Scientific Abstract Highlights

Research and Investigator Initiated Trials Supported by Alcon Presented at The American Academy of Ophthalmology Annual Meeting

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Introduction

2020 American Academy of Ophthalmology

We are excited to showcase some of the scientific abstracts accepted for presentation at the 2020 American Academy of Ophthalmology Meeting within this abstract book. The presentations range from studies conducted by Alcon to studies on Alcon products independently conducted. We are particularly proud of our support for investigator-initiated clinical studies that further the ophthalmology community's knowledge of how Alcon products can best support patient care. Ultimately, this allows Alcon to ensure that what we do and what we say is backed by high quality clinical data.

In addition to this publication, you are welcome and encouraged to contact our medical affairs associates with any further clinical science related questions. Our goal is to ensure clinicians are well informed of both the science and technology behind Alcon's products, and thus, are in the best position to deliver the highest quality care to patients. We encourage you to visit our Alcon Medical Affairs website – AlconScience.com – in order to learn more about how medical science matters to us. In addition to scientific and medical publications on products and therapeutic areas relating to Alcon devices, you can find more information on educational grants, wetlabs, equipment placement, and our areas of interest for investigator-initiated trials.

Through all of these scientific and educational activities, we are proud to support your ability to provide exceptional patient care.

Table of Contents

This abstract book includes studies executed by Alcon or supported through independent research grants from Alcon. Studies which used Alcon products outside their FDA approved indications for use are not included in this abstract book.

Prevalence and Incidence of Allergic Conjunctivitis in the AAO IRIS® Registry

Marguerite B. McDonald, MD, FACS[1]; Thao N. Yeh, OD, PhD, MPH, FAAO[2]; Mohinder M. Merchea, OD, PhD, MBA, FAAO[2]

Purpose

The epidemiology of allergic conjunctivitis (AC) has been difficult to establish because allergic conjunctival symptoms are not always recorded in large epidemiological studies, and there is some overlap of symptoms with other conditions. This study aimed to determine prevalence, incidence, and seasonal pattern of AC in the United States using the American Academy of Ophthalmology IRIS® Registry.

Methods

Patients with AC were identified by diagnosis of acute atopic, chronic giant papillary, vernal, and other chronic allergic conjunctivitis. Of 43,551,958 patients in the database in 2017-2019, 1,038,387 were positively diagnosed based on ICD-10 codes.

Results

Prevalence and incidence of AC ranged between 0.85-1.74% and 0.85-1.53%, respectively; highest in spring, and among females and 11-30 year olds.

Conclusions

Prevalence and incidence of AC has been reported as high as 30% in rhinoconjunctivitis and questionnaire-based epidemiological studies, but rates were significantly less in this real-world database.

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Prevalence of Preoperative Dry Eye Diagnosis and Treatment Among Cataract Patients: An AAO IRIS® Registry Analysis

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Purpose
Using the IRIS® Registry to determine prevalence of preoperative dry eye disease (DED) diagnosis and treatment in the United States, and the association between treatment and receiving advanced technology IOL (AT-IOL).

Methods
Noninterventional, retrospective study of cataract patients between January 2016 and March 2018. DED diagnoses were identified by ICD-9/10 codes; treatments included procedures (eyelid heat therapy, punctal, and amniotic membrane) or medications (cyclosporine, lifitegrast) within 12 weeks preoperatively.

Results
26,543 cataract patients (29.5%) were diagnosed with DED; 3.0% of diagnosed received treatment. 66.1% of treated received AT-IOLs. Patients had 2.1 greater odds of receiving DED treatment when given an AT-IOL (95% CI: 1.8, 2.4).

Conclusions
Preoperative DED has been reported as high as 80% in a clinical study, but significantly fewer patients were diagnosed and even fewer treated in this real-world population. Preoperative DED treatment was significantly associated with receiving an AT-IOL.

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Clinical Outcomes of a New Nondiffractive Presbyopia-Correcting IOL from Two Large Confirmatory Studies

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Purpose
To evaluate a new nondiffractive presbyopia-correcting IOL, DFT015 (AcrySof® IQ Vivity) versus an aspheric monofocal IOL (SN60WF) in two large confirmatory multicountry studies.

Methods
273 (OUS study) and 219 (US study) patients were bilaterally implanted with DFT015 (completion: OUS: n=151; US: n=106) or SN60WF (completion: OUS: n=117; US: n=111). Binocular best corrected distance visual acuity (BCDVA, 4 m), distance-corrected intermediate (DCIVA, 66 cm) and near VA (DCNVA, 40 cm), defocus curve and quality of vision were assessed at 6 months.

Results
Mean BCDVA was similar between the two groups; DCIVA improved by >1 line with DFT015; DCNVA improved by ~1 (OUS) and >1 line (US) with DFT015 versus SN60WF. DFT015 had a >0.5D extended mean binocular defocus range at 0.2 logMAR versus SN60WF. In both groups, similar low rates of severe and bothersome glare, halos, or starbursts were reported.

Conclusions
Compared with an aspheric monofocal IOL, DFT015 improved near and intermediate VA without reducing distance VA, while maintaining comparable low rates of visual disturbances.

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SURGICAL
Paper | Session: PA005 | Topic: Cataract

Differences Between Axial Length Measurements Using a Specific Refractive Index for Each Segment of the Eye vs. a Single Group Refractive Index for the Entire Eye: Effect on IOL Power Calculation and Expected Clinical Outcomes

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Purpose
To compare axial length measurements using a specific refractive index for each segment of the eye (ALSRI) versus a single group refractive index for the entire eye (ALGRI), and to evaluate the effects of any differences on IOL power calculation.

Methods
Eyes undergoing cataract surgery and where biometry was performed with an ALSRI were evaluated. ALGRI was calculated for each case. The expected residual refractions based on different IOL formulas were calculated for both AL groups.

Results
595 eligible eyes were evaluated. The average mean prediction error (MPE) based on the ALSRI was lower than the average MPE based on ALGRI across all axial lengths and formulas.

Conclusions
Differences were found between ALSRI and ALGRI, mainly in the short and long eyes, which had some effect on IOL power calculation.

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Real-World Characteristics of Patients Undergoing Cataract Surgery: Analysis of United States Medicare Claims Database

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Purpose

To characterize cataract patient characteristics and complications in Medicare Fee-for-service (FFS) population.

Methods

Medicare FFS Parts A and Part B databases from CMS were queried between October 2015 and December 2017. Patients continuously enrolled for 6 months prior to and with at least 1 month of follow-up post-cataract surgery were included. Claims with at least 1 cataract surgery CPT code (66982/66984) were analyzed (excluding traumatic cataracts).

Results

Baseline demographics: N=133,896 cataract procedures; setting: 71.3% ASC, 27.6% in HOPD, and 1.1% in physician office; mean patient age= 73.8 years. Median time between first and second eye cataract surgery=15 days. Common comorbidities at time of cataract surgery: diabetes (28.6%), glaucoma (22.1%), macular degeneration (21.7%); mean Charlson Comorbidity Index= 1.63. Post-op complications (1-year incidence): YAG capsulotomy (6.5%), IOL exchange (0.2%), repositioning (0.2%), endophthalmitis (0.2%).

Conclusions

Real-world characteristics and complications rates for Medicare patients undergoing cataract surgery may help surgeons in optimizing postoperative outcomes.

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Geographic and Demographic Distribution of Implanted IOL Types: An Analysis of the AAO IRIS® Registry

Maria C. Scott, MD[1]; Jessica Mathew, OD, PhD, FAAO[2]; Xiaolin Gu, MD, PhD[2]; Mohinder M. Merchea, OD, PhD, MBA, FAAO[2]

Purpose

To study IOL type usage by demographics and across geographic locations in the United States.

Methods

Retrospective analysis of 76,140 cataract patients from the IRIS® Registry who received an AcrySof or Tecnis IOL implant from January 2016 to December 2018. Primary outcomes included age, gender and geographic region.

Results

Mean age for those receiving monofocal IOLs was 71 years, and multifocal IOLs, 67.5 years. Overall, 63% received a monofocal IOL while 37% multifocal (of the monofocal and multifocal groups, 15.9% were monofocal toric and 23.1% multifocal toric). Regional breakdown (Midwest, North, South, West) for those receiving monofocal were 27.5%, 12%, 52.1%, 8.4%, respectively and for those receiving multifocal were 20.4%, 10.1%, 51.7%, 17.8%.

Conclusions

Based on this cohort from the IRIS® Registry, overall IOL implantations were the highest in the South, and monofocal usage was higher than multifocal across all regions, except in the West, where multifocal usage was higher.

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Visual Outcomes under Bright and Dim Light Conditions with a New Nondiffractive Presbyopia-Correcting IOL

Brian Foster, MD[1]; Cathleen M. McCabe, MD[2]; Gary J. Foster, MD[3]; Aldo A. Martinez, PhD, FAAO[4]

Purpose

To evaluate visual performance under bright and dim conditions with a new nondiffractive presbyopia-correcting IOL, DFT015 (AcrySof® IQ Vivity) versus an aspheric monofocal IOL (SN60WF).

Methods

Randomized study of 219 bilaterally implanted patients (completion: DFT015, n=106; SN60WF, n=111) at 11 US sites. Visual outcomes according to photopic pupil size (small <3mm, medium 3–4mm, large >4mm) and quality of vision without spectacles, in bright and dim light (IOL Satisfaction Questionnaire (IOLSAT) questionnaire), were evaluated at 6 months.

Results

Ninety-two percent of patients were categorized into the medium and large pupil size groups. DFT015 maintained ≥1-line improvements in binocular distance-corrected intermediate and near visual acuity (DCIVA and DCNVA) for all pupil sizes, including large (>4mm) pupils. Differences in mean binocular BCDVA were <0.1 logMAR; binocular BCDVA was ≥20/20 at each pupil size for both IOLs. For DFT015, approximately 30% more patients reported “good” or “very good” quality of vision without the use of spectacles, at intermediate and near distances, in both bright and dim light, compared to SN60WF.

Conclusions

The extended vision behavior of DFT015 is maintained in bright and dim light.

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Cumulative Binocular Vision Outcomes with a New Trifocal IOL

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Purpose

To evaluate the cumulative binocular visual performance of a new trifocal IOL in comparison to a monofocal IOL.

Methods

Bilateral implantation in 243 subjects after femtosecond laser–assisted cataract surgery (FLACS) with PanOptix Trifocal IOL TFNT00 (T) and Monofocal IOL SN60AT (S), to compare cumulative uncorrected and distance-corrected visual acuities (UCVA and DCVA) at distance (4 m), intermediate (66 cm) and near (40 cm).

Results

Mean (±SD) photopic binocular DCVA (logMAR) at 4 m was −0.062 (0.066) [T] and −0.086 (0.063) [S]. There were clinically relevant differences in mean photopic DCVA at 40 cm and 66 cm in favor of T. The percentage of subjects who reached 20/25-2 or better were as follows: at 40 cm, 92.1% (UCVA, T) versus 9% (UCVA, S); 96.1% (DCVA, T) versus 0% (DCVA, S); at 66 cm, 93.7% (UCVA, T) versus 50.5% (UCVA, S), 97.6% (DCVA, T) versus 26.1% (DCVA, S); at all three distances UCVA was 83.5% (T) and 8.1% (S).

Conclusions

PanOptix trifocal IOL provides superior visual performance of $20/25^{-2}$ at near and intermediate and is comparable at distance to the monofocal IOL.

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U.S. Multicenter Study of the Visual Outcomes of a New Nondiffractive Presbyopia-Correcting IOL

Cathleen M. McCabe, MD[1]; Harvey J. Reiser, MD[2]; Aldo A. Martinez, PhD, FAAO[3]

Purpose

To evaluate the distance-corrected visual outcomes of a new non-diffractive presbyopia-correcting IOL, AcrySof® IQ Vivity (DFT015), versus an aspheric monofocal IOL (SN60WF).

Methods

Randomized study of 220 bilaterally implanted patients; 218 completed the study (DFT015, n=106; SN60WF, n=111) at 11 US sites. Binocular defocus curve and best corrected distance visual acuity (BCDVA) (4 m), distance-corrected intermediate VA (DCIVA) (66 cm) and distance-corrected near VA (DCNVA) (40cm) were assessed at 6 months. Visual disturbances were assessed subjectively with a validated patient-reported outcome questionnaire (Questionnaire for Visual Disturbances, QUVID).

Results

Both groups achieved mean binocular BCDVA <0.0 logMAR; 97.2% (DFT015) and 98.2% (SN60WF) achieved ≥20/25. DFT015 provided >1-line increase in DCIVA and DCNVA versus SN60WF, with 88% achieving DCIVA of 20/25 or better. DFT015 extended binocular negative depth of focus ≥0.5D versus SN60WF. There were no significant differences between groups in percent of patients experiencing starbursts, halos, or glare.

Conclusions

The non-diffractive IOL DFT015 improved near and intermediate visual acuity while maintaining distance VA and a visual disturbance profile similar to an aspheric monofocal IOL.

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Clinical Outcomes of a New Nondiffractive Presbyopia-Correcting IOL in Canada

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Purpose

To evaluate effectiveness and safety of a nondiffractive presbyopia-correcting IOL, AcrySof® IQ Vivity (model DFT015) versus an aspheric monofocal IOL (model SN60WF) at investigational sites in Canada.

Methods

Prospective, multicentre, randomised, parallel-group, controlled, assessor- and patient-masked study bilateral implantation with DFT015 (n=39) or SN60WF (n=33). Refractive outcomes, binocular defocus curve and quality of vision (QoV Questionnaire, McAlinden) were assessed at Month 6.

Results

DFT015 had >0.5D extended range of vision at 0.2 logMAR compared with SN60WF. Visual disturbances profile was similar between groups, with low rates (<4%) of starbursts, halos and glare in both groups.

Conclusions

The nondiffractive presbyopia-correcting IOL DFT015 provided extended range of vision, with similar visual disturbance profile to an aspheric monofocal IOL, providing the advantages of a multifocal IOL without the photic phenomena.

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A Retrospective Analysis of the AAO Clinical Registry to Correlate IOL Type and Biomaterial to Time to PCO Diagnosis

Bret L. Fisher, MD[1]; Daniel C. Terveen, MD[2]; Xiaolin Gu, MD, PhD[3]; Mohinder M. Merchea, OD, PhD, MBA, FAAO[3]

Purpose

To compare the mean time to posterior capsule opacification (PCO) diagnosis (TDx) in different types of IOLs with two hydrophobic acrylic material: AcrySof (A) or Tecnis (T).

Methods

Retrospective analysis of AAO IRIS® Registry assembled 43,023 eyes from 2016 to 2018 with ≥ 2 years of follow-up after cataract surgery. Mean TDx by IOL type (monofocal or multifocal (MF) / extended depth of focus [EDOF]) and material (A or T) were analyzed.

Results

35.7% eyes with ≥ 2 year follow-up had PCO diagnosis, with mean TDx at 268 days. MF/EDOF implanted eyes, regardless of material, had shorter mean TDx compared to monofocal eyes ($P<0.0001$). Age-, sex- and race-adjusted mean monofocal TDx was 300 days for A vs 269 days for T ($P<0.0001$). Among MF/EDOF eyes, mean TDx was 251 days for A MFIOL versus 196 and 214 days for T MFIOL and EDOF respectively ($P<0.001$), suggesting AcrySof IOLs are more resistant to PCO formation.

Conclusions

Earlier PCO diagnosis was observed in MF/EDOF than monofocal eyes. Biomaterial has an impact on time to PCO diagnosis.

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Refractive Accuracy with Global or Personalized Lens Constants: An Analysis of Intraoperative Aberrometry Database

Bret L. Fisher, MD[1]; Xiaolin Gu, MD, PhD[2]; Raiju J. Babu, PhD, FAAO[2]; Michael Breen, OD[2]

Purpose
To assess refractive accuracy using the initial globalized (G) and initial personalized (P) lens constants (LC) when using intraoperative aberrometry (IA) for final IOL power selection.

Methods
Eyes implanted with AcrySof IQ toric IOLs that met inclusion/exclusion criteria were assembled into G (n=1101) or P (n=3085) groups from multisite data in the IA database. Primary analysis was on absolute IA prediction error (AIAPE).

Results
The differences of mean AIAPE between the two groups (P-G) were -0.03 D (P=0.002) in all eyes, with P being significantly superior. Further comparison in normal and long eyes showed superiority of P to G (P<0.025). Significantly greater % of eyes with an AIAPE ≤ 0.50 D in P than G was shown (84.6 vs 80.5, P = 0.002), especially in normal (84.1 vs. 80.6, p=0.015) and long eyes (91 vs. 79.5, P=0.001).

Conclusions
Superior refractive outcomes can be achieved with initial IA personalized lens constants vs. initial IA global optimized lens constants.

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Accuracy of IOL Power Calculations for Eyes with Short AL in Cases Using Intraoperative Aberrometry for IOL Power Selection

John L. Davidson, MD[1]

Purpose

To report on the accuracy of Intraoperative Aberrometry (IA) IOL calculations for eyes with axial length measurements of 22.50 mm or less.

Methods

A retrospective analysis of 95 consecutive eyes implanted with a single piece acrylic IOL using IA to determine IOL power. Eyes with AL measurements of 22.50 mm or less were included. The 1 month postop manifest refraction was used to calculate mean and median absolute value of the prediction error (APE) and to determine the proportion of eyes with a mean absolute prediction error of ≤ 50 D.

Results

Mean (standard deviation) and median (range) APE were 0.26 D (0.19) and 0.23 D (0.00–0.78), respectively. Cumulative distribution of APEs: 54% ≤0.25D, 89% ≤0.50D, 99% ≤0.75D, 100% ≤1.00D.

Conclusions

IA provided accurate IOL calculations in these patients with AL measuring 22.50 mm or less and implanted with implanted with single-piece acrylic IOLs.

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Incidence and Frequency Distribution of Monovision with Monofocal IOLs: An Analysis of the AAO Clinical Registry

Shamik Bafna, MD[1]; Xiaolin Gu, MD, PhD[2]; Mohinder M. Merchea, OD, PhD, MBA, FAAO[2]

Purpose

To describe the incidence and distribution of monofocal-monovision based on post-op refractive outcomes (MRSE).

Methods

A retrospective analysis of AAO IRIS® Registry demonstrated 45,317 patients that had bilateral cataract surgeries from 2016 to 2019, with ≥90 days of follow-up and MRSEs reported. Primary outcome included the incidence of monovision (MV, ≥0.5D myopic offset) with monofocal IOLs. MV distribution was further analyzed.

Results

16,765 (37%) patients had monofocal IOL implanted bilaterally. Among them, 4,796 (28.6%) patients had at least one eye with MRSE at plano ±0.25D; and 34.2% of these patients presented as MV with a myopic offset ≥0.5D. The majority of MV patients (58.1%) had a myopic offset between 0.51 and 1.49D, with 32.5% between 0.51-0.99D and 25.6% between 1.00 – 1.49D.

Conclusions

Less than 1.50D myopic offset is most commonly adopted for monovision with monofocal IOL for presbyopia mitigation.

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Clinical Outcomes of a New Nondiffractive Presbyopia-Correcting IOL in a Multicenter U.S. Study

John P. Berdahl, MD[1]; Brandon J. Baartman, MD[2]; Vance M. Thompson, MD[1]; Aldo A. Martinez, PhD, FAAO[3]

Purpose

To evaluate uncorrected visual acuity (UCVA) after bilateral implantation of a new nondiffractive presbyopia-correcting IOL AcrySof® IQ Vivity (DFT015), versus an aspheric monofocal IOL (SN60WF).

Methods

220 patients in 11 US sites were bilaterally implanted with DFT015 (completion: n=106) or SN60WF (completion: n=111). Photopic uncorrected distance, intermediate and near visual acuities (UCDVA, UCIVA and UCNVA) and MRSE were measured at 6 months. Uncorrected quality of vision and visual disturbances were assessed with validated questionnaires, the IOL Satisfaction Questionnaire (IOLSAT) and the Questionnaire for Visual Disturbances (QUVID).

Results

Ninety-two percent and 87% of first eyes achieved absolute MRSE ≤0.5D for DFT015 and SN60WF, respectively. Mean binocular between-group differences (DFT015 vs SN60WF) was <1 line for UCDVA, ~1-line improvement for UCIVA, and >1-line improvement for UCNVA. Ninety-four percent, 92% and 57% reported good vision without spectacles at distance, intermediate and near with DFT015, versus 90%, 63% and 25% with SN60WF; <2% in each group reported very bothersome starbursts, halos, and glare at 1 and 6 months.

Conclusions

DFT015 improves intermediate and near vision quality while maintaining good distance vision and low rate of visual disturbances.

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Objective and Subjective Assessment of Vision Quality of a New Trifocal IOL

Jeffrey D. Horn, MD[1]; Satish S. Modi, MD[2]

Purpose

To evaluate binocular contrast sensitivity (CS) using CSV-1000 under photopic and mesopic conditions with and without glare with PanOptix Trifocal IOL, TFNT00 (T) versus bilateral implantation of AcrySof Monofocal IOL SN60AT (S).

Methods

Assess binocular low-contrast visual acuity (VA) under photopic conditions at 4 m, 66 cm and 40 cm and visual disturbances using a validated patient-reported outcomes questionnaire.

Results

Mean CS values for T were within the normal range, with no clinically relevant differences observed between groups at any spatial frequency in photopic or mesopic CS with or without glare. Starbursts and halos were perceived in the T group (57% and 65%), with a majority of subjects reporting these symptoms as “not bothered at all” to “bothered somewhat” (88% and 89%, respectively). Less than five percent of subjects with the T IOL reported starbursts and halos as “bothered very much” at Month 6.

Conclusions

99.2% of patients said they would have TFNT00 implanted again, versus 87.4% for SN60AT recipients.

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Intraoperative Wavefront Aberrometry vs. Barrett True K Formula for IOL Power Calculations in Post-LASIK Eyes

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Purpose

To compare the refractive prediction error for IOL power calculations performed with the Barrett True K formula and intraoperative wavefront aberrometry in post-corneal refractive surgery eyes.

Methods

Retrospective chart review of 145 post-hyperopic or post-myopic LASIK eyes that underwent cataract surgery. IOL power calculations were performed using Barrett True K formula and intraoperative aberrometry (ORA, Alcon). Refractive mean numerical error (MNE) and mean absolute error (MAE) of the IOL power calculation formulas were compared.

Results

Barrett True K and ORA showed comparable values of MAE (0.57±0.54 D vs 0.54±0.50 D, $p>0.05$). The percentage of eyes with refractive prediction error outside 0.75 D, as calculated by Barrett True K and ORA, was 29% vs 26% respectively.

Conclusions

In post-corneal refractive surgery eyes, the Barrett True K formula and ORA performed similarly.

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The Impact of Image Registration for Ablation Orientation on Clinical Outcomes After WFO Refractive Surgery in Eyes with Myopia and Astigmatism

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Purpose

To compare clinical outcomes from laser refractive surgery performed with the same laser with and without incorporating iris registration technology to compensate for ocular cyclotorsion.

Methods

Clinical outcomes at a single site after wavefront-optimized (WFO) LASIK using the Wavelight excimer laser with and without the Vario imaging system for iris registration (IR) were evaluated. Eligible subjects were those that received on-label WFO treatment of myopia with astigmatism > 1.5 D. Measures of interest included the amount of residual refractive cylinder, refractive error, and the best-corrected (BCVA) and uncorrected (UCVA) visual acuities, with a target follow up of 90 days.

Results

112 eligible eyes that were treated with IR, and 126 similar eyes treated without IR (NO IR), were included. Total eyes with residual cylinder > 0.50 D was higher in the NO IR group vs IR group (6% vs. 1%, respectively, p = 0.04). Significantly more eyes in the IR group had UCVA (p = 0.01) and BCVA of 20/15 or better (p = 0.003). 96% IR group eyes and 91% NO IR group eyes had UCVA of 20/20 or better.

Conclusions

IR with the VARIO imaging device reduced overall variability in outcomes.

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Clinical Outcomes After Topography-Guided Refractive Surgery in Eyes with Myopia and Astigmatism: Comparing Results with New Planning Software to Those Obtained Using the Manifest Refraction

Paul M. Mann II, MD[1]; Paul M. Mann, MD, FACS[1]; Phillip B. Brunson, OD, FAAO[1]; Rick Potvin, OD, MASc, FAAO[2]

Purpose

To compare clinical outcomes from topography-guided laser refractive surgery based on new planning software to outcomes based on the manifest refraction.

Methods

Clinical outcomes at a single site compared eligible eyes that received on-label topography-guided LASIK treatment of myopia or myopic astigmatism with correction based on either the manifest refraction or results from the Phorcides Analytical Engine (PAE), with a target postoperative follow up time of 90 days. Measures analyzed included the uncorrected (UCVA) and best corrected (BCVA) visual acuity, the magnitude of refractive cylinder after surgery, the refractive error and changes from preoperative BCVA.

Results

115 eyes treated with PAE planning and 133 eyes treated based off manifest refractions were included. Significantly more eyes in the PAE group had a BCVA of 20/15 or better ($p = 0.05$) and a UCVA of 20/15 or better ($p = 0.05$). Significantly more eyes in the manifest group had a UCVA of 20/25 or worse (13/133 vs. 1/115 in the PAE group, $p = 0.002$).

Conclusions

Topography-guided LASIK treatments utilizing PAE planning resulted in improved visual acuity and less residual cylinder.

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Clinical Outcomes of a Diffractive Trifocal IOL with FLACS, Digital Tracking and Intraoperative Aberrometry

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Purpose

To evaluate outcomes of a trifocal IOL using femtosecond laser–assisted cataract surgery (FLACS), digital tracking (DT) and intraoperative aberrometry (IA).

Methods

Retrospective, single surgeon, study examining 200 eyes of 100 bilaterally implanted patients. At 3 months post-op, manifest refraction spherical equivalent (MRSE), refractive astigmatism (RA) and monocular uncorrected distance, intermediate, and near visual acuity (UDVA, UIVA, UNVA) were collected.

Results

93.5% of eyes had a MRSE of ±0.50D (mean=0.006D±0.27). 98.5% of eyes had a RA ≤ 0.50D (mean=0.064D±0.17). Eighty-six percent of eyed achieved UDVA of 20/25 or better, 66.0% were 20/20. 99.5% of eyes achieved UIVA of 20/25 or better, 95.0% were 20/20; 91.5% of eyes achieved UNVA of 20/25 or better, 73.5% were 20/20.

Conclusions

The results demonstrate that trifocal implantation with FLACS, DT, and IA can provide excellent refractive and visual outcomes.

Affiliations

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Important Product Information

AcrySof® Family of Single-Piece IOLs

(AcrySof® UV, AcrySof® IQ, AcrySof® IQ Toric, AcrySof® IQ ReSTOR®, AcrySof® IQ ReSTOR® Toric, AcrySof® IQ PanOptix® and AcrySof® IQ PanOptix® Toric IOLs)

Caution: Federal law restricts these devices to sale by or on the order of a physician.

Indication: The family of AcrySof® single-piece intraocular lenses (IOLs) includes AcrySof® UV-absorbing IOLs ("AcrySof® UV"), AcrySof® IQ, AcrySof® IQ Toric, AcrySof® IQ ReSTOR®, AcrySof® IQ ReSTOR® Toric, AcrySof® IQ PanOptix® and AcrySof® IQ PanOptix® Toric IOLs. Each of these IOLs is indicated for visual correction of aphakia in adult patients following cataract surgery. In addition, the AcrySof Toric IOLs are indicated to correct pre-existing corneal astigmatism at the time of cataract surgery. The AcrySof® IQ ReSTOR IOLs are for cataract patients with or without presbyopia, who desire increased spectacle independence with a multifocal vision. The AcrySof® IQ PanOptix® lens mitigates the effects of presbyopia by providing improved intermediate and near visual acuity, while maintaining comparable distance visual acuity with a reduced need for eyeglasses, compared to a monofocal IOL. All of these IOLs are intended for placement in the capsular bag.

Warnings / Precautions:
General cautions for all AcrySof® and AcrySof® UV IOLs: Careful preoperative evaluation and sound clinical judgment should be used by the surgeon to decide the risk/benefit ratio before implanting any IOL in a patient with any of the conditions described in the Directions for Use that accompany each IOL. Caution should be used prior to lens encapsulation to avoid lens decentration or dislocation. Physicians should target emmetropia, and ensure that IOL centration is achieved.

Additional Cautions associated with AcrySof® IQ ReSTOR® and AcrySof® IQ PanOptix® IOLs: Some patients may experience visual disturbances and/or discomfort due to multifocality, especially under dim light conditions. These may include some perceptions of halos or starbursts, as well as other visual symptoms. Therefore, patients implanted with multifocal IOLs should exercise caution when driving at night or in poor visibility conditions. A reduction in contrast sensitivity may occur in low light conditions. Spectacle independence rates vary with all multifocal IOLs; as such, some patients may need glasses when reading small print or looking at small objects. Patients should be advised that unexpected outcomes could lead to continued spectacle dependence or the need for secondary surgical intervention (e.g., intraocular lens replacement or repositioning). Posterior capsule opacification (PCO), may significantly affect the vision of patients with multifocal IOLs sooner in its progression than patients with monofocal IOLs.

Additional Cautions associated with AcrySof® IQ Toric, AcrySof® UV Toric ReSTOR® Toric, and AcrySof® IQ PanOptix® Toric IOLs: Optical theory suggests that, high astigmatic patients (i.e. > 2.5 D) may experience spatial distortions. Possible toric IOL related factors may include residual cylindrical error or axis misalignments. Toric IOLs should not be implanted if the posterior capsule is ruptured, if the zonules are damaged, or if a primary posterior capsulotomy is planned. Rotation can reduce astigmatic correction; if necessary lens repositioning should occur as early as possible prior to lens encapsulation. Prior to surgery, physicians should provide prospective patients with a copy of the appropriate Patient Information Brochure available from Alcon informing them of possible risks and benefits associated with the AcrySof® IQ Toric, AcrySof® IQ ReSTOR®, AcrySof® IQ ReSTOR® Toric, and AcrySof® IQ PanOptix® Trifocal IOLs.

Attention: Refer to the Directions for Use labeling for the specific IOL for a complete list of indications, warnings and precautions.

AcrySof® IQ Vivity™ Family of Extended Vision IOLs

Caution: Federal (USA) law restricts this device to the sale by or on the order of a physician.

Indication: The AcrySof® IQ Vivity™ Extended Vision IOLs include AcrySof® IQ Vivity™ and AcrySof® IQ Vivity™ Toric and are indicated for primary implantation for the visual correction of aphakia in adult patients with <1.00 D of preoperative corneal astigmatism, in whom a cataractous lens has been removed by extracapsular cataract extraction. The lens mitigates the effects of presbyopia by providing an extended depth of focus. Compared to an aspheric monofocal IOL, the lens provides improved intermediate and near visual acuity, while maintaining comparable distance visual acuity. The AcrySof® IQ Vivity™ IOL is intended for capsular bag placement only. In addition, the AcrySof® IQ Vivity™ Toric IOL is indicated for the reduction of residual refractive astigmatism in adult patients with pre-existing corneal astigmatism.

Warnings / Precautions: Careful preoperative evaluation and sound clinical judgment should be used by the surgeon to decide the risk/benefit ratio before implanting a lens in a patient with any of the conditions described in the Directions for Use labeling. This lens should not be implanted if the posterior capsule is ruptured, if the zonules are damaged, or if a primary posterior capsulotomy is planned. Rotation can reduce astigmatic correction; if necessary lens repositioning should occur as early as possible prior to lens encapsulation. Most patients implanted with the Vivity™ IOL are likely to experience significant loss of contrast sensitivity as compared to a monofocal IOL. Therefore, it is essential that prospective patients be fully informed of this risk before giving their consent for implantation of the Vivity IOL. In addition, patients should be warned that they will need to exercise caution when engaging in activities that require good vision in dimly lit environments, such as driving at night or in poor visibility conditions, especially in the presence of oncoming traffic. It is possible to experience very bothersome visual disturbances, significant enough that the patient could request explant of the IOL. In the Vivity™ clinical study, 1% to 2% of Vivity™ patients reported very bothersome starbursts, halos, blurred vision, or dark area visual disturbances; however, no explants were reported. Prior to surgery, physicians should provide prospective patients with a copy of the Patient Information Brochure available from Alcon informing them of possible risks and benefits associated with the AcrySof® IQ Vivity™ IOLs.

Attention: Reference the Directions for Use labeling for each IOL for a complete listing of indications, warnings and precautions.

WaveLight® Excimer Laser Systems

This information pertains to all WaveLight® Excimer Laser Systems, including the WaveLight® ALLEGRETTO WAVE®, the ALLEGRETTO WAVE® Eye-Q and the WaveLight® EX500.

Caution: Federal (U.S.) law restricts the WaveLight® Excimer Laser Systems to sale by or on the order of a physician. Only practitioners who are experienced in the medical mangement and surgical treatment of the cornea, who have been trained in laser refractive surgery (including laser calibration and operation) should use a WaveLight® Excimer Laser System.

Indication: FDA has approved the WaveLight® Excimer Laser systems for use in laser-assisted in situ keratomileusis (LASIK) treatments for: the reduction or elimination of myopia of up to -12.00 D and up to 6.00 D of astigmatism at the spectacle plane; the reduction or elimination of hyperopia up to + 6.00 D with and without astigmatic refractive errors up to 5.00 D at the spectacle plane, with a maximum manifest refraction spherical equivalent of + 6.00 D; • the reduction or elimination of naturally occurring mixed astigmatism of up to 6.00 D at the spectacle plane; and the wavefront-guided reduction or elimination of myopia of up to -7.00 D and up to 3.00 D of astigmatism at the spectacle plane. In addition, FDA has approved the WaveLight® ALLEGRETTO WAVE® Eye-Q Excimer Laser System, when used with the WaveLight® ALLEGRO Topolyzer® and topography-guided treatment planning software for topography-guided LASIK treatments for the reduction or elimination of up to -9.00 D of myopia, or for the reduction or elimination of myopia with astigmatism, with up to -8.00 D of myopia and up to 3.00 D of astigmatism. The WaveLight® Excimer Laser Systems are only indicated for use in patients who are 18 years of age or older (21 years of age or older for mixed astigmatism) with documentation of a stable manifest refraction defined as ≤ 0.50 D of preoperative spherical equivalent shift over one year prior to surgery, exclusive of changes due to unmasking latent hyperopia.

Contraindications: The WaveLight® Excimer Laser Systems are contraindicated for use with patients who: are pregnant or nursing; have a diagnosed collagen vascular, autoimmune or immunodeficiency disease; have been diagnosed keratoconus or if there are any clinical pictures suggestive of keratoconus; are taking isotretinoin (Accutane*) and/or amiodarone hydrochloride (Cordarone*); have severe dry eye; have corneas too thin for LASIK; have recurrent corneal erosion; have advanced glaucoma; or have uncontrolled diabetes.

Warnings: The WaveLight® Excimer Laser Systems are not recommended for use with patients who have: systemic diseases likely to affect wound healing, such as connective tissue disease, insulin dependent diabetes, severe atopic disease or an immunocompromised status; a history of Herpes simplex or Herpes zoster keratitis; significant dry eye that is unresponsive to treatment; severe allergies; a history of glaucoma; an unreliable preoperative wavefront examination that precludes wavefront-guided treatment; or a poor quality preoperative topography map that precludes topography-guided LASIK treatment. The wavefront-guided LASIK procedure requires accurate and reliable data from the wavefront examination. Every step of every wavefront measurement that may be used as the basis for a wavefront-guided LASIK procedure must be validated by the user. Inaccurate or unreliable data from the wavefront examination will lead to an inaccurate treatment. Topography-guided LASIK requires preoperative topography maps of sufficient quality to use for planning a topography-guided LASIK treatment. Poor quality topography maps may affect the accuracy of the topography-guided LASIK treatment and may result in poor vision after topography-guided LASIK.

Precautions: The safety and effectiveness of the WaveLight® Excimer Laser Systems have not been established for patients with: progressive myopia, hyperopia, astigmatism and / or mixed astigmatism, ocular disease, previous corneal or intraocular surgery, or trauma in the ablation zone; corneal abnormalities including, but not limited to, scars, irregular astigmatism and corneal warpage; residual corneal thickness after ablation of less than 250 microns due to the increased risk for corneal ectasia; pupil size below 7.0 mm after mydriatics where applied for wavefront-guided ablation planning; history of glaucoma or ocular hypertension of > 23 mmHg; taking the medications sumatriptan succinate (Imitrex*); corneal, lens and/or vitreous opacities including, but not limited to cataract; iris problems including, but not limited to,

coloboma and previous iris surgery compormising proper eye tracking; or taking medications likely to affect wound healing including (but not limited to) antimetabolites. In addition, safety and effectiveness of the WaveLight® Excimer Laser Systems have not been established for: treatments with an optical zone < 6.0 mm or > 6.5 mm in diameter, or an ablation zone > 9.0 mm in diameter; or wavefront-guided treatment targets different from emmetropia (plano) in which the wavefront calculated defocus (spherical term) has been adjusted; In the WaveLight® Excimer Laser System clinical studies, there were few subjects with cylinder amounts > 4 D and ≤ 6 D N. ot all complications, adverse events, and levels of effectiveness may have been determined for this population. Pupil sizes should be evaluated under mesopic illumination conditions. Effects of treatment on vision under poor illumination cannot be predicted prior to surgery.

Adverse Events and Complications:

Myopia: In the myopia clinical study, 0.2% (2/876) of the eyes had a lost, misplaced, or misaligned flap reported at the 1 month examination. The following complications were reported 6 months after LASIK: 0.9% (7/818) had ghosting or double images in the operative eye; 0.1% (1/818) of the eyes had a corneal epithelial defect. **Hyperopia:** In the hyperopia clinical study, 0.4% (1/276) of the eyes had a retinal detachment or retinal vascular accident reported at the 3 month examination. The following complications were reported 6 months after LASIK: 0.8% (2/262) of the eyes had a corneal epithelial defect and 0.8% (2/262) had any epithelium in the interface. **Mixed Astigmatism:** In the mixed astigmatism clinical study, two adverse events were reported. The first event involved a patient who postoperatively was subject to blunt trauma to the treatment eye 6 days after surgery. The patient was found to have an intact globe with no rupture, inflammation or any dislodgement of the flap. UCVA was decreased due to this event. The second event involved the treatment of an incorrect axis of astigmatism. The axis was treated at 60 degrees instead of 160 degrees. The following complications were reported 6 months after LASIK: 1.8% (2/111) of the eyes had ghosting or double images in the operative eye. **Wavefront-Guided Myopia:** The wavefront-guided myopia clinical study included 374 eyes treated; 188 with wavefront-guided LASIK (Study Cohort) and 186 with Wavefront Optimized® LASIK (Control Cohort). No adverse events occurred during the postoperative period of the wavefront-guided LASIK procedures. In the Control Cohort, one subject undergoing traditional LASIK had the axis of astigmatism programmed as 115 degrees instead of the actual 155 degree axis. This led to cylinder in the left eye. The following complications were reported 6 months after wavefront-guided LASIK in the Study Cohort: 1.2% (2/166) of the eyes had a corneal epithelial defect; 1.2% (2/166) had foreign body sensation; and 0.6% (1/166) had pain. No complications were reported in the Control Cohort. **Topography-Guided Myopia:** There were six adverse events reported in the topography-guided myopia study. Four of the eyes experienced transient or temporary decreases in vision prior to the final 12 month follow-up visit, all of which were resolved by the final follow-up visit. One subject suffered from decreased vision in the treated eye, following blunt force trauma 4 days after surgery. One subject experienced retinal detachment, which was concluded to be unrelated to the surgical procedure.

Clinical Data:

Myopia: The myopia clinical study included 901 eyes treated, of which 813 of 866 eligible eyes were followed for 12 months. Accountability at 3 months was 93.8%, at 6 months was 91.9%, and at 12 months was 93.9%. Of the 782 eyes that were eligible for the uncorrected visual acuity (UCVA) analysis of effectiveness at the 6-month stability time point, 98.3% were corrected to 20/40 or better, and 87.7% were corrected to 20/20 or better. Subjects who responded to a patient satisfaction questionnaire before and after LASIK reported the following visual symptoms at a "moderate" or "severe" level at least 1% higher at 3 months post-treatment than at baseline: visual fluctuations (28.6% vs. 12.8% at baseline). Long term risks of LASIK for myopia with and without astigmatism have not been studied beyond 12 months. **Hyperopia:** The hyperopia clinical study included 290 eyes treated, of which 100 of 290 eligible eyes were followed for 12 months. Accountability at 3 months was 95.2%, at 6 months was 93.9%, and at 12 months was 69.9%. Of the 212 eyes that were eligible for the UCVA analysis of effectiveness at the 6-month stability time point, 95.3% were corrected to 20/40 or better, and 69.4% were corrected to 20/20 or better. Subjects who responded to a patient satisfaction questionnaire before and after LASIK reported the following visual symptoms as "much worse" at 6 months post-treatment: halos (6.4%); visual fluctuations (6.1%); light sensitivity (4.9%); night driving glare (4.2%); and glare from bright lights (3.0%). Long term risks of LASIK for hyperopia with and without astigmatism have not been studied beyond 12 months. **Mixed Astigmatism:** The mixed astigmatism clinical study included 162 eyes treated, of which 111 were eligible to be followed for 6 months. Accountability at 1 month was 99.4%, at 3 months was 96.0%, and at 6 months was 100.0%. Of the 142 eyes that were eligible for the UCVA analysis of effectiveness at the 6-month stability time point, 97.3% achieved acuity of 20/40 or better, and 69.4% achieved acuity of 20/20 or better. Subjects who responded to a patient satisfaction questionnaire before and after LASIK reported the following visual symptoms at a "moderate" or "severe" level at least 1% higher at 3 months post-treatment than at baseline: sensitivity to light (52.9% vs. 43.3% at baseline); visual fluctuations (43.0% vs. 32.1% at baseline); and halos (42.3% vs. 37.0% at baseline). Long term risks of LASIK for mixed astigmatism have not been studied beyond 6 months. **Wavefront-Guided Myopia:** The wavefront-guided myopia clinical study included 374 eyes treated; 188 with wavefront-guided LASIK (Study Cohort) and 186 with Wavefront Optimized® LASIK (Control Cohort). 166 of the Study Cohort and 166 of the Control Cohort were eligible to be followed at 6 months. In the Study Cohort, accountability at 1 month was 96.8%, at 3 months was 96.8%, and at 6 months was 93.3%. In the Control Cohort, accountability at 1 month was 94.6%, at 3 months was 94.6%, and at 6 months was 92.2%. Of the 166 eyes in the Study Cohort that were eligible for the UCVA analysis of effectiveness at the 6-month stability time point, 99.4% were corrected to 20/40 or better, and 93.4% were corrected to 20/20 or better. Of the 166 eyes in the Control Cohort eligible for the UCVA analysis of effectiveness at the 6-month stability time point, 99.4% were corrected to 20/40 or better, and 92.8% were corrected to 20/20. In the Study Cohort, subjects who responded to a patient satisfaction questionnaire before and after LASIK reported the following visual symptoms at a "moderate" or "severe" level at least 1% higher at 3 months post-treatment than at baseline: light sensitivity (47.8% vs. 37.2% at baseline) and visual fluctuations (20.0% vs. 13.8% at baseline). In the Control Cohort, the following visual symptoms were reported at a "moderate" or "severe" level at least 1% higher at 3 months post-treatment than at baseline: halos (45.4% vs. 36.6% at baseline) and visual fluctuations (219% vs. 18.3% at baseline). Long term risks of wavefront-guided LASIK for myopia with and without astigmatism have not been studied beyond 6 months. **Topography-Guided Myopia:** The topography-guided myopia clinical study included 249 eyes treated, of which 230 eyes were followed for 12 months. Accountability at 3 months was 99.2%, at 6 months was 98.0%, and at 12 months was 92.4%. Of the 247 eyes that were eligible for the UCVA analysis at the 3-month stability time point, 99.2% were corrected to 20/40 or better, and 92.7% were corrected to 20/20 or better. Subjects who responded to a patient satisfaction questionnaire before and after LASIK reported the following visual symptoms as "marked" or "severe" at an incidence greater than 5% at 1 month after surgery: dryness (7% vs. 4% at baseline) and light sensitivity (7% vs. 5% at baseline). Visual symptoms continued to improve with time, and none of the visual symptoms were rated as being "marked" or "severe" with an incidence of at least 5% at 3 months or later after surgery. Long term risks of topography-guided LASIK for myopia with and without astigmatism have not been studied beyond 12 months.

Information for Patients: Prior to undergoing LASIK surgery with a WaveLight® Excimer Laser System, prospective patients must receive a copy of the relevant Patient Information Booklet, and must be informed of the alternatives for correcting their vision, including (but not limited to) eyeglasses, contact lenses, photorefractive keratectomy, and other refractive surgeries.

Attention: Please refer to a current WaveLight® Excimer Laser System Procedure Manual for a complete listing of the indications, complications, warnings, precautions, and side effects.

ARGOS® Optical Biometer

Caution: Federal (USA) law restricts this device to the sale by or on the order of a physician.

Indication: ARGOS® is a non-invasive, non-contact biometer based on swept-source optical coherence tomography (SS-OCT). The device is intended to acquire ocular measurements as well as perform calculations to determine the appropriate intraocular lens (IOL) power and type for implantation during intraocular lens placement.

Intended Use: The Reference Image functionality is intended for use as a preoperative and postoperative image capture tool. It is intended for use by ophthalmologists, physicians, and other eye-care professionals and may only be used under the supervision of a physician.

Warnings and Precautions:

- Only properly trained personnel with experience may operate the device and control software and interpret the results.
- Factors that influence the measurement of patient's eyes are listed in the User Manual (Table 1): pseudophakic eye, wearing contact lenses, fixation problem, cornea opacity, non-intact cornea, refractive surgery, blood in the vitreous humor, retinal detachment, keratoconus, asteroid hyalosis, ambient light in the room, and deformation of the corneal shape. Please consider the guidance provided in Table 1 when you encounter these factors.
- Optical Radiation - This device is equipped with a Class 1 laser light source.

Attention: Refer to the ARGOS® User Manual for a complete description of proper use and maintenance, optical and technical specifications, as well as a complete list of warnings and precautions.

Important Product Information (continued)

LenSx® Laser

Caution: United States Federal Law restricts this device to sale and use by or on the order of a physician or licensed eye care practitioner.

Indication: The LenSx® Laser is indicated for use in patients undergoing cataract surgery for removal of the crystalline lens. Intended uses in cataract surgery include anterior capsulotomy, phacofragmentation, and the creation of single plane and multi-plane arc cuts/incisions in the cornea, each of which may be performed either individually or consecutively during the same procedure.

Restrictions: Patients must be able to lie flat and motionless in a supine position. Patient must be able to understand and give an informed consent. Patients must be able to tolerate local or topical anesthesia. Patients with elevated IOP should use topical steroids only under close medical supervision.

Contraindication: Corneal disease that precludes applanation of the cornea or transmission of laser light at 1030 nm wavelength. Descemetocele with impending corneal rupture. Presence of blood or other material in the anterior chamber. Poorly dilating pupil, such that the iris is not peripheral to the intended diameter for the capsulotomy. Conditions which would cause inadequate clearance between the intended capsulotomy depth and the endothelium (applicable to capsulotomy only). Previous corneal incisions that might provide a potential space into which the gas produced by the procedure can escape. Corneal thickness requirements that are beyond the range of the system. Corneal opacity that would interfere with the laser beam. Hypotony or the presence of a corneal implant. Residual, recurrent, active ocular or eyelid disease, including any corneal abnormality (for example, recurrent corneal erosion, severe basement membrane disease).

History of lens or zonular instability. Any contraindication to cataract or keratoplasty. This device is not intended for use in pediatric surgery.

Warnings: The LenSx® Laser System should only be operated by a physician trained in its use.

The LenSx® Laser delivery system employs one sterile disposable LenSx® Laser Patient Interface consisting of an applanation lens and suction ring. The Patient Interface is intended for single use only. The disposables used in conjunction with ALCON® instrument products constitute a complete surgical system. Use of disposables other than those manufactured by Alcon may affect system performance and create potential hazards.

The physician should base patient selection criteria on professional experience, published literature, and educational courses. Adult patients should be scheduled to undergo cataract extraction.

Precautions: Do not use cell phones or pagers of any kind in the same room as the LenSx® Laser. Discard used Patient Interfaces as medical waste.

AES / Complications: Capsulotomy, phacofragmentation, or cut or incision decentration. Incomplete or interrupted capsulotomy, fragmentation, or corneal incision procedure. Capsular tear. Corneal abrasion or defect. Pain. Infection. Bleeding. Damage to intraocular structures. Anterior chamber fluid leakage, anterior chamber collapse. Elevated pressure to the eye.

Attention: Refer to the LenSx® Laser Operator's Manual for a complete listing of indications, warnings and precautions.

ORA SYSTEM® with VerifEye® Lynk Technology ("Verifeye® Lynk")

Caution: Federal (USA) law restricts this device to the sale by or on the order of a physician.

Indication: Federal (USA) law restricts this device to sale by, or on the order of, a physician.

Intended Use: VerifEye® Lynk Technology is a single system incorporating ORA SYSTEM® technology (wavefront aberrometry) to measure and analyze the refractive power of the eye to support cataract surgical procedures, and integrating the image guidance capabilities of the VERION® Image Guided System Digital Marker ("DMM') and Microscope Integrated Display ("MID").

Contraindication: Changes in a patient's eye between pre-operative measurement and surgery, an irregular elliptic limbus (due to eye fixation during surgery; bleeding or bloated conjunctiva due to anesthesia) may affect the function of the DMM component of VerifEye® Lynk. In addition, the use of eye drops that constrict sclera vessels before or during surgery should be avoided.

Warnings and Precautions: The following conditions may make it difficult to obtain accurate readings from the ORA SYSTEM® technology component of VerifEye® Lynk. Patients having:

- Progressive retinal pathology such as diabetic retinopathy, macular degeneration, or any other pathology that may interfere with patient fixation;
- Corneal pathology such as Fuchs', EBMD, keratoconus, advanced pterygium impairing the cornea, or any other pathology that may interfere with the measurement process;
- A preoperative regimen that includes residual viscous substances left on the corneal surface such as lidocaine gel or viscoelastics;
- Visually significant media opacity, such as prominent floaters or asteroid hyalosis, that may limit/prohibit the measurement process or those who received retro or peribulbar block or treatment that impairs their ability to visualize the fixation light.
- Significant central corneal irregularities resulting in higher order aberrations, post-refractive keratectomy eyes might yield inaccurate refractive measurements. Use of iris hooks during image capture may yield inaccurate measurements.
- The safety and effectiveness of using the data from ORA SYSTEM® technology have not been established for determining treatments involving higher order aberrations of the eye such as coma and spherical aberrations.

In addition the following conditions may affect the proper functioning of VerifEye® Lynk components:

- Only use the DMM in conjunction with compatible surgical microscopes.
- Improper use of this device may result in exposure to dangerous voltage or hazardous laser-like radiation exposure. Do not use in the presence of flammable anesthetics or volatile solvents.

Attention: Refer to the VerifEye® Lynk Operator's Manual for a complete description of proper installation, use and maintenance, as well as a complete list of contraindications, warnings and precautions. You may also refer to the ORA SYSTEM® technology or VERION® technology manuals for additional information.