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## Highlights of the American Society of Cataract and Refractive Surgery (ASCRS) 2005 Symposium on Cataract, IOL, and Refractive Surgery

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### Cataract Surgery

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The annual symposium of the American Society of Cataract & Refractive Surgery (ASCRS) took place in Washington, DC, from April 15-20, 2005. The meeting's paper sessions highlighted the increasing experience of investigators with new cataract, refractive, and corneal surgical techniques/technology. This article will discuss the major findings.

Topics of continued interest in cataract surgery included microincision phacoemulsification, intraocular lens (IOL) advances for management of presbyopia, and the newly recognized intraoperative floppy iris syndrome.

#### Microincision Cataract Surgery (MICS)

Bimanual phacoemulsification cataract extraction, with separation of the phacoemulsification tip/aspiration handpiece from the infusion/second instrument handpiece, continues to receive a significant amount of attention. The technique permits cataract removal through small incisions, with improvement in anterior chamber stability, reduction in surgically induced astigmatism, and a potential decrease in ultrasound energy. However, conversion to this new technique has a definite learning curve, which may require a significant number of cases to deliver a complication rate comparable to conventional coaxial phacoemulsification.<sup>[1,2]</sup> Multiple investigators described their experience with different platforms and instruments for bimanual phacoemulsification.<sup>[3-5]</sup> Histologic and ultrastructural wound changes in bimanual phaco were compared with surgery performed with coaxial infusion.<sup>[6,7]</sup> The bimanual wounds showed greater levels of collagen damage consistent with burning, internal disruption of Descemet's membrane, and peri-wound endothelial cell loss. However, the clinical significance of these findings is undetermined. No difference in central endothelial cell loss was found between bimanual and coaxial cataract cases in a study by Rita Mencucci, MD.<sup>[8]</sup>

MICS techniques using small-sleeve coaxial infusion were presented by several authors. Takayuki Akahoshi, MD<sup>[9]</sup> successfully performed phacoemulsification with the Infiniti (Alcon Labs, Fort Worth, Texas) system through a 1.7-mm incision, followed by injection of single-piece AcrySof (Alcon Labs) IOL. He also used a small-diameter infusion sleeve with a third port directed inferiorly to increase irrigation, improve chamber depth, and maintain separation between the phaco tip and the posterior capsule.<sup>[10]</sup> "Ultrasleeve" techniques were also described by Donald Serafano, MD,<sup>[11]</sup> and Khiun Tjia, MD.<sup>[12]</sup>

#### Accommodative and Pseudoaccommodative Intraocular Lenses

Presbyopic correction with cataract surgery or refractive lens exchange is becoming more feasible with advances in IOL design. Several papers provided updates on the different lens technologies in current use or in development. The Crystalens (Eyeonics, Aliso Viejo, California), a single-optic accommodating silicone IOL approved for use in November 2004, was the subject of several papers. Steven Dell, MD,<sup>[13]</sup> reviewed the 3-year results for the US Food and Drug Administration (FDA) clinical trial. Three hundred sixty-eight unilaterally and 123 bilaterally implanted patients were examined. Ninety-eight percent had uncorrected distance visual acuity (UCDVA) of 20/40 or better and 98% had uncorrected near visual acuity (UCNVA) of J3 or better. All patients had distance corrected near visual acuity (DCNVA) of J3 or better. Wavefront analysis using the Tracey Visual Function Analyzer in a subset of patients demonstrated a refractive change (myopic astigmatism) with accommodation, suggesting movement of the optic within the eye. The accommodative effect of the Crystalens appeared stable in this group of patients at 3 years following implantation.

Christopher Starr and colleagues<sup>[14]</sup> offered their results following 1 year of Crystalens implantation. All patients achieved best corrected distance visual acuity (BCDVA) of 20/25 or better, while 60% had UCDVA of  $\geq 20/25$ . UCNVA was J5 or better in 85% and DCNVA was  $\geq J5$  in 95% of patients. The authors felt that UCDVA was limited in this group of patients by preexisting astigmatism, prior LASIK surgery, and eyes that were larger/smaller than normal. Another series of bilateral Crystalens implantation with 2 years of follow-up was presented by Carlos Verges, MD.<sup>[15]</sup> Fifty eyes of 25 patients received the accommodating IOL, with 90% obtaining UCDVA  $\geq 20/30$  and 96% with BCDVA of 20/30 or greater. DCNVA was J3 or better in 92% of cases, with only 8% achieving J1. Twenty-four percent reported halos and 39% developed posterior capsule opacification requiring YAG laser capsulotomy. Other authors reported similar findings with the Crystalens, achieving accommodative amplitudes in the range of 1-2D.<sup>[16,17]</sup>

One-year results for the Synchrony (Visiogen, Irvine, California) dual-optic accommodating IOL were offered by Ivan Ossma-Gomez, MD.<sup>[18]</sup> Twenty-five eyes were implanted with the single-piece, foldable silicone IOL and demonstrated a mean accommodative range of 2.87D. High-definition ultrasound biomicroscopy showed forward movement of the anterior optic, as well as an increase in the inter-optic gap, by up to 0.83 mm.<sup>[19]</sup> The results of these studies reflect the higher accommodation-to-movement ratio in dual-optic accommodating IOLs, compared with single-optic designs. BCDVA was 20/40 or better in 97%, while DCNVA of  $\geq 20/40$  was seen in 94% of eyes.

The ReStor (Alcon Labs, Fort Worth, Texas) pseudoaccommodating multifocal IOL was approved for use by the FDA in April 2005. This IOL uses an apodization process to create concentric steps on the lens surface -- thereby creating a hybrid diffractive-refractive optic to provide balanced distance and near vision. Anja Liekfeld, MD, discussed the 1-year results for 118 patients who underwent bilateral implantation of the ReStor IOL. UCDVA and BCDVA of 20/25 or better were achieved in 84% and 97% of eyes, respectively. UCNVA was  $\geq 20/32$  in 88% and DCNVA was 20/32 or better in 93% of eyes. At the 6-month postoperative visit, 88% reported never wearing glasses for distance and 85% for near, as compared with 6% prior to surgery. In another series, 25 patients who received bilateral ReStor IOLs functioned comfortably without glasses for both near and distance activities, reported Robert Kaufer, MD.<sup>[20]</sup> Near vision was considered excellent/very good in 96% and good in 4% of patients. All patients found their distance vision to be excellent/very good and expressed spectacle independence. Several other papers were presented which showed similar visual results.<sup>[21-25]</sup> A quality-of-life study comparing patients with bilateral ReStor IOLs to those with bilateral AcrySof MA60BM IOLs was presented by Robert Cionni, MD.<sup>[26]</sup> Both groups showed similar reductions in glare complaints following cataract surgery. The ReStor patients reported significantly less limitation in social activities without glasses and experienced overall greater satisfaction. Andrew Maxwell, MD,<sup>[27]</sup> found no significant difference between ReStor and AcrySof patients with regard to photopic/mesopic contrast sensitivity and performance in a night driving simulator.

The Array (Advanced Medical Optics, Santa Ana, California) silicone multifocal IOL, a well-established FDA-approved lens, uses refractive optics with concentric optical zones weighted for near and distance focal points. The Array 2 is a new multifocal IOL made of acrylic, rather than silicone. Magda Rau, MD,<sup>[28]</sup> compared visual results in 40 patients with bilaterally implanted Array IOLs to those in 40 patients with bilateral Array 2 IOLs. Visual outcomes were very similar between groups, with mean UCDVAs of 0.72 for the Array and 0.73 for the Array2. Mean UCNVAs were 0.72 and 0.68 for the Array and Array 2 groups, respectively, with 35% and 39% expressing spectacle independence. Glare complaints were reduced by 69% with the acrylic IOL. Dr. Rau<sup>[29]</sup> also presented results for 11 patients receiving bilateral Tecnis (Advanced Medical Optics) multifocal IOLs. Mean UCDVA was 0.92 and mean BCDVA was 0.98. The mean UCNVA was 0.92, with 82% of patients achieving spectacle independence. Eighteen percent complained of disturbing haloes and 9% of glare. All patients were satisfied with the surgical outcome. These studies show promising results for accommodating and pseudoaccommodating IOL technology.

### **A New Syndrome**

David Chang, MD, and colleagues<sup>[30]</sup> characterized a newly recognized, small pupil syndrome associated with cataract surgery, the intraoperative floppy iris. Intraoperative floppy-iris syndrome (IFIS) is associated with the systemic use of alpha-1 receptor antagonists, such as tamsulosin, and is characterized by iris billowing, prolapse, and progressive intraoperative miosis. Their retrospective chart review of 706 cases determined the frequency of tamsulosin use and the percentage of patients manifesting IFIS. They also performed a prospective study of 900

cases with a similar analysis. Three percent of patients and 3% of eyes in the retrospective study were taking tamsulosin for benign prostatic hypertrophy (BPH), of which 64% demonstrated IFIS. The prospective arm had 2.3% of patients manifesting IFIS. Nineteen of these 21 eyes were taking tamsulosin. Surgical management included pupil stretching, sphincterotomies, viscodilation, iris hooks, and mechanical pupil dilators (eg, Perfect Pupil). The authors found pupil stretching and sphincterotomies to be ineffective management tools. They also found posterior capsule rupture to be more common in eyes with IFIS. Specific preoperative questioning with regard to tamsulosin use with subsequent surgical planning is recommended.

## Refractive Surgery

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Exciting developments in refractive surgery were offered in the areas of femtosecond laser flap creation, epi-LASIK surface ablation, phakic IOLs, and wavefront advances.

### Femtosecond Laser LASIK Flap Creation

The use of the femtosecond laser (Intralase; Intralase Corp, Irvine, California) in refractive surgery received a significant amount of attention. Several studies compared the postoperative visual outcomes of both standard and wavefront-guided treatments using the IntraLase with various mechanical microkeratomes. David Tanzer, MD,<sup>[31]</sup> reported higher postoperative visual acuities at 1 month in eyes with IntraLase-created flaps than in those with flaps made with the Hansatome (Bausch & Lomb, Rochester, New York) and Amadeus (Advanced Medical Optics) microkeratomes (50 patients per group). Although the visual acuities in all groups were similar after 3 months, the IntraLase group gained 1 line of BCVA and performed better on mesopic contrast sensitivity testing. The induction of higher order aberrations was similar between microkeratomes in patients who underwent flap creation, followed 1 month later by wavefront-guided treatment. Dan Durrie, MD,<sup>[32]</sup> presented data on patients who underwent LASIK surgery with an IntraLase flap in 1 eye and a Hansatome flap in the other. His results indicated that postoperative visual acuity was better at all time points (up to 12 months) with the IntraLase-treated eyes. He also reported increased contrast sensitivity and a patient preference for eyes with IntraLase-created flaps. In contrast to the aforementioned studies, Maria Chalita, MD,<sup>[33]</sup> found no statistical difference in postoperative clinical outcomes and induction of high order aberrations (HOA) for wavefront-guided LASIK when comparing 129 eyes with IntraLase flaps to 282 eyes with Moria flaps.

Flap architecture and ultrastructural analysis of the stromal bed were also addressed. Confocal microscopy was employed by Ramon Naranjo-Tackman, MD,<sup>[34]</sup> to compare corneal structure in eyes receiving IntraLase- or Hansatome-created flaps. His results showed that there was no statistically significant difference in the reduction of anterior or posterior keratocytes at the 1-week and 1-month time points. Renee Soloman, MD,<sup>[35]</sup> evaluated the surface ultrastructural characteristics with scanning electron microscopy in specimens cut at different corneal depths using the femtosecond laser and the Amadeus II microkeratome. She found that the femtosecond laser created a more irregular surface at all levels when compared with the Amadeus. Dan Tran, MD,<sup>[36]</sup> showed that flap depth affects the morphology of the stromal bed, with thinner flaps appearing smoother on scanning electron microscope (SEM). In addition, he noted more irregularity when a microkeratome blade is used a second time. Anne Bottros, MD,<sup>[37]</sup> illustrated that changing femtosecond laser parameters can affect the appearance of the stromal bed. Decreased spot energy and separation resulted in a smoother stromal bed.

Epithelial ingrowth is a known complication of LASIK surgery. Perry Binder, MD,<sup>[38]</sup> performed a retrospective chart review of 7287 LASIK cases, both primary and enhancement, to evaluate the incidence of epithelial ingrowth with the IntraLase, SKBM (Alcon Labs), and Chiron Automated Corneal Shaper (Chiron, Emeryville, California) microkeratomes. In primary LASIK surgery, there was no statistically significant difference in the incidence of epithelial ingrowth for all groups. However, there was a higher incidence for the SKBM (25/552) and ACS (10/779), compared with the IntraLase (2/144). Dr. Binder attributed the difference to the side cut architecture. A new technique for LASIK enhancement, which uses the IntraLase was presented by Jon Dishler, MD.<sup>[39]</sup> He described his technique in which the femtosecond laser is used to make a side cut within the border of the original flap. This method allowed for successful enhancement of eyes that were 3-7 years remote from their original surgery.

### Epi-LASIK and Surface Ablation

Epi-LASIK is a new surface ablation technique in which an epithelial flap is created by mechanically separating it from the underlying Bowman's membrane. The epithelium is preserved, and following excimer laser ablation, the flap is repositioned and covered with a bandage soft contact lens until it is healed. Several studies evaluated the time to removal of the soft contact lens, postoperative comfort level, and postoperative visual acuity.<sup>[40-43]</sup> The time to contact lens removal ranged from 3 to 5 days, with an average of 4 days for most studies. Terrence O'Brien, MD,<sup>[43]</sup> presented data on 13 patients and noted an average pain score of 2.3 on a scale of 0 to 4. Efehan Coskunseven, MD,<sup>[40]</sup> found that 80% in a series of 49 patients reported no pain or major discomfort. Twenty-two percent had trace haze, which resolved by 6 months. In a study of 95 eyes, Vikentia Katsanevaki, MD,<sup>[41]</sup> reported that 46% of patients gained 1 to 2 lines of BSCV at 6 months, while 8% had trace haze at 6 months. Corneal sensitivity was compared following Epi-LASIK and conventional LASIK by Maria Kalyvianaki, MD.<sup>[44]</sup> Corneal sensitivity returned to baseline by 3 months following Epi-LASIK, but continued to show a reduction at 6 months post-LASIK. While most results are preliminary, Epi-LASIK may prove to be a safe and effective alternative to LASIK and other surface ablation techniques.

### Phakic Intraocular Lenses

LASIK and photorefractive keratectomy (PRK) work very well for low-to-moderate myopia and hyperopia, with and without astigmatism, but may not be suitable for all patients. Phakic intraocular lenses provide a means for correcting refractive error that preserves corneal integrity, minimally affects the ocular surface, maintains accommodation, and limits the risk of retinal detachment. Experience continues to grow with phakic IOLs, which come in angle- or iris-supported anterior chamber and sulcus-supported posterior chamber varieties.

The Verisyse (Advanced Medical Optics, Santa Ana, California) iris-supported phakic IOL was recently approved by the US FDA for the correction of myopia (-5 to -20D). During the clinical study, 84% of eyes had UCVDAs of 20/40 or better, while 100% had BCDVA of  $\geq 20/40$  at 3 years following implantation.<sup>[45]</sup> Endothelial cell loss between baseline and 3 years was 1.6%. Virgilio Galvis, MD,<sup>[46]</sup> reported a cumulative endothelial cell loss of 5% and nuclear cataract development in 0.7% at 8 years in his series of 253 eyes; 86% had received IOLs for myopic correction. The interim US FDA phase 3 clinical results for the Artisan (Ophthec, Groningen, The Netherlands) hyperopia phakic IOL (+4 to +12D) were delivered by Edward Manche, MD. At 1 year, 70 eyes were available for analysis, with 89% and 26% having UCVDAs of  $\geq 20/40$  and  $\geq 20/20$ , respectively. The mean spherical equivalent was  $-0.59 \pm 0.70D$  and no eyes lost more than 1 line of BCVA. The Artiflex, a foldable version of the Artisan phakic IOL, was evaluated by Antonio Marinho, MD,<sup>[47]</sup> who found 94% of patients to have a spherical equivalent within  $\pm 0.5D$  at 9 months after surgery. No patients lost BCVA and endothelial cell loss was not significant. Burkhard Dick, MD,<sup>[48]</sup> found that the surgically induced astigmatism of the smaller sclerocorneal incisions achievable with the Artiflex IOL was low, with a mean of 0.5D at 1 year.

Clinical trials for the AcrySof angle-supported phakic IOL are in progress in the US and Europe. The results were presented by Andrew Maxwell, MD, with follow-up ranging from 3 to 5 years. In phase 1, 90% of patients (10/10 US and 7/9 Europe) had UCVDAs of  $\geq 20/40$ , while in the phase 2 European study, 91% achieved 20/40 or better acuity. The phase 3 European data found 55% of eyes with UCVA  $\geq 20/20$ , and 20/40 or better in 100% of eyes.<sup>[49]</sup> BCVDAs were  $\geq 20/40$  and  $\geq 20/20$  in 100% and 73%, respectively. Endothelial cell concentrations decreased by 2.7% centrally and 4.6% peripherally.

John Vukich, MD,<sup>[50]</sup> compared results for the Visian (Staar Surgical, Switzerland) posterior chamber sulcus-supported phakic IOL, formerly the implantable collamer lens (ICL), to those for a refractively similar group of LASIK patients. One hundred sixty-four eyes in each group were analyzed. UCVA was  $\geq 20/40$  in 99% of the ICL group and 95% of the LASIK group. BCVA of 20/20 or better was achieved in 85% of LASIK eyes and 95% of ICL eyes. A toric version of the ICL was evaluated by Kjell Gunderson, MD,<sup>[51]</sup> for 88 eyes of 44 patients with spherical ametropia of -15 to +6D and regular astigmatism from -1.75 to -6D. The mean UCVA was 0.85, with subjects gaining a mean of 1.7 lines (range 0.5 to 7) of BCVA. Four lenses required postoperative adjustment for rotation and refractions were stable after less than 1 week. No patients developed cataract and no lenses required explantation.

Sizing of phakic IOLs continues to be of critical importance to insure adequate vault of the lenses and minimize postoperative complications, such as cataract, endothelial cell loss, and uveitis. Dan Reinstein, MD,<sup>[52]</sup> assessed

the correlation of white-to-white (WTW) measurements with sulcus-to-sulcus (STS) and angle-to-angle (ATA) dimensions using high-resolution anterior segment ultrasonography (Artemis, Ultralink, LLC). Neither myopes nor hyperopes showed a significant correlation between WTW and STS or WTW and ATA. Hyperopes showed some correlation with multiple parameters, such as MR, age, or anterior chamber depth, but no such trends were found for myopes. He recommended direct measurement of ATA and STS dimensions to maximize the safety of phakic IOL implantation.

### Miscellaneous

Other topics of interest at the Annual Symposium included iris registration software for the VISX (recently FDA-approved) and the B&L Zyoptix platforms.<sup>[53-55]</sup> Early results show promise with improvement in safety and refractive outcomes. Other results for Fourier-based wavefront ablation and presbyopic correction with multifocal laser ablation were also discussed and demonstrated clinical efficacy.<sup>[56,57]</sup>

## Corneal Surgery

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Advances in corneal surgical techniques have been increasing, as demonstrated in the areas of posterior lamellar keratoplasty, anterior lamellar keratoplasty, and intracorneal rings for the management of keratoconus.

### Posterior/Anterior Lamellar Keratoplasty

Posterior lamellar keratoplasty (PLK) is a promising new technique, in which the posterior cornea is replaced with a donor button containing posterior stroma, Descemet's membrane, and endothelium. Several techniques were described for PLK, which may provide improved refractive results and greater immune privilege when compared with conventional penetrating keratoplasty (PKP). Mark Terry, MD,<sup>[58]</sup> presented postoperative graft rejection rates for his deep lamellar endothelial keratoplasty (DLEK) technique as compared with standard PKP statistics. He reported a total of 4 graft rejections at varying time points and 1 graft failure in 200 DLEK patients. Endothelial cell counts showed a 20% loss at 24 months when compared with preoperative levels. This was not statistically significant compared with the 26% loss found in PKP patients at 24 months.<sup>[59]</sup> Descemet stripping with endothelial keratoplasty (DSEK) was described by Frank Price, MD.<sup>[60]</sup> Results on 100 patients showed that postoperative visual acuity at 6 months averaged 20/40 with a minimal change in postoperative spherical equivalent or cylinder.

Anterior lamellar keratoplasty (ALK) involves dissection of the host cornea to the level of deep stroma, followed by transplantation of donor corneal tissue sans Descemet's membrane and endothelium. Two studies evaluated the use of the femtosecond laser for ALK in patients with keratoconus.<sup>[61,62]</sup> Both studies used the Intralase laser to both recipient and donor trephination. Ramon Naranjo-Tackman, MD, reported results for 18 patients, with postoperative corneal thicknesses ranging from 500 to 590  $\mu\text{m}$ . UCVA improved by 2 lines in 75% of patients. At 3 months, the grafts were all clear; however 18% were found to have interface debris.

### Intracorneal Ring Segments (ICR) for Keratoectasia

The FDA's approval of intracorneal ring segments (Intacs, Addition Technology, Des Plaines, Illinois) under a Humanitarian Device Exemption (HDE) for the treatment of keratoectasia has led to rapidly increasing clinical experience, as reflected in the presentations by several investigators in the Cornea paper sessions. Mark A. Swanson, MD,<sup>[63]</sup> presented his results for 393 patients (363 keratoconus and 30 post-surgical ectasia) over a 2-year period using the steepest refractive axis incision technique. One hundred percent of mild cases and 55% of moderate-to-severe cases achieved UCVA of 20/40 or better. All cases gained lines of vision and reported improved quality of life. Patients with stage III keratoconus benefitted the most from the technique.

The results of a single-segment technique for the management of both keratoconus and LASIK-induced ectasia were offered by Lawrence Chao, MD, and colleagues.<sup>[64]</sup> Thirty-four eyes of 27 patients underwent placement of a single ICR in the lower cornea, with 67% also receiving concurrent C3-R (collagen crosslinking with riboflavin) treatment. The mean preoperative UCVA improved from < 20/200 to better than 20/63. BCVA increased from 20/40 preoperatively to 20/25 postoperatively. The investigators computed the L-U ratio (difference between the sum of 5 upper keratometry values and 5 lower keratometry values referenced to the steepest lower keratometric measurement), and found that the L-U ratio decreased from 29.72 to 21.04 following surgery, indicating localized

flattening of the inferior cornea. The vast majority of the curvature change was seen in the lower cornea, suggesting that the single-ring approach avoids unnecessary flattening of the already flat superior cornea.

Jaime Martiz, MD, and colleagues<sup>[65]</sup> prospectively analyzed the effect of ICR placement in 40 eyes of 25 keratoconus patients using the Intralase femtosecond laser to create the ICR tunnels. They placed 2 rings in each cornea using the Albertazzi nomogram and demonstrated improvement in both UCVA (2 to 9 lines) and BCVA. Their patients showed a decrease in irregular astigmatism and improved contact lens tolerance, while none required penetrating keratoplasty. The response of pellucid marginal degeneration (PMD) to ICR placement was studied by Giorgio Tassinari, MD.<sup>[66]</sup> Eight eyes of 8 patients received ICR segments in both the superior (0.25-mm segment) and inferior (0.45-mm segment) cornea with a follow-up of 12 to 42 months. One hundred percent of eyes experienced an improvement in UCVA while 75% achieved a BCVA of 20/25. No eyes lost any lines of BCVA. The mean postoperative refractive astigmatism was -2.53D (range -1.25 to -4.50D). Refractive stability was present at the third month following implantation and no intra- or postoperative complications were noted. Several other authors presented their results during the Cornea sessions,<sup>[67-69]</sup> reflecting the increased popularity of this procedure as an adjunctive treatment that may reduce the need for penetrating keratoplasty in certain patients with keratoectasia.

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