanced Aspheric Monofocal IOL

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To evaluate uncorrected near visual acuity (UCNVA) by axial length (AL) in a cohort of patients implanted with a biaspheric monofocal IOL.

A retrospective chart review of 220 eyes (176 patients) was conducted. Included in the review were all eyes implanted with a newly FDA approved biaspheric monofocal IOL between April 15 and August 9, 2010, and targeted for emmetropia. Uncorrected and best corrected near VA (Rosenbaum Pocket Vision Screener) was entered into a spreadsheet and evaluated as a whole cohort and by preoperative AL.

UCNVA J3 or better was attained by 25% of all eyes and 27.9% of eyes with NVA correctable to J1 or better. Data was parsed by AL as follows: <22 mm, 22-23 mm, 23-24 mm, 24-25 mm, >25 mm. In order of AL, UCNVA J3 or better was attained by 33.3%, 28.6%, 27.1%, 33.3% and 0% of eyes respectively. Of note, 22% of eyes with AL <22 mm achieved UCNVA of J1 or better.

When compared with standard results, a greater percentage of distance targeted patients may obtain good UCNVA with a biaspheric monofocal IOL. Patients with shorter AL may be more likely to spontaneously achieve near spectacle independence.

March 28, 2011 4:13-4:18 PM

Contralateral Aspheric IOL Implantation: Visual and Refractive Outcomes With IOLs Offered in 0.25 D Increments

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To compare 12 month postoperative visual and refractive outcomes in patients contralaterally implanted with an anterior prolate aspheric IOL in one eye and a biaspheric IOL offered in 0.25 D increments in the other eye.

Twenty-five patients were unilaterally implanted with a single-piece, acrylic, biaspheric IOL as part of an FDA safety and effectiveness trial. Of these patients, 18 were implanted with IOLs offered in 0.25 D increments (18.0 – 25.0 D range); 10 of these were contralaterally implanted with an anterior prolate aspheric IOL (18.0 – 25.0 D range), were targeted for emmetropia, and completed a 12 month postoperative exam. Uncorrected visual acuity (UCVA) and refraction data was collected on these 10 patients. Manifest refraction spherical equivalent (MRSE) was compared with predicted targeted refraction to obtain target versus achieved refraction (TVAR).

Twelve months postoperative, biaspheric IOL eyes had a mean TVAR of 0.18 ± 0.11 D. Ninety percent (90%) achieved a MRSE within ± 0.25 D of target and 100% were within ± 0.5 D of target. Cumulatively 60, 80 and 90% of eyes obtained UCVA 20/20, 20/25 and 20/30 or better respectively. Mean TVAR for eyes implanted with the anterior prolate aspheric IOL was 0.29 ± 0.18 D. Respectively, 60 and 80% of eyes were within ± 0.25 D and ± 0.5 D of target refraction. Cumulatively 40, 50 and 90% of eyes obtained UCVA 20/20, 20/25 and 20/30 or better respectively.

Both sets of eyes achieved good TVAR and UCVA outcomes, with the biaspheric IOL achieving the best results. With such excellent outcomes, the investigator now utilizes the biaspheric IOL in difficult eyes including those with keratoconus, corneal transplant, preoperative LASIK, basement membrane and irregular astigmatism.

March 29, 2011 8:47-8:52 AM

**Determining Most Effective Power Calculation Formula With IOL
Manufactured to Improve Refractive Outcomes**

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To compare refractive outcomes with preoperative targets predicted by 3rd and 4th generation IOL power calculation formulas; and to determine which formula is most effective when implanting an IOL manufactured with a 0.11 D tolerance.

185 patients implanted with a bi-aspheric Lenstec Softec IOL manufactured with a 0.11 D tolerance as part of a US FDA clinical trial. Each of the 26 surgeons involved in the study utilized their preferred IOL power calculation formula. After completion of the trial, preoperative patient data was entered into four popular power calculations - the Holladay II, SRK/T, Hoffer Q, and Haigis. One year postoperative manifest refraction spherical equivalent was compared with predicted refractions from each of the four formulas. Refractive predictability was also assessed by axial length.

When surgeons utilized their preferred power calculation, 40.6, 68.7, and 92.8% of patients were within 0.25, 0.50, and 1.0 D of predicted target respectively. When reanalyzed with each of the aforementioned formulas, postoperative outcomes were most accurately predicted with the Holladay II formula overall although results were similar to that using Hoffer Q where axial length was <22 mm and SRK-T when axial length > 22 mm.

The Holladay II power calculation formula most effectively predicted postoperative refractive outcomes in eyes implanted with a bi-aspheric IOL manufactured with a tolerance of 0.11 D. This combination of power calculation formula and lens may enhance refractive outcomes.

March 29, 2011 10:07-10:12 AM

Postoperative Refractive Outcomes With IOLs Incremented in 0.25 D Steps

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To report target versus achieved refractive (TVAR) outcomes in a subset of clinical trial patients implanted with a biaspheric monofocal IOL available in 0.25 D increments.

Three-hundred, ninety (390) patients were prospectively enrolled in the FDA safety and efficacy trial of a biaspheric monofocal IOL. Patients were in good ocular health and willing to have the test article implanted unilaterally in the study eye. Patients underwent routine cataract surgery and attended postoperative visits 1 week, 1 month, 3-6 months and 12 months postoperatively. Subjective manifest refraction data was captured, though not reported as part of the FDA trial. Preoperative measures and surgical technique were not standardized across the eight investigative sites. An IOL a-constant had not been optimized at the time of patient surgeries.

Of the 390 study patients, 308 (79.0 %) were implanted with an IOL available in 0.25 D increments (18.0 - 25.0 D IOL range). These IOLs are manufactured with a tolerance of ± 0.11 D. Preoperative target refraction was compared with postoperative manifest refraction spherical equivalent (MRSE). TVAR for each postoperative time periods will be presented. Twelve months postoperative the cumulative percent of patients achieving TVAR within 0.25 D, 0.5 D, 0.75 D and 1.0 D were 42.3, 68.4, 85.9 and 93.1 respectively. Mean TVAR was 0.42 ± 0.37 .

Where available, IOLs incremented in 0.25 D steps with tight manufacturing tolerances may enhance refractive outcomes compared with published refractive outcome standards. Optimizing each of the factors affecting refractive outcomes (e.g. preoperative biometry, personalized a-constant, etc.) will further improve outcomes with 0.25 D increment IOLs.